



National Toxicology Program
Department of Health and Human Services

NTP Historical Controls Report

All Routes and Vehicles

Harlan Sprague-Dawley 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.

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

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

Male

M1
M2
M3
M4
M5

Female

F1
F2
F3
F4
F5

the data would be shown as:

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

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

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

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
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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	052000603	03/14/07	727	50(3)	20(644)	584.8	Indole-3-carbinol
Battelle Northwest	051047203	01/17/11	729	50(5)	25(661)	609.4	p-Chloro-a,a,a-trifluorotoluene
Female							
Battelle Columbus Laboratory	052000603	03/15/07	729	50(5)	21(637)	353.0	Indole-3-carbinol
Battelle Northwest	051047203	01/17/11	731	50(5)	22(626)	377.3	p-Chloro-a,a,a-trifluorotoluene

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

Version: Aug2016
 Contract/Lab: All Laboratories
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Toxicology Data Management System
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		Male			Female		
#All Organs:							
Benign Tumors							
		27/50 (54%)	30/50 (60%)		40/50 (80%)	39/50 (78%)	
Overall Incidence	Total	57/100 (57%)	Mean 57%	SD 4.24%	Total	79/100 (79%)	Mean 79% SD 1.41%
.....							
#All Organs:							
Malignant Tumors							
		12/50 (24%)	12/50 (24%)		14/50 (28%)	11/50 (22%)	
Overall Incidence	Total	24/100 (24%)	Mean 24%	SD 0%	Total	25/100 (25%)	Mean 25% SD 4.24%
.....							
#All Organs:							
Malignant and Benign Tumors							
		33/50 (66%)	37/50 (74%)		46/50 (92%)	41/50 (82%)	
Overall Incidence	Total	70/100 (70%)	Mean 70%	SD 5.66%	Total	87/100 (87%)	Mean 87% SD 7.07%
.....							
#All Organs:							
Hemangioma							
		0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Hemangiosarcoma							
		1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1% SD 1.41%
.....							
#All Organs:							
Hemangiosarcoma or Hemangioma							
		1/50 (2%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	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
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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%)	1/50	(2%)	0/50	(0%)	
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%	SD 1.41%
.....										
#All Organs:										
Leukemia: Granulocytic										
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
#All Organs:										
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated										
		0/50	(0%)	3/50	(6%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	3/100	(3%)	Mean 3%	SD 4.24%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
#All Organs:										
Mesothelioma: Benign, Malignant, NOS										
		1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	2/100	(2%)	Mean 2%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
#All Organs:										
Mesothelioma: Malignant										
		1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	2/100	(2%)	Mean 2%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
*Adrenal Cortex:										
Adenoma										
		0/50	(0%)	3/50	(6%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	3/100	(3%)	Mean 3%	SD 4.24%	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
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

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		Male			Female		
*Adrenal Medulla:							
 Pheochromocytoma Benign							
		5/50 (10%)	12/50 (24%)		0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	17/100 (17%)	Mean 17%	SD 9.9%	Total	0/99 (0%)	Mean 0%
							SD 0%
*Adrenal Medulla:							
 Pheochromocytoma Complex							
		1/50 (2%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%
							SD 0%
*Adrenal Medulla:							
 Pheochromocytoma Malignant							
		2/50 (4%)	2/50 (4%)		0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	0/99 (0%)	Mean 0%
							SD 0%
*Adrenal Medulla:							
 Pheochromocytoma: Benign, Complex, Malignant, NOS							
		8/50 (16%)	14/50 (28%)		0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	22/100 (22%)	Mean 22%	SD 8.49%	Total	0/99 (0%)	Mean 0%
							SD 0%
*Brain:							
 Glioma Malignant							
		0/50 (0%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/100 (1%)	Mean 1%
							SD 1.41%
*Brain:							
 Granular Cell Tumor Benign							
		0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (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
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

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	Male					Female				
*Brain:										
Oligodendroglioma, Glioma, or Astrocytoma										
		0/50	(0%)	2/50	(4%)		0/50	(0%)	1/50	(2%)
Overall Incidence	Total	2/100	(2%)	Mean 2%	SD 2.83%	Total	1/100	(1%)	Mean 1%	SD 1.41%
.....										
*Brain:										
Schwannoma Malignant										
		0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%	SD 1.41%
.....										
*Epididymis:										
Sarcoma										
		0/50	(0%)	1/50	(2%)					
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%					
.....										
#Eye:										
Leiomyoma										
		0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
*Heart:										
Schwannoma Malignant										
		1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
#Intestine Large: Colon/Rectum:										
Leiomyoma										
		0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	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
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
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		Male				Female					
#Intestine Small: Jejunum:											
Leiomyosarcoma											
		0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Intestine Small: Site Unspecified:											
Leiomyosarcoma											
		0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Islets, Pancreatic:											
Adenoma											
		2/50	(4%)	8/50	(16%)			0/50	(0%)	1/50	(2%)
Overall Incidence	Total	10/100	(10%)	Mean 10%	SD 8.49%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
*Islets, Pancreatic:											
Carcinoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
*Islets, Pancreatic:											
Carcinoma or Adenoma											
		2/50	(4%)	8/50	(16%)			0/50	(0%)	2/50	(4%)
Overall Incidence	Total	10/100	(10%)	Mean 10%	SD 8.49%	Total	2/100	(2%)	Mean 2%	SD 2.83%	
.....											
*Kidney: Renal Tubule:											
Adenoma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	1/50	(2%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	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: Harlan Sprague-Dawley
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

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		Male				Female					
*Kidney: Renal Tubule:											
 Carcinoma or Adenoma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	1/50	(2%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
*Liver:											
 Hepatocellular Adenoma											
		1/50	(2%)	0/50	(0%)			2/50	(4%)	2/50	(4%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	4/100	(4%)	Mean 4%	SD 0%	
.....											
*Liver:											
 Hepatocellular Carcinoma or Hepatocellular Adenoma											
		1/50	(2%)	0/50	(0%)			2/50	(4%)	2/50	(4%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	4/100	(4%)	Mean 4%	SD 0%	
.....											
*Liver:											
 Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma											
		1/50	(2%)	0/50	(0%)			2/50	(4%)	2/50	(4%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	4/100	(4%)	Mean 4%	SD 0%	
.....											
*Lung:											
 Alveolar/Bronchiolar Adenoma											
		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%	
.....											
*Lung:											
 Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma											
		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: Harlan Sprague-Dawley
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
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		Male				Female				
*Lung:										
Sarcoma										
		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%
.....										
#Lymph Node, Mesenteric:										
Hemangiosarcoma										
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
#Mammary Gland:										
Adenoma										
		0/50	(0%)	0/50	(0%)	3/50	(6%)	4/50	(8%)	
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	7/100	(7%)	Mean 7%	SD 1.41%
.....										
#Mammary Gland:										
Carcinoma										
		0/50	(0%)	0/50	(0%)	3/50	(6%)	5/50	(10%)	
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	8/100	(8%)	Mean 8%	SD 2.83%
.....										
#Mammary Gland:										
Carcinoma or Adenoma										
		0/50	(0%)	0/50	(0%)	6/50	(12%)	9/50	(18%)	
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	15/100	(15%)	Mean 15%	SD 4.24%
.....										
#Mammary Gland:										
Fibroadenoma										
		1/50	(2%)	2/50	(4%)	29/50	(58%)	20/50	(40%)	
Overall Incidence	Total	3/100	(3%)	Mean 3%	SD 1.41%	Total	49/100	(49%)	Mean 49%	SD 12.73%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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		Male				Female					
#Mammary Gland:											
Fibroma, Fibroadenoma or Adenoma											
		1/50	(2%)	2/50	(4%)			30/50	(60%)	23/50	(46%)
Overall Incidence	Total	3/100	(3%)	Mean 3%	SD 1.41%	Total	53/100	(53%)	Mean 53%	SD 9.9%	
.....											
#Mammary Gland:											
Fibroma, Fibroadenoma, Carcinoma, or Adenoma											
		1/50	(2%)	2/50	(4%)			32/50	(64%)	27/50	(54%)
Overall Incidence	Total	3/100	(3%)	Mean 3%	SD 1.41%	Total	59/100	(59%)	Mean 59%	SD 7.07%	
.....											
#Mammary Gland:											
Myoepithelioma											
		0/50	(0%)	0/50	(0%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/100	(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											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):											
Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Oral Mucosa:											
Squamous Cell Carcinoma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	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
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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				Male					Female
*Ovary:									
Granulosa Cell Tumor Benign									
					0/50 (0%)		3/50 (6%)		
Overall Incidence				Total	3/100 (3%)		Mean 3%		SD 4.24%
.....									
*Ovary:									
Granulosa Cell Tumor: Benign, Malignant, NOS									
					0/50 (0%)		3/50 (6%)		
Overall Incidence				Total	3/100 (3%)		Mean 3%		SD 4.24%
.....									
*Ovary:									
Granulosa-Theca Tumor Benign									
					1/50 (2%)		0/50 (0%)		
Overall Incidence				Total	1/100 (1%)		Mean 1%		SD 1.41%
.....									
*Ovary:									
Thecoma Benign									
					0/50 (0%)		1/50 (2%)		
Overall Incidence				Total	1/100 (1%)		Mean 1%		SD 1.41%
.....									
*Ovary:									
Tubulostromal Carcinoma									
					1/50 (2%)		0/50 (0%)		
Overall Incidence				Total	1/100 (1%)		Mean 1%		SD 1.41%
.....									
*Pancreas:									
Adenoma									
		5/50 (10%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 7.07%	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: Harlan Sprague-Dawley
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
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		Male			Female			
*Pancreas:								
Carcinoma or Adenoma								
		5/50 (10%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 7.07%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
*Pituitary Gland: Pars Distalis or Unspecified Site:								
Adenoma								
		5/50 (10%)	11/50 (22%)		18/50 (36%)	18/50 (36%)		
Overall Incidence	Total	16/100 (16%)	Mean 16%	SD 8.49%	Total	36/100 (36%)	Mean 36%	SD 0%
.....								
*Pituitary Gland: Pars Distalis or Unspecified Site:								
Carcinoma or Adenoma								
		5/50 (10%)	11/50 (22%)		18/50 (36%)	18/50 (36%)		
Overall Incidence	Total	16/100 (16%)	Mean 16%	SD 8.49%	Total	36/100 (36%)	Mean 36%	SD 0%
.....								
*Salivary Glands:								
Schwannoma Malignant								
		1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Skeletal Muscle:								
Liposarcoma								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
.....								
#Skeletal Muscle:								
Sarcoma								
		0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	0/100 (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
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 Length of Study: CHRONIC

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

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 Report Date: 08/09/2016

		Male				Female					
#Skin:											
Basal Cell Carcinoma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	1/50	(2%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
#Skin:											
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	1/50	(2%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
#Skin:											
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	1/50	(2%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	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											
		6/50	(12%)	4/50	(8%)			0/50	(0%)	1/50	(2%)
Overall Incidence	Total	10/100	(10%)	Mean 10%	SD 2.83%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
#Skin:											
Fibroma											
		5/50	(10%)	0/50	(0%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	5/100	(5%)	Mean 5%	SD 7.07%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
#Skin:											
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma											
		7/50	(14%)	1/50	(2%)			2/50	(4%)	0/50	(0%)
Overall Incidence	Total	8/100	(8%)	Mean 8%	SD 8.49%	Total	2/100	(2%)	Mean 2%	SD 2.83%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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 Report Date: 08/09/2016

		Male				Female					
#Skin:											
Fibrosarcoma											
		1/50	(2%)	0/50	(0%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
#Skin:											
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma											
		2/50	(4%)	1/50	(2%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	3/100	(3%)	Mean 3%	SD 1.41%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
#Skin:											
Fibrous Histiocytoma											
		1/50	(2%)	1/50	(2%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/100	(2%)	Mean 2%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Skin:											
Hemangioma											
		0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Skin:											
Hemangiosarcoma											
		0/50	(0%)	0/50	(0%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
#Skin:											
Keratoacanthoma											
		4/50	(8%)	3/50	(6%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	7/100	(7%)	Mean 7%	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

		Male				Female			
#Skin:									
Lipoma									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%
SD 0%									
#Skin:									
Neurofibrosarcoma or Schwannoma (malignant or NOS)									
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%
SD 1.41%									
#Skin:									
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)									
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%
SD 1.41%									
#Skin:									
Schwannoma Malignant									
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%
SD 1.41%									
#Skin:									
Squamous Cell Carcinoma									
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%
SD 0%									
#Skin:									
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma									
		2/50	(4%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	2/100	(2%)	Mean 2%	SD 2.83%	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: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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		Male				Female			
#Skin:									
Squamous Cell Papilloma									
		1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/100	(2%)	Mean 2%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Skin:									
Squamous Cell Papilloma or Papilloma									
		1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/100	(2%)	Mean 2%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma									
		5/50	(10%)	4/50	(8%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	9/100	(9%)	Mean 9%	SD 1.41%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma									
		5/50	(10%)	4/50	(8%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	9/100	(9%)	Mean 9%	SD 1.41%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Skin: Sebaceous Gland:									
Adenoma									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Skin: Sebaceous Gland:									
Carcinoma or Adenoma									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	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: Harlan Sprague-Dawley
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
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		Male				Female					
#Stomach, Forestomach:											
Squamous Cell Carcinoma											
		1/50	(2%)	0/50	(0%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
#Stomach, Forestomach:											
Squamous Cell Carcinoma or Papilloma Squamous											
		1/50	(2%)	0/50	(0%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
*Testes:											
Adenoma											
		3/49	(6%)	0/50	(0%)						
Overall Incidence	Total	3/99	(3.03%)	Mean 3.06%	SD 4.33%						
.....											
*Thymus:											
Thymoma Benign											
		1/46	(2%)	0/48	(0%)			0/47	(0%)	0/50	(0%)
Overall Incidence	Total	1/94	(1.06%)	Mean 1.09%	SD 1.54%	Total	0/97	(0%)	Mean 0%	SD 0%	
.....											
*Thymus:											
Thymoma: Benign, Malignant, NOS											
		1/46	(2%)	0/48	(0%)			0/47	(0%)	0/50	(0%)
Overall Incidence	Total	1/94	(1.06%)	Mean 1.09%	SD 1.54%	Total	0/97	(0%)	Mean 0%	SD 0%	
.....											
*Thyroid Gland: C-Cell:											
Adenoma											
		13/50	(26%)	2/50	(4%)			11/49	(22%)	2/50	(4%)
Overall Incidence	Total	15/100	(15%)	Mean 15%	SD 15.56%	Total	13/99	(13.13%)	Mean 13.22%	SD 13.05%	

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Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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 Report Date: 08/09/2016

		Male				Female			
*Thyroid Gland: C-Cell: Carcinoma									
		0/50 (0%)	1/50 (2%)			0/49 (0%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
		13/50 (26%)	3/50 (6%)			11/49 (22%)	2/50 (4%)		
Overall Incidence	Total	16/100 (16%)	Mean 16%	SD 14.14%	Total	13/99 (13.13%)	Mean 13.22%	SD 13.05%	
#Tooth: Odontoma									
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Uterus: Carcinoma									
						0/50 (0%)	1/50 (2%)		
Overall Incidence	Total				Total	1/100 (1%)	Mean 1%	SD 1.41%	
#Uterus: Polyp Stromal									
						10/50 (20%)	7/50 (14%)		
Overall Incidence	Total				Total	17/100 (17%)	Mean 17%	SD 4.24%	
#Uterus: Sarcoma Stromal									
						2/50 (4%)	0/50 (0%)		
Overall Incidence	Total				Total	2/100 (2%)	Mean 2%	SD 2.83%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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					Male						Female
#Uterus:											
Sarcoma Stromal or Polyp Stromal											
						12/50	(24%)		7/50	(14%)	
Overall Incidence					Total	19/100	(19%)	Mean	19%	SD	7.07%
.....											
#Uterus:											
Squamous Cell Carcinoma											
						0/50	(0%)		1/50	(2%)	
Overall Incidence					Total	1/100	(1%)	Mean	1%	SD	1.41%
.....											
#Vagina:											
Granular Cell Tumor Benign											
						0/50	(0%)		1/50	(2%)	
Overall Incidence					Total	1/100	(1%)	Mean	1%	SD	1.41%
.....											
#Vagina:											
Polyp											
						1/50	(2%)		0/50	(0%)	
Overall Incidence					Total	1/100	(1%)	Mean	1%	SD	1.41%
.....											
#Vagina:											
Schwannoma Malignant											
						1/50	(2%)		1/50	(2%)	
Overall Incidence					Total	2/100	(2%)	Mean	2%	SD	0%
.....											
#Zymbal's Gland:											
Carcinoma											
						0/50	(0%)		0/50	(0%)	
Overall Incidence					Total	1/100	(1%)	Mean	1%	SD	1.41%
						0/50	(0%)		0/50	(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: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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		Male				Female				
#Zymbal's Gland:										
Carcinoma or Adenoma										
		0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	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