

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

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 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

B6C3F1/N MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Disposition Summary					
Animals Initially In Study	70	70	70	70	70
Early Deaths					
Accidentally Killed				1	
Moribund Sacrifice	4	2	3	3	6
Natural Death	6	8	3	7	6
Survivors					
Natural Death		1			
Terminal Sacrifice	40	39	44	39	38
Animals Examined Microscopically	50	50	50	50	50

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)
Inflammation, Acute	1 (2%)				
Ulcer	1 (2%)				
Intestine Large, Rectum	(50)	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)	(50)
Perforation			1 (2%)		
Polyarteritis Nodosa	1 (2%)				
Ulcer			1 (2%)		
Intestine Small, Ileum	(50)	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)	(50)
Epithelium, Hyperplasia	1 (2%)		2 (4%)		
Peyer's Patch, Hyperplasia, Lymphocyte	4 (8%)	5 (10%)	3 (6%)	2 (4%)	4 (8%)
Peyer's Patch, Inflammation, Chronic Active					1 (2%)
Liver	(50)	(50)	(50)	(50)	(50)
Amyloid			1 (2%)		
Angiectasis	1 (2%)				1 (2%)
Basophilic Focus	6 (12%)	1 (2%)			
Clear Cell Focus	3 (6%)	1 (2%)	3 (6%)	1 (2%)	4 (8%)
Eosinophilic Focus	7 (14%)	5 (10%)	2 (4%)	1 (2%)	4 (8%)

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

Experiment Number: 00058 - 04

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

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

B6C3F1/N MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Extramedullary Hematopoiesis			1 (2%)	1 (2%)	2 (4%)
Fatty Change	2 (4%)		1 (2%)		1 (2%)
Hemorrhage					1 (2%)
Hepatodiaphragmatic Nodule					1 (2%)
Infiltration Cellular, Lymphocyte			3 (6%)		
Inflammation, Chronic Active		1 (2%)	1 (2%)		
Intrahepatocellular Erythrocytes	2 (4%)	1 (2%)	1 (2%)	2 (4%)	
Mixed Cell Focus			3 (6%)		1 (2%)
Necrosis	2 (4%)		1 (2%)	1 (2%)	8 (16%)
Pigment	1 (2%)				
Tension Lipidosis	2 (4%)	2 (4%)	4 (8%)	1 (2%)	
Bile Duct, Cyst	1 (2%)				
Hepatocyte, Atrophy	1 (2%)		1 (2%)		
Mesentery	(6)	(2)	(0)	(2)	(1)
Inflammation, Granulomatous	1 (17%)				
Fat, Necrosis	4 (67%)	1 (50%)			
Pancreas	(50)	(50)	(50)	(49)	(50)
Infiltration Cellular, Adipocyte		1 (2%)			
Acinar Cell, Vacuolation, Cytoplasmic	1 (2%)				
Acinus, Atrophy	3 (6%)	1 (2%)	1 (2%)	1 (2%)	
Acinus, Hypertrophy		1 (2%)			
Duct, Cyst				1 (2%)	
Salivary Glands	(50)	(50)	(50)	(50)	(50)
Atrophy		1 (2%)			
Infiltration Cellular, Lymphocyte			1 (2%)		
Polyarteritis Nodosa	1 (2%)				1 (2%)
Duct, Hyperplasia					1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)	(50)
Diverticulum	1 (2%)				
Ulcer		1 (2%)			
Epithelium, Hyperplasia, Focal		2 (4%)	1 (2%)		
Stomach, Glandular	(50)	(50)	(50)	(50)	(50)
Mineral	1 (2%)	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Polyarteritis Nodosa	1 (2%)				
Epithelium, Hyperplasia		1 (2%)			
Tongue	(0)	(0)	(1)	(0)	(0)

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

Experiment Number: 00058 - 04

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

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

B6C3F1/N MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Tooth	(0)	(3)	(0)	(2)	(0)
Inflammation, Acute				1 (50%)	
Necrosis		1 (33%)		1 (50%)	
CARDIOVASCULAR SYSTEM					
Aorta	(1)	(0)	(0)	(0)	(1)
Polyarteritis Nodosa	1 (100%)				
Blood Vessel	(50)	(48)	(49)	(49)	(49)
Infiltration Cellular, Lymphocyte		1 (2%)			
Heart	(50)	(50)	(50)	(50)	(50)
Cardiomyopathy	8 (16%)	5 (10%)	8 (16%)	11 (22%)	12 (24%)
Mineral	1 (2%)				
Polyarteritis Nodosa	2 (4%)				
Valve, Degeneration, Myxomatous	1 (2%)				
Valve, Inflammation, Acute	1 (2%)				
Valve, Inflammation, Chronic Active					1 (2%)
ENDOCRINE SYSTEM					
Adrenal Cortex	(50)	(50)	(50)	(50)	(50)
Hyperplasia, Focal	1 (2%)				
Hypertrophy, Focal	1 (2%)			1 (2%)	1 (2%)
Infiltration Cellular, Lymphocyte		1 (2%)			
Vacuolation, Cytoplasmic, Focal				1 (2%)	
Bilateral, Vacuolation, Cytoplasmic, Focal	2 (4%)				
Subcapsular, Hyperplasia			1 (2%)		
Adrenal Medulla	(50)	(50)	(50)	(50)	(50)
Hyperplasia, Focal	1 (2%)				1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)	(50)
Atrophy				1 (2%)	
Hyperplasia	7 (14%)		3 (6%)		1 (2%)
Parathyroid Gland	(41)	(45)	(42)	(41)	(42)
Pituitary Gland	(49)	(49)	(50)	(50)	(50)
Hemorrhage				1 (2%)	

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

Experiment Number: 00058 - 04

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

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

B6C3F1/N MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Pars Distalis, Atypia Cellular	1 (2%)				
Pars Distalis, Hyperplasia, Focal	8 (16%)	8 (16%)	10 (20%)	7 (14%)	8 (16%)
Pars Distalis, Hypertrophy	2 (4%)	1 (2%)		3 (6%)	4 (8%)
Pars Intermedia, Hyperplasia, Focal	1 (2%)				
Thyroid Gland	(50)	(50)	(49)	(49)	(50)
Cyst, Congenital					1 (2%)
Infiltration Cellular, Lymphocyte		1 (2%)			
Bilateral, Follicle, Dilation					1 (2%)
Follicle, Dilation		1 (2%)	1 (2%)	1 (2%)	5 (10%)
Follicular Cell, Hyperplasia			1 (2%)		
GENERAL BODY SYSTEM					
Peritoneum	(0)	(0)	(0)	(1)	(0)
Tissue NOS	(0)	(0)	(1)	(0)	(0)
Fat, Necrosis			1 (100%)		
GENITAL SYSTEM					
Clitoral Gland	(50)	(49)	(50)	(50)	(49)
Ovary	(49)	(50)	(50)	(50)	(50)
Angiectasis			2 (4%)		1 (2%)
Atrophy	35 (71%)	38 (76%)	34 (68%)	39 (78%)	30 (60%)
Cyst, Epithelial, Multiple		2 (4%)	1 (2%)		
Cyst, Epithelial	3 (6%)	4 (8%)	2 (4%)	3 (6%)	6 (12%)
Fatty Change			1 (2%)		
Hemorrhage			1 (2%)	1 (2%)	
Infiltration Cellular, Lymphocyte	2 (4%)		1 (2%)		
Pigment			1 (2%)		
Polyarteritis Nodosa					1 (2%)
Thrombus	1 (2%)	1 (2%)	1 (2%)		1 (2%)
Bilateral, Follicle, Cyst			1 (2%)		1 (2%)
Bursa, Cyst			2 (4%)		1 (2%)
Follicle, Cyst	10 (20%)	3 (6%)	4 (8%)	5 (10%)	8 (16%)
Follicle, Cyst, Multiple		1 (2%)			

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

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

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 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

B6C3F1/N MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Germinal Epithelium, Hyperplasia	1 (2%)		1 (2%)		1 (2%)
Interstitial Cell, Hyperplasia		1 (2%)	3 (6%)	2 (4%)	1 (2%)
Paraovarian Tissue, Cyst				1 (2%)	
Rete Ovarii, Cyst	1 (2%)			2 (4%)	1 (2%)
Uterus	(50)	(50)	(50)	(50)	(50)
Adenomyosis		1 (2%)			
Angiectasis	2 (4%)	2 (4%)	1 (2%)		3 (6%)
Dilation		1 (2%)			
Hemorrhage					1 (2%)
Inflammation, Acute	5 (10%)	1 (2%)	2 (4%)	5 (10%)	
Polyarteritis Nodosa					1 (2%)
Thrombus				2 (4%)	
Endometrium, Hyperplasia, Cystic	41 (82%)	31 (62%)	45 (90%)	41 (82%)	45 (90%)
Endometrium, Metaplasia, Squamous	2 (4%)			1 (2%)	1 (2%)
Vagina	(50)	(50)	(49)	(49)	(50)
Congestion					1 (2%)
Inflammation, Acute	21 (42%)	6 (12%)	8 (16%)	6 (12%)	3 (6%)
Polyarteritis Nodosa					1 (2%)
Epithelium, Hyperplasia, Cystic		1 (2%)			
Epithelium, Hyperplasia, Squamous	31 (62%)	38 (76%)	41 (84%)	37 (76%)	33 (66%)
HEMATOPOIETIC SYSTEM					
Bone Marrow	(50)	(50)	(50)	(50)	(50)
Angiectasis					1 (2%)
Fibrosis				1 (2%)	
Hypercellularity	1 (2%)	2 (4%)	5 (10%)	5 (10%)	3 (6%)
Necrosis			1 (2%)		
Lymph Node	(6)	(1)	(2)	(5)	(7)
Lumbar, Angiectasis			1 (50%)		
Lumbar, Hyperplasia, Lymphocyte					1 (14%)
Lymph Node, Mandibular	(50)	(49)	(50)	(50)	(50)
Atrophy	1 (2%)	1 (2%)		1 (2%)	
Hyperplasia, Lymphocyte		4 (8%)	5 (10%)		7 (14%)
Infiltration Cellular, Plasma Cell			1 (2%)	1 (2%)	1 (2%)

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

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

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 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

B6C3F1/N MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Pigment		2 (4%)			
Sinus, Infiltration Cellular, Neutrophil			1 (2%)		
Lymph Node, Mesenteric	(50)	(49)	(50)	(49)	(50)
Angiectasis			1 (2%)		
Atrophy	1 (2%)		1 (2%)	1 (2%)	1 (2%)
Extramedullary Hematopoiesis	1 (2%)	1 (2%)	1 (2%)	1 (2%)	
Hemorrhage	1 (2%)				
Hyperplasia, Lymphocyte	11 (22%)	10 (20%)	11 (22%)	4 (8%)	7 (14%)
Infiltration Cellular, Histiocyte				1 (2%)	1 (2%)
Infiltration Cellular, Plasma Cell	1 (2%)		1 (2%)	3 (6%)	
Inflammation, Chronic Active					1 (2%)
Spleen	(50)	(50)	(50)	(50)	(50)
Extramedullary Hematopoiesis, Increased	17 (34%)	21 (42%)	22 (44%)	14 (28%)	11 (22%)
Hyperplasia, Lymphocyte	10 (20%)	18 (36%)	10 (20%)	14 (28%)	7 (14%)
Pigment	2 (4%)	2 (4%)			1 (2%)
White Pulp, Atrophy	2 (4%)	4 (8%)	3 (6%)	5 (10%)	2 (4%)
Thymus	(48)	(46)	(48)	(49)	(46)
Hyperplasia, Epithelial			1 (2%)		
INTEGUMENTARY SYSTEM					
Mammary Gland	(50)	(50)	(50)	(47)	(50)
Galactocele					1 (2%)
Duct, Hyperplasia			1 (2%)		
Epithelium, Hyperplasia		1 (2%)	1 (2%)		1 (2%)
Skin	(50)	(50)	(50)	(50)	(50)
Erosion				1 (2%)	
Infiltration Cellular, Lymphocyte		1 (2%)			
Ulcer			2 (4%)		2 (4%)
Epidermis, Hyperplasia				1 (2%)	
Subcutaneous Tissue, Fibrosis	1 (2%)				
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	(50)

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

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

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 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

B6C3F1/N MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Fibro-Osseous Lesion	8 (16%)	3 (6%)	2 (4%)	2 (4%)	7 (14%)
Increased Bone			1 (2%)		1 (2%)
Joint, Degeneration			1 (2%)	3 (6%)	
Skeletal Muscle	(1)	(2)	(0)	(1)	(1)

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)	(50)
Gliosis					1 (2%)
Hemorrhage				1 (2%)	
Hydrocephalus			2 (4%)		1 (2%)
Infiltration Cellular, Lymphocyte		2 (4%)			1 (2%)
Inflammation, Chronic Active	1 (2%)				
Necrosis			1 (2%)		
Polyarteritis Nodosa	2 (4%)			1 (2%)	3 (6%)
Medulla, Necrosis	1 (2%)				
Peripheral Nerve	(2)	(0)	(0)	(1)	(1)
Axon, Sciatic, Degeneration					1 (100%)
Spinal Cord	(2)	(0)	(0)	(1)	(1)
Polyarteritis Nodosa				1 (100%)	
Axon, Degeneration	1 (50%)			1 (100%)	1 (100%)

RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)	(50)
Hemorrhage	1 (2%)	1 (2%)	1 (2%)		
Infiltration Cellular, Histiocyte	1 (2%)			1 (2%)	
Infiltration Cellular, Lymphocyte		3 (6%)	1 (2%)		
Inflammation, Chronic Active					1 (2%)
Pigment		1 (2%)			
Polyarteritis Nodosa				1 (2%)	
Alveolus, Epithelium, Hyperplasia	2 (4%)	2 (4%)	2 (4%)	1 (2%)	1 (2%)
Nose	(50)	(50)	(50)	(50)	(50)
Olfactory Epithelium, Accumulation, Hyaline Droplet			1 (2%)		

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

Experiment Number: 00058 - 04

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

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

B6C3F1/N MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Olfactory Epithelium, Atrophy	1 (2%)		1 (2%)		3 (6%)
Olfactory Epithelium, Metaplasia, Respiratory	4 (8%)	7 (14%)	5 (10%)	7 (14%)	3 (6%)
Respiratory Epithelium, Accumulation, Hyaline Droplet	13 (26%)	14 (28%)	15 (30%)	13 (26%)	10 (20%)
Respiratory Epithelium, Hyperplasia	17 (34%)	19 (38%)	9 (18%)	13 (26%)	18 (36%)
Respiratory Epithelium, Inflammation, Acute	2 (4%)	1 (2%)	1 (2%)		1 (2%)
Respiratory Epithelium, Inflammation, Chronic				1 (2%)	
Respiratory Epithelium, Inflammation, Chronic Active	1 (2%)		1 (2%)	1 (2%)	
Trachea	(50)	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM					
Ear	(0)	(0)	(0)	(0)	(1)
Eye	(50)	(50)	(50)	(50)	(50)
Phthisis Bulbi	1 (2%)	2 (4%)			
Anterior Chamber, Inflammation, Acute		1 (2%)		1 (2%)	
Ciliary Body, Inflammation, Acute		1 (2%)		1 (2%)	
Cornea, Inflammation, Acute		1 (2%)		1 (2%)	
Cornea, Inflammation, Chronic Active	1 (2%)				
Lens, Cataract	3 (6%)				1 (2%)
Harderian Gland	(50)	(50)	(50)	(50)	(50)
Fibrosis	1 (2%)				
Hyperplasia	1 (2%)		3 (6%)	4 (8%)	3 (6%)
URINARY SYSTEM					
Kidney	(50)	(50)	(50)	(50)	(50)
Glomerulosclerosis					1 (2%)
Infarct, Chronic	3 (6%)	2 (4%)			
Infiltration Cellular, Lymphocyte	1 (2%)	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Nephropathy, Chronic Progressive	13 (26%)	14 (28%)	10 (20%)	20 (40%)	17 (34%)
Polyarteritis Nodosa	1 (2%)				
Glomerulus, Amyloid				1 (2%)	
Glomerulus, Cyst		1 (2%)			

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

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

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
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

B6C3F1/N MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Renal Tubule, Accumulation, Hyaline Droplet		3 (6%)	1 (2%)		
Renal Tubule, Cyst	2 (4%)			1 (2%)	
Urinary Bladder	(50)	(50)	(50)	(50)	(49)
Fibrosis				1 (2%)	
Infiltration Cellular, Lymphocyte	2 (4%)		1 (2%)		
Polyarteritis Nodosa	1 (2%)				
Ulcer				1 (2%)	

*** END OF REPORT ***

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