

# NTP Historical Controls Report

All Routes and Vehicles

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.

The report combines all the data from all of the historical control studies into one section. To see this data broken up by route and vehicle you must run the "By Route And Vehicle" 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:

<b>Male</b>			<b>Female</b>		
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.

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: ALL ROUTES  
Vehicle: ALL VEHICLES

Page: 3  
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
<b>Male</b>							
Battelle Columbus Laboratory	052020303	07/18/07	727	50(3)	35(687)	632.7	Green tea extract
Battelle Northwest	052051503	04/14/08	729	50(5)	33(688)	602.8	Metal working fluids (CIMSTAR 3800)
Battelle Columbus Laboratory	052032003	07/25/07	727	50(3)	33(642)	662.9	Tetrabromobisphenol A
<b>Female</b>							
Battelle Columbus Laboratory	052020303	07/19/07	729	50(5)	26(671)	369.7	Green tea extract
Battelle Northwest	052051503	04/14/08	731	50(5)	35(700)	384.9	Metal working fluids (CIMSTAR 3800)
Battelle Columbus Laboratory	052032003	07/26/07	728	50(5)	34(678)	375.2	Tetrabromobisphenol A

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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 4  
 Report Date: 06/12/2013

		Male			Female		
<b>#All Organs:</b>							
<b>Benign Tumors</b>							
		26/50 (52%)	32/50 (64%)	30/50 (60%)	38/50 (76%)	42/50 (84%)	38/50 (76%)
<b>Overall Incidence</b>	Total	88/150 (58.67%)	Mean 58.67%	SD 6.11%	Total 118/150 (78.67%)	Mean 78.67%	SD 4.62%
.....							
<b>#All Organs:</b>							
<b>Malignant Tumors</b>							
		12/50 (24%)	13/50 (26%)	8/50 (16%)	16/50 (32%)	11/50 (22%)	10/50 (20%)
<b>Overall Incidence</b>	Total	33/150 (22%)	Mean 22%	SD 5.29%	Total 37/150 (24.67%)	Mean 24.67%	SD 6.43%
.....							
<b>#All Organs:</b>							
<b>Malignant and Benign Tumors</b>							
		36/50 (72%)	37/50 (74%)	34/50 (68%)	43/50 (86%)	43/50 (86%)	40/50 (80%)
<b>Overall Incidence</b>	Total	107/150 (71.33%)	Mean 71.33%	SD 3.06%	Total 126/150 (84%)	Mean 84%	SD 3.46%
.....							
<b>#All Organs:</b>							
<b>Hemangioma</b>							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
<b>#All Organs:</b>							
<b>Hemangiosarcoma</b>							
		0/50 (0%)	3/50 (6%)	3/50 (6%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
<b>Overall Incidence</b>	Total	6/150 (4%)	Mean 4%	SD 3.46%	Total 5/150 (3.33%)	Mean 3.33%	SD 1.15%
.....							
<b>#All Organs:</b>							
<b>Hemangiosarcoma or Hemangioma</b>							
		0/50 (0%)	3/50 (6%)	4/50 (8%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
<b>Overall Incidence</b>	Total	7/150 (4.67%)	Mean 4.67%	SD 4.16%	Total 5/150 (3.33%)	Mean 3.33%	SD 1.15%

\*: 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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 5  
 Report Date: 06/12/2013

		Male				Female			
<b>#All Organs:</b>									
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#All Organs:</b>									
<b>Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%	
.....									
<b>#All Organs:</b>									
<b>Mesothelioma: Benign, Malignant, NOS</b>									
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#All Organs:</b>									
<b>Mesothelioma: Malignant</b>									
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#All Organs:</b>									
<b>Osteoma</b>									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#All Organs:</b>									
<b>Osteosarcoma</b>									
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 6  
 Report Date: 06/12/2013

		Male				Female			
<b>#All Organs:</b>									
<b>Osteosarcoma or Osteoma</b>									
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>*Adrenal Cortex:</b>									
<b>Adenoma</b>									
		1/50 (2%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/150 (2%)	Mean 2%	SD 2%	
.....									
<b>*Adrenal Cortex:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
<b>*Adrenal Medulla:</b>									
<b>Pheochromocytoma Benign</b>									
		1/50 (2%)	4/50 (8%)	0/49 (0%)		1/50 (2%)	1/49 (2%)	2/49 (4%)	
<b>Overall Incidence</b>	Total	5/149 (3.36%)	Mean 3.33%	SD 4.16%	Total	4/148 (2.7%)	Mean 2.71%	SD 1.19%	
.....									
<b>*Adrenal Medulla:</b>									
<b>Pheochromocytoma Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/49 (2%)	0/49 (0%)	
<b>Overall Incidence</b>	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/148 (0.68%)	Mean 0.68%	SD 1.18%	
.....									
<b>*Adrenal Medulla:</b>									
<b>Pheochromocytoma: Benign, Complex, Malignant, NOS</b>									
		1/50 (2%)	4/50 (8%)	0/49 (0%)		1/50 (2%)	2/49 (4%)	2/49 (4%)	
<b>Overall Incidence</b>	Total	5/149 (3.36%)	Mean 3.33%	SD 4.16%	Total	5/148 (3.38%)	Mean 3.39%	SD 1.2%	

\*: 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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 7  
 Report Date: 06/12/2013

		Male			Female		
<b>#Blood Vessel:</b>							
<b>Hemangiosarcoma</b>							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
<b>*Bone Marrow:</b>							
<b>Hemangiosarcoma</b>							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
<b>#Bone:</b>							
<b>Osteoma</b>							
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
<b>#Bone:</b>							
<b>Osteosarcoma</b>							
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
<b>#Bone:</b>							
<b>Osteosarcoma or Osteoma</b>							
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
<b>#Bone:</b>							
<b>Sarcoma</b>							
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 8  
 Report Date: 06/12/2013

		Male			Female			
<b>*Brain:</b>								
<b>Glioma</b>								
		0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>*Brain:</b>								
<b>Glioma Malignant</b>								
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>*Brain:</b>								
<b>Granular Cell Tumor Benign</b>								
		2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	3/150 (2%)	Mean 2%	SD 2%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
.....								
<b>*Brain:</b>								
<b>Meningioma Malignant</b>								
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>*Brain:</b>								
<b>Meningioma: Benign, Malignant, NOS</b>								
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>*Brain:</b>								
<b>Oligodendroglioma, Glioma, or Astrocytoma</b>								
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 9  
 Report Date: 06/12/2013

		Male			Female		
<b>*Clitoral/Preputial Gland: Carcinoma</b>							
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/149 (0%)	Mean 0% SD 0%
.....							
<b>*Clitoral/Preputial Gland: Carcinoma or Adenoma</b>							
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/149 (0%)	Mean 0% SD 0%
.....							
<b>*Heart: Schwannoma Benign</b>							
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
<b>#Intestine Small: Duodenum: Leiomyosarcoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
<b>#Intestine Small: Jejunum: Leiomyosarcoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
<b>#Intestine Small: Site Unspecified: Leiomyosarcoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33% SD 1.15%

\*: 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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 10  
 Report Date: 06/12/2013

		Male			Female		
<b>*Islets, Pancreatic:</b>							
<b>Adenoma</b>							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/49 (2%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/149 (0.67%)	Mean 0.68%
							SD 1.18%
.....							
<b>*Islets, Pancreatic:</b>							
<b>Carcinoma or Adenoma</b>							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/49 (2%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/149 (0.67%)	Mean 0.68%
							SD 1.18%
.....							
<b>*Kidney: Pelvis and Transitional Epithelium:</b>							
<b>Papilloma</b>							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
<b>*Kidney: Renal Tubule:</b>							
<b>Adenoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%
							SD 1.15%
.....							
<b>*Kidney: Renal Tubule:</b>							
<b>Carcinoma or Adenoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%
							SD 1.15%
.....							
<b>*Kidney: Renal Tubule:</b>							
<b>Lipoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%
							SD 1.15%

\*: 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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 11  
 Report Date: 06/12/2013

		Male			Female			
<b>*Kidney: Renal Tubule:</b>								
<b>Liposarcoma</b>								
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>*Liver:</b>								
<b>Hepatocellular Adenoma</b>								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
.....								
<b>*Liver:</b>								
<b>Hepatocellular Carcinoma or Hepatocellular Adenoma</b>								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
.....								
<b>*Liver:</b>								
<b>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma</b>								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
.....								
<b>*Lung:</b>								
<b>Alveolar/Bronchiolar Adenoma</b>								
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>*Lung:</b>								
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>								
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 12  
 Report Date: 06/12/2013

		Male			Female		
<b>#Lymph Node, Mesenteric: Hemangioma</b>							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
<b>#Lymph Node, Mesenteric: Hemangiosarcoma</b>							
		0/50 (0%)	3/50 (6%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
<b>Overall Incidence</b>	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	Total	3/150 (2%)	Mean 2% SD 0%
.....							
<b>#Mammary Gland: Adenoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	2/50 (4%)	4/50 (8%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	8/150 (5.33%)	Mean 5.33% SD 2.31%
.....							
<b>#Mammary Gland: Carcinoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	6/50 (12%)	4/50 (8%)	1/50 (2%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	11/150 (7.33%)	Mean 7.33% SD 5.03%
.....							
<b>#Mammary Gland: Carcinoma or Adenoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	8/50 (16%)	6/50 (12%)	4/50 (8%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	18/150 (12%)	Mean 12% SD 4%
.....							
<b>#Mammary Gland: Fibroadenoma</b>							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	11/50 (22%)	9/50 (18%)	8/50 (16%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	28/150 (18.67%)	Mean 18.67% SD 3.06%

\*: 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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 13  
 Report Date: 06/12/2013

		Male			Female		
<b>#Mammary Gland:</b>							
<b>Fibroma, Fibroadenoma or Adenoma</b>							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	11/50 (22%)	11/50 (22%)	12/50 (24%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total 34/150 (22.67%)	Mean 22.67%	SD 1.15%
.....							
<b>#Mammary Gland:</b>							
<b>Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	15/50 (30%)	13/50 (26%)	12/50 (24%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total 40/150 (26.67%)	Mean 26.67%	SD 3.06%
.....							
<b>#Mesentery:</b>							
<b>Hemangiosarcoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total 1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....							
<b>#Mesentery:</b>							
<b>Schwannoma Malignant</b>							
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
<b>*Nose:</b>							
<b>Olfactory Neuroblastoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	1/50 (2%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total 1/149 (0.67%)	Mean 0.67%	SD 1.15%
.....							
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):</b>							
<b>Squamous Cell Carcinoma</b>							
		1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total 1/150 (0.67%)	Mean 0.67%	SD 1.15%

\*: 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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 14  
 Report Date: 06/12/2013

	Male					Female								
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):</b>														
<b>Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma</b>														
		1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)			
<b>Overall Incidence</b>	Total	1/150 (0.67%)		Mean	0.67%	SD	1.15%	Total	1/150 (0.67%)		Mean	0.67%	SD	1.15%
.....														
<b>#Oral Mucosa:</b>														
<b>Squamous Cell Carcinoma</b>														
		1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)			
<b>Overall Incidence</b>	Total	1/150 (0.67%)		Mean	0.67%	SD	1.15%	Total	1/150 (0.67%)		Mean	0.67%	SD	1.15%
.....														
<b>*Ovary:</b>														
<b>Granulosa Cell Tumor Benign</b>														
								0/50	(0%)	1/50	(2%)	0/50	(0%)	
<b>Overall Incidence</b>								Total	1/150 (0.67%)		Mean	0.67%	SD	1.15%
.....														
<b>*Ovary:</b>														
<b>Granulosa Cell Tumor Malignant</b>														
								0/50	(0%)	0/50	(0%)	1/50	(2%)	
<b>Overall Incidence</b>								Total	1/150 (0.67%)		Mean	0.67%	SD	1.15%
.....														
<b>*Ovary:</b>														
<b>Granulosa Cell Tumor: Benign, Malignant, NOS</b>														
								0/50	(0%)	1/50	(2%)	1/50	(2%)	
<b>Overall Incidence</b>								Total	2/150 (1.33%)		Mean	1.33%	SD	1.15%
.....														
<b>*Ovary:</b>														
<b>Sex Cord Stromal Tumor, Benign</b>														
								0/50	(0%)	0/50	(0%)	2/50	(4%)	
<b>Overall Incidence</b>								Total	2/150 (1.33%)		Mean	1.33%	SD	2.31%

\*: 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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 15  
 Report Date: 06/12/2013

		Male			Female			
<b>*Pancreas:</b>								
<b>Adenoma</b>								
		0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/149 (0%)	Mean 0%	SD 0%
.....								
<b>*Pancreas:</b>								
<b>Carcinoma or Adenoma</b>								
		0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/149 (0%)	Mean 0%	SD 0%
.....								
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>								
<b>Adenoma</b>								
		17/50 (34%)	16/49 (33%)	21/50 (42%)	32/50 (64%)	35/50 (70%)	21/50 (42%)	
<b>Overall Incidence</b>	Total	54/149 (36.24%)	Mean 36.22%	SD 5.05%	Total	88/150 (58.67%)	Mean 58.67%	SD 14.74%
.....								
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>								
<b>Carcinoma or Adenoma</b>								
		17/50 (34%)	16/49 (33%)	21/50 (42%)	32/50 (64%)	35/50 (70%)	21/50 (42%)	
<b>Overall Incidence</b>	Total	54/149 (36.24%)	Mean 36.22%	SD 5.05%	Total	88/150 (58.67%)	Mean 58.67%	SD 14.74%
.....								
<b>*Pituitary Gland: Pars Intermedia:</b>								
<b>Adenoma</b>								
		1/50 (2%)	2/49 (4%)	2/50 (4%)	2/50 (4%)	1/50 (2%)	4/50 (8%)	
<b>Overall Incidence</b>	Total	5/149 (3.36%)	Mean 3.36%	SD 1.18%	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%
.....								
<b>*Pituitary Gland: Pars Intermedia:</b>								
<b>Carcinoma or Adenoma</b>								
		1/50 (2%)	2/49 (4%)	2/50 (4%)	2/50 (4%)	1/50 (2%)	4/50 (8%)	
<b>Overall Incidence</b>	Total	5/149 (3.36%)	Mean 3.36%	SD 1.18%	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%

\*: 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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 16  
 Report Date: 06/12/2013

		Male			Female			
<b>*Prostate:</b>								
<b>Adenoma</b>								
		0/50 (0%)	1/50 (2%)	0/50 (0%)				
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
.....								
<b>*Prostate:</b>								
<b>Carcinoma or Adenoma</b>								
		0/50 (0%)	1/50 (2%)	0/50 (0%)				
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
.....								
<b>*Salivary Glands:</b>								
<b>Myoepithelioma</b>								
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/149 (0%)	Mean 0%	SD 0%
.....								
<b>*Salivary Glands:</b>								
<b>Schwannoma Malignant</b>								
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/149 (0%)	Mean 0%	SD 0%
.....								
<b>#Seminal Vesicle:</b>								
<b>Adenoma</b>								
		0/50 (0%)	1/50 (2%)	0/50 (0%)				
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
.....								
<b>#Skeletal Muscle:</b>								
<b>Sarcoma</b>								
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 17  
 Report Date: 06/12/2013

		Male			Female		
<b>#Skin:</b>							
<b>Basal Cell Adenoma</b>							
		2/50 (4%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
<b>#Skin:</b>							
<b>Basal Cell Adenoma or Basosquamous Tumor Benign</b>							
		2/50 (4%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
<b>#Skin:</b>							
<b>Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma</b>							
		2/50 (4%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
<b>#Skin:</b>							
<b>Basal Cell Carcinoma</b>							
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
<b>#Skin:</b>							
<b>Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)</b>							
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
<b>#Skin:</b>							
<b>Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma</b>							
		2/50 (4%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	5/150 (3.33%)	Mean 3.33%	SD 1.15%	Total	0/150 (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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 18  
 Report Date: 06/12/2013

	Male				Female			
<b>#Skin:</b>								
<b>Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma</b>								
		6/50 (12%)	2/50 (4%)	7/50 (14%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	15/150 (10%)	Mean 10%	SD 5.29%	Total	0/150 (0%)	Mean 0%	SD 0%
<b>#Skin:</b>								
<b>Fibroma</b>								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
<b>#Skin:</b>								
<b>Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma</b>								
		1/50 (2%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
<b>#Skin:</b>								
<b>Fibrosarcoma</b>								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
<b>#Skin:</b>								
<b>Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma</b>								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
<b>#Skin:</b>								
<b>Hamartoma</b>								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 19  
 Report Date: 06/12/2013

		Male			Female			
<b>#Skin:</b>								
<b>Hemangiosarcoma</b>								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
<b>#Skin:</b>								
<b>Keratoacanthoma</b>								
		2/50 (4%)	1/50 (2%)	4/50 (8%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Lipoma</b>								
		1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Liposarcoma</b>								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
<b>#Skin:</b>								
<b>Neurofibrosarcoma or Schwannoma (malignant or NOS)</b>								
		2/50 (4%)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
.....								
<b>#Skin:</b>								
<b>Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)</b>								
		2/50 (4%)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%

\*: 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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 20  
 Report Date: 06/12/2013

		Male			Female			
<b>#Skin:</b>								
<b>Schwannoma Malignant</b>								
		2/50 (4%)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
.....								
<b>#Skin:</b>								
<b>Squamous Cell Carcinoma</b>								
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma</b>								
		1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	3/150 (2%)	Mean 2%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Squamous Cell Papilloma</b>								
		1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Squamous Cell Papilloma or Papilloma</b>								
		1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>								
		4/50 (8%)	1/50 (2%)	5/50 (10%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	10/150 (6.67%)	Mean 6.67%	SD 4.16%	Total	0/150 (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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 21  
 Report Date: 06/12/2013

	Male				Female			
<b>#Skin:</b>								
<b>Squamous Cell Papilloma, Papilloma, or Keratoacanthoma</b>								
		3/50 (6%)	1/50 (2%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	9/150 (6%)	Mean 6%	SD 4%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin: Sebaceous Gland:</b>								
<b>Adenoma</b>								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin: Sebaceous Gland:</b>								
<b>Carcinoma or Adenoma</b>								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>*Spleen:</b>								
<b>Hemangiosarcoma</b>								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>#Stomach, Forestomach:</b>								
<b>Leiomyoma</b>								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>#Stomach, Forestomach:</b>								
<b>Leiomyosarcoma</b>								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

\*: 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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 22  
 Report Date: 06/12/2013

		Male			Female			
<b>#Stomach, Forestomach:</b>								
<b>Sarcoma</b>								
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>#Stomach, Forestomach:</b>								
<b>Squamous Cell Carcinoma</b>								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
<b>#Stomach, Forestomach:</b>								
<b>Squamous Cell Carcinoma or Papilloma Squamous</b>								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
<b>#Stomach, Glandular:</b>								
<b>Leiomyosarcoma</b>								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
.....								
<b>#Stomach, Glandular:</b>								
<b>Sarcoma</b>								
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>*Testes:</b>								
<b>Adenoma</b>								
		2/50 (4%)	2/50 (4%)	0/50 (0%)				
<b>Overall Incidence</b>	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%				

\*: 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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 23  
 Report Date: 06/12/2013

		Male			Female			
<b>*Thymus:</b>								
<b>Sarcoma</b>								
		0/49 (0%)	0/40 (0%)	0/49 (0%)	0/49 (0%)	0/48 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	0/138 (0%)	Mean 0%	SD 0%	Total	1/147 (0.68%)	Mean 0.67%	SD 1.15%
.....								
<b>*Thymus:</b>								
<b>Thymoma Benign</b>								
		2/49 (4%)	1/40 (3%)	1/49 (2%)	3/49 (6%)	5/48 (10%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	4/138 (2.9%)	Mean 2.87%	SD 1.07%	Total	9/147 (6.12%)	Mean 6.18%	SD 4.21%
.....								
<b>*Thymus:</b>								
<b>Thymoma: Benign, Malignant, NOS</b>								
		2/49 (4%)	1/40 (3%)	1/49 (2%)	3/49 (6%)	5/48 (10%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	4/138 (2.9%)	Mean 2.87%	SD 1.07%	Total	9/147 (6.12%)	Mean 6.18%	SD 4.21%
.....								
<b>*Thyroid Gland: C-Cell:</b>								
<b>Adenoma</b>								
		4/50 (8%)	7/50 (14%)	5/50 (10%)	3/50 (6%)	3/50 (6%)	7/50 (14%)	
<b>Overall Incidence</b>	Total	16/150 (10.67%)	Mean 10.67%	SD 3.06%	Total	13/150 (8.67%)	Mean 8.67%	SD 4.62%
.....								
<b>*Thyroid Gland: C-Cell:</b>								
<b>Carcinoma</b>								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
<b>*Thyroid Gland: C-Cell:</b>								
<b>Carcinoma or Adenoma</b>								
		4/50 (8%)	7/50 (14%)	5/50 (10%)	4/50 (8%)	3/50 (6%)	7/50 (14%)	
<b>Overall Incidence</b>	Total	16/150 (10.67%)	Mean 10.67%	SD 3.06%	Total	14/150 (9.33%)	Mean 9.33%	SD 4.16%

\*: 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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 24  
 Report Date: 06/12/2013

		Male			Female		
<b>*Thyroid Gland: Follicular Cell: Adenoma</b>							
		0/50 (0%)	1/50 (2%)	3/50 (6%)	1/50 (2%)	1/50 (2%)	3/50 (6%)
<b>Overall Incidence</b>	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	Total	5/150 (3.33%)	Mean 3.33% SD 2.31%
.....							
<b>*Thyroid Gland: Follicular Cell: Carcinoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
<b>*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma</b>							
		0/50 (0%)	1/50 (2%)	3/50 (6%)	1/50 (2%)	2/50 (4%)	3/50 (6%)
<b>Overall Incidence</b>	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	Total	6/150 (4%)	Mean 4% SD 2%
.....							
<b>*Urinary Bladder: Carcinoma or Papilloma</b>							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/49 (0%)	0/50 (0%)	1/50 (2%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/149 (0.67%)	Mean 0.67% SD 1.15%
.....							
<b>*Urinary Bladder: Papilloma</b>							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/49 (0%)	0/50 (0%)	1/50 (2%)
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/149 (0.67%)	Mean 0.67% SD 1.15%
.....							
<b>#Uterus: Carcinoma</b>							
					3/50 (6%)	1/50 (2%)	3/50 (6%)
<b>Overall Incidence</b>	Total				7/150 (4.67%)	Mean 4.67%	SD 2.31%

\*: 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: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 25  
 Report Date: 06/12/2013

	Male	Female
<b>#Uterus:</b> <b>Polyp Stromal</b>		
	3/50 (6%)	5/50 (10%)
<b>Overall Incidence</b>	Total 10/150 (6.67%)	Mean 6.67% SD 3.06%
.....		
<b>#Uterus:</b> <b>Sarcoma Stromal</b>		
	1/50 (2%)	2/50 (4%)
<b>Overall Incidence</b>	Total 3/150 (2%)	Mean 2% SD 2%
.....		
<b>#Uterus:</b> <b>Sarcoma Stromal or Polyp Stromal</b>		
	4/50 (8%)	6/50 (12%)
<b>Overall Incidence</b>	Total 12/150 (8%)	Mean 8% SD 4%
.....		
<b>#Uterus:</b> <b>Schwannoma Malignant</b>		
	1/50 (2%)	0/50 (0%)
<b>Overall Incidence</b>	Total 1/150 (0.67%)	Mean 0.67% SD 1.15%
.....		
<b>#Uterus:</b> <b>Squamous Cell Papilloma</b>		
	0/50 (0%)	1/50 (2%)
<b>Overall Incidence</b>	Total 1/150 (0.67%)	Mean 0.67% SD 1.15%
.....		
<b>#Vagina:</b> <b>Leiomyoma</b>		
	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total 1/150 (0.67%)	Mean 0.67% SD 1.15%
.....		

\*: 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: ALL ROUTES**  
**Vehicle: ALL VEHICLES**

Page: 26  
 Report Date: 06/12/2013

		Male			Female		
<b>#Vagina:</b>							
<b>Polyp</b>							
			1/50 (2%)		0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>				Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....							
<b>#Zymbal's Gland:</b>							
<b>Carcinoma</b>							
		1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%
						SD 0%	
.....							
<b>#Zymbal's Gland:</b>							
<b>Carcinoma or Adenoma</b>							
		1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%
						SD 0%	

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