



National Toxicology Program
Department of Health and Human Services

NTP Historical Controls Report

All Routes and Vehicles

Harlan Sprague-Dawley RATS

November 2019

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.

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	051018801	02/17/11	733	50(2)	32(675)	525.8	Di(2-ethylhexyl) Phthalate
Battelle Columbus Laboratory	051018802	06/27/11	729	50(2)	25(648)	593.4	Di(2-ethylhexyl) Phthalate
Battelle Columbus Laboratory	051098701	08/30/10	729	49(2)	27(672)	628.3	Dibutyl Phthalate
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
Battelle Columbus Laboratory	052061401	10/27/08	N/A	0(0)	0(0)	N/A	Perfluorooctanoic Acid
Battelle Columbus Laboratory	052061402	07/27/09	743	50(2)	36(684)	609.5	Perfluorooctanoic Acid
I. I. T. Research Institute	052010556	09/16/12	730	90(1)	25(642)	658.1	Radiofrequency Radiation
Battelle Columbus Laboratory	050303803	01/30/12	729	50(2)	12(621)	610.8	Sodium Tungstate Dihydrate
Female							
Battelle Columbus Laboratory	051018801	02/18/11	736	50(4)	33(691)	329.5	Di(2-ethylhexyl) Phthalate
Battelle Columbus Laboratory	051018802	06/28/11	732	50(4)	31(684)	376.1	Di(2-ethylhexyl) Phthalate
Battelle Columbus Laboratory	051098701	08/31/10	730	50(4)	29(668)	397.3	Dibutyl Phthalate
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
Battelle Columbus Laboratory	052061401	10/28/08	744	50(4)	23(649)	385.9	Perfluorooctanoic Acid
Battelle Columbus Laboratory	052061402	N/A	N/A	0(0)	0(0)	N/A	Perfluorooctanoic Acid
I. I. T. Research Institute	052010556	09/16/12	737	90(1)	48(659)	462.4	Radiofrequency Radiation
Battelle Columbus Laboratory	050303803	01/31/12	730	50(5)	30(667)	393.3	Sodium Tungstate Dihydrate

Version: Nov2019
 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			
#All Organs:									
Benign Tumors									
		27/50 (54%)	28/50 (56%)	35/49 (71%)	37/50 (74%)	41/50 (82%)	40/50 (80%)		
		38/50 (76%)	27/50 (54%)	30/50 (60%)	41/50 (82%)	40/50 (80%)	39/50 (78%)		
			32/50 (64%)	49/90 (54%)	39/50 (78%)		82/90 (91%)		
		29/50 (58%)			39/50 (78%)				
Overall Incidence	Total	295/489 (60.33%)	Mean 60.87%	SD 8.05%	Total	398/490 (81.22%)	Mean 80.35%	SD 4.72%	
.....									
#All Organs:									
Malignant Tumors									
		13/50 (26%)	15/50 (30%)	14/49 (29%)	16/50 (32%)	14/50 (28%)	13/50 (26%)		
		11/50 (22%)	12/50 (24%)	12/50 (24%)	15/50 (30%)	19/50 (38%)	11/50 (22%)		
			9/50 (18%)	24/90 (27%)	14/50 (28%)		37/90 (41%)		
		14/50 (28%)			17/50 (34%)				
Overall Incidence	Total	124/489 (25.36%)	Mean 25.25%	SD 3.71%	Total	156/490 (31.84%)	Mean 31.01%	SD 5.98%	
.....									
#All Organs:									
Malignant and Benign Tumors									
		32/50 (64%)	36/50 (72%)	41/49 (84%)	41/50 (82%)	44/50 (88%)	44/50 (88%)		
		42/50 (84%)	33/50 (66%)	37/50 (74%)	47/50 (94%)	46/50 (92%)	41/50 (82%)		
			37/50 (74%)	57/90 (63%)	47/50 (94%)		89/90 (99%)		
		36/50 (72%)			47/50 (94%)				
Overall Incidence	Total	351/489 (71.78%)	Mean 72.56%	SD 7.59%	Total	446/490 (91.02%)	Mean 90.32%	SD 5.77%	
.....									
#All Organs:									
Hemangioma									
		1/50 (2%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
			0/50 (0%)	0/90 (0%)	0/50 (0%)		0/90 (0%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	2/489 (0.41%)	Mean 0.44%	SD 0.88%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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			
#All Organs:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
			0/50 (0%)	3/90 (3%)		0/50 (0%)		3/90 (3%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	5/489 (1.02%)		Mean 0.81%	SD 1.28%	Total		5/490 (1.02%)	
							Mean 0.81%		SD 1.28%
.....									
#All Organs:									
Hemangiosarcoma or Hemangioma									
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
			0/50 (0%)	3/90 (3%)		0/50 (0%)		3/90 (3%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	7/489 (1.43%)		Mean 1.26%	SD 1.27%	Total		6/490 (1.22%)	
							Mean 1.04%		SD 1.64%
.....									
#All Organs:									
Histiocytic Sarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		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%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/489 (0%)		Mean 0%	SD 0%	Total		1/490 (0.2%)	
							Mean 0.22%		SD 0.67%
.....									
#All Organs:									
Leukemia: Granulocytic									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)		Mean 0.22%	SD 0.67%	Total		1/490 (0.2%)	
							Mean 0.22%		SD 0.67%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
#All Organs:									
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated									
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
			3/50 (6%)	0/90 (0%)	1/50 (2%)		0/90 (0%)		
		1/50 (2%)			0/50 (0%)				
Overall Incidence	Total	7/489 (1.43%)	Mean 1.56%	SD 2.6%	Total	2/490 (0.41%)	Mean 0.44%	SD 0.88%	
#All Organs:									
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type									
		2/50 (4%)	0/50 (0%)	1/49 (2%)	1/50 (2%)	0/50 (0%)	1/50 (2%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
			1/50 (2%)	2/90 (2%)	1/50 (2%)		5/90 (6%)		
		1/50 (2%)			2/50 (4%)				
Overall Incidence	Total	7/489 (1.43%)	Mean 1.36%	SD 1.43%	Total	10/490 (2.04%)	Mean 1.73%	SD 2%	
#All Organs:									
Malignant Schwannoma									
		3/50 (6%)	6/50 (12%)	3/49 (6%)	1/50 (2%)	3/50 (6%)	2/50 (4%)		
		1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	2/50 (4%)		
			1/50 (2%)	3/90 (3%)	0/50 (0%)		4/90 (4%)		
		1/50 (2%)			2/50 (4%)				
Overall Incidence	Total	20/489 (4.09%)	Mean 4.16%	SD 3.55%	Total	16/490 (3.27%)	Mean 3.16%	SD 2.06%	
#All Organs:									
Mesothelioma: Benign, Malignant, NOS									
		2/50 (4%)	1/50 (2%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
			1/50 (2%)	2/90 (2%)	0/50 (0%)		0/90 (0%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	10/489 (2.04%)	Mean 2.03%	SD 1%	Total	0/490 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
#All Organs:									
Mesothelioma: Malignant									
		2/50 (4%)	1/50 (2%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
			1/50 (2%)	2/90 (2%)	0/50 (0%)			0/90 (0%)	
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	10/489 (2.04%)	Mean 2.03%	SD 1%	Total	0/490 (0%)	Mean 0%	SD 0%	
#All Organs:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)	1/50 (2%)			0/90 (0%)	
		0/50 (0%)			1/50 (2%)				
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	2/490 (0.41%)	Mean 0.44%	SD 0.88%	
#All Organs:									
Osteosarcoma or Osteoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)	1/50 (2%)			0/90 (0%)	
		0/50 (0%)			1/50 (2%)				
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	2/490 (0.41%)	Mean 0.44%	SD 0.88%	
*Adrenal Cortex:									
Adenoma									
		1/50 (2%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		3/50 (6%)	0/50 (0%)	3/50 (6%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	1/90 (1%)	2/50 (4%)			1/90 (1%)	
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	8/489 (1.64%)	Mean 1.68%	SD 2.55%	Total	6/490 (1.22%)	Mean 1.23%	SD 2.22%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
*Adrenal Cortex:									
 Carcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		1/90 (1%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%	
.....									
*Adrenal Medulla:									
 Ganglioneuroma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/49 (0%)	
			0/50 (0%)	0/88 (0%)		0/50 (0%)		0/86 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/487 (0.21%)	Mean 0.22%	SD 0.67%	Total	1/485 (0.21%)	Mean 0.22%	SD 0.67%	
.....									
*Adrenal Medulla:									
 Pheochromocytoma Benign									
		4/50 (8%)	5/50 (10%)	7/49 (14%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		9/50 (18%)	5/50 (10%)	12/50 (24%)		3/50 (6%)	0/50 (0%)	0/49 (0%)	
			8/50 (16%)	10/88 (11%)		1/50 (2%)		1/86 (1%)	
		10/50 (20%)				1/50 (2%)			
Overall Incidence	Total	70/487 (14.37%)	Mean 14.63%	SD 5.33%	Total	7/485 (1.44%)	Mean 1.46%	SD 1.94%	
.....									
*Adrenal Medulla:									
 Pheochromocytoma Complex									
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
			0/50 (0%)	1/88 (1%)		0/50 (0%)		0/86 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	3/487 (0.62%)	Mean 0.57%	SD 0.89%	Total	0/485 (0%)	Mean 0%	SD 0%	

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#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
*Adrenal Medulla:									
 Pheochromocytoma Malignant									
		1/50 (2%)	0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		3/50 (6%)	2/50 (4%)	2/50 (4%)	2/50 (4%)	0/50 (0%)	0/49 (0%)	0/49 (0%)	
			0/50 (0%)	1/88 (1%)	0/50 (0%)	0/86 (0%)	0/86 (0%)	0/86 (0%)	
		2/50 (4%)			1/50 (2%)				
Overall Incidence	Total	12/487 (2.46%)	Mean 2.58%	SD 2.05%	Total	3/485 (0.62%)	Mean 0.67%	SD 1.41%	
.....									
*Adrenal Medulla:									
 Pheochromocytoma: Benign, Complex, Malignant, NOS									
		5/50 (10%)	6/50 (12%)	8/49 (16%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		12/50 (24%)	8/50 (16%)	14/50 (28%)	5/50 (10%)	0/50 (0%)	0/49 (0%)	0/49 (0%)	
			8/50 (16%)	11/88 (13%)	1/50 (2%)	1/86 (1%)	1/86 (1%)	1/86 (1%)	
		12/50 (24%)			2/50 (4%)				
Overall Incidence	Total	84/487 (17.25%)	Mean 17.65%	SD 6.24%	Total	10/485 (2.06%)	Mean 2.13%	SD 3.25%	
.....									
#Bone:									
 Osteosarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)	1/50 (2%)	0/90 (0%)	0/90 (0%)	0/90 (0%)	
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
#Bone:									
 Osteosarcoma or Osteoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)	1/50 (2%)	0/90 (0%)	0/90 (0%)	0/90 (0%)	
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
*Brain:									
 Glioma Malignant									
		4/50 (8%)	0/50 (0%)	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)		2/50 (4%)		0/50 (0%)		1/50 (2%)	
			1/50 (2%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	11/439 (2.51%)	Mean 2.76%	SD 2.82%	Total	2/440 (0.45%)	Mean 0.5%	SD 0.93%	
.....									
*Brain:									
 Granular Cell Tumor Benign									
		3/50 (6%)	0/50 (0%)	0/49 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)		
		2/50 (4%)		0/50 (0%)	1/50 (2%)		0/50 (0%)		
			2/50 (4%)	1/90 (1%)	0/50 (0%)		1/90 (1%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	8/439 (1.82%)	Mean 1.89%	SD 2.41%	Total	5/440 (1.14%)	Mean 1.14%	SD 1.46%	
.....									
*Brain:									
 Granular Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)	0/50 (0%)	0/90 (0%)		0/90 (0%)	
		1/50 (2%)			0/50 (0%)				
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	0/440 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
 Meningioma Benign									
		0/50 (0%)	0/50 (0%)	1/49 (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%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/90 (0%)	
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	1/439 (0.23%)	Mean 0.26%	SD 0.72%	Total	0/440 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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			
*Brain:									
Meningioma Malignant									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/90 (0%)			0/90 (0%)		
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	1/440 (0.23%)	Mean 0.25%	SD 0.71%	
.....									
*Brain:									
Meningioma: Benign, Malignant, NOS									
		0/50 (0%)	0/50 (0%)	1/49 (2%)	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%)			0/90 (0%)		
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/439 (0.23%)	Mean 0.26%	SD 0.72%	Total	1/440 (0.23%)	Mean 0.25%	SD 0.71%	
.....									
*Brain:									
Oligodendroglioma, Glioma, or Astrocytoma									
		4/50 (8%)	0/50 (0%)	2/49 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)		
		0/50 (0%)		2/50 (4%)	0/50 (0%)		1/50 (2%)		
			1/50 (2%)	0/90 (0%)			0/90 (0%)		
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	11/439 (2.51%)	Mean 2.76%	SD 2.82%	Total	2/440 (0.45%)	Mean 0.5%	SD 0.93%	
.....									
*Brain:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)		0/50 (0%)	0/50 (0%)		1/50 (2%)		
			1/50 (2%)	0/90 (0%)			0/90 (0%)		
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	1/440 (0.23%)	Mean 0.25%	SD 0.71%	

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

Version: Nov2019
 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: 02/17/2020

		Male				Female			
*Clitoral/Preputial Gland: Adenoma									
		0/49 (0%)	0/50 (0%)	1/49 (2%)		0/49 (0%)	0/50 (0%)	0/49 (0%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/88 (0%)		0/50 (0%)		0/87 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/485 (0.21%)	Mean 0.23%	SD 0.68%	Total	0/483 (0%)	Mean 0%	SD 0%	

*Clitoral/Preputial Gland: Carcinoma									
		1/49 (2%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)	
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/88 (0%)		1/50 (2%)		0/87 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/485 (0.41%)	Mean 0.45%	SD 0.9%	Total	1/483 (0.21%)	Mean 0.22%	SD 0.67%	

*Clitoral/Preputial Gland: Carcinoma or Adenoma									
		1/49 (2%)	0/50 (0%)	1/49 (2%)		0/49 (0%)	0/50 (0%)	0/49 (0%)	
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/88 (0%)		1/50 (2%)		0/87 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	3/485 (0.62%)	Mean 0.68%	SD 1.02%	Total	1/483 (0.21%)	Mean 0.22%	SD 0.67%	

*Clitoral/Preputial Gland: Squamous Cell Carcinoma									
		0/49 (0%)	0/50 (0%)	1/49 (2%)		0/49 (0%)	0/50 (0%)	0/49 (0%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/88 (0%)		0/50 (0%)		0/87 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/485 (0.21%)	Mean 0.23%	SD 0.68%	Total	0/483 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
*Clitoral/Preputial Gland:									
Squamous Cell Papilloma									
		0/49 (0%)	1/50 (2%)	0/49 (0%)	1/49 (2%)	0/50 (0%)	0/49 (0%)		
		0/49 (0%)	0/50 (0%)	0/50 (0%)	0/48 (0%)	0/50 (0%)	0/50 (0%)		
			0/50 (0%)	0/88 (0%)	0/50 (0%)		0/87 (0%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	1/485 (0.21%)	Mean 0.22%	SD 0.67%	Total	1/483 (0.21%)	Mean 0.23%	SD 0.68%	
.....									
*Epididymis:									
Sarcoma									
		0/50 (0%)	0/49 (0%)	0/49 (0%)					
		0/50 (0%)	0/50 (0%)	1/50 (2%)					
			0/50 (0%)	0/90 (0%)					
		0/50 (0%)							
Overall Incidence	Total	1/488 (0.2%)	Mean 0.22%	SD 0.67%					
.....									
#Eye:									
Leiomyoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)	0/50 (0%)			0/90 (0%)	
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
*Heart:									
Schwannoma Malignant									
		3/50 (6%)	2/50 (4%)	2/49 (4%)	1/50 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)	0/50 (0%)			0/90 (0%)	
		0/50 (0%)			2/50 (4%)				
Overall Incidence	Total	9/489 (1.84%)	Mean 2.01%	SD 2.25%	Total	3/488 (0.61%)	Mean 0.67%	SD 1.41%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
#Intestine Large: Colon/Rectum:									
Granular Cell Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		1/90 (1%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%	

#Intestine Large: Colon/Rectum:									
Leiomyoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%	

#Intestine Small: Jejunum:									
Carcinoma									
		1/50 (2%)	2/50 (4%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
			1/50 (2%)	2/90 (2%)		1/50 (2%)		0/90 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	8/489 (1.64%)	Mean 1.58%	SD 1.34%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	

#Intestine Small: Jejunum:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		1/90 (1%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
#Intestine Small: Site Unspecified:									
Carcinoma									
		1/50 (2%)	2/50 (4%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	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%)	0/50 (0%)
			1/50 (2%)	2/90 (2%)	1/50 (2%)			0/90 (0%)	
		1/50 (2%)			0/50 (0%)				
Overall Incidence	Total	8/489 (1.64%)	Mean 1.58%	SD 1.34%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
#Intestine Small: Site Unspecified:									
Carcinoma or Adenoma									
		1/50 (2%)	2/50 (4%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	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%)	0/50 (0%)
			1/50 (2%)	2/90 (2%)	1/50 (2%)			0/90 (0%)	
		1/50 (2%)			0/50 (0%)				
Overall Incidence	Total	8/489 (1.64%)	Mean 1.58%	SD 1.34%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
#Intestine Small: Site Unspecified:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/90 (0%)	0/50 (0%)			1/90 (1%)	
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%	
.....									
*Islets, Pancreatic:									
Adenoma									
		3/49 (6%)	2/50 (4%)	4/49 (8%)	1/50 (2%)	3/49 (6%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		3/50 (6%)	2/50 (4%)	8/50 (16%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
			5/50 (10%)	5/90 (6%)	1/50 (2%)			5/90 (6%)	
		2/50 (4%)			1/50 (2%)				
Overall Incidence	Total	34/488 (6.97%)	Mean 7.09%	SD 3.91%	Total	13/489 (2.66%)	Mean 2.41%	SD 2.13%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
*Islets, Pancreatic:									
 Carcinoma									
		0/49 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/49 (0%)	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%)	1/50 (2%)	1/50 (2%)
			0/50 (0%)	8/90 (9%)		0/50 (0%)		2/90 (2%)	
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	9/488 (1.84%)	Mean 1.21%	SD 2.95%	Total	5/489 (1.02%)	Mean 0.91%	SD 1.09%	
.....									
*Islets, Pancreatic:									
 Carcinoma or Adenoma									
		3/49 (6%)	2/50 (4%)	4/49 (8%)	1/50 (2%)	3/49 (6%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		3/50 (6%)	2/50 (4%)	8/50 (16%)	1/50 (2%)	0/50 (0%)	2/50 (4%)	2/50 (4%)	2/50 (4%)
			5/50 (10%)	13/90 (14%)	1/50 (2%)		7/90 (8%)	7/90 (8%)	
		3/50 (6%)			2/50 (4%)				
Overall Incidence	Total	43/488 (8.81%)	Mean 8.3%	SD 4.36%	Total	18/489 (3.68%)	Mean 3.32%	SD 2.41%	
.....									
*Kidney: Pelvis and Transitional Epithelium:									
 Papilloma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	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%)	0/50 (0%)
			0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/90 (0%)	0/90 (0%)
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule:									
 Adenoma									
		0/50 (0%)	1/50 (2%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
			1/50 (2%)	3/90 (3%)	0/50 (0%)		1/90 (1%)	1/90 (1%)	
		2/50 (4%)			0/50 (0%)				
Overall Incidence	Total	9/489 (1.84%)	Mean 1.71%	SD 1.46%	Total	2/490 (0.41%)	Mean 0.35%	SD 0.72%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
*Kidney: Renal Tubule: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	1/90 (1%)		0/50 (0%)		1/90 (1%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.12%	SD 0.37%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%	

*Kidney: Renal Tubule: Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
			1/50 (2%)	3/90 (3%)		0/50 (0%)		2/90 (2%)	
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	9/489 (1.84%)	Mean 1.71%	SD 1.46%	Total	3/490 (0.61%)	Mean 0.47%	SD 0.93%	

*Kidney: Renal Tubule: Lipoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	1/90 (1%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.12%	SD 0.37%	Total	0/490 (0%)	Mean 0%	SD 0%	

*Kidney: Renal Tubule: Liposarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
			1/50 (2%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
*Kidney: Renal Tubule:									
 Nephroblastoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	
			1/50 (2%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule:									
 Oncocytoma Benign									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	
			0/50 (0%)	1/90 (1%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.12%	SD 0.37%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule:									
 Polyp Adenomatous									
		1/50 (2%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
#Lacrimal Gland:									
 Carcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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			
*Liver:									
Cholangiocarcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
			1/50 (2%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/489 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Cholangioma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%)	1/49 (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%)	0/90 (0%)		1/50 (2%)		0/90 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	3/489 (0.61%)	Mean 0.67%	SD 1.01%	
.....									
*Liver:									
Hemangioma									
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (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%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/489 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Hepatocellular Adenoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/49 (2%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	2/50 (4%)	
			0/50 (0%)	0/90 (0%)		2/50 (4%)		7/90 (8%)	
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	2/489 (0.41%)	Mean 0.44%	SD 0.88%	Total	15/489 (3.07%)	Mean 2.65%	SD 2.59%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
*Liver:									
Hepatocellular Carcinoma									
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/49 (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%)	0/90 (0%)		1/50 (2%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/489 (0.41%)	Mean 0.45%	SD 0.89%	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
*Liver:									
Hepatocellular Carcinoma or Hepatoblastoma									
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/49 (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%)	0/90 (0%)		1/50 (2%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/489 (0.41%)	Mean 0.45%	SD 0.89%	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
*Liver:									
Hepatocellular Carcinoma or Hepatocellular Adenoma									
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	1/49 (2%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	2/50 (4%)	
			0/50 (0%)	0/90 (0%)		3/50 (6%)		7/90 (8%)	
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	4/489 (0.82%)	Mean 0.89%	SD 1.06%	Total	16/489 (3.27%)	Mean 2.87%	SD 2.8%	
.....									
*Liver:									
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma									
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	1/49 (2%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	2/50 (4%)	
			0/50 (0%)	0/90 (0%)		3/50 (6%)		7/90 (8%)	
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	4/489 (0.82%)	Mean 0.89%	SD 1.06%	Total	16/489 (3.27%)	Mean 2.87%	SD 2.8%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
*Lung:									
Alveolar/Bronchiolar Adenoma									
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)	
			0/50 (0%)	1/90 (1%)		0/50 (0%)		0/90 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	3/488 (0.61%)	Mean 0.57%	SD 0.9%	Total	1/488 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
*Lung:									
Alveolar/Bronchiolar Carcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/488 (0.41%)	Mean 0.44%	SD 0.88%	Total	0/488 (0%)	Mean 0%	SD 0%	
.....									
*Lung:									
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma									
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)	
			0/50 (0%)	1/90 (1%)		0/50 (0%)		0/90 (0%)	
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	5/488 (1.02%)	Mean 1.02%	SD 1.42%	Total	1/488 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
*Lung:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/488 (0%)	Mean 0%	SD 0%	Total	1/488 (0.2%)	Mean 0.22%	SD 0.67%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
*Lung:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
			1/50 (2%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/488 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/488 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node, Mesenteric:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
#Mammary Gland:									
Adenolipoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
#Mammary Gland:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	4/50 (8%)	
			0/50 (0%)	0/90 (0%)		1/50 (2%)		8/90 (9%)	
		0/50 (0%)				3/50 (6%)			
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	20/490 (4.08%)	Mean 3.65%	SD 3.59%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
#Mammary Gland:									
Carcinoma									
		0/50 (0%)	1/50 (2%)	0/49 (0%)	8/50 (16%)	1/50 (2%)	4/50 (8%)		
		2/50 (4%)	0/50 (0%)	0/50 (0%)	7/50 (14%)	3/50 (6%)	5/50 (10%)		
			0/50 (0%)	0/90 (0%)	3/50 (6%)		10/90 (11%)		
		0/50 (0%)			2/50 (4%)				
Overall Incidence	Total	3/489 (0.61%)	Mean 0.67%	SD 1.41%	Total	43/490 (8.78%)	Mean 8.57%	SD 4.62%	
.....									
#Mammary Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	0/49 (0%)	8/50 (16%)	2/50 (4%)	4/50 (8%)		
		2/50 (4%)	0/50 (0%)	0/50 (0%)	7/50 (14%)	6/50 (12%)	9/50 (18%)		
			0/50 (0%)	0/90 (0%)	4/50 (8%)		16/90 (18%)		
		0/50 (0%)			5/50 (10%)				
Overall Incidence	Total	3/489 (0.61%)	Mean 0.67%	SD 1.41%	Total	61/490 (12.45%)	Mean 11.98%	SD 4.87%	
.....									
#Mammary Gland:									
Fibroadenoma									
		0/50 (0%)	2/50 (4%)	1/49 (2%)	25/50 (50%)	28/50 (56%)	33/50 (66%)		
		2/50 (4%)	1/50 (2%)	2/50 (4%)	32/50 (64%)	29/50 (58%)	20/50 (40%)		
			2/50 (4%)	2/90 (2%)	21/50 (42%)		63/90 (70%)		
		0/50 (0%)			30/50 (60%)				
Overall Incidence	Total	12/489 (2.45%)	Mean 2.47%	SD 1.66%	Total	281/490 (57.35%)	Mean 56.22%	SD 10.41%	
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma or Adenoma									
		0/50 (0%)	2/50 (4%)	1/49 (2%)	25/50 (50%)	29/50 (58%)	33/50 (66%)		
		2/50 (4%)	1/50 (2%)	2/50 (4%)	32/50 (64%)	30/50 (60%)	23/50 (46%)		
			2/50 (4%)	2/90 (2%)	22/50 (44%)		64/90 (71%)		
		0/50 (0%)			32/50 (64%)				
Overall Incidence	Total	12/489 (2.45%)	Mean 2.47%	SD 1.66%	Total	290/490 (59.18%)	Mean 58.12%	SD 9.46%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
#Mammary Gland:									
Fibroma, Fibroadenoma, Carcinoma, or Adenoma									
		0/50 (0%)	3/50 (6%)	1/49 (2%)	29/50 (58%)	30/50 (60%)	35/50 (70%)		
		3/50 (6%)	1/50 (2%)	2/50 (4%)	36/50 (72%)	32/50 (64%)	27/50 (54%)		
			2/50 (4%)	2/90 (2%)	25/50 (50%)		66/90 (73%)		
		0/50 (0%)			34/50 (68%)				
Overall Incidence	Total	14/489 (2.86%)	Mean 2.92%	SD 2.25%	Total	314/490 (64.08%)	Mean 63.26%	SD 8.26%	
.....									
#Mammary Gland:									
Myoepithelioma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)	0/50 (0%)		0/90 (0%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
*Nose:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/89 (0%)	1/50 (2%)		0/90 (0%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	0/488 (0%)	Mean 0%	SD 0%	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	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%)	0/90 (0%)	0/50 (0%)		2/90 (2%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	2/489 (0.41%)	Mean 0.45%	SD 0.89%	Total	2/490 (0.41%)	Mean 0.25%	SD 0.74%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma									
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		2/90 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/489 (0.41%)		Mean 0.45%	SD 0.89%	Total	2/490 (0.41%)		Mean 0.25% SD 0.74%
.....									
#Oral Mucosa:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		1/90 (1%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/489 (0.41%)		Mean 0.45%	SD 0.89%	Total	1/490 (0.2%)		Mean 0.12% SD 0.37%
.....									
*Ovary:									
Cystadenoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)		1/90 (1%)	
						0/50 (0%)			
Overall Incidence	Total					Total	1/490 (0.2%)		Mean 0.12% SD 0.37%
.....									
*Ovary:									
Granulosa Cell Tumor Benign									
						1/50 (2%)	1/50 (2%)	0/50 (0%)	
						0/50 (0%)	0/50 (0%)	3/50 (6%)	
						1/50 (2%)		1/90 (1%)	
						0/50 (0%)			
Overall Incidence	Total					Total	7/490 (1.43%)		Mean 1.46% SD 1.94%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

	Male		Female			
*Ovary:						
Granulosa Cell Tumor Malignant						
		0/50 (0%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)		2/90 (2%)		
		1/50 (2%)				
Overall Incidence	Total	4/490 (0.82%)	Mean 0.69%	SD 1.04%		
.....						
*Ovary:						
Granulosa Cell Tumor: Benign, Malignant, NOS						
		1/50 (2%)	2/50 (4%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	3/50 (6%)		
		1/50 (2%)		3/90 (3%)		
		1/50 (2%)				
Overall Incidence	Total	11/490 (2.24%)	Mean 2.15%	SD 2.05%		
.....						
*Ovary:						
Granulosa-Theca Tumor Benign						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)		0/90 (0%)		
		0/50 (0%)				
Overall Incidence	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%		
.....						
*Ovary:						
Granulosa-Theca Tumor Malignant						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)		0/90 (0%)		
		1/50 (2%)				
Overall Incidence	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%		

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

	Male		Female			
*Ovary:						
Luteoma						
		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%)	0/50 (0%)
		0/50 (0%)		0/90 (0%)	0/90 (0%)	
		0/50 (0%)				
Overall Incidence	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%		
.....						
*Ovary:						
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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)		0/90 (0%)	0/90 (0%)	
		0/50 (0%)				
Overall Incidence	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%		
.....						
*Ovary:						
Sertoli Cell 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%)	0/50 (0%)
		0/50 (0%)		1/90 (1%)	1/90 (1%)	
		0/50 (0%)				
Overall Incidence	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%		
.....						
*Ovary:						
Thecoma Benign						
		0/50 (0%)	0/50 (0%)	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%)		0/90 (0%)	0/90 (0%)	
		0/50 (0%)				
Overall Incidence	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%		

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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			
*Ovary:									
Tubulostromal Carcinoma									
						0/50 (0%)		0/50 (0%)	0/50 (0%)
						0/50 (0%)		1/50 (2%)	0/50 (0%)
						0/50 (0%)			0/90 (0%)
						0/50 (0%)			
Overall Incidence					Total	1/490 (0.2%)		Mean 0.22%	SD 0.67%
.....									
*Pancreas:									
Adenoma									
		1/49 (2%)	10/50 (20%)	4/49 (8%)		0/50 (0%)		0/49 (0%)	0/50 (0%)
		5/50 (10%)	5/50 (10%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)
			3/50 (6%)	18/90 (20%)		0/50 (0%)			0/90 (0%)
		14/50 (28%)				0/50 (0%)			
Overall Incidence	Total	60/488 (12.3%)	Mean 11.58%	SD 9.25%	Total	0/489 (0%)		Mean 0%	SD 0%
.....									
*Pancreas:									
Carcinoma									
		0/49 (0%)	0/50 (0%)	2/49 (4%)		0/50 (0%)		0/49 (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%)	1/90 (1%)		0/50 (0%)			0/90 (0%)
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	4/488 (0.82%)	Mean 0.8%	SD 1.42%	Total	0/489 (0%)		Mean 0%	SD 0%
.....									
*Pancreas:									
Carcinoma or Adenoma									
		1/49 (2%)	10/50 (20%)	6/49 (12%)		0/50 (0%)		0/49 (0%)	0/50 (0%)
		5/50 (10%)	5/50 (10%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)
			3/50 (6%)	18/90 (20%)		0/50 (0%)			0/90 (0%)
		14/50 (28%)				0/50 (0%)			
Overall Incidence	Total	62/488 (12.7%)	Mean 12.03%	SD 9.16%	Total	0/489 (0%)		Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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			
*Parathyroid Gland:									
Adenoma									
		0/43 (0%)	0/42 (0%)	0/48 (0%)	0/42 (0%)	0/42 (0%)	0/45 (0%)		
		0/49 (0%)	0/43 (0%)	0/48 (0%)	1/41 (2%)	0/47 (0%)	0/45 (0%)		
			0/41 (0%)	1/83 (1%)	0/47 (0%)		0/87 (0%)		
		0/43 (0%)			0/46 (0%)				
Overall Incidence	Total	1/440 (0.23%)	Mean 0.13%	SD 0.4%	Total	1/442 (0.23%)	Mean 0.27%	SD 0.81%	
.....									
#Peripheral Nerve:									
Paranglioma									
		0/50 (0%)	0/50 (0%)	1/49 (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%)	0/50 (0%)		
			0/50 (0%)	0/90 (0%)	0/50 (0%)		0/90 (0%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	1/489 (0.2%)	Mean 0.23%	SD 0.68%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
#Peripheral Nerve:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	1/49 (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%)	0/50 (0%)		
			0/50 (0%)	0/90 (0%)	0/50 (0%)		0/90 (0%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	1/489 (0.2%)	Mean 0.23%	SD 0.68%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
#Peripheral Nerve:									
Schwannoma: Benign, Malignant, NOS									
		0/50 (0%)	0/50 (0%)	1/49 (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%)	0/50 (0%)		
			0/50 (0%)	0/90 (0%)	0/50 (0%)		0/90 (0%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	1/489 (0.2%)	Mean 0.23%	SD 0.68%	Total	0/490 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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			
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Adenoma									
		3/50 (6%)	4/50 (8%)	15/48 (31%)	13/49 (27%)	15/49 (31%)	12/50 (24%)		
		14/50 (28%)	5/50 (10%)	11/50 (22%)	19/50 (38%)	18/50 (36%)	18/50 (36%)		
			5/50 (10%)	17/89 (19%)	22/50 (44%)		43/90 (48%)		
		8/50 (16%)			16/50 (32%)				
Overall Incidence	Total	82/487 (16.84%)	Mean 16.71%	SD 9.04%	Total	176/488 (36.07%)	Mean 34.99%	SD 7.72%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/48 (0%)	0/49 (0%)	1/49 (2%)	1/50 (2%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
			0/50 (0%)	0/89 (0%)	0/50 (0%)		1/90 (1%)		
		1/50 (2%)			1/50 (2%)				
Overall Incidence	Total	1/487 (0.21%)	Mean 0.22%	SD 0.67%	Total	4/488 (0.82%)	Mean 0.79%	SD 0.98%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma or Adenoma									
		3/50 (6%)	4/50 (8%)	15/48 (31%)	13/49 (27%)	16/49 (33%)	13/50 (26%)		
		14/50 (28%)	5/50 (10%)	11/50 (22%)	19/50 (38%)	18/50 (36%)	18/50 (36%)		
			5/50 (10%)	17/89 (19%)	22/50 (44%)		44/90 (49%)		
		9/50 (18%)			17/50 (34%)				
Overall Incidence	Total	83/487 (17.04%)	Mean 16.93%	SD 9.04%	Total	180/488 (36.89%)	Mean 35.79%	SD 7.4%	
.....									
*Pituitary Gland: Pars Intermedia:									
Adenoma									
		1/50 (2%)	0/50 (0%)	0/48 (0%)	0/49 (0%)	0/49 (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%)	0/89 (0%)	0/50 (0%)		0/90 (0%)		
		1/50 (2%)			0/50 (0%)				
Overall Incidence	Total	4/487 (0.82%)	Mean 0.89%	SD 1.45%	Total	0/488 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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							
*Pituitary Gland: Pars Intermedia:													
 Carcinoma or Adenoma													
		1/50	(2%)	0/50	(0%)	0/48	(0%)	0/49	(0%)	0/49	(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%)	0/89	(0%)	0/50	(0%)			0/90	(0%)
		1/50	(2%)					0/50	(0%)				
Overall Incidence	Total	4/487 (0.82%)		Mean 0.89%		SD 1.45%		Total 0/488 (0%)		Mean 0%		SD 0%	
.....													
*Pituitary Gland: Pars Nervosa:													
 Schwannoma Malignant													
		0/50	(0%)	0/50	(0%)	0/48	(0%)	0/49	(0%)	0/49	(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%)	0/89	(0%)	0/50	(0%)			0/90	(0%)
		1/50	(2%)					0/50	(0%)				
Overall Incidence	Total	1/487 (0.21%)		Mean 0.22%		SD 0.67%		Total 0/488 (0%)		Mean 0%		SD 0%	
.....													
*Prostate:													
 Adenoma													
		1/50	(2%)	0/50	(0%)	1/49	(2%)						
		0/50	(0%)	0/50	(0%)	0/50	(0%)						
				3/50	(6%)	2/90	(2%)						
		0/50	(0%)										
Overall Incidence	Total	7/489 (1.43%)		Mean 1.36%		SD 2.01%							
.....													
*Prostate:													
 Carcinoma or Adenoma													
		1/50	(2%)	0/50	(0%)	1/49	(2%)						
		0/50	(0%)	0/50	(0%)	0/50	(0%)						
				3/50	(6%)	2/90	(2%)						
		0/50	(0%)										
Overall Incidence	Total	7/489 (1.43%)		Mean 1.36%		SD 2.01%							

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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			
*Salivary Glands:									
Schwannoma Malignant									
		0/50 (0%)	2/50 (4%)	0/49 (0%)	0/49 (0%)	0/49 (0%)	0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/49 (0%)	0/90 (0%)	0/49 (0%)	0/49 (0%)		0/90 (0%)	0/90 (0%)
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	3/488 (0.61%)	Mean 0.67%	SD 1.41%	Total	0/485 (0%)	Mean 0%	SD 0%	
.....									
#Seminal Vesicle:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
			0/50 (0%)	0/90 (0%)					
		1/50 (2%)							
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%					
.....									
#Skeletal Muscle:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/90 (0%)
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
#Skeletal Muscle:									
Liposarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
			0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/90 (0%)
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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			
#Skeletal Muscle:									
Sarcoma									
		0/50 (0%)	1/50 (2%)	0/49 (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%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
#Skin:									
Basal Cell Adenoma									
		0/50 (0%)	0/50 (0%)	1/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
			1/50 (2%)	1/90 (1%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	3/489 (0.61%)	Mean 0.57%	SD 0.9%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Adenoma or Basosquamous Tumor Benign									
		0/50 (0%)	0/50 (0%)	1/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
			1/50 (2%)	1/90 (1%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	3/489 (0.61%)	Mean 0.57%	SD 0.9%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma									
		0/50 (0%)	1/50 (2%)	1/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
			1/50 (2%)	1/90 (1%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	4/489 (0.82%)	Mean 0.79%	SD 0.98%	Total	0/490 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
#Skin:									
Basal Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
#Skin:									
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
#Skin:									
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma									
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
			1/50 (2%)	1/90 (1%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	5/489 (1.02%)	Mean 1.02%	SD 1.01%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
#Skin:									
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma									
		1/50 (2%)	4/50 (8%)	9/49 (18%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		4/50 (8%)	6/50 (12%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
			6/50 (12%)	8/90 (9%)		0/50 (0%)		0/90 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	43/489 (8.79%)	Mean 8.81%	SD 5.08%	Total	2/490 (0.41%)	Mean 0.44%	SD 0.88%	

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

		Male				Female			
#Skin:									
Fibroma									
		3/50 (6%)	3/50 (6%)	3/49 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		3/50 (6%)	5/50 (10%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)		
			1/50 (2%)	2/90 (2%)	0/50 (0%)		2/90 (2%)		
		3/50 (6%)			1/50 (2%)				
Overall Incidence	Total	23/489 (4.7%)	Mean 4.93%	SD 3%	Total	4/490 (0.82%)	Mean 0.69%	SD 1.04%	
.....									
#Skin:									
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, Malignant Fibrous Histiocytoma, or Hemangiopericytoma									
		3/50 (6%)	3/50 (6%)	4/49 (8%)	1/50 (2%)	1/50 (2%)	1/50 (2%)		
		3/50 (6%)	7/50 (14%)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)		
			2/50 (4%)	5/90 (6%)	1/50 (2%)		5/90 (6%)		
		3/50 (6%)			3/50 (6%)				
Overall Incidence	Total	31/489 (6.34%)	Mean 6.41%	SD 3.3%	Total	14/490 (2.86%)	Mean 2.62%	SD 2.16%	
.....									
#Skin:									
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma									
		3/50 (6%)	3/50 (6%)	4/49 (8%)	1/50 (2%)	1/50 (2%)	1/50 (2%)		
		3/50 (6%)	7/50 (14%)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)		
			2/50 (4%)	5/90 (6%)	1/50 (2%)		5/90 (6%)		
		3/50 (6%)			2/50 (4%)				
Overall Incidence	Total	31/489 (6.34%)	Mean 6.41%	SD 3.3%	Total	13/490 (2.65%)	Mean 2.4%	SD 1.85%	
.....									
#Skin:									
Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	1/49 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)		
			1/50 (2%)	1/90 (1%)	0/50 (0%)		0/90 (0%)		
		0/50 (0%)			1/50 (2%)				
Overall Incidence	Total	4/489 (0.82%)	Mean 0.79%	SD 0.98%	Total	3/490 (0.61%)	Mean 0.67%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
#Skin:									
Fibrosarcoma, Sarcoma, Myxosarcoma, or Malignant Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	1/49 (2%)		1/50 (2%)	1/50 (2%)	1/50 (2%)	
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
			1/50 (2%)	3/90 (3%)		1/50 (2%)		3/90 (3%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	8/489 (1.64%)	Mean 1.49%	SD 1.56%	Total	9/490 (1.84%)	Mean 1.7%	SD 1.06%	
.....									
#Skin:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Hemangiopericytoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
#Skin:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		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%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
#Skin:									
Keratoacanthoma									
		1/50 (2%)	2/50 (4%)	8/49 (16%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	4/50 (8%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
			5/50 (10%)	5/90 (6%)	0/50 (0%)			0/90 (0%)	
		1/50 (2%)			0/50 (0%)				
Overall Incidence	Total	31/489 (6.34%)	Mean 6.43%	SD 4.54%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Lipoma									
		3/50 (6%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	2/90 (2%)	0/50 (0%)			0/90 (0%)	
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	8/489 (1.64%)	Mean 1.58%	SD 2.19%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
#Skin:									
Liposarcoma									
		0/50 (0%)	1/50 (2%)	0/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)	0/50 (0%)			0/90 (0%)	
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Malignant Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)	0/50 (0%)			1/90 (1%)	
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	2/489 (0.41%)	Mean 0.44%	SD 0.88%	Total	2/490 (0.41%)	Mean 0.35%	SD 0.72%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
#Skin:									
Neurofibrosarcoma or Schwannoma (malignant or NOS)									
		0/50 (0%)	2/50 (4%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/489 (0.41%)		Mean 0.44%	SD 1.33%	Total	3/490 (0.61%)		Mean 0.67% SD 1%
.....									
#Skin:									
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)									
		0/50 (0%)	2/50 (4%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/489 (0.41%)		Mean 0.44%	SD 1.33%	Total	3/490 (0.61%)		Mean 0.67% SD 1%
.....									
#Skin:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/489 (0%)		Mean 0%	SD 0%	Total	1/490 (0.2%)		Mean 0.22% SD 0.67%
.....									
#Skin:									
Pilomatixoma									
		0/50 (0%)	0/50 (0%)	3/49 (6%)		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%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	3/489 (0.61%)		Mean 0.68%	SD 2.04%	Total	0/490 (0%)		Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
#Skin:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	
			0/50 (0%)	2/90 (2%)		1/50 (2%)		2/90 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/489 (0.41%)	Mean 0.25%	SD 0.74%	Total	4/490 (0.82%)	Mean 0.69%	SD 1.04%	
.....									
#Skin:									
Schwannoma Malignant									
		0/50 (0%)	2/50 (4%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/489 (0.41%)	Mean 0.44%	SD 1.33%	Total	3/490 (0.61%)	Mean 0.67%	SD 1%	
.....									
#Skin:									
Squamous Cell Carcinoma									
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/489 (0.41%)	Mean 0.44%	SD 0.88%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
#Skin:									
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma									
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	3/489 (0.61%)	Mean 0.67%	SD 1.41%	Total	2/490 (0.41%)	Mean 0.44%	SD 0.88%	

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

Version: Nov2019
 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: 02/17/2020

		Male				Female			
#Skin:									
Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	2/90 (2%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	6/489 (1.23%)	Mean 1.14%	SD 1.47%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma or Papilloma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	2/90 (2%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	6/489 (1.23%)	Mean 1.14%	SD 1.47%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma									
		1/50 (2%)	3/50 (6%)	8/49 (16%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		4/50 (8%)	5/50 (10%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
			5/50 (10%)	7/90 (8%)		0/50 (0%)		0/90 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	38/489 (7.77%)	Mean 7.79%	SD 4.37%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma									
		1/50 (2%)	2/50 (4%)	8/49 (16%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		4/50 (8%)	5/50 (10%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
			5/50 (10%)	7/90 (8%)		0/50 (0%)		0/90 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	37/489 (7.57%)	Mean 7.57%	SD 4.52%	Total	0/490 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
#Skin:									
Trichoepithelioma									
		0/50 (0%)	1/50 (2%)	0/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
#Skin: Sebaceous Gland:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	1/90 (1%)	0/50 (0%)			0/90 (0%)	
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	2/489 (0.41%)	Mean 0.35%	SD 0.72%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
#Skin: Sebaceous Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	1/90 (1%)	0/50 (0%)			0/90 (0%)	
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	2/489 (0.41%)	Mean 0.35%	SD 0.72%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
#Spinal Cord:									
Astrocytoma Malignant									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/90 (0%)		1/50 (2%)		0/90 (0%)	
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
*Spleen:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/49 (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%)	3/90 (3%)		0/50 (0%)		1/90 (1%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	3/489 (0.61%)	Mean 0.37%	SD 1.11%	Total	2/489 (0.41%)	Mean 0.35%	SD 0.73%	
.....									
#Stomach, Forestomach:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		1/90 (1%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma or Papilloma Squamous									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
			0/50 (0%)	1/90 (1%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/489 (0.41%)	Mean 0.35%	SD 0.72%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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: 02/17/2020

		Male				Female			
#Stomach, Forestomach:									
Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	
			0/50 (0%)	1/90 (1%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.12%	SD 0.37%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
*Testis:									
Adenoma									
		7/50 (14%)	3/49 (6%)	2/49 (4%)					
		1/50 (2%)	3/49 (6%)	0/50 (0%)					
			0/50 (0%)	2/90 (2%)					
		1/50 (2%)							
Overall Incidence	Total	19/487 (3.9%)	Mean 4.06%	SD 4.36%					
.....									
*Thymus:									
Thymoma Benign									
		0/48 (0%)	0/47 (0%)	0/48 (0%)		0/49 (0%)	0/46 (0%)	0/49 (0%)	
		0/46 (0%)	1/46 (2%)	0/48 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)	
			0/48 (0%)	0/88 (0%)		0/49 (0%)		1/87 (1%)	
		0/48 (0%)				0/47 (0%)			
Overall Incidence	Total	1/467 (0.21%)	Mean 0.24%	SD 0.72%	Total	1/473 (0.21%)	Mean 0.13%	SD 0.38%	
.....									
*Thymus:									
Thymoma Malignant									
		0/48 (0%)	0/47 (0%)	0/48 (0%)		0/49 (0%)	0/46 (0%)	0/49 (0%)	
		0/46 (0%)	0/46 (0%)	0/48 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)	
			0/48 (0%)	0/88 (0%)		0/49 (0%)		1/87 (1%)	
		0/48 (0%)				0/47 (0%)			
Overall Incidence	Total	0/467 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.13%	SD 0.38%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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 Tumor Incidence for Selected Control Animal Groups
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		Male				Female			
*Thymus:									
Thymoma: Benign, Malignant, NOS									
		0/48 (0%)	0/47 (0%)	0/48 (0%)	0/49 (0%)	0/46 (0%)	0/49 (0%)		
		0/46 (0%)	1/46 (2%)	0/48 (0%)	0/49 (0%)	0/47 (0%)	0/50 (0%)		
			0/48 (0%)	0/88 (0%)	0/49 (0%)		2/87 (2%)		
		0/48 (0%)			0/47 (0%)				
Overall Incidence	Total	1/467 (0.21%)	Mean 0.24%	SD 0.72%	Total	2/473 (0.42%)	Mean 0.26%	SD 0.77%	

*Thyroid Gland: C-Cell:									
Adenoma									
		13/50 (26%)	10/50 (20%)	8/49 (16%)	12/50 (24%)	8/49 (16%)	12/50 (24%)		
		7/50 (14%)	13/50 (26%)	2/50 (4%)	5/50 (10%)	11/49 (22%)	2/50 (4%)		
			11/49 (22%)	8/89 (9%)	9/50 (18%)		6/90 (7%)		
		4/50 (8%)			5/50 (10%)				
Overall Incidence	Total	76/487 (15.61%)	Mean 16.2%	SD 8.05%	Total	70/488 (14.34%)	Mean 15.05%	SD 7.65%	

*Thyroid Gland: C-Cell:									
Carcinoma									
		2/50 (4%)	1/50 (2%)	1/49 (2%)	2/50 (4%)	0/49 (0%)	1/50 (2%)		
		1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/49 (0%)	0/50 (0%)		
			0/49 (0%)	2/89 (2%)	1/50 (2%)		0/90 (0%)		
		0/50 (0%)			2/50 (4%)				
Overall Incidence	Total	8/487 (1.64%)	Mean 1.59%	SD 1.35%	Total	7/488 (1.43%)	Mean 1.56%	SD 1.67%	

*Thyroid Gland: C-Cell:									
Carcinoma or Adenoma									
		14/50 (28%)	10/50 (20%)	8/49 (16%)	14/50 (28%)	8/49 (16%)	13/50 (26%)		
		8/50 (16%)	13/50 (26%)	3/50 (6%)	6/50 (12%)	11/49 (22%)	2/50 (4%)		
			11/49 (22%)	10/89 (11%)	9/50 (18%)		6/90 (7%)		
		4/50 (8%)			7/50 (14%)				
Overall Incidence	Total	81/487 (16.63%)	Mean 17.11%	SD 7.72%	Total	76/488 (15.57%)	Mean 16.38%	SD 8.21%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
*Thyroid Gland: Follicular Cell: Adenoma									
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
			0/49 (0%)	0/89 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/487 (0.21%)	Mean 0.23%	SD 0.68%	Total	0/488 (0%)	Mean 0%	SD 0%	
.....									
*Thyroid Gland: Follicular Cell: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
			0/49 (0%)	0/89 (0%)		0/50 (0%)		1/90 (1%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/487 (0%)	Mean 0%	SD 0%	Total	1/488 (0.2%)	Mean 0.12%	SD 0.37%	
.....									
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
			0/49 (0%)	0/89 (0%)		0/50 (0%)		1/90 (1%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/487 (0.21%)	Mean 0.23%	SD 0.68%	Total	1/488 (0.2%)	Mean 0.12%	SD 0.37%	
.....									
#Tissue NOS: Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	
			0/50 (0%)	1/90 (1%)		0/50 (0%)		1/90 (1%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.12%	SD 0.37%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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			
#Tongue:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		1/90 (1%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%	
.....									
#Tongue:									
Squamous Cell Carcinoma or Papilloma Squamous									
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		1/90 (1%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%	
.....									
#Tooth:									
Odontoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%	
.....									
*Urinary Bladder:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)	
			0/49 (0%)	0/89 (0%)		0/50 (0%)		1/88 (1%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/487 (0%)	Mean 0%	SD 0%	Total	1/486 (0.21%)	Mean 0.13%	SD 0.38%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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:		
Adenocarcinoma		
	2/50 (4%)	3/50 (6%)
	5/50 (10%)	5/50 (10%)
	1/50 (2%)	
	3/50 (6%)	1/50 (2%)
Overall Incidence	Total 20/350 (5.71%)	Mean 5.71% SD 3.35%
.....		
#Uterus:		
Adenocarcinoma or Adenoma		
	2/50 (4%)	3/50 (6%)
	5/50 (10%)	5/50 (10%)
	2/50 (4%)	
	3/50 (6%)	1/50 (2%)
Overall Incidence	Total 21/350 (6%)	Mean 6% SD 3.06%
.....		
#Uterus:		
Adenoma		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
	1/50 (2%)	
	0/50 (0%)	0/50 (0%)
Overall Incidence	Total 1/350 (0.29%)	Mean 0.29% SD 0.76%
.....		
#Uterus:		
Deciduoma Benign		
	0/50 (0%)	1/50 (2%)
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	
	0/50 (0%)	0/50 (0%)
Overall Incidence	Total 1/350 (0.29%)	Mean 0.29% SD 0.76%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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:		
Granular Cell Tumor Benign		
	0/50 (0%)	1/50 (2%)
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	
	0/50 (0%)	
Overall Incidence	Total 1/350 (0.29%)	Mean 0.29% SD 0.76%
.....		
#Uterus:		
Polyp Stromal		
	5/50 (10%)	8/50 (16%)
	8/50 (16%)	10/50 (20%)
	16/50 (32%)	
	5/50 (10%)	
Overall Incidence	Total 57/350 (16.29%)	Mean 16.29% SD 7.95%
.....		
#Uterus:		
Sarcoma		
	1/50 (2%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	
	0/50 (0%)	
Overall Incidence	Total 1/350 (0.29%)	Mean 0.29% SD 0.76%
.....		
#Uterus:		
Sarcoma Stromal		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	2/50 (4%)
	1/50 (2%)	
	1/50 (2%)	
Overall Incidence	Total 5/350 (1.43%)	Mean 1.43% SD 1.51%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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		
	5/50 (10%)	8/50 (16%)
	8/50 (16%)	12/50 (24%)
	16/50 (32%)	
	6/50 (12%)	
Overall Incidence	Total 61/350 (17.43%)	Mean 17.43% SD 7.89%
#Uterus:		
Schwannoma Malignant		
	0/50 (0%)	1/50 (2%)
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	
	0/50 (0%)	
Overall Incidence	Total 1/350 (0.29%)	Mean 0.29% SD 0.76%
#Uterus:		
Squamous Cell Carcinoma		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	
	2/50 (4%)	
Overall Incidence	Total 2/350 (0.57%)	Mean 0.57% SD 1.51%
#Vagina:		
Granular Cell Tumor Benign		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/90 (0%)
	0/50 (0%)	
Overall Incidence	Total 1/490 (0.2%)	Mean 0.22% SD 0.67%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2019
 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			
#Vagina:									
Polyp									
						0/50 (0%)		0/50 (0%)	
						0/50 (0%)		1/50 (2%)	0/50 (0%)
						0/50 (0%)			0/90 (0%)
						1/50 (2%)			
Overall Incidence					Total	2/490 (0.41%)		Mean 0.44%	SD 0.88%
.....									
#Vagina:									
Schwannoma Malignant									
						0/50 (0%)		1/50 (2%)	0/50 (0%)
						0/50 (0%)		1/50 (2%)	1/50 (2%)
						0/50 (0%)			1/90 (1%)
						0/50 (0%)			
Overall Incidence					Total	4/490 (0.82%)		Mean 0.79%	SD 0.98%
.....									
#Zymbal's Gland:									
Carcinoma									
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)		0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)		0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/90 (0%)		0/50 (0%)			0/90 (0%)
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	4/489 (0.82%)	Mean 0.89%	SD 1.06%	Total	0/490 (0%)		Mean 0%	SD 0%
.....									
#Zymbal's Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)		0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)		0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/90 (0%)		0/50 (0%)			0/90 (0%)
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	4/489 (0.82%)	Mean 0.89%	SD 1.06%	Total	0/490 (0%)		Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied