

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:

	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.

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

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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 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
Female							
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
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 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

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 Report Date: 06/12/2013

		Male			Female		
#All Organs:							
Benign Tumors							
		26/50 (52%)	32/50 (64%)	30/50 (60%)	38/50 (76%)	42/50 (84%)	38/50 (76%)
Overall Incidence	Total	88/150 (58.67%)	Mean 58.67%	SD 6.11%	Total	118/150 (78.67%)	Mean 78.67% SD 4.62%
.....							
#All Organs:							
Malignant Tumors							
		12/50 (24%)	13/50 (26%)	8/50 (16%)	16/50 (32%)	11/50 (22%)	10/50 (20%)
Overall Incidence	Total	33/150 (22%)	Mean 22%	SD 5.29%	Total	37/150 (24.67%)	Mean 24.67% SD 6.43%
.....							
#All Organs:							
Malignant and Benign Tumors							
		36/50 (72%)	37/50 (74%)	34/50 (68%)	43/50 (86%)	43/50 (86%)	40/50 (80%)
Overall Incidence	Total	107/150 (71.33%)	Mean 71.33%	SD 3.06%	Total	126/150 (84%)	Mean 84% SD 3.46%
.....							
#All Organs:							
Hemangioma							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Hemangiosarcoma							
		0/50 (0%)	3/50 (6%)	3/50 (6%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	6/150 (4%)	Mean 4%	SD 3.46%	Total	5/150 (3.33%)	Mean 3.33% SD 1.15%
.....							
#All Organs:							
Hemangiosarcoma or Hemangioma							
		0/50 (0%)	3/50 (6%)	4/50 (8%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
Overall Incidence	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
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

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

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 #: 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: ALL ROUTES
 Vehicle: ALL VEHICLES

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 Report Date: 06/12/2013

		Male			Female		
#Blood Vessel:							
Hemangiosarcoma							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
*Bone Marrow:							
Hemangiosarcoma							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
#Bone:							
Osteoma							
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
#Bone:							
Osteosarcoma							
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
#Bone:							
Osteosarcoma or Osteoma							
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
#Bone:							
Sarcoma							
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	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			
*Brain:								
Glioma								
		0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Brain:								
Glioma Malignant								
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Brain:								
Granular Cell Tumor Benign								
		2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
.....								
*Brain:								
Meningioma Malignant								
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Brain:								
Meningioma: Benign, Malignant, NOS								
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Brain:								
Oligodendroglioma, Glioma, or Astrocytoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	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

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

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

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

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

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

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

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

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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		Male				Female			
*Pancreas:									
Adenoma									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/149 (0%)	Mean 0%	SD 0%	
.....									
*Pancreas:									
Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/149 (0%)	Mean 0%	SD 0%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Adenoma									
		17/50 (34%)	16/49 (33%)	21/50 (42%)		32/50 (64%)	35/50 (70%)	21/50 (42%)	
Overall Incidence	Total	54/149 (36.24%)	Mean 36.22%	SD 5.05%	Total	88/150 (58.67%)	Mean 58.67%	SD 14.74%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma or Adenoma									
		17/50 (34%)	16/49 (33%)	21/50 (42%)		32/50 (64%)	35/50 (70%)	21/50 (42%)	
Overall Incidence	Total	54/149 (36.24%)	Mean 36.22%	SD 5.05%	Total	88/150 (58.67%)	Mean 58.67%	SD 14.74%	
.....									
*Pituitary Gland: Pars Intermedia:									
Adenoma									
		1/50 (2%)	2/49 (4%)	2/50 (4%)		2/50 (4%)	1/50 (2%)	4/50 (8%)	
Overall Incidence	Total	5/149 (3.36%)	Mean 3.36%	SD 1.18%	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%	
.....									
*Pituitary Gland: Pars Intermedia:									
Carcinoma or Adenoma									
		1/50 (2%)	2/49 (4%)	2/50 (4%)		2/50 (4%)	1/50 (2%)	4/50 (8%)	
Overall Incidence	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
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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%)	1/50 (2%)	0/50 (0%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%			
.....							
*Prostate:							
Carcinoma or Adenoma							
		0/50 (0%)	1/50 (2%)	0/50 (0%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%			
.....							
*Salivary Glands:							
Myoepithelioma							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total 0/149 (0%)	Mean 0%	SD 0%
.....							
*Salivary Glands:							
Schwannoma Malignant							
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total 0/149 (0%)	Mean 0%	SD 0%
.....							
#Seminal Vesicle:							
Adenoma							
		0/50 (0%)	1/50 (2%)	0/50 (0%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%			
.....							
#Skeletal Muscle:							
Sarcoma							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							

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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:								
Basal Cell Adenoma								
		2/50 (4%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Basal Cell Adenoma or Basosquamous Tumor Benign								
		2/50 (4%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma								
		2/50 (4%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Basal Cell Carcinoma								
		0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)								
		0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma								
		2/50 (4%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	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
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Toxicology Data Management System
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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%)	2/50 (4%)	7/50 (14%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	15/150 (10%)	Mean 10%	SD 5.29%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Fibroma							
		1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma							
		1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Fibrosarcoma							
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma							
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Hamartoma							
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%

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 #: 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
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		Male			Female			
#Skin:								
Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Skin:								
Keratoacanthoma								
		2/50 (4%)	1/50 (2%)	4/50 (8%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Lipoma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Skin:								
Neurofibrosarcoma or Schwannoma (malignant or NOS)								
		2/50 (4%)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
.....								
#Skin:								
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)								
		2/50 (4%)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	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
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 Tumor Incidence for Selected Control Animal Groups
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		Male			Female			
#Skin:								
Schwannoma Malignant								
		2/50 (4%)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
.....								
#Skin:								
Squamous Cell Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma								
		1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Squamous Cell Papilloma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Squamous Cell Papilloma or Papilloma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma								
		4/50 (8%)	1/50 (2%)	5/50 (10%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	10/150 (6.67%)	Mean 6.67%	SD 4.16%	Total	0/150 (0%)	Mean 0%	SD 0%

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

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 #: 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%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Stomach, Forestomach:								
Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Stomach, Forestomach:								
Squamous Cell Carcinoma or Papilloma Squamous								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Stomach, Glandular:								
Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
.....								
#Stomach, Glandular:								
Sarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Testes:								
Adenoma								
		2/50 (4%)	2/50 (4%)	0/50 (0%)				
Overall Incidence	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
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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		Male			Female			
*Thymus:								
Sarcoma								
		0/49 (0%)	0/40 (0%)	0/49 (0%)	0/49 (0%)	0/48 (0%)	1/50 (2%)	
Overall Incidence	Total	0/138 (0%)	Mean 0%	SD 0%	Total	1/147 (0.68%)	Mean 0.67%	SD 1.15%
.....								
*Thymus:								
Thymoma Benign								
		2/49 (4%)	1/40 (3%)	1/49 (2%)	3/49 (6%)	5/48 (10%)	1/50 (2%)	
Overall Incidence	Total	4/138 (2.9%)	Mean 2.87%	SD 1.07%	Total	9/147 (6.12%)	Mean 6.18%	SD 4.21%
.....								
*Thymus:								
Thymoma: Benign, Malignant, NOS								
		2/49 (4%)	1/40 (3%)	1/49 (2%)	3/49 (6%)	5/48 (10%)	1/50 (2%)	
Overall Incidence	Total	4/138 (2.9%)	Mean 2.87%	SD 1.07%	Total	9/147 (6.12%)	Mean 6.18%	SD 4.21%
.....								
*Thyroid Gland: C-Cell:								
Adenoma								
		4/50 (8%)	7/50 (14%)	5/50 (10%)	3/50 (6%)	3/50 (6%)	7/50 (14%)	
Overall Incidence	Total	16/150 (10.67%)	Mean 10.67%	SD 3.06%	Total	13/150 (8.67%)	Mean 8.67%	SD 4.62%
.....								
*Thyroid Gland: C-Cell:								
Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
*Thyroid Gland: C-Cell:								
Carcinoma or Adenoma								
		4/50 (8%)	7/50 (14%)	5/50 (10%)	4/50 (8%)	3/50 (6%)	7/50 (14%)	
Overall Incidence	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

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

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

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