

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

F_RD

C Number: C20203
Lock Date: 11/14/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.1.0

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------|--|---|---|---|---|---|---|---|---|---|---|
| FISCHER 344-TACONIC RATS | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 mg/kg | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| * TOTALS | | | | | | | | | | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | 10 |
| Liver | + | + | + | + | + | + | + | + | + | + | 10 |
| Hepatodiaphragmatic Nodule | X | | | | | | | | | | 1 |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | | 1 | 1 | | 1 | | | 7 1.0 |
| Pancreas | + | + | + | + | + | + | + | + | + | + | 10 |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | 10 |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | 10 |

* .. 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

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---------------------------------|---|---|---|---|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| <hr/> | | | | | | | | | | |
| FISCHER 344-TACONIC RATS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 mg/kg | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| ANIMAL ID | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| | | | | | | | | | | * TOTALS |

| | | | | | | | | | | | |
|--------------------|---|---|---|---|---|---|---|---|---|---|-----------|
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | 10 |
|--------------------|---|---|---|---|---|---|---|---|---|---|-----------|

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | |
|--------------|---|---|---|---|---|---|---|---|---|---|-----------|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | 10 |
|--------------|---|---|---|---|---|---|---|---|---|---|-----------|

| | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|--------------|
| Heart | + | + | + | + | + | + | + | + | + | + | 10 |
| Cardiomyopathy | 1 | 1 | 1 | | 2 | 1 | 2 | 2 | 1 | 1 | 9 1.3 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|--------------|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | 10 |
| Vacuolization Cytoplasmic | | 1 | | | | | 1 | | | 1 | 3 1.0 |

| | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|-----------|
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | 10 |
|-----------------|---|---|---|---|---|---|---|---|---|---|-----------|

| | | | | | | | | | | | |
|--------------------|---|---|---|---|---|---|---|---|---|---|-----------|
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | 10 |
|--------------------|---|---|---|---|---|---|---|---|---|---|-----------|

| | | | | | | | | | | | |
|-------------------|---|---|---|---|---|---|---|---|---|---|----------|
| Parathyroid Gland | + | + | + | + | + | + | M | + | + | M | 8 |
|-------------------|---|---|---|---|---|---|---|---|---|---|----------|

| | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|-----------|
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | 10 |
|-----------------|---|---|---|---|---|---|---|---|---|---|-----------|

| | | | | | | | | | | | |
|----------------------|---|---|---|---|---|---|---|---|---|---|-----------|
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | 10 |
| Ultimobranchial Cyst | | | | | | X | | | | | 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
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 3

| | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |

**FISCHER 344-TACONIC RATS
MALE**

ANIMAL ID

| | | | | | | | | | | |
|---------|---|---|---|---|---|---|---|---|---|---|
| 0 mg/kg | 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 | 1 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

*** TOTALS**

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|----|---|-----|
| Epididymis Inflammation | + | + | + | + | + | + | + | + | + | + | 10 | 1 | 1.0 |
| Preputial Gland Inflammation | + | + | + | + | + | + | + | + | + | + | 10 | 9 | 1.7 |
| Prostate | + | + | + | + | + | + | + | + | + | + | 10 | | |
| Seminal Vesicle | + | + | + | + | + | + | + | + | + | + | 10 | | |
| Testes Seminiferous Tubule, Degeneration | + | + | + | + | + | + | + | + | + | + | 10 | 3 | 1.0 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|----|---|-----|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | 10 | | |
| Lymph Node, Mandibular Hyperplasia, Lymphoid Hyperplasia, Plasma Cell | + | + | + | + | + | + | + | + | + | + | 10 | 3 | 2.3 |
| | 2 | 1 | | 1 | | 3 | | 2 | 1 | | | 5 | 1.4 |

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

+ .. Tissue examined microscopically

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I .. Insufficient tissue

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A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------|--|---|---|---|---|---|---|---|---|---|---|
| FISCHER 344-TACONIC RATS | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| 0 mg/kg | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

* TOTALS

| | | | | | | | | | | | | |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|----|
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | 10 |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | 10 |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | 10 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | |
|---------------|---|---|---|---|---|---|---|---|---|---|---|----|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | 10 |
| Skin | + | + | + | + | + | + | + | + | + | + | + | 10 |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | |
|------|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone | + | + | + | + | + | + | + | + | + | + | + | 10 |
|------|---|---|---|---|---|---|---|---|---|---|---|----|

NERVOUS SYSTEM

| | | | | | | | | | | | | |
|-------|---|---|---|---|---|---|---|---|---|---|---|----|
| Brain | + | + | + | + | + | + | + | + | + | + | + | 10 |
|-------|---|---|---|---|---|---|---|---|---|---|---|----|

RESPIRATORY SYSTEM

| | | | | | | | | | | | | |
|------|---|---|---|---|---|---|---|---|---|---|---|----|
| Lung | + | + | + | + | + | + | + | + | + | + | + | 10 |
|------|---|---|---|---|---|---|---|---|---|---|---|----|

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

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

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BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
|-------------------------------------|--|---|---|---|---|---|---|---|---|---|---|----------|
| FISCHER 344-TACONIC RATS MALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0 mg/kg | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS |
| Hemorrhage | | 1 | 1 | 1 | 2 | 1 | | | 1 | | | 6 1.2 |
| Inflammation | | 2 | 3 | 2 | 3 | 3 | 1 | | 1 | 1 | 1 | 9 1.9 |
| Nose | | + | + | + | + | + | + | + | + | + | + | 10 |
| Inflammation | | | 1 | 1 | | | | | | | | 2 1.0 |
| Respiratory Epithelium, Hyperplasia | | | | | | | | 2 | | | | 1 2.0 |
| Trachea | | + | + | + | + | + | + | + | + | + | + | 10 |
| Inflammation | | | | | | | | | | 1 | | 1 1.0 |
| SPECIAL SENSES SYSTEM | | | | | | | | | | | | |
| Eye | | + | + | + | + | + | + | + | + | + | + | 10 |
| Harderian Gland | | + | + | + | + | + | + | + | + | + | + | 10 |
| Inflammation | | 2 | | | | | | | | | | 1 2.0 |
| URINARY SYSTEM | | | | | | | | | | | | |
| Kidney | | + | + | + | + | + | + | + | + | + | + | 10 |
| Nephropathy | | 1 | | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 8 1.0 |
| Urinary Bladder | | + | + | + | + | + | + | + | + | + | + | 10 |

* .. 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

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------|--|---|---|---|---|---|---|---|---|---|---|
| FISCHER 344-TACONIC RATS | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 62.5 mg/kg | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| * TOTALS | | | | | | | | | | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Liver | + | + | + | + | + | + | + | + | + | + | 10 |
| Clear Cell Focus | X | | | | | | | | | | 1 |
| Hepatodiaphragmatic Nodule | X | | | | | | | | | | 1 |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | | 9 1.1 |
| Bile Duct, Hyperplasia | | | | | | 1 | | | | | 1 1.0 |

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|--------------|
| Testes | + | + | + | + | + | + | + | + | + | + | 10 |
| Seminiferous Tubule, Degeneration | | | 1 | | | | | | | | 1 1.0 |

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

M .. Missing tissue

A .. Autolysis precludes evaluation

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Page 7

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---------------------------------|---|---|---|---|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| FISCHER 344-TACONIC RATS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 62.5 mg/kg | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| | | | | | | | | | | * TOTALS |

| | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|----|----------------|
| Lymph Node, Mandibular Hyperplasia, Plasma Cell | + | + | + | + | + | + | + | + | + | + | 10 | |
| | 1 | 2 | 2 | 1 | 1 | 1 | 2 | 2 | 1 | 1 | | 10 1.4 |
| Lymph Node, Mesenteric Hyperplasia, Lymphoid Infiltration Cellular, Histiocyte | + | + | + | + | + | + | + | + | + | + | 10 | |
| | | | 2 | 2 | | | | 2 | | | | 1 2.0 2 2.0 |
| Thymus | + | + | + | + | + | + | + | + | + | + | 10 | |

INTEGUMENTARY SYSTEM

NONE

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

| | | | | | | | | | | | | |
|----------------------|---|---|---|---|---|---|---|---|---|---|----|-------|
| Nose Inflammation | + | + | + | + | + | + | + | + | + | + | 10 | |
| | | | | 1 | | | 1 | | | 1 | | 3 1.0 |

SPECIAL SENSES SYSTEM

NONE

* .. 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

Page 8

1-4 .. Lesion qualified as:

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TDMS No. 20203 - 01

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Green tea extract

CAS Number: GREENTEAEXTR

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First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

| | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |

FISCHER 344-TACONIC RATS
MALE

ANIMAL ID

62.5 mg/kg

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 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 |
| 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | | 0 |

* TOTALS

URINARY SYSTEM

NONE

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

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| | | | | | | | | | | | |
|---------------------------------|---|---|---|---|---|---|---|---|---|---|-----------------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| FISCHER 344-TACONIC RATS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 125 mg/kg | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS |

ALIMENTARY SYSTEM

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Liver | + | + | + | + | + | + | + | + | + | + | 10 |
| Infiltration Cellular, Mononuclear Cell | 1 | | 1 | 1 | | 1 | 1 | 1 | 1 | | 7 1.0 |

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|--------------|
| Testes | + | + | + | + | + | + | + | + | + | + | 10 |
| Seminiferous Tubule, Degeneration | | | 1 | 1 | | | | | | | 2 1.0 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | |
|------------------------|---|---|---|---|---|---|---|---|---|---|--------------|
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | 10 |
| Ectasia | | | | | | 3 | | | | | 1 3.0 |
| Hyperplasia, Lymphoid | | | | 3 | | | | | 2 | | 2 2.5 |

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| | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |

FISCHER 344-TACONIC RATS
MALE

ANIMAL ID

125 mg/kg

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 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 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |

* TOTALS

Hyperplasia, Plasma Cell

| | | | | | | | | | | |
|---|---|---|---|--|---|---|--|---|--|--|
| 1 | 2 | 1 | 1 | | 2 | 2 | | 2 | | |
|---|---|---|---|--|---|---|--|---|--|--|

7 1.6

Lymph Node, Mesenteric
Infiltration Cellular, Histiocyte

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + |
| | 1 | | 2 | 2 | 1 | 2 | 1 | | | |

10
6 1.5

Thymus

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + |
|---|---|---|---|---|---|---|---|---|---|---|

10

INTEGUMENTARY SYSTEM

NONE

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

Nose
Inflammation
Olfactory Epithelium, Atrophy
Olfactory Epithelium, Metaplasia

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + |
| | 1 | | | | | | | | | |
| | | | | | | 1 | 1 | | | |
| | | | | | | 1 | | | | |

10
1 1.0
2 1.0
1 1.0

SPECIAL SENSES SYSTEM

NONE

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

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I .. Insufficient tissue

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| | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |

FISCHER 344-TACONIC RATS
MALE

ANIMAL ID

125 mg/kg

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 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 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |

* TOTALS

URINARY SYSTEM

NONE

* .. 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

| | | | | | | | | | | | |
|---------------------------------|---|---|---|---|---|---|---|---|---|---|-----------------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| FISCHER 344-TACONIC RATS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | |
| 250 mg/kg | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS |

ALIMENTARY SYSTEM

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Liver | + | + | + | + | + | + | + | + | + | + | 10 |
| Infiltration Cellular, Mononuclear Cell | | | | 1 | | | 1 | 1 | 1 | 1 | 5 1.0 |

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|--------------|
| Testes | + | + | + | + | + | + | + | + | + | + | 10 |
| Seminiferous Tubule, Degeneration | 1 | | | | 1 | | | 1 | | | 3 1.0 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | |
|--------------------------|---|---|---|---|---|---|---|---|---|---|--------------|
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | 10 |
| Hyperplasia, Plasma Cell | 1 | 2 | 1 | 1 | | 1 | 2 | 1 | 1 | 1 | 9 1.2 |

* .. 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

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
|-----------------------------------|--|---|---|---|---|---|---|---|---|---|---|----------|
| FISCHER 344-TACONIC RATS MALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 250 mg/kg | | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS |
| Lymph Node, Mesenteric | | + | + | + | + | + | + | + | + | + | + | 10 |
| Infiltration Cellular, Histiocyte | | 2 | 1 | 2 | 2 | 2 | | 2 | 2 | | | 7 1.9 |
| Thymus | | + | + | + | + | + | + | + | + | + | + | 10 |
| Atrophy | | 1 | | | | | | | | | | 1 1.0 |

INTEGUMENTARY SYSTEM

NONE

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

| | | | | | | | | | | | | |
|-------------------------------|--|---|---|---|---|---|---|---|---|---|---|-------|
| Nose | | + | + | + | + | + | + | + | + | + | + | 10 |
| Inflammation | | | | 1 | | | | | | 1 | | 2 1.0 |
| Olfactory Epithelium, Atrophy | | | | | 1 | | | | | | | 1 1.0 |

SPECIAL SENSES SYSTEM

NONE

* .. 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. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

| | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |

FISCHER 344-TACONIC RATS
MALE

ANIMAL ID

250 mg/kg

| | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|
| | 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 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

* TOTALS

URINARY SYSTEM

NONE

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

+ .. Tissue examined microscopically

x .. Lesion present

l .. 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

| | | | | | | | | | | | |
|---------------------------------|---|---|---|---|---|---|---|---|---|---|-----------------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | | | | | | | | | | | |
| FISCHER 344-TACONIC RATS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | |
| 500 mg/kg | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS |

ALIMENTARY SYSTEM

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|-------|
| Liver | + | + | + | + | + | + | + | + | + | + | 10 |
| Hepatodiaphragmatic Nodule | | | | | | | X | | | | 1 |
| Infiltration Cellular, Mononuclear Cell | | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 8 1.0 |

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|-------|
| Testes | + | + | + | + | + | + | + | + | + | + | 10 |
| Seminiferous Tubule, Degeneration | 1 | | 1 | | | | 1 | | | | 3 1.0 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | |
|------------------------|---|---|---|---|---|---|---|---|---|---|-------|
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | 10 |
| Hyperplasia, Lymphoid | 1 | | | | | | | | | | 1 1.0 |

* .. 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

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
|-----------------------------------|--|---|---|---|---|---|---|---|---|---|---|----------|
| FISCHER 344-TACONIC RATS MALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | |
| 500 mg/kg | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS |
| Hyperplasia, Plasma Cell | | 2 | | 1 | 2 | 1 | 1 | | 1 | 1 | 2 | 8 1.4 |
| Lymph Node, Mesenteric | | + | + | + | + | + | + | + | + | + | + | 10 |
| Infiltration Cellular, Histiocyte | | 2 | 2 | 2 | | | | 1 | 1 | 2 | 2 | 7 1.7 |
| Thymus | | + | + | + | + | + | + | + | + | + | + | 10 |

INTEGUMENTARY SYSTEM

NONE

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

| | | | | | | | | | | | | |
|---|--|---|---|---|---|---|---|---|---|---|---|-------|
| Nose | | + | + | + | + | + | + | + | + | + | + | 10 |
| Inflammation | | | | | 1 | | 1 | | 2 | | | 3 1.3 |
| Glands, Olfactory Epithelium, Hyperplasia | | 2 | | | 1 | 1 | | | | | | 3 1.3 |
| Nasopharyngeal Duct, Degeneration | | | | | | 3 | 1 | | 2 | | | 3 2.0 |
| Nasopharyngeal Duct, Inflammation | | | | | | 1 | 1 | | | | | 2 1.0 |
| Nerve, Atrophy | | 1 | 3 | | 1 | 2 | 2 | | | | | 5 1.8 |
| Olfactory Epithelium, Atrophy | | | 1 | | | 1 | 1 | | | | | 3 1.0 |
| Olfactory Epithelium, Hyperplasia, Basal | | | 1 | | | | | | | | | 1 1.0 |

* .. 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

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
|-------------------------------------|--|---|---|---|---|---|---|---|---|---|-----------------|--------------|
| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| DAY ON TEST | | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | |
| DAY ON TEST | | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | | | | | | | | | | | | |
| FISCHER 344-TACONIC RATS | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| MALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 500 mg/kg | | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | |
| ANIMAL ID | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |
| | | | | | | | | | | | * TOTALS | |
| Cell | | | | | | | | | | | | |
| Olfactory Epithelium, Metaplasia | | 1 | 3 | | | 1 | 2 | 1 | | | 1 | 6 1.5 |
| Olfactory Epithelium, Necrosis | | | | | | | | | | | | 1 1.0 |
| Olfactory Epithelium, Pigmentation | | 1 | 1 | | | | | 1 | 1 | | | 4 1.0 |
| Respiratory Epithelium, Hyperplasia | | | | | | | | | | | | 2 1.0 |

SPECIAL SENSES SYSTEM

NONE

URINARY SYSTEM

NONE

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

+ .. Tissue examined microscopically

x .. Lesion present

l .. 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

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------|--|---|---|---|---|---|---|---|---|---|---|
| FISCHER 344-TACONIC RATS | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1000 mg/kg | | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| * TOTALS | | | | | | | | | | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | 10 |
| Liver | + | + | + | + | + | + | + | + | + | + | 10 |
| Hepatodiaphragmatic Nodule | | | X | | | | | | X | | 2 |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | | 1 | | | | | | 4 1.0 |
| Pancreas | + | + | + | + | + | + | + | + | + | + | 10 |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | 10 |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | 10 |

* .. 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

| 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 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| <hr/> | | | | | | | | | | | |
| FISCHER 344-TACONIC RATS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | |
| 1000 mg/kg | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |
| | | | | | | | | | | | * TOTALS |

| | | | | | | | | | | | |
|---------------------------------|---|---|---|---|---|---|---|---|---|---|-------|
| Stomach, Glandular Inflammation | + | + | + | + | + | + | + | + | + | + | 10 |
| | | | | | | | | | | | 1 1.0 |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|-------|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | 10 |
| Heart | + | + | + | + | + | + | + | + | + | + | 10 |
| Cardiomyopathy | 2 | 1 | 1 | 1 | 1 | | 1 | 1 | | 1 | 8 1.1 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | |
|--------------------|---|---|---|---|---|---|---|---|---|---|----|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | 10 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | 10 |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | 10 |
| Parathyroid Gland | + | + | + | M | M | + | + | + | + | + | 8 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | 10 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | 10 |

GENERAL BODY 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

Page 20

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

| | | | | | | | | | | | |
|---------------------------------|---|---|---|---|---|---|---|---|---|---|-----------------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | | | | | | | | | | | |
| FISCHER 344-TACONIC RATS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | |
| 1000 mg/kg | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS |

NONE

GENITAL SYSTEM

| | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|-------|
| Epididymis | + | + | + | + | + | + | + | + | + | + | 10 |
| Preputial Gland Inflammation | + | + | + | + | + | + | + | + | + | + | 10 |
| | 1 | 1 | 1 | 1 | 1 | 2 | 3 | | 3 | 2 | 9 1.7 |
| Prostate | + | + | + | + | + | + | + | + | + | + | 10 |
| Seminal Vesicle | + | + | + | + | + | + | + | + | + | + | 10 |
| Testes | + | + | + | + | + | + | + | + | + | + | 10 |
| Seminiferous Tubule, Degeneration | | 1 | | 1 | 1 | | 1 | 1 | 1 | 1 | 7 1.0 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|-------|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | 10 |
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | 10 |
| Hyperplasia, Lymphoid | | | 1 | | | | | 2 | | | 2 1.5 |
| Hyperplasia, Plasma Cell | 2 | 1 | 2 | 3 | | 1 | 1 | 2 | | 2 | 8 1.8 |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | 10 |
| Infiltration Cellular, Histiocyte | | 2 | 2 | 2 | 2 | | | 1 | 1 | 2 | 7 1.7 |

* .. 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

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
|-------------------------------|--|---|---|---|---|---|---|---|---|---|---|----------|
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| FISCHER 344-TACONIC RATS MALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 1000 mg/kg | | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | * TOTALS |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |
| Spleen | | + | + | + | + | + | + | + | + | + | + | 10 |
| Thymus Atrophy | | + | M | + | + | + | + | + | M | + | + | 8 |
| | | 1 | | 1 | 1 | 1 | | | 1 | | | 5 1.0 |
| INTEGUMENTARY SYSTEM | | | | | | | | | | | | |
| Mammary Gland | | + | + | + | + | + | + | + | + | + | + | 10 |
| Skin | | + | + | + | + | + | + | + | + | + | + | 10 |
| MUSCULOSKELETAL SYSTEM | | | | | | | | | | | | |
| Bone | | + | + | + | + | + | + | + | + | + | + | 10 |
| NERVOUS SYSTEM | | | | | | | | | | | | |
| Brain | | + | + | + | + | + | + | + | + | + | + | 10 |
| RESPIRATORY SYSTEM | | | | | | | | | | | | |
| Lung Inflammation | | + | + | + | + | + | + | + | + | + | + | 10 |
| | | | 1 | 1 | 1 | 1 | | | 1 | 1 | 1 | 7 1.0 |

* .. 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. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

| | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |

FISCHER 344-TACONIC RATS
MALE

ANIMAL ID

1000 mg/kg

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 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 |
| 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |

* TOTALS

URINARY SYSTEM

| | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|-------|
| Kidney | + | + | + | + | + | + | + | + | + | + | 10 |
| Mineralization | | | | | | 1 | | 1 | | | 2 1.0 |
| Nephropathy | | | | | 1 | 1 | 1 | 1 | 1 | | 5 1.0 |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | 10 |

*** END OF MALE DATA ***

* .. 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

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------|--|---|---|---|---|---|---|---|---|---|---|
| FISCHER 344-TACONIC RATS | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FEMALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 mg/kg | | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| * TOTALS | | | | | | | | | | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | 10 |
| Liver | + | + | + | + | + | + | + | + | + | + | 10 |
| Hepatodiaphragmatic Nodule | | | | | | | X | | | | 1 |
| Infiltration Cellular, Mononuclear Cell | 2 | | 1 | 2 | 2 | 1 | 1 | 1 | 2 | 1 | 9 1.4 |
| Pancreas | + | + | + | + | + | + | + | + | + | + | 10 |
| Inflammation, Chronic Active | | | 1 | | | | | | | | 1 1.0 |
| Acinus, Atrophy | | | 1 | | | | | | | | 1 1.0 |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | 10 |

* .. 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

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
|---------------------------------|---|---|---|---|---|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| <hr/> | | | | | | | | | | | |
| FISCHER 344-TACONIC RATS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | |
| 0 mg/kg | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | 10 |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | 10 |
| <hr/> | | | | | | | | | | | |
| CARDIOVASCULAR SYSTEM | | | | | | | | | | | |
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | 10 |
| Heart | + | + | + | + | + | + | + | + | + | + | 10 |
| Cardiomyopathy | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 9 1.0 |
| <hr/> | | | | | | | | | | | |
| ENDOCRINE SYSTEM | | | | | | | | | | | |
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | 10 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | 10 |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | 10 |
| Parathyroid Gland | + | M | + | + | + | + | + | M | + | + | 8 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | 10 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | 10 |

* .. 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
Page 26

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---------------------------------|---|---|---|---|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| <hr/> | | | | | | | | | | |
| FISCHER 344-TACONIC RATS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 mg/kg | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| | | | | | | | | | | * TOTALS |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | |
|-----------------------------|---|---|---|---|---|---|---|---|---|---|----|---|-----|
| Clitoral Gland Inflammation | + | + | + | + | + | + | + | + | + | + | 10 | 5 | 1.2 |
| Ovary | + | + | + | + | + | + | + | + | + | + | 10 | | |
| Uterus | + | + | + | + | + | + | + | + | + | + | 10 | | |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|----|---|-----|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | 10 | | |
| Lymph Node, Mandibular Hyperplasia, Lymphoid | + | + | + | + | + | + | + | + | + | + | 10 | 3 | 2.0 |
| Hyperplasia, Plasma Cell | 2 | | | | 2 | | | 2 | | 2 | | 4 | 2.0 |
| Lymph Node, Mesenteric Infiltration Cellular, Histiocyte | + | + | + | + | + | + | + | + | + | + | 10 | 8 | 2.6 |
| Spleen | + | + | + | + | + | + | + | + | + | + | 10 | | |

* .. 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

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
|---------------------------------|---|---|---|---|---|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | | | | | | | | | | | |
| FISCHER 344-TACONIC RATS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | |
| 0 mg/kg | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS |
| Thymus | + | + | + | + | + | + | + | + | + | + | 10 |
| | | | | | | | | | | | |
| INTEGUMENTARY SYSTEM | | | | | | | | | | | |
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | 10 |
| Skin | + | + | + | + | + | + | + | + | + | + | 10 |
| | | | | | | | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | | | | | | | |
| Bone | + | + | + | + | + | + | + | + | + | + | 10 |
| | | | | | | | | | | | |
| NERVOUS SYSTEM | | | | | | | | | | | |
| Brain | + | + | + | + | + | + | + | + | + | + | 10 |
| | | | | | | | | | | | |
| RESPIRATORY SYSTEM | | | | | | | | | | | |
| Lung | + | + | + | + | + | + | + | + | + | + | 10 |
| Hemorrhage | | | | | | 1 | | | | | 1 1.0 |
| Inflammation | 1 | 1 | 1 | 1 | | 2 | 1 | 1 | | 1 | 8 1.1 |
| Nose | + | + | + | + | + | + | + | + | + | + | 10 |
| Inflammation | | | | 1 | | | | | | 1 | 2 1.0 |

* .. 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

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
|------------------------------------|--|---|---|---|---|---|---|---|---|---|---|-------------|
| FISCHER 344-TACONIC RATS FEMALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0 mg/kg | | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 0 | * TOTALS |
| Trachea | | + | + | + | + | + | + | + | + | + | + | 10 |
| SPECIAL SENSES SYSTEM | | | | | | | | | | | | |
| Eye | | + | + | + | + | + | + | + | + | + | + | 10 |
| Harderian Gland Inflammation | | + | + | + | + | + | + | + | + | + | + | 10 1 1.0 |
| URINARY SYSTEM | | | | | | | | | | | | |
| Kidney Mineralization | | + | + | + | + | + | + | + | + | + | + | 10 5 1.0 |
| Urinary Bladder | | + | + | + | + | + | + | + | + | + | + | 10 |

* .. 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

| | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |

**FISCHER 344-TACONIC RATS
FEMALE**

ANIMAL ID

62.5 mg/kg

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 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 |
| 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 8 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 9 | 0 |

*** TOTALS**

ALIMENTARY SYSTEM

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Liver | + | + | + | + | + | + | + | + | + | + |
| Infiltration Cellular, Mononuclear Cell | 2 | | 1 | | 1 | 1 | 1 | 1 | 1 | 1 |

**10
8 1.1**

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

NONE

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | |
|--------------------------|---|---|---|---|---|---|---|---|---|---|
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia, Lymphoid | | | | 2 | | 2 | | 1 | | 1 |
| Hyperplasia, Plasma Cell | | 1 | | 1 | | | 1 | | 1 | 1 |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + |

**10
4 1.5
5 1.0**

* .. 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

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---------------------------------|---|---|---|---|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| <hr/> | | | | | | | | | | |
| FISCHER 344-TACONIC RATS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 8 |
| 62.5 mg/kg | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| | | | | | | | | | | * TOTALS |

Infiltration Cellular, Histiocyte 3 2 2 2 2 2 1 2 2 1 **10 1.9**

Thymus + + + + + + + + + + **10**

INTEGUMENTARY SYSTEM

NONE

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

Nose + + + + + + + + + + **10**

Inflammation 1 **1 1.0**

Olfactory Epithelium, Atrophy 1 **1 1.0**

SPECIAL SENSES SYSTEM

Eye + **1**

Cornea, Degeneration 2 **1 2.0**

* .. 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. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

| | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |

FISCHER 344-TACONIC RATS
FEMALE

ANIMAL ID

62.5 mg/kg

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 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 |
| 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 8 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |

* TOTALS

URINARY SYSTEM

NONE

* .. 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

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------|--|---|---|---|---|---|---|---|---|---|---|
| FISCHER 344-TACONIC RATS | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FEMALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 125 mg/kg | | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| * TOTALS | | | | | | | | | | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | |
|---|--|--|--|--|--|--|--|--|--|--|--|---|---|---|---|---|---|---|---|---|---|-------|
| Esophagus | | | | | | | | | | | | + | 1 | | | | | | | | | |
| Intestine Large, Cecum | | | | | | | | | | | | + | 1 | | | | | | | | | |
| Intestine Large, Colon | | | | | | | | | | | | + | 1 | | | | | | | | | |
| Intestine Large, Rectum | | | | | | | | | | | | + | 1 | | | | | | | | | |
| Intestine Small, Duodenum | | | | | | | | | | | | + | 1 | | | | | | | | | |
| Intestine Small, Ileum | | | | | | | | | | | | + | 1 | | | | | | | | | |
| Intestine Small, Jejunum | | | | | | | | | | | | + | 1 | | | | | | | | | |
| Liver | | | | | | | | | | | | + | + | + | + | + | + | + | + | + | + | 10 |
| Hepatodiaphragmatic Nodule | | | | | | | | | | | | | | | | | | | | | | 1 |
| Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | 1 | 2 | 1 | 1 | | | | 1 | 1 | | 6 1.2 |
| Pancreas | | | | | | | | | | | | + | 1 | | | | | | | | | |
| Salivary Glands | | | | | | | | | | | | + | 1 | | | | | | | | | |
| Stomach, Forestomach | | | | | | | | | | | | + | 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
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------|--|---|---|---|---|---|---|---|---|---|---|
| FISCHER 344-TACONIC RATS | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FEMALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 125 mg/kg | | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| * TOTALS | | | | | | | | | | | |

Stomach, Glandular + 1

CARDIOVASCULAR SYSTEM

Blood Vessel + 1

Heart + 1

Cardiomyopathy 1 1.0

ENDOCRINE SYSTEM

Adrenal Cortex + 1

Adrenal Medulla + 1

Islets, Pancreatic + 1

Parathyroid Gland + 1

Pituitary Gland + 1

Thyroid Gland + 1

GENERAL BODY SYSTEM

NONE

* .. 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

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---------------------------------|--|---|---|---|---|---|---|---|---|---|-----------------|
| 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 9 | | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 4 |
| 3 | | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 |
| | | | | | | | | | | | |
| FISCHER 344-TACONIC RATS | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FEMALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8 | | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 |
| 125 mg/kg | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| | | | | | | | | | | | * TOTALS |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | |
|---------------|--|--|--|--|--|--|--|--|--|--|--|---|---|
| Mammary Gland | | | | | | | | | | | | + | 1 |
| Skin | | | | | | | | | | | | + | 1 |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | |
|------|--|--|--|--|--|--|--|--|--|--|--|---|---|
| Bone | | | | | | | | | | | | + | 1 |
|------|--|--|--|--|--|--|--|--|--|--|--|---|---|

NERVOUS SYSTEM

| | | | | | | | | | | | | | |
|-------|--|--|--|--|--|--|--|--|--|--|--|---|---|
| Brain | | | | | | | | | | | | + | 1 |
|-------|--|--|--|--|--|--|--|--|--|--|--|---|---|

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Lung | | | | | | | | | | | | + | 1 | |
| Inflammation | | | | | | | | | | | | 1 | | 1 1.0 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | | 10 | |
| Inflammation | | | 1 | | | | | | | | | | | 1 1.0 |
| Olfactory Epithelium, Atrophy | | | 1 | | | | | | | | | | | 1 1.0 |
| Trachea | | | | | | | | | | | | + | 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

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---------------------------------|--|---|---|---|---|---|---|---|---|---|---|
| 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 9 | | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 4 |
| 3 | | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 |
| FISCHER 344-TACONIC RATS | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FEMALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 125 mg/kg | | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| * TOTALS | | | | | | | | | | | |

SPECIAL SENSES SYSTEM

| | | |
|-----------------|---|---|
| Eye | + | 1 |
| Harderian Gland | + | 1 |

URINARY SYSTEM

| | | |
|-----------------|---|---|
| Kidney | + | 1 |
| Urinary Bladder | + | 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

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|-------------|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |

| FISCHER 344-TACONIC RATS 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 | 1 |
| ANIMAL ID | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |
| 250 mg/kg | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

*** TOTALS**

ALIMENTARY SYSTEM

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|-------|
| Liver | + | + | + | + | + | + | + | + | + | + | 10 |
| Hepatodiaphragmatic Nodule | | | | | X | X | | | | | 2 |
| Infiltration Cellular, Mononuclear Cell | | 2 | 1 | | 2 | 2 | | 1 | 1 | 1 | 7 1.4 |

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

NONE

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | |
|--------------------------|---|---|---|---|---|---|---|---|---|---|-------|
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | 10 |
| Hyperplasia, Lymphoid | | | | | | | | | | 1 | 1 1.0 |
| Hyperplasia, Plasma Cell | | 2 | | 1 | 2 | | 1 | 1 | 1 | 1 | 7 1.3 |

* .. 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

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| <hr/> | | | | | | | | | | | |
| FISCHER 344-TACONIC RATS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | |
| ANIMAL ID | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | |
| 250 mg/kg | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | 10 |
| Infiltration Cellular, Histiocyte | 1 | | 2 | | 2 | 3 | 1 | | 2 | 3 | 7 2.0 |
| Thymus | + | + | + | + | + | + | + | + | + | + | 10 |

INTEGUMENTARY SYSTEM

NONE

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Nose | + | + | + | + | + | + | + | + | + | + | 10 |
| Inflammation | 1 | | | 1 | | 1 | 1 | | | | 4 1.0 |
| Glands, Olfactory Epithelium, Hyperplasia | | | | 1 | | | | 1 | | | 2 1.0 |
| Nerve, Atrophy | | | | | | | | 1 | | | 1 1.0 |
| Olfactory Epithelium, Hyperplasia, Basal Cell | | | | | | | | 1 | | | 1 1.0 |
| Olfactory Epithelium, Pigmentation | | | | 1 | | | | 1 | | | 2 1.0 |
| Respiratory Epithelium, Hyperplasia | | | | | | 1 | | | | | 1 1.0 |

* .. 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

| | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |

**FISCHER 344-TACONIC RATS
FEMALE**

| | | | | | | | | | | |
|------------------|---|---|---|---|---|---|---|---|---|---|
| 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 | 1 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |
| 250 mg/kg | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

*** TOTALS**

SPECIAL SENSES SYSTEM

NONE

URINARY SYSTEM

NONE

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

+ .. Tissue examined microscopically

x .. Lesion present

l .. 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

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---------------------------------|---|---|---|---|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| <hr/> | | | | | | | | | | |
| FISCHER 344-TACONIC RATS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 500 mg/kg | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| | | | | | | | | | | * TOTALS |

ALIMENTARY SYSTEM

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Liver | + | + | + | + | + | + | + | + | + | + | 10 |
| Hepatodiaphragmatic Nodule | | | | | | | X | | | | 1 |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | | | 2 | 1 | 1 | 1 | 1 | 1 | 8 1.1 |

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

NONE

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | |
|--------------------------|---|---|---|---|---|---|---|---|---|---|--------------|
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | 10 |
| Hyperplasia, Plasma Cell | 1 | 1 | 2 | 1 | | 1 | 1 | | | 2 | 7 1.3 |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | 10 |

* .. 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

Page 41

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
|-----------------------------------|--|---|---|---|---|---|---|---|---|---|---|-----------------|
| FISCHER 344-TACONIC RATS | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| FEMALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| 500 mg/kg | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS |
| Infiltration Cellular, Histiocyte | | 2 | 2 | | 2 | 2 | 1 | | 1 | 1 | | 7 1.6 |
| Thymus | | + | + | + | + | + | + | + | + | + | + | 10 |

INTEGUMENTARY SYSTEM

NONE

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---------------|
| Nose | + | + | + | + | + | + | + | + | + | + | 10 |
| Inflammation | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 10 1.2 |
| Glands, Olfactory Epithelium, Hyperplasia | | | | | | | | 1 | | | 1 1.0 |
| Nasopharyngeal Duct, Degeneration | | | | 1 | | | | | 2 | | 2 1.5 |
| Nerve, Atrophy | | | | 1 | 1 | | 1 | 1 | | | 4 1.0 |
| Olfactory Epithelium, Metaplasia | | | | 1 | 1 | | 1 | 2 | | 1 | 5 1.2 |
| Olfactory Epithelium, Pigmentation | | | 1 | 1 | | | | | | 1 | 3 1.0 |
| Respiratory Epithelium, Hyperplasia | 1 | | | | | | | | | | 1 1.0 |

SPECIAL SENSES 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

Page 42

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

| | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |

FISCHER 344-TACONIC RATS
FEMALE

ANIMAL ID

500 mg/kg

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | | 0 |

* TOTALS

NONE

URINARY SYSTEM

NONE

* .. 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

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------|--|---|---|---|---|---|---|---|---|---|---|
| FISCHER 344-TACONIC RATS | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FEMALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 1000 mg/kg | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| * TOTALS | | | | | | | | | | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | 10 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | 10 |
| Liver | + | + | + | + | + | + | + | + | + | + | 10 |
| Hepatodiaphragmatic Nodule | | | X | X | | | | | | | 2 |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | | | 1 | | 2 | 1 | 1 | 1 | 7 1.1 |
| Inflammation, Chronic | | | 2 | | | | | | | | 1 2.0 |
| Mitosis | | | 2 | 1 | | | | | | | 2 1.5 |
| Mixed Cell Focus | | X | | | | | | | | | 1 |
| Pigmentation | | 2 | | 2 | | | | | | | 2 2.0 |
| Bile Duct, Hyperplasia | | 1 | 1 | 1 | | | | | | | 3 1.0 |
| Hepatocyte, Necrosis | | | 3 | | | | | | | | 1 3.0 |
| Oval Cell, Hyperplasia | | 1 | 2 | 2 | | | | | | | 3 1.7 |
| Periportal, Hypertrophy | | | 2 | 1 | | | | | | | 2 1.5 |

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

+ .. Tissue examined microscopically

x .. Lesion present

l .. 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

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
|--------------------------|--|---|---|---|---|---|---|---|---|---|-----------------|--|
| FISCHER 344-TACONIC RATS | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| FEMALE | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| 1000 mg/kg | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | |
| | | | | | | | | | | | * TOTALS | |

| | | | | | | | | | | | | |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|----|-------|
| Pancreas | + | + | + | + | + | + | + | + | + | + | 10 | |
| Atrophy | | | | | | | 1 | | | | | 1 1.0 |
| Inflammation, Chronic Active | | | | | | | 1 | | | | | 1 1.0 |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | 10 | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | 10 | |
| Stomach, Glandular Hyperplasia | + | + | + | + | + | + | + | + | + | + | 10 | 1 2.0 |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|----|-------|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | 10 | |
| Heart | + | + | + | + | + | + | + | + | + | + | 10 | |
| Cardiomyopathy | 1 | 1 | 1 | | 1 | 1 | | 1 | | | | 6 1.0 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|----|-------|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | 10 | |
| Vacuolization Cytoplasmic | | | | 1 | | | | | | | | 1 1.0 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | 10 | |

* .. 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

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
|--------------------------------|--|---|---|---|---|---|---|---|---|---|---|-------------|
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 1000 mg/kg | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS |
| Islets, Pancreatic | | + | + | + | + | + | + | + | + | + | + | 10 |
| Parathyroid Gland | | + | + | + | + | + | | | + | + | + | 9 |
| Pituitary Gland Cyst | | + | + | + | + | + | | + | + | + | + | 10 1 |
| Thyroid Gland | | + | + | + | + | + | + | + | + | + | + | 10 |
| GENERAL BODY SYSTEM | | | | | | | | | | | | |
| NONE | | | | | | | | | | | | |
| GENITAL SYSTEM | | | | | | | | | | | | |
| Clitoral Gland Inflammation | | + | + | + | + | + | + | + | + | + | + | 10 2 1.5 |
| Ovary | | + | + | + | + | + | + | + | + | + | + | 10 |
| Uterus | | + | + | + | + | + | + | + | + | + | + | 10 |
| HEMATOPOIETIC SYSTEM | | | | | | | | | | | | |
| Bone Marrow | | + | + | + | + | + | + | + | + | + | + | 10 |

* .. 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

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
|-----------------------------------|--|---|---|---|---|---|---|---|---|---|---|-----------------|
| ANIMAL ID | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| FISCHER 344-TACONIC RATS | | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | |
| FEMALE | | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| 1000 mg/kg | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS |
| Lymph Node, Mandibular | | + | + | + | + | + | + | + | + | + | + | 10 |
| Hyperplasia, Lymphoid | | | | 1 | 2 | | | | | | | 2 1.5 |
| Hyperplasia, Plasma Cell | | 3 | 2 | 2 | 2 | 2 | | 1 | 1 | 2 | | 8 1.9 |
| Lymph Node, Mesenteric | | + | + | + | + | + | + | + | + | + | + | 10 |
| Atrophy | | | | | | | | 2 | | | | 1 2.0 |
| Infiltration Cellular, Histiocyte | | 2 | 1 | 2 | | 2 | | 1 | 2 | | | 6 1.7 |
| Spleen | | + | + | + | + | + | + | + | + | + | + | 10 |
| Thymus | | + | + | + | + | + | + | + | + | + | + | 10 |
| Atrophy | | 1 | 1 | 1 | 1 | 1 | | 1 | | | | 6 1.0 |
| INTEGUMENTARY SYSTEM | | | | | | | | | | | | |
| Mammary Gland | | + | + | + | + | + | + | + | + | + | + | 10 |
| Skin | | + | + | + | + | + | + | + | + | + | + | 10 |
| MUSCULOSKELETAL SYSTEM | | | | | | | | | | | | |
| Bone | | + | + | + | + | + | + | + | + | + | + | 10 |
| NERVOUS 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

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---------------------------------|---|---|---|---|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| <hr/> | | | | | | | | | | |
| FISCHER 344-TACONIC RATS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1000 mg/kg | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| ANIMAL ID | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| | | | | | | | | | | * TOTALS |

| | | | | | | | | | | | |
|-------|---|---|---|---|---|---|---|---|---|---|-----------|
| Brain | + | + | + | + | + | + | + | + | + | + | 10 |
|-------|---|---|---|---|---|---|---|---|---|---|-----------|

RESPIRATORY SYSTEM

| | | | | | | | | | | | |
|---------------------|---|---|---|---|---|---|---|---|---|---|--------------|
| Lung | + | + | + | + | + | + | + | + | + | + | 10 |
| Hemorrhage | | 1 | | | 1 | | | | | | 2 1.0 |
| Inflammation | 1 | 2 | 1 | | 2 | 1 | 1 | 1 | 1 | 1 | 9 1.2 |
| Metaplasia, Osseous | | | | | | | | | 1 | | 1 1.0 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Nose | + | + | + | + | + | + | + | + | + | + | 10 |
| Infiltration Cellular, Mononuclear Cell | | | | | | | 2 | | | | 1 2.0 |
| Inflammation | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | | 8 1.0 |
| Glands, Olfactory Epithelium, Hyperplasia | | | | 1 | | | | 1 | 1 | 1 | 4 1.0 |
| Lamina Propria, Pigmentation, Histiocyte | | | | 1 | | | | | | | 1 1.0 |
| Nerve, Atrophy | | | 2 | 2 | | | | 1 | 2 | 2 | 5 1.8 |
| Olfactory Epithelium, Atrophy | | | 1 | 2 | 1 | | 1 | 1 | 1 | 1 | 7 1.1 |
| Olfactory Epithelium, Metaplasia | | | 1 | 1 | | | | | 1 | 1 | 4 1.0 |
| Olfactory Epithelium, Pigmentation | | | 1 | 1 | | | | 1 | 1 | 1 | 5 1.0 |

| | | | | | | | | | | | |
|---------|---|---|---|---|---|---|---|---|---|---|-----------|
| Trachea | + | + | + | + | + | + | + | + | + | + | 10 |
|---------|---|---|---|---|---|---|---|---|---|---|-----------|

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | |
|---------|---|---|---|---|---|---|---|---|---|---|--------------|
| Eye | + | + | + | + | + | + | + | + | + | + | 10 |
| Atrophy | | | | | | | 2 | | | | 1 2.0 |

| | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|-----------|
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | 10 |
|-----------------|---|---|---|---|---|---|---|---|---|---|-----------|

* .. 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. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

| | | | | | | | | | | | |
|---------------------------------|---|---|---|---|---|---|---|---|---|---|-----------------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | | | | | | | | | | | |
| FISCHER 344-TACONIC RATS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | |
| 1000 mg/kg | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS |
| Inflammation | 1 | | | | | | | | | | 1 1.0 |

URINARY SYSTEM

| | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|--------------|
| Kidney | + | + | + | + | + | + | + | + | + | + | 10 |
| Mineralization | 1 | | | 1 | 1 | | 1 | | 1 | | 5 1.0 |
| Nephropathy | | | 1 | | | | | | | | 1 1.0 |
| | | | | | | | | | | | |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | 10 |

*** END OF REPORT ***

* .. 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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1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked