

NTP Historical Controls Report

By Route and Vehicle

Wistar Han RATS

June 2013

REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

This report is broken up into sections based on the route and vehicle used to deliver the chemical. The Table of Contents on Page 3 shows the different Route/Vehicle combinations. To see the data from all routes and vehicles combined into one set, you must run the "All Routes" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male

M1

M2

M3

M4

M5

Female

F1

F2

F3

F4

F5

the data would be shown as:

| Male | | | Female | | |
|-------------|----|----|---------------|----|----|
| M1 | M2 | M3 | F1 | F2 | F3 |
| M4 | M5 | | F4 | F5 | |

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

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| GAVAGE | CORN OIL | 4 |
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| INHALATION | AIR | 52 |

Version: Jun2013
Contract/Lab: All Laboratories
Species: RATS
Strain: Wistar Han
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: CORN OIL

Page: 4
Report Date: 06/12/2013

Study Summary

| Laboratory Name | Study Number | Study Start Date | Length of Study in Days | Number of Animals Total and (#/Cage) | Number Surviving and (Mean Life Span) | Maximum Mean Weekly Body Weight | Chemical |
|------------------------------|---------------------|-------------------------|--------------------------------|---|--|--|-----------------------|
| Male | | | | | | | |
| Battelle Columbus Laboratory | 052032003 | 07/25/07 | 727 | 50(3) | 33(642) | 662.9 | Tetrabromobisphenol A |
| Female | | | | | | | |
| Battelle Columbus Laboratory | 052032003 | 07/26/07 | 728 | 50(5) | 34(678) | 375.2 | Tetrabromobisphenol A |

Version: Jun2013
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/12/2013

| | Male | | | | Female | | | |
|--------------------------------------|-------|-------------|----------|-------|-------------|-------------|----------|-------|
| #All Organs: | | | | | | | | |
| Benign Tumors | | | | | | | | |
| | | 30/50 (60%) | | | 38/50 (76%) | | | |
| Overall Incidence | Total | 30/50 (60%) | Mean 60% | SD 0% | Total | 38/50 (76%) | Mean 76% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Malignant Tumors | | | | | | | | |
| | | 8/50 (16%) | | | 10/50 (20%) | | | |
| Overall Incidence | Total | 8/50 (16%) | Mean 16% | SD 0% | Total | 10/50 (20%) | Mean 20% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Malignant and Benign Tumors | | | | | | | | |
| | | 34/50 (68%) | | | 40/50 (80%) | | | |
| Overall Incidence | Total | 34/50 (68%) | Mean 68% | SD 0% | Total | 40/50 (80%) | Mean 80% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 3/50 (6%) | | | 2/50 (4%) | | | |
| Overall Incidence | Total | 3/50 (6%) | Mean 6% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | | |
| | | 4/50 (8%) | | | 2/50 (4%) | | | |
| Overall Incidence | Total | 4/50 (8%) | Mean 8% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
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 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| | Male | | | | Female | | | |
|--|-------|------|------|---------|--------|-------|---------|-------|
| #All Organs: | | | | | | | | |
| Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Malignant | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Osteoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Osteosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 7
 Report Date: 06/12/2013

| | | Male | | | Female | | |
|--|-------|-----------|---------|-------|-----------|--------------|------------------|
| #All Organs: | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Adrenal Cortex: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| *Adrenal Cortex: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma Benign | | | | | | | |
| | | 0/49 (0%) | | | 2/49 (4%) | | |
| Overall Incidence | Total | 0/49 (0%) | Mean 0% | SD 0% | Total | 2/49 (4.08%) | Mean 4.08% SD 0% |
| | | | | | | | |
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma Malignant | | | | | | | |
| | | 0/49 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/49 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | |
| | | 0/49 (0%) | | | 2/49 (4%) | | |
| Overall Incidence | Total | 0/49 (0%) | Mean 0% | SD 0% | Total | 2/49 (4.08%) | Mean 4.08% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| | Male | | | | Female | | | |
|--------------------------------|-------|------|------|---------|--------|-------|---------|-------|
| #Blood Vessel: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Bone: | | | | | | | | |
| Osteoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Bone: | | | | | | | | |
| Osteosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Bone: | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Bone: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |

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 #: Denominator is number of animals necropsied

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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/12/2013

| | | Male | | | | Female | | | |
|--|-------|------|------|---------|-------|--------|------|------|---------------|
| *Brain: | | | | | | | | | |
| Glioma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Glioma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Oligodendroglioma, Glioma, or Astrocytoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | | Male | | | | Female | | | |
|---|-------|------|------|---------|-------|--------|------|------|---------------|
| *Clitoral/Preputial Gland: Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Heart: Schwannoma Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Duodenum: Leiomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Jejunum: Leiomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: Leiomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| | | Male | | | Female | | |
|---|-------|------|------|---------|--------|-------|-----------|
| *Islets, Pancreatic: | | | | | | | |
| Adenoma | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Islets, Pancreatic: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | |
| Papilloma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | |
| Lipoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| Male | | | | | Female | | | | |
|--|-------|------|------|---------|--------|-------|------|------|---------------|
| *Kidney: Renal Tubule: | | | | | | | | | |
| Liposarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | | Male | | | Female | | |
|---|-------|-----------|---------|-------|------------|------------|----------------|
| #Lymph Node, Mesenteric: Hemangioma | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Lymph Node, Mesenteric: Hemangiosarcoma | | | | | | | |
| | | 1/50 (2%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| #Mammary Gland: Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 4/50 (8%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 4/50 (8%) | Mean 8% SD 0% |
| | | | | | | | |
| #Mammary Gland: Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| #Mammary Gland: Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 4/50 (8%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 4/50 (8%) | Mean 8% SD 0% |
| | | | | | | | |
| #Mammary Gland: Fibroadenoma | | | | | | | |
| | | 1/50 (2%) | | | 8/50 (16%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 8/50 (16%) | Mean 16% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| | | Male | | | Female | | |
|---|-------|-----------|---------|-------|--------|-------------|----------------|
| #Mammary Gland: | | | | | | | |
| Fibroma, Fibroadenoma or Adenoma | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 12/50 (24%) | Mean 24% SD 0% |
| | | | | | | | |
| #Mammary Gland: | | | | | | | |
| Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 12/50 (24%) | Mean 24% SD 0% |
| | | | | | | | |
| #Mesentery: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Mesentery: | | | | | | | |
| Schwannoma Malignant | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Nose: | | | | | | | |
| Olfactory Neuroblastoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
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 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| | Male | | | | Female | | | |
|---|-------|------|------|---------|--------|-------|------|------|
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | |
| Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Oral Mucosa: | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor Benign | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor Malignant | | | | | | | | |
| | | | | | | 1/50 | (2%) | |
| Overall Incidence | | | | | | Total | 1/50 | (2%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | | | | | | | |
| | | | | | | 1/50 | (2%) | |
| Overall Incidence | | | | | | Total | 1/50 | (2%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Sex Cord Stromal Tumor, Benign | | | | | | | | |
| | | | | | | 2/50 | (4%) | |
| Overall Incidence | | | | | | Total | 2/50 | (4%) |
| | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| | Male | | | | Female | | | |
|---|-------|-------------|----------|-------|--------|-------------|----------|-------|
| *Pancreas: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 1/50 (2%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Pancreas: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 1/50 (2%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 21/50 (42%) | | | | 21/50 (42%) | | |
| Overall Incidence | Total | 21/50 (42%) | Mean 42% | SD 0% | Total | 21/50 (42%) | Mean 42% | SD 0% |
| | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 21/50 (42%) | | | | 21/50 (42%) | | |
| Overall Incidence | Total | 21/50 (42%) | Mean 42% | SD 0% | Total | 21/50 (42%) | Mean 42% | SD 0% |
| | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 2/50 (4%) | | | | 4/50 (8%) | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 4/50 (8%) | Mean 8% | SD 0% |
| | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 2/50 (4%) | | | | 4/50 (8%) | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 4/50 (8%) | Mean 8% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | | Male | | | | Female | | | |
|---|-------|------|------|---------|-------|--------|------|------|---------------|
| *Prostate: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | | | | |
| | | | | | | | | | |
| *Prostate: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | | | | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Myoepithelioma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Seminal Vesicle: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | | | | |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *: Denominator is number of animals with tissues examined microscopically | | | | | | | | | |
| #: Denominator is number of animals necropsied | | | | | | | | | |

Version: Jun2013
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 Length of Study: CHRONIC

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 Route: GAVAGE
 Vehicle: CORN OIL

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| | Male | | | | Female | | | |
|--|-------|------|------|---------|--------|-------|-----------|---------------|
| #Skin: | | | | | | | | |
| Basal Cell Adenoma | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Adenoma or Basosquamous Tumor Benign | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Carcinoma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | Male | | | | Female | | | |
|--|-------|------------|----------|-------|-----------|-----------|---------|-------|
| #Skin: | | | | | | | | |
| Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma | | | | | | | | |
| | | 7/50 (14%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 7/50 (14%) | Mean 14% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| #Skin: | | | | | | | | |
| Fibroma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| #Skin: | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| #Skin: | | | | | | | | |
| Fibrosarcoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| #Skin: | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| #Skin: | | | | | | | | |
| Hamartoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | | Male | | | | Female | | | |
|--|-------|------|------|---------|-------|--------|------|------|---------------|
| #Skin: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Keratoacanthoma | | | | | | | | | |
| | | 4/50 | (8%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 4/50 | (8%) | Mean 8% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Liposarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibrosarcoma or Schwannoma (malignant or NOS) | | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
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 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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| | Male | | | | Female | | | |
|---|-------|------|-------|----------|--------|-------|---------|-------|
| #Skin: | | | | | | | | |
| Schwannoma Malignant | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | | |
| | | 5/50 | (10%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 5/50 | (10%) | Mean 10% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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| | Male | | | | Female | | | |
|---|-------|------------|----------|-------|--------|-----------|---------|-------|
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | | |
| | | 5/50 (10%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Spleen: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 1/50 (2%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | |
| Leiomyoma | | | | | | | | |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | |
| Leiomyosarcoma | | | | | | | | |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
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 Strain: Wistar Han
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| Male | | | | | Female | | | | |
|--|-------|------|------|---------|--------|-------|------|------|---------------|
| #Stomach, Forestomach: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/12/2013

| | | Male | | | Female | | |
|--|-------|--------------|------------|-------|------------|------------|----------------|
| *Thymus: | | | | | | | |
| Sarcoma | | | | | | | |
| | | 0/49 (0%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 0/49 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma Benign | | | | | | | |
| | | 1/49 (2%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 1/49 (2.04%) | Mean 2.04% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | |
| | | 1/49 (2%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 1/49 (2.04%) | Mean 2.04% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Adenoma | | | | | | | |
| | | 5/50 (10%) | | | 7/50 (14%) | | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total | 7/50 (14%) | Mean 14% SD 0% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 5/50 (10%) | | | 7/50 (14%) | | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total | 7/50 (14%) | Mean 14% SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| | | Male | | | | Female | | | |
|--|-------|-----------|---------|-------|-------|-----------|---------|-------|--|
| *Thyroid Gland: Follicular Cell: Adenoma | | | | | | | | | |
| Overall Incidence | Total | 3/50 (6%) | Mean 6% | SD 0% | Total | 3/50 (6%) | Mean 6% | SD 0% | |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | | | |
| Overall Incidence | Total | 3/50 (6%) | Mean 6% | SD 0% | Total | 3/50 (6%) | Mean 6% | SD 0% | |
| | | | | | | | | | |
| *Urinary Bladder: Carcinoma or Papilloma | | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% | |
| | | | | | | | | | |
| *Urinary Bladder: Papilloma | | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% | |
| | | | | | | | | | |
| #Uterus: Carcinoma | | | | | | | | | |
| Overall Incidence | | | | | Total | 3/50 (6%) | Mean 6% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| | Male | | Female | |
|--|------|-------|-----------|---------------|
| #Uterus: Polyp Stromal | | | | |
| Overall Incidence | | Total | 2/50 (4%) | Mean 4% SD 0% |
| #Uterus: Sarcoma Stromal | | | | |
| Overall Incidence | | Total | 0/50 (0%) | Mean 0% SD 0% |
| #Uterus: Sarcoma Stromal or Polyp Stromal | | | | |
| Overall Incidence | | Total | 2/50 (4%) | Mean 4% SD 0% |
| #Uterus: Schwannoma Malignant | | | | |
| Overall Incidence | | Total | 0/50 (0%) | Mean 0% SD 0% |
| #Uterus: Squamous Cell Papilloma | | | | |
| Overall Incidence | | Total | 0/50 (0%) | Mean 0% SD 0% |
| #Vagina: Leiomyoma | | | | |
| Overall Incidence | | Total | 1/50 (2%) | Mean 2% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| Male | | | | | Female | | | | | |
|-----------------------------|-------|------|------|---------|--------|-------|------|---------|---------|-------|
| #Vagina: | | | | | | | | | | |
| Polyp | | | | | | | | | | |
| | | | | | 0/50 | (0%) | | | | |
| Overall Incidence | | | | | Total | 0/50 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | | | |
| Carcinoma | | | | | | | | | | |
| | | | | | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | |
| | | | | | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
Contract/Lab: All Laboratories
Species: RATS
Strain: Wistar Han
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: WATER

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Study Summary

| Laboratory Name | Study Number | Study Start Date | Length of Study in Days | Number of Animals Total and (#/Cage) | Number Surviving and (Mean Life Span) | Maximum Mean Weekly Body Weight | Chemical |
|------------------------------|--------------|------------------|-------------------------|--------------------------------------|---------------------------------------|---------------------------------|-------------------|
| Male | | | | | | | |
| Battelle Columbus Laboratory | 052020303 | 07/18/07 | 727 | 50(3) | 35(687) | 632.7 | Green tea extract |
| Female | | | | | | | |
| Battelle Columbus Laboratory | 052020303 | 07/19/07 | 729 | 50(5) | 26(671) | 369.7 | Green tea extract |

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/12/2013

| | Male | | | | Female | | | |
|--------------------------------------|-------|-------------|----------|-------|-------------|-------------|----------|-------|
| #All Organs: | | | | | | | | |
| Benign Tumors | | | | | | | | |
| | | 26/50 (52%) | | | 38/50 (76%) | | | |
| Overall Incidence | Total | 26/50 (52%) | Mean 52% | SD 0% | Total | 38/50 (76%) | Mean 76% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Malignant Tumors | | | | | | | | |
| | | 12/50 (24%) | | | 16/50 (32%) | | | |
| Overall Incidence | Total | 12/50 (24%) | Mean 24% | SD 0% | Total | 16/50 (32%) | Mean 32% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Malignant and Benign Tumors | | | | | | | | |
| | | 36/50 (72%) | | | 43/50 (86%) | | | |
| Overall Incidence | Total | 36/50 (72%) | Mean 72% | SD 0% | Total | 43/50 (86%) | Mean 86% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | | | 2/50 (4%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | | |
| | | 0/50 (0%) | | | 2/50 (4%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/12/2013

| | Male | | | | Female | | | |
|--|-------|------|------|---------|--------|-------|------|------|
| #All Organs: | | | | | | | | |
| Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Malignant | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Osteoma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Osteosarcoma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/12/2013

| | Male | | | | Female | | | |
|--|-------|-----------|---------|-------|-----------|-----------|---------|-------|
| #All Organs: | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | |
| | | 2/50 (4%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | |
| Pheochromocytoma Benign | | | | | | | | |
| | | 1/50 (2%) | | | 1/50 (2%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | |
| Pheochromocytoma Malignant | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | | |
| | | 1/50 (2%) | | | 1/50 (2%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/12/2013

| | | Male | | | Female | | |
|--------------------------------|-------|------|------|---------|--------|-------|-----------|
| #Blood Vessel: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Bone Marrow: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Bone: | | | | | | | |
| Osteoma | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Bone: | | | | | | | |
| Osteosarcoma | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Bone: | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | |
| | | 2/50 | (4%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Bone: | | | | | | | |
| Sarcoma | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/12/2013

| | | Male | | | | Female | | | |
|--|-------|------|------|---------|-------|--------|------|------|---------------|
| *Brain: | | | | | | | | | |
| Glioma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Glioma Malignant | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Oligodendroglioma, Glioma, or Astrocytoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/12/2013

| | | Male | | | Female | | |
|---|-------|-----------|---------|-------|--------|-----------|---------------|
| *Clitoral/Preputial Gland: Carcinoma | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Clitoral/Preputial Gland: Carcinoma or Adenoma | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Heart: Schwannoma Benign | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Duodenum: Leiomyosarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Jejunum: Leiomyosarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Leiomyosarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/12/2013

| | | Male | | | | Female | | | |
|---|-------|------|------|---------|-------|--------|------|------|---------------|
| *Islets, Pancreatic: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Papilloma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | | Female | | | |
|--|-------|------|------|---------|-------|--------|------|------|---------------|
| *Kidney: Renal Tubule: | | | | | | | | | |
| Liposarcoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | Male | | | | Female | | | |
|---|-------|-----------|---------|-------|--------|-------------|----------|-------|
| #Lymph Node, Mesenteric: Hemangioma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Lymph Node, Mesenteric: Hemangiosarcoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| #Mammary Gland: Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | |
| #Mammary Gland: Carcinoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 6/50 (12%) | Mean 12% | SD 0% |
| | | | | | | | | |
| #Mammary Gland: Carcinoma or Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 8/50 (16%) | Mean 16% | SD 0% |
| | | | | | | | | |
| #Mammary Gland: Fibroadenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 11/50 (22%) | Mean 22% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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| | Male | | | | Female | | | |
|---|-------|------|------|---------|--------|-------|-------------|----------|
| #Mammary Gland: | | | | | | | | |
| Fibroma, Fibroadenoma or Adenoma | | | | | | | | |
| | | 0/50 | (0%) | | | 11/50 | (22%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 11/50 (22%) | Mean 22% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Mammary Gland: | | | | | | | | |
| Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | | |
| | | 0/50 | (0%) | | | 15/50 | (30%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 15/50 (30%) | Mean 30% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Mesentery: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Mesentery: | | | | | | | | |
| Schwannoma Malignant | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| *Nose: | | | | | | | | |
| Olfactory Neuroblastoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/49 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | |
| | | 1/50 | (2%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 1/50 (2%) | Mean 2% |
| | | | | | | | | SD 0% |
| | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | Male | | | | Female | | | |
|---|-------|------|------|---------|--------|-------|---------|---------|
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | |
| Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma | | | | | | | | |
| | | 1/50 | (2%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 1/50 | (2%) |
| | | | | | | | Mean 2% | SD 0% |
| #Oral Mucosa: | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | |
| | | 1/50 | (2%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 1/50 | (2%) |
| | | | | | | | Mean 2% | SD 0% |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor Benign | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | Total | | | | | 0/50 | (0%) | Mean 0% |
| | | | | | | | | SD 0% |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor Malignant | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | Total | | | | | 0/50 | (0%) | Mean 0% |
| | | | | | | | | SD 0% |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | Total | | | | | 0/50 | (0%) | Mean 0% |
| | | | | | | | | SD 0% |
| *Ovary: | | | | | | | | |
| Sex Cord Stromal Tumor, Benign | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | Total | | | | | 0/50 | (0%) | Mean 0% |
| | | | | | | | | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
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 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | | Male | | | Female | | |
|---|-------|-------------|----------|-------|-------------|-------------|----------------|
| *Pancreas: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Pancreas: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Adenoma | | | | | | | |
| | | 17/50 (34%) | | | 32/50 (64%) | | |
| Overall Incidence | Total | 17/50 (34%) | Mean 34% | SD 0% | Total | 32/50 (64%) | Mean 64% SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 17/50 (34%) | | | 32/50 (64%) | | |
| Overall Incidence | Total | 17/50 (34%) | Mean 34% | SD 0% | Total | 32/50 (64%) | Mean 64% SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | |
| Adenoma | | | | | | | |
| | | 1/50 (2%) | | | 2/50 (4%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 2/50 (4%) | Mean 4% SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 1/50 (2%) | | | 2/50 (4%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 2/50 (4%) | Mean 4% SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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| Male | | | | | Female | | | |
|-----------------------------|-------|------|------|---------|--------|-------|---------|-------|
| *Prostate: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 0/50 | (0%) | | | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | | | |
| | | | | | | | | |
| *Prostate: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 | (0%) | | | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | | | |
| | | | | | | | | |
| *Salivary Glands: | | | | | | | | |
| Myoepithelioma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/49 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/49 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| *Salivary Glands: | | | | | | | | |
| Schwannoma Malignant | | | | | | | | |
| | | 0/50 | (0%) | | | 0/49 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/49 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Seminal Vesicle: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 0/50 | (0%) | | | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | | | |
| | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
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 Species: RATS
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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| | Male | | | | Female | | | |
|--|-------|------|------|---------|--------|-------|---------|-------|
| #Skin: | | | | | | | | |
| Basal Cell Adenoma | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Adenoma or Basosquamous Tumor Benign | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Carcinoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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| Male | | | | | Female | | | |
|--|-------|------------|----------|-------|-----------|-----------|---------|-------|
| #Skin: | | | | | | | | |
| Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma | | | | | | | | |
| | | 6/50 (12%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 6/50 (12%) | Mean 12% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibroma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrosarcoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Hamartoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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| | Male | | | | Female | | | |
|--|-------|------|------|---------|--------|-------|------|------|
| #Skin: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Keratoacanthoma | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Lipoma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Liposarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neurofibrosarcoma or Schwannoma (malignant or NOS) | | | | | | | | |
| | | 2/50 | (4%) | | | 2/50 | (4%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 2/50 | (4%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | | |
| | | 2/50 | (4%) | | | 2/50 | (4%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 2/50 | (4%) |
| | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
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 Route: GAVAGE
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| | Male | | | | Female | | | |
|---|-------|------|------|---------|--------|-------|------|---------|
| #Skin: | | | | | | | | |
| Schwannoma Malignant | | | | | | | | |
| | | 2/50 | (4%) | | | 2/50 | (4%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 2/50 | (4%) |
| | | | | | | | | Mean 4% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | | |
| | | 4/50 | (8%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 4/50 | (8%) | Mean 8% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

Page: 46
 Report Date: 06/12/2013

| | Male | | | | Female | | | |
|---|-------|-----------|---------|-------|-----------|-----------|---------|-------|
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | | |
| | | 3/50 (6%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 3/50 (6%) | Mean 6% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Spleen: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | |
| Leiomyoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | |
| Leiomyosarcoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

Page: 47
 Report Date: 06/12/2013

| | | Male | | | | Female | | | |
|--|-------|------|------|---------|-------|--------|------|------|---------------|
| #Stomach, Forestomach: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 2/50 | (4%) | | | | | | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/12/2013

| | | Male | | | Female | | |
|--|-------|------|---------|------------|--------|-------|--------------|
| *Thymus: | | | | | | | |
| Sarcoma | | | | | | | |
| | | 0/49 | (0%) | | 0/49 | (0%) | |
| Overall Incidence | Total | 0/49 | (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma Benign | | | | | | | |
| | | 2/49 | (4%) | | 3/49 | (6%) | |
| Overall Incidence | Total | 2/49 | (4.08%) | Mean 4.08% | SD 0% | Total | 3/49 (6.12%) |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | |
| | | 2/49 | (4%) | | 3/49 | (6%) | |
| Overall Incidence | Total | 2/49 | (4.08%) | Mean 4.08% | SD 0% | Total | 3/49 (6.12%) |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Adenoma | | | | | | | |
| | | 4/50 | (8%) | | 3/50 | (6%) | |
| Overall Incidence | Total | 4/50 | (8%) | Mean 8% | SD 0% | Total | 3/50 (6%) |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 1/50 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 4/50 | (8%) | | 4/50 | (8%) | |
| Overall Incidence | Total | 4/50 | (8%) | Mean 8% | SD 0% | Total | 4/50 (8%) |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

Page: 49
 Report Date: 06/12/2013

| | | Male | | | | Female | | | |
|--|-------|-----------|---------|-------|-------|-----------|---------|-------|--|
| *Thyroid Gland: Follicular Cell: Adenoma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% | |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% | |
| | | | | | | | | | |
| *Urinary Bladder: Carcinoma or Papilloma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Urinary Bladder: Papilloma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Uterus: Carcinoma | | | | | | | | | |
| Overall Incidence | | | | | Total | 3/50 (6%) | Mean 6% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/12/2013

| | Male | | Female | |
|---|-------|-----------|---------|-------|
| #Uterus: Polyp Stromal | | | | |
| Overall Incidence | Total | 3/50 (6%) | Mean 6% | SD 0% |
| #Uterus: Sarcoma Stromal | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% |
| #Uterus: Sarcoma Stromal or Polyp Stromal | | | | |
| Overall Incidence | Total | 4/50 (8%) | Mean 8% | SD 0% |
| #Uterus: Schwannoma Malignant | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% |
| #Uterus: Squamous Cell Papilloma | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% |
| #Vagina: Leiomyoma | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/12/2013

| Male | | | | | Female | | | |
|-----------------------------|-------|-----------|---------|-------|--------|-----------|---------|-------|
| #Vagina: | | | | | | | | |
| Polyp | | | | | | | | |
| | | | | | 1/50 | (2%) | | |
| Overall Incidence | | | | | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
Contract/Lab: All Laboratories
Species: RATS
Strain: Wistar Han
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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Report Date: 06/12/2013

Study Summary

| Laboratory Name | Study Number | Study Start Date | Length of Study in Days | Number of Animals Total and (#/Cage) | Number Surviving and (Mean Life Span) | Maximum Mean Weekly Body Weight | Chemical |
|--------------------|--------------|------------------|-------------------------|--------------------------------------|---------------------------------------|---------------------------------|-------------------------------------|
| Male | | | | | | | |
| Battelle Northwest | 052051503 | 04/14/08 | 729 | 50(5) | 33(688) | 602.8 | Metal working fluids (CIMSTAR 3800) |
| Female | | | | | | | |
| Battelle Northwest | 052051503 | 04/14/08 | 731 | 50(5) | 35(700) | 384.9 | Metal working fluids (CIMSTAR 3800) |

NOTE: The text on page 2 ("Report Description") describes how the studies listed here are displayed on the data pages that follow.

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

Page: 53
 Report Date: 06/12/2013

| | | Male | | | Female | | |
|--------------------------------------|-------|-------------|----------|-------|-------------|-------------|----------------|
| #All Organs: | | | | | | | |
| Benign Tumors | | | | | | | |
| | | 32/50 (64%) | | | 42/50 (84%) | | |
| Overall Incidence | Total | 32/50 (64%) | Mean 64% | SD 0% | Total | 42/50 (84%) | Mean 84% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant Tumors | | | | | | | |
| | | 13/50 (26%) | | | 11/50 (22%) | | |
| Overall Incidence | Total | 13/50 (26%) | Mean 26% | SD 0% | Total | 11/50 (22%) | Mean 22% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant and Benign Tumors | | | | | | | |
| | | 37/50 (74%) | | | 43/50 (86%) | | |
| Overall Incidence | Total | 37/50 (74%) | Mean 74% | SD 0% | Total | 43/50 (86%) | Mean 86% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangioma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 3/50 (6%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 3/50 (6%) | Mean 6% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | |
| | | 3/50 (6%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 3/50 (6%) | Mean 6% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

Page: 54
 Report Date: 06/12/2013

| | Male | | | | Female | | | |
|--|-------|------|------|---------|--------|-------|------|------|
| #All Organs: | | | | | | | | |
| Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | | |
| | | 0/50 | (0%) | | | 2/50 | (4%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 2/50 | (4%) |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Malignant | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Osteoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Osteosarcoma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

Page: 55
 Report Date: 06/12/2013

| | Male | | | | Female | | | |
|--|-------|-----------|---------|-------|--------|--------------|------------|-------|
| #All Organs: | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | |
| | | 1/50 (2%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 2/50 (4%) | | | | 2/50 (4%) | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 1/50 (2%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | |
| Pheochromocytoma Benign | | | | | | | | |
| | | 4/50 (8%) | | | | 1/49 (2%) | | |
| Overall Incidence | Total | 4/50 (8%) | Mean 8% | SD 0% | Total | 1/49 (2.04%) | Mean 2.04% | SD 0% |
| | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | |
| Pheochromocytoma Malignant | | | | | | | | |
| | | 0/50 (0%) | | | | 1/49 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/49 (2.04%) | Mean 2.04% | SD 0% |
| | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | | |
| | | 4/50 (8%) | | | | 2/49 (4%) | | |
| Overall Incidence | Total | 4/50 (8%) | Mean 8% | SD 0% | Total | 2/49 (4.08%) | Mean 4.08% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

Page: 56
 Report Date: 06/12/2013

| | | Male | | | | Female | | | |
|--------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Blood Vessel: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

Page: 57
 Report Date: 06/12/2013

| | | Male | | | | Female | | | |
|--|-------|------|------|---------|-------|--------|------|------|---------|
| *Brain: | | | | | | | | | |
| Glioma | | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Glioma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 2/50 | (4%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 2/50 | (4%) | Mean 4% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Malignant | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Oligodendroglioma, Glioma, or Astrocytoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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 Report Date: 06/12/2013

| | | Male | | | | Female | | | |
|---|-------|-----------|---------|-------|-------|-----------|---------|-------|--|
| *Clitoral/Preputial Gland: Carcinoma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: Carcinoma or Adenoma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Heart: Schwannoma Benign | | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Duodenum: Leiomyosarcoma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Jejunum: Leiomyosarcoma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: Leiomyosarcoma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

Page: 59
 Report Date: 06/12/2013

| | | Male | | | | Female | | | |
|---|-------|------|------|---------|-------|--------|--------------|------------|-------|
| *Islets, Pancreatic: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/49 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/49 (2.04%) | Mean 2.04% | SD 0% |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/49 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/49 (2.04%) | Mean 2.04% | SD 0% |
| | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Papilloma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

Page: 60
 Report Date: 06/12/2013

| Male | | | | | Female | | | | | |
|--|-------|------|------|---------|--------|-------|------|------|---------|-------|
| *Kidney: Renal Tubule: | | | | | | | | | | |
| Liposarcoma | | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |
| *Liver: | | | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |
| *Liver: | | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |
| *Liver: | | | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |
| *Lung: | | | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |
| *Lung: | | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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 Report Date: 06/12/2013

| | | Male | | | Female | | |
|---|-------|------|------|---------|--------|-------|------------|
| #Lymph Node, Mesenteric: Hemangioma | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Lymph Node, Mesenteric: Hemangiosarcoma | | | | | | | |
| | | 3/50 | (6%) | | | 1/50 | (2%) |
| Overall Incidence | Total | 3/50 | (6%) | Mean 6% | SD 0% | Total | 1/50 (2%) |
| | | | | | | | |
| #Mammary Gland: Adenoma | | | | | | | |
| | | 0/50 | (0%) | | | 2/50 | (4%) |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 2/50 (4%) |
| | | | | | | | |
| #Mammary Gland: Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | | 4/50 | (8%) |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 4/50 (8%) |
| | | | | | | | |
| #Mammary Gland: Carcinoma or Adenoma | | | | | | | |
| | | 0/50 | (0%) | | | 6/50 | (12%) |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 6/50 (12%) |
| | | | | | | | |
| #Mammary Gland: Fibroadenoma | | | | | | | |
| | | 0/50 | (0%) | | | 9/50 | (18%) |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 9/50 (18%) |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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 Report Date: 06/12/2013

| | | Male | | | Female | | |
|---|-------|------|------|---------|--------|-------------|----------|
| #Mammary Gland: | | | | | | | |
| Fibroma, Fibroadenoma or Adenoma | | | | | | | |
| | | 0/50 | (0%) | | 11/50 | (22%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | Total | 11/50 (22%) | Mean 22% |
| | | | | SD 0% | | | SD 0% |
| | | | | | | | |
| #Mammary Gland: | | | | | | | |
| Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | |
| | | 0/50 | (0%) | | 13/50 | (26%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | Total | 13/50 (26%) | Mean 26% |
| | | | | SD 0% | | | SD 0% |
| | | | | | | | |
| #Mesentery: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | Total | 0/50 (0%) | Mean 0% |
| | | | | SD 0% | | | SD 0% |
| | | | | | | | |
| #Mesentery: | | | | | | | |
| Schwannoma Malignant | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | Total | 0/50 (0%) | Mean 0% |
| | | | | SD 0% | | | SD 0% |
| | | | | | | | |
| *Nose: | | | | | | | |
| Olfactory Neuroblastoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | Total | 0/50 (0%) | Mean 0% |
| | | | | SD 0% | | | SD 0% |
| | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | Total | 0/50 (0%) | Mean 0% |
| | | | | SD 0% | | | SD 0% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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 Report Date: 06/12/2013

| | Male | | | | Female | | | |
|---|-------|------|------|---------|--------|-------|------|------|
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | |
| Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Oral Mucosa: | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor Benign | | | | | | | | |
| | | | | | | 1/50 | (2%) | |
| Overall Incidence | | | | | | Total | 1/50 | (2%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor Malignant | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | | | | | | | |
| | | | | | | 1/50 | (2%) | |
| Overall Incidence | | | | | | Total | 1/50 | (2%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Sex Cord Stromal Tumor, Benign | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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 Report Date: 06/12/2013

| | Male | | | | Female | | | |
|---|-------|----------------|-------------|-------|-------------|-------------|----------|-------|
| *Pancreas: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/49 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/49 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Pancreas: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/49 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/49 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 16/49 (33%) | | | 35/50 (70%) | | | |
| Overall Incidence | Total | 16/49 (32.65%) | Mean 32.65% | SD 0% | Total | 35/50 (70%) | Mean 70% | SD 0% |
| | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 16/49 (33%) | | | 35/50 (70%) | | | |
| Overall Incidence | Total | 16/49 (32.65%) | Mean 32.65% | SD 0% | Total | 35/50 (70%) | Mean 70% | SD 0% |
| | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 2/49 (4%) | | | 1/50 (2%) | | | |
| Overall Incidence | Total | 2/49 (4.08%) | Mean 4.08% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 2/49 (4%) | | | 1/50 (2%) | | | |
| Overall Incidence | Total | 2/49 (4.08%) | Mean 4.08% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

Page: 65
 Report Date: 06/12/2013

| | Male | | | | Female | | | |
|-----------------------------|-------|------|------|---------|--------|-------|---------|-------|
| *Prostate: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 1/50 | (2%) | | | | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | | | |
| | | | | | | | | |
| *Prostate: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 1/50 | (2%) | | | | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | | | |
| | | | | | | | | |
| *Salivary Glands: | | | | | | | | |
| Myoepithelioma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| *Salivary Glands: | | | | | | | | |
| Schwannoma Malignant | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Seminal Vesicle: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 1/50 | (2%) | | | | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | | | |
| | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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 Report Date: 06/12/2013

| | | Male | | | | Female | | | |
|--|-------|------|------|---------|-------|--------|------|------|---------------|
| #Skin: | | | | | | | | | |
| Basal Cell Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Adenoma or Basosquamous Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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 Report Date: 06/12/2013

| | | Male | | | Female | | |
|---|-------|-----------|---------|-------|-----------|-----------|---------------|
| #Skin: | | | | | | | |
| Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma | | | | | | | |
| | | 2/50 (4%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Fibroma | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | |
| | | 2/50 (4%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Fibrosarcoma | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Hamartoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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| | Male | | | | Female | | | |
|--|-------|------|------|---------|--------|-------|------|------|
| #Skin: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Keratoacanthoma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Lipoma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Liposarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neurofibrosarcoma or Schwannoma (malignant or NOS) | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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| | Male | | | | Female | | | |
|---|-------|------|------|---------|--------|-------|------|------|
| #Skin: | | | | | | | | |
| Schwannoma Malignant | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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 Report Date: 06/12/2013

| | Male | | | | Female | | | |
|---|-------|-----------|---------|-------|-----------|-----------|---------|-------|
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Spleen: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | |
| Leiomyoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | |
| Leiomyosarcoma | | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | | Male | | | Female | | |
|--|-------|------|------|---------|--------|-------|-----------|
| #Stomach, Forestomach: | | | | | | | |
| Sarcoma | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Stomach, Forestomach: | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Stomach, Forestomach: | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Stomach, Glandular: | | | | | | | |
| Leiomyosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 1/50 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) |
| | | | | | | | Mean 2% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Stomach, Glandular: | | | | | | | |
| Sarcoma | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Testes: | | | | | | | |
| Adenoma | | | | | | | |
| | | 2/50 | (4%) | | | | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | | |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | | Male | | | Female | | |
|--|-------|-------------|-----------|-------|------------|---------------|-------------------|
| *Thymus: | | | | | | | |
| Sarcoma | | | | | | | |
| | | 0/40 (0%) | | | 0/48 (0%) | | |
| Overall Incidence | Total | 0/40 (0%) | Mean 0% | SD 0% | Total | 0/48 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma Benign | | | | | | | |
| | | 1/40 (3%) | | | 5/48 (10%) | | |
| Overall Incidence | Total | 1/40 (2.5%) | Mean 2.5% | SD 0% | Total | 5/48 (10.42%) | Mean 10.42% SD 0% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | |
| | | 1/40 (3%) | | | 5/48 (10%) | | |
| Overall Incidence | Total | 1/40 (2.5%) | Mean 2.5% | SD 0% | Total | 5/48 (10.42%) | Mean 10.42% SD 0% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Adenoma | | | | | | | |
| | | 7/50 (14%) | | | 3/50 (6%) | | |
| Overall Incidence | Total | 7/50 (14%) | Mean 14% | SD 0% | Total | 3/50 (6%) | Mean 6% SD 0% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 7/50 (14%) | | | 3/50 (6%) | | |
| Overall Incidence | Total | 7/50 (14%) | Mean 14% | SD 0% | Total | 3/50 (6%) | Mean 6% SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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 Report Date: 06/12/2013

| | Male | | | | Female | | | |
|--|-------|-----------|---------|-------|--------|-----------|---------|-------|
| *Thyroid Gland: Follicular Cell: Adenoma | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | |
| *Urinary Bladder: Carcinoma or Papilloma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Urinary Bladder: Papilloma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Uterus: Carcinoma | | | | | | | | |
| Overall Incidence | | | | | Total | 1/50 (2%) | Mean 2% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | Male | Female |
|---|------------------|----------------|
| #Uterus: | | |
| Polyp Stromal | | |
| Overall Incidence | Total 5/50 (10%) | Mean 10% SD 0% |
| | | |
| #Uterus: | | |
| Sarcoma Stromal | | |
| Overall Incidence | Total 2/50 (4%) | Mean 4% SD 0% |
| | | |
| #Uterus: | | |
| Sarcoma Stromal or Polyp Stromal | | |
| Overall Incidence | Total 6/50 (12%) | Mean 12% SD 0% |
| | | |
| #Uterus: | | |
| Schwannoma Malignant | | |
| Overall Incidence | Total 0/50 (0%) | Mean 0% SD 0% |
| | | |
| #Uterus: | | |
| Squamous Cell Papilloma | | |
| Overall Incidence | Total 1/50 (2%) | Mean 2% SD 0% |
| | | |
| #Vagina: | | |
| Leiomyoma | | |
| Overall Incidence | Total 0/50 (0%) | Mean 0% SD 0% |
| | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar Han
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| Male | | | | | Female | | | | | |
|-----------------------------|-------|------|------|---------|--------|-------|------|---------|---------|-------|
| #Vagina: | | | | | | | | | | |
| Polyp | | | | | | | | | | |
| | | | | | 0/50 | (0%) | | | | |
| Overall Incidence | | | | | Total | 0/50 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | | | |
| Carcinoma | | | | | | | | | | |
| | | | | | 2/50 | (4%) | | | | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | |
| | | | | | 2/50 | (4%) | | | | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied