TDMS No. 99007 - 06	P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]	Date Report Requested: 08/14/2008
Test Type: CHRONIC	Goldenseal root powder	Time Report Requested: 12:25:59
Route: DOSED FEED	CAS Number: GOLDENSEALRT	First Dose M/F: 05/12/03 / 05/12/03
Species/Strain: MICE/B6C3F1		Lab: SRI
	F1_Rev.1_M3	

C Number:	C99007B
Lock Date:	08/29/2006
Cage Range:	ALL
Date Range:	ALL
Reasons For Removal:	ALL
Removal Date Range:	ALL
Treatment Groups:	Include ALL
Study Gender:	Both
TDMSE Version:	2.0.0

TDMS No. 99007 - 06 Test Type: CHRONIC

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH

Date Report Requested: 08/14/2008

AVERAGE SEVERITY GRADES[b] Goldenseal root powder

Time Report Requested: 12:25:59 **F:** 05/12/03 / 05/12/03

ute: DOSED FEED ecies/Strain: MICE/B6C3F1					
B6C3F1 MICE MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM	
Disposition Summary					
Animals Initially in Study	50	50	50	50	
Early Deaths					
Moribund Sacrifice		3 9	2 3	3 2	
Natural Death	7	9	3	2	
Survivors					
Natural Death	40	1	45	45	
Terminal Sacrifice	43	37 50	45 50	45	
Animals Examined Microscopically	50	50	50	50	
ALIMENTARY SYSTEM					
Intestine Large, Cecum	(47)	(46)	(48)	(50)	
Intestine Small, Duodenum	(44)́	(43)	(47)	(50)	
Intestine Small, Jejunum	(46)	(43)	(47)	(48)	
Hyperplasia Lymphoid	1 [2 0]	1 [2 0]	3 [2 0]	2 [3 0]	

Intestine Small, Duodenum	(44)	(43)	(47)	(50)
Intestine Small, Jejunum	(46)	(43)	(47)	(48)
Hyperplasia, Lymphoid	1 [2.0]	1 [2.0]	3 [2.0]	2 [3.0]
Epithelium, Hyperplasia				1 [2.0]
Liver	(50)	(50)	(50)	(50)
Angiectasis			(),	1 [1.0]
Basophilic Focus	1	3	3	3
Clear Cell Focus	10	10	11	12
Cyst		1		1
Eosinophilic Focus	7	14	14	24
Fibrosis			1 [2.0]	
Hematopoietic Cell Proliferation		1 [2.0]	1 [2.0]	
Hemorrhage		1 [4.0]		
Hepatodiaphragmatic Nodule	1	1		
Infiltration Cellular, Lymphocyte	1 [1.0]	1 [2.0]	4 [1.5]	3 [1.0]
Infiltration Cellular, Mixed Cell	3 [1.0]	6 [1.2]	3 [1.0]	4 [1.0]
Mixed Cell Focus	1	7	9	6
Necrosis, Focal	2 [2.5]	3 [2.0]	5 [1.8]	6 [2.0]
Tension Lipidosis		1		
Bile Duct, Hyperplasia		1 [1.0]		
Hepatocyte, Hyperplasia, Focal			1 [4.0]	
Hepatocyte, Hypertrophy			1 [3.0]	
Hepatocyte, Vacuolization Cytoplasmic	6 [1.7]	11 [1.7]	15 [1.6]	7 [1.4]
Hepatocyte, Vacuolization Cytoplasmic,	-		1 [2.0]	-

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

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

Date Report Requested: 08/14/2008

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

Goldenseal root powder

CAS Number: GOLDENSEALRT

Time Report Requested: 12:25:59 First Dose M/F: 05/12/03 / 05/12/03 Lab: SRI

B6C3F1 MICE MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM	
Focal Kupffer Cell, Pigmentation Mesentery Fibrosis	1 [1.0] (6) 1 [2.0]	1 [1.0] (3)	2 [2.0] (12) 1 [3.0]	1 [2.0] (1) 1 [3.0]	
Inflammation, Suppurative Fat, Necrosis Pancreas Atrophy Cyst	5 [2.4] (49)	1 [4.0] 1 [2.0] (50)	1 [2.0] 6 [2.7] (50) 1 [1.0] 1	(50)	
Infiltration Cellular, Lymphocyte Acinus, Cytoplasmic Alteration Acinus, Hyperplasia, Focal	2 [2.5] 1 [2.0]	5 [2.8]		1 [2.0] 2 [3.0]	
Salivary Glands Infiltration Cellular, Lymphocyte Stomach, Forestomach Inflammation, Chronic	(50) 1 [2.0] (50) 1 [3.0]	(50) 1 [1.0] (50)	(50) 2 [1.0] (50)	(50) 1 [2.0] (50)	
Ulcer Epithelium, Hyperplasia Stomach, Glandular Cyst	1 [2.0] 3 [2.3] (50)	2 [2.0] 5 [2.2] (50) 5	3 [2.3] (50) 3	2 [2.0] (50) 1	
Edema Erosion Epithelium, Hyperplasia Glands, Cyst	1 [3.0] 1	1 [3.0]		4 [1.3] 1 [2.0]	
CARDIOVASCULAR SYSTEM					
Heart Cardiomyopathy Thrombosis Artery, Inflammation, Chronic	(50) 45 [1.4] 1 [4.0] 1 [2.0]	(50) 42 [1.3]	(50) 44 [1.5]	(50) 44 [1.4]	
ENDOCRINE SYSTEM					
Adrenal Cortex Accessory Adrenal Cortical Nodule Hypertrophy	(50)	(50) 1 [2.0]	(50) 1 [2.0] 3 [3.0]	(50)	
Hypertrophy, Focal Capsule, Hyperplasia	13 [1.3] 39 [1.5]	18 [1.6] 37 [1.2]	3 [3.0] 10 [1.6] 41 [1.1]	5 [1.8] 37 [1.2]	

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

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

Date Report Requested: 08/14/2008

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

Goldenseal root powder

CAS Number: GOLDENSEALRT

Time Report Requested: 12:25:59 First Dose M/F: 05/12/03 / 05/12/03 Lab: SRI

B6C3F1 MICE MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM	
Adrenal Medulla	(50)	(50)	(50)	(49)	
Hyperplasia		(= =)	1 [1.0]		
Islets, Pancreatic	(49)	(50)	(50)	(50)	
Hyperplasia	4 [2.0]	12 [1.7]	11 [2.1]	4 [1.5]	
Parathyroid Gland	(45)	(45)	(47)	(49)	
Cyst Pituitary Gland	(50)	(40)	3	(50)	
Pars Distalis, Cyst	(50) 2	(49) 2	(49) 1	(50) 3	
Pars Distalis, Hyperplasia, Focal	2 [2.0]	Z	Ī	1 [1.0]	
Thyroid Gland	(50)	(50)	(50)	(50)	
Follicle, Cyst	(50)	2	(30)	(50)	
Follicle, Degeneration, Focal	5 [2.0]	6 [1.2]	6 [1.3]	4 [1.8]	
Follicular Cell, Hyperplasia	- [- .0]	- [''-]	0 [110]	1 [2.0]	
ENITAL SYSTEM					
Coagulating Gland	(0)	(1)	(0)	(0)	
Inflammation, Suppurative	(50)	1 [3.0]	(50)	(50)	
Epididymis	(50)				
	(00)	(50)	(50)	(50)	
Cyst	(00)	(30)		(30)	
Granuloma Sperm		1	1 [2.0]		
Granuloma Sperm Preputial Gland	(50)		1 [2.0] (50)	(50)	
Granuloma Sperm Preputial Gland Atrophy	(50)	1 (50)	1 [2.0] (50) 1 [3.0]	(50)	
Granuloma Sperm Preputial Gland Atrophy Cyst		1 (50) 17	1 [2.0] (50) 1 [3.0] 25	(50) 13	
Granuloma Sperm Preputial Gland Atrophy Cyst Hyperplasia	(50) 19	1 (50) 17 1 [2.0]	1 [2.0] (50) 1 [3.0] 25 4 [2.0]	(50) 13 2 [2.0]	
Granuloma Sperm Preputial Gland Atrophy Cyst Hyperplasia Inflammation, Suppurative	(50) 19 1 [4.0]	1 (50) 17 1 [2.0] 3 [2.7]	1 [2.0] (50) 1 [3.0] 25 4 [2.0] 4 [3.3]	(50) 13 2 [2.0] 2 [3.0]	
Granuloma Sperm Preputial Gland Atrophy Cyst Hyperplasia Inflammation, Suppurative Inflammation, Chronic	(50) 19	1 (50) 17 1 [2.0]	1 [2.0] (50) 1 [3.0] 25 4 [2.0]	(50) 13 2 [2.0]	
Granuloma Sperm Preputial Gland Atrophy Cyst Hyperplasia Inflammation, Suppurative Inflammation, Chronic Bilateral, Cyst Prostate	(50) 19 1 [4.0] 1 [2.0]	1 (50) 17 1 [2.0] 3 [2.7]	1 [2.0] (50) 1 [3.0] 25 4 [2.0] 4 [3.3] 3 [2.7]	(50) 13 2 [2.0] 2 [3.0]	
Granuloma Sperm Preputial Gland Atrophy Cyst Hyperplasia Inflammation, Suppurative Inflammation, Chronic Bilateral, Cyst Prostate Inflammation, Suppurative	(50) 19 1 [4.0]	1 (50) 17 1 [2.0] 3 [2.7] 4 [3.0]	1 [2.0] (50) 1 [3.0] 25 4 [2.0] 4 [3.3] 3 [2.7] 1 (50)	(50) 13 2 [2.0] 2 [3.0] 2 [2.0]	
Granuloma Sperm Preputial Gland Atrophy Cyst Hyperplasia Inflammation, Suppurative Inflammation, Chronic Bilateral, Cyst Prostate Inflammation, Suppurative Inflammation, Granulomatous	(50) 19 1 [4.0] 1 [2.0]	1 (50) 17 1 [2.0] 3 [2.7] 4 [3.0] (50) 1 [3.0]	1 [2.0] (50) 1 [3.0] 25 4 [2.0] 4 [3.3] 3 [2.7] 1	(50) 13 2 [2.0] 2 [3.0] 2 [2.0]	
Granuloma Sperm Preputial Gland Atrophy Cyst Hyperplasia Inflammation, Suppurative Inflammation, Chronic Bilateral, Cyst Prostate Inflammation, Suppurative Inflammation, Granulomatous Inflammation, Chronic	(50) 19 1 [4.0] 1 [2.0] (50)	1 (50) 17 1 [2.0] 3 [2.7] 4 [3.0] (50) 1 [3.0] 2 [2.0]	1 [2.0] (50) 1 [3.0] 25 4 [2.0] 4 [3.3] 3 [2.7] 1 (50) 1 [1.0]	(50) 13 2 [2.0] 2 [3.0] 2 [2.0] (50)	
Granuloma Sperm Preputial Gland Atrophy Cyst Hyperplasia Inflammation, Suppurative Inflammation, Chronic Bilateral, Cyst Prostate Inflammation, Suppurative Inflammation, Granulomatous Inflammation, Chronic Epithelium, Hyperplasia	(50) 19 1 [4.0] 1 [2.0] (50) 2 [2.0]	1 (50) 17 1 [2.0] 3 [2.7] 4 [3.0] (50) 1 [3.0] 2 [2.0] 1 [2.0]	1 [2.0] (50) 1 [3.0] 25 4 [2.0] 4 [3.3] 3 [2.7] 1 (50) 1 [1.0] 1 [2.0]	(50) 13 2 [2.0] 2 [3.0] 2 [2.0] (50) 3 [1.7]	
Granuloma Sperm Preputial Gland Atrophy Cyst Hyperplasia Inflammation, Suppurative Inflammation, Chronic Bilateral, Cyst Prostate Inflammation, Suppurative Inflammation, Granulomatous Inflammation, Chronic	(50) 19 1 [4.0] 1 [2.0] (50)	1 (50) 17 1 [2.0] 3 [2.7] 4 [3.0] (50) 1 [3.0] 2 [2.0]	1 [2.0] (50) 1 [3.0] 25 4 [2.0] 4 [3.3] 3 [2.7] 1 (50) 1 [1.0]	(50) 13 2 [2.0] 2 [3.0] 2 [2.0] (50)	

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

TDMS No. 99007 - 06
Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH

Date Report Requested: 08/14/2008

AVERAGE SEVERITY GRADES[b] Goldenseal root powder

CAS Number: GOLDENSEALRT

Time Report Requested: 12:25:59 First Dose M/F: 05/12/03 / 05/12/03 Lab: SRI

B6C3F1 MICE MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM	
Testes Germinal Epithelium, Atrophy	(50) 1 [3.0]	(50)	(50) 5 [2.4]	(50) 2 [2.5]	
HEMATOPOIETIC SYSTEM					
Bone Marrow Angiectasis Depletion Cellular	(50) 1 [2.0]	(50)	(50)	(50)	
Hyperplasia Lymph Node Bronchial, Hyperplasia	6 [2.3] (2)	1 [2.0] 17 [2.1] (5)	14 [1.9] (2)	14 [2.0] (2) 1 [3.0]	
Iliac, Hemorrhage Pancreatic, Hemorrhage Renal, Hemorrhage	1 [3.0]	1 [3.0] 1 [2.0]			
Lymph Node, Mandibular Atrophy Hyperplasia, Lymphoid	(46)	(46) 3 [3.0]	(50) 1 [2.0] 2 [2.0]	(49) 2 [2.5]	
Lymph Node, Mesenteric Atrophy Hemorrhage Hyperplasia, Histiocytic	(48) 2 [1.5]	(44) 1 [3.0] 1 [2.0]	(49) 1 [1.0]	(48) 1 [1.0]	
Hyperplasia, Lymphoid Hyperplasia, Plasma Cell Spleen	3 [2.7] (50)	2 [2.5] (49)	2 [2.5] 1 [4.0] (50)	2 [2.5] (50)	
Atrophy Hematopoietic Cell Proliferation Hyperplasia	23 [1.7] 2 [1.0]	2 [3.0] 33 [1.9]	1 [2.0] 27 [1.8]	20 [1.9] 1 [1.0]	
Lymphoid Follicle, Hyperplasia Thymus Atrophy	4 [2.3] (44) 3 [3.0]	3 [2.0] (39) 8 [2.9]	4 [1.8] (43) 1 [3.0]	3 [2.3] (41) 2 [2.5]	
Cyst Hyperplasia, Lymphoid Necrosis, Lymphoid		1 [2.0]	2	1 [3.0]	
INTEGUMENTARY SYSTEM					
Skin Cyst Epithelial Inclusion	(50)	(50)	(50) 1	(50)	
Inflammation, Chronic	1 [3.0]	1 [3.0]	•		

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MS No. 99007 - 06 st Type: CHRONIC oute: DOSED FEED ecies/Strain: MICE/B6C3F1	P18: INCIDENCE RA	Date Report Requested: 08/14/2008 Time Report Requested: 12:25:59 First Dose M/F: 05/12/03 / 05/12/03 Lab: SRI			
B6C3F1 MICE MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM	
Ulcer Epidermis, Hyperplasia Hair Follicle, Cyst	1 [2.0] 1	1 [3.0] 1 [4.0]			
MUSCULOSKELETAL SYSTEM					
Bone Cranium, Hyperostosis	(50) 1 [3.0]	(50)	(50)	(50)	
Maxilla, Fibrosis Skeletal Muscle	(0)	1 [3.0] (1)	(3)	(0)	
NERVOUS SYSTEM					
None					
RESPIRATORY SYSTEM					
Lung Edema	(50)	(50) 1 [2.0]	(50)	(50)	
Fibrosis Infiltration Cellular, Histiocyte Infiltration Cellular, Lymphocyte	1 [3.0] 2 [3.0] 3 [2.0]		1 [1.0]	2 [1.0] 1 [2.0]	
Alveolar Epithelium, Hyperplasia Nose	6 [1.8] (50)	2 [2.5] (50)	3 [1.7] (50)	5 [1.8] (50)	
Inflammation, Suppurative Glands, Degeneration, Cystic	(00)	1 [2.0]	1 [2.0]	(00)	
Nasolacrimal Duct, Inflammation, Suppurative	1 [2.0]	. [=.0]			
Trachea	(50)	(50)	(50)	(50)	
SPECIAL SENSES SYSTEM					
Eye Cataract	(46)	(50)	(49) 1 [1.0]	(50)	
Inflammation, Acute Cornea, Inflammation, Chronic	1 [1.0]	1 [2.0]	. []		
Harderian Gland Atrophy	(50)	(50)	(50) 1 [3.0]	(50)	

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MS No. 99007 - 06	P18: INCIDENCE RA			IATOMIC SITE (a) WITH	Date Report Requested: 08/14/200	
st Type: CHRONIC ute: DOSED FEED ecies/Strain: MICE/B6C3F1		AVERAGE SEVERITY GRADES[b] Goldenseal root powder CAS Number: GOLDENSEALRT			Time Report Requested: 12:25:59 First Dose M/F: 05/12/03 / 05/12/03 Lab: SRI	
B6C3F1 MICE MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM		
Hyperplasia Hyperplasia, Focal Infiltration Cellular, Lymphocyte	1 [2.0]	1 [2.0]	1 [2.0]	1 [2.0]		
URINARY SYSTEM						
Kidney Cyst Glomerulosclerosis Hydronephrosis Infarct Infiltration Cellular, Lymphocyte Inflammation, Suppurative Metaplasia, Osseous Nephropathy Thrombosis Bilateral, Hydronephrosis Papilla, Inflammation, Suppurative Papilla, Necrosis Renal Tubule, Accumulation, Hyaline	(50) 4 2 [2.0] 1 [1.0] 1 [2.0] 1 [2.0] 42 [1.5] 1 [2.0]	(50) 3 1 [3.0] 4 [1.8] 2 [1.5] 1 [3.0] 1 [2.0] 43 [1.3] 1 [4.0] 1 [2.0]	(50) 9 1 [3.0] 2 [2.0] 2 [1.5] 46 [1.5] 1 [2.0] 1 [2.0]	(50) 2 1 [2.0] 2 [2.0] 3 [1.7] 48 [1.5]		
Droplet Renal Tubule, Pigmentation Urinary Bladder Calculus Gross Observation Hemorrhage Infiltration Cellular, Lymphocyte Inflammation, Chronic Transitional Epithelium, Hyperplasia	(49)	(50) 1 1 [2.0] 1 [3.0] 1 [3.0]	(50) 1 [2.0]	2 [2.5] (50) 1 [2.0] 1 [1.0]		

*** END OF MALE ***

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)

TDMS No. 99007 - 06 Test Type: CHRONIC

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Species/Strain: MICE/B6C3F1

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Date Report Requested: 08/14/2008

AVERAGE SEVERITY GRADES[b] Goldenseal root powder

CAS Number: GOLDENSEALRT

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B6C3F1 MICE FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM	
Disposition Summary					
Animals Initially in Study	50	50	50	50	
Early Deaths		0	0	0	
Moribund Sacrifice Natural Death	4 1	2 4	2 12	3 4	
Survivors	I	4	12	+	
Natural Death	1				
Terminal Sacrifice	44	44	36	43	
Animals Examined Microscopically	50	50	50	50	
LIMENTARY SYSTEM					
Gallbladder	(48)	(46)	(39)	(47)	
Inflammation, Chronic	(40)	1 [3.0]			
Intestine Large, Cecum Cyst	(48)	(46)	(41)	(47) 1	
Intestine Large, Rectum	(48)	(47)	(43)	(47)	
Intestine Small, Ileum	(48)	(46)	(39)	(47)	
Hyperplasia, Lymphoid	1 [2.0]	()		(
Intestine Small, Jejunum	(48)	(46)	(43)	(48)	
Hyperplasia, Lymphoid Inflammation, Suppurative		1 [2.0]	2 [2.0] 1 [1.0]		
Liver	(50)	(50)	(49)	(50)	
Angiectasis		(1 [1.0]	
Basophilic Focus	1	•	3	1	
Clear Cell Focus Cyst		2	1	2 2	
Eosinophilic Focus	3	3	2	4	
Hematopoietic Cell Proliferation	3 [1.3]	2 [2.0]	2 [1.5]	1 [2.0]	
Hepatodiaphragmatic Nodule				1	
Infarct	0.4.54.01		00.14.41	1 [2.0]	
Infiltration Cellular, Lymphocyte	24 [1.2]	24 [1.1]	26 [1.1]	21 [1.1]	
Infiltration Cellular, Mixed Cell Inflammation, Acute	7 [1.0]	9 [1.0]	10 [1.0]	6 [1.2] 1 [1.0]	
Mixed Cell Focus		3	2	4	
Necrosis, Focal	1 [1.0]	1 [1.0]			
Tension Lipidosis	3	1			

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Species/Strain: MICE/B6C3F1

Goldenseal root powder

CAS Number: GOLDENSEALRT

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B6C3F1 MICE FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM	
Capsule, Fibrosis Hepatocyte, Vacuolization Cytoplasmic Kupffer Cell, Pigmentation	1 [2.0]	3 [1.7]	1 [2.0] 7 [1.9]	4 [2.0] 1 [2.0]	
Mesentery Hemorrhage Infiltration Cellular, Lymphocyte	(10) 1 [2.0]	(6)	(9) 1 [4.0] 1 [3.0]	(2)	
Fat, Necrosis Pancreas Atrophy	8 [2.0] (48) 1 [3.0]	6 [2.2] (48) 1 [1.0]	7 [2.3] (47)	2 [2.5] (50) 1 [2.0]	
Cyst Infiltration Cellular, Lymphocyte Inflammation, Granulomatous, Chronic	1	1 1 1 [4.0]	1	1 2 [2.0]	
Acinus, Cytoplasmic Alteration Artery, Inflammation Salivary Glands	4 [1.5]	2 [1.0]	1 [1.0] 1 [3.0]	1 [2.0]	
Fibrosis Infiltration Cellular, Lymphocyte	(50) 1 [2.0] 2 [1.5]	(50) 1 [2.0] 2 [1.5]	(50) 1 [2.0] 5 [1.6]	(50) 3 [1.0]	
Stomach, Forestomach Cyst Edema Infiltration Cellular, Lymphocyte	(49)	(50) 1 [3.0]	(48) 2 1 [2.0]	(50) 1 [2.0]	
Inflammation, Granulomatous, Chronic Inflammation, Chronic Ulcer	1 [2.0]	1 [3.0] 1 [3.0]	2 [2.0]	2 [2.0]	
Epithelium, Hyperplasia Stomach, Glandular Cyst	(49) 7	3 [2.0] (49) 4	3 [2.0] (48) 2	2 [2.0] 2 [2.0] (50) 6	
Ulcer Glands, Ectasia		·	1 [2.0]	1 [2.0]	
CARDIOVASCULAR SYSTEM					
Heart Cardiomyopathy Mineralization	(50) 39 [1.2] 1 [2.0]	(50) 38 [1.1]	(50) 37 [1.0]	(50) 33 [1.2]	
ENDOCRINE SYSTEM					
Adrenal Cortex	(50)	(50)	(48)	(50)	

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P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH

Date Report Requested: 08/14/2008

AVERAGE SEVERITY GRADES[b] Goldenseal root powder

Time Report Requested: 12:25:59 First Dose M/F: 05/12/03 / 05/12/03 Lab: SRI

B6C3F1 MICE FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM	
cies/Strain: MICE/B6C3F1					
te: DOSED FEED	CAS Number: GOLDENSEALRT				
Type: CHRONIC	Goldenseal root powder				

Accessory Adrenal Cortical Nodule	1 [2.0]				
Angiectasis		1 [3.0]	1 [3.0]		
Degeneration, Cystic	1 [1.0]		2 [3.0]	1 [4.0]	
Degeneration, Fatty		1 [2.0]			
Hematopoietic Cell Proliferation	1 [1.0]				
Hyperplasia, Focal	1 [1.0]	1 [2.0]			
Hypertrophy, Focal	1 [3.0]	1 [3.0]		4 [2.0]	
Inflammation, Granulomatous, Chronic		1 [2.0]			
Vacuolization Cytoplasmic		L - J		1 [2.0]	
Capsule, Hyperplasia	49 [2.0]	50 [1.8]	47 [1.6]	49 [2.0]	
Adrenal Medulla	(50)	(50)	(49)	(50)	
Amyloid Deposition	()	()	1 [2.0]	()	
Hyperplasia	1 [2.0]	2 [1.0]	2 [1.0]		
slets, Pancreatic	(48)	(49)	(48)	(50)	
Hyperplasia	4 [2.0]	2 [1.5]	1 [2.0]	1 [2.0]	
Parathyroid Gland	(45)	(44)	(48)	(47)	
Cyst	()	1	()	1	
Infiltration Cellular, Lymphocyte	1 [2.0]	1 [2.0]		·	
Pituitary Gland	(50)	(49)	(49)	(49)	
Angiectasis	1 [1.0]	1 [1.0]	1 [3.0]	(10)	
Pars Distalis, Cyst	.[]	. []	2	3	
Pars Distalis, Hyperplasia, Focal	8 [1.8]	5 [1.8]	6 [1.2]	4 [1.8]	
Thyroid Gland	(50)	(50)	(48)	(50)	
Inflammation, Suppurative	(00)	1 [1.0]	(10)	(00)	
Follicle, Cyst		3	2	2	
Follicle, Degeneration, Focal	18 [1.4]	18 [1.6]	16 [1.4]	10 [1.6]	
Follicular Cell, Hyperplasia	נד.ין טי	10[1:0]	1 [1.0]	1 [1.0]	

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland Cyst	(50)	(50)	(49) 4	(50)
Ovary	(49)	(48) 1 [2.0]	(50)	(50)
Angiectasis Cyst	10	14	10	12

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

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH

Date Report Requested: 08/14/2008

AVERAGE SEVERITY GRADES[b] Goldenseal root powder

CAS Number: GOLDENSEALRT

Time Report Requested: 12:25:59 First Dose M/F: 05/12/03 / 05/12/03 Lab: SRI

P18: INCIDENCE RATES OF
A

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

B6C3F1 MICE FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM	
Hemorrhage Mineralization Pigmentation	10 [1.6]	6 [1.7]	7 [1.6] 1 [3.0] 1 [4.0]	5 [1.8]	
Thrombosis Bilateral, Cyst		1 [4.0] 1	1 [3.0]	1	
Corpus Luteum, Hyperplasia Granulosa Cell, Hyperplasia	4 [2.3]	1 [2.0]		2 [2.5] 2 [2.0]	
Uterus Fibrosis	(50)	(49)	(50)	2 [2.0] (50) 1 [2.0]	
Hyperplasia, Cystic	48 [2.5]	46 [2.4]	45 [2.3]	44 [2.4]	
Infiltration Cellular, Histiocyte Inflammation, Suppurative	1 [3.0]	1 [2.0]		1 [2.0]	
Inflammation, Granulomatous, Chronic Thrombosis Myometrium, Hypertrophy		1 [4.0] 2 [2.5]	1 [3.0]	1 [3.0]	
HEMATOPOIETIC SYSTEM					
Bone Marrow Depletion Cellular	(49)	(50)	(50)	(50) 1 [3.0]	
Hyperplasia Inflammation, Chronic	2 [3.5]	2 [2.5]	1 [3.0] 1 [2.0]	2 [3.5]	
Myelofibrosis Lymph Node	6 [1.7] (6)	1 [3.0] (4)	5 [2.6] (5)	5 [1.6] (4)	
Iliac, Hyperplasia, Lymphoid Pancreatic, Hyperplasia, Lymphoid Renal, Hyperplasia, Lymphoid	1 [3.0] 1 [2.0]		1 [2.0] 1 [2.0] 1 [2.0]		
Lymph Node, Mandibular Hyperplasia, Lymphoid	(50) 6 [2.8]	(49) 2 [2.5]	(48) 4 [2.5]	(49) 7 [2.3]	
Pigmentation Lymph Node, Mesenteric	1 [2.0] (48)	(43)	(48)	(49)	
Ectasia Hyperplasia, Histiocytic Hyperplasia, Lymphoid	1 [1.0] 4 [2.5]	3 [3.0] 1 [1.0] 1 [2.0]	3 [3.3] 1 [1.0] 3 [2.7]	2 [4.0] 1 [1.0] 4 [2.8]	
Inflammation, Granulomatous, Chronic Spleen Atrophy	(48)	1 [4.0] (48)	(47) 1 [2.0]	(49)	
Hematopoietic Cell Proliferation Lymphoid Follicle, Hyperplasia	5 [3.0] 24 [2.4]	7 [2.4] 26 [2.1]	8 [2.5] 18 [2.3]	4 [2.8] 22 [2.4]	

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

MS No. 99007 - 06 st Type: CHRONIC ute: DOSED FEED ecies/Strain: MICE/B6C3F1	P18: INCIDENCE RA	Date Report Requested: 08/14/200 Time Report Requested: 12:25:59 First Dose M/F: 05/12/03 / 05/12/03 Lab: SRI			
B6C3F1 MICE FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM	
Thymus Atrophy Hemorrhage	(49) 1 [2.0]	(48) 1 [2.0]	(50) 1 [3.0]	(48)	
Hyperplasia, Lymphoid Necrosis, Lymphoid	4 [2.5]	2 [2.5] 1 [3.0]	4 [1.8]	7 [2.3]	
INTEGUMENTARY SYSTEM					
Mammary Gland Cyst Hyperplasia	(49)	(49) 1 1 [2.0]	(48)	(50)	
Skin	(50)	(50)	(50)	(50)	
Edema Mineralization	1 [3.0]			1 [2.0]	
Pigmentation Subcutaneous Tissue, Infiltration Cellular, Lymphocyte				1 [2.0] 1 [3.0]	
MUSCULOSKELETAL SYSTEM					
Bone Fracture	(50)	(50)	(50) 1 [3.0]	(50)	
Maxilla, Fibrosis Skeletal Muscle Necrosis	(1)	(1)	(2) 1 [2.0]	1 [3.0] (0)	
NERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(50)	
Compression Hemorrhage		1 [2.0]	1 [2.0]		
RESPIRATORY SYSTEM					
Lung	(50)	(50)	(50)	(50)	
Foreign Body Hemorrhage Hyperplasia, Lymphoid	2 [2.0]		1 [1.0] 2 [1.0]	1 [2.0] 1 [3.0]	

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)

TDMS No. 99007 - 06 Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH

Date Report Requested: 08/14/2008

AVERAGE SEVERITY GRADES[b] Goldenseal root powder

CAS Number: GOLDENSEALRT

Time Report Requested: 12:25:59 First Dose M/F: 05/12/03 / 05/12/03 Lab: SRI

B6C3F1 MICE FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM	
Infiltration Cellular, Histiocyte				1 [1.0]	
Infiltration Cellular, Lymphocyte Inflammation, Suppurative	7 [1.9]	2 [2.0]	1 [2.0]	2 [2.0]	
Inflammation, Supportative	1 [2.0]		1 [2.0]		
Metaplasia, Osseous	1 [1.0]				
Alveolar Epithelium, Hyperplasia	1 [1.0]	3 [2.0]	2 [2.0]		
Nose	(50)	(50)	(50)	(50)	
Foreign Body Inflammation, Suppurative			1 [2.0] 1 [2.0]		
Glands, Degeneration, Cystic			2 [2.5]	1 [2.0]	
Glands, Inflammation				1 [2.0]	
Respiratory Epithelium, Hyperplasia	(50)	(50)	(10)	1 [1.0]	
Trachea Glands, Degeneration, Cystic	(50)	(50)	(49)	(50) 1 [3.0]	
				1 [0.0]	
SPECIAL SENSES SYSTEM					
Eye	(49)	(47)	(41)	(46)	
Atrophy	1 [2.0]				
Cornea, Inflammation, Suppurative Harderian Gland	1 [3.0] (50)	(49)	(50)	(50)	
Hyperplasia	(50)	(49)	1 [4.0]	(50)	
Hyperplasia, Focal	5 [1.8]	2 [1.5]	4 [1.5]	2 [1.5]	
Inflammation, Chronic	1 [3.0]				
URINARY SYSTEM					
Kidney	(50)	(49)	(50)	(50)	
Atrophy Casts Protein	2 [4 5]	1 [4.0]	1 [1 0]		
Casts Protein Cyst	2 [1.5] 1		1 [1.0]		
Hydronephrosis	·	1 [3.0]			
Infarct		1 [1.0]	3 [1.7]		
Infiltration Cellular, Lymphocyte	7 [2.1]	7 [1.6]	4 [1.8]	9 [1.4]	
Metaplasia, Osseous Nephropathy	1 [1.0] 13 [1.1]	1 [2.0] 19 [1.1]	1 [2.0] 15 [1.0]	15 [1.1]	
Renal Tubule, Accumulation, Hyaline	10[1.1]	10[1.1]	10 [1.0]	2 [2.5]	
Droplet				L - J	
Renal Tubule, Dilatation		1 [1.0]			

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

TDMS No. 99007 - 06 P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WIT AVERAGE SEVERITY GRADES[b] Test Type: CHRONIC Goldenseal root powder Route: DOSED FEED CAS Number: GOLDENSEALRT Species/Strain: MICE/B6C3F1 Species/Strain: MICE/B6C3F1			ATOMIC SITE (a) WITH	Date Report Requested: 08/14/2008 Time Report Requested: 12:25:59 First Dose M/F: 05/12/03 / 05/12/03 Lab: SRI	
B6C3F1 MICE FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM	
Transitional Epithelium, Hyperplasia Urinary Bladder Infiltration Cellular, Lymphocyte	(49) 7 [1.7]	1 [3.0] (49) 6 [1.7]	(50) 5 [1.2]	(50) 3 [1.3]	

*** 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)