

Experiment Number: 00058 - 04

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS  
ABRIDGED) (a)**

Date Report Requested: 12/10/2020

Test Type: CHRONIC

Black Cohosh

Time Report Requested: 11:32:38

Route: GAVAGE

CAS Number: 84776-26-1

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

Species/Strain: MICE/B6C3F1/N

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

Test Type: CHRONIC

Black Cohosh

Time Report Requested: 11:32:38

Route: GAVAGE

CAS Number: 84776-26-1

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

Species/Strain: MICE/B6C3F1/N

Lab: BAT

B6C3F1/N MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
----------------------	---------	----------	-----------	-----------	------------

**Disposition Summary**

<b>Animals Initially In Study</b>	<b>70</b>	<b>70</b>	<b>70</b>	<b>70</b>	<b>70</b>
<b>Early Deaths</b>					
<b>Accidentally Killed</b>				<b>1</b>	
<b>Moribund Sacrifice</b>	<b>4</b>	<b>2</b>	<b>3</b>	<b>3</b>	<b>6</b>
<b>Natural Death</b>	<b>6</b>	<b>8</b>	<b>3</b>	<b>7</b>	<b>6</b>
<b>Survivors</b>					
<b>Natural Death</b>		<b>1</b>			
<b>Terminal Sacrifice</b>	<b>40</b>	<b>39</b>	<b>44</b>	<b>39</b>	<b>38</b>
<b>Animals Examined Microscopically</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>

## ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)	(50)
Gallbladder	(46)	(50)	(50)	(49)	(50)
Intestine Large, Cecum	(50)	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(50)	(50)
Hemangiosarcoma		1 (2%)	1 (2%)		
Hepatocellular Adenoma	1 (2%)	9 (18%)	3 (6%)	4 (8%)	4 (8%)
Hepatocellular Adenoma, Multiple	5 (10%)		1 (2%)		
Hepatocellular Carcinoma	3 (6%)	3 (6%)		2 (4%)	1 (2%)
Osteosarcoma, Metastatic, Uncertain Primary Site	1 (2%)				
Stellate Cell Tumor, Benign				1 (2%)	
Mesentery	(6)	(2)	(0)	(2)	(1)
Hemangiosarcoma, Metastatic, Spleen	1 (17%)				
Pancreas	(50)	(50)	(50)	(49)	(50)
Leiomyosarcoma, Metastatic, Uterus				1 (2%)	
Salivary Glands	(50)	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)	(50)

a - Number of animals examined microscopically at site and number of animals with lesion

Test Type: CHRONIC

Black Cohosh

Time Report Requested: 11:32:38

Route: GAVAGE

CAS Number: 84776-26-1

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

Species/Strain: MICE/B6C3F1/N

Lab: BAT

B6C3F1/N MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Stomach, Glandular	(50)	(50)	(50)	(50)	(50)
Tongue	(0)	(0)	(1)	(0)	(0)
Squamous Cell Carcinoma			1 (100%)		
Tooth	(0)	(3)	(0)	(2)	(0)

## CARDIOVASCULAR SYSTEM

Aorta	(1)	(0)	(0)	(0)	(1)
Blood Vessel	(50)	(48)	(49)	(49)	(49)
Heart	(50)	(50)	(50)	(50)	(50)

## ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)	(50)
Adenoma					1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(50)	(50)
Pheochromocytoma Benign					1 (2%)
Rhabdomyosarcoma, Metastatic, Skeletal Muscle	1 (2%)				
Islets, Pancreatic	(50)	(50)	(50)	(50)	(50)
Parathyroid Gland	(41)	(45)	(42)	(41)	(42)
Pituitary Gland	(49)	(49)	(50)	(50)	(50)
Pars Distalis, Adenoma	2 (4%)		5 (10%)	1 (2%)	3 (6%)
Thyroid Gland	(50)	(50)	(49)	(49)	(50)
Follicular Cell, Carcinoma	1 (2%)				

## GENERAL BODY SYSTEM

Peritoneum	(0)	(0)	(0)	(1)	(0)
Leiomyosarcoma, Metastatic, Uterus				1 (100%)	
Tissue NOS	(0)	(0)	(1)	(0)	(0)

## GENITAL SYSTEM

a - Number of animals examined microscopically at site and number of animals with lesion

Test Type: CHRONIC

Black Cohosh

Time Report Requested: 11:32:38

Route: GAVAGE

CAS Number: 84776-26-1

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

Species/Strain: MICE/B6C3F1/N

Lab: BAT

B6C3F1/N MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Clitoral Gland	(50)	(49)	(50)	(50)	(49)
Ovary	(49)	(50)	(50)	(50)	(50)
Cystadenoma	2 (4%)	3 (6%)	4 (8%)	4 (8%)	1 (2%)
Hemangiosarcoma		1 (2%)			
Luteoma					1 (2%)
Tubulostromal Adenoma					1 (2%)
Bilateral, Cystadenoma					1 (2%)
Uterus	(50)	(50)	(50)	(50)	(50)
Adenocarcinoma				1 (2%)	
Granular Cell Tumor Benign	1 (2%)				
Hemangioma	1 (2%)			1 (2%)	1 (2%)
Hemangiosarcoma		1 (2%)			
Leiomyoma			1 (2%)		1 (2%)
Leiomyosarcoma				1 (2%)	
Polyp Stromal	1 (2%)				3 (6%)
Cervix, Sarcoma	1 (2%)				
Vagina	(50)	(50)	(49)	(49)	(50)

## HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)	(50)
Lymph Node	(6)	(1)	(2)	(5)	(7)
Lumbar, Leiomyosarcoma, Metastatic, Uterus				1 (20%)	
Mediastinal, Osteosarcoma, Metastatic, Uncertain Primary Site	1 (17%)				
Mediastinal, Rhabdomyosarcoma, Metastatic, Skeletal Muscle	1 (17%)				
Renal, Leiomyosarcoma, Metastatic, Uterus				1 (20%)	
Renal, Rhabdomyosarcoma, Metastatic, Skeletal Muscle	1 (17%)				
Lymph Node, Mandibular	(50)	(49)	(50)	(50)	(50)
Mast Cell Tumor Benign					1 (2%)
Lymph Node, Mesenteric	(50)	(49)	(50)	(49)	(50)
Hemangiosarcoma			1 (2%)		
Hemangiosarcoma, Metastatic, Liver			1 (2%)		
Leiomyosarcoma, Metastatic, Uterus				1 (2%)	

a - Number of animals examined microscopically at site and number of animals with lesion

Test Type: CHRONIC

Black Cohosh

Time Report Requested: 11:32:38

Route: GAVAGE

CAS Number: 84776-26-1

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

Species/Strain: MICE/B6C3F1/N

Lab: BAT

B6C3F1/N MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Plasma Cell Tumor Benign			1 (2%)		
Spleen	(50)	(50)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)				
Thymus	(48)	(46)	(48)	(49)	(46)
<b>INTEGUMENTARY SYSTEM</b>					
Mammary Gland	(50)	(50)	(50)	(47)	(50)
Skin	(50)	(50)	(50)	(50)	(50)
Basal Cell Adenoma					1 (2%)
Fibrosarcoma		1 (2%)	1 (2%)		1 (2%)
Keratoacanthoma				1 (2%)	
Myxosarcoma			1 (2%)		
Sarcoma	1 (2%)		2 (4%)	1 (2%)	
<b>MUSCULOSKELETAL SYSTEM</b>					
Bone	(50)	(50)	(50)	(50)	(50)
Hemangiosarcoma, Metastatic, Spleen	1 (2%)				
Osteosarcoma	1 (2%)				
Rhabdomyosarcoma, Metastatic, Skeletal Muscle	1 (2%)				
Skeletal Muscle	(1)	(2)	(0)	(1)	(1)
Rhabdomyosarcoma	1 (100%)	1 (50%)			
<b>NERVOUS SYSTEM</b>					
Brain	(50)	(50)	(50)	(50)	(50)
Lipoma		1 (2%)			
Meningioma Malignant	1 (2%)				
Peripheral Nerve	(2)	(0)	(0)	(1)	(1)
Spinal Cord	(2)	(0)	(0)	(1)	(1)
Astrocytoma Malignant	1 (50%)				

a - Number of animals examined microscopically at site and number of animals with lesion

Test Type: CHRONIC

Black Cohosh

Time Report Requested: 11:32:38

Route: GAVAGE

CAS Number: 84776-26-1

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

Species/Strain: MICE/B6C3F1/N

Lab: BAT

B6C3F1/N MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
<b>RESPIRATORY SYSTEM</b>					
Lung	(50)	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	2 (4%)	4 (8%)	2 (4%)	2 (4%)	1 (2%)
Alveolar/Bronchiolar Carcinoma			1 (2%)	2 (4%)	1 (2%)
Hemangiosarcoma, Metastatic, Uterus		1 (2%)			
Hepatocellular Carcinoma, Metastatic, Liver					1 (2%)
Osteosarcoma, Metastatic, Uncertain Primary Site	1 (2%)				
Rhabdomyosarcoma, Metastatic, Skeletal Muscle	1 (2%)				
Nose	(50)	(50)	(50)	(50)	(50)
Trachea	(50)	(50)	(50)	(50)	(50)
<b>SPECIAL SENSES SYSTEM</b>					
Ear	(0)	(0)	(0)	(0)	(1)
Eye	(50)	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)	(50)
Adenoma	2 (4%)	3 (6%)	2 (4%)	3 (6%)	1 (2%)
<b>URINARY SYSTEM</b>					
Kidney	(50)	(50)	(50)	(50)	(50)
Urinary Bladder	(50)	(50)	(50)	(50)	(49)
<b>SYSTEMIC LESIONS</b>					
Multiple Organ	*(50)	*(50)	*(50)	*(50)	*(50)
Amyloid			1 (2%)	1 (2%)	
Histiocytic Sarcoma	2 (4%)	2 (4%)	3 (6%)	1 (2%)	
Leukemia Mononuclear	1 (2%)			1 (2%)	
Lymphoma Malignant	10 (20%)	8 (16%)	9 (18%)	9 (18%)	13 (26%)

a - Number of animals examined microscopically at site and number of animals with lesion

\* Number of animals with any tissue examined microscopically

Experiment Number: 00058 - 04

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)**

Date Report Requested: 12/10/2020

Test Type: CHRONIC

Black Cohosh

Time Report Requested: 11:32:38

Route: GAVAGE

CAS Number: 84776-26-1

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

Species/Strain: MICE/B6C3F1/N

Lab: BAT

---

B6C3F1/N MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
----------------------	---------	----------	-----------	-----------	------------

---

**Tumor Summary for Females**

Total Animals with Primary Neoplasms (b)	30	27	26	26	28
Total Primary Neoplasms	41	38	39	35	38
Total Animals with Benign Neoplasms	15	16	14	15	19
Total Benign Neoplasms	17	20	19	17	22
Total Animals with Malignant Neoplasms	21	15	16	15	15
Total Malignant Neoplasms	24	18	20	18	16
Total Animals with Metastatic Neoplasms	3	1	1	1	1
Total Metastatic Neoplasms	10	1	1	5	1
Total Animals with Malignant Neoplasms Uncertain Primary Site	1				
Total Animals with Neoplasms Uncertain- Benign or Malignant					
Total Uncertain Neoplasms					

---

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

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors