Experiment Number: 91069 - 01
Test Type: 28-DAY
Route: GAVAGE
Species/Strain: RATS/HSD

NTP Study Number: C91069
Lock Date: 04/25/2016
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.2.3_002
PWG Approval Date: NONE

Wyeth 14,643 (WY)
CAS Number: 50892-23-4

Date Report Requested: 02/06/2018
Time Report Requested: 12:39:53
First Dose M/F: 01/26/12 / 01/27/12
Lab: BAT

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

Wyeth_Final 1
## Disposition Summary

<table>
<thead>
<tr>
<th></th>
<th>0mg/kg/d M</th>
<th>6.25mg/kg/d M</th>
<th>12.5mg/kg/d M</th>
<th>25mg/kg/d M</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Animals Initially In Study</strong></td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td><strong>Early Deaths</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Survivors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Terminal Sacrifice</strong></td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td><strong>Animals Examined Microscopically</strong></td>
<td>10</td>
<td>10</td>
<td>10</td>
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</tr>
</tbody>
</table>

### ALIMENTARY SYSTEM

- **Esophagus**: (10) 0 0 0 10
- **Intestine Large, Cecum**: (10) 0 0 0 10
- **Intestine Large, Colon**: (10) 0 0 0 10
- **Intestine Large, Rectum**: (10) 0 0 0 10
- **Intestine Small, Duodenum**: (10) 0 0 0 10
- **Intestine Small, Ileum**: (10) 0 0 0 10
- **Intestine Small, Jejunum**: (10) 0 0 0 10
- **Liver**: (10) (10) 10 10 (10)
- **Pancreas**: (10) (10) 10 10 (10)
- **Salivary Glands**: (10) 0 0 0 10
- **Stomach, Foreestomach**: (10) 0 0 0 10
- **Stomach, Glandular**: (10) 0 0 0 10

### CARDIOVASCULAR SYSTEM

- **Blood Vessel**: (10) 0 0 0 10
- **Heart**: (10) 0 0 0 10

### ENDOCRINE SYSTEM

- **Adrenal Cortex**: (10) 0 0 0 10
- **Adrenal Medulla**: (10) 0 0 0 10
- **Islets, Pancreatic**: (10) 0 0 0 10
- **Parathyroid Gland**: (7) 0 0 0 8
- **Pituitary Gland**: (10) 0 0 0 10

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*a - Number of animals examined microscopically at site and number of animals with lesion*
<table>
<thead>
<tr>
<th>System</th>
<th>0mg/kg/d M</th>
<th>6.25mg/kg/d M</th>
<th>12.5mg/kg/d M</th>
<th>25mg/kg/d M</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Thyroid Gland</strong></td>
<td>(10)</td>
<td>(10)</td>
<td>(10)</td>
<td>(10)</td>
</tr>
<tr>
<td><strong>GENITAL SYSTEM</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Epididymis</td>
<td>(10)</td>
<td>(0)</td>
<td>(10)</td>
<td>(10)</td>
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<tr>
<td>Preputial Gland</td>
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<td>(0)</td>
<td>(10)</td>
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<tr>
<td>Prostate</td>
<td>(10)</td>
<td>(0)</td>
<td>(0)</td>
<td>(10)</td>
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<tr>
<td>Seminal Vesicle</td>
<td>(10)</td>
<td>(0)</td>
<td>(0)</td>
<td>(10)</td>
</tr>
<tr>
<td>Testes</td>
<td>(10)</td>
<td>(10)</td>
<td>(10)</td>
<td>(10)</td>
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<tr>
<td><strong>HEMATOPOIETIC SYSTEM</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone Marrow</td>
<td>(10)</td>
<td>(10)</td>
<td>(10)</td>
<td>(10)</td>
</tr>
<tr>
<td>Lymph Node, Mandibular</td>
<td>(10)</td>
<td>(0)</td>
<td>(0)</td>
<td>(10)</td>
</tr>
<tr>
<td>Lymph Node, Mesenteric</td>
<td>(10)</td>
<td>(0)</td>
<td>(0)</td>
<td>(10)</td>
</tr>
<tr>
<td>Spleen</td>
<td>(10)</td>
<td>(10)</td>
<td>(10)</td>
<td>(10)</td>
</tr>
<tr>
<td>Thymus</td>
<td>(10)</td>
<td>(0)</td>
<td>(0)</td>
<td>(10)</td>
</tr>
<tr>
<td><strong>INTEGUMENTARY SYSTEM</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Mammary Gland</td>
<td>(10)</td>
<td>(0)</td>
<td>(0)</td>
<td>(10)</td>
</tr>
<tr>
<td>Skin</td>
<td>(10)</td>
<td>(0)</td>
<td>(0)</td>
<td>(10)</td>
</tr>
<tr>
<td><strong>MUSCULOSKELETAL SYSTEM</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone</td>
<td>(10)</td>
<td>(0)</td>
<td>(0)</td>
<td>(10)</td>
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</table>

a - Number of animals examined microscopically at site and number of animals with lesion
<table>
<thead>
<tr>
<th>Harlan Sprague Dawley RATS MALE</th>
<th>0mg/kg/d M</th>
<th>6.25mg/kg/d M</th>
<th>12.5mg/kg/d M</th>
<th>25mg/kg/d M</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NERVOUS SYSTEM</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brain</td>
<td>(10)</td>
<td>(0)</td>
<td>(0)</td>
<td>(10)</td>
</tr>
<tr>
<td><strong>RESPIRATORY SYSTEM</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td>(10)</td>
<td>(0)</td>
<td>(0)</td>
<td>(10)</td>
</tr>
<tr>
<td>Nose</td>
<td>(10)</td>
<td>(10)</td>
<td>(10)</td>
<td>(10)</td>
</tr>
<tr>
<td>Trachea</td>
<td>(10)</td>
<td>(0)</td>
<td>(0)</td>
<td>(10)</td>
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<tr>
<td><strong>SPECIAL SENSES SYSTEM</strong></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Eye</td>
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<td>(0)</td>
<td>(0)</td>
<td>(10)</td>
</tr>
<tr>
<td>Harderian Gland</td>
<td>(10)</td>
<td>(0)</td>
<td>(0)</td>
<td>(10)</td>
</tr>
<tr>
<td><strong>URINARY SYSTEM</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kidney</td>
<td>(10)</td>
<td>(10)</td>
<td>(10)</td>
<td>(10)</td>
</tr>
<tr>
<td>Urinary Bladder</td>
<td>(10)</td>
<td>(0)</td>
<td>(0)</td>
<td>(10)</td>
</tr>
</tbody>
</table>

a - Number of animals examined microscopically at site and number of animals with lesion
Tumor Summary for Males

<table>
<thead>
<tr>
<th>Total Animals with Primary Neoplasms (b)</th>
<th>Total Primary Neoplasms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Animals with Benign Neoplasms</td>
<td>Total Benign Neoplasms</td>
</tr>
<tr>
<td>Total Animals with Malignant Neoplasms</td>
<td>Total Malignant Neoplasms</td>
</tr>
<tr>
<td>Total Animals with Metastatic Neoplasms</td>
<td>Total Metastatic Neoplasms</td>
</tr>
<tr>
<td>Total Animals with Malignant Neoplasms Uncertain Primary Site</td>
<td></td>
</tr>
<tr>
<td>Total Animals with Neoplasms Uncertain-Benign or Malignant</td>
<td>Total Uncertain Neoplasms</td>
</tr>
</tbody>
</table>

*** END OF MALE ***

---

a - Number of animals examined microscopically at site and number of animals with lesion
b - Primary tumors: all tumors except metastatic tumors
Disposition Summary

Animals Initially In Study
Early Deaths
Survivors
Terminal Sacrifice
Animals Examined Microscopically

ALIMENTARY SYSTEM

Esophagus
Intestine Large, Cecum
Intestine Large, Colon
Intestine Large, Rectum
Intestine Small, Duodenum
Intestine Small, Ileum
Intestine Small, Jejunum
Liver
Pancreas
Salivary Glands
Stomach, Foreestomach
Stomach, Glandular

CARDIOVASCULAR SYSTEM

Blood Vessel
Heart

ENDOCRINE SYSTEM

Adrenal Cortex
Adrenal Medulla
Islets, Pancreatic
Parathyroid Gland
Pituitary Gland

---
a - Number of animals examined microscopically at site and number of animals with lesion
<table>
<thead>
<tr>
<th>Harlan Sprague Dawley RATS FEMALE</th>
<th>0mg/kg/d F</th>
<th>6.25mg/kg/d F</th>
<th>12.5mg/kg/d F</th>
<th>25mg/kg/d F</th>
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</thead>
<tbody>
<tr>
<td>Thyroid Gland</td>
<td>(10)</td>
<td>(10)</td>
<td>(10)</td>
<td>(10)</td>
</tr>
</tbody>
</table>

**GENERAL BODY SYSTEM**
None

**GENITAL SYSTEM**
- Clitoral Gland: (9) (0) (0) (10)
- Ovary: (10) (10) (10) (10)
- Uterus: (10) (0) (0) (10)

**HEMATOPOIETIC SYSTEM**
- Bone Marrow: (10) (10) (10) (10)
- Lymph Node, Mandibular: (10) (0) (0) (10)
- Lymph Node, Mesenteric: (10) (0) (0) (10)
- Spleen: (10) (10) (10) (10)
- Thymus: (10) (0) (0) (10)

**INTEGUMENTARY SYSTEM**
- Mammary Gland: (10) (0) (0) (10)
- Skin: (10) (0) (0) (10)

**MUSCULOSKELETAL SYSTEM**
- Bone: (10) (0) (0) (10)

**NERVOUS SYSTEM**
- Brain: (10) (0) (0) (10)

*a* - Number of animals examined microscopically at site and number of animals with lesion
Experiment Number: 91069 - 01  
Test Type: 28-DAY  
Route: GAVAGE  
Species/Strain: RATS/HSD

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</tr>
</thead>
</table>

### RESPIRATORY SYSTEM

- **Lung**: (10) (0) (0) (10)  
- **Nose**: (10) (10) (10) (10)  
- **Trachea**: (10) (0) (0) (10)

### SPECIAL SENSES SYSTEM

- **Eye**: (10) (0) (0) (10)  
- **Harderian Gland**: (10) (0) (0) (10)

### URINARY SYSTEM

- **Kidney**: (10) (10) (10) (10)  
- **Urinary Bladder**: (10) (0) (0) (10)

---

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

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Page 8
<table>
<thead>
<tr>
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</tr>
</thead>
</table>

**Tumor Summary for Females**

- Total Animals with Primary Neoplasms (b)
  - Total Primary Neoplasms

- Total Animals with Benign Neoplasms
  - Total Benign Neoplasms

- Total Animals with Malignant Neoplasms
  - Total Malignant Neoplasms

- Total Animals with Metastatic Neoplasms
  - Total Metastatic Neoplasms

- Total Animals with Malignant Neoplasms Uncertain Primary Site

- Total Animals with Neoplasms Uncertain-Benign or Malignant
  - Total Uncertain Neoplasms

*** END OF REPORT ***

---

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

b - Primary tumors: all tumors except metastatic tumors