



National Toxicology Program
Department of Health and Human Services

NTP Historical Controls Report

All Routes and Vehicles

Harlan Sprague-Dawley RATS

November 2017

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: Nov2017
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

Page: 3
Report Date: 01/20/2018

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	051026001	11/08/10	729	50(2)	30(706)	615.3	2-Hydroxy-4-methoxybenzophenone
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
I. I. T. Research Institute	052010556	09/16/12	730	90(1)	25(642)	658.1	Radiofrequency Radiation
Female							
Battelle Columbus Laboratory	051026001	11/09/10	730	50(4)	30(657)	379.6	2-Hydroxy-4-methoxybenzophenone
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
I. I. T. Research Institute	052010556	09/16/12	737	90(1)	48(659)	462.4	Radiofrequency Radiation

Version: Nov2017
 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

Page: 4
 Report Date: 01/20/2018

		Male			Female		
#All Organs:							
Benign Tumors							
		38/50 (76%)	27/50 (54%)	30/50 (60%)	41/50 (82%)	40/50 (80%)	39/50 (78%)
		49/90 (54%)			82/90 (91%)		
Overall Incidence	Total	144/240 (60%)	Mean 61.11%	SD 10.29%	Total	202/240 (84.17%)	Mean 82.78% SD 5.79%
.....							
#All Organs:							
Malignant Tumors							
		11/50 (22%)	12/50 (24%)	12/50 (24%)	15/50 (30%)	14/50 (28%)	11/50 (22%)
		24/90 (27%)			37/90 (41%)		
Overall Incidence	Total	59/240 (24.58%)	Mean 24.17%	SD 1.91%	Total	77/240 (32.08%)	Mean 30.28% SD 7.98%
.....							
#All Organs:							
Malignant and Benign Tumors							
		42/50 (84%)	33/50 (66%)	37/50 (74%)	47/50 (94%)	46/50 (92%)	41/50 (82%)
		57/90 (63%)			89/90 (99%)		
Overall Incidence	Total	169/240 (70.42%)	Mean 71.83%	SD 9.29%	Total	223/240 (92.92%)	Mean 91.72% SD 7.1%
.....							
#All Organs:							
Hemangioma							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)			0/90 (0%)		
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	0/240 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Hemangiosarcoma							
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
		3/90 (3%)			3/90 (3%)		
Overall Incidence	Total	4/240 (1.67%)	Mean 1.33%	SD 1.63%	Total	4/240 (1.67%)	Mean 1.33% SD 1.63%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 5
 Report Date: 01/20/2018

		Male				Female			
#All Organs:									
Hemangiosarcoma or Hemangioma									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		3/90 (3%)				3/90 (3%)			
Overall Incidence	Total	5/240 (2.08%)	Mean 1.83%	SD 1.37%	Total	4/240 (1.67%)	Mean 1.33%	SD 1.63%	
.....									
#All Organs:									
Histiocytic Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/240 (0%)	Mean 0%	SD 0%	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	
.....									
#All Organs:									
Leukemia: Granulocytic									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated									
		0/50 (0%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	3/240 (1.25%)	Mean 1.5%	SD 3%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/90 (2%)				5/90 (6%)			
Overall Incidence	Total	2/240 (0.83%)	Mean 0.56%	SD 1.11%	Total	5/240 (2.08%)	Mean 1.39%	SD 2.78%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 6
 Report Date: 01/20/2018

		Male				Female			
#All Organs:									
Malignant Schwannoma									
		1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	2/50 (4%)		
		3/90 (3%)			4/90 (4%)				
Overall Incidence	Total	6/240 (2.5%)	Mean 2.33%	SD 1.76%	Total	8/240 (3.33%)	Mean 3.11%	SD 2.08%	
.....									
#All Organs:									
Mesothelioma: Benign, Malignant, NOS									
		1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		2/90 (2%)			0/90 (0%)				
Overall Incidence	Total	5/240 (2.08%)	Mean 2.06%	SD 0.11%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Mesothelioma: Malignant									
		1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		2/90 (2%)			0/90 (0%)				
Overall Incidence	Total	5/240 (2.08%)	Mean 2.06%	SD 0.11%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Cortex:									
Adenoma									
		3/50 (6%)	0/50 (0%)	3/50 (6%)	3/50 (6%)	0/50 (0%)	0/50 (0%)		
		1/90 (1%)			1/90 (1%)				
Overall Incidence	Total	7/240 (2.92%)	Mean 3.28%	SD 3.18%	Total	4/240 (1.67%)	Mean 1.78%	SD 2.86%	
.....									
*Adrenal Cortex:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/90 (0%)			1/90 (1%)				
Overall Incidence	Total	0/240 (0%)	Mean 0%	SD 0%	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 7
 Report Date: 01/20/2018

		Male				Female			
*Adrenal Medulla:									
Pheochromocytoma Benign									
		9/50 (18%)	5/50 (10%)	12/50 (24%)		3/50 (6%)	0/50 (0%)	0/49 (0%)	
		10/88 (11%)				1/86 (1%)			
Overall Incidence	Total	36/238 (15.13%)	Mean 15.84%	SD 6.47%	Total	4/235 (1.7%)	Mean 1.79%	SD 2.86%	
.....									
*Adrenal Medulla:									
Pheochromocytoma Complex									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		1/88 (1%)				0/86 (0%)			
Overall Incidence	Total	2/238 (0.84%)	Mean 0.78%	SD 0.97%	Total	0/235 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla:									
Pheochromocytoma Malignant									
		3/50 (6%)	2/50 (4%)	2/50 (4%)		2/50 (4%)	0/50 (0%)	0/49 (0%)	
		1/88 (1%)				0/86 (0%)			
Overall Incidence	Total	8/238 (3.36%)	Mean 3.78%	SD 2%	Total	2/235 (0.85%)	Mean 1%	SD 2%	
.....									
*Adrenal Medulla:									
Pheochromocytoma: Benign, Complex, Malignant, NOS									
		12/50 (24%)	8/50 (16%)	14/50 (28%)		5/50 (10%)	0/50 (0%)	0/49 (0%)	
		11/88 (13%)				1/86 (1%)			
Overall Incidence	Total	45/238 (18.91%)	Mean 20.12%	SD 7.12%	Total	6/235 (2.55%)	Mean 2.79%	SD 4.84%	
.....									
*Brain:									
Glioma Malignant									
		0/50 (0%)		2/50 (4%)		0/50 (0%)		1/50 (2%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	2/190 (1.05%)	Mean 1.33%	SD 2.31%	Total	1/190 (0.53%)	Mean 0.67%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 8
 Report Date: 01/20/2018

		Male				Female			
*Brain:									
Granular Cell Tumor Benign									
		2/50	(4%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		1/90	(1%)			1/90	(1%)		
Overall Incidence	Total	3/190 (1.58%)		Mean 1.7%		SD 2.06%		Total	2/190 (1.05%)
				Mean 1.04%					SD 1%
.....									
*Brain:									
Oligodendroglioma, Glioma, or Astrocytoma									
		0/50	(0%)	2/50	(4%)	0/50	(0%)	1/50	(2%)
		0/90	(0%)			0/90	(0%)		
Overall Incidence	Total	2/190 (1.05%)		Mean 1.33%		SD 2.31%		Total	1/190 (0.53%)
				Mean 0.67%					SD 1.15%
.....									
*Brain:									
Schwannoma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/90	(0%)			0/90	(0%)		
Overall Incidence	Total	0/190 (0%)		Mean 0%		SD 0%		Total	1/190 (0.53%)
				Mean 0.67%					SD 1.15%
.....									
*Clitoral/Preputial Gland:									
Carcinoma									
		1/49	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/88	(0%)			0/87	(0%)	0/50	(0%)
Overall Incidence	Total	1/237 (0.42%)		Mean 0.51%		SD 1.02%		Total	0/235 (0%)
				Mean 0%					SD 0%
.....									
*Clitoral/Preputial Gland:									
Carcinoma or Adenoma									
		1/49	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/88	(0%)			0/87	(0%)	0/50	(0%)
Overall Incidence	Total	1/237 (0.42%)		Mean 0.51%		SD 1.02%		Total	0/235 (0%)
				Mean 0%					SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 9
 Report Date: 01/20/2018

		Male				Female			
*Epididymis:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)					
		0/90 (0%)							
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%					
.....									
#Eye:									
Leiomyoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
*Heart:									
Schwannoma Malignant									
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	2/240 (0.83%)	Mean 1%	SD 1.15%	Total	0/239 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Large: Colon/Rectum:									
Granular Cell Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				1/90 (1%)			
Overall Incidence	Total	0/240 (0%)	Mean 0%	SD 0%	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	
.....									
#Intestine Large: Colon/Rectum:									
Leiomyoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	0/240 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 10
 Report Date: 01/20/2018

		Male				Female			
#Intestine Small: Jejunum: Carcinoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/90 (2%)				0/90 (0%)			
Overall Incidence	Total	3/240 (1.25%)	Mean 1.06%	SD 1.22%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Jejunum: Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				1/90 (1%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	
.....									
#Intestine Small: Site Unspecified: Carcinoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/90 (2%)				0/90 (0%)			
Overall Incidence	Total	3/240 (1.25%)	Mean 1.06%	SD 1.22%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified: Carcinoma or Adenoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/90 (2%)				0/90 (0%)			
Overall Incidence	Total	3/240 (1.25%)	Mean 1.06%	SD 1.22%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified: Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				1/90 (1%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 11
 Report Date: 01/20/2018

		Male				Female			
*Islets, Pancreatic:									
Adenoma									
		3/50 (6%)	2/50 (4%)	8/50 (16%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		5/90 (6%)				5/90 (6%)			
Overall Incidence	Total	18/240 (7.5%)	Mean 7.89%	SD 5.47%	Total	6/240 (2.5%)	Mean 1.89%	SD 2.62%	
.....									
*Islets, Pancreatic:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	
		8/90 (9%)				2/90 (2%)			
Overall Incidence	Total	8/240 (3.33%)	Mean 2.22%	SD 4.44%	Total	4/240 (1.67%)	Mean 1.56%	SD 1.04%	
.....									
*Islets, Pancreatic:									
Carcinoma or Adenoma									
		3/50 (6%)	2/50 (4%)	8/50 (16%)		1/50 (2%)	0/50 (0%)	2/50 (4%)	
		13/90 (14%)				7/90 (8%)			
Overall Incidence	Total	26/240 (10.83%)	Mean 10.11%	SD 5.99%	Total	10/240 (4.17%)	Mean 3.44%	SD 3.32%	
.....									
*Kidney: Pelvis and Transitional Epithelium:									
Papilloma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule:									
Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		3/90 (3%)				1/90 (1%)			
Overall Incidence	Total	4/240 (1.67%)	Mean 1.33%	SD 1.63%	Total	2/240 (0.83%)	Mean 0.78%	SD 0.97%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 12
 Report Date: 01/20/2018

		Male				Female			
*Kidney: Renal Tubule: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/90 (1%)				1/90 (1%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	
.....									
*Kidney: Renal Tubule: Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		3/90 (3%)				2/90 (2%)			
Overall Incidence	Total	4/240 (1.67%)	Mean 1.33%	SD 1.63%	Total	3/240 (1.25%)	Mean 1.06%	SD 1.22%	
.....									
*Kidney: Renal Tubule: Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/90 (1%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Oncocytoma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/90 (1%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
*Liver: Hepatocellular Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	2/50 (4%)	
		0/90 (0%)				7/90 (8%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	11/240 (4.58%)	Mean 3.94%	SD 3.18%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
*Liver:									
Hepatocellular Carcinoma or Hepatocellular Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	2/50 (4%)	
		0/90 (0%)				7/90 (8%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	11/240 (4.58%)	Mean 3.94%	SD 3.18%	
.....									
*Liver:									
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	2/50 (4%)	
		0/90 (0%)				7/90 (8%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	11/240 (4.58%)	Mean 3.94%	SD 3.18%	
.....									
*Lung:									
Alveolar/Bronchiolar Adenoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)	
		1/90 (1%)				0/90 (0%)			
Overall Incidence	Total	1/239 (0.42%)	Mean 0.28%	SD 0.56%	Total	1/239 (0.42%)	Mean 0.5%	SD 1%	
.....									
*Lung:									
Alveolar/Bronchiolar Carcinoma									
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	1/239 (0.42%)	Mean 0.5%	SD 1%	Total	0/239 (0%)	Mean 0%	SD 0%	
.....									
*Lung:									
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma									
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)	
		1/90 (1%)				0/90 (0%)			
Overall Incidence	Total	2/239 (0.84%)	Mean 0.78%	SD 0.97%	Total	1/239 (0.42%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 14
 Report Date: 01/20/2018

		Male				Female			
*Lung:									
Sarcoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/239 (0%)	Mean 0%	SD 0%	Total	1/239 (0.42%)	Mean 0.5%	SD 1%	
.....									
#Lymph Node, Mesenteric:									
Hemangiosarcoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
#Mammary Gland:									
Adenolipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/240 (0%)	Mean 0%	SD 0%	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	
.....									
#Mammary Gland:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	4/50 (8%)	
		0/90 (0%)				8/90 (9%)			
Overall Incidence	Total	0/240 (0%)	Mean 0%	SD 0%	Total	15/240 (6.25%)	Mean 5.72%	SD 4%	
.....									
#Mammary Gland:									
Carcinoma									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		7/50 (14%)	3/50 (6%)	5/50 (10%)	
		0/90 (0%)				10/90 (11%)			
Overall Incidence	Total	2/240 (0.83%)	Mean 1%	SD 2%	Total	25/240 (10.42%)	Mean 10.28%	SD 3.31%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 15
 Report Date: 01/20/2018

		Male				Female			
#Mammary Gland:									
Carcinoma or Adenoma									
		2/50 (4%)	0/50 (0%)	0/50 (0%)	7/50 (14%)	6/50 (12%)	9/50 (18%)		
		0/90 (0%)			16/90 (18%)				
Overall Incidence	Total	2/240 (0.83%)	Mean 1%	SD 2%	Total	38/240 (15.83%)	Mean 15.44%	SD 2.94%	
.....									
#Mammary Gland:									
Fibroadenoma									
		2/50 (4%)	1/50 (2%)	2/50 (4%)	32/50 (64%)	29/50 (58%)	20/50 (40%)		
		2/90 (2%)			63/90 (70%)				
Overall Incidence	Total	7/240 (2.92%)	Mean 3.06%	SD 1.09%	Total	144/240 (60%)	Mean 58%	SD 12.96%	
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma or Adenoma									
		2/50 (4%)	1/50 (2%)	2/50 (4%)	32/50 (64%)	30/50 (60%)	23/50 (46%)		
		2/90 (2%)			64/90 (71%)				
Overall Incidence	Total	7/240 (2.92%)	Mean 3.06%	SD 1.09%	Total	149/240 (62.08%)	Mean 60.28%	SD 10.57%	
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma, Carcinoma, or Adenoma									
		3/50 (6%)	1/50 (2%)	2/50 (4%)	36/50 (72%)	32/50 (64%)	27/50 (54%)		
		2/90 (2%)			66/90 (73%)				
Overall Incidence	Total	8/240 (3.33%)	Mean 3.56%	SD 1.86%	Total	161/240 (67.08%)	Mean 65.83%	SD 8.9%	
.....									
#Mammary Gland:									
Myoepithelioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)		
		0/90 (0%)			0/90 (0%)				
Overall Incidence	Total	0/240 (0%)	Mean 0%	SD 0%	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 16
 Report Date: 01/20/2018

		Male				Female			
#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%)
		0/90 (0%)				2/90 (2%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	2/240 (0.83%)	Mean 0.56%	SD 1.11%	
.....									
#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%)
		0/90 (0%)				2/90 (2%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	2/240 (0.83%)	Mean 0.56%	SD 1.11%	
.....									
#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%)
		0/90 (0%)				1/90 (1%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	
.....									
*Ovary: Cystadenoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
						1/90 (1%)			
Overall Incidence					Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	
.....									
*Ovary: Granulosa Cell Tumor Benign									
						0/50 (0%)	0/50 (0%)	3/50 (6%)	3/50 (6%)
						1/90 (1%)			
Overall Incidence					Total	4/240 (1.67%)	Mean 1.78%	SD 2.86%	

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

Version: Nov2017
 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

Page: 17
 Report Date: 01/20/2018

	Male	Female
*Ovary:		
Granulosa Cell Tumor Malignant		
	0/50 (0%) 2/90 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total 2/240 (0.83%)	Mean 0.56% SD 1.11%
.....		
*Ovary:		
Granulosa Cell Tumor: Benign, Malignant, NOS		
	0/50 (0%) 3/90 (3%)	0/50 (0%) 3/50 (6%)
Overall Incidence	Total 6/240 (2.5%)	Mean 2.33% SD 2.91%
.....		
*Ovary:		
Granulosa-Theca Tumor Benign		
	0/50 (0%) 0/90 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total 1/240 (0.42%)	Mean 0.5% SD 1%
.....		
*Ovary:		
Sertoli Cell Tumor Benign		
	0/50 (0%) 1/90 (1%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total 1/240 (0.42%)	Mean 0.28% SD 0.56%
.....		
*Ovary:		
Thecoma Benign		
	0/50 (0%) 0/90 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total 1/240 (0.42%)	Mean 0.5% SD 1%

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

Version: Nov2017
 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

Page: 18
 Report Date: 01/20/2018

		Male			Female		
*Ovary:							
Tubulostromal Carcinoma							
					0/50 (0%)	1/50 (2%)	0/50 (0%)
					0/90 (0%)		
Overall Incidence					Total 1/240 (0.42%)	Mean 0.5%	SD 1%
.....							
*Pancreas:							
Adenoma							
		5/50 (10%)	5/50 (10%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		18/90 (20%)			0/90 (0%)		
Overall Incidence	Total	28/240 (11.67%)	Mean 10%	SD 8.16%	Total 0/240 (0%)	Mean 0%	SD 0%
.....							
*Pancreas:							
Carcinoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/90 (1%)			0/90 (0%)		
Overall Incidence	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	Total 0/240 (0%)	Mean 0%	SD 0%
.....							
*Pancreas:							
Carcinoma or Adenoma							
		5/50 (10%)	5/50 (10%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		18/90 (20%)			0/90 (0%)		
Overall Incidence	Total	28/240 (11.67%)	Mean 10%	SD 8.16%	Total 0/240 (0%)	Mean 0%	SD 0%
.....							
*Parathyroid Gland:							
Adenoma							
		0/49 (0%)	0/43 (0%)	0/48 (0%)	1/41 (2%)	0/47 (0%)	0/45 (0%)
		1/83 (1%)			0/87 (0%)		
Overall Incidence	Total	1/223 (0.45%)	Mean 0.3%	SD 0.6%	Total 1/220 (0.45%)	Mean 0.61%	SD 1.22%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 19
 Report Date: 01/20/2018

		Male				Female			
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Adenoma									
		14/50 (28%)	5/50 (10%)	11/50 (22%)		19/50 (38%)	18/50 (36%)	18/50 (36%)	
		17/89 (19%)				43/90 (48%)			
Overall Incidence	Total	47/239 (19.67%)	Mean 19.78%	SD 7.5%	Total	98/240 (40.83%)	Mean 39.44%	SD 5.63%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/89 (0%)				1/90 (1%)			
Overall Incidence	Total	0/239 (0%)	Mean 0%	SD 0%	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma or Adenoma									
		14/50 (28%)	5/50 (10%)	11/50 (22%)		19/50 (38%)	18/50 (36%)	18/50 (36%)	
		17/89 (19%)				44/90 (49%)			
Overall Incidence	Total	47/239 (19.67%)	Mean 19.78%	SD 7.5%	Total	99/240 (41.25%)	Mean 39.72%	SD 6.18%	
.....									
*Pituitary Gland: Pars Intermedia:									
Adenoma									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/89 (0%)				0/90 (0%)			
Overall Incidence	Total	2/239 (0.84%)	Mean 1%	SD 2%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
*Pituitary Gland: Pars Intermedia:									
Carcinoma or Adenoma									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/89 (0%)				0/90 (0%)			
Overall Incidence	Total	2/239 (0.84%)	Mean 1%	SD 2%	Total	0/240 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 20
 Report Date: 01/20/2018

		Male				Female			
*Prostate:									
Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)		
		2/90	(2%)						
Overall Incidence	Total	2/240 (0.83%)		Mean 0.56%		SD 1.11%			
.....									
*Prostate:									
Carcinoma or Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)		
		2/90	(2%)						
Overall Incidence	Total	2/240 (0.83%)		Mean 0.56%		SD 1.11%			
.....									
*Salivary Glands:									
Schwannoma Malignant									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/49	(0%)
		0/90	(0%)					0/90	(0%)
Overall Incidence	Total	1/240 (0.42%)		Mean 0.5%		SD 1%		Total	0/239 (0%)
								Mean	0%
								SD	0%
.....									
#Skeletal Muscle:									
Liposarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)					0/90	(0%)
Overall Incidence	Total	0/240 (0%)		Mean 0%		SD 0%		Total	1/240 (0.42%)
								Mean	0.5%
								SD	1%
.....									
#Skeletal Muscle:									
Sarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/90	(0%)					0/90	(0%)
Overall Incidence	Total	0/240 (0%)		Mean 0%		SD 0%		Total	1/240 (0.42%)
								Mean	0.5%
								SD	1%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 21
 Report Date: 01/20/2018

		Male				Female			
#Skin:									
Basal Cell Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/90 (1%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	Total	0/240 (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%)	
		1/90 (1%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	Total	0/240 (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%)	
		1/90 (1%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Carcinoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
#Skin:									
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		1/90 (1%)				0/90 (0%)			
Overall Incidence	Total	2/240 (0.83%)	Mean 0.78%	SD 0.97%	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma									
		4/50 (8%)	6/50 (12%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		8/90 (9%)				0/90 (0%)			
Overall Incidence	Total	22/240 (9.17%)	Mean 9.22%	SD 1.9%	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Fibroma									
		3/50 (6%)	5/50 (10%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		2/90 (2%)				2/90 (2%)			
Overall Incidence	Total	10/240 (4.17%)	Mean 4.56%	SD 4.39%	Total	3/240 (1.25%)	Mean 1.06%	SD 1.22%	
.....									
#Skin:									
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, Malignant Fibrous Histiocytoma, or Hemangiopericytoma									
		3/50 (6%)	7/50 (14%)	1/50 (2%)		0/50 (0%)	2/50 (4%)	0/50 (0%)	
		5/90 (6%)				5/90 (6%)			
Overall Incidence	Total	16/240 (6.67%)	Mean 6.89%	SD 5.07%	Total	7/240 (2.92%)	Mean 2.39%	SD 2.83%	
.....									
#Skin:									
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma									
		3/50 (6%)	7/50 (14%)	1/50 (2%)		0/50 (0%)	2/50 (4%)	0/50 (0%)	
		5/90 (6%)				5/90 (6%)			
Overall Incidence	Total	16/240 (6.67%)	Mean 6.89%	SD 5.07%	Total	7/240 (2.92%)	Mean 2.39%	SD 2.83%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 23
 Report Date: 01/20/2018

		Male				Female			
#Skin:									
Fibrosarcoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		1/90 (1%)				0/90 (0%)			
Overall Incidence	Total	2/240 (0.83%)	Mean 0.78%	SD 0.97%	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Fibrosarcoma, Sarcoma, Myxosarcoma, or Malignant Fibrous Histiocytoma									
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		3/90 (3%)				3/90 (3%)			
Overall Incidence	Total	6/240 (2.5%)	Mean 2.33%	SD 1.76%	Total	4/240 (1.67%)	Mean 1.33%	SD 1.63%	
.....									
#Skin:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/240 (0%)	Mean 0%	SD 0%	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Keratoacanthoma									
		2/50 (4%)	4/50 (8%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		5/90 (6%)				0/90 (0%)			
Overall Incidence	Total	14/240 (5.83%)	Mean 5.89%	SD 1.65%	Total	0/240 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 24
 Report Date: 01/20/2018

		Male				Female			
#Skin:									
Lipoma									
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/90 (2%)				0/90 (0%)			
Overall Incidence	Total	5/240 (2.08%)	Mean 2.06%	SD 1.64%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Malignant Fibrous Histiocytoma									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				1/90 (1%)			
Overall Incidence	Total	2/240 (0.83%)	Mean 1%	SD 1.15%	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	
.....									
#Skin:									
Neurofibrosarcoma or Schwannoma (malignant or NOS)									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/240 (0%)	Mean 0%	SD 0%	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/240 (0%)	Mean 0%	SD 0%	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/90 (2%)				2/90 (2%)			
Overall Incidence	Total	2/240 (0.83%)	Mean 0.56%	SD 1.11%	Total	2/240 (0.83%)	Mean 0.56%	SD 1.11%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 25
 Report Date: 01/20/2018

		Male				Female			
#Skin:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/240 (0%)	Mean 0%	SD 0%	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Squamous Cell Carcinoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma									
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	2/240 (0.83%)	Mean 1%	SD 2%	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Squamous Cell Papilloma									
		2/50 (4%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/90 (2%)				0/90 (0%)			
Overall Incidence	Total	6/240 (2.5%)	Mean 2.56%	SD 0.97%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma or Papilloma									
		2/50 (4%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/90 (2%)				0/90 (0%)			
Overall Incidence	Total	6/240 (2.5%)	Mean 2.56%	SD 0.97%	Total	0/240 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 26
 Report Date: 01/20/2018

		Male				Female			
#Skin:									
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma									
		4/50 (8%)	5/50 (10%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		7/90 (8%)				0/90 (0%)			
Overall Incidence	Total	20/240 (8.33%)	Mean 8.44%	SD 1.04%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma									
		4/50 (8%)	5/50 (10%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		7/90 (8%)				0/90 (0%)			
Overall Incidence	Total	20/240 (8.33%)	Mean 8.44%	SD 1.04%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
#Skin: Sebaceous Gland:									
Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/90 (1%)				0/90 (0%)			
Overall Incidence	Total	2/240 (0.83%)	Mean 0.78%	SD 0.97%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
#Skin: Sebaceous Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/90 (1%)				0/90 (0%)			
Overall Incidence	Total	2/240 (0.83%)	Mean 0.78%	SD 0.97%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		3/90 (3%)				1/90 (1%)			
Overall Incidence	Total	3/240 (1.25%)	Mean 0.83%	SD 1.67%	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 27
 Report Date: 01/20/2018

		Male				Female			
#Stomach, Forestomach:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				1/90 (1%)			
Overall Incidence	Total	0/240 (0%)	Mean 0%	SD 0%	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma or Papilloma Squamous									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		1/90 (1%)				0/90 (0%)			
Overall Incidence	Total	2/240 (0.83%)	Mean 0.78%	SD 0.97%	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	
.....									
#Stomach, Forestomach:									
Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/90 (1%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
*Testis:									
Adenoma									
		1/50 (2%)	3/49 (6%)	0/50 (0%)					
		2/90 (2%)							
Overall Incidence	Total	6/239 (2.51%)	Mean 2.59%	SD 2.56%					

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 28
 Report Date: 01/20/2018

		Male				Female			
*Thymus:									
Thymoma Benign									
		0/46 (0%)	1/46 (2%)	0/48 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)	
		0/88 (0%)				1/87 (1%)			
Overall Incidence	Total	1/228 (0.44%)	Mean 0.54%	SD 1.09%	Total	1/233 (0.43%)	Mean 0.29%	SD 0.57%	
.....									
*Thymus:									
Thymoma Malignant									
		0/46 (0%)	0/46 (0%)	0/48 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)	
		0/88 (0%)				1/87 (1%)			
Overall Incidence	Total	0/228 (0%)	Mean 0%	SD 0%	Total	1/233 (0.43%)	Mean 0.29%	SD 0.57%	
.....									
*Thymus:									
Thymoma: Benign, Malignant, NOS									
		0/46 (0%)	1/46 (2%)	0/48 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)	
		0/88 (0%)				2/87 (2%)			
Overall Incidence	Total	1/228 (0.44%)	Mean 0.54%	SD 1.09%	Total	2/233 (0.86%)	Mean 0.57%	SD 1.15%	
.....									
*Thyroid Gland: C-Cell:									
Adenoma									
		7/50 (14%)	13/50 (26%)	2/50 (4%)		5/50 (10%)	11/49 (22%)	2/50 (4%)	
		8/89 (9%)				6/90 (7%)			
Overall Incidence	Total	30/239 (12.55%)	Mean 13.25%	SD 9.43%	Total	24/239 (10.04%)	Mean 10.78%	SD 8.16%	
.....									
*Thyroid Gland: C-Cell:									
Carcinoma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/49 (0%)	0/50 (0%)	
		2/89 (2%)				0/90 (0%)			
Overall Incidence	Total	4/239 (1.67%)	Mean 1.56%	SD 1.05%	Total	1/239 (0.42%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 29
 Report Date: 01/20/2018

		Male				Female			
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
		8/50 (16%)	13/50 (26%)	3/50 (6%)	6/50 (12%)	11/49 (22%)	2/50 (4%)		
		10/89 (11%)			6/90 (7%)				
Overall Incidence	Total	34/239 (14.23%)	Mean 14.81%	SD 8.51%	Total	25/239 (10.46%)	Mean 11.28%	SD 8.16%	
.....									
*Thyroid Gland: Follicular Cell: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)		
		0/89 (0%)			1/90 (1%)				
Overall Incidence	Total	0/239 (0%)	Mean 0%	SD 0%	Total	1/239 (0.42%)	Mean 0.28%	SD 0.56%	
.....									
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)		
		0/89 (0%)			1/90 (1%)				
Overall Incidence	Total	0/239 (0%)	Mean 0%	SD 0%	Total	1/239 (0.42%)	Mean 0.28%	SD 0.56%	
.....									
#Tissue NOS: Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/90 (1%)			1/90 (1%)				
Overall Incidence	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	
.....									
#Tongue: Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/90 (0%)			1/90 (1%)				
Overall Incidence	Total	0/240 (0%)	Mean 0%	SD 0%	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 30
 Report Date: 01/20/2018

		Male				Female			
#Tongue:									
Squamous Cell Carcinoma or Papilloma Squamous									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				1/90 (1%)			
Overall Incidence	Total	0/240 (0%)	Mean 0%	SD 0%	Total	1/240 (0.42%)	Mean 0.28%	SD 0.56%	
.....									
#Tooth:									
Odontoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	0/240 (0%)	Mean 0%	SD 0%	
.....									
*Urinary Bladder:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)	
		0/89 (0%)				1/88 (1%)			
Overall Incidence	Total	0/239 (0%)	Mean 0%	SD 0%	Total	1/236 (0.42%)	Mean 0.28%	SD 0.57%	
.....									
#Uterus:									
Carcinoma									
						5/50 (10%)	0/50 (0%)	1/50 (2%)	
						3/90 (3%)			
Overall Incidence					Total	9/240 (3.75%)	Mean 3.83%	SD 4.33%	
.....									
#Uterus:									
Hemangiosarcoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						2/90 (2%)			
Overall Incidence					Total	2/240 (0.83%)	Mean 0.56%	SD 1.11%	

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

Version: Nov2017
 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

Page: 31
 Report Date: 01/20/2018

	Male	Female
#Uterus: Leiomyosarcoma		
	0/50 (0%) 1/90 (1%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total 1/240 (0.42%)	Mean 0.28% SD 0.56%
#Uterus: Polyp Stromal		
	8/50 (16%) 16/90 (18%)	10/50 (20%) 7/50 (14%)
Overall Incidence	Total 41/240 (17.08%)	Mean 16.94% SD 2.56%
#Uterus: Sarcoma Stromal		
	0/50 (0%) 0/90 (0%)	2/50 (4%) 0/50 (0%)
Overall Incidence	Total 2/240 (0.83%)	Mean 1% SD 2%
#Uterus: Sarcoma Stromal or Polyp Stromal		
	8/50 (16%) 16/90 (18%)	12/50 (24%) 7/50 (14%)
Overall Incidence	Total 43/240 (17.92%)	Mean 17.94% SD 4.32%
#Uterus: Schwannoma Malignant		
	0/50 (0%) 2/90 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total 2/240 (0.83%)	Mean 0.56% SD 1.11%

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

Version: Nov2017
 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

Page: 32
 Report Date: 01/20/2018

		Male				Female			
#Uterus:									
Squamous Cell Carcinoma									
			0/50 (0%)		0/50 (0%)		1/50 (2%)		
			0/90 (0%)						
Overall Incidence		Total	1/240 (0.42%)		Mean 0.5%		SD 1%		
.....									
#Vagina:									
Granular Cell Tumor Benign									
			0/50 (0%)		0/50 (0%)		1/50 (2%)		
			0/90 (0%)						
Overall Incidence		Total	1/240 (0.42%)		Mean 0.5%		SD 1%		
.....									
#Vagina:									
Polyp									
			0/50 (0%)		1/50 (2%)		0/50 (0%)		
			0/90 (0%)						
Overall Incidence		Total	1/240 (0.42%)		Mean 0.5%		SD 1%		
.....									
#Vagina:									
Schwannoma Malignant									
			0/50 (0%)		1/50 (2%)		1/50 (2%)		
			1/90 (1%)						
Overall Incidence		Total	3/240 (1.25%)		Mean 1.28%		SD 0.95%		
.....									
#Zymbal's Gland:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	0/240 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2017
 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

Page: 33
 Report Date: 01/20/2018

		Male				Female			
#Zymbal's Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	1/240 (0.42%)	Mean 0.5%	SD 1%	Total	0/240 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied