

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

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

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ALIMENTARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

| .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

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1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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B6C3F1 MICE MALE 0 PPM	ANIMAL ID	DAY ON TEST																				males (cont...)
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		7	7	7	6	7	7	7	7	7	7	6	7	6	7	7	7	7	7	7	7	
		3	3	3	7	3	3	3	3	3	2	3	3	3	3	8	3	3	2	3	3	
		1	0	0	7	0	0	0	0	1	9	1	0	2	1	1	0	1	9	0	1	9
Necrosis, Focal																						
Hepatocyte, Vacuolization																						
Cytoplasmic		1																				
Kupffer Cell, Pigmentation																						
Mesentery																						
Fibrosis																						
Fat, Necrosis																						
Pancreas																						
Acinus, Cytoplasmic Alteration																						
Acinus, Hyperplasia, Focal																						
Salivary Glands																						
Infiltration Cellular, Lymphocyte																						
Stomach, Forestomach																						
Inflammation, Chronic																						
Ulcer																						
Epithelium, Hyperplasia																						
Stomach, Glandular																						
Erosion																						
Glands, Cyst																						

CARDIOVASCULAR SYSTEM

Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cardiomyopathy	1	1	1	2	2	2	1	1	1	1	1	1	1	2	2	1	2	1	1	2	1	1

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Thrombosis
Artery, Inflammation, Chronic

ENDOCRINE SYSTEM

Adrenal Cortex Hypertrophy, Focal Capsule, Hyperplasia	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	2	
	1	1	1			1	1	1	1	1	1	2	3	1			2	1	2		1	2	2							
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Islets, Pancreatic Hyperplasia	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	2	
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Pituitary Gland Pars Distalis, Cyst Pars Distalis, Hyperplasia, Focal	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	X	X	
Thyroid Gland Follicle, Degeneration, Focal	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	2	2	3

GENERAL BODY SYSTEM

NONE

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Page 4

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Lab: SR

GENITAL SYSTEM

HEMATOPOIETIC SYSTEM

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Lab: SRI

INTEGUMENTARY SYSTEM

MUSCULOSKELETAL SYSTEM

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Date Report Requested: 08/14/2008

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First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

Eye
Inflammation, Acute

+ + + + + + + + + + + + + + + A + + + + + + + + + + + + + +

Harderian Gland Hyperplasia

URINARY SYSTEM

Kidney
Cyst
Infarct
Infiltration Cellular, Lymphocytic
Inflammation, Suppurative
Metaplasia, Osseous
Nephropathy
Thrombosis

Urinary Bladder

+ + + + + + + + + + + + + + + A + + + + + + + + + + + +

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Route: DOSFD FFED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEAL R7

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SR

ALIMENTARY SYSTEM

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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

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First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| B6C3F1 MICE MALE
0 PPM | ANIMAL ID | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|-------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 4 | 7 | | |
| | | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 5 | 3 | 3 | 0 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 9 | 2 | | |
| | | 0 | 1 | 0 | 4 | 0 | 0 | 2 | 0 | 9 | 1 | 9 | 0 | 0 | 2 | 0 | 5 | 9 | 1 | 0 | 0 | 0 | 0 | 0 | 6 | 9 | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Necrosis, Focal | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.5 |
| Hepatocyte, Vacuolization | Cytoplasmic | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | 6 1.7 |
| Kupffer Cell, Pigmentation | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | | | 6 |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | 5 2.4 |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | | | | | 49 |
| Acinus, Cytoplasmic Alteration | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.5 |
| Acinus, Hyperplasia, Focal | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.0 |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 2.3 |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Glands, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cardiomyopathy | 1 | 1 | 2 | 1 | 1 | 2 | 2 | 2 | 1 | 1 | 2 | 2 | 2 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 3 | 45 | 1.4 |

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Lab: SR

| | | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|------|
| | | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 1.40 |
| 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 4 | .7 |
| 3 | 3 | 3 | 6 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 5 | 3 | 3 | 0 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 9 | .2 |
| 0 | 1 | 0 | 4 | 0 | 0 | 2 | 0 | 9 | 1 | 9 | 0 | 0 | 2 | 0 | 5 | 9 | 1 | 0 | 0 | 0 | 0 | 6 | .9 |
| | | | | | | | | | | | | | | | | | | | | | | | |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | .5 |
| 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

ENDOCRINE SYSTEM

GENERAL BODY SYSTEM

NONE

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GENITAL SYSTEM

HEMATOPOIETIC SYSTEM

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Lab: SRI

| B6C3F1 MICE MALE
0 PPM | ANIMAL ID | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|-----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|---|
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 4 | 7 |
| | | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 5 | 3 | 3 | 0 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 9 | 2 |
| | | 0 | 1 | 0 | 4 | 0 | 0 | 2 | 0 | 9 | 1 | 9 | 0 | 0 | 2 | 0 | 5 | 9 | 1 | 0 | 0 | 0 | 0 | 0 | 6 | 9 |
| Lymph Node, Mandibular | | + | + | + | M | + | + | + | + | + | M | + | M | + | + | + | + | + | + | + | + | + | + | + | 46 | |
| Lymph Node, Mesenteric | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | |
| Hyperplasia, Histiocytic | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.5 | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | 3 2.7 | |
| Spleen | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Hematopoietic Cell Proliferation | | 1 | 1 | | | 3 | 1 | 1 | | | 2 | 2 | 1 | 1 | | | | | | | | | | | 23 1.7 | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.0 | |
| Lymphoid Follicle, Hyperplasia | | 2 | | | | | | | | | 2 | | | 3 | | | | | | | | | | | 4 2.3 | |
| Thymus | | + | + | + | I | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 44 | |
| Atrophy | | | | | | | | | | | 4 | | | | | | | | | | | | | 3 | 3 3.0 | |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Mammary Gland | M | + | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 3 |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Epidermis, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Hair Follicle, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cranium, Hyperostosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |

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Lab: SR

NERVOUS SYSTEM

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|-------|--|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 3.0 | |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | 3 | | | |
| Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | 3 | 2 | 3.0 | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | 3 | 2 | 0.0 | |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | 3 | 1 | 6 1.8 | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 2.0 | |
| Nasolacrimal Duct, Inflammation,
Suppurative | | | | | | | | | | | | | | | | | | | | | 2 | | | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |

SPECIAL SENSES SYSTEM

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M Missing tissue

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Lab: SRI

URINARY SYSTEM

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TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEAL RT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

ALIMENTARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

| .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

GENITAL SYSTEM

Coagulating Gland Inflammation, Suppurative

Epididymis
Cyst

Preputial Gland
Cyst
Hyperplasia
Inflammation, Suppurative
Inflammation, Chronic

Prostate
Inflammation, Suppurative
Inflammation, Chronic
Epithelium, Hyperplasia

Seminal Vesicle Inflammation, Suppurative

Testes

**males
(cont...)**

HEMATOPOIETIC SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

| .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1-4: Lesion qualified as:

1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

INTEGUMENTARY SYSTEM

Mammary Gland

M M M M M M M M + M M M M M M + + + M M M M M M M M M M M M M M M M

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TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

Bilateral, Hydronephrosis
Papilla, Necrosis

Ureter

Urinary Bladder

Calculus Gross Observation

Infiltration Cellular, Lymphocyte

Inflammation, Chronic

Transitional Epithelium, Hyperplasia

2

**males
(cont...)**

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

I .. Insufficient tissue

M., Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSFD FFED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEAL R⁷

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SR

ALIMENTARY SYSTEM

* ... Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

| .. Insufficient tissue

M .. Missing tissue

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BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

CARDIOVASCULAR SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

.. Lesion present
 Insufficient tissue

M.. Missing tissue

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BLANK Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SR

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|-----|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 2.0 |
| Accessory Adrenal Cortical Nodule | | | | | | | | | | | | | | | | | | | | | | | 18 | 1.6 |
| Hypertrophy, Focal | 2 | | | | 2 | 1 | 1 | | | 1 | 2 | | 1 | 2 | | 1 | | 2 | 1 | | | | | |
| Capsule, Hyperplasia | 1 | 2 | | | 1 | 1 | 1 | 1 | | 2 | | 1 | 1 | 1 | 1 | | 1 | | 1 | 2 | 1 | | 37 | 1.2 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Hyperplasia | 2 | 2 | | | 1 | 2 | | | | | | | | 2 | 2 | | 2 | | 2 | 1 | | | 12 | 1.7 |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | M | + | + | M | 45 | |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | |
| Pars Distalis, Cyst | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Follicle, Cyst | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Follicle, Degeneration, Focal | 2 | | | | 1 | 1 | 1 | | | | | | | | | | | | | 1 | | 6 | 1.2 | |

GENERAL BODY SYSTEM

NONE

* .. Total animals with tissue examined microscopically: Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

X .. Eosin present
I .. Insufficient tissue

M Missing tissue

A .. Autolysis precludes evaluation

BLANK - Not examined microscopically

1-4 Lesion qualified as

1) Minimal 3) Moderate

1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

GENITAL SYSTEM

HEMATOPOIETIC SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

| .. Insufficient tissue

M., Missing tissue

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1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

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Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

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
3000 PPM | ANIMAL ID | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|----------------------------------|-----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----------|-------|
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 6 | 6 | 5 | 7 | 7 | 7 | 7 | | |
| | | 3 | 2 | 6 | 3 | 2 | 2 | 2 | 3 | 2 | 3 | 2 | 3 | 7 | 2 | 3 | 8 | 3 | 3 | 2 | 2 | 5 | 3 | 3 | 3 | | |
| | | 1 | 9 | 3 | 2 | 9 | 9 | 9 | 0 | 9 | 1 | 9 | 9 | 0 | 7 | 9 | 0 | 0 | 0 | 4 | 5 | 5 | 0 | 2 | 1 | | |
| Bone Marrow | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Depletion Cellular | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Hyperplasia | | 2 | 2 | 3 | 3 | 2 | | | | 2 | | | | | | | | | 2 | 2 | 2 | 3 | | | | 17 2.1 | |
| Lymph Node | | | | | | | + | | | | | | | | | | | | | | | | | | | 5 | |
| Pancreatic, Hemorrhage | | | | | | | 3 | | | | | | | | | | | | | | | | | | | 1 3.0 | |
| Renal, Hemorrhage | | | | | | | 2 | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Lymph Node, Mandibular | | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | 46 | |
| Hyperplasia, Lymphoid | | | | | | | 3 | | | | | | | | | | | | | 3 | | | | | | | 3 3.0 |
| Lymph Node, Mesenteric | | + | + | M | + | + | M | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | 44 | |
| Atrophy | | | | | | | 3 | | | | | | | | | | | | | | | | | | | 1 3.0 | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.5 | |
| Spleen | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | 49 | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | 2 3.0 | |
| Hematopoietic Cell Proliferation | | 1 | 2 | 3 | 2 | 3 | 3 | 4 | 1 | 2 | 2 | | | 3 | 1 | 3 | 3 | 3 | 2 | 2 | 1 | 1 | 1 | | | 33 1.9 | |
| Lymphoid Follicle, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 3 2.0 | |
| Thymus | | + | + | I | + | + | I | + | M | + | + | + | + | A | + | + | + | M | + | + | 4 | + | + | + | + | 39 | |
| Atrophy | | | | | | | 4 | | | | | | | | | | | | 3 | 1 | | | | | | 8 2.9 | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland | M | M | M | M | M | + | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 4 |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

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1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SR

MUSCULOSKELETAL SYSTEM

NERVOUS SYSTEM

RESPIRATORY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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.. Lesion present
 Insufficient tissue

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TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

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TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSFD FFED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

ALIMENTARY SYSTEM

* .. Total animals with tissue examined microscopically: Total animals with lesion and mean severity grade

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TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow
Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 2 |
| Lymph Node | | | | | | | | | | | | | | | | | | | | | | | | | + |
| Lymph Node, Mandibular
Atrophy
Hyperplasia, Lymphoid | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 2 |
| Lymph Node, Mesenteric
Hyperplasia, Histiocytic
Hyperplasia, Lymphoid
Hyperplasia, Plasma Cell | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | 1 |
| Spleen
Atrophy
Hematopoietic Cell Proliferation
Lymphoid Follicle, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 2 |
| Thymus
Atrophy
Cyst | + | + | M | + | + | + | + | M | + | M | + | + | M | + | + | A | + | + | + | + | I | + | + | + | X |

INTEGUMENTARY SYSTEM

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TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

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TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSFD FFED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEAL RT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SR

ALIMENTARY SYSTEM

* ... Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

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
9000 PPM | ANIMAL ID | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|---|-----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|-------|---------|
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | | | |
| | | 2 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 2 | 3 | 3 | 2 | 2 | 2 | 3 | 3 | 3 | 2 | 6 | 2 | | |
| | | 9 | 0 | 2 | 0 | 9 | 1 | 9 | 1 | 0 | 0 | 9 | 0 | 0 | 1 | 9 | 1 | 0 | 9 | 9 | 0 | 2 | 0 | 9 | 3 | 9 | | |
| Mixed Cell Focus | | | | X | | X | X | X | | | | | | | | | | | | | | | | | X | 9 | | |
| Necrosis, Focal | | | | 2 | | | | | 2 | | | | | | | | | | | | | | | | X | 5 1.8 | | |
| Hepatocyte, Hyperplasia, Focal | | | | | 4 | | | | | | | | | | | | | | | | | | | | | | 1 4.0 | |
| Hepatocyte, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Hepatocyte, Vacuolization Cytoplasmic | 1 | 2 | | | | 1 | | | | | | | | | | | | | | | | | | | | | | 15 1.6 |
| Hepatocyte, Vacuolization Cytoplasmic,
Focal | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Kupffer Cell, Pigmentation | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Mesentery | | | | + | | + | | | + | | + | | | | | | | | | | | | | | | | + | 12 |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | 6 2.7 |
| Pancreas | | | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Salivary Glands | | | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.0 |
| Stomach, Forestomach | | | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 3 2.3 |
| Stomach, Glandular | | | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

CARDIOVASCULAR SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SR

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

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CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SR

HEMATOPOIETIC SYSTEM

INTEGUMENTARY SYSTEM

* ... Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

| .. Insufficient tissue

M .. Missing tissue

A.. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SR

SPECIAL SENSES SYSTEM

URINARY SYSTEM

* ... Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

| .. Insufficient tissue

M .. Missing tissue

M: Missing teeth

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

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First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

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+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M., Missing tissue

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1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSFD FFED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEAL RT

Date Report Requested: 08/14/2008

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First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Gallbladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum
Hyperplasia, Lymphoid
Epithelium, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | A | + |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | |
| Clear Cell Focus | | | | | | | | X | X | | | | | | | | | | | | | |
| Cyst | | | | | | | | | | | | | | | | | | X | | | | |
| Eosinophilic Focus | | X | X | X | | X | | X | X | | X | | | | | | X | | | X | X | X |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | X | X | X | X | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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x ... Lesion present

.. Lesion present
 Insufficient tissue

M Missing tissue

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2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

**males
(cont...)**

HEMATOPOIETIC SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

**males
(cont...)**

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSFD FFED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEAL R7

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SR

ALIMENTARY SYSTEM

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+ .. Tissue examined microscopically

x .. Lesion present

| .. Insufficient tissue

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A.. Autolysis precludes evaluation

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2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

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
25000 PPM | ANIMAL ID | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---------------------------------------|-----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 3 | 2 | 3 | 2 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | |
| | | 1 | 1 | 0 | 0 | 1 | 9 | 1 | 2 | 2 | 9 | 0 | 9 | 0 | 1 | 9 | 1 | 9 | 1 | 0 | 9 | 9 | 1 | 0 | 1 | |
| Infiltration Cellular, Mixed Cell | | | | | | | | | | | | | | | | | | | | | | | | | | 4 1.0 |
| Mixed Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | | | 6 |
| Necrosis, Focal | | 2 | X | | | | | | | | | | | | | | | | | | | | | | | 6 2.0 |
| Hepatocyte, Vacuolization Cytoplasmic | | | | 1 | | | | 2 | | | | | | | | | | | | | | | | | | 7 1.4 |
| Kupffer Cell, Pigmentation | | | | | | | | 2 | | | | | | | | | | | | | | | | | | 1 2.0 |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Acinus, Cytoplasmic Alteration | | | | | | | | | | | | | | | | | | | | | | | | | | 2 3.0 |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | | | 4 1.3 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--------|
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Cardiomyopathy | 2 | 2 | 2 | 2 | 1 | 1 | 2 | 2 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 2 | 2 | 1 | 1 | 44 1.4 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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M .. Missing tissue

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1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

ENDOCRINE SYSTEM

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

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BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

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TDMS No. 99007 - 06

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Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

HEMATOPOIETIC SYSTEM

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+ .. Tissue examined microscopically

x .. Lesion present

| .. Insufficient tissue

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Goldenseal root powder

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Lab: SRI

*** END OF MALE DATA ***

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Species/Strain: MICE/B6C3F1

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Lab: SRI

ALIMENTARY SYSTEM

* .. Total animals with tissue examined microscopically: Total animals with lesion and mean severity grade

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BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1-4 :: Lesion qualified as:

1) Minimal 3) Moderate
2) Mild 4) Marked

Hepatocyte, Vacuolization Cytoplasmic

Mesentery + + + + + +
Hemorrhage 2 2 3 2 2 2
Fat. Necrosis

CARDIOVASCULAR SYSTEM

Heart
Cardiomyopathy
Mineralization

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+ .. Tissue examined microscopically

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I .. Insufficient tissue

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TDMS No. 99007 - 06

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Route: DOSED FEED

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Lab: SRI

ENDOCRINE SYSTEM

GENERAL BODY SYSTEM

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Goldenseal root powder

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Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland Cyst | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | X | |
| | | | | | | | | | | | | | | | | | | | | | | | |
| Ovary Cyst | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Hemorrhage | | | | | | X | | X | | | | | | | | | | X | | X | X | | |
| Corpus Luteum, Hyperplasia | | 2 | | | | 2 | | | | | | | | | | 1 | | 2 | | 2 | | | 1 |
| | | | | | | | | | | | | | | | | | | | | | | | |
| Uterus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Hyperplasia, Cystic | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 4 | |
| Inflammation, Suppurative | | | | | | | | | | | | | | | | | | 3 | 2 | 2 | 3 | 3 | |

HEMATOPOIETIC SYSTEM

* Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade.

+ Tissue examined microscopically

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.. Lesion present
 Insufficient tissue

M Missing tissue

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First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

Atrophy
Cornea, Inflammation, Suppurative

Harderian Gland Hyperplasia, Focal Inflammation, Chronic

females (cont...)

URINARY SYSTEM

Kidney
Casts Protein
Cyst
Infiltration Cellular, Lymphocyte
Metaplasia, Osseous
Nephropathy

Urinary Bladder
Infiltration Cellular, Lymphocyte

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Lab: SR

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----|---|--------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Gallbladder | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | M | + | + | + | 48 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | A | + | + | + | 48 |
| Intestine Large, Colon | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | A | + | + | + | 48 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | A | + | + | + | 48 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | A | + | + | + | 48 |
| Intestine Small, Ileum
Hyperplasia, Lymphoid | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | A | + | + | + | 48 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | A | + | + | + | 48 |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | 1 |
| Eosinophilic Focus | | | | | | | | X | | | | | | | | | | | | 3 |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | 3 1.3 |
| Infiltration Cellular, Lymphocyte | 1 | 2 | | | 1 | 1 | 1 | | 1 | 1 | 2 | | | | | | 1 | 1 | 1 | 24 1.2 |
| Infiltration Cellular, Mixed Cell | | | | | | | | | 1 | | | | | | | | | 1 | 1 | 7 1.0 |
| Necrosis, Focal | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Tension Lipidosis | | | | | | | | X | | | | | | | | | | X X | | 3 |

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Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

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First Dose M/F: 05/12/03 / 05/12/03

Lab: SR

| | | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | |
|--|--|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| | | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 3 | 3 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 2 | 3 | 5 | 3 | 3 | 4 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 |
| B6C3F1 MICE FEMALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 PPM | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |
| | | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| | | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS |
| Hepatocyte, Vacuolization Cytoplasmic | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| + | | | | | | | | | | | | | | | | | | | | | | | | |
| + + + + + + + + A + + + + + + + + M + + + + + + + + 48 | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 2.0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | |
| Aacinus, Cytoplasmic Alteration | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| X | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| X | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| X | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| X | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |

CARDIOVASCULAR SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

| .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SR

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 2.0 |
| Accessory Adrenal Cortical Nodule | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Degeneration, Cystic | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Hyperplasia, Focal | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Hypertrophy, Focal | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Capsule, Hyperplasia | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 49 | 2.0 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 2.0 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | M | + | + | + | + | 48 | 4 | 2.0 |
| Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | |
| Parathyroid Gland | + | + | + | + | + | + | + | + | M | + | M | + | + | + | + | + | M | + | + | + | + | 45 | 1 | 2.0 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 1.0 |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | |
| Pars Distalis, Hyperplasia, Focal | 1 | | | | | | | | | | | | | | | | | | | | | | 8 | 1.8 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 18 | 1.4 |
| Follicle, Degeneration, Focal | 1 | | | | | | | | 2 | 1 | | | | | | | 2 | 1 | 2 | 2 | 1 | | | |

GENERAL BODY SYSTEM

* ... Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

| .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

.. Eczema qualified as:

2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

NONE

GENITAL SYSTEM

HEMATOPOIETIC SYSTEM

* Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade.

† .. Total animals with tissue examined

x ... Lesion present

X .. Eosin present
I .. Insufficient tissue

M Missing tissue

A .. Autolysis precludes evaluation

BLANK - Not examined microscopically

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.. Lesion qualified as:

1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

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 | ANIMAL ID | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|------------------------------------|-----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----------|
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 3 | 3 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 2 | 3 | 5 | 3 | 3 | 4 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |
| Hyperplasia, Lymphoid Pigmentation | | | | | | | | | | | | | | | | | | | | | | | | | | 6 2.8 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Lymph Node, Mesenteric | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | |
| Hyperplasia, Histiocytic | | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | 4 2.5 |
| Spleen | | + | + | + | + | + | + | + | A | + | + | + | + | + | 3 | + | + | + | + | + | M | + | + | + | + | 48 |
| Hematopoietic Cell Proliferation | | | | | | | | | | | 2 | 3 | | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 5 3.0 |
| Lymphoid Follicle, Hyperplasia | | 2 | 2 | | 2 | 2 | | | | | | | | | | | | | | | | | | | | 24 2.4 |
| Thymus | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | 49 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | 4 2.5 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Skin Edema | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

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1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

Atrophy 1 2.0
Cornea, Inflammation, Suppurative 1 3.0

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Casts Protein | | | | | 1 | | | | | | | | | | | | | | | 2 1.5 |
| Cyst | | | | | | | | | | X | | | | | | | | | | 1 |
| Infiltration Cellular, Lymphocyte | | | | 2 | | | | 2 | | | | 2 | | 2 | | | | 3 | | 7 2.1 |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Nephropathy | 1 | 1 | | | | | | | | | | | | 1 | | | 2 | | 1 | 13 1.1 |
| <hr/> | | | | | | | | | | | | | | | | | | | | |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | 49 |
| Infiltration Cellular, Lymphocyte | | | | 2 | 1 | | | | | | | | | 2 | | | 2 | | | 7 1.7 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

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Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

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First Dose M/F: 05/12/03 / 05/12/03

Lab: SR

ALIMENTARY SYSTEM

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Lab: SRI

ENDOCRINE SYSTEM

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+ .. Tissue examined microscopically

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TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

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Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-----------|-------|-------|---------|-------|
| | 5 | 7 | 7 | 7 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| | 2 | 3 | 3 | 3 | 3 | 3 | 8 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 3 |
| | 2 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 6 | 6 | 3 | 3 | 9 | 3 | 3 | 3 | 3 | 3 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3000 PPM | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | females | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | (cont...) | | | | |

Cyst Hyperplasia

Skin

MUSCULOSKELETAL SYSTEM

Bone

Skeletal Muscle

NERVOUS SYSTEM

Brain Compression

RESPIRATORY SYSTEM

Lung
Infiltration Cellular, Lymphocyte
Alveolar Epithelium, Hyperplasia

Nose

Trachea

* = Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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TDMS No. 99007 - 06

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Route: DOSED FEED

Species/Strain: MICE/B6C3F1

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Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
|---------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|------------------------------|-------|-------|---|
| | 5 | 7 | 7 | 7 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | 2 | 3 | 3 | 3 | 3 | 3 | 8 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 3 | 3 | |
| | 2 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 6 | 6 | 3 | 3 | 9 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 3000 PPM | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | | | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | females
(cont...) | | | |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + |
| Harderian Gland
Hyperplasia, Focal | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 2 | 1 | + | + |

URINARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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| .. Insufficient tissue

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TDMS No. 99007 - 06

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Species/Strain: MICE/B6C3F1

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CAS Number: GOLDENSEALRT

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Lab: SRI

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

HEMATOPOIETIC SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

X .. Eosin present
I .. Insufficient tissue

M Missing tissue

A .. Autolysis precludes evaluation

BLANK - Not examined microscopically

1-4 Lesion qualified as:

1) Minimal 3) Moderate

1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

Lymph Node + 4

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------------|--------------|
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | 48 | |
| Hematopoietic Cell Proliferation | | | 2 | 2 | | | | | | | 3 | | 2 | | | | | | | | | | | 3 | 7 2.4 |
| Lymphoid Follicle, Hyperplasia | 2 | | 3 | 2 | | | 3 | | | 2 | 3 | 3 | | 2 | 2 | | 1 | 2 | | | | | 2 | 26 2.1 | |

INTEGUMENTARY SYSTEM

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|---------------------------|-------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| | DAY ON TEST | 0
7
3
3 |
| B6C3F1 MICE FEMALE | | 0
0
2
7 | 0
0
2
7 | 0
0
2
8 |
| 3000 PPM | ANIMAL ID | 0
0
2
7 | 0
0
2
7 | 0
0
2
8 |
| | | | | | | | | | | | | | | | | | | | | | |

*** TOTALS**

| | | |
|-------------|---|-------|
| Cyst | X | 1 |
| Hyperplasia | 2 | 1 2.0 |
| Skin | + | 50 |

MUSCULOSKELETAL SYSTEM

| | | |
|-----------------|---|----|
| Bone | + | 50 |
| Skeletal Muscle | + | 1 |

NERVOUS SYSTEM

| | | |
|-------------|---|-------|
| Brain | + | 50 |
| Compression | + | 1 2.0 |

RESPIRATORY SYSTEM

| | | |
|-----------------------------------|---|-------|
| Lung | + | 50 |
| Infiltration Cellular, Lymphocyte | 2 | 2 2.0 |
| Alveolar Epithelium, Hyperplasia | 2 | 3 2.0 |
| Nose | + | 50 |
| Trachea | + | 50 |

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Lab: SRI

SPECIAL SENSES SYSTEM

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|--------|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | 49 | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | 1 4.0 | |
| Hydronephrosis | | | | | | | | | | | | | | | | | | | | | | 1 3.0 | |
| Infarct | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | 1 | | | 2 | | | 2 | | 7 1.6 |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Nephropathy | 1 | 1 | | | | | | 1 | 1 | | | | | | | 1 | 1 | | 1 | 1 | 2 | 1 | 19 1.1 |
| Renal Tubule, Dilatation | | | | | 1 | | | | | | | | | | | | | | | | | | 1 1.0 |
| Transitional Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | 49 | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | 1 | | | 2 | | | 1 | 2 | 6 1.7 |

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ENDOCRINE SYSTEM

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Lab: SRI

| B6C3F1 MICE FEMALE
9000 PPM | ANIMAL ID | Day on Test | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|-----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 0 | 7 | 7 | |
| | | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 0 | 1 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 1 | 0 | 3 | 3 |
| | | 3 | 8 | 3 | 3 | 3 | 3 | 2 | 7 | 2 | 2 | 2 | 3 | 3 | 9 | 3 | 3 | 4 | 2 | 2 | 2 | 2 | 6 | 5 | 2 | 2 |
| Bone Marrow | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Myelofibrosis | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node | | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Iliac, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pancreatic, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Renal, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mandibular | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | 3 | |
| Lymph Node, Mesenteric | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | |
| Ectasia | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Histiocytic | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Spleen | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymphoid Follicle, Hyperplasia | | 2 | 3 | | | | | | 3 | 1 | 3 | 2 | | | | 3 | 3 | 1 | 3 | | | 2 | | | 4 | |
| Thymus | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |

INTEGUMENTARY SYSTEM

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Lab: SR

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|--------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | 49 | |
| Gallbladder | + | + | + | + | + | + | + | M | + | + | A | + | + | + | A | + | + | A | + | + | 39 | |
| Intestine Large, Cecum | A | + | + | + | + | + | + | A | + | + | A | + | + | + | + | + | + | A | + | + | 41 | |
| Intestine Large, Colon | A | + | + | + | + | + | + | A | + | + | A | + | + | + | + | + | + | A | + | + | 39 | |
| Intestine Large, Rectum | A | + | + | + | + | + | + | A | + | + | A | + | + | + | + | + | + | A | + | + | 43 | |
| Intestine Small, Duodenum | A | + | + | + | + | + | + | A | + | + | A | + | + | + | + | + | + | A | + | + | 38 | |
| Intestine Small, Ileum | A | + | + | + | + | + | + | A | + | + | A | + | + | + | + | + | + | A | + | + | 39 | |
| Intestine Small, Jejunum
Hyperplasia, Lymphoid
Inflammation, Suppurative | A | + | + | + | + | + | + | A | + | + | A | + | + | + | + | + | + | A | + | + | 43 | |
| Liver | + | + | + | + | + | + | + | + | + | + | X | | | | | | | A | + | + | 49 | |
| Basophilic Focus | | | | | | | | | | | X | | | | | | | | | | 3 | |
| Cyst | | | | | | | | | | | X | | | | | | | | | | 1 | |
| Eosinophilic Focus | | | | | | | | | | | X | | | | | | | | | | 2 | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | 2 1.5 | |
| Infiltration Cellular, Lymphocyte | 1 | | 2 | 1 | 1 | 1 | | | | | | 1 | 1 | 1 | 1 | 1 | 1 | | | 2 | 1 | 26 1.1 |
| Infiltration Cellular, Mixed Cell | | | | | | | | | | | | 1 | 1 | 1 | 1 | | | | | 1 | 10 1.0 | |

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Lab: SRI

| B6C3F1 MICE FEMALE
9000 PPM | ANIMAL ID | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---------------------------------------|-----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----------|
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | 6 | 7 | 7 | 3 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | |
| | | 7 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | | 2 | 2 | 2 | 9 | 2 | 6 | 6 | 3 | 6 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 9 | 3 | 3 | 7 | 3 | 3 | 3 | 3 | |
| Mixed Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Capsule, Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Hepatocyte, Vacuolization Cytoplasmic | | 1 | 1 | | | | | | | | | | | | | | | | | | | | | | | 7 1.9 |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | 9 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | 7 2.3 |
| Pancreas | | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 47 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Acinus, Cytoplasmic Alteration | | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Artery, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Salivary Glands | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.20 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | 5 1.6 |
| Stomach, Forestomach | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 3 2.0 |
| Stomach, Glandular | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |

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Lab: SRI

| | | | |
|-----------------------------------|---|---|-----|
| Foreign Body | | 1 | 1.0 |
| Hemorrhage | | 1 | 1.0 |
| Infiltration Cellular, Lymphocyte | 2 | | 2.0 |
| Inflammation, Suppurative | | | 2.0 |
| Alveolar Epithelium, Hyperplasia | | | 2.0 |

Trachea + M + + 49

SPECIAL SENSES SYSTEM

URINARY SYSTEM

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TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

X .. Essien present
I .. Insufficient tissue

M., Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1-4: Lesion qualified as:

1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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Lab: SRI

INTEGUMENTARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

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M., Missing tissue

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ALIMENTARY SYSTEM

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TDMS No. 99007 - 06

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Lab: SRI

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+ .. Tissue examined microscopically

x ... Lesion present

.. Lesion present
 Insufficient tissue

M.. Missing tissue

A .. Autolysis precludes evaluation

BLANK Not examined microscopically

1-4 .. Lesion qualified as:

1-4.2. Emission qualified as:

1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

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Lab: SR

CARDIOVASCULAR SYSTEM

ENDOCRINE SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x ... Lesion present

| Insufficient tissue

M.. Missing tissue

A .. Autolysis precludes evaluation

BLANK Not examined microscopically

1-4 .. Lesion qualified as:

1-4: Lesion qualified as:

1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

HEMATOPOIETIC SYSTEM

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TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

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Lab: SRI

INTEGUMENTARY SYSTEM

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Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

Pigmentation

Subcutaneous Tissue, Infiltration Cellular Lymphocyte

2

12.0

1 3,0

MUSCULOSKELETAL SYSTEM

NERVOUS SYSTEM

RESPIRATORY SYSTEM

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M Missing tissue

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1-4: Lesion qualified as:

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First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

SPECIAL SENSES SYSTEM

URINARY SYSTEM

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Route: DOSED FEED

Species/Strain: MICE/B6C3F1

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Goldenseal root powder

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Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|
| | 5 | 3 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | | | |
| | 2 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 9 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | | |
| | 1 | 7 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 3 | 3 | 3 | 3 | 3 | 4 | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 25000 PPM | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 0 | 0 | 0 | 0 | * TOTALS |

*** END OF REPORT ***

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