

NTP Historical Controls Report

All Routes and Vehicles

Harlan Sprague-Dawley RATS

April 2019

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	М3	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.

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

				Stu	dy 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 Battelle Columbus Laboratory Battelle Northwest Battelle Columbus Laboratory Battelle Columbus Laboratory I. I. T. Research Institute Battelle Columbus Laboratory	051026001 052000603 051047203 052061401 052061402 052010556 050303803	11/08/10 03/14/07 01/17/11 10/27/08 07/27/09 09/16/12 01/30/12	729 727 729 N/A 743 730 729	50(2) 50(3) 50(5) 0(0) 50(2) 90(1) 50(2)	30(706) 20(644) 25(661) 0(0) 36(684) 25(642) 12(621)	615.3 584.8 609.4 N/A 609.5 658.1 610.8	2-Hydroxy-4-methoxybenzophenone Indole-3-carbinol p-Chloro-a,a,a-trifluorotoluene Perfluorooctanoic Acid Perfluorooctanoic Acid Radiofrequency Radiation Sodium Tungstate Dihydrate
					Female		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Northwest Battelle Columbus Laboratory Battelle Columbus Laboratory I. I. T. Research Institute Battelle Columbus Laboratory	051026001 052000603 051047203 052061401 052061402 052010556 050303803	11/09/10 03/15/07 01/17/11 10/28/08 N/A 09/16/12 01/31/12	730 729 731 744 N/A 737 730	50(4) 50(5) 50(5) 50(4) 0(0) 90(1) 50(5)	30(657) 21(637) 22(626) 23(649) 0(0) 48(659) 30(667)	379.6 353.0 377.3 385.9 N/A 462.4 393.3	2-Hydroxy-4-methoxybenzophenone Indole-3-carbinol p-Chloro-a,a,a-trifluorotoluene Perfluorooctanoic Acid Perfluorooctanoic Acid Radiofrequency Radiation Sodium Tungstate Dihydrate

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

Page: 4 Report Date: 07/01/2019

			Male				Female	
#All Organs: Benign Tumors								
-		38/50 (76%)	27/50 (54%) 32/50 (64%)	30/50 (60%) 49/90 (54%)		41/50 (82%) 39/50 (78%)	40/50 (80%)	39/50 (78%) 82/90 (91%)
		29/50 (58%)				39/50 (78%)		
Overall Incidence	Total	205/340 (60.29%)	Mean 61.07%	SD 8.2%	Total	280/340 (82.35%)	Mean 81.19%	SD 5.12%
#All Organs: Malignant Tumors								
		11/50 (22%)	12/50 (24%) 9/50 (18%)	12/50 (24%) 24/90 (27%)		15/50 (30%) 14/50 (28%)	19/50 (38%)	11/50 (22%) 37/90 (41%)
0	T . (.)	14/50 (28%)	Mara 00 700/		T . (. 1	17/50 (34%)	Mara 00.400/	00.0070/
Overall Incidence	Total	82/340 (24.12%)	Mean 23.78%	SD 3.54%	Total	113/340 (33.24%)	Mean 32.19%	SD 6.97%
All Organs: Malignant and Benign T	umors							
5 5		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	242/340 (71.18%)	Mean 72.22%	SD 7.25%	Total	317/340 (93.24%)	Mean 92.48%	SD 5.62%
#All Organs: Hemangioma								
		0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	0/340 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

Version: Apr2019

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: 07/01/2019

			Male				Female	
#All Organs: Hemangiosarcoma								
Ū		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 3/90 (3%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 3/90 (3%)
		1/50 (2%)	· · · ·			0/50 (0%)		()
Overall Incidence	Total	5/340 (1.47%)	Mean 1.22%	SD 1.42%	Total	4/340 (1.18%)	Mean 0.89%	SD 1.44%
#All Organs: Hemangiosarcoma or Hen								
		0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 3/90 (3%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 3/90 (3%)
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	6/340 (1.76%)	Mean 1.56%	SD 1.31%	Total	4/340 (1.18%)	Mean 0.89%	SD 1.44%
#All Organs: Histiocytic Sarcoma								
		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%) 0/50 (0%)		0/90 (0%)
Overall Incidence	Total	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
#All Organs: Leukemia: Granulocytic								
		0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)	. ,	. ,		0/50 (0%)		
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	0/340 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

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

Page: 6 Report Date: 07/01/2019

					Male						F	emale		
#All Organs:														
Leukemia: Lymphocyti	ic, Monocytic, M	ononuclear, or Un	differen	tiated										
		0/50 ((0%)	0/50 3/50	(0%) (6%)	3/50 0/90	(6%) (0%)		0/50 1/50	(0%) (2%)	0/50	(0%)	0/50 0/90	(0%) (0%)
		1/50 ((2%)		· · /				0/50	(0%)				
Overall Incidence	Total	7/340 (2.06%)		Mean 2		SD 2.94%		Total	1/340 (0.	,		0.33%	SD 0.	
#All Organs:								••••••		•••••			•••••	
Malignant Lymphoma:	Histiocytic, I vm	phocytic Mixed	NOS. or	Undifferen	tiated Cel	l Type								
manghan Eymphomai			(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0,00 ((070)	1/50	(2%)	2/90	(2%)		1/50	(2%)	0,00	(070)	5/90	(6%)
		1/50 ((2%)	1/00	(270)	2/00	(270)		2/50	(4%)			0/00	(070)
Overall Incidence	Total	4/340 (1.18%)	· ·	Mean 1	.04%	SD 1.14%	6	Total	8/340 (2.	()	Mean	1.93%	SD 2.	39%
		· · · · · · · · · · · · · · · · · · ·							·····	· · · · · · · · · · · · · · · · · · ·			•••••	
#All Organs:														
Malignant Schwannom	a													
		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	8/340 (2.35%)		Mean 2		SD 1.38%		Total	10/340 (2	,		2.74%	SD 2.	13%
#All Organs:													•••••	
Mesothelioma: Benign	Malignant NOS													
wesothenollia. Benigh	, manynant, NOS		(2%)	1/50	(2%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50 (~ /0)	1/50	(2%)	2/90	(2%)		0/50	(0%)	0/50	(070)	0/90	(0%)
		0/50 /	(00/)	1/50	(270)	2/90	(270)			· · /			0/90	(0%)
	-	· · · · · ·	(0%)	••					0/50	(0%)				
Overall Incidence	Total	6/340 (1.76%))	Mean 1	.7%	SD 0.84%	6	Total	0/340 (0	J%)	Mear	n 0%	SD	0%

*: Denominator is number of animals with tissues examined microscopically

Version: Apr2019 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: 07/01/2019

			Male				Female	
#All Organs: Mesothelioma: Malignant								
		1/50 (2%)	1/50 (2%) 1/50 (2%)	1/50 (2%) 2/90 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	6/340 (1.76%)	Mean 1.7%	SD 0.84%	Total	0/340 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma								
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)	0/00 (070)	0/00 (070)		1/50 (2%)		0/50 (070)
Overall Incidence	Total	0/340 (0%)	Mean 0%	SD 0%	Total	2/340 (0.59%)	Mean 0.67%	SD 1.03%
All Organs: Osteosarcoma or Osteoma								
		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	0/340 (0%)	Mean 0%	SD 0%	Total	2/340 (0.59%)	Mean 0.67%	SD 1.03%
Adrenal Cortex: Adenoma								
		3/50 (6%)	0/50 (0%) 0/50 (0%)	3/50 (6%) 1/90 (1%)		3/50 (6%) 2/50 (4%)	0/50 (0%)	0/50 (0%) 1/90 (1%)
		0/50 (0%)				0/50 (0%)		()
Overall Incidence	Total	7/340 (2.06%)	Mean 2.19%	SD 2.99%	Total	6/340 (1.76%)	Mean 1.85%	SD 2.56%

*: Denominator is number of animals with tissues examined microscopically

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

Page: 8 Report Date: 07/01/2019

			Male				Female	
*Adrenal Cortex: Carcinoma								
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/90 (1%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.19%	SD 0.45%
*Adrenal Medulla: Ganglioneuroma								
		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	1/338 (0.3%)	Mean 0.33%	SD 0.82%	Total	0/335 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Be	enign							
		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	54/338 (15.98%)	Mean 16.56%	SD 5.28%	Total	6/335 (1.79%)	Mean 1.86%	SD 2.22%
*Adrenal Medulla: Pheochromocytoma Co								
-	·	0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 1/88 (1%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%) 0/86 (0%)
		0/50 (0%)	. ,			0/50 (0%)		
Overall Incidence	Total	2/338 (0.59%)	Mean 0.52%	SD 0.85%	Total	0/335 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

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

Page: 9 Report Date: 07/01/2019

			Male				Female	
*Adrenal Medulla: Pheochromocytoma Ma	alignant							
	0	3/50 (6%)	2/50 (4%) 0/50 (0%)	2/50 (4%) 1/88 (1%)		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/49 (0%) 0/86 (0%)
		2/50 (4%)				1/50 (2%)		
Overall Incidence	Total	10/338 (2.96%)	Mean 3.19%	SD 2.2%	Total	3/335 (0.9%)	Mean 1%	SD 1.67%
*Adrenal Medulla: Pheochromocytoma: B								
		12/50 (24%)	8/50 (16%) 8/50 (16%)	14/50 (28%) 11/88 (13%)		5/50 (10%) 1/50 (2%)	0/50 (0%)	0/49 (0%) 1/86 (1%)
Overall Incidence	Total	12/50 (24%) 65/338 (19.23%)	Mean 20.08%	SD 6.07%	Total	2/50 (4%) 9/335 (2.69%)	Mean 2.86%	SD 3.8%
#Bone: Osteosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/340 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/90 (0%) SD 0%	Total	0/50 (0%) 1/50 (2%) 0/50 (0%) 1/340 (0.29%)	0/50 (0%) Mean 0.33%	0/50 (0%) 0/90 (0%) SD 0.82%
		0/340 (0%)				. ,		
#Bone: Osteosarcoma or Osteo	oma							
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
o	T ()	0/50 (0%)	N. 00/	00.00/	-	0/50 (0%)	N 0.000/	
Overall Incidence	Total	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%

*: Denominator is number of animals with tissues examined microscopically

Version: Apr2019 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: 07/01/2019

			Male				Female	
*Brain: Glioma Malignant								
J J J J J J J J J J J J J J J J J J J		0/50 (0%)	1/50 (2%)	2/50 (4%) 0/90 (0%)		0/50 (0%) 0/50 (0%)		1/50 (2%) 0/90 (0%)
		2/50 (4%)	(270)			0/50 (0%)		
Overall Incidence	Total	5/290 (1.72%)	Mean 2%	SD 2%	Total	1/290 (0.34%)	Mean 0.4%	SD 0.89%
*Brain: Granular Cell Tumor Be								
		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	5/290 (1.72%)	Mean 1.82%	SD 2.04%	Total	2/290 (0.69%)	Mean 0.62%	SD 0.91%
*Brain: Granular Cell Tumor M								
	angnant	0/50 (0%)		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	1/290 (0.34%)	Mean 0.4%	SD 0.89%	Total	0/290 (0%)	Mean 0%	SD 0%
*Brain:								
Oligodendroglioma, Gl	ionia, or Astroc	0/50 (0%)		2/50 (4%)		0/50 (0%)		1/50 (2%)
		0/00 (0/0)	1/50 (2%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		2/50 (4%)		0,00 (0,0)		0/50 (0%)		
Overall Incidence	Total	5/290 (1.72%)	Mean 2%	SD 2%	Total	1/290 (0.34%)	Mean 0.4%	SD 0.89%

*: Denominator is number of animals with tissues examined microscopically

Version: Apr2019

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: 07/01/2019

			Male				Female	
Brain: Schwannoma Malignant								
-		0/50 (0%)	1/50 (2%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 0/50 (0%)		1/50 (2%) 0/90 (0%)
		0/50 (0%)		()		0/50 (0%)		(,
verall Incidence	Total	1/290 (0.34%)	Mean 0.4%	SD 0.89%	Total	1/290 (0.34%)	Mean 0.4%	SD 0.89%
Clitoral/Preputial Gland: Carcinoma								
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (00/)	0/50 (0%)	0/88 (0%)		1/50 (2%)		0/87 (0%)
	T - (-)	0/50 (0%)	Maran 0.040/	00.000/	T - (- 1	0/50 (0%)	Marca 0.000/	00.0000
Overall Incidence	Total	1/337 (0.3%)	Mean 0.34%	SD 0.83%	Total	1/335 (0.3%)	Mean 0.33%	SD 0.82%
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (00/)	0/50 (0%)	0/88 (0%)		1/50 (2%)		0/87 (0%)
Overall Incidence	Total	0/50 (0%) 1/337 (0.3%)	Mean 0.34%	SD 0.83%	Total	0/50 (0%) 1/335 (0.3%)	Mean 0.33%	SD 0.82%
		()				()		
Epididymis: Sarcoma								
		0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/90 (0%)				
		0/50 (0%)						
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%				

*: Denominator is number of animals with tissues examined microscopically

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

Page: 12 Report Date: 07/01/2019

			Male				Female	
#Eye: Leiomyoma								
		0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Verall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	0/340 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Malignar								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (00/)	0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
	T ()	0/50 (0%)	M 0.070/	00 4 000/	T ()	2/50 (4%)		00 4 0004
Overall Incidence	Total	2/340 (0.59%)	Mean 0.67%	SD 1.03%	Total	2/339 (0.59%)	Mean 0.67%	SD 1.63%
Intestine Large: Colon/F Granular Cell Tumor B								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (00/)	0/50 (0%)	0/90 (0%)		0/50 (0%)		1/90 (1%)
Overall Incidence	Total	0/50 (0%)	Maan 0%	SD 0%	Total	0/50 (0%)	Maan 0 10%	SD 0 459/
	Total	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.19%	SD 0.45%
Intestine Large: Colon/F Leiomyoma	Rectum:							
-		0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	0/340 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

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

Page: 13 Report Date: 07/01/2019

			Male				Female	
#Intestine Small: Jejunum: Carcinoma								
		1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 2/90 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	5/340 (1.47%)	Mean 1.37%	SD 1.06%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
#Intestine Small: Jejunum: Leiomyosarcoma								
		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%) 0/50 (0%)		1/90 (1%)
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	1/340 (0.29%)	Mean 0.19%	SD 0.45%
#Intestine Small: Site Unspe Carcinoma	cified:							
		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	5/340 (1.47%)	Mean 1.37%	SD 1.06%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
#Intestine Small: Site Unspe Carcinoma or Adenoma								
		1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 2/90 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		1/50 (2%)				0/50 (0%)		()
Overall Incidence	Total	5/340 (1.47%)	Mean 1.37%	SD 1.06%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%

*: Denominator is number of animals with tissues examined microscopically

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

Page: 14 Report Date: 07/01/2019

			Male				Female	
#Intestine Small: Site Unspe Leiomyosarcoma	cified:							
·		0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/90 (1%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	1/340 (0.29%)	Mean 0.19%	SD 0.45%
*Islets, Pancreatic: Adenoma								
		3/50 (6%)	2/50 (4%)	8/50 (16%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		2/50 (4%)	5/50 (10%)	5/90 (6%)		1/50 (2%) 1/50 (2%)		5/90 (6%)
Overall Incidence	Total	2/30 (47%)	Mean 7.59%	SD 4.67%	Total	8/340 (2.35%)	Mean 1.93%	SD 2.03%
Islets, Pancreatic: Carcinoma		·····				····· / / / / / / / / / / / / / / / / /		
earonnonna		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
			0/50 (0%)	8/90 (9%)		0/50 (0%)		2/90 (2%)
O	Tatal	1/50 (2%)	Magaz 4 0404		T = (= 1	1/50 (2%)	Mara 4.070/	00 4 000/
Overall Incidence	Total	9/340 (2.65%)	Mean 1.81%	SD 3.56%	Total	5/340 (1.47%)	Mean 1.37%	SD 1.06%
*Islets, Pancreatic: Carcinoma or Adenoma								
		3/50 (6%)	2/50 (4%)	8/50 (16%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
			5/50 (10%)	13/90 (14%)		1/50 (2%)		7/90 (8%)
Overall Incidence	Total	3/50 (6%) 34/340 (10%)	Mean 9.41%	SD 4.93%	Total	2/50 (4%) 13/340 (3.82%)	Mean 3.3%	SD 2.66%
	TOLA	34/340 (10%)	Weall 9.4170	JU 4.93%	TULAI	13/340 (3.02%)		SD 2.00%

*: Denominator is number of animals with tissues examined microscopically

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

Page: 15 Report Date: 07/01/2019

			Male				Female	
Kidney: Pelvis and Transitic Papilloma	onal Epitheliu	um:						
		1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)	()			0/50 (0%)		
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	0/340 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 3/90 (3%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%) 1/90 (1%)
		2/50 (4%)	1,00 (2,0)	0,00 (0,0)		0/50 (0%)		(170)
Overall Incidence	Total	7/340 (2.06%)	Mean 1.89%	SD 1.66%	Total	2/340 (0.59%)	Mean 0.52%	SD 0.85%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (00/)	0/50 (0%)	1/90 (1%)		0/50 (0%)		1/90 (1%)
Overall Incidence	Total	0/50 (0%) 1/340 (0.29%)	Mean 0.19%	SD 0.45%	Total	0/50 (0%) 1/340 (0.29%)	Mean 0.19%	SD 0.45%
		()						
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 3/90 (3%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%) 2/90 (2%)
		2/50 (4%)	. ,	. ,		0/50 (0%)		. ,
Overall Incidence	Total	7/340 (2.06%)	Mean 1.89%	SD 1.66%	Total	3/340 (0.88%)	Mean 0.7%	SD 1.09%

*: Denominator is number of animals with tissues examined microscopically

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

Page: 16 Report Date: 07/01/2019

			Male				Female	
*Kidney: Renal Tubule: Lipoma								
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/90 (1%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/340 (0.29%)	Mean 0.19%	SD 0.45%	Total	0/340 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
			1/50 (2%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	0/340 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Nephroblastoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (00()	1/50 (2%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
	Tatal	0/50 (0%)	Maan 0.000/	CD 0.000/	Tatal	0/50 (0%)	Maar 00/	CD 00/
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	0/340 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Oncocytoma Benign								
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/90 (1%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/340 (0.29%)	Mean 0.19%	SD 0.45%	Total	0/340 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

Version: Apr2019

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: 07/01/2019

					Male						F	emale		
*Liver:														
Cholangiocarcinoma		0/50	(00()	0/50	(00()	0/50	(00()		0/50	(00()	0/50	(00()	0/50	(22()
		0/50 ((0%)	0/50 1/50	(0%) (2%)	0/50 0/90	(0%) (0%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50 0/90	(0%) (0%)
		0/50 ((0%)	1/50	(270)	0/90	(078)		0/50	(0%)			0/90	(078)
Overall Incidence	Total	1/340 (0.29%))	Mean 0.		SD 0.82%		Total	0/340 (0%)		an 0%	SD	
*Liver: Cholangioma														
-		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	1/340 (0.29%))	Mean 0.	.33%	SD 0.82%	6	Total	1/340 (0.	29%)	Mean	0.33%	SD 0.	.82%
*Liver: Hepatocellular Adenoma														
-		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%)
		,	(2%)						1/50	(2%)				
Overall Incidence	Total	2/340 (0.59%)		Mean 0.		SD 1.03%		Total	14/340 (4	,		3.63%	SD 2.	
*Liver: Hepatocellular Carcinoma														
-		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	0/340 (0%)		Mean	0%	SD 0%		Total	1/340 (0.	29%)	Mean	0.33%	SD 0.	.82%

*: Denominator is number of animals with tissues examined microscopically

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

Page: 18 Report Date: 07/01/2019

			Male			Female	
*Liver:							
Hepatocellular Carcino	oma or Hepatobl	astoma					
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)			0/50 (0%)		
Overall Incidence	Total	0/340 (0%)	Mean 0%	SD 0%	Total 1/340 (0.29%)	Mean 0.33%	SD 0.82%
*Liver:							
Hepatocellular Carcino	oma or Hepatoce	ellular Adenoma					
	•	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	2/340 (0.59%)	Mean 0.67%	SD 1.03%	Total 15/340 (4.41%)	Mean 3.96%	SD 2.77%
*Liver:							
	oma, Hepatocellu	ular Adenoma, or Hepato	blastoma				
•	<i>·</i>	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	2/340 (0.59%)	Mean 0.67%	SD 1.03%	Total 15/340 (4.41%)	Mean 3.96%	SD 2.77%
*Lung:							
Alveolar/Bronchiolar A	denoma						
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%)
		(370)	0/50 (0%)	1/90 (1%)	0/50 (0%)		0/90 (0%)
		1/50 (2%)	(070)	(170)	0/50 (0%)		
	-	2/339 (0.59%)	Mean 0.52%	SD 0.85%	Total 1/339 (0.29%)	Mean 0.33%	SD 0.82%
Overall Incidence	Total						

*: Denominator is number of animals with tissues examined microscopically

Version: Apr2019

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: 07/01/2019

			Male				Female	
*Lung:								
Alveolar/Bronchiolar Care	cinoma							
		1/50 (2%	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		1/50 (2%				0/50 (0%)		
Overall Incidence	Total	2/339 (0.59%)	Mean 0.67%	SD 1.03%	Total	0/339 (0%)	Mean 0%	SD 0%
*Lung:								
Alveolar/Bronchiolar Card	cinoma or Alv	eolar/Bronchiolar Ad	enoma					
		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	4/339 (1.18%)	Mean 1.19%	SD 1.6%	Total	1/339 (0.29%)	Mean 0.33%	SD 0.82%
*Lung:								
Sarcoma								
		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	0/339 (0%)	Mean 0%	SD 0%	Total	1/339 (0.29%)	Mean 0.33%	SD 0.82%
*Lung:						••••••		
Squamous Cell Carcinom	a							
	-	0/50 (0%	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		(070	1/50 (2%)	0/90 (0%)		0/50 (0%)	(-,-)	0/90 (0%)
		0/50 (0%	()			0/50 (0%)		(0,0)
Overall Incidence	Total	1/339 (0.29%)	Mean 0.33%	SD 0.82%	Total	0/339 (0%)	Mean 0%	SD 0%
				00 0.0270	Total	0,000 (070)		00 070

*: Denominator is number of animals with tissues examined microscopically

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

Page: 20 Report Date: 07/01/2019

			Male				Female	
#Lymph Node, Mesenteric: Hemangiosarcoma								
-		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	0/340 (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%)
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	4/50 (8%)
		0/50 (00/)	0/50 (0%)	0/90 (0%)		1/50 (2%)		8/90 (9%)
Duarall Incidence	Total	0/50 (0%)	Maan 00/	SD 00/	Total	3/50 (6%)	Maan 5 150/	CD 2.460/
Overall Incidence	Total	0/340 (0%)	Mean 0%	SD 0%	Total	19/340 (5.59%)	Mean 5.15%	SD 3.46%
#Mammary Gland: Carcinoma								
		2/50 (4%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		7/50 (14%) 3/50 (6%)	3/50 (6%)	5/50 (10%) 10/90 (11%)
		0/50 (0%)	. ,			2/50 (4%)		
Overall Incidence	Total	2/340 (0.59%)	Mean 0.67%	SD 1.63%	Total	30/340 (8.82%)	Mean 8.52%	SD 3.8%

*: Denominator is number of animals with tissues examined microscopically

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

Page: 21 Report Date: 07/01/2019

			Male				Female	
#Mammary Gland: Carcinoma or Adenoma								
		2/50 (4%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		7/50 (14%) 4/50 (8%)	6/50 (12%)	9/50 (18%) 16/90 (18%)
		0/50 (0%)				5/50 (10%)		
Overall Incidence	Total	2/340 (0.59%)	Mean 0.67%	SD 1.63%	Total	47/340 (13.82%)	Mean 13.3%	SD 4.08%
#Mammary Gland: Fibroadenoma								
		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	9/340 (2.65%)	Mean 2.7%	SD 1.62%	Total	195/340 (57.35%)	Mean 55.67%	SD 12.09%
#Mammary Gland: Fibroma, Fibroadenoma o	or Adenoma							
		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	9/340 (2.65%)	Mean 2.7%	SD 1.62%	Total	203/340 (59.71%)	Mean 58.19%	SD 10.84%
#Mammary Gland: Fibroma, Fibroadenoma, (
,,,,,, -	,-	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	10/340 (2.94%)	Mean 3.04%	SD 2.08%	Total	220/340 (64.71%)	Mean 63.56%	SD 9.61%

*: Denominator is number of animals with tissues examined microscopically

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

Page: 22 Report Date: 07/01/2019

			Male				Female	
#Mammary Gland: Myoepithelioma								
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/90 (0%)
Overell Incidence	Tatal	0/50 (0%)	Maga 00/		Tatal	0/50 (0%)	Maan 0 000/	
Overall Incidence	Total	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
*Nose: Carcinoma								
		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%) 0/50 (0%)		0/90 (0%)
Overall Incidence	Total	0/339 (0%)	Mean 0%	SD 0%	Total	1/339 (0.29%)	Mean 0.33%	SD 0.82%
Oral Cavity (Oral Mucos) Squamous Cell Carcin		ynx, Tooth, Gingiva):						
		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%) 0/50 (0%)		2/90 (2%)
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	2/340 (0.59%)	Mean 0.37%	SD 0.91%
#Oral Cavity (Oral Mucos	sa, Tongue, Phar	ynx, Tooth, Gingiva): Squamous, or Papilloma						
oquanious con carcin		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	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	2/340 (0.59%)	Mean 0.37%	SD 0.91%

*: Denominator is number of animals with tissues examined microscopically

Version: Apr2019
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

			Male				Female	
#Oral Mucosa: Squamous Cell Carcinoi	ma							
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/90 (1%)
Overall Incidence	Total	0/50 (0%) 1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	0/50 (0%) 1/340 (0.29%)	Mean 0.19%	SD 0.45%
Ovary: Cystadenoma								
eyelladololla						0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/90 (1%)
Overall Incidence					Total	1/340 (0.29%)	Mean 0.19%	SD 0.45%
Ovary: Granulosa Cell Tumor B								
	-					0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%)	3/50 (6%) 1/90 (1%)
Overall Incidence					Total	5/340 (1.47%)	Mean 1.52%	SD 2.34%
Ovary: Granulosa Cell Tumor M								
						0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 2/90 (2%)
Overall Incidence					Total	3/340 (0.88%)	Mean 0.7%	SD 1.09%

*: Denominator is number of animals with tissues examined microscopically

Version: Apr2019 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 Dat	e: 07/01/2019
	Male		Female	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
Granulosa Cell Tullior. Delligit, Malighant, NCO		0/50 (0%) 1/50 (2%) 1/50 (2%)	0/50 (0%)	3/50 (6%) 3/90 (3%)
Overall Incidence	Total	8/340 (2.35%)	Mean 2.22%	SD 2.26%
*Ovary: Granulosa-Theca Tumor Benign				
Ū		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/90 (0%)
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
*Ovary:				
Granulosa-Theca Tumor Malignant		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
*Ovary: Sertoli Cell Tumor Benign				
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/90 (1%)
Overall Incidence	Total	1/340 (0.29%)	Mean 0.19%	SD 0.45%

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

Version: Apr2019 Contract/Lab: All Laboratories Species: RATS Strain: Harlan Sprague-Dawley Length of Study: CHRONIC			Page: 25 Report Dat	e: 07/01/2019				
			Male				Female	
*Ovary: Thecoma Benign						0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%) 0/90 (0%)
Overall Incidence					Total	0/50 (0%) 1/340 (0.29%)	Mean 0.33%	SD 0.82%
*Ovary: Tubulostromal Carcinoma Overall Incidence					Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/340 (0.29%)	1/50 (2%) Mean 0.33%	0/50 (0%) 0/90 (0%) SD 0.82%
Pancreas: Adenoma Overall Incidence	Total	5/50 (10%) 14/50 (28%) 45/340 (13.24%)	5/50 (10%) 3/50 (6%) Mean 12.33%	0/50 (0%) 18/90 (20%) SD 10.07%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/340 (0%)	0/50 (0%) Mean 0%	0/50 (0%) 0/90 (0%) SD 0%
Pancreas: Carcinoma		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/90 (1%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
Overall Incidence	Total	2/340 (0.59%)	Mean 0.52%	SD 0.85%	Total	0/340 (0%)	Mean 0%	SD 0%

Version: Apr2019

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: 07/01/2019

			Male		Female	
Pancreas: Carcinoma or Adenoma						
		5/50 (10%)	5/50 (10%) 3/50 (6%)	0/50 (0%) 18/90 (20%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)
		14/50 (28%)			0/50 (0%)	
overall Incidence	Total	45/340 (13.24%)		SD 10.07% Total	0/340 (0%) Mean 0%	SD 0%
Parathyroid Gland: Adenoma						
		0/49 (0%)	0/43 (0%) 0/41 (0%)	0/48 (0%) 1/83 (1%)	1/41 (2%) 0/47 (0%) 0/47 (0%)	0/45 (0%) 0/87 (0%)
		0/43 (0%)			0/46 (0%)	
verall Incidence	Total	1/307 (0.33%)		SD 0.49% Total	1/313 (0.32%) Mean 0.41%	SD 1%
Pituitary Gland: Pars Dist Adenoma						
		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	60/339 (17.7%)		SD 7.04% Total	136/340 (40%) Mean 38.96%	SD 5.83%
Pituitary Gland: Pars Dist Carcinoma						
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/89 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/90 (1%)
		1/50 (2%)			1/50 (2%)	
		1/00 (2/0)			1/50 (2/0)	

*: Denominator is number of animals with tissues examined microscopically

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

Page: 27 Report Date: 07/01/2019

			Male				Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma												
		14/50 (28%)	5/50 (10%) 5/50 (10%)	11/50 (22%) 17/89 (19%)		19/50 (38%) 22/50 (44%)	18/50 (36%)	18/50 (36%) 44/90 (49%)				
		9/50 (18%)				17/50 (34%)						
Overall Incidence	Total	61/339 (17.99%)	Mean 17.85%	SD 7%	Total	138/340 (40.59%)	Mean 39.48%	SD 5.75%				
Pituitary Gland: Pars Inter Adenoma												
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		1/50 (2%)	0/50 (0%)	0/89 (0%)		0/50 (0%) 0/50 (0%)		0/90 (0%)				
Overall Incidence	Total	3/339 (0.88%)	Mean 1%	SD 1.67%	Total	0/340 (0%)	Mean 0%	SD 0%				
Pituitary Gland: Pars Inter Carcinoma or Adenoma	media:											
		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%)	•• •••	0.5. / 0.5.		0/50 (0%)		65				
Overall Incidence	Total	3/339 (0.88%)	Mean 1%	SD 1.67%	Total	0/340 (0%)	Mean 0%	SD 0%				
Pituitary Gland: Pars Nerv Schwannoma Malignant	osa:											
-		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/89 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)				
		1/50 (2%)	0/00 (0/0)	0/00 (0/0)		0/50 (0%)		0/00 (0/0)				
Overall Incidence	Total	1/339 (0.29%)	Mean 0.33%	SD 0.82%	Total	0/340 (0%)	Mean 0%	SD 0%				

*: Denominator is number of animals with tissues examined microscopically

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

Page: 28 Report Date: 07/01/2019

			Male				Female	
*Prostate: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	3/50 (6%)	2/90 (2%)				
Overall Incidence	Total	5/340 (1.47%)	Mean 1.37%	SD 2.44%				
*Prostate: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%) 3/50 (6%)	0/50 (0%) 2/90 (2%)				
		0/50 (0%)		_, (_ , . ,				
Overall Incidence	Total	5/340 (1.47%)	Mean 1.37%	SD 2.44%				
Salivary Glands: Schwannoma Malignant								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (00/)	0/49 (0%)	0/90 (0%)		0/49 (0%)		0/90 (0%)
Overall Incidence	Total	0/50 (0%) 1/339 (0.29%)	Mean 0.33%	SD 0.82%	Total	0/50 (0%) 0/338 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)				
		1/50 (2%)		- ()				
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%				

*: Denominator is number of animals with tissues examined microscopically

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

Page: 29 Report Date: 07/01/2019

			Male				Female	
#Skeletal Muscle: Liposarcoma								
-		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%) 0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
#Skeletal Muscle: Sarcoma								
		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	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
#Skin: Basal Cell Adenoma								
		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	T . (.)	0/50 (0%)	Marca 0 500/	00.005%	T - 1 - 1	0/50 (0%)	Mara 00/	00.00/
Overall Incidence	Total	2/340 (0.59%)	Mean 0.52%	SD 0.85%	Total	0/340 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or E								
	•	0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 1/90 (1%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	2/340 (0.59%)	Mean 0.52%	SD 0.85%	Total	0/340 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

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

			Male				Female				
#Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma											
	·	0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 1/90 (1%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)			
		0/50 (0%)		(,		0/50 (0%)		()			
Overall Incidence	Total	2/340 (0.59%)	Mean 0.52%	SD 0.85%	Total	0/340 (0%)	Mean 0%	SD 0%			
Skin: Basal Cell Carcinoma											
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%) 0/90 (0%)			
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%			
#Skin: Basal Cell Carcinoma (or Basosquamo	us Tumor (malignant or 0/50 (0%) 0/50 (0%)	NOS) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%) 0/90 (0%)			
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%			
#Skin:		oma, Basosquamous T	umor (benign, maligna	nt or							
Basal Cell Carcinoma, NOS), or Trichoepithel			1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)			
		0/50 (0%)	1/50 (2%) 1/50 (2%)	1/90 (1%)		0/50 (0%)		0/90 (0%)			
		0/50 (0%) 0/50 (0%) 3/340 (0.88%)	· · /	()		0/50 (0%) 0/50 (0%) 1/340 (0.29%)		0/90 (0%) SD 0.82%			

*: Denominator is number of animals with tissues examined microscopically

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

			Male				Female	
#Skin:								
Basal or Sq. Cell Carci Adenoma Papilloma	inoma, Carcinon	na, Basosq. Tumor (M or eratoacanthoma, Trichoe	B), Basal Cell Adenor pithelioma	na,				
Adenoma, r apinoma, v	oq i upinoniu, iti	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	29/340 (8.53%)	Mean 8.48%	SD 3.67%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
#Skin:								
Fibroma								
		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	14/340 (4.12%)	Mean 4.37%	SD 3.64%	Total	4/340 (1.18%)	Mean 1.04%	SD 1.14%
#Skin:								
Fibroma, Fibrosarcom Hemangiopericytoma	a, Sarcoma, My	xoma, Myxosarcoma, Ma	lignant Fibrous Histion	sytoma, or				
Hemangiopencytoma		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%)	2,000 (1,0)	5/90 (6%)
		3/50 (6%)	(),	(),		3/50 (6%)		· · · ·
Overall Incidence	Total	21/340 (6.18%)	Mean 6.26%	SD 4.09%	Total	11/340 (3.24%)	Mean 2.93%	SD 2.66%
#Skin: Fibroaco	a Saraama Mu	vene Muveeereene er	Valianent Fibraus List	inautoma				
FIDROMA, FIDROSARCOM	ia, Sarcoma, wy	xoma, Myxosarcoma, or I 3/50 (6%)	7/50 (14%)	1/50 (2%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
		5/50 (078)	2/50 (4%)	5/90 (6%)		1/50 (2%)	2/30 (470)	5/90 (6%)
		3/50 (6%)	2,000 (170)	0,00 (0,0)		2/50 (4%)		0,00 (0,0)
		3/30 (0/0)						

*: Denominator is number of animals with tissues examined microscopically

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

Page: 32 Report Date: 07/01/2019

			Male			Female				
#Skin: Fibrosarcoma										
		0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 1/90 (1%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/90 (0%)		
.	T	0/50 (0%)	N. 0.050/		T	1/50 (2%)	N 0.070/			
Overall Incidence	Total	3/340 (0.88%)	Mean 0.85%	SD 0.99%	Total	2/340 (0.59%)	Mean 0.67%	SD 1.03%		
#Skin:										
Fibrosarcoma, Sarcoma,	Myxosarcom	a, or Malignant Fibrous H	listiocytoma							
		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	7/340 (2.06%)	Mean 1.89%	SD 1.66%	Total	6/340 (1.76%)	Mean 1.56%	SD 1.31%		
≭Skin: Hemangioma										
		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	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	0/340 (0%)	Mean 0%	SD 0%		
#Skin: Hemangiopericytoma										
5 , 7 , 7 , 7		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	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%		

*: Denominator is number of animals with tissues examined microscopically

Version: Apr2019

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: 07/01/2019

			Male				Female	
#Skin: Hemangiosarcoma								
Ū		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
∜Skin: Keratoacanthoma								
		2/50 (4%)	4/50 (8%)	3/50 (6%)		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	20/340 (5.88%)	Mean 5.93%	SD 2.83%	Total	0/340 (0%)	Mean 0%	SD 0%
έSkin: Lipoma								
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	2/90 (2%)		0/50 (0%)		0/90 (0%)
Overall Incidence	Total	0/50 (0%)	Moon 1 270/		Total	0/50 (0%)	Moon 0%	SD 00/
	Total	5/340 (1.47%)	Mean 1.37%	SD 1.65%	Total	0/340 (0%)	Mean 0%	SD 0%
#Skin: Malignant Fibrous Histi	iocytoma							
-	-	0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/90 (1%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	2/340 (0.59%)	Mean 0.67%	SD 1.03%	Total	1/340 (0.29%)	Mean 0.19%	SD 0.45%

*: Denominator is number of animals with tissues examined microscopically

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

Page: 34 Report Date: 07/01/2019

			Male				Female	
#Skin: Neurofibrosarcoma or	Schwannoma (n	nalignant or NOS)						
	·	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
					•••••			
#Skin: Neurofibrosarcoma, N	eurofibroma, or s	Schwannoma (benign, m	alignant or NOS)					
nou on bi ocui ocina, na		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	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
#Skin:								
Osteosarcoma								
		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	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
#Skin:								
Sarcoma								
		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	2/340 (0.59%)	Mean 0.37%	SD 0.91%	Total	3/340 (0.88%)	Mean 0.7%	SD 1.09%

*: Denominator is number of animals with tissues examined microscopically

Version: Apr2019 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: 35 Report Date: 07/01/2019

					Male			Female						
#Skin: Schwannoma Malignant														
-		0/50	(0%)	0/50 0/50	(0%) (0%)	0/50 0/90	(0%) (0%)		0/50 0/50	(0%) (0%)	1/50	(2%)	0/50 0/90	(0%) (0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/340 (0%)		Mean		SD 0%		Total	1/340 (0.2	,		0.33%	SD 0.	.82%
#Skin: Squamous Cell Carcinoma														
		0/50	(0%)	1/50 0/50	(2%) (0%)	0/50 0/90	(0%) (0%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50 0/90	(0%) (0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/340 (0.29%	,	Mean 0		SD 0.82%		Total	0/340 (0	,		n 0%	SD	0%
#Skin: Squamous Cell Carcinoma or Carcinoma	a, Basal Cell	Carcinoma, Base 0/50	osquamo (0%)	2/50	(4%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
Squamous Cell Carcinoma	ı, Basal Cell	0/50	(0%)		•		(0%) (0%)		0/50	(0%)		(0%)	1/50 0/90	(2%) (0%)
Squamous Cell Carcinoma or Carcinoma Overall Incidence	Total	0/50 0/50 2/340 (0.59%	(0%) (0%) %)	2/50 0/50 Mean 0	(4%) (0%) .67%	0/50 0/90 SD 1.63%	(0%) %	Total	0/50 0/50 1/340 (0.2	(0%) (0%) 29%)	0/50 Mean	0.33%	0/90 SD 0.	(0%) .82%
Squamous Cell Carcinoma or Carcinoma Overall Incidence #Skin:	Total	0/50 0/50 2/340 (0.59%	(0%) (0%) %)	2/50 0/50 Mean 0	(4%) (0%) .67%	0/50 0/90 SD 1.63%	(0%) %		0/50 0/50 1/340 (0.2	(0%) (0%) 29%)	0/50 Mean	0.33%	0/90 SD 0.	(0%) .82%
	Total	0/50 0/50 2/340 (0.59%	(0%) (0%) %)	2/50 0/50 Mean 0	(4%) (0%) .67%	0/50 0/90 SD 1.63%	(0%) %		0/50 0/50 1/340 (0.2	(0%) (0%) 29%)	0/50 Mean	0.33%	0/90 SD 0.	(0%) .82%
Squamous Cell Carcinoma or Carcinoma Overall Incidence #Skin:	Total	0/50 0/50 2/340 (0.599	(0%) (0%) %)	2/50 0/50 Mean 0	(4%) (0%) .67% (2%)	0/50 0/90 SD 1.639 1/50	(0%) 6 		0/50 0/50 1/340 (0.: 0/50	(0%) (0%) 29%) (0%)	0/50 Mean	0.33%	0/90 SD 0. 0/50	(0%) .82%

*: Denominator is number of animals with tissues examined microscopically

Version: Apr2019

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: 36 Report Date: 07/01/2019

			Male				Female	
#Skin: Squamous Cell Papilloma	a or Papilloma							
	a or Fapinonia	2/50 (4%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 2/90 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)		2,000 (2,0)		0/50 (0%)		
Overall Incidence	Total	6/340 (1.76%)	Mean 1.7%	SD 1.52%	Total	0/340 (0%)	Mean 0%	SD 0%
#Skin:								
Squamous Cell Papillom	a, Papilloma, S	quamous Cell Carcin	oma or Keratoacanthon	na				
		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	26/340 (7.65%)	Mean 7.63%	SD 2.94%	Total	0/340 (0%)	Mean 0%	SD 0%
#Skin:								
Squamous Cell Papillom	a, Papilloma, o	r Keratoacanthoma						
		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	26/340 (7.65%)	Mean 7.63%	SD 2.94%	Total	0/340 (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%)
		0,00 (0,0)	0/50 (0%)	1/90 (1%)		0/50 (0%)	(0,00	0/90 (0%)
		0/50 (0%)	0,00 (0,0)	1,00 (1,0)		0/50 (0%)		
Overall Incidence	Total	2/340 (0.59%)	Mean 0.52%	SD 0.85%	Total	0/340 (0%)	Mean 0%	SD 0%
	iotai	2,340 (0.3370)	Wear 0.52 /0	0.00%	iotai	0/040 (0/0)		50 070

*: Denominator is number of animals with tissues examined microscopically

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

Page: 37 Report Date: 07/01/2019

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 1/90 (1%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	2/340 (0.59%)	Mean 0.52%	SD 0.85%	Total	0/340 (0%)	Mean 0%	SD 0%
≭Spinal Cord: Astrocytoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/90 (0%)		1/50 (2%) 0/50 (0%)		0/90 (0%)
Overall Incidence	Total	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
Spleen: Hemangiosarcoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		o (= o (o o ()	0/50 (0%)	3/90 (3%)		0/50 (0%)		1/90 (1%)
Overall Incidence	Total	0/50 (0%) 3/340 (0.88%)	Mean 0.56%	SD 1.36%	Total	0/50 (0%) 1/340 (0.29%)	Mean 0.19%	SD 0.45%
		()				()		
#Stomach, Forestomach: Sarcoma								
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/90 (1%)
		0/50 (0%)	0/00 (070)	0/00 (0/0)		0/50 (0%)		1750 (176)
Overall Incidence	Total	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.19%	SD 0.45%

*: Denominator is number of animals with tissues examined microscopically

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

Page: 38 Report Date: 07/01/2019

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinoma								
•		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
#Stomach, Forestomach:								
Squamous Cell Carcinoma	or Papillom	a Squamous						
	-	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	2/340 (0.59%)	Mean 0.52%	SD 0.85%	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%
#Stomach, Forestomach: Squamous Cell Papilloma								
		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%)		0D 00 <i>i</i>
Overall Incidence	Total	1/340 (0.29%)	Mean 0.19%	SD 0.45%	Total	0/340 (0%)	Mean 0%	SD 0%
Testis: Adenoma								
		1/50 (2%)	3/49 (6%) 0/50 (0%)	0/50 (0%) 2/90 (2%)				
		1/50 (2%)						
Overall Incidence	Total	7/339 (2.06%)	Mean 2.06%	SD 2.24%				

*: Denominator is number of animals with tissues examined microscopically

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

Page: 39 Report Date: 07/01/2019

			Male				Female	
*Thymus: Thymoma Benign								
		0/46 (0%)	1/46 (2%) 0/48 (0%)	0/48 (0%) 0/88 (0%)		0/49 (0%) 0/49 (0%)	0/47 (0%)	0/50 (0%) 1/87 (1%)
Overall Incidence	Total	0/48 (0%) 1/324 (0.31%)	Mean 0.36%	SD 0.89%	Total	0/47 (0%) 1/329 (0.3%)	Mean 0.19%	SD 0.47%
*Thymus: Thymoma Malignant								
		0/46 (0%) 0/48 (0%)	0/46 (0%) 0/48 (0%)	0/48 (0%) 0/88 (0%)		0/49 (0%) 0/49 (0%) 0/47 (0%)	0/47 (0%)	0/50 (0%) 1/87 (1%)
Overall Incidence	Total	0/324 (0%)	Mean 0%	SD 0%	Total	1/329 (0.3%)	Mean 0.19%	SD 0.47%
*Thymus: Thymoma: Benign, Maligna	ant, NOS							
		0/46 (0%)	1/46 (2%) 0/48 (0%)	0/48 (0%) 0/88 (0%)		0/49 (0%) 0/49 (0%)	0/47 (0%)	0/50 (0%) 2/87 (2%)
Overall Incidence	Total	0/48 (0%) 1/324 (0.31%)	Mean 0.36%	SD 0.89%	Total	0/47 (0%) 2/329 (0.61%)	Mean 0.38%	SD 0.94%
*Thyroid Gland: C-Cell: Adenoma								
		7/50 (14%)	13/50 (26%) 11/49 (22%)	2/50 (4%) 8/89 (9%)		5/50 (10%) 9/50 (18%)	11/49 (22%)	2/50 (4%) 6/90 (7%)
Overall Incidence	Total	4/50 (8%) 45/338 (13.31%)	Mean 13.91%	SD 8.68%	Total	5/50 (10%) 38/339 (11.21%)	Mean 11.85%	SD 7.01%

*: Denominator is number of animals with tissues examined microscopically

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

Page: 40 Report Date: 07/01/2019

			Male				Female	
Thyroid Gland: C-Cell: Carcinoma								
		1/50 (2%)	0/50 (0%) 0/49 (0%)	1/50 (2%) 2/89 (2%)		1/50 (2%) 1/50 (2%)	0/49 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	4/338 (1.18%)	Mean 1.04%	SD 1.14%	Total	4/339 (1.18%)	Mean 1.33%	SD 1.63%
*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%)
		4/50 (8%)	11/49 (22%)	10/89 (11%)		9/50 (18%) 7/50 (14%)		6/90 (7%)
Overall Incidence	Total	49/338 (14.5%)	Mean 14.95%	SD 8.02%	Total	41/339 (12.09%)	Mean 12.85%	SD 6.89%
Thyroid Gland: Follicular Ce Carcinoma	·II:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/89 (0%)		0/50 (0%) 0/50 (0%)		1/90 (1%)
Overall Incidence	Total	0/338 (0%)	Mean 0%	SD 0%	Total	1/339 (0.29%)	Mean 0.19%	SD 0.45%
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		- / // .	0/49 (0%)	0/89 (0%)		0/50 (0%)		1/90 (1%)
•	T	0/50 (0%)	N. 00/	00.00/	T ()	0/50 (0%)	N. 0.400/	00 0 4504
Overall Incidence	Total	0/338 (0%)	Mean 0%	SD 0%	Total	1/339 (0.29%)	Mean 0.19%	SD 0.45%

*: Denominator is number of animals with tissues examined microscopically

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

Page: 41 Report Date: 07/01/2019

			Male			Female				
#Tissue NOS: Schwannoma Malignant										
-		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/90 (1%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/90 (1%)		
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	1/340 (0.29%)	Mean 0.19%	SD 0.45%	Total	1/340 (0.29%)	Mean 0.19%	SD 0.45%		
#Tongue: Squamous Cell Carcinom										
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/90 (1%)		
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.19%	SD 0.45%		
#Tongue: Squamous Cell Carcinom	a or Papillom	a Squamous								
		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	0/340 (0%)	Mean 0%	SD 0%	Total	1/340 (0.29%)	Mean 0.19%	SD 0.45%		
#Tooth: Odontoma										
		0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)		
		0/50 (0%)	(),			0/50 (0%)				
Overall Incidence	Total	1/340 (0.29%)	Mean 0.33%	SD 0.82%	Total	0/340 (0%)	Mean 0%	SD 0%		

*: Denominator is number of animals with tissues examined microscopically

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

Page: 42 Report Date: 07/01/2019

			Male				Female	
Urinary Bladder: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/89 (0%)		0/49 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%) 1/88 (1%)
Overall Incidence	Total	0/50 (0%) 0/338 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 1/336 (0.3%)	Mean 0.19%	SD 0.46%
Uterus: Standard or Ext Adenocarcinoma		ns (Combined):						
						5/50 (10%) 1/50 (2%)	5/50 (10%)	
Overall Incidence					Total	11/150 (7.33%)	Mean 7.33%	SD 4.62%
Uterus: Standard or Ext Adenocarcinoma or Ad	ended Evaluatior	ns (Combined):						
						5/50 (10%) 2/50 (4%)	5/50 (10%)	
Overall Incidence					Total	12/150 (8%)	Mean 8%	SD 3.46%
	ended Evaluatior	is (Combined):						
#Uterus: Standard or Ext Adenoma	ended Evaluatior	is (Combined):				0/50 (0%) 1/50 (2%)	0/50 (0%)	

Version: Apr2019 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: 43 Report Date: 07/01/2019			
	Male			ŀ	Female			
#Uterus: Standard or Extended Evaluations (Combined): Polyp Stromal								
		8/50 16/50	· · ·	10/50	(20%)			
Overall Incidence	Tota	34/150 (2	22.67%)		22.67%	SD 8.33%		
#Uterus: Standard or Extended Evaluations (Combined): Sarcoma Stromal								
		0/50 1/50	· · ·	2/50	(4%)			
Overall Incidence	Tota	3/150	(2%)	Mea	an 2%	SD 2%		
#Uterus: Standard or Extended Evaluations (Combined): Sarcoma Stromal or Polyp Stromal								
		8/50 16/50	()	12/50	(24%)			
Overall Incidence	Tota	36/150	(24%)	Mea	n 24%	SD 8%		
≇Vagina: Granular Cell Tumor Benign								
		0/50 0/50 0/50	(0%)	0/50	(0%)	1/50 (2%) 0/90 (0%)		
Overall Incidence	Tota		()	Mear	0.33%	SD 0.82%		

Version: Apr2019
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: 44 Report Date: 07/01/2019

			Male					Female	
#Vagina: Polyp									
гојур							0/50 (0%)	1/50 (2%)	0/50 (0%)
							0/50 (0%)		0/90 (0%)
							1/50 (2%)		
Overall Incidence						Total	2/340 (0.59%)	Mean 0.67%	SD 1.03%
#Vagina: Schwannoma Malignant									
e e							0/50 (0%)	1/50 (2%)	1/50 (2%)
							0/50 (0%)		1/90 (1%)
							0/50 (0%)		
Overall Incidence						Total	3/340 (0.88%)	Mean 0.85%	SD 0.99%
#Zymbal's Gland: Carcinoma									
		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%)
Overall Incidence	Total	1/50 (2%) 2/340 (0.59%)	Mean 0.67%	SD 1.039	07.	Total	0/50 (0%) 0/340 (0%)	Mean 0%	SD 0%
		()							
#Zymbal's Gland: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	1/50	(2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/90	(0%)		0/50 (0%)		0/90 (0%)
		1/50 (2%)					0/50 (0%)		
Overall Incidence	Total	2/340 (0.59%)	Mean 0.67%	SD 1.039	%	Total	0/340 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically