

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
Black Cohosh  
**CAS Number:** 84776-26-1

**Date Report Requested:** 11/10/2020  
**Time Report Requested:** 17:07:28  
**First Dose M/F:** 07/03/12 / 07/02/12  
**Lab:** BAT

### Step Section Report with Litter-Based Statistics

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

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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney: Renal Tubule (Original Sections)</b>				
<b>Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	0/37.00	1/38.80	0/37.21
POLY-3 PERCENT (g)	0%	0%	2.6%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	0/16 (0%)
FIRST INCIDENCE	---	---	730 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.789N	(e)	P=0.501	(e)
POLY 1.5	P=0.787N	(e)	P=0.501	(e)
POLY 6	P=0.791N	(e)	P=0.506	(e)
RAO-SCOTT	P=0.790N	(e)	P=0.605	(e)
LITTER C-A/FISHERS	P=0.787N	(e)	P=0.500	(e)

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STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney: Renal Tubule (Step Sections)</b>				
<b>Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	1/25 (4%)	1/25 (4%)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (c)	1/38.61	1/37.51	2/38.88	1/37.21
POLY-3 PERCENT (g)	2.6%	2.7%	5.1%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	1/16 (6%)
FIRST INCIDENCE	718	575	711	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.649N	P=0.755	P=0.502	P=0.753
POLY 1.5	P=0.643N	P=0.758	P=0.501	P=0.757
POLY 6	P=0.642	P=0.753	P=0.511	P=0.749
RAO-SCOTT	P=0.619N	P=0.712	P=0.473	P=0.709
LITTER C-A/FISHERS	P=0.642N	P=0.755	P=0.500	P=0.755

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney: Renal Tubule (Original or Step Sections)</b>				
<b>Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	3/50 (6%)	1/50 (2%)
LITTERS (b)	1/25 (4%)	1/25 (4%)	3/25 (12%)	1/25 (4%)
POLY-3 RATE (c)	1/38.61	1/37.51	3/38.88	1/37.21
POLY-3 PERCENT (g)	2.6%	2.7%	7.7%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	2/21 (10%)	1/16 (6%)
FIRST INCIDENCE	718	575	711	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.630N	P=0.755	P=0.307	P=0.753
POLY 1.5	P=0.623N	P=0.758	P=0.306	P=0.757
POLY 6	P=0.636	P=0.753	P=0.314	P=0.749
RAO-SCOTT	P=0.606N	P=0.719	P=0.310	P=0.716
LITTER C-A/FISHERS	P=0.620N	P=0.755	P=0.305	P=0.755

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney: Renal Tuble (Step Sections) Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	1/37.00	0/38.80	0/37.21
POLY-3 PERCENT (g)	0%	2.7%	0%	0%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	730 (T)	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.584N	P=0.492	(e)	(e)
POLY 1.5	P=0.580N	P=0.496	(e)	(e)
POLY 6	P=0.588N	P=0.488	(e)	(e)
RAO-SCOTT	P=0.639N	P=0.593	(e)	(e)
LITTER C-A/FISHERS	P=0.577N	P=0.500	(e)	(e)

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DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney: Renal Tuble (Original or Step Sections) Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	1/37.00	0/38.80	0/37.21
POLY-3 PERCENT (g)	0%	2.7%	0%	0%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	730 (T)	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.584N	P=0.492	(e)	(e)
POLY 1.5	P=0.580N	P=0.496	(e)	(e)
POLY 6	P=0.588N	P=0.488	(e)	(e)
RAO-SCOTT	P=0.639N	P=0.593	(e)	(e)
LITTER C-A/FISHERS	P=0.577N	P=0.500	(e)	(e)

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DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney: Renal Tubule (Original Sections) Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	0/37.00	1/38.80	0/37.21
POLY-3 PERCENT (g)	0%	0%	2.6%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	0/16 (0%)
FIRST INCIDENCE	---	---	730 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.789N	(e)	P=0.501	(e)
POLY 1.5	P=0.787N	(e)	P=0.501	(e)
POLY 6	P=0.791N	(e)	P=0.506	(e)
RAO-SCOTT	P=0.790N	(e)	P=0.605	(e)
LITTER C-A/FISHERS	P=0.787N	(e)	P=0.500	(e)

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TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney: Renal Tubule (Step Sections) Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	1/25 (4%)	2/25 (8%)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (c)	1/38.61	2/37.51	2/38.88	1/37.21
POLY-3 PERCENT (g)	2.6%	5.3%	5.1%	2.7%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	1/21 (5%)	1/16 (6%)
FIRST INCIDENCE	718	575	711	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.534N	P=0.490	P=0.502	P=0.753
POLY 1.5	P=0.526N	P=0.495	P=0.501	P=0.757
POLY 6	P=0.542N	P=0.486	P=0.511	P=0.749
RAO-SCOTT	P=0.509N	P=0.461	P=0.476	P=0.710
LITTER C-A/FISHERS	P=0.522N	P=0.500	P=0.500	P=0.755



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TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney: Renal Tuble (Original or Step Sections) Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	3/50 (6%)	1/50 (2%)
LITTERS (b)	1/25 (4%)	2/25 (8%)	3/25 (12%)	1/25 (4%)
POLY-3 RATE (c)	1/38.61	2/37.51	3/38.88	1/37.21
POLY-3 PERCENT (g)	2.6%	5.3%	7.7%	2.7%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	2/21 (10%)	1/16 (6%)
FIRST INCIDENCE	718	575	711	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.525N	P=0.490	P=0.307	P=0.753
POLY 1.5	P=0.516N	P=0.495	P=0.306	P=0.757
POLY 6	P=0.535N	P=0.486	P=0.314	P=0.749
RAO-SCOTT	P=0.504N	P=0.466	P=0.304	P=0.713
LITTER C-A/FISHERS	P=0.510N	P=0.500	P=0.305	P=0.755

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney (Original Sections)</b>				
<b>Adenoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	0/37.00	2/40.41	2/38.54
POLY-3 PERCENT (g)	0%	0%	5%	5.2%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	---	413	434
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.125	(e)	P=0.247	P=0.236
POLY 1.5	P=0.125	(e)	P=0.243	P=0.238
POLY 6	P=0.126	(e)	P=0.256	P=0.235
RAO-SCOTT	P=0.313	(e)	P=0.499	P=0.482
LITTER C-A/FISHERS	P=0.302	(e)	P=0.500	P=0.500

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney (Step Sections)</b>				
<b>Adenoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	1/37.00	2/40.41	1/37.75
POLY-3 PERCENT (g)	0%	2.7%	5%	2.7%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	730 (T)	413	564
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.495	P=0.492	P=0.247	P=0.496
POLY 1.5	P=0.499	P=0.496	P=0.243	P=0.498
POLY 6	P=0.492	P=0.488	P=0.256	P=0.494
RAO-SCOTT	P=0.540	P=0.588	P=0.375	P=0.595
LITTER C-A/FISHERS	P=0.485	P=0.500	P=0.500	P=0.500

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TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney (Original or Step Sections)</b>				
<b>Adenoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	2/50 (4%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	1/37.00	2/40.41	2/38.54
POLY-3 PERCENT (g)	0%	2.7%	5%	5.2%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	730 (T)	413	434
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.232	P=0.492	P=0.247	P=0.236
POLY 1.5	P=0.232	P=0.496	P=0.243	P=0.238
POLY 6	P=0.232	P=0.488	P=0.256	P=0.235
RAO-SCOTT	P=0.365	P=0.650	P=0.439	P=0.423
LITTER C-A/FISHERS	P=0.485	P=0.500	P=0.500	P=0.500

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TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney (Original Sections)</b>				
<b>Carcinoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	0/37.00	2/40.41	1/37.75
POLY-3 PERCENT (g)	0%	0%	5%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	---	413	564
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.348	(e)	P=0.247	P=0.496
POLY 1.5	P=0.351	(e)	P=0.243	P=0.498
POLY 6	P=0.348	(e)	P=0.256	P=0.494
RAO-SCOTT	P=0.476	(e)	P=0.446	P=0.663
LITTER C-A/FISHERS	P=0.302	(e)	P=0.500	P=0.500

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DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney (Step Sections)</b>				
<b>Carcinoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	0/37.00	2/40.41	1/37.75
POLY-3 PERCENT (g)	0%	0%	5%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	---	413	564
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.348	(e)	P=0.247	P=0.496
POLY 1.5	P=0.351	(e)	P=0.243	P=0.498
POLY 6	P=0.348	(e)	P=0.256	P=0.494
RAO-SCOTT	P=0.476	(e)	P=0.446	P=0.663
LITTER C-A/FISHERS	P=0.302	(e)	P=0.500	P=0.500

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney (Original or Step Sections)</b>				
<b>Carcinoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	0/37.00	2/40.41	1/37.75
POLY-3 PERCENT (g)	0%	0%	5%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	---	413	564
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.348	(e)	P=0.247	P=0.496
POLY 1.5	P=0.351	(e)	P=0.243	P=0.498
POLY 6	P=0.348	(e)	P=0.256	P=0.494
RAO-SCOTT	P=0.476	(e)	P=0.446	P=0.663
LITTER C-A/FISHERS	P=0.302	(e)	P=0.500	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney (Original Sections)</b>				
<b>Adenoma, Amphophilic-vacuolar or Carcinoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	0/37.00	2/40.41	2/38.54
POLY-3 PERCENT (g)	0%	0%	5%	5.2%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	---	413	434
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.125	(e)	P=0.247	P=0.236
POLY 1.5	P=0.125	(e)	P=0.243	P=0.238
POLY 6	P=0.126	(e)	P=0.256	P=0.235
RAO-SCOTT	P=0.313	(e)	P=0.499	P=0.482
LITTER C-A/FISHERS	P=0.302	(e)	P=0.500	P=0.500



Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney (Step Sections)</b>				
<b>Adenoma, Amphophilic-vacuolar or Carcinoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	1/37.00	2/40.41	1/37.75
POLY-3 PERCENT (g)	0%	2.7%	5%	2.7%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	730 (T)	413	564
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.495	P=0.492	P=0.247	P=0.496
POLY 1.5	P=0.499	P=0.496	P=0.243	P=0.498
POLY 6	P=0.492	P=0.488	P=0.256	P=0.494
RAO-SCOTT	P=0.540	P=0.588	P=0.375	P=0.595
LITTER C-A/FISHERS	P=0.485	P=0.500	P=0.500	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney (Original or Step Sections)</b>				
<b>Adenoma, Amphophilic-vacuolar or Carcinoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	2/50 (4%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	1/37.00	2/40.41	2/38.54
POLY-3 PERCENT (g)	0%	2.7%	5%	5.2%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	730 (T)	413	434
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.232	P=0.492	P=0.247	P=0.236
POLY 1.5	P=0.232	P=0.496	P=0.243	P=0.238
POLY 6	P=0.232	P=0.488	P=0.256	P=0.235
RAO-SCOTT	P=0.365	P=0.650	P=0.439	P=0.423
LITTER C-A/FISHERS	P=0.485	P=0.500	P=0.500	P=0.500

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Black Cohosh  
 CAS Number: 84776-26-1

Date Report Requested: 11/10/2020  
 Time Report Requested: 17:07:28  
 First Dose M/F: 07/03/12 / 07/02/12  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney (Original Sections)</b>				
Hyperplasia, Amphophilic-vacuolar				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	0/37.00	1/39.59	1/37.75
POLY-3 PERCENT (g)	0%	0%	2.5%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	---	435	564
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.302	(e)	P=0.505	P=0.496
POLY 1.5	P=0.304	(e)	P=0.503	P=0.498
POLY 6	P=0.301	(e)	P=0.512	P=0.494
RAO-SCOTT	P=0.364	(e)	P=0.566	P=0.549
LITTER C-A/FISHERS	P=0.302	(e)	P=0.500	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney (Step Sections)</b> Hyperplasia, Amphophilic-vacuolar				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	0/37.00	1/39.59	2/38.54
POLY-3 PERCENT (g)	0%	0%	2.5%	5.2%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	---	435	434
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.086	(e)	P=0.505	P=0.236
POLY 1.5	P=0.085	(e)	P=0.503	P=0.238
POLY 6	P=0.086	(e)	P=0.512	P=0.235
RAO-SCOTT	P=0.240	(e)	P=0.685	P=0.436
LITTER C-A/FISHERS	P=0.302	(e)	P=0.500	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney (Original or Step Sections)</b> Hyperplasia, Amphophilic-vacuolar				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	0/37.00	1/39.59	2/38.54
POLY-3 PERCENT (g)	0%	0%	2.5%	5.2%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	---	435	434
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.086	(e)	P=0.505	P=0.236
POLY 1.5	P=0.085	(e)	P=0.503	P=0.238
POLY 6	P=0.086	(e)	P=0.512	P=0.235
RAO-SCOTT	P=0.240	(e)	P=0.685	P=0.436
LITTER C-A/FISHERS	P=0.302	(e)	P=0.500	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS

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

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

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

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Black Cohosh  
 CAS Number: 84776-26-1

Date Report Requested: 11/10/2020  
 Time Report Requested: 17:07:28  
 First Dose M/F: 07/03/12 / 07/02/12  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney (Original Sections)</b>				
<b>Oncocytoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	1/25 (4%)	1/25 (4%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	1/38.56	1/37.00	0/38.80	0/37.21
POLY-3 PERCENT (g)	2.6%	2.7%	0%	0%
TERMINAL (d)	1/15 (7%)	1/15 (7%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.305N	P=0.752	P=0.499N	P=0.507N
POLY 1.5	P=0.304N	P=0.756	P=0.499N	P=0.503N
POLY 6	P=0.307N	P=0.748	P=0.494N	P=0.511N
RAO-SCOTT	P=0.365N	P=0.740	P=0.558N	P=0.556N
LITTER C-A/FISHERS	P=0.302N	P=0.755	P=0.500N	P=0.500N



Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney (Step Sections)</b>				
<b>Oncocytoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	2/25 (8%)	1/25 (4%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	2/39.04	1/37.00	0/38.80	0/37.21
POLY-3 PERCENT (g)	5.1%	2.7%	0%	0%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	616	730 (T)	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.168N	P=0.519N	P=0.238N	P=0.247N
POLY 1.5	P=0.168N	P=0.510N	P=0.237N	P=0.242N
POLY 6	P=0.168N	P=0.530N	P=0.234N	P=0.254N
RAO-SCOTT	P=0.227N	P=0.536N	P=0.304N	P=0.308N
LITTER C-A/FISHERS	P=0.167N	P=0.500N	P=0.245N	P=0.245N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<b>Kidney (Original or Step Sections)</b>				
<b>Oncocytoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	3/25 (12%)	2/25 (8%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	3/39.04	2/37.00	0/38.80	0/37.21
POLY-3 PERCENT (g)	7.7%	5.4%	0%	0%
TERMINAL (d)	1/15 (7%)	2/15 (13%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	616	730 (T)	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.071N	P=0.525N	P=0.119N	P=0.126N
POLY 1.5	P=0.071N	P=0.512N	P=0.119N	P=0.122N
POLY 6	P=0.071N	P=0.540N	P=0.115N	P=0.131N
RAO-SCOTT	P=0.118N	P=0.535N	P=0.180N	P=0.185N
LITTER C-A/FISHERS	P=0.069N	P=0.500N	P=0.117N	P=0.117N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney: Renal Tuble (Original Sections)</b>				
<b>Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/49 (2%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	1/39.52	0/42.83	1/34.89
POLY-3 PERCENT (g)	0%	2.5%	0%	2.9%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	1/20 (5%)
FIRST INCIDENCE	---	634	---	729 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.420	P=0.489	(e)	P=0.464
POLY 1.5	P=0.434	P=0.492	(e)	P=0.476
POLY 6	P=0.401	P=0.487	(e)	P=0.447
RAO-SCOTT	P=0.464	P=0.581	(e)	P=0.537
LITTER C-A/FISHERS	P=0.463	P=0.500	(e)	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney: Renal Tuble (Step Sections)</b>				
<b>Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/38.24	0/42.83	0/34.39
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney: Renal Tubule (Original or Step Sections)</b>				
<b>Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/49 (2%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	1/39.52	0/42.83	1/34.89
POLY-3 PERCENT (g)	0%	2.5%	0%	2.9%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	1/20 (5%)
FIRST INCIDENCE	---	634	---	729 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.420	P=0.489	(e)	P=0.464
POLY 1.5	P=0.434	P=0.492	(e)	P=0.476
POLY 6	P=0.401	P=0.487	(e)	P=0.447
RAO-SCOTT	P=0.464	P=0.581	(e)	P=0.537
LITTER C-A/FISHERS	P=0.463	P=0.500	(e)	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney: Renal Tuble (Step Sections) Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/38.24	0/42.83	0/34.39
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Black Cohosh  
 CAS Number: 84776-26-1

Date Report Requested: 11/10/2020  
 Time Report Requested: 17:07:28  
 First Dose M/F: 07/03/12 / 07/02/12  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney: Renal Tuble (Original or Step Sections) Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/34.89
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney: Renal Tubule (Original Sections) Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/49 (2%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	1/39.52	0/42.83	1/34.89
POLY-3 PERCENT (g)	0%	2.5%	0%	2.9%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	1/20 (5%)
FIRST INCIDENCE	---	634	---	729 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.420	P=0.489	(e)	P=0.464
POLY 1.5	P=0.434	P=0.492	(e)	P=0.476
POLY 6	P=0.401	P=0.487	(e)	P=0.447
RAO-SCOTT	P=0.464	P=0.581	(e)	P=0.537
LITTER C-A/FISHERS	P=0.463	P=0.500	(e)	P=0.500



Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

**Kidney: Renal Tubule (Step Sections)  
Carcinoma or Adenoma**

---

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/38.24	0/42.83	0/34.39
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---

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**STATISTICAL TESTS**

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

---

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney: Renal Tubule (Original or Step Sections) Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/49 (2%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	1/39.52	0/42.83	1/34.89
POLY-3 PERCENT (g)	0%	2.5%	0%	2.9%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	1/20 (5%)
FIRST INCIDENCE	---	634	---	729 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.420	P=0.489	(e)	P=0.464
POLY 1.5	P=0.434	P=0.492	(e)	P=0.476
POLY 6	P=0.401	P=0.487	(e)	P=0.447
RAO-SCOTT	P=0.464	P=0.581	(e)	P=0.537
LITTER C-A/FISHERS	P=0.463	P=0.500	(e)	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney (Original Sections)</b>				
<b>Adenoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/49 (2%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	1/39.52	1/43.43	1/35.39
POLY-3 PERCENT (g)	0%	2.5%	2.3%	2.8%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	634	538	578
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.427	P=0.489	P=0.507	P=0.467
POLY 1.5	P=0.447	P=0.492	P=0.504	P=0.478
POLY 6	P=0.400	P=0.487	P=0.511	P=0.452
RAO-SCOTT	P=0.436	P=0.504	P=0.539	P=0.466
LITTER C-A/FISHERS	P=0.485	P=0.500	P=0.500	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney (Step Sections)</b>				
<b>Adenoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/49 (2%)	1/50 (2%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	1/38.59	1/43.43	0/34.39
POLY-3 PERCENT (g)	0%	2.6%	2.3%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	634	538	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.581N	P=0.484	P=0.507	(e)
POLY 1.5	P=0.568N	P=0.487	P=0.504	(e)
POLY 6	P=0.599N	P=0.482	P=0.511	(e)
RAO-SCOTT	P=0.575N	P=0.555	P=0.594	(e)
LITTER C-A/FISHERS	P=0.537N	P=0.500	P=0.500	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney (Original or Step Sections)</b>				
<b>Adenoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/49 (2%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	1/39.52	1/43.43	1/35.39
POLY-3 PERCENT (g)	0%	2.5%	2.3%	2.8%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	634	538	578
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.427	P=0.489	P=0.507	P=0.467
POLY 1.5	P=0.447	P=0.492	P=0.504	P=0.478
POLY 6	P=0.400	P=0.487	P=0.511	P=0.452
RAO-SCOTT	P=0.436	P=0.504	P=0.539	P=0.466
LITTER C-A/FISHERS	P=0.485	P=0.500	P=0.500	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Black Cohosh

CAS Number: 84776-26-1

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

Lab: BAT

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney (Original Sections)</b>				
<b>Carcinoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	1/49 (2%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	2/39.59	1/43.43	1/35.39
POLY-3 PERCENT (g)	0%	5.1%	2.3%	2.8%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	634	538	578
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.555	P=0.225	P=0.507	P=0.467
POLY 1.5	P=0.577	P=0.228	P=0.504	P=0.478
POLY 6	P=0.526	P=0.223	P=0.511	P=0.452
RAO-SCOTT	P=0.597	P=0.377	P=0.662	P=0.592
LITTER C-A/FISHERS	P=0.485	P=0.500	P=0.500	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Black Cohosh

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

Lab: BAT

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney (Step Sections)</b>				
<b>Carcinoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/49 (2%)	1/50 (2%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	1/38.59	1/43.43	0/34.39
POLY-3 PERCENT (g)	0%	2.6%	2.3%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	634	538	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.581N	P=0.484	P=0.507	(e)
POLY 1.5	P=0.568N	P=0.487	P=0.504	(e)
POLY 6	P=0.599N	P=0.482	P=0.511	(e)
RAO-SCOTT	P=0.575N	P=0.555	P=0.594	(e)
LITTER C-A/FISHERS	P=0.537N	P=0.500	P=0.500	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

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**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney (Original or Step Sections) Carcinoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	1/49 (2%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	2/39.59	1/43.43	1/35.39
POLY-3 PERCENT (g)	0%	5.1%	2.3%	2.8%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	634	538	578
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.555	P=0.225	P=0.507	P=0.467
POLY 1.5	P=0.577	P=0.228	P=0.504	P=0.478
POLY 6	P=0.526	P=0.223	P=0.511	P=0.452
RAO-SCOTT	P=0.597	P=0.377	P=0.662	P=0.592
LITTER C-A/FISHERS	P=0.485	P=0.500	P=0.500	P=0.500



Experiment Number: 00058 - 03

Test Type: CHRONIC

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Black Cohosh

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Lab: BAT

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney (Original Sections)</b>				
<b>Adenoma, Amphophilic-vacuolar or Carcinoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	1/49 (2%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	2/39.59	1/43.43	1/35.39
POLY-3 PERCENT (g)	0%	5.1%	2.3%	2.8%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	634	538	578
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.555	P=0.225	P=0.507	P=0.467
POLY 1.5	P=0.577	P=0.228	P=0.504	P=0.478
POLY 6	P=0.526	P=0.223	P=0.511	P=0.452
RAO-SCOTT	P=0.597	P=0.377	P=0.662	P=0.592
LITTER C-A/FISHERS	P=0.485	P=0.500	P=0.500	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney (Step Sections)</b>				
<b>Adenoma, Amphophilic-vacuolar or Carcinoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/49 (2%)	1/50 (2%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	1/38.59	1/43.43	0/34.39
POLY-3 PERCENT (g)	0%	2.6%	2.3%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	634	538	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.581N	P=0.484	P=0.507	(e)
POLY 1.5	P=0.568N	P=0.487	P=0.504	(e)
POLY 6	P=0.599N	P=0.482	P=0.511	(e)
RAO-SCOTT	P=0.575N	P=0.555	P=0.594	(e)
LITTER C-A/FISHERS	P=0.537N	P=0.500	P=0.500	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney (Original or Step Sections)</b>				
<b>Adenoma, Amphophilic-vacuolar or Carcinoma, Amphophilic-vacuolar</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	1/49 (2%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	2/39.59	1/43.43	1/35.39
POLY-3 PERCENT (g)	0%	5.1%	2.3%	2.8%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	634	538	578
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.555	P=0.225	P=0.507	P=0.467
POLY 1.5	P=0.577	P=0.228	P=0.504	P=0.478
POLY 6	P=0.526	P=0.223	P=0.511	P=0.452
RAO-SCOTT	P=0.597	P=0.377	P=0.662	P=0.592
LITTER C-A/FISHERS	P=0.485	P=0.500	P=0.500	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

Time Report Requested: 17:07:28

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney (Original Sections)</b>				
Hyperplasia, Amphophilic-vacuolar				
<hr/>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/49 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	1/43.43	0/34.89
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	538	---
<hr/>				
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.778	(e)	P=0.507	(e)
POLY 1.5	P=0.797	(e)	P=0.504	(e)
POLY 6	P=0.747	(e)	P=0.511	(e)
RAO-SCOTT	P=0.792N	(e)	P=0.633	(e)
LITTER C-A/FISHERS	P=0.787N	(e)	P=0.500	(e)

---

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney (Step Sections)</b> Hyperplasia, Amphophilic-vacuolar				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/49 (2%)	1/50 (2%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	1/38.59	1/43.43	0/34.39
POLY-3 PERCENT (g)	0%	2.6%	2.3%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	634	538	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.581N	P=0.484	P=0.507	(e)
POLY 1.5	P=0.568N	P=0.487	P=0.504	(e)
POLY 6	P=0.599N	P=0.482	P=0.511	(e)
RAO-SCOTT	P=0.575N	P=0.555	P=0.594	(e)
LITTER C-A/FISHERS	P=0.537N	P=0.500	P=0.500	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney (Original or Step Sections)</b> Hyperplasia, Amphophilic-vacuolar				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/49 (0%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	1/39.52	1/43.43	0/34.89
POLY-3 PERCENT (g)	0%	2.5%	2.3%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	634	538	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.580N	P=0.489	P=0.507	(e)
POLY 1.5	P=0.566N	P=0.492	P=0.504	(e)
POLY 6	P=0.598N	P=0.487	P=0.511	(e)
RAO-SCOTT	P=0.569N	P=0.553	P=0.587	(e)
LITTER C-A/FISHERS	P=0.537N	P=0.500	P=0.500	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

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Date Report Requested: 11/10/2020

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

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

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 11/10/2020

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

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



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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Black Cohosh  
 CAS Number: 84776-26-1

Date Report Requested: 11/10/2020  
 Time Report Requested: 17:07:28  
 First Dose M/F: 07/03/12 / 07/02/12  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>Kidney (Step Sections)</b>				
<b>Oncocytoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/38.24	0/42.83	0/34.39
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Black Cohosh

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

**Kidney (Original or Step Sections)**  
**Oncocytoma**

---

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/34.89
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---

---

**STATISTICAL TESTS**

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

---

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

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## LEGEND

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

\*\*\* END OF REPORT \*\*\*