



National Toxicology Program
Department of Health and Human Services

NTP Historical Controls Report

By Route and Vehicle

Wistar-Han RATS

August 2016

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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Version: Aug2016
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: 08/04/2016

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							
Southern Research Institute	052020903	08/26/08	729	49(3)	36(671)	673.4	Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)]
Battelle Columbus Laboratory	052032003	07/25/07	727	50(3)	33(642)	662.9	Tetrabromobisphenol A
Female							
Southern Research Institute	052020903	08/26/08	732	50(5)	37(678)	389.6	Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)]
Battelle Columbus Laboratory	052032003	07/26/07	728	50(5)	34(678)	375.2	Tetrabromobisphenol A

Version: Aug2016
 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: 08/04/2016

		Male			Female		
#All Organs:							
Benign Tumors							
		33/49 (67%)	30/50 (60%)		37/50 (74%)	38/50 (76%)	
Overall Incidence	Total	63/99 (63.64%)	Mean 63.67%	SD 5.2%	Total	75/100 (75%)	Mean 75% SD 1.41%
.....							
#All Organs:							
Malignant Tumors							
		13/49 (27%)	8/50 (16%)		10/50 (20%)	10/50 (20%)	
Overall Incidence	Total	21/99 (21.21%)	Mean 21.27%	SD 7.45%	Total	20/100 (20%)	Mean 20% SD 0%
.....							
#All Organs:							
Malignant and Benign Tumors							
		36/49 (73%)	34/50 (68%)		40/50 (80%)	40/50 (80%)	
Overall Incidence	Total	70/99 (70.71%)	Mean 70.73%	SD 3.87%	Total	80/100 (80%)	Mean 80% SD 0%
.....							
#All Organs:							
Hemangioma							
		1/49 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	0/100 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Hemangiosarcoma							
		8/49 (16%)	3/50 (6%)		2/50 (4%)	2/50 (4%)	
Overall Incidence	Total	11/99 (11.11%)	Mean 11.16%	SD 7.3%	Total	4/100 (4%)	Mean 4% SD 0%
.....							
#All Organs:							
Hemangiosarcoma or Hemangioma							
		9/49 (18%)	4/50 (8%)		2/50 (4%)	2/50 (4%)	
Overall Incidence	Total	13/99 (13.13%)	Mean 13.18%	SD 7.33%	Total	4/100 (4%)	Mean 4% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
#All Organs:									
Histiocytic Sarcoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#All Organs:									
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated									
		1/49	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/99	(2.02%)	Mean 2.02%	SD 0.03%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#All Organs:									
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#All Organs:									
Mesothelioma: Benign, Malignant, NOS									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#All Organs:									
Mesothelioma: Malignant									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#All Organs:									
Osteoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%

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

Version: Aug2016
 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: 08/04/2016

	Male				Female			
#All Organs:								
Osteosarcoma								
		0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
.....								
#All Organs:								
Osteosarcoma or Osteoma								
		0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
.....								
*Adrenal Cortex:								
Adenoma								
		0/49 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
.....								
*Adrenal Cortex:								
Carcinoma								
		1/49 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	1/100 (1%)	Mean 1%	SD 1.41%
.....								
*Adrenal Medulla:								
Pheochromocytoma Benign								
		0/49 (0%)	0/49 (0%)		1/50 (2%)	2/49 (4%)		
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	3/99 (3.03%)	Mean 3.04%	SD 1.47%
.....								
*Adrenal Medulla:								
Pheochromocytoma Complex								
		0/49 (0%)	0/49 (0%)		1/50 (2%)	0/49 (0%)		
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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				
*Adrenal Medulla:										
Pheochromocytoma Malignant										
		1/49	(2%)	0/49	(0%)	0/50	(0%)	0/49	(0%)	
Overall Incidence	Total	1/98	(1.02%)	Mean 1.02%	SD 1.44%	Total	0/99	(0%)	Mean 0%	SD 0%
.....										
*Adrenal Medulla:										
Pheochromocytoma: Benign, Complex, Malignant, NOS										
		1/49	(2%)	0/49	(0%)	2/50	(4%)	2/49	(4%)	
Overall Incidence	Total	1/98	(1.02%)	Mean 1.02%	SD 1.44%	Total	4/99	(4.04%)	Mean 4.04%	SD 0.06%
.....										
#Blood Vessel:										
Hemangiosarcoma										
		0/49	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	1/99	(1.01%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
*Bone Marrow:										
Hemangiosarcoma										
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
#Bone:										
Osteoma										
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
#Bone:										
Osteosarcoma										
		0/49	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%	SD 1.41%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
#Bone:								
Osteosarcoma or Osteoma								
		0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
.....								
#Bone:								
Sarcoma								
		0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
*Brain:								
Glioma								
		0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
*Brain:								
Glioma Malignant								
		1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
*Brain:								
Granular Cell Tumor Benign								
		1/49 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
*Brain:								
Granular Cell Tumor Malignant								
		0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
*Brain:									
Meningioma Malignant									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Brain:									
Meningioma: Benign, Malignant, NOS									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Brain:									
Oligodendroglioma Benign									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Brain:									
Oligodendroglioma, Glioma, or Astrocytoma									
		1/49	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/99	(1.01%)	Mean 1.02%	SD 1.44%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Clitoral/Preputial Gland:									
Carcinoma									
		1/49	(2%)	0/50	(0%)	0/49	(0%)	0/50	(0%)
Overall Incidence	Total	1/99	(1.01%)	Mean 1.02%	SD 1.44%	Total	0/99	(0%)	Mean 0% SD 0%
.....									
*Clitoral/Preputial Gland:									
Carcinoma or Adenoma									
		1/49	(2%)	0/50	(0%)	0/49	(0%)	0/50	(0%)
Overall Incidence	Total	1/99	(1.01%)	Mean 1.02%	SD 1.44%	Total	0/99	(0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
*Heart:									
Schwannoma Benign									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1% SD 1.41%
.....									
*Heart:									
Schwannoma NOS									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Intestine Small: Duodenum:									
Fibroma									
		1/49	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/99	(1.01%)	Mean 1.02%	SD 1.44%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Intestine Small: Duodenum:									
Leiomyosarcoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1% SD 1.41%
.....									
#Intestine Small: Jejunum:									
Leiomyoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Intestine Small: Jejunum:									
Leiomyosarcoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
#Intestine Small: Site Unspecified:									
Fibroma									
		1/49	(2%)	0/50	(0%)			0/50	(0%)
Overall Incidence	Total	1/99	(1.01%)	Mean 1.02%	SD 1.44%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
#Intestine Small: Site Unspecified:									
Leiomyoma									
		0/49	(0%)	0/50	(0%)			0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
#Intestine Small: Site Unspecified:									
Leiomyosarcoma									
		0/49	(0%)	0/50	(0%)			0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%
									SD 1.41%
.....									
*Islets, Pancreatic:									
Adenoma									
		4/49	(8%)	1/50	(2%)			0/50	(0%)
Overall Incidence	Total	5/99	(5.05%)	Mean 5.08%	SD 4.36%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
*Islets, Pancreatic:									
Carcinoma									
		2/49	(4%)	0/50	(0%)			0/50	(0%)
Overall Incidence	Total	2/99	(2.02%)	Mean 2.04%	SD 2.89%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
*Islets, Pancreatic:									
Carcinoma or Adenoma									
		6/49	(12%)	1/50	(2%)			0/50	(0%)
Overall Incidence	Total	7/99	(7.07%)	Mean 7.12%	SD 7.24%	Total	0/100	(0%)	Mean 0%
									SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
*Kidney: Pelvis and Transitional Epithelium:									
Papilloma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
*Kidney: Renal Tubule:									
Adenoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
*Kidney: Renal Tubule:									
Carcinoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
*Kidney: Renal Tubule:									
Carcinoma or Adenoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
*Kidney: Renal Tubule:									
Lipoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
*Kidney: Renal Tubule:									
Liposarcoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%

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

Version: Aug2016
 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			
*Liver:									
Cholangioma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Liver:									
Hemangioma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Liver:									
Hepatocellular Adenoma									
		3/49	(6%)	0/50	(0%)	3/50	(6%)	1/50	(2%)
Overall Incidence	Total	3/99	(3.03%)	Mean 3.06%	SD 4.33%	Total	4/100	(4%)	Mean 4% SD 2.83%
.....									
*Liver:									
Hepatocellular Carcinoma or Hepatocellular Adenoma									
		3/49	(6%)	0/50	(0%)	3/50	(6%)	1/50	(2%)
Overall Incidence	Total	3/99	(3.03%)	Mean 3.06%	SD 4.33%	Total	4/100	(4%)	Mean 4% SD 2.83%
.....									
*Liver:									
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma									
		3/49	(6%)	0/50	(0%)	3/50	(6%)	1/50	(2%)
Overall Incidence	Total	3/99	(3.03%)	Mean 3.06%	SD 4.33%	Total	4/100	(4%)	Mean 4% SD 2.83%
.....									
*Lung:									
Alveolar/Bronchiolar Adenoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
*Lung:									
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma									
		0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node:									
Hemangioma									
		0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node, Mandibular:									
Hemangioma									
		0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node, Mesenteric:									
Hemangioma									
		1/49 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node, Mesenteric:									
Hemangiosarcoma									
		7/49 (14%)	1/50 (2%)		2/50 (4%)	1/50 (2%)			
Overall Incidence	Total	8/99 (8.08%)	Mean 8.14%	SD 8.69%	Total	3/100 (3%)	Mean 3%	SD 1.41%	
.....									
#Mammary Gland:									
Adenoma									
		0/49 (0%)	0/50 (0%)		0/50 (0%)	4/50 (8%)			
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	4/100 (4%)	Mean 4%	SD 5.66%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
 Length of Study: CHRONIC

Toxicology Data Management System
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		Male				Female			
#Mammary Gland:									
Carcinoma									
		0/49	(0%)	0/50	(0%)	1/50	(2%)	1/50	(2%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	2/100	(2%)	Mean 2%
.....									
#Mammary Gland:									
Carcinoma or Adenoma									
		0/49	(0%)	0/50	(0%)	1/50	(2%)	4/50	(8%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	5/100	(5%)	Mean 5%
.....									
#Mammary Gland:									
Fibroadenoma									
		0/49	(0%)	1/50	(2%)	9/50	(18%)	8/50	(16%)
Overall Incidence	Total	1/99	(1.01%)	Mean 1%	SD 1.41%	Total	17/100	(17%)	Mean 17%
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma or Adenoma									
		0/49	(0%)	1/50	(2%)	9/50	(18%)	12/50	(24%)
Overall Incidence	Total	1/99	(1.01%)	Mean 1%	SD 1.41%	Total	21/100	(21%)	Mean 21%
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma, Carcinoma, or Adenoma									
		0/49	(0%)	1/50	(2%)	10/50	(20%)	12/50	(24%)
Overall Incidence	Total	1/99	(1.01%)	Mean 1%	SD 1.41%	Total	22/100	(22%)	Mean 22%
.....									
#Mesentery:									
Hemangiosarcoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
.....									

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

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
 Length of Study: CHRONIC

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		Male				Female					
#Mesentery:											
Lipoma											
		1/49	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/99	(1.01%)	Mean 1.02%	SD 1.44%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Mesentery:											
Schwannoma Malignant											
		0/49	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Nose:											
Adenoma											
		0/49	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Nose:											
Chondroma											
		0/49	(0%)	0/50	(0%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
*Nose:											
Olfactory Neuroblastoma											
		0/49	(0%)	0/50	(0%)			0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):											
Squamous Cell Carcinoma											
		0/49	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
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	Male				Female			
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):								
Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma								
		0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Oral Mucosa:								
Squamous Cell Carcinoma								
		0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
*Ovary:								
Adenoma								
					0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
.....								
*Ovary:								
Cystadenoma								
					0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
.....								
*Ovary:								
Granulosa Cell Tumor Benign								
					1/50 (2%)	0/50 (0%)		
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%
.....								
*Ovary:								
Granulosa Cell Tumor Malignant								
					1/50 (2%)	1/50 (2%)		
Overall Incidence					Total	2/100 (2%)	Mean 2%	SD 0%

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

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
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Male					Female						
*Ovary:											
Granulosa Cell Tumor: Benign, Malignant, NOS											
					2/50	(4%)	1/50	(2%)			
Overall Incidence					Total	3/100 (3%)	Mean	3%	SD	1.41%	
.....											
*Ovary:											
Granulosa-Theca Tumor Malignant											
					0/50	(0%)	0/50	(0%)			
Overall Incidence					Total	0/100 (0%)	Mean	0%	SD	0%	
.....											
*Ovary:											
Sex Cord Stromal Tumor, Benign											
					0/50	(0%)	2/50	(4%)			
Overall Incidence					Total	2/100 (2%)	Mean	2%	SD	2.83%	
.....											
*Ovary:											
Tubulostromal Adenoma											
					0/50	(0%)	0/50	(0%)			
Overall Incidence					Total	0/100 (0%)	Mean	0%	SD	0%	
.....											
*Pancreas:											
Adenoma											
		1/46	(2%)	1/50	(2%)			0/50	(0%)	0/50	(0%)
Overall Incidence		Total	2/96 (2.08%)	Mean	2.09%	SD	0.12%	Total	0/100 (0%)	Mean	0%
.....											
*Pancreas:											
Carcinoma or Adenoma											
		1/46	(2%)	1/50	(2%)			0/50	(0%)	0/50	(0%)
Overall Incidence		Total	2/96 (2.08%)	Mean	2.09%	SD	0.12%	Total	0/100 (0%)	Mean	0%
.....											

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
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		Male			Female			
*Parathyroid Gland:								
Adenoma								
		2/47 (4%)	0/45 (0%)		1/49 (2%)	0/48 (0%)		
Overall Incidence	Total	2/92 (2.17%)	Mean 2.13%	SD 3.01%	Total	1/97 (1.03%)	Mean 1.02%	SD 1.44%
.....								
*Pituitary Gland: Pars Distalis or Unspecified Site:								
Adenoma								
		19/49 (39%)	21/50 (42%)		23/50 (46%)	21/50 (42%)		
Overall Incidence	Total	40/99 (40.4%)	Mean 40.39%	SD 2.28%	Total	44/100 (44%)	Mean 44%	SD 2.83%
.....								
*Pituitary Gland: Pars Distalis or Unspecified Site:								
Carcinoma								
		0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
*Pituitary Gland: Pars Distalis or Unspecified Site:								
Carcinoma or Adenoma								
		19/49 (39%)	21/50 (42%)		23/50 (46%)	21/50 (42%)		
Overall Incidence	Total	40/99 (40.4%)	Mean 40.39%	SD 2.28%	Total	44/100 (44%)	Mean 44%	SD 2.83%
.....								
*Pituitary Gland: Pars Intermedia:								
Adenoma								
		0/49 (0%)	2/50 (4%)		1/50 (2%)	4/50 (8%)		
Overall Incidence	Total	2/99 (2.02%)	Mean 2%	SD 2.83%	Total	5/100 (5%)	Mean 5%	SD 4.24%
.....								
*Pituitary Gland: Pars Intermedia:								
Carcinoma or Adenoma								
		0/49 (0%)	2/50 (4%)		1/50 (2%)	4/50 (8%)		
Overall Incidence	Total	2/99 (2.02%)	Mean 2%	SD 2.83%	Total	5/100 (5%)	Mean 5%	SD 4.24%
.....								

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
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		Male				Female			
*Prostate:									
Adenoma									
		0/49	(0%)	0/50	(0%)				
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%				
.....									
*Prostate:									
Carcinoma									
		0/49	(0%)	0/50	(0%)				
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%				
.....									
*Prostate:									
Carcinoma or Adenoma									
		0/49	(0%)	0/50	(0%)				
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%				
.....									
*Salivary Glands:									
Adenoma									
		1/46	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/96	(1.04%)	Mean 1.09%	SD 1.54%	Total 0/100	(0%)	Mean 0%	SD 0%
.....									
*Salivary Glands:									
Carcinoma									
		0/46	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/96	(0%)	Mean 0%	SD 0%	Total 1/100	(1%)	Mean 1%	SD 1.41%
.....									
*Salivary Glands:									
Carcinoma or Adenoma									
		1/46	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	1/96	(1.04%)	Mean 1.09%	SD 1.54%	Total 1/100	(1%)	Mean 1%	SD 1.41%

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

Version: Aug2016
 Contract/Lab: All Laboratories
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		Male				Female					
*Salivary Glands:											
Myoepithelioma											
		0/46	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/96	(1.04%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Salivary Glands:											
Schwannoma Malignant											
		0/46	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/96	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Seminal Vesicle:											
Adenoma											
		0/49	(0%)	0/50	(0%)						
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%						
.....											
#Skeletal Muscle:											
Hemangiosarcoma											
		1/49	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/99	(1.01%)	Mean 1.02%	SD 1.44%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Skeletal Muscle:											
Sarcoma											
		0/49	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/99	(1.01%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Skin:											
Basal Cell Adenoma											
		1/49	(2%)	2/50	(4%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	3/99	(3.03%)	Mean 3.02%	SD 1.39%	Total	1/100	(1%)	Mean 1%	SD 1.41%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
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	Male					Female								
#Skin:														
Basal Cell Adenoma or Basosquamous Tumor Benign														
		1/49	(2%)	2/50	(4%)			1/50	(2%)	0/50	(0%)			
Overall Incidence	Total	3/99	(3.03%)	Mean	3.02%	SD	1.39%	Total	1/100	(1%)	Mean	1%	SD	1.41%
.....														
#Skin:														
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma														
		1/49	(2%)	2/50	(4%)			1/50	(2%)	0/50	(0%)			
Overall Incidence	Total	3/99	(3.03%)	Mean	3.02%	SD	1.39%	Total	1/100	(1%)	Mean	1%	SD	1.41%
.....														
#Skin:														
Basal Cell Carcinoma														
		0/49	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	1/99	(1.01%)	Mean	1%	SD	1.41%	Total	0/100	(0%)	Mean	0%	SD	0%
.....														
#Skin:														
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)														
		0/49	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	1/99	(1.01%)	Mean	1%	SD	1.41%	Total	0/100	(0%)	Mean	0%	SD	0%
.....														
#Skin:														
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma														
		1/49	(2%)	2/50	(4%)			1/50	(2%)	0/50	(0%)			
Overall Incidence	Total	3/99	(3.03%)	Mean	3.02%	SD	1.39%	Total	1/100	(1%)	Mean	1%	SD	1.41%
.....														
#Skin:														
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma														
		3/49	(6%)	7/50	(14%)			1/50	(2%)	0/50	(0%)			
Overall Incidence	Total	10/99	(10.1%)	Mean	10.06%	SD	5.57%	Total	1/100	(1%)	Mean	1%	SD	1.41%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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 Contract/Lab: All Laboratories
 Species: RATS
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		Male				Female			
#Skin:									
Fibroma									
		1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma									
		1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Fibrosarcoma									
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma									
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Fibrous Histiocytoma									
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Hamartoma									
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
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		Male				Female			
#Skin:									
Hemangiosarcoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1% SD 1.41%
.....									
#Skin:									
Keratoacanthoma									
		2/49	(4%)	4/50	(8%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	6/99	(6.06%)	Mean 6.04%	SD 2.77%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Skin:									
Lipoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Skin:									
Liposarcoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Skin:									
Myxoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Skin:									
Neurofibrosarcoma or Schwannoma (malignant or NOS)									
		0/49	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/99	(2.02%)	Mean 2%	SD 2.83%	Total	0/100	(0%)	Mean 0% SD 0%

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

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
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 Tumor Incidence for Selected Control Animal Groups
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	Male					Female						
#Skin:												
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)												
		0/49	(0%)	2/50	(4%)		0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	2/99 (2.02%)			Mean 2%	SD 2.83%	Total	0/100 (0%)			Mean 0%	SD 0%
.....												
#Skin:												
Schwannoma Malignant												
		0/49	(0%)	2/50	(4%)		0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	2/99 (2.02%)			Mean 2%	SD 2.83%	Total	0/100 (0%)			Mean 0%	SD 0%
.....												
#Skin:												
Squamous Cell Carcinoma												
		0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	0/99 (0%)			Mean 0%	SD 0%	Total	0/100 (0%)			Mean 0%	SD 0%
.....												
#Skin:												
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma												
		0/49	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	1/99 (1.01%)			Mean 1%	SD 1.41%	Total	0/100 (0%)			Mean 0%	SD 0%
.....												
#Skin:												
Squamous Cell Papilloma												
		0/49	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	1/99 (1.01%)			Mean 1%	SD 1.41%	Total	0/100 (0%)			Mean 0%	SD 0%
.....												
#Skin:												
Squamous Cell Papilloma or Papilloma												
		0/49	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	1/99 (1.01%)			Mean 1%	SD 1.41%	Total	0/100 (0%)			Mean 0%	SD 0%

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

Version: Aug2016
 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:								
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma								
		2/49 (4%)	5/50 (10%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	7/99 (7.07%)	Mean 7.04%	SD 4.18%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma								
		2/49 (4%)	5/50 (10%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	7/99 (7.07%)	Mean 7.04%	SD 4.18%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Skin: Sebaceous Gland:								
Adenoma								
		0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Skin: Sebaceous Gland:								
Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
*Spleen:								
Hemangiosarcoma								
		1/47 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/97 (2.06%)	Mean 2.06%	SD 0.09%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Stomach, Forestomach:								
Fibrosarcoma								
		1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%

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

Version: Aug2016
 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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 Vehicle: CORN OIL

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		Male				Female			
#Stomach, Forestomach:									
Leiomyoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Stomach, Forestomach:									
Leiomyosarcoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Stomach, Forestomach:									
Sarcoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma									
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma or Papilloma Squamous									
		1/49	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/99	(1.01%)	Mean 1.02%	SD 1.44%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Stomach, Forestomach:									
Squamous Cell Papilloma									
		1/49	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/99	(1.01%)	Mean 1.02%	SD 1.44%	Total	0/100	(0%)	Mean 0% SD 0%

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

Version: Aug2016
 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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 Vehicle: CORN OIL

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		Male				Female				
#Stomach, Glandular:										
Fibrosarcoma										
		1/49	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	1/99	(1.01%)	Mean 1.02%	SD 1.44%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
#Stomach, Glandular:										
Leiomyosarcoma										
		0/49	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%	SD 1.41%
.....										
#Stomach, Glandular:										
Sarcoma										
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
*Testes:										
Adenoma										
		2/49	(4%)	0/50	(0%)					
Overall Incidence	Total	2/99	(2.02%)	Mean 2.04%	SD 2.89%					
.....										
*Testes:										
Hemangiosarcoma										
		0/49	(0%)	0/50	(0%)					
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%					
.....										
*Thymus:										
Sarcoma										
		0/45	(0%)	0/49	(0%)	0/50	(0%)	1/50	(2%)	
Overall Incidence	Total	0/94	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%	SD 1.41%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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		
*Thymus:							
Thymoma Benign							
		0/45 (0%)	1/49 (2%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/94 (1.06%)	Mean 1.02%	SD 1.44%	Total	1/100 (1%)	Mean 1% SD 1.41%
.....							
*Thymus:							
Thymoma: Benign, Malignant, NOS							
		0/45 (0%)	1/49 (2%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/94 (1.06%)	Mean 1.02%	SD 1.44%	Total	1/100 (1%)	Mean 1% SD 1.41%
.....							
*Thyroid Gland:							
Carcinoma							
		0/45 (0%)	0/50 (0%)		0/45 (0%)	0/50 (0%)	
Overall Incidence	Total	0/95 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0% SD 0%
.....							
*Thyroid Gland: C-Cell:							
Adenoma							
		11/45 (24%)	5/50 (10%)		7/45 (16%)	7/50 (14%)	
Overall Incidence	Total	16/95 (16.84%)	Mean 17.22%	SD 10.21%	Total	14/95 (14.74%)	Mean 14.78% SD 1.1%
.....							
*Thyroid Gland: C-Cell:							
Carcinoma							
		0/45 (0%)	0/50 (0%)		0/45 (0%)	0/50 (0%)	
Overall Incidence	Total	0/95 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0% SD 0%
.....							
*Thyroid Gland: C-Cell:							
Carcinoma or Adenoma							
		11/45 (24%)	5/50 (10%)		7/45 (16%)	7/50 (14%)	
Overall Incidence	Total	16/95 (16.84%)	Mean 17.22%	SD 10.21%	Total	14/95 (14.74%)	Mean 14.78% SD 1.1%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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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 Vehicle: CORN OIL

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		Male				Female			
*Thyroid Gland: Follicular Cell: Adenoma									
		1/45 (2%)	3/50 (6%)		1/45 (2%)	3/50 (6%)			
Overall Incidence	Total	4/95 (4.21%)	Mean 4.11%	SD 2.67%	Total	4/95 (4.21%)	Mean 4.11%	SD 2.67%	
.....									
*Thyroid Gland: Follicular Cell: Carcinoma									
		0/45 (0%)	0/50 (0%)		0/45 (0%)	0/50 (0%)			
Overall Incidence	Total	0/95 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%	
.....									
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma									
		1/45 (2%)	3/50 (6%)		1/45 (2%)	3/50 (6%)			
Overall Incidence	Total	4/95 (4.21%)	Mean 4.11%	SD 2.67%	Total	4/95 (4.21%)	Mean 4.11%	SD 2.67%	
.....									
*Urinary Bladder: Carcinoma or Papilloma									
		0/49 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
.....									
*Urinary Bladder: Papilloma									
		0/49 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
.....									
#Uterus: Adenoma									
					1/50 (2%)	0/50 (0%)			
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%	

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

Version: Aug2016
 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: Carcinoma		
Overall Incidence	Total 1/50 (2%) 4/100 (4%)	3/50 (6%) Mean 4% SD 2.83%
#Uterus: Granular Cell Tumor Benign		
Overall Incidence	Total 1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1% SD 1.41%
#Uterus: Hemangiosarcoma		
Overall Incidence	Total 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
#Uterus: Leiomyosarcoma		
Overall Incidence	Total 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
#Uterus: Malignant Mixed Mullerian Tumor		
Overall Incidence	Total 1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1% SD 1.41%
#Uterus: Polyp Stromal		
Overall Incidence	Total 3/50 (6%) 5/100 (5%)	2/50 (4%) Mean 5% SD 1.41%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: Sarcoma Stromal		
Overall Incidence	Total 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal		
Overall Incidence	Total 3/50 (6%) 5/100 (5%)	2/50 (4%) Mean 5% SD 1.41%
#Uterus: Schwannoma Malignant		
Overall Incidence	Total 1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1% SD 1.41%
#Uterus: Squamous Cell Papilloma		
Overall Incidence	Total 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
#Vagina: Fibrosarcoma		
Overall Incidence	Total 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
#Vagina: Leiomyoma		
Overall Incidence	Total 0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1% SD 1.41%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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%)			0/50	(0%)					
Overall Incidence					Total	0/100	(0%)	Mean	0%	SD	0%				
.....															
#Zymbal's Gland:															
Carcinoma															
		0/49	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)				
Overall Incidence		Total	0/99	(0%)	Mean	0%	SD	0%	Total	0/100	(0%)	Mean	0%	SD	0%
.....															
#Zymbal's Gland:															
Carcinoma or Adenoma															
		0/49	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)				
Overall Incidence		Total	0/99	(0%)	Mean	0%	SD	0%	Total	0/100	(0%)	Mean	0%	SD	0%

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

Version: Aug2016
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: Aug2016
 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			
#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: Aug2016
 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		
#All Organs:							
Histiocytic 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%
.....							
#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%)
							Mean 0%
							SD 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%)
							Mean 2%
							SD 0%
.....							
#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%)
							Mean 0%
							SD 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%)
							Mean 0%
							SD 0%
.....							
#All Organs:							
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%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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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 Vehicle: WATER

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	Male				Female			
#All Organs:								
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%
.....								
#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 Complex								
		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: Aug2016
 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		
*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%
.....							
#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%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/04/2016

		Male			Female		
#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%
.....							
*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:							
Granular Cell Tumor 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%
.....							

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

Version: Aug2016
 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		
*Brain:							
Meningioma Malignant							
		0/50	(0%)		0/50	(0%)	
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (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%)
.....							
*Brain:							
Oligodendroglioma Benign							
		0/50	(0%)		0/50	(0%)	
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (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%)
.....							
*Clitoral/Preputial Gland:							
Carcinoma							
		1/50	(2%)		0/49	(0%)	
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/49 (0%)
.....							
*Clitoral/Preputial Gland:							
Carcinoma or Adenoma							
		1/50	(2%)		0/49	(0%)	
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/49 (0%)
.....							

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
*Heart:									
Schwannoma 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%
.....									
*Heart:									
Schwannoma 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%
.....									
#Intestine Small: Duodenum:									
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%
.....									
#Intestine Small: Duodenum:									
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: Jejunum:									
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%
.....									
#Intestine Small: Jejunum:									
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: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
 Length of Study: CHRONIC

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		Male			Female		
#Intestine Small: Site Unspecified:							
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%
.....							
#Intestine Small: Site Unspecified:							
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%
.....							
#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%
.....							
*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							
		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%
.....							

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
*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									
		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%
.....									
*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%

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

Version: Aug2016
 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			
*Liver:									
Cholangioma									
		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:									
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%
.....									
*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%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
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 Tumor Incidence for Selected Control Animal Groups
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	Male				Female			
*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%
.....								
#Lymph Node:								
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%
.....								
#Lymph Node, Mandibular:								
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%
.....								
#Lymph Node, Mesenteric:								
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%
.....								
#Lymph Node, Mesenteric:								
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%
.....								
#Mammary Gland:								
Adenoma								
		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: Aug2016
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 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		
#Mammary Gland:							
Carcinoma							
		0/50	(0%)		6/50	(12%)	
Overall Incidence	Total	0/50	(0%)	Mean 0%	6/50	(12%)	Mean 12%
				SD 0%			SD 0%
.....							
#Mammary Gland:							
Carcinoma or Adenoma							
		0/50	(0%)		8/50	(16%)	
Overall Incidence	Total	0/50	(0%)	Mean 0%	8/50	(16%)	Mean 16%
				SD 0%			SD 0%
.....							
#Mammary Gland:							
Fibroadenoma							
		0/50	(0%)		11/50	(22%)	
Overall Incidence	Total	0/50	(0%)	Mean 0%	11/50	(22%)	Mean 22%
				SD 0%			SD 0%
.....							
#Mammary Gland:							
Fibroma, Fibroadenoma or Adenoma							
		0/50	(0%)		11/50	(22%)	
Overall Incidence	Total	0/50	(0%)	Mean 0%	11/50	(22%)	Mean 22%
				SD 0%			SD 0%
.....							
#Mammary Gland:							
Fibroma, Fibroadenoma, Carcinoma, or Adenoma							
		0/50	(0%)		15/50	(30%)	
Overall Incidence	Total	0/50	(0%)	Mean 0%	15/50	(30%)	Mean 30%
				SD 0%			SD 0%
.....							
#Mesentery:							
Hemangiosarcoma							
		0/50	(0%)		1/50	(2%)	
Overall Incidence	Total	0/50	(0%)	Mean 0%	1/50	(2%)	Mean 2%
				SD 0%			SD 0%
.....							

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
#Mesentery:									
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%
.....									
#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:									
Adenoma									
		0/50	(0%)			0/49	(0%)		
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/49	(0%)	Mean 0% SD 0%
.....									
*Nose:									
Chondroma									
		0/50	(0%)			0/49	(0%)		
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/49	(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: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
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Toxicology Data Management System
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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:								
Adenoma								
					0/50 (0%)			
Overall Incidence	Total				0/50 (0%)	Mean 0%	SD 0%	
.....								
*Ovary:								
Cystadenoma								
					0/50 (0%)			
Overall Incidence	Total				0/50 (0%)	Mean 0%	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%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
 Length of Study: CHRONIC

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Male					Female					
*Ovary:										
Granulosa Cell Tumor: Benign, Malignant, NOS										
					0/50	(0%)				
Overall Incidence					Total	0/50 (0%)	Mean	0%	SD	0%
.....										
*Ovary:										
Granulosa-Theca Tumor Malignant										
					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%
.....										
*Ovary:										
Tubulostromal Adenoma										
					0/50	(0%)				
Overall Incidence					Total	0/50 (0%)	Mean	0%	SD	0%
.....										
*Pancreas:										
Adenoma										
					0/50	(0%)				
Overall Incidence					Total	0/50 (0%)	Mean	0%	SD	0%
.....										
*Pancreas:										
Carcinoma or 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: Aug2016
 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			
*Parathyroid Gland:								
Adenoma								
		0/47	(0%)			0/47	(0%)	
Overall Incidence	Total	0/47	(0%)	Mean 0%	SD 0%	Total	0/47	(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								
		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:								
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: Aug2016
 Contract/Lab: All Laboratories
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Toxicology Data Management System
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		Male			Female			
*Prostate:								
Adenoma								
		0/50	(0%)					
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%			
.....								
*Prostate:								
Carcinoma								
		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:								
Adenoma								
		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:								
Carcinoma								
		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:								
Carcinoma or Adenoma								
		0/50	(0%)			0/49	(0%)	
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/49	(0%)
							Mean 0%	SD 0%
.....								
*: Denominator is number of animals with tissues examined microscopically								
#: Denominator is number of animals necropsied								

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
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Toxicology Data Management System
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		Male				Female			
*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:									
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%
.....									
#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%
.....									
#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%

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

Version: Aug2016
 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			
#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%
.....								
#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%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
#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:								
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: Aug2016
 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: 08/04/2016

		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:							
Myxoma							
		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%)
.....							

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
#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%)
								Mean 4%
								SD 0%
.....								
#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%

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

Version: Aug2016
 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			
#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%
.....								
#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:								
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%

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

Version: Aug2016
 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		
#Stomach, Forestomach:							
Leiomyoma							
		0/50	(0%)		0/50	(0%)	
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)
.....							
#Stomach, Forestomach:							
Leiomyosarcoma							
		1/50	(2%)		0/50	(0%)	
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/50 (0%)
.....							
#Stomach, Forestomach:							
Sarcoma							
		0/50	(0%)		0/50	(0%)	
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (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%)
.....							
#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%)
.....							
#Stomach, Forestomach:							
Squamous Cell Papilloma							
		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: Aug2016
 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		
#Stomach, Glandular:							
Fibrosarcoma							
		0/50	(0%)			0/50	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)
.....							
#Stomach, Glandular:							
Leiomyosarcoma							
		0/50	(0%)			0/50	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)
.....							
#Stomach, Glandular:							
Sarcoma							
		0/50	(0%)			0/50	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)
.....							
*Testes:							
Adenoma							
		2/50	(4%)				
Overall Incidence	Total	2/50	(4%)	Mean 4%	SD 0%		
.....							
*Testes:							
Hemangiosarcoma							
		0/50	(0%)				
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%		
.....							
*Thymus:							
Sarcoma							
		0/49	(0%)			0/49	(0%)
Overall Incidence	Total	0/49	(0%)	Mean 0%	SD 0%	Total	0/49 (0%)
.....							

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

Version: Aug2016
 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				
*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%)	Mean 6.12%	SD 0%
.....									
*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%)	Mean 6.12%	SD 0%
.....									
*Thyroid 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%
.....									
*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%)	Mean 6%	SD 0%
.....									
*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%)	Mean 2%	SD 0%
.....									
*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%)	Mean 8%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
*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: Adenoma									
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: Aug2016
 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
#Uterus: Carcinoma		
Overall Incidence	Total 3/50 (6%)	Mean 6% SD 0%
#Uterus: Granular Cell Tumor Benign		
Overall Incidence	Total 0/50 (0%)	Mean 0% SD 0%
#Uterus: Hemangiosarcoma		
Overall Incidence	Total 0/50 (0%)	Mean 0% SD 0%
#Uterus: Leiomyosarcoma		
Overall Incidence	Total 0/50 (0%)	Mean 0% SD 0%
#Uterus: Malignant Mixed Mullerian Tumor		
Overall Incidence	Total 0/50 (0%)	Mean 0% SD 0%
#Uterus: Polyp Stromal		
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: Aug2016
 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	
#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: Fibrosarcoma				
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: Aug2016
 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			
#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: Aug2016
 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: 08/04/2016

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	052060103	09/22/08	729	50(5)	30(672)	606.7	Antimony trioxide
Battelle Northwest	052072503	08/17/09	729	50(5)	36(692)	615.2	2,3-Butanedione
Battelle Northwest	052051503	04/14/08	729	50(5)	33(688)	602.8	Metal Working Fluids: CIMSTAR 3800
Battelle Northwest	052052303	07/20/09	729	50(5)	36(696)	622.2	Metal Working Fluids: TRIM VX
Female							
Battelle Northwest	052060103	09/22/08	730	50(5)	39(704)	395.6	Antimony trioxide
Battelle Northwest	052072503	08/17/09	731	50(5)	34(688)	400.0	2,3-Butanedione
Battelle Northwest	052051503	04/14/08	731	50(5)	35(700)	384.9	Metal Working Fluids: CIMSTAR 3800
Battelle Northwest	052052303	07/20/09	731	50(5)	30(681)	391.1	Metal Working Fluids: TRIM VX

Version: Aug2016
 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			
#All Organs:									
Benign Tumors									
		34/50 (68%)	27/50 (54%)	32/50 (64%)		33/50 (66%)	39/50 (78%)	42/50 (84%)	
		24/50 (48%)				42/50 (84%)			
Overall Incidence	Total	117/200 (58.5%)	Mean 58.5%	SD 9.15%	Total	156/200 (78%)	Mean 78%	SD 8.49%	
.....									
#All Organs:									
Malignant Tumors									
		6/50 (12%)	13/50 (26%)	13/50 (26%)		17/50 (34%)	12/50 (24%)	11/50 (22%)	
		4/50 (8%)				13/50 (26%)			
Overall Incidence	Total	36/200 (18%)	Mean 18%	SD 9.38%	Total	53/200 (26.5%)	Mean 26.5%	SD 5.26%	
.....									
#All Organs:									
Malignant and Benign Tumors									
		36/50 (72%)	35/50 (70%)	37/50 (74%)		40/50 (80%)	40/50 (80%)	43/50 (86%)	
		26/50 (52%)				47/50 (94%)			
Overall Incidence	Total	134/200 (67%)	Mean 67%	SD 10.13%	Total	170/200 (85%)	Mean 85%	SD 6.63%	
.....									
#All Organs:									
Hemangioma									
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#All Organs:									
Hemangiosarcoma									
		3/50 (6%)	3/50 (6%)	3/50 (6%)		1/50 (2%)	2/50 (4%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	9/200 (4.5%)	Mean 4.5%	SD 3%	Total	4/200 (2%)	Mean 2%	SD 1.63%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
#All Organs:									
Hemangiosarcoma or Hemangioma									
		4/50 (8%)	4/50 (8%)	3/50 (6%)		1/50 (2%)	3/50 (6%)	1/50 (2%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	12/200 (6%)	Mean 6%	SD 2.83%	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	
.....									
#All Organs:									
Histiocytic Sarcoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				2/50 (4%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 2%	
.....									
#All Organs:									
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type									
		0/50 (0%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	2/50 (4%)	
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.83%	Total	4/200 (2%)	Mean 2%	SD 1.63%	
.....									
#All Organs:									
Mesothelioma: Benign, Malignant, NOS									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
#All Organs:									
Mesothelioma: Malignant									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Osteoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Osteosarcoma or Osteoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Cortex:									
Adenoma									
		3/50 (6%)	2/50 (4%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	2/50 (4%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	8/200 (4%)	Mean 4%	SD 1.63%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
*Adrenal Cortex:									
 Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla:									
 Pheochromocytoma Benign									
		1/49 (2%)	1/50 (2%)	4/50 (8%)		0/49 (0%)	3/50 (6%)	1/49 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	6/199 (3.02%)	Mean 3.01%	SD 3.46%	Total	4/198 (2.02%)	Mean 2.01%	SD 2.83%	
.....									
*Adrenal Medulla:									
 Pheochromocytoma Complex									
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/198 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla:									
 Pheochromocytoma Malignant									
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	1/49 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	
.....									
*Adrenal Medulla:									
 Pheochromocytoma: Benign, Complex, Malignant, NOS									
		2/49 (4%)	1/50 (2%)	4/50 (8%)		0/49 (0%)	3/50 (6%)	2/49 (4%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	7/199 (3.52%)	Mean 3.52%	SD 3.42%	Total	5/198 (2.53%)	Mean 2.52%	SD 3.01%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
#Blood Vessel:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Bone Marrow:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Osteoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Osteosarcoma or Osteoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
 Length of Study: CHRONIC

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 Tumor Incidence for Selected Control Animal Groups
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		Male				Female			
#Bone:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Glioma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Glioma Malignant									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Granular Cell Tumor Benign									
		1/50 (2%)	3/50 (6%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	2/50 (4%)	2/50 (4%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.83%	Total	4/200 (2%)	Mean 2%	SD 1.63%	
.....									
*Brain:									
Granular Cell Tumor Malignant									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
*Brain:									
Meningioma Malignant									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Meningioma: Benign, Malignant, NOS									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Oligodendroglioma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Brain:									
Oligodendroglioma, Glioma, or Astrocytoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Clitoral/Preputial Gland:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/49 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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
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		Male				Female			
*Clitoral/Preputial Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/49 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Heart:									
Schwannoma Benign									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Heart:									
Schwannoma NOS									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Duodenum:									
Fibroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Duodenum:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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
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		Male				Female			
#Intestine Small: Jejunum:									
Leiomyoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Intestine Small: Jejunum:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified:									
Fibroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified:									
Leiomyoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Intestine Small: Site Unspecified:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
*Islets, Pancreatic:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/49 (2%)	
		5/50 (10%)				0/50 (0%)			
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 5%	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	
.....									
*Islets, Pancreatic:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Islets, Pancreatic:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/49 (2%)	
		5/50 (10%)				0/50 (0%)			
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 5%	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	
.....									
*Kidney: Pelvis and Transitional Epithelium:									
Papilloma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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
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		Male				Female			
*Kidney: Renal Tubule: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Kidney: Renal Tubule: Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Liposarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Liver: Cholangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 3%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
*Liver:									
Hemangioma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Hepatocellular Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Liver:									
Hepatocellular Carcinoma or Hepatocellular Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Liver:									
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Lung:									
Alveolar/Bronchiolar Adenoma									
		3/50 (6%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
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		Male				Female			
*Lung:									
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma									
		3/50 (6%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node, Mandibular:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Lymph Node, Mesenteric:									
Hemangioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node, Mesenteric:									
Hemangiosarcoma									
		2/50 (4%)	2/50 (4%)	3/50 (6%)		0/50 (0%)	2/50 (4%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 2.52%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
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		Male				Female			
#Mammary Gland: Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	5/50 (10%)	2/50 (4%)	
		0/50 (0%)				4/50 (8%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	11/200 (5.5%)	Mean 5.5%	SD 4.43%	
.....									
#Mammary Gland: Carcinoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		5/50 (10%)	4/50 (8%)	4/50 (8%)	
		0/50 (0%)				4/50 (8%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	17/200 (8.5%)	Mean 8.5%	SD 1%	
.....									
#Mammary Gland: Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		5/50 (10%)	8/50 (16%)	6/50 (12%)	
		0/50 (0%)				8/50 (16%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	27/200 (13.5%)	Mean 13.5%	SD 3%	
.....									
#Mammary Gland: Fibroadenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		7/50 (14%)	13/50 (26%)	9/50 (18%)	
		0/50 (0%)				2/50 (4%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	31/200 (15.5%)	Mean 15.5%	SD 9.15%	
.....									
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		7/50 (14%)	15/50 (30%)	11/50 (22%)	
		0/50 (0%)				6/50 (12%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	39/200 (19.5%)	Mean 19.5%	SD 8.23%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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		Male				Female			
#Mammary Gland:									
Fibroma, Fibroadenoma, Carcinoma, or Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		10/50 (20%)	15/50 (30%)	13/50 (26%)	
		0/50 (0%)				9/50 (18%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	47/200 (23.5%)	Mean 23.5%	SD 5.51%	
.....									
#Mesentery:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Nose:									
Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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		Male				Female			
*Nose:									
Chondroma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Nose:									
Olfactory Neuroblastoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Oral Mucosa:									
Squamous Cell Carcinoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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	Male		Female
*Ovary:			
Adenoma			
		2/50 (4%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1% SD 2%
.....			
*Ovary:			
Cystadenoma			
		1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5% SD 1%
.....			
*Ovary:			
Granulosa Cell Tumor Benign			
		0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5% SD 1%
.....			
*Ovary:			
Granulosa Cell Tumor Malignant			
		0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5% SD 1%
.....			
*Ovary:			
Granulosa Cell Tumor: Benign, Malignant, NOS			
		0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)
Overall Incidence	Total	2/200 (1%)	Mean 1% SD 1.15%

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

Version: Aug2016
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					Male						Female														
*Ovary:																									
Granulosa-Theca Tumor Malignant																									
					0/50	(0%)						1/50	(2%)												
					0/50	(0%)						0/50	(0%)												
Overall Incidence					Total		1/200 (0.5%)		Mean		0.5%		SD		1%										
.....																									
*Ovary:																									
Sex Cord Stromal Tumor, Benign																									
					0/50	(0%)						0/50	(0%)												
					0/50	(0%)						0/50	(0%)												
Overall Incidence					Total		0/200 (0%)		Mean		0%		SD		0%										
.....																									
*Ovary:																									
Tubulostromal Adenoma																									
					2/50	(4%)						1/50	(2%)												
					0/50	(0%)						0/50	(0%)												
Overall Incidence					Total		3/200 (1.5%)		Mean		1.5%		SD		1.91%										
.....																									
*Pancreas:																									
Adenoma																									
			0/50	(0%)	0/50		(0%)	1/50		(2%)				0/50	(0%)	0/50		(0%)	0/49		(0%)				
			1/50	(2%)	Mean		1%		SD		1.15%					0/50	(0%)	Mean		0%		SD		0%	
Overall Incidence					Total		2/200 (1%)		Total		0/199 (0%)		Mean		0%		SD		0%						
.....																									
*Pancreas:																									
Carcinoma or Adenoma																									
			0/50	(0%)	0/50		(0%)	1/50		(2%)				0/50	(0%)	0/50		(0%)	0/49		(0%)				
			1/50	(2%)	Mean		1%		SD		1.15%					0/50	(0%)	Mean		0%		SD		0%	
Overall Incidence					Total		2/200 (1%)		Total		0/199 (0%)		Mean		0%		SD		0%						

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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		Male				Female			
*Parathyroid Gland:									
Adenoma									
		0/44 (0%)	1/49 (2%)	0/43 (0%)		0/39 (0%)	0/46 (0%)	0/47 (0%)	
		0/39 (0%)				1/42 (2%)			
Overall Incidence	Total	1/175 (0.57%)	Mean 0.51%	SD 1.02%	Total	1/174 (0.57%)	Mean 0.6%	SD 1.19%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Adenoma									
		14/50 (28%)	9/50 (18%)	16/49 (33%)		19/50 (38%)	26/50 (52%)	35/50 (70%)	
		14/50 (28%)				34/50 (68%)			
Overall Incidence	Total	53/199 (26.63%)	Mean 26.66%	SD 6.18%	Total	114/200 (57%)	Mean 57%	SD 15.01%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma or Adenoma									
		14/50 (28%)	9/50 (18%)	16/49 (33%)		20/50 (40%)	26/50 (52%)	35/50 (70%)	
		14/50 (28%)				34/50 (68%)			
Overall Incidence	Total	53/199 (26.63%)	Mean 26.66%	SD 6.18%	Total	115/200 (57.5%)	Mean 57.5%	SD 14.18%	
.....									
*Pituitary Gland: Pars Intermedia:									
Adenoma									
		1/50 (2%)	2/50 (4%)	2/49 (4%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	6/199 (3.02%)	Mean 3.02%	SD 1.18%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
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		Male				Female			
*Pituitary Gland: Pars Intermedia:									
 Carcinoma or Adenoma									
		1/50 (2%)	2/50 (4%)	2/49 (4%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	6/199 (3.02%)	Mean 3.02%	SD 1.18%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	
.....									
*Prostate:									
 Adenoma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)					
		0/50 (0%)							
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%					
.....									
*Prostate:									
 Carcinoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)					
		0/50 (0%)							
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%					
.....									
*Prostate:									
 Carcinoma or Adenoma									
		1/50 (2%)	1/50 (2%)	1/50 (2%)					
		0/50 (0%)							
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%					
.....									
*Salivary Glands:									
 Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
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		Male				Female			
*Salivary Glands:									
 Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Salivary Glands:									
 Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Salivary Glands:									
 Myoepithelioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Salivary Glands:									
 Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Seminal Vesicle:									
 Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)					
		0/50 (0%)							
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%					

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
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		Male				Female			
#Skeletal Muscle:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skeletal Muscle:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Adenoma or Basosquamous Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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 Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma									
		1/50 (2%)	3/50 (6%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Fibroma									
		2/50 (4%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	2/200 (1%)	Mean 1%	SD 2%	

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

Version: Aug2016
 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:									
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma									
		2/50 (4%)	2/50 (4%)	2/50 (4%)		2/50 (4%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 2%	
.....									
#Skin:									
Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Fibrous Histiocytoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Hamartoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Keratoacanthoma									
		1/50 (2%)	3/50 (6%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Lipoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Liposarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Myxoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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:									
Neurofibrosarcoma or Schwannoma (malignant or NOS)									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	

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

Version: Aug2016
 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:									
Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma or Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma									
		1/50 (2%)	3/50 (6%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma									
		1/50 (2%)	3/50 (6%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin: Sebaceous Gland:									
Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%	

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

Version: Aug2016
 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
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		Male				Female			
#Skin: Sebaceous Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
Hemangiosarcoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Forestomach:									
Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Forestomach:									
Leiomyoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Stomach, Forestomach:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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
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		Male				Female			
#Stomach, Forestomach:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma or Papilloma Squamous									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Stomach, Forestomach:									
Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Stomach, Glandular:									
Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
#Stomach, Glandular:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Stomach, Glandular:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Testes:									
Adenoma									
		6/50 (12%)	3/50 (6%)	2/50 (4%)					
		0/50 (0%)							
Overall Incidence	Total	11/200 (5.5%)	Mean 5.5%	SD 5%					
.....									
*Testes:									
Hemangiosarcoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)							
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%					
.....									
*Thymus:									
Sarcoma									
		0/41 (0%)	0/47 (0%)	0/40 (0%)		0/46 (0%)	0/49 (0%)	0/48 (0%)	
		0/48 (0%)				0/48 (0%)			
Overall Incidence	Total	0/176 (0%)	Mean 0%	SD 0%	Total	0/191 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
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		Male				Female			
*Thymus:									
Thymoma Benign									
		3/41 (7%)	1/47 (2%)	1/40 (3%)		6/46 (13%)	0/49 (0%)	5/48 (10%)	
		3/48 (6%)				8/48 (17%)			
Overall Incidence	Total	8/176 (4.55%)	Mean 4.55%	SD 2.62%	Total	19/191 (9.95%)	Mean 10.03%	SD 7.16%	
.....									
*Thymus:									
Thymoma: Benign, Malignant, NOS									
		3/41 (7%)	1/47 (2%)	1/40 (3%)		6/46 (13%)	0/49 (0%)	5/48 (10%)	
		3/48 (6%)				8/48 (17%)			
Overall Incidence	Total	8/176 (4.55%)	Mean 4.55%	SD 2.62%	Total	19/191 (9.95%)	Mean 10.03%	SD 7.16%	
.....									
*Thyroid Gland:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Thyroid Gland: C-Cell:									
Adenoma									
		5/50 (10%)	6/50 (12%)	7/50 (14%)		4/50 (8%)	2/50 (4%)	3/50 (6%)	
		3/50 (6%)				7/49 (14%)			
Overall Incidence	Total	21/200 (10.5%)	Mean 10.5%	SD 3.42%	Total	16/199 (8.04%)	Mean 8.07%	SD 4.45%	
.....									
*Thyroid Gland: C-Cell:									
Carcinoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
 Length of Study: CHRONIC

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 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
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		Male				Female			
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
		6/50 (12%)	6/50 (12%)	7/50 (14%)		5/50 (10%)	3/50 (6%)	3/50 (6%)	
		3/50 (6%)				7/49 (14%)			
Overall Incidence	Total	22/200 (11%)	Mean 11%	SD 3.46%	Total	18/199 (9.05%)	Mean 9.07%	SD 3.95%	
.....									
*Thyroid Gland: Follicular Cell: Adenoma									
		0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%)	2/50 (4%)	1/50 (2%)	
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	4/199 (2.01%)	Mean 2%	SD 1.63%	
.....									
*Thyroid Gland: Follicular Cell: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				1/49 (2%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	
.....									
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma									
		0/50 (0%)	2/50 (4%)	1/50 (2%)		2/50 (4%)	2/50 (4%)	2/50 (4%)	
		0/50 (0%)				1/49 (2%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	7/199 (3.52%)	Mean 3.51%	SD 0.98%	
.....									
*Urinary Bladder: Carcinoma or Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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			
*Urinary Bladder:									
Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Uterus:									
Adenoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						1/50 (2%)			
Overall Incidence	Total				Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Uterus:									
Carcinoma									
						3/50 (6%)	2/50 (4%)	1/50 (2%)	
						1/50 (2%)			
Overall Incidence	Total				Total	7/200 (3.5%)	Mean 3.5%	SD 1.91%	
.....									
#Uterus:									
Granular Cell Tumor Benign									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						1/50 (2%)			
Overall Incidence	Total				Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Uterus:									
Hemangiosarcoma									
						1/50 (2%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
Overall Incidence	Total				Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

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

Version: Aug2016
 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
#Uterus: Leiomyosarcoma	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total 1/200 (0.5%)	Mean 0.5% SD 1%
#Uterus: Malignant Mixed Mullerian Tumor	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total 0/200 (0%)	Mean 0% SD 0%
#Uterus: Polyp Stromal	2/50 (4%) 6/50 (12%)	9/50 (18%) 5/50 (10%)
Overall Incidence	Total 22/200 (11%)	Mean 11% SD 5.77%
#Uterus: Sarcoma Stromal	1/50 (2%) 1/50 (2%)	1/50 (2%) 2/50 (4%)
Overall Incidence	Total 5/200 (2.5%)	Mean 2.5% SD 1%
#Uterus: Sarcoma Stromal or Polyp Stromal	3/50 (6%) 7/50 (14%)	10/50 (20%) 6/50 (12%)
Overall Incidence	Total 26/200 (13%)	Mean 13% SD 5.77%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Wistar-Han
 Length of Study: CHRONIC

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 Tumor Incidence for Selected Control Animal Groups
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	Male	Female
#Uterus: Schwannoma Malignant		
	0/50 (0%) 2/50 (4%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total 3/200 (1.5%)	Mean 1.5% SD 1.91%
#Uterus: Squamous Cell Papilloma		
	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total 1/200 (0.5%)	Mean 0.5% SD 1%
#Vagina: Fibrosarcoma		
	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total 1/200 (0.5%)	Mean 0.5% SD 1%
#Vagina: Leiomyoma		
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total 0/200 (0%)	Mean 0% SD 0%
#Vagina: Polyp		
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total 0/200 (0%)	Mean 0% SD 0%

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

Version: Aug2016
 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			
#Zymbal's Gland:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Zymbal's Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied