

Experiment Number: 00058 - 03

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH  
AVERAGE SEVERITY GRADES[b]**

Date Report Requested: 10/07/2020

Test Type: CHRONIC

Black Cohosh

Time Report Requested: 11:17:00

Route: GAVAGE

CAS Number: 84776-26-1

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

Species/Strain: RATS/HSD

Lab: BAT

Rats Final 1

**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:** 3.0.2.3\_002  
**PWG Approval Date:** NONE

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Harlan Sprague Dawley RATS MALE	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
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**Disposition Summary**

<b>Animals Initially In Study</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>
<b>Early Deaths</b>				
<b>Moribund Sacrifice</b>	<b>16</b>	<b>14</b>	<b>11</b>	<b>8</b>
<b>Natural Death</b>	<b>19</b>	<b>20</b>	<b>18</b>	<b>26</b>
<b>Survivors</b>				
<b>Natural Death</b>		<b>1</b>		
<b>Terminal Sacrifice</b>	<b>15</b>	<b>15</b>	<b>21</b>	<b>16</b>
<b>Animals Examined Microscopically</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>

## ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(49)	(50)	(49)
Erosion	3 [1.7]	4 [1.5]		2 [2.0]
Infiltration Cellular, Lymphoid		1 [2.0]		
Inflammation, Acute	1 [1.0]			1 [1.0]
Inflammation, Chronic	2 [1.0]	2 [1.5]		1 [2.0]
Inflammation, Chronic Active	1 [3.0]	1 [1.0]		3 [2.7]
Mineral	3 [2.3]	4 [1.8]	1 [1.0]	5 [1.6]
Polyarteritis Nodosa	3 [2.0]	8 [1.8]	1 [2.0]	4 [1.8]
Ulcer	2 [2.5]	1 [2.0]		1 [3.0]
Intestine Large, Colon	(50)	(50)	(50)	(50)
Infiltration Cellular, Lymphoid		1 [2.0]		
Inflammation, Chronic	1 [1.0]			
Inflammation, Chronic Active				1 [1.0]
Mineral		1 [3.0]	1 [1.0]	
Parasite Metazoan	1	2	1	1
Polyarteritis Nodosa	1 [2.0]	2 [1.5]	2 [1.0]	3 [1.3]
Ulcer			1 [2.0]	
Lymphoid Tissue, Hyperplasia	1 [3.0]	4 [2.5]	2 [3.0]	
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Parasite Metazoan		3	1	2
Polyarteritis Nodosa	2 [1.5]	2 [2.0]	1 [1.0]	
Intestine Small, Duodenum	(50)	(50)	(49)	(49)

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Polyarteritis Nodosa	2 [2.0]		3 [1.7]	1 [2.0]
Intestine Small, Ileum	(49)	(50)	(50)	(50)
Polyarteritis Nodosa	1 [1.0]	1 [1.0]		1 [1.0]
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Polyarteritis Nodosa	2 [2.0]	1 [1.0]		1 [2.0]
Peyer's Patch, Hyperplasia		1 [2.0]	1 [4.0]	1 [3.0]
Liver	(50)	(50)	(50)	(50)
Angiectasis	1 [3.0]			
Basophilic Focus		2	1	4
Clear Cell Focus	19	13	24	17
Degeneration, Cystic			2 [1.0]	1 [1.0]
Eosinophilic Focus	5	7	2	1
Extramedullary Hematopoiesis		3 [1.3]	1 [1.0]	3 [1.3]
Fatty Change, Focal		1 [2.0]		1 [1.0]
Hepatodiaphragmatic Nodule		1	2	3
Inflammation, Granulomatous		1 [4.0]		
Mixed Cell Focus	2	1		2
Necrosis	8 [1.6]	3 [2.3]	4 [1.8]	2 [2.5]
Polyarteritis Nodosa	2 [1.0]			1 [1.0]
Artery, Inflammation, Chronic Active	1 [2.0]			
Bile Duct, Cyst	4	4	1	1
Bile Duct, Dilation	3 [2.7]	1 [2.0]	1 [4.0]	
Bile Duct, Hyperplasia	27 [1.1]	19 [1.1]	25 [1.0]	18 [1.1]
Bile Duct, Inflammation, Chronic Active				1 [2.0]
Centrilobular, Degeneration				1 [2.0]
Centrilobular, Necrosis		1 [2.0]		
Mesentery	(0)	(3)	(1)	(0)
Hemorrhage		1 [3.0]		
Pigment		1 [2.0]		
Polyarteritis Nodosa		1 [3.0]		
Fat, Necrosis			1 [2.0]	
Oral Mucosa	(0)	(0)	(1)	(0)
Pancreas	(50)	(50)	(50)	(50)
Polyarteritis Nodosa	6 [1.7]	6 [1.8]	7 [1.3]	10 [1.5]
Acinus, Atrophy	5 [1.4]	4 [1.3]	1 [1.0]	4 [1.3]
Acinus, Hyperplasia	9 [2.3]	9 [2.8]	8 [3.4]	6 [1.8]

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Harlan Sprague Dawley RATS MALE	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Duct, Cyst				1
Salivary Glands	(50)	(50)	(50)	(50)
Atrophy	1 [2.0]	1 [2.0]		
Inflammation, Chronic Active		1 [2.0]		
Stomach, Forestomach	(50)	(50)	(50)	(50)
Cyst, Squamous		1		
Edema				1 [2.0]
Erosion			1 [1.0]	
Foreign Body		1		
Infiltration Cellular, Lipocyte		1 [1.0]		
Inflammation, Granulomatous	1 [1.0]			
Inflammation, Acute		1 [1.0]	2 [1.0]	
Inflammation, Chronic	2 [1.5]		1 [1.0]	1 [2.0]
Inflammation, Chronic Active		2 [2.0]	3 [1.7]	2 [1.0]
Mineral	1 [1.0]	2 [2.5]	1 [1.0]	
Necrosis			1 [1.0]	
Polyarteritis Nodosa	1 [2.0]	1 [2.0]	2 [1.0]	1 [2.0]
Ulcer		1 [2.0]	3 [1.0]	
Epithelium, Hyperplasia	1 [2.0]	6 [1.7]	5 [2.2]	7 [1.7]
Epithelium, Hyperplasia, Basal Cell	1 [3.0]	1 [2.0]	1 [1.0]	1 [2.0]
Stomach, Glandular	(50)	(50)	(50)	(50)
Infiltration Cellular, Lipocyte		1 [2.0]		
Infiltration Cellular, Lymphocyte	1 [1.0]			
Inflammation, Acute		1 [2.0]		
Inflammation, Chronic	1 [1.0]			
Mineral	15 [2.3]	16 [2.6]	10 [1.9]	10 [2.4]
Polyarteritis Nodosa			1 [2.0]	
Tongue	(0)	(1)	(0)	(0)
Edema		1 [3.0]		
Inflammation, Chronic Active		1 [2.0]		
Tooth	(0)	(3)	(0)	(0)
Metaplasia, Osseous		1 [1.0]		
Dentine, Degeneration		2 [2.5]		
Pulp, Inflammation, Chronic		1 [2.0]		

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<b>CARDIOVASCULAR SYSTEM</b>				
Blood Vessel	(32)	(33)	(32)	(33)
Aneurysm		1 [3.0]		
Mineral	14 [1.6]	15 [2.2]	13 [1.3]	11 [2.0]
Aorta, Dilation		2 [3.0]	1 [2.0]	1 [3.0]
Carotid Artery, Polyarteritis Nodosa				1 [2.0]
Intima, Hyperplasia	1 [2.0]			
Pulmonary Artery, Thrombus				1
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	37 [1.4]	40 [1.8]	40 [1.4]	37 [1.7]
Inflammation, Acute		1 [1.0]		
Inflammation, Chronic Active				1 [4.0]
Mineral	4 [1.3]	8 [2.0]	1 [1.0]	3 [1.7]
Polyarteritis Nodosa	2 [1.5]	1 [2.0]		
Thrombus		1		
Atrium, Thrombus	2	1	4	3
Perivascular, Infiltration Cellular, Lymphocyte		1 [2.0]	2 [1.0]	
Valve, Inflammation, Chronic			1 [1.0]	
Valve, Thrombus				1

**ENDOCRINE SYSTEM**

Adrenal Cortex	(50)	(50)	(50)	(50)
Amyloid Deposition, Focal			1 [1.0]	
Angiectasis				1 [2.0]
Degeneration, Cystic	5 [1.0]	4 [1.0]	5 [1.0]	4 [1.0]
Hyperplasia, Focal	6 [1.5]	10 [1.6]	8 [1.1]	9 [1.7]
Hypertrophy, Focal	1 [1.0]			
Necrosis	2 [1.0]	3 [1.7]	4 [1.5]	3 [1.3]
Thrombus		2		4
Vacuolization Cytoplasmic	1 [2.0]			1 [2.0]
Bilateral, Hyperplasia, Focal	1 [2.0]		1 [2.0]	5 [1.2]
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia, Focal	9 [1.9]	9 [1.6]	13 [2.2]	15 [2.0]

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Bilateral, Hyperplasia, Focal Islets, Pancreatic	5 [2.6] (50)	2 [2.5] (50)	3 [2.3] (50)	4 [2.8] (50)
Atrophy	1 [4.0]			
Hyperplasia	2 [2.0] (49)	3 [2.0] (47)	1 [1.0] (44)	3 [2.3] (39)
Parathyroid Gland				
Hyperplasia, Diffuse	13 [2.9] (50)	24 [2.9] (50)	16 [2.3] (50)	14 [2.6] (50)
Pituitary Gland				
Inflammation, Chronic Active	1 [2.0]			
Pars Distalis, Hyperplasia	20 [1.6]	15 [1.5]	15 [1.7]	15 [1.9]
Pars Nervosa, Thrombus				1
Thyroid Gland	(50)	(50)	(50)	(50)
Ectopic Thymus	1 [1.0]			
Polyarteritis Nodosa		1 [2.0]		1 [2.0]
C-cell, Hyperplasia	9 [2.8]	10 [2.0]	9 [3.1]	6 [2.7]

## GENERAL BODY SYSTEM

None

## GENITAL SYSTEM

Epididymis	(50)	(50)	(50)	(50)
Atrophy	1 [2.0]	2 [2.0]		1 [2.0]
Granuloma Sperm		1 [4.0]		
Inflammation, Chronic Active			1 [1.0]	
Polyarteritis Nodosa			2 [1.0]	
Bilateral, Atrophy	1 [2.0]			
Preputial Gland	(50)	(50)	(50)	(50)
Duct, Hyperplasia, Squamous	1 [3.0]		1 [3.0]	1 [2.0]
Prostate	(50)	(50)	(50)	(50)
Hyperplasia	2 [1.0]	3 [1.0]	2 [1.0]	3 [1.0]
Inflammation, Chronic		1 [1.0]	5 [1.0]	2 [1.0]
Inflammation, Chronic Active	9 [2.0]	6 [1.7]	4 [2.0]	4 [1.8]
Polyarteritis Nodosa			2 [1.0]	
Seminal Vesicle	(50)	(50)	(50)	(50)

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Inflammation, Chronic Active	3 [2.0]	2 [2.5]	1 [1.0]	1 [3.0]
Metaplasia, Squamous			1 [2.0]	
Mineral		1 [2.0]		
Polyarteritis Nodosa			2 [1.0]	
Testis	(50)	(50)	(50)	(50)
Edema				1 [3.0]
Granuloma Sperm	1 [1.0]			1 [1.0]
Mineral	1 [2.0]			
Polyarteritis Nodosa	24 [1.6]	25 [1.8]	24 [1.8]	23 [1.7]
Bilateral, Germinal Epithelium, Degeneration	14 [2.4]	21 [2.3]	19 [2.1]	10 [2.2]
Germinal Epithelium, Degeneration	12 [2.2]	5 [1.2]	6 [2.0]	16 [1.5]
Interstitial Cell, Hyperplasia	1 [2.0]	2 [2.0]	2 [2.5]	1 [2.0]

## HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Hemorrhage	10 [2.8]	19 [1.9]	15 [2.0]	21 [2.3]
Hypercellularity	28 [2.4]	27 [2.1]	30 [1.9]	29 [1.8]
Myelofibrosis		2 [1.0]		
Necrosis				1 [3.0]
Lymph Node	(5)	(4)	(3)	(4)
Lumbar, Hemorrhage			1 [2.0]	
Lumbar, Hyperplasia, Lymphoid	1 [3.0]			
Lumbar, Hyperplasia, Plasma Cell				1 [2.0]
Lumbar, Infiltration Cellular, Histiocyte			1 [2.0]	
Lumbar, Pigment			1 [2.0]	
Lumbar, Lymphatic Sinus, Ectasia				1 [2.0]
Mediastinal, Hemorrhage		1 [2.0]		1 [2.0]
Mediastinal, Infiltration Cellular, Histiocyte	1 [1.0]			
Mediastinal, Pigment				1 [2.0]
Mediastinal, Thrombus	1			
Pancreatic, Infiltration Cellular, Plasma Cell			1 [2.0]	
Renal, Ectasia				2 [3.5]
Renal, Hemorrhage	1 [2.0]	1 [2.0]	1 [2.0]	
Renal, Pigment		1 [2.0]	1 [2.0]	

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Lymph Node, Mandibular	(50)	(50)	(50)	(50)
Atrophy			1 [4.0]	
Ectasia			2 [3.0]	
Hyperplasia, Lymphoid	1 [4.0]			1 [2.0]
Infiltration Cellular, Plasma Cell	2 [3.0]	2 [2.5]		2 [2.0]
Inflammation		2 [2.5]		
Lymph Node, Mesenteric	(50)	(50)	(49)	(48)
Atrophy	1 [3.0]			1 [4.0]
Hyperplasia, Lymphoid	1 [4.0]	1 [3.0]		
Infiltration Cellular, Histiocyte	1 [1.0]			
Necrosis	1 [2.0]			
Spleen	(50)	(50)	(49)	(50)
Extramedullary Hematopoiesis	41 [2.3]	41 [2.0]	42 [2.0]	39 [2.1]
Hemorrhage		1 [3.0]		
Necrosis				1 [3.0]
Pigment	38 [1.3]	39 [1.3]	43 [1.3]	40 [1.4]
Polyarteritis Nodosa	1 [2.0]			
White Pulp, Atrophy	17 [3.0]	19 [3.3]	13 [2.8]	17 [3.4]
Thymus	(46)	(48)	(46)	(49)
Atrophy	43 [2.9]	41 [2.7]	44 [2.4]	40 [3.0]
Cyst			1	
Ectopic Parathyroid Gland	2 [3.0]	1 [2.0]	2	
Hyperplasia, Lymphoid				1 [2.0]
Polyarteritis Nodosa	2 [2.0]	1 [1.0]	1 [1.0]	

## INTEGUMENTARY SYSTEM

Mammary Gland	(48)	(48)	(49)	(48)
Galactocele	1 [2.0]			
Hyperplasia	1 [1.0]	1 [2.0]	1 [2.0]	
Mineral		1 [2.0]		
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion	1	2	1	1
Edema				1 [2.0]
Foreign Body				1

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Hemorrhage				1 [2.0]
Inflammation, Granulomatous	1 [4.0]		1 [3.0]	1 [2.0]
Inflammation, Chronic Active	1 [3.0]	1 [4.0]	1 [3.0]	6 [3.3]
Ulcer	1 [3.0]	1 [4.0]	1 [2.0]	5 [3.0]
Epidermis, Hyperplasia				3 [1.7]
Subcutaneous Tissue, Polyarteritis Nodosa			1 [1.0]	

## MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Cyst		1		
Fibrous Osteodystrophy			1 [1.0]	
Osteopetrosis			2 [1.0]	1 [3.0]
Cartilage, Joint, Degeneration			1 [1.0]	
Skeletal Muscle	(0)	(0)	(1)	(3)
Degeneration				1 [2.0]
Polyarteritis Nodosa				1 [1.0]

## NERVOUS SYSTEM

Brain	(50)	(50)	(49)	(50)
Edema			1 [1.0]	
Gliosis			2 [1.0]	1 [2.0]
Hemorrhage	1 [3.0]	2 [2.5]		
Inflammation, Chronic Active				1 [2.0]
Necrosis		1 [2.0]	2 [3.5]	2 [2.5]
Thrombus			1	
Nerve Trigeminal	(0)	(1)	(0)	(0)
Peripheral Nerve	(0)	(1)	(1)	(2)
Degeneration				1 [2.0]
Axon, Sciatic, Degeneration			1 [1.0]	1 [2.0]
Axon, Tibial, Degeneration			1 [1.0]	1 [3.0]
Axon, Trigeminal, Degeneration			1 [2.0]	2 [1.5]
Trigeminal, Fibrosis				1 [2.0]
Spinal Cord	(0)	(1)	(1)	(2)

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Gliosis			1 [2.0]	
Hemorrhage		1 [3.0]		
Axon, Degeneration		1 [2.0]	1 [2.0]	1 [2.0]

## RESPIRATORY SYSTEM

	(50)	(50)	(50)	(50)
Lung				
Hemorrhage		2 [3.0]		
Infiltration Cellular, Histiocyte	21 [1.3]	19 [1.5]	29 [1.6]	26 [1.7]
Inflammation, Granulomatous	10 [1.2]	9 [1.0]	13 [1.2]	9 [1.1]
Inflammation, Acute	3 [1.7]	4 [1.3]	1 [1.0]	1 [2.0]
Inflammation, Chronic Active			1 [3.0]	4 [1.8]
Mineral	6 [1.2]	11 [1.9]	1 [3.0]	5 [1.4]
Polyarteritis Nodosa				1 [2.0]
Squamous Metaplasia		1 [2.0]		
Thrombus				2
Alveolar Epithelium, Hyperplasia	2 [1.5]	1 [1.0]	2 [1.5]	2 [1.0]
Alveolar Epithelium, Hypertrophy				1 [1.0]
Alveolus, Fibrosis		1 [1.0]		
Alveolus, Foreign Body	1			
Bronchiole, Fibrosis		1 [2.0]	1 [1.0]	1 [2.0]
Bronchiole, Foreign Body		1		
Interstitial, Fibrosis	1 [1.0]	1 [1.0]		1 [2.0]
Peribronchiolar, Fibrosis			1 [2.0]	
Perivascular, Infiltration Cellular, Lymphoid	1 [2.0]			
Perivascular, Inflammation, Chronic		1 [2.0]		
Pleura, Fibrosis				1 [1.0]
Nose	(50)	(50)	(50)	(50)
Foreign Body	6	1	1	
Inflammation, Suppurative	5 [1.6]	6 [2.2]		3 [2.0]
Inflammation, Acute	2 [1.0]		2 [1.0]	
Inflammation, Chronic	3 [1.0]		2 [1.0]	
Inflammation, Chronic Active	3 [1.7]	4 [1.5]	3 [1.0]	4 [1.3]
Nasolacrimal Duct, Inflammation, Suppurative	1 [3.0]	1 [3.0]		
Nasolacrimal Duct, Inflammation, Chronic	8 [1.3]	4 [1.3]	2 [1.0]	5 [1.0]

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Test Type: CHRONIC

Black Cohosh

Time Report Requested: 11:17:00

Route: GAVAGE

CAS Number: 84776-26-1

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

Species/Strain: RATS/HSD

Lab: BAT

Harlan Sprague Dawley RATS MALE	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Nasolacrimal Duct, Inflammation, Chronic Active	2 [1.0]	4 [1.3]	4 [1.3]	5 [1.6]
Nasopharyngeal Duct, Inflammation, Chronic Active		1 [3.0]		
Nasopharyngeal Duct, Squamous Metaplasia		1 [3.0]		
Olfactory Epithelium, Degeneration				1 [2.0]
Olfactory Epithelium, Metaplasia, Respiratory	1 [2.0]	1 [1.0]		
Olfactory Epithelium, Squamous Metaplasia		1 [1.0]		
Respiratory Epithelium, Hyperplasia	1 [1.0]	1 [1.0]	1 [1.0]	2 [1.5]
Respiratory Epithelium, Squamous Metaplasia			1 [2.0]	1 [1.0]
Trachea	(50)	(50)	(50)	(50)
Mineral		1 [2.0]		

## SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Cataract	1 [1.0]			
Inflammation, Acute			1 [2.0]	
Inflammation, Chronic		1 [1.0]		
Cornea, Inflammation, Acute	5 [2.4]	5 [1.6]	2 [2.0]	4 [1.5]
Cornea, Inflammation, Chronic	2 [1.5]	2 [1.5]		2 [2.5]
Cornea, Inflammation, Chronic Active	1 [4.0]	6 [2.0]	11 [2.2]	4 [1.5]
Optic Nerve, Polyarteritis Nodosa				1 [1.0]
Retina, Degeneration	3 [1.7]		1 [1.0]	
Retina, Dysplasia		1 [2.0]		
Retina, Fibrosis	1 [1.0]			
Retina, Hyperplasia		1 [2.0]		
Harderian Gland	(50)	(50)	(50)	(50)
Atrophy	1 [2.0]		2 [1.0]	1 [2.0]
Inflammation, Suppurative				1 [3.0]
Metaplasia		1 [1.0]	1 [2.0]	
Zymbal's Gland	(2)	(1)	(1)	(0)

## URINARY SYSTEM

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Black Cohosh

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Harlan Sprague Dawley RATS MALE	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Kidney	(50)	(50)	(50)	(50)
Amphophilic/Vacuolar Hyperplasia			1 [3.0]	1 [3.0]
Calculus Micro Observation Only	1	2		
Cyst				1
Hemorrhage	1 [4.0]	1 [4.0]		1 [2.0]
Hyperplasia, Oncocytic	2 [3.0]			
Infarct	1 [1.0]			1 [1.0]
Inflammation, Chronic				1 [1.0]
Nephropathy, Chronic Progressive	50 [3.4]	50 [3.6]	50 [3.4]	50 [3.3]
Polyarteritis Nodosa	1 [1.0]	2 [1.5]		
Pelvis, Dilation	1 [2.0]			
Pelvis, Inflammation, Acute	1 [2.0]		1 [1.0]	
Pelvis, Inflammation, Chronic Active	2 [2.5]	2 [2.0]	1 [2.0]	
Renal Tubule, Accumulation, Hyaline Droplet	2 [2.5]			2 [2.0]
Renal Tubule, Cyst	4	5	4	6
Renal Tubule, Dilation	1 [2.0]			
Urinary Bladder	(50)	(50)	(50)	(50)
Infiltration Cellular, Lymphocyte			1 [2.0]	
Inflammation, Chronic	4 [1.3]	1 [2.0]		1 [2.0]
Inflammation, Chronic Active		1 [2.0]		
Polyarteritis Nodosa		1 [2.0]		1 [2.0]
Perivascular, Infiltration Cellular, Lymphocyte	1 [2.0]			
Transitional Epithelium, Hyperplasia		1 [2.0]		

\*\*\* END OF MALE \*\*\*

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Black Cohosh

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CAS Number: 84776-26-1

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

Species/Strain: RATS/HSD

Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
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**Disposition Summary**

<b>Animals Initially In Study</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>
<b>Early Deaths</b>				
<b>Moribund Sacrifice</b>	<b>13</b>	<b>14</b>	<b>15</b>	<b>14</b>
<b>Natural Death</b>	<b>9</b>	<b>12</b>	<b>6</b>	<b>16</b>
<b>Survivors</b>				
<b>Terminal Sacrifice</b>	<b>28</b>	<b>24</b>	<b>29</b>	<b>20</b>
<b>Animals Examined Microscopically</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>

## ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(49)
Intestine Large, Cecum	(50)	(50)	(50)	(49)
Erosion				1 [2.0]
Polyarteritis Nodosa		1 [2.0]	1 [2.0]	1 [1.0]
Intestine Large, Colon	(50)	(50)	(50)	(50)
Parasite Metazoan	1	1	1	1
Polyarteritis Nodosa		1 [2.0]	1 [2.0]	
Lymphoid Tissue, Hyperplasia			2 [2.0]	
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Parasite Metazoan	1	4	3	3
Polyarteritis Nodosa		2 [1.5]	2 [2.0]	3 [2.3]
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Polyarteritis Nodosa			1 [2.0]	
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Polyarteritis Nodosa				1 [2.0]
Liver	(50)	(50)	(50)	(48)
Angiectasis	2 [2.0]	1 [1.0]	2 [1.5]	3 [1.0]
Basophilic Focus	4	3	2	
Clear Cell Focus	15	6	8	4
Degeneration, Cystic				2 [1.0]
Eosinophilic Focus	10	5	10	13
Extramedullary Hematopoiesis	3 [1.3]	5 [1.2]	8 [1.0]	5 [1.4]
Hepatodiaphragmatic Nodule		2		1

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Harlan Sprague Dawley RATS FEMALE	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Mixed Cell Focus		1		
Necrosis	4 [2.3]	10 [2.0]	3 [1.3]	9 [1.9]
Pigment		3 [2.5]		
Regeneration		1 [2.0]		
Bile Duct, Cyst	4	7	10	8
Bile Duct, Dilation			3 [1.0]	1 [2.0]
Bile Duct, Hyperplasia	11 [1.1]	14 [1.1]	14 [1.1]	9 [1.3]
Centrilobular, Necrosis	1 [2.0]	1 [2.0]		
Hepatocyte, Hyperplasia	1 [2.0]			
Hepatocyte, Hypertrophy		1 [3.0]		
Hepatocyte, Multinucleated		1 [3.0]		
Oval Cell, Hyperplasia	1 [1.0]			
Serosa, Fibrosis		1 [1.0]	1 [2.0]	
Mesentery	(1)	(0)	(1)	(1)
Hemorrhage	1 [3.0]			
Oral Mucosa	(0)	(0)	(1)	(0)
Pancreas	(50)	(50)	(50)	(49)
Basophilic Focus	1		1	
Inflammation, Chronic				1 [1.0]
Polyarteritis Nodosa	1 [1.0]	2 [1.5]	1 [2.0]	3 [2.0]
Acinus, Atrophy	3 [1.3]	2 [2.5]		2 [2.5]
Acinus, Hyperplasia, Focal		1 [2.0]		
Salivary Glands	(50)	(50)	(50)	(48)
Atrophy		1 [2.0]		
Polyarteritis Nodosa			1 [2.0]	
Stomach, Forestomach	(50)	(50)	(50)	(50)
Cyst, Squamous				1
Inflammation, Acute	1 [2.0]	1 [2.0]		
Inflammation, Chronic	2 [1.0]		2 [1.5]	1 [2.0]
Inflammation, Chronic Active	1 [3.0]			1 [2.0]
Mineral	1 [1.0]			3 [1.0]
Polyarteritis Nodosa		1 [2.0]	1 [2.0]	2 [2.0]
Ulcer	1 [2.0]	1 [2.0]		1 [2.0]
Epithelium, Hyperplasia	3 [3.0]	2 [1.5]	1 [3.0]	4 [1.8]
Stomach, Glandular	(50)	(50)	(50)	(50)
Erosion			1 [2.0]	1 [2.0]

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Harlan Sprague Dawley RATS FEMALE	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Mineral	2 [1.0]	4 [1.3]	5 [1.2]	2 [1.5]
Polyarteritis Nodosa				1 [2.0]
Submucosa, Inflammation, Chronic			1 [1.0]	
Tooth	(0)	(0)	(1)	(1)
Dysplasia				1 [3.0]
Inflammation, Chronic				1 [2.0]
Malformation			1	

## CARDIOVASCULAR SYSTEM

Blood Vessel	(49)	(48)	(48)	(43)
Mineral			2 [1.0]	1 [1.0]
Carotid Artery, Polyarteritis Nodosa				1 [2.0]
Media, Hypertrophy		1 [3.0]		
Heart	(50)	(50)	(50)	(48)
Cardiomyopathy	4 [1.0]	9 [1.1]	13 [1.2]	9 [1.2]
Infiltration Cellular, Histiocyte		1 [2.0]		
Polyarteritis Nodosa				1 [2.0]
Atrium, Thrombus		1		
Endocardium, Hyperplasia, Schwann Cell				1 [2.0]

## ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(48)
Angiectasis	5 [2.0]	2 [2.0]	3 [2.0]	3 [1.3]
Degeneration, Cystic	6 [1.2]	11 [1.0]	9 [1.0]	7 [1.3]
Extramedullary Hematopoiesis		2 [1.5]		
Hyperplasia, Focal	2 [1.0]	2 [1.5]	4 [1.3]	4 [1.8]
Hypertrophy, Focal	1 [2.0]		1 [2.0]	
Infiltration Cellular, Lipocyte	1 [2.0]			
Metaplasia, Osseous	1 [1.0]			
Necrosis		2 [3.0]	1 [2.0]	2 [2.0]
Thrombus	2	1	1	1
Bilateral, Degeneration, Cystic	2 [1.0]	3 [1.3]	1 [2.0]	
Bilateral, Hyperplasia, Focal	1 [2.0]			1 [1.0]

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Harlan Sprague Dawley RATS FEMALE	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Bilateral, Hypertrophy, Focal Adrenal Medulla	(50)	(50)	1 [2.0] (50)	(48)
Hyperplasia, Focal Necrosis	5 [1.4]	7 [1.6] 1 [4.0]	12 [1.8]	5 [1.4]
Bilateral, Hyperplasia, Focal Islets, Pancreatic	(50)	(50)	(50)	3 [1.7] (49)
Hyperplasia	2 [1.5]	2 [1.5]	1 [3.0]	1 [1.0]
Parathyroid Gland	(46)	(40)	(39)	(38)
Hyperplasia, Focal Hyperplasia, Diffuse		1 [1.0] 1 [2.0]		
Pituitary Gland	(50)	(50)	(50)	(50)
Cyst Polyarteritis Nodosa		1		1 [2.0]
Pars Distalis, Hyperplasia	18 [2.1]	18 [1.8]	19 [2.6]	24 [2.3]
Thyroid Gland	(50)	(49)	(50)	(49)
Polyarteritis Nodosa			1 [2.0]	
C-cell, Hyperplasia	14 [2.2]	6 [2.0]	10 [2.5]	6 [2.5]
Follicle, Cyst	1			
Follicular Cell, Hyperplasia				1 [2.0]

## GENERAL BODY SYSTEM

Peritoneum	(0)	(2)	(1)	(0)
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## GENITAL SYSTEM

Clitoral Gland	(49)	(48)	(49)	(49)
Squamous Metaplasia	1 [3.0]			1 [1.0]
Ovary	(50)	(50)	(50)	(49)
Atrophy	32 [2.1]	39 [2.4]	38 [2.2]	47 [2.1]
Cyst	1			4
Inflammation, Chronic Active			1 [4.0]	
Polyarteritis Nodosa			1 [1.0]	1 [2.0]
Bursa, Cyst	1	2	2	
Corpus Luteum, Cyst			1	

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Harlan Sprague Dawley RATS FEMALE	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Follicle, Cyst	12	7	9	6
Follicle, Cyst, Multiple	1			
Interstitial Cell, Hyperplasia			1 [3.0]	
Periovarian Tissue, Cyst	1	3	3	
Rete Ovarii, Cyst	1			
Oviduct	(0)	(0)	(2)	(0)
Cyst			1	
Inflammation, Acute			1 [2.0]	
Uterus	(50)	(50)	(50)	(49)
Adenomyosis		2 [1.5]	2 [2.5]	1 [3.0]
Angiectasis			1 [3.0]	1 [4.0]
Cyst, Squamous				1
Dilation	2 [4.0]	3 [3.3]	9 [3.4]	22 [3.8]
Hemorrhage	1 [3.0]			8 [3.1]
Hyperplasia, Atypical	3 [1.3]	4 [1.5]	5 [3.6]	5 [1.2]
Hyperplasia, Stromal			1 [2.0]	
Inflammation, Acute	2 [1.5]		2 [2.0]	4 [2.8]
Inflammation, Chronic		1 [1.0]		
Inflammation, Chronic Active	4 [1.5]	5 [2.4]	7 [2.4]	7 [2.4]
Polyarteritis Nodosa			2 [1.5]	1 [2.0]
Squamous Metaplasia	21 [1.8]	25 [1.4]	30 [2.1]	38 [2.3]
Thrombus	1		5	5
Ulcer		1 [1.0]	3 [1.7]	9 [2.7]
Cervix, Cyst, Squamous		1		
Cervix, Hyperplasia, Squamous	3 [1.7]	1 [2.0]	1 [2.0]	3 [2.3]
Cervix, Hyperplasia, Stromal	1 [4.0]		1 [3.0]	
Cervix, Hypertrophy, Stromal	1 [2.0]			
Endometrium, Hyperplasia, Cystic	19 [1.6]	26 [1.3]	23 [1.4]	13 [1.6]
Vagina	(50)	(50)	(50)	(50)
Hyperplasia, Squamous		1 [2.0]		1 [2.0]
Inflammation, Acute	1 [1.0]		4 [1.5]	
Inflammation, Chronic				1 [1.0]
Inflammation, Chronic Active		1 [2.0]		

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Harlan Sprague Dawley RATS FEMALE	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(50)	(50)	(50)
Hemorrhage	10 [1.2]			9 [1.3]
Hypercellularity	31 [2.8]	31 [3.3]	34 [2.9]	42 [3.2]
Lymph Node	(0)	(6)	(0)	(3)
Lumbar, Hemorrhage		1 [2.0]		
Lumbar, Infiltration Cellular, Plasma Cell				1 [3.0]
Lumbar, Sinus, Ectasia		1 [3.0]		
Mediastinal, Hemorrhage		1 [3.0]		1 [2.0]
Mediastinal, Infiltration Cellular, Plasma Cell		1 [3.0]		
Lymph Node, Mandibular	(50)	(50)	(50)	(49)
Atrophy				1 [3.0]
Infiltration Cellular, Plasma Cell			2 [2.0]	
Lymph Node, Mesenteric	(50)	(50)	(50)	(49)
Spleen	(50)	(50)	(50)	(49)
Accessory Spleen			1	
Extramedullary Hematopoiesis	47 [2.3]	48 [2.4]	47 [2.3]	47 [2.5]
Hemorrhage		1 [2.0]	1 [2.0]	
Pigment	35 [1.3]	34 [1.5]	37 [1.4]	21 [1.2]
White Pulp, Atrophy	9 [2.1]	10 [2.3]	3 [3.0]	9 [2.4]
Thymus	(49)	(49)	(48)	(48)
Atrophy	46 [1.8]	44 [2.0]	43 [1.9]	45 [2.3]
Ectopic Parathyroid Gland				2 [2.5]
Polyarteritis Nodosa				1 [1.0]
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(50)	(50)	(50)	(49)
Galactocele	2 [4.0]		4 [2.5]	2 [2.5]
Hyperplasia	13 [2.0]	8 [1.6]	4 [1.3]	2 [3.0]
Hyperplasia, Atypical	1 [3.0]			
Skin	(50)	(50)	(50)	(50)
Inflammation, Chronic			1 [2.0]	

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Harlan Sprague Dawley RATS FEMALE	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
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## MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(0)	(0)	(1)

## NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Gliosis				2 [2.0]
Necrosis	1 [2.0]			
Glial Cell, Hyperplasia	1 [2.0]			

## RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(48)
Infiltration Cellular, Histiocyte	39 [1.7]	38 [1.7]	45 [1.8]	46 [2.3]
Inflammation, Granulomatous	7 [1.0]	6 [1.0]	16 [1.1]	10 [1.2]
Inflammation, Acute	1 [1.0]			2 [3.0]
Inflammation, Chronic Active	1 [1.0]	1 [1.0]	4 [1.3]	1 [1.0]
Polyarteritis Nodosa				1 [1.0]
Squamous Metaplasia		1 [1.0]		4 [1.5]
Thrombus				2
Alveolar Epithelium, Hyperplasia	4 [1.3]	2 [1.5]	1 [1.0]	1 [1.0]
Alveolar Epithelium, Metaplasia, Respiratory		1 [1.0]		
Bronchiole, Foreign Body				1
Bronchiole, Foreign Body, Multiple			1	
Bronchiole, Hyperplasia	1 [1.0]			
Interstitialium, Fibrosis			1 [1.0]	
Peribronchiolar, Fibrosis		1 [3.0]		
Nose	(50)	(50)	(50)	(50)
Foreign Body			2	2
Inflammation, Suppurative		2 [1.0]	1 [3.0]	1 [4.0]
Inflammation, Acute	1 [2.0]		2 [2.5]	3 [1.7]
Inflammation, Chronic	1 [1.0]		1 [1.0]	3 [1.7]

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Inflammation, Chronic Active				1 [1.0]
Nasolacrimal Duct, Inflammation, Chronic	4 [1.0]		1 [2.0]	5 [1.0]
Nasolacrimal Duct, Inflammation, Chronic Active			1 [2.0]	
Respiratory Epithelium, Hyperplasia		1 [1.0]	2 [2.0]	1 [1.0]
Respiratory Epithelium, Squamous Metaplasia			1 [2.0]	
Turbinate, Atrophy				1 [1.0]
Trachea	(50)	(50)	(50)	(48)

## SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Phthisis Bulbi		1 [2.0]		
Cornea, Inflammation, Acute				1 [1.0]
Harderian Gland	(50)	(50)	(50)	(50)
Fibrosis			1 [2.0]	
Lacrimal Gland	(1)	(0)	(0)	(0)
Inflammation, Granulomatous	1 [3.0]			

## URINARY SYSTEM

Kidney	(50)	(50)	(50)	(49)
Amphophilic/Vacuolar Hyperplasia			1 [2.0]	
Edema, Focal				1 [2.0]
Infarct				2 [1.5]
Inflammation, Chronic				1 [2.0]
Inflammation, Chronic Active				1 [4.0]
Nephropathy, Chronic Progressive	43 [1.3]	40 [1.4]	45 [1.6]	47 [1.8]
Polyarteritis Nodosa				2 [2.0]
Capsule, Inflammation, Chronic				1 [1.0]
Pelvis, Dilation	1 [2.0]	2 [2.0]		1 [2.0]
Pelvis, Inflammation, Acute		1 [1.0]		
Pelvis, Inflammation, Chronic				1 [2.0]
Renal Tubule, Accumulation, Hyaline Droplet	2 [1.5]			1 [1.0]
Renal Tubule, Apoptosis				4 [2.3]

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

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Experiment Number: 00058 - 03

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH  
AVERAGE SEVERITY GRADES[b]**

Date Report Requested: 10/07/2020

Test Type: CHRONIC

Black Cohosh

Time Report Requested: 11:17:00

Route: GAVAGE

CAS Number: 84776-26-1

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

Species/Strain: RATS/HSD

Lab: BAT

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Harlan Sprague Dawley RATS FEMALE	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Renal Tubule, Cyst			1	
Renal Tubule, Dilation		1 [2.0]		1 [2.0]
Urinary Bladder	(50)	(50)	(50)	(50)
Inflammation, Acute		1 [2.0]		
Inflammation, Chronic Active		2 [2.0]		

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

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

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)