

# NTP Historical Controls Report

All Routes and Vehicles

Harlan Sprague-Dawley RATS

December 2020

## 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
М3
M4
M5
Female
Female F1
F1
F1 F2

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.

Species: RATS

**Toxicology Data Management System** 

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Report Date: 12/30/2020

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

**Strain:** Harlan Sprague-Dawley **Length of Study:** CHRONIC

## **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	050005803	07/03/12	730	50(2)	15(656)	628.4	Black Cohosh
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	052032305	05/07/12	729	50(2)	29(669)	597.1	Resveratrol
Battelle Columbus Laboratory	050303803	01/30/12	729	50(2)	12(621)	610.8	Sodium Tungstate Dihydrate
Battelle Columbus Laboratory	052071203	12/12/11	729	50(2)	25(652)	589.0	Tris(Chloropropyl)phosphate
					Female		
Battelle Columbus Laboratory	050005803	07/02/12	729	50(5)	28(679)	426.6	Black Cohosh
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	052032305	05/08/12	730	50(5)	34(690)	394.3	Resveratrol
Battelle Columbus Laboratory	050303803	01/31/12	730	50(5)	30(667)	393.3	Sodium Tungstate Dihydrate
Battelle Columbus Laboratory	052071203	12/13/11	731	50(4)	22(629)	380.1	Tris(Chloropropyl)phosphate

Contract/Lab: All Laboratories Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 4

			Male				Female	
#All Organs: Benign Tumors								
		30/50 (60%)	27/50 (54%)	28/50 (56%)		44/50 (88%)	37/50 (74%)	41/50 (82%)
		35/49 (71%)	38/50 (76%)	27/50 (54%)		40/50 (80%)	41/50 (82%)	40/50 (80%)
		30/50 (60%)		32/50 (64%)		39/50 (78%)	39/50 (78%)	
		49/90 (54%)	33/50 (66%)	29/50 (58%)		82/90 (91%)	43/50 (86%)	39/50 (78%)
		25/50 (50%)				41/50 (82%)		
Overall Incidence	Total	383/639 (59.94%)	Mean 60.32%	SD 7.75%	Total	526/640 (82.19%)	Mean 81.59%	SD 4.8%
#All Organs:								
Malignant Tumors								
		10/50 (20%)	13/50 (26%)	15/50 (30%)		7/50 (14%)	16/50 (32%)	14/50 (28%)
		14/49 (29%)	11/50 (22%)	12/50 (24%)		13/50 (26%)	15/50 (30%)	19/50 (38%)
		12/50 (24%)		9/50 (18%)		11/50 (22%)	14/50 (28%)	
		24/90 (27%)	13/50 (26%)	14/50 (28%)		37/90 (41%)	10/50 (20%)	17/50 (34%)
		9/50 (18%)				10/50 (20%)		
Overall Incidence	Total	156/639 (24.41%)	Mean 24.27%	SD 4.04%	Total	183/640 (28.59%)	Mean 27.76%	SD 7.93%
#All Organs: Malignant and Benign								
		33/50 (66%)	32/50 (64%)	36/50 (72%)		46/50 (92%)	41/50 (82%)	44/50 (88%)
		41/49 (84%)	42/50 (84%)	33/50 (66%)		44/50 (88%)	47/50 (94%)	46/50 (92%)
		37/50 (74%)	(	37/50 (74%)		41/50 (82%)	47/50 (94%)	(,
		57/90 (63%)	39/50 (78%)	36/50 (72%)		89/90 (99%)	45/50 (90%)	47/50 (94%)
		30/50 (60%)	(,	(,		46/50 (92%)	(,	(,
Overall Incidence	Total	453/639 (70.89%)	Mean 71.42%	SD 7.84%	Total	583/640 (91.09%)	Mean 90.57%	SD 4.96%
#All Organs:								
Hemangioma								
. J		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		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%)	(- · - /
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	2.22 (0,0)	(0,0)		1/50 (2%)	(=/0)	(0,0)
Overall Incidence	Total	2/639 (0.31%)	Mean 0.33%	SD 0.78%	Total	3/640 (0.47%)	Mean 0.5%	SD 0.9%
		` ,				` ,		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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

					Male						F	emale		
#All Organs:		·							·					
Hemangiosarcoma														
•		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	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%)		
		3/90	(3%)	0/50	(0%)	1/50	(2%)		3/90	(3%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	5/639 (0.789	%)	Mean 0	.61%	SD 1.159	%	Total	5/640 (0.	78%)	Mean	0.61%	SD 1.	15%
‡All Organs:														
Hemangiosarcoma or Hem	nangioma													
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	2/50	(4%)
		0/49	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		1/50	(2%)			0/50	(0%)		0/50	(0%)	0/50	(0%)		
		3/90	(3%)	0/50	(0%)	1/50	(2%)		3/90	(3%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)						1/50	(2%)				
Overall Incidence	Total	7/639 (1.1%	•	Mean 0		SD 1.229		Total	8/640 (1.	,		1.11%	SD 1.	49%
#All Organs: Histiocytic Sarcoma														
•		1/50	(2%)	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%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)		` ,	0/50	(0%)		0/50	(0%)	0/50	(0%)		` ,
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)		, ,				0/50	(0%)				. ,
Overall Incidence	Total	2/639 (0.319	•	Mean 0		SD 0.789		Total	1/640 (0.	,		0.17%	SD 0.	
#All Organs:														
Leukemia: Granulocytic														
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	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%)		
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	2/639 (0.319	%)	Mean 0	.33%	SD 0.789	%	Total	1/640 (0.	16%)	Mean	0.17%	SD 0.	58%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

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Report Date: 12/30/2020

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

**Strain:** Harlan Sprague-Dawley **Length of Study:** CHRONIC

Contract/Lab: All Laboratories

		Male						Female						
#All Organs:		_												
Leukemia: Lymphocytic, Monoc	ytic, Mononuclear, c	or Undiffere	ntiated											
	0/50	` ,	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)	
	0/49	()	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
	3/50	` ,			3/50	(6%)		0/50	(0%)	1/50	(2%)			
	0/90	` ,	0/50	(0%)	1/50	(2%)		0/90	(0%)	1/50	(2%)	0/50	(0%)	
	1/50	` ,						2/50	(4%)					
Overall Incidence T	otal 8/639 (1.:		Mean 1		SD 2.31		Total	5/640 (0	.78%)	Mean	0.83%	SD 1	34%	
#All Organs:														
Malignant Lymphoma: Histiocy	ic, Lymphocytic, Mix	xed, NOS, o	r Undifferen	tiated Cel	II Туре									
	0/50	()	2/50	(4%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)	
	1/49	(2%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)	
	0/50	( - · - /			1/50	(2%)		0/50	(0%)	1/50	(2%)			
	2/90	` ,	1/50	(2%)	1/50	(2%)		5/90	(6%)	1/50	(2%)	2/50	(4%)	
	2/50	(4%)						0/50	(0%)					
Overall Incidence T	otal 10/639 (1	,	Mean 1		SD 1.52		Total	11/640 (1	,		1.46%	SD 1		
#All Organs: Malignant Schwannoma														
_	0/50	(0%)	3/50	(6%)	6/50	(12%)		1/50	(2%)	1/50	(2%)	3/50	(6%)	
	3/49	(6%)	1/50	(2%)	2/50	(4%)		2/50	(4%)	0/50	(0%)	2/50	(4%)	
	0/50	(0%)			1/50	(2%)		2/50	(4%)	0/50	(0%)			
	3/90	(3%)	0/50	(0%)	1/50	(2%)		4/90	(4%)	1/50	(2%)	2/50	(4%)	
	0/50	(0%)						0/50	(0%)					
	otal 20/639 (3	,	Mean 3		SD 3.56		Total	18/640 (2			2.7%	SD	2%	
#All Organs:														
Mesothelioma: Benign, Maligna	nt, NOS													
	2/50	(4%)	2/50	(4%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
	1/49	(/	1/50	(2%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
	1/50	` ,		(/	1/50	(2%)		0/50	(0%)	0/50	(0%)		/	
	2/90	` ,	1/50	(2%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)	
		` ,		(-,-,	2. 30	(-,-,		0/50	(0%)		(- / - /	2. 20	( - / - /	
	1/50	(2%)						0/50	(0%)					

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

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Report Date: 12/30/2020

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

Vehicle: ALL VEHICLES

	Male						Female						
#All Organs: Mesothelioma: Malignant													
J		2/50 (4%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		1/49 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		1/50 (2%)		1/50 (2%)		0/50 (0%)	0/50 (0%)						
		2/90 (2%) 1/50 (2%)	1/50 (2%)	0/50 (0%)		0/90 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	14/639 (2.19%)	Mean 2.19%	SD 1.03%	Total	0/640 (0%)	Mean 0%	SD 0%					
#All Organs: Osteosarcoma													
		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%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)		0/50 (0%)		0/50 (0%)	1/50 (2%)						
		0/90 (0%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	1/50 (2%)					
		0/50 (0%)				0/50 (0%)							
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	2/640 (0.31%)	Mean 0.33%	SD 0.78%					
#All Organs: Osteosarcoma or Osteoma													
		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%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)	, ,	0/50 (0%)		0/50 (0%)	1/50 (2%)	, ,					
		0/90 (0%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	1/50 (2%)					
		0/50 (0%)	, ,	, ,		0/50 (0%)	, ,	, ,					
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	2/640 (0.31%)	Mean 0.33%	SD 0.78%					
Adrenal Cortex: Adenoma													
		0/50 (0%)	1/50 (2%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)					
		0/49 (0%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	0/50 (0%)					
		3/50 (6%)		0/50 (0%)		0/50 (0%)	2/50 (4%)						
		1/90 (1%)	0/50 (0%)	0/50 (0%)		1/90 (1%)	3/50 (6%)	0/50 (0%)					
		0/50 (0%)	, ,	, ,		0/50 (0%)	, ,	, ,					
Overall Incidence	Total	8/639 (1.25%)	Mean 1.26%	SD 2.3%	Total	11/640 (1.72%)	Mean 1.76%	SD 2.49%					

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Harlan Sprague-Dawley
Length of Study: CHRONIC

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 8

	Male							Female						
*Adrenal Cortex:														
Carcinoma														
		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%)	0/50	(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%)		1/90	(1%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/639 (0.16	5%)	Mean 0	.17%	SD 0.58	%	Total	1/640 (0	.16%)	Mean	0.09%	SD 0	.32%
*Adrenal Medulla: Ganglioneuroma														
Ganghoneuroma		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/30	(070)	0/50	(0%)		0/30	(0%)	0/50	(0%)	0/30	(070)
		0/88	(0%)	0/50	(0%)	1/50	(2%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/30	(070)	1/30	(270)		0/50	(0%)	0/30	(076)	0/30	(070)
Overall Incidence	Total	1/637 (0.16	` ,	Mean 0	17%	SD 0.58	%	Total	1/635 (0	` '	Mean	0.17%	SD 0	58%
		•	,											
*Adrenal Medulla: Pheochromocytoma Benign	ı													
3		14/50	(28%)	4/50	(8%)	5/50	(10%)		3/50	(6%)	1/50	(2%)	0/50	(0%)
		7/49	(14%)	9/50	(18%)	5/50	(10%)		0/50	(0%)	3/50	(6%)	0/50	(0%)
		12/50	(24%)	0,00	(1070)	8/50	(16%)		0/49	(0%)	1/50	(2%)	0,00	(0,0)
		10/88	(11%)	4/50	(8%)	10/50	(20%)		1/86	(1%)	3/50	(6%)	1/50	(2%)
			(12%)	30	(-,-,		(,-,		0/50	(0%)		(-,-)		(-,-,
Overall Incidence	Total	94/637 (14.7	` '	Mean 14	4.97%	SD 6.44	%	Total	13/635 (2	` ,	Mear	2.1%	SD 2	2.5%
		······							·····					
*Adrenal Medulla: Pheochromocytoma Comple	ex													
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		0/49	(0%)	0/50	(0%)		
		1/88	(1%)	0/50	(0%)	0/50	(0%)		0/86	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		. ,		, ,		0/50	(0%)				
Overall Incidence	Total	3/637 (0.47	'0/. \	Mean 0	120/	SD 0.89	)/	Total	0/635 (	ω.	Moo	n 0%	SD	Ω0/

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS
Strain: Harlan Sprague-Dawley
Length of Study: CHRONIC

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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					Male						F	emale		
Adrenal Medulla: Pheochromocytoma Malig	nant													
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/49	(2%)	3/50	(6%)	2/50	(4%)		0/50	(0%)	2/50	(4%)	0/50	(0%)
		2/50	(4%)			0/50	(0%)		0/49	(0%)	0/50	(0%)		
		1/88	(1%)	1/50	(2%)	2/50	(4%)		0/86	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	13/637 (2.0	4%)	Mean 2	2.1%	SD 2.019	%	Total	3/635 (0	.47%)	Mear	0.5%	SD 1.	.24%
*Adrenal Medulla:														
Pheochromocytoma: Beni	gn, Complex	k, Malignant, NC	S											
		14/50	(28%)	5/50	(10%)	6/50	(12%)		3/50	(6%)	1/50	(2%)	0/50	(0%)
		8/49	(16%)	12/50	(24%)	8/50	(16%)		0/50	(0%)	5/50	(10%)	0/50	(0%)
		14/50	(28%)			8/50	(16%)		0/49	(0%)	1/50	(2%)		
		11/88	(13%)	5/50	(10%)	12/50	(24%)		1/86	(1%)	3/50	(6%)	2/50	(4%)
			(12%)						0/50	(0%)				
Overall Incidence	Total	109/637 (17.	,	Mean 1		SD 6.8%		Total	16/635 (2	•		1 2.6%	SD 3.	.25%
#Bone: Osteosarcoma														
		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%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		, ,	0/50	(0%)		0/50	(0%)	1/50	(2%)		, ,
		0/90	(0%)	1/50	(2%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)		•		
Overall Incidence	Total	1/639 (0.16	5%)	Mean 0	.17%	SD 0.589	%	Total	1/640 (0	.16%)	Mean	0.17%	SD 0.	.58%
#Bone:														
Osteosarcoma or Osteoma	a													
		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%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		()	0/50	(0%)		0/50	(0%)	1/50	(2%)		()
		0/90	(0%)	1/50	(2%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	5 6	()	2. 20	(-,-,		0/50	(0%)	3	(-,-)		(-,-)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Species: RATS

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES **Page:** 10

Male						Female						
*Brain:												
Glioma Malignant												
		1/50 (2%)	4/50 (8%)	0/50 (09	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)				
		2/49 (4%)	0/50 (0%)			1/50 (2%)	0/50 (0%)					
		2/50 (4%)		1/50 (29	,	1/50 (2%)	0/50 (0%)					
		0/90 (0%)	0/50 (0%)	2/50 (49	%)	0/90 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	12/589 (2.04%)	Mean 2.19%	SD 2.61%	Total	2/590 (0.34%)	Mean 0.36%	SD 0.81%				
Brain:												
Granular Cell Tumor Be	enign											
	-	3/50 (6%)	3/50 (6%)	0/50 (09	%)	0/50 (0%)	2/50 (4%)	1/50 (2%)				
		0/49 (0%)	2/50 (4%)			0/50 (0%)	1/50 (2%)					
		0/50 (0%)		2/50 (49	%)	0/50 (0%)	0/50 (0%)					
		1/90 (1%)	0/50 (0%)	0/50 (09	%)	1/90 (1%)	0/50 (0%)	0/50 (0%)				
		1/50 (2%)				0/50 (0%)						
Overall Incidence	Total	12/589 (2.04%)	Mean 2.1%	SD 2.46%	Total	5/590 (0.85%)	Mean 0.83%	SD 1.33%				
Brain:												
Granular Cell Tumor Ma	alignant											
		0/50 (0%)	0/50 (0%)	0/50 (09	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
		0/50 (0%)		0/50 (09	%)	0/50 (0%)	0/50 (0%)					
		0/90 (0%)	0/50 (0%)	1/50 (29	%)	0/90 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%				
Brain:												
Meningioma Benign												
J J		0/50 (0%)	0/50 (0%)	0/50 (09	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)				
		1/49 (2%)	0/50 (0%)	(-	,	0/50 (0%)	0/50 (0%)	( -)				
		0/50 (0%)	, ,	0/50 (09	%)	0/50 (0%)	0/50 (0%)					
		0/90 (0%)	0/50 (0%)	0/50 (09	,	0/90 (0%)	0/50 (0%)	0/50 (0%)				
			` ,	,	•	` '	` '	` '				
		0/50 (0%)				0/50 (0%)						

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

\*Brain:

\*Brain:

\*Brain:

Contract/Lab: All Laboratories

Species: RATS

**Strain:** Harlan Sprague-Dawley **Length of Study:** CHRONIC

Meningioma Malignant

Overall Incidence

**Overall Incidence** 

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups Report Date: 12/30/2020 Route: ALL ROUTES Vehicle: ALL VEHICLES Male **Female** 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%)0/50 (0%)Mean 0.18% SD 0.6% Total 1/590 (0.17%) Mean 0.18% SD 0.6% 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%) 0/90 0/50 0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)Mean 0.37% SD 0.82% Total 1/590 (0.17%) Mean 0.18% SD 0.6% 4/50 (8%) 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%)

0/90

(0%)

0/50

(0%)

0/50

(0%)

Oligodendroglioma,	Glioma,	or	Astrocytoma	

Meningioma: Benign, Malignant, NOS

Total

Total

0/50

0/49

0/50

0/90

1/50

1/589 (0.17%)

0/50

1/49

0/50

0/90

1/50

2/589 (0.34%)

1/50

2/49

2/50

0/90

(0%)

(0%)

(0%)

(0%)

(2%)

(0%)

(2%)

(0%)

(0%)

(2%)

(2%)

(4%)

(4%)

(0%)

Overall Incidence	Total	0/50 (0%) 12/589 (2.04%)	Mean 2.19%	SD 2.61%	Total	0/50 (0%) 2/590 (0.34%)	Mean 0.36%	SD 0.81%
*Brain: Schwannoma Malignant								
		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%) 0/50 (0%)	0/50 (0%)
		0/90 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%

2/50

(4%)

(0%)

0/50

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Harlan Sprague-Dawley
Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

**Page:** 12

					Male						F	emale		
*Clitoral/Preputial Gland:														
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/50	(0%)
		1/49	(2%)	0/49	(0%)	0/50	(0%)		0/49	(0%)	0/48	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/88	(0%)	0/50	(0%)	0/50	(0%)		0/87	(0%)	0/48	(0%)	0/50	(0%)
		0/50	(0%)						0/46	(0%)				
Overall Incidence	Total	1/635 (0.16		Mean 0		SD 0.599		Total	0/626 (	,		n 0%	SD	
*Clitoral/Preputial Gland: Carcinoma														
		0/50	(0%)	1/49	(2%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/50	(0%)
		0/49	(0%)	1/49	(2%)	0/50	(0%)		0/49	(0%)	0/48	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		0/50	(0%)	1/50	(2%)		
		0/88	(0%)	0/50	(0%)	0/50	(0%)		0/87	(0%)	0/48	(0%)	0/50	(0%)
		0/50	(0%)						0/46	(0%)				
Overall Incidence	Total	2/635 (0.31		Mean 0		SD 0.799		Total	1/626 (0.			0.17%	SD 0	
*Clitoral/Preputial Gland: Carcinoma or Adenoma														
		0/50	(0%)	1/49	(2%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/50	(0%)
		1/49	(2%)	1/49	(2%)	0/50	(0%)		0/49	(0%)	0/48	(0%)	0/50	(0%)
		0/50	(0%)		, ,	0/50	(0%)		0/50	(0%)	1/50	(2%)		,
		0/88	(0%)	0/50	(0%)	0/50	(0%)		0/87	(0%)	0/48	(0%)	0/50	(0%)
		0/50	(0%)						0/46	(0%)				
Overall Incidence	Total	3/635 (0.47		Mean 0		SD 0.929		Total	1/626 (0.	,		0.17%	SD 0	.58%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma														
•		0/50	(0%)	0/49	(0%)	0/50	(0%)		1/49	(2%)	0/49	(0%)	0/50	(0%)
		1/49	(2%)	0/49	(0%)	0/50	(0%)		0/49	(0%)	0/48	(0%)	0/50	(0%)
		0/50	(0%)		` '	0/50	(0%)		0/50	(0%)	0/50	(0%)		` ,
		0/88	(0%)	0/50	(0%)	0/50	(0%)		0/87	(0%)	1/48	(2%)	0/50	(0%)
		1/50	(2%)		` ,		. ,		0/46	(0%)		. ,		` ,
	Total	2/635 (0.31		Mean 0		SD 0.799		Total	2/626 (0.			0.34%	SD (	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

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Report Date: 12/30/2020

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: ALL ROUTES
Vehicle: ALL VEHICLES

			Male				Female	
Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/49 (0%)	1/49 (2%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/88 (0%)	1/50 (2%)	0/50 (0%)		0/87 (0%)	0/48 (0%)	0/50 (0%)
Normall In all Inner	T-1-1	0/50 (0%)	Maran 0.000/	00.0700/	T-1-1	0/46 (0%)	Mars 0.470/	OD 0.500/
verall Incidence	Total	2/635 (0.31%)	Mean 0.33%	SD 0.78%	Total	1/626 (0.16%)	Mean 0.17%	SD 0.59%
Epididymis: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)				
		0/49 (0%)	0/50 (0%)	0/50 (0%)				
		1/50 (2%)	2 (22 (22)	0/50 (0%)				
		0/90 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Tatal	0/50 (0%)	Mann 0.470/	CD 0.500/				
	Total	1/638 (0.16%)	Mean 0.17%	SD 0.58%				
Eye: Leiomyoma								
		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%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (00/)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
		0/90 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/640 (0%)	Mean 0%	SD 0%
		` '				0/040 (0 /0)		
Heart: Schwannoma Malignant								
		0/50 (0%)	3/50 (6%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	0/49 (0%)
		2/49 (4%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	9/639 (1.41%)	Mean 1.51%	SD 2.12%	Total	4/638 (0.63%)	Mean 0.67%	SD 1.3%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 14

Report Date: 12/30/2020

Species: RATS

Route: ALL ROUTES
Vehicle: ALL VEHICLES

			Male				Female	
Intestine Large: Cecum:								
Liposarcoma								
		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%)	0/50 (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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				1/50 (2%)		
verall Incidence	Total	0/639 (0%)	Mean 0%	SD 0%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%
Intestine Large: Colon/Re Granular Cell Tumor Ben								
	•	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%)	0/50 (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%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/639 (0%)	Mean 0%	SD 0%	Total	1/640 (0.16%)	Mean 0.09%	SD 0.32%
Intestine Large: Colon/Re Leiomyoma								
		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%)	0/50 (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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/640 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Carcinoma								
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	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%)	. ,	1/50 (2%)		0/50 (0%)	1/50 (2%)	
		2/90 (2%)	1/50 (2%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

**Strain:** Harlan Sprague-Dawley **Length of Study:** CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

**Page:** 15

					Male						F	emale		
#Intestine Small: Jejunun Leiomyosarcoma	n:													
•		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%)	0/50	(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%)		1/90	(1%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/639 (0.16	,	Mean 0		SD 0.589		Total	1/640 (0.	,		0.09%	SD 0.	
fintestine Small: Site Uns Carcinoma														
		0/50	(0%)	1/50	(2%)	2/50	(4%)		0/50	(0%)	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%)			1/50	(2%)		0/50	(0%)	1/50	(2%)		
		2/90	(2%)	1/50	(2%)	1/50	(2%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	9/639 (1.41		Mean 1		SD 1.319		Total	1/640 (0.			0.17%	SD 0.	
#Intestine Small: Site Uns Carcinoma or Adenoma	specified:													
		0/50	(0%)	1/50	(2%)	2/50	(4%)		0/50	(0%)	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%)			1/50	(2%)		0/50	(0%)	1/50	(2%)		
		2/90	(2%)	1/50	(2%)	1/50	(2%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	9/639 (1.41		Mean 1		SD 1.319		Total	1/640 (0.	,		0.17%	SD 0.	
#Intestine Small: Site Uns														
•		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%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)		()	0/50	(0%)		0/50	(0%)	0/50	(0%)		\-·-/
			(0%)	0/50	(0%)	0/50	(0%)		1/90	(1%)	0/50	(0%)	0/50	(0%)
		0/90	(070)											
		0/90 0/50	(0%)	0/00	(070)	0,00	(0,0)		0/50	(0%)	0,00	(070)	0,00	(070)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Harlan Sprague-Dawley
Length of Study: CHRONIC

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

**Page:** 16

			Male				Female	
*Islets, Pancreatic:								
Adenoma		./=- (00/)	2/12 (22/)	0/50 (404)		. (=0 (00))		2/12 (22/)
		4/50 (8%)	3/49 (6%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	3/49 (6%)
		4/49 (8%)	3/50 (6%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		8/50 (16%)		5/50 (10%)		1/50 (2%)	1/50 (2%)	
		5/90 (6%)	2/50 (4%)	2/50 (4%)		5/90 (6%)	2/50 (4%)	1/50 (2%)
		4/50 (8%)				0/49 (0%)		
Overall Incidence	Total	44/638 (6.9%)	Mean 6.99%	SD 3.48%	Total	16/638 (2.51%)	Mean 2.31%	SD 2.01%
*Islets, Pancreatic: Carcinoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (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%)	,
		8/90 (9%)	3/50 (6%)	1/50 (2%)		2/90 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	()	( 11,		0/49 (0%)	()	(,
Overall Incidence	Total	12/638 (1.88%)	Mean 1.41%	SD 2.94%	Total	5/638 (0.78%)	Mean 0.69%	SD 1.01%
*Islets, Pancreatic: Carcinoma or Adenoma								
		4/50 (8%)	3/49 (6%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	3/49 (6%)
		4/49 (8%)	3/50 (6%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		8/50 (16%)	(273)	5/50 (10%)		2/50 (4%)	1/50 (2%)	(3,73)
		13/90 (14%)	5/50 (10%)	3/50 (6%)		7/90 (8%)	2/50 (4%)	2/50 (4%)
		4/50 (8%)	3,30 (1070)	3,33 (370)		0/49 (0%)	_, 55 (176)	_, 55 (170)
Overall Incidence	Total	56/638 (8.78%)	Mean 8.39%	SD 3.76%	Total	21/638 (3.29%)	Mean 2.99%	SD 2.31%
		, ,				` ,		
*Kidney: Pelvis and Transiti Papilloma	ional Epitheli							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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

					Male						F	emale		
*Kidney: Renal Tubule: Adenoma														
7.40.10.114		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	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%)		` ,	1/50	(2%)		1/50	(2%)	0/50	(0%)		` ,
		3/90	(3%)	0/50	(0%)	2/50	(4%)		1/90	(1%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	9/639 (1.419		Mean 1		SD 1.469		Total	2/640 (0.			0.26%	SD 0	
Kidney: Renal Tubule: Carcinoma														
		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%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		0/50	(0%)	0/50	(0%)		
		1/90	(1%)	0/50	(0%)	0/50	(0%)		1/90	(1%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/639 (0.169	,	Mean 0		SD 0.329		Total	1/640 (0.			0.09%	SD 0	
*Kidney: Renal Tubule: Carcinoma or Adenoma														
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	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%)			1/50	(2%)		1/50	(2%)	0/50	(0%)		
		3/90	(3%)	0/50	(0%)	2/50	(4%)		2/90	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	9/639 (1.419	,	Mean 1		SD 1.469		Total	3/640 (0.	,		0.35%	SD 0	.82%
*Kidney: Renal Tubule: Hemangioma														
-		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%)	0/50	(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%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)		•		
Overall Incidence	Total	0/639 (0%	)	Mean	0%	SD 0%		Total	1/640 (0.	16%)	Mean	0.17%	SD 0	58%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES **Page:** 18

			Male				Female	
Kidney: Renal Tubule: Lipoma								
•		1/50 (2%)	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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/90 (1%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	2/639 (0.31%)	Mean 0.26%	SD 0.63%	Total	0/640 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (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%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	2/639 (0.31%)	Mean 0.33%	SD 0.78%	Total	0/640 (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%)
		0/49 (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%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/640 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Oncocytoma Benign								
•		1/50 (2%)	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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/90 (1%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
O II I I I	T - 1 - 1	0/50 (0%)	Maran 0.000/	OD 0.000/	T-1-1	0/50 (0%)	M 00/	00.00/
Overall Incidence	Total	2/639 (0.31%)	Mean 0.26%	SD 0.63%	Total	0/640 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley

#### **Toxicology Data Management System**

**Page:** 19

Report Date: 12/30/2020

Tumor Incidence for Selected Control Animal Groups

**Route: ALL ROUTES** Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** \*Kidney: Renal Tubule: **Polyp Adenomatous** 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/639 (0.16%) Mean 0.17% SD 0.58% Total 0/640 (0%) Mean 0% SD 0% ..... #Lacrimal Gland: Carcinoma 1/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(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%)0/90 (0%)0/50 (0%)0/50 (0%)0/90 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/639 (0%) Mean 0% SD 0% Total 1/640 (0.16%) Mean 0.17% SD 0.58% \*Liver: Cholangiocarcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%) 0/50 (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%)0/50 0/90 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/639 (0.16%) Mean 0.17% SD 0.58% Total 0/639 (0%) Mean 0% SD 0% \*Liver: Cholangioma (0%) (0%)0/50 0/50 (0%)0/50 (0%)0/50 1/50 (2%)1/49 (2%)0/49 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/50 0/50 (0%)1/50 (2%)(0%)0/90 0/50 (0%)1/50 (2%)0/90 (0%)0/50 (0%)0/50 (0%)

SD 0.58%

1/50

4/639 (0.63%)

Total

(2%)

Mean 0.67%

SD 0.99%

Total

0/50

1/639 (0.16%)

(0%)

Mean 0.17%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page:** 20

Report Date: 12/30/2020

Route: ALL ROUTES
Vehicle: ALL VEHICLES

		Male				Female	
	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (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%)	0/50 (0%)	
	0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)				0/50 (0%)		
Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/639 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	1/49 (2%)
	` ,	` ,	` ,		` '	` '	2/50 (4%)
	0/50 (0%)	(,	0/50 (0%)		2/50 (4%)	` ,	( 11)
	0/90 (0%)	0/50 (0%)	1/50 (2%)		7/90 (8%)	2/50 (4%)	1/50 (2%)
	1/50 (2%)	, ,	,		1/50 (2%)	, ,	,
Total	3/639 (0.47%)	Mean 0.5%	SD 0.9%	Total	20/639 (3.13%)	Mean 2.82%	SD 2.28%
							•••••
	0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/49 (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%)	1/50 (2%)	, ,
	0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)				0/50 (0%)		
Total	2/639 (0.31%)	Mean 0.34%	SD 0.79%	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%
r Hepatobl	astoma						
		0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
	` ,	, ,	, ,		` ,	` ,	0/50 (0%)
	` ,		` '		` '	` '	()
	` ,	0/50 (0%)	` '			` ,	0/50 (0%)
	0/50 (0%)	2.22 (370)	(-,3)		` ,	(-,-)	(-,-)
Total	` '	Mean 0.34%	SD 0.79%	Total	, ,	Mean 0.17%	SD 0.58%
i otai	2/639 (0.31%)	Mean 0.34%	SD 0.79%	I otal	1/639 (0.16%)	Mean 0.17%	SD 0.58%
	Total	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%) 0/50 (0%) Total 1/639 (0.16%)  0/50 (0%) 0/49 (0%) 0/50 (0%) 0/90 (0%) 1/50 (2%)  Total 3/639 (0.47%)  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 2/639 (0.31%)  r Hepatoblastoma  0/50 (0%) 1/49 (2%) 0/50 (0%) 1/49 (2%) 0/50 (0%) 1/49 (2%) 0/50 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%) 0/50 (0%) Total 1/639 (0.16%) Mean 0.17%   0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%)  Total 3/639 (0.47%) Mean 0.5%   0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%) 0/49 (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%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 1/639 (0.16%) Mean 0.17% SD 0.58%   0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/90 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%) 1/50 (2%)  Total 3/639 (0.47%) Mean 0.5% SD 0.9%   0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (	0/50 (0%)	0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

**Strain:** Harlan Sprague-Dawley **Length of Study:** CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

**Page:** 21

					Male						F	emale		
*Liver:														·
Hepatocellular Carcino	ma or Hepatoce	Ilular Adenoma												
		0/50	(0%)	0/50	(0%)	1/50	(2%)		2/50	(4%)	0/50	(0%)	1/49	(2%)
		1/49	(2%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	2/50	(4%)
		0/50	(0%)			0/50	(0%)		2/50	(4%)	3/50	(6%)		
		0/90	(0%)	0/50	(0%)	1/50	(2%)		7/90	(8%)	2/50	(4%)	1/50	(2%)
		1/50	(2%)						1/50	(2%)				
Overall Incidence	Total	5/639 (0.78	s%)	Mean 0	.84%	SD 1.03	%	Total	21/639 (3	3.29%)	Mean	2.98%	SD 2	.44%
*Liver:														
Hepatocellular Carcino	ma, Hepatocellu	ılar Adenoma, c	r Hepatol	blastoma										
		0/50	(0%)	0/50	(0%)	1/50	(2%)		2/50	(4%)	0/50	(0%)	1/49	(2%)
		1/49	(2%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	2/50	(4%)
		0/50	(0%)			0/50	(0%)		2/50	(4%)	3/50	(6%)		
		0/90	(0%)	0/50	(0%)	1/50	(2%)		7/90	(8%)	2/50	(4%)	1/50	(2%)
		1/50	(2%)						1/50	(2%)				
Overall Incidence	Total	5/639 (0.78	,	Mean 0		SD 1.03		Total	21/639 (3	,		2.98%	SD 2	.44%
*Lung: Alveolar/Bronchiolar A														
7.1.7.00.01.7.1.01.101.101.101.101.101.1		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/49	(0%)
		1/49	(2%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	0/49	(0%)	1/50	(2%)
		0/50	(0%)	0,00	(070)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1700	(= /0)
		1/90	(1%)	1/50	(2%)	1/50	(2%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		()		(- / - /		0/50	(0%)	-, - 0	(- / - /	0	(-,-)
Overall Incidence	Total	4/638 (0.63	3%)	Mean (		SD 0.919		Total	1/638 (0	.16%)		0.17%	SD 0	.58%
*Lung:														
Alveolar/Bronchiolar C	arcinoma													
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/49	(0%)
		0/49	(0%)	1/50	(2%)	0/49	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50	(0%)		(/	0/50	(0%)		0/50	(0%)	0/50	(0%)		(/
		0/90	(0%)	0/50	(0%)	1/50	(2%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	2.20	(-,-)		(- / - /		0/50	(0%)	-, - 0	(- / - /	0	(,
Overall Incidence	Total	3/638 (0.47		Mean (	0.5%	SD 0.9%	6	Total	0/638 (	, ,	Mea	n 0%	SD	0%
		3,000 (0.17	,			02 0.07	- 			,			25	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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: 22

					Male						F	emale		
Lung:														
Alveolar/Bronchiolar Card	cinoma or Alv													
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/49	(0%)
		1/49	(2%)	1/50	(2%)	0/49	(0%)		0/50	(0%)	0/49	(0%)	1/50	(2%)
		0/50	(0%)			0/50	(0%)		0/50	(0%)	0/50	(0%)		
		1/90	(1%)	1/50	(2%)	2/50	(4%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)						0/50	(0%)				
Overall Incidence	Total	7/638 (1.1	,	Mean 1		SD 1.31		Total	1/638 (0	,		0.17%	SD 0	.58%
Lung: Sarcoma														
Jai Collia		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/49	(0%)
		0/30	(0%)	0/50	(0%)	0/30	(0%)		0/50	(0%)	0/30	(0%)	1/50	(2%)
		0/49	(0%)	0/30	(0 /0)	0/49	(0%)		0/50	(0%)	0/49	(0%)	1/50	(2 /0)
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/30	(0 /0)	0/30	(0 /0)		0/90	(0%)	0/30	(0 /0)	0/30	(0 /0)
Overall Incidence	Total	0/638 (0%	` ,	Mean	Ω9/.	SD 0%		Total	1/638 (0.		Moon	0.17%	SD 0	EQ0/:
									•			0.17 /0	ں توں	
Lung: Squamous Cell Carcinom	na													
•		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%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50	(0%)		(/	1/50	(2%)		0/50	(0%)	0/50	(0%)		()
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		` '		` '		0/50	(0%)		` '	-	` '
Overall Incidence	Total	1/638 (0.16	6%)	Mean 0		SD 0.589		Total	0/638 (	0%)		ın 0%	SD	
#Lymph Node, Mesenteric:														
Hemangiosarcoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	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%)		` ,
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		()	<del>-</del>	()		0/50	(0%)		\ /		()

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

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Report Date: 12/30/2020

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: ALL ROUTES
Vehicle: ALL VEHICLES

			Male				Female	
#Mammary Gland: Adenolipoma								
•		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%)	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%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/639 (0%)	Mean 0%	SD 0%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%
Mammary Gland:								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
		0/50 (0%)		0/50 (0%)		4/50 (8%)	1/50 (2%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		8/90 (9%)	1/50 (2%)	3/50 (6%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/639 (0%)	Mean 0%	SD 0%	Total	22/640 (3.44%)	Mean 3.07%	SD 3.27%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		3/50 (6%)	8/50 (16%)	1/50 (2%)
		0/49 (0%)	2/50 (4%)	0/50 (0%)		4/50 (8%)	7/50 (14%)	3/50 (6%)
		0/50 (0%)		0/50 (0%)		5/50 (10%)	3/50 (6%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		10/90 (11%)	2/50 (4%)	2/50 (4%)
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	3/639 (0.47%)	Mean 0.5%	SD 1.24%	Total	49/640 (7.66%)	Mean 7.43%	SD 4.53%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		4/50 (8%)	8/50 (16%)	2/50 (4%)
		0/49 (0%)	2/50 (4%)	0/50 (0%)		4/50 (8%)	7/50 (14%)	6/50 (12%)
		0/50 (0%)		0/50 (0%)		9/50 (18%)	4/50 (8%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		16/90 (18%)	3/50 (6%)	5/50 (10%)
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	3/639 (0.47%)	Mean 0.5%	SD 1.24%	Total	69/640 (10.78%)	Mean 10.31%	SD 5.29%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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						ı	Female		
#Mammary Gland:														
Fibroadenoma														
		3/50	(6%)	0/50	(0%)	2/50	(4%)		29/50	(58%)	25/50	(50%)	28/50	(56%)
		1/49	(2%)	2/50	(4%)	1/50	(2%)		33/50	(66%)	32/50	(64%)	29/50	(58%)
		2/50	(4%)			2/50	(4%)		20/50	(40%)	21/50	(42%)		
		2/90	(2%)	0/50	(0%)	0/50	(0%)		63/90	(70%)	28/50	(56%)	30/50	(60%)
		2/50	(4%)						29/50	(58%)				
Overall Incidence	Total	17/639 (2.6	,	Mean 2	.69%	SD 1.969	%	Total	367/640 (5	57.34%)	Mear	า 56.5%	SD 8	.91%
#Mammary Gland:														
Fibroma, Fibroadenom	na or Adenoma													
		3/50	(6%)	0/50	(0%)	2/50	(4%)		29/50	(58%)	25/50	(50%)	29/50	(58%)
		1/49	(2%)	2/50	(4%)	1/50	(2%)		33/50	(66%)	32/50	(64%)	30/50	(60%)
		2/50	(4%)			2/50	(4%)		23/50	(46%)	22/50	(44%)		
		2/90	(2%)	0/50	(0%)	0/50	(0%)		64/90	(71%)	28/50	(56%)	32/50	(64%)
		2/50	(4%)						29/50	(58%)				
			` '							` ,				
	Total	17/639 (2.6	6%) ´	Mean 2		SD 1.969		Total	376/640 (5	58.75%)		57.93%	SD 8	
Overall Incidence #Mammary Gland: Fibroma Fibroadenom		17/639 (2.6	6%) ´						376/640 (5	58.75%)				
		17/639 (2.6	6%)						376/640 (5	58.75%)				
#Mammary Gland:		17/639 (2.6 or Adenoma 3/50	6%)  (6%)	0/50	(0%)	3/50	(6%)		376/640 (5	(60%)	29/50	(58%)	30/50	(60%)
#Mammary Gland:		17/639 (2.6 <b>r Adenoma</b> 3/50 1/49	(6%) (6%) (2%)			3/50 1/50	(6%) (2%)		376/640 (5 30/50 35/50	(60%) (70%)	29/50 36/50	(58%) (72%)		
#Mammary Gland:		17/639 (2.6 r Adenoma 3/50 1/49 2/50	(6%) (6%) (2%) (4%)	0/50 3/50	(0%) (6%)	3/50 1/50 2/50	(6%) (2%) (4%)		376/640 (5 30/50 35/50 27/50	(60%) (70%) (54%)	29/50 36/50 25/50	(58%) (72%) (50%)	30/50 32/50	(60%) (64%)
#Mammary Gland:		17/639 (2.6 <b>r Adenoma</b> 3/50 1/49 2/50 2/90	(6%) (2%) (4%) (2%)	0/50	(0%)	3/50 1/50	(6%) (2%)		376/640 (5 30/50 35/50 27/50 66/90	(60%) (70%) (54%) (73%)	29/50 36/50	(58%) (72%)	30/50	(60%)
#Mammary Gland: Fibroma, Fibroadenom		17/639 (2.6 r Adenoma 3/50 1/49 2/50	(6%) (2%) (4%) (2%) (4%)	0/50 3/50	(0%) (6%) (0%)	3/50 1/50 2/50	(6%) (2%) (4%) (0%)		376/640 (5 30/50 35/50 27/50	(60%) (70%) (54%) (73%) (60%)	29/50 36/50 25/50 29/50	(58%) (72%) (50%)	30/50 32/50	(60%) (64%) (68%)
#Mammary Gland: Fibroma, Fibroadenom Overall Incidence	na, Carcinoma, o	17/639 (2.6 <b>r Adenoma</b> 3/50 1/49 2/50 2/90 2/50 19/639 (2.9	(6%) (2%) (4%) (2%) (4%) (4%) 7%)	0/50 3/50 0/50 Mean 3	(0%) (6%) (0%)	3/50 1/50 2/50 0/50 SD 2.33	(6%) (2%) (4%) (0%)	Total	376/640 (5 30/50 35/50 27/50 66/90 30/50 403/640 (6	(60%) (70%) (54%) (73%) (60%) 62.97%)	29/50 36/50 25/50 29/50 Mean	(58%) (72%) (50%) (58%) 62.28%	30/50 32/50 34/50 SD 7	(60%) (64%) (68%)
#Mammary Gland: Fibroma, Fibroadenom	na, Carcinoma, o	17/639 (2.6 <b>r Adenoma</b> 3/50 1/49 2/50 2/90 2/50 19/639 (2.9	(6%) (2%) (4%) (2%) (4%) (4%) 7%)	0/50 3/50 0/50 Mean 3	(0%) (6%) (0%)	3/50 1/50 2/50 0/50 SD 2.33	(6%) (2%) (4%) (0%)	Total	376/640 (5 30/50 35/50 27/50 66/90 30/50 403/640 (6	(60%) (70%) (54%) (73%) (60%) 62.97%)	29/50 36/50 25/50 29/50 Mean	(58%) (72%) (50%) (58%) 62.28%	30/50 32/50 34/50 SD 7	(60%) (64%) (68%)
#Mammary Gland: Fibroma, Fibroadenom Overall Incidence #Mammary Gland:	na, Carcinoma, o	17/639 (2.6 <b>r Adenoma</b> 3/50 1/49 2/50 2/90 2/50 19/639 (2.9	(6%) (2%) (4%) (2%) (4%) (4%) 7%)	0/50 3/50 0/50 Mean 3	(0%) (6%) (0%)	3/50 1/50 2/50 0/50 SD 2.33	(6%) (2%) (4%) (0%)	Total	376/640 (5 30/50 35/50 27/50 66/90 30/50 403/640 (6	(60%) (70%) (54%) (73%) (60%) 62.97%)	29/50 36/50 25/50 29/50 Mean	(58%) (72%) (50%) (58%) 62.28%	30/50 32/50 34/50 SD 7	(60%) (64%) (68%)
#Mammary Gland: Fibroma, Fibroadenom Overall Incidence #Mammary Gland:	na, Carcinoma, o	17/639 (2.6 <b>r Adenoma</b> 3/50 1/49 2/50 2/90 2/50 19/639 (2.9	(6%) (2%) (4%) (2%) (4%) (4%) 7%)	0/50 3/50 0/50 Mean 3	(0%) (6%) (0%)	3/50 1/50 2/50 0/50 SD 2.33	(6%) (2%) (4%) (0%)	Total	376/640 (5 30/50 35/50 27/50 66/90 30/50 403/640 (6	(60%) (70%) (54%) (73%) (60%) 62.97%)	29/50 36/50 25/50 29/50 Mean	(58%) (72%) (50%) (58%) 62.28%	30/50 32/50 34/50 SD 7	(60%) (64%) (68%)
#Mammary Gland: Fibroma, Fibroadenom Overall Incidence #Mammary Gland:	na, Carcinoma, o	17/639 (2.6 or Adenoma 3/50 1/49 2/50 2/90 2/50 19/639 (2.9	(6%) (2%) (4%) (2%) (4%) 7%)	0/50 3/50 0/50 Mean 3	(0%) (6%) (0%) .02%	3/50 1/50 2/50 0/50 SD 2.33 <sup>4</sup>	(6%) (2%) (4%) (0%)	Total	376/640 (5 30/50 35/50 27/50 66/90 30/50 403/640 (6	(60%) (70%) (54%) (73%) (60%) 62.97%)	29/50 36/50 25/50 29/50 Mean	(58%) (72%) (50%) (58%) 62.28%	30/50 32/50 34/50 SD 7	(60%) (64%) (68%) 2.28%
#Mammary Gland: Fibroma, Fibroadenom Overall Incidence #Mammary Gland:	na, Carcinoma, o	17/639 (2.6 or Adenoma 3/50 1/49 2/50 2/90 2/50 19/639 (2.9 0/50 0/49	(6%) (2%) (4%) (2%) (4%) 7%) (0%)	0/50 3/50 0/50 Mean 3	(0%) (6%) (0%) .02%	3/50 1/50 2/50 0/50 SD 2.33 <sup>4</sup> 0/50 0/50	(6%) (2%) (4%) (0%) %	Total	376/640 (5 30/50 35/50 27/50 66/90 30/50 403/640 (6	(60%) (70%) (54%) (73%) (60%) 62.97%) (0%) (0%)	29/50 36/50 25/50 29/50 Mean 0/50 0/50	(58%) (72%) (50%) (58%) 62.28%	30/50 32/50 34/50 SD 7	(60%) (64%) (68%) 2.28%
#Mammary Gland: Fibroma, Fibroadenom Overall Incidence #Mammary Gland:	na, Carcinoma, o	17/639 (2.6 or Adenoma 3/50 1/49 2/50 2/90 2/50 19/639 (2.9 0/50 0/49 0/50	(6%) (2%) (4%) (2%) (4%) (7%) (0%) (0%) (0%)	0/50 3/50 0/50 Mean 3 0/50 0/50	(0%) (6%) (0%) .02% .02%	3/50 1/50 2/50 0/50 SD 2.33 <sup>4</sup> 0/50 0/50 0/50	(6%) (2%) (4%) (0%) %	Total	376/640 (5 30/50 35/50 27/50 66/90 30/50 403/640 (6 0/50 0/50	(60%) (70%) (54%) (73%) (60%) 62.97%) (0%) (0%) (0%)	29/50 36/50 25/50 29/50 Mean 0/50 0/50 0/50	(58%) (72%) (50%) (58%) 62.28% (0%) (0%) (0%)	30/50 32/50 34/50 SD 7	(60%) (64%) (68%) 2.28% (0%) (2%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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						F	emale		
Nose: Carcinoma														
		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%)	0/50	(0%)	0/49	(0%)
		0/50	(0%)	0./=0	(00/)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0.450	(00()
		0/89	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
	<b>T</b>	0/50	(0%)		00/	<b>OD</b> 00/		<b>-</b>	0/49	(0%)		0.470/	00.0	<b>50</b> 0/
erall Incidence	Total	0/638 (0%		Mean		SD 0%		Total	1/638 (0.	.16%)	Mean	0.17%	SD 0.	58%
Oral Cavity (Oral Mucos Squamous Cell Carcing	a, Tongue, Phar													
·		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	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%)	0/50	(0%)		
		0/90	(0%)	1/50	(2%)	0/50	(0%)		2/90	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
/erall Incidence	Total	3/639 (0.47)		Mean (		SD 0.919		Total	2/640 (0.	,		0.19%	SD 0.	
Oral Cavity (Oral Mucos Squamous Cell Carcino	a, Tongue, Phar	ynx, Tooth, Gin Squamous, or P	giva): Papilloma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	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%)	4/50	(00()	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(00()
		0/90	(0%)	1/50	(2%)	0/50	(0%)		2/90	(2%)	0/50	(0%)	0/50	(0%)
vanali la ai danaa	Tatal	0/50	(0%)	Mann	2.50/	CD 0.040	v/	Tatal	0/50	(0%)	Mana	0.400/	CD 0	C 40/
verall Incidence	Total	3/639 (0.47	,	Mean (		SD 0.919		Total	2/640 (0.	,		0.19%	SD 0.	
Oral Mucosa: Squamous Cell Carcino	oma													
•		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	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%)	0/50	(0%)		
		0/90	(0%)	1/50	(2%)	0/50	(0%)		1/90	(1%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
		0/000 /0 47		11		CD 0.040			4/040 /0			0.000/	CD 0	

SD 0.91%

Total

1/640 (0.16%)

Mean 0.09%

SD 0.32%

Total

3/639 (0.47%)

Mean 0.5%

**Overall Incidence** 

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

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Report Date: 12/30/2020

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

	Male		Female	
*Ovary: Cystadenoma				
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/640 (0.16%)	Mean 0.09%	SD 0.32%
*Ovary:				
Granulosa Cell Tumor Benign		0/50 (00/)	4/50 (00/)	4/50 (00/)
		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	1/50 (2%)	0/50 (00/)
		1/90 (1%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)		
Overall Incidence	Total	7/640 (1.09%)	Mean 1.09%	SD 1.78%
*Ovary: Granulosa Cell Tumor Malignant				
gg.		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	(175)
		2/90 (2%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	,	` ,
Overall Incidence	Total	5/640 (0.78%)	Mean 0.69%	SD 1.01%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
Cranalosa con rumor. Benign, manghair, 1900		0/50 (0%)	1/50 (2%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	1/50 (2%)	0,00 (0,70)
		3/90 (3%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	1/00 (2/0)	1700 (270)
Overall Incidence	Total	12/640 (1.88%)	Mean 1.78%	SD 1.93%
Overall incluence	rotai	12/040 (1.00%)	Wear 1.70%	JU 1.93%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

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Report Date: 12/30/2020

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Male			Female	
Ovary: Granulosa-Theca Tumor Benign				
		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%)	0/50 (0%)
		1/50 (2%)		
verall Incidence	Total	2/640 (0.31%)	Mean 0.33%	SD 0.78%
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%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)		
Overall Incidence	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%
Ovary: Luteoma				
		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%)
		0/50 (0%)		
Overall Incidence	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%
Ovary: Schwannoma Malignant				
		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%)	0/50 (0%)
		0/50 (0%)	,	` '

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

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Report Date: 12/30/2020

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

			Male				Female	
*Ovary: Sertoli Cell Tumor Benign	1							
						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%)	0/50 (0%)
						0/50 (0%)		
Overall Incidence					Total	1/640 (0.16%)	Mean 0.09%	SD 0.32%
*Ovary:								
Thecoma Benign								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						1/50 (2%)	0/50 (0%)	
						0/90 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)		
Overall Incidence					Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%
*Ovary: Tubulostromal Carcinoma								
						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%)	0/50 (0%)
						0/50 (0%)	, ,	, ,
Overall Incidence					Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%
*Pancreas:								
, additioning		6/50 (12%)	1/49 (2%)	10/50 (20%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		4/49 (8%)	5/50 (10%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/00 (10/0)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0,00 (0,0)
		18/90 (20%)	8/50 (16%)	14/50 (28%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		9/50 (18%)	0/30 (10/0)	17/00 (20/0)		0/49 (0%)	0,00 (0,70)	0,00 (0,0)
Overall Incidence	Total	83/638 (13.01%)	Mean 12.52%	SD 8.17%	Total	0/638 (0%)	Mean 0%	SD 0%
Overall incluence	TULAI	03/030 (13.01%)	IVICALI 12.32%	3D 0.17%	i Ulai	0/030 (070)	IVICALI U70	3D 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

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Report Date: 12/30/2020

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: ALL ROUTES
Vehicle: ALL VEHICLES

			Male		Female				
Pancreas:									
Carcillollia		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		2/49 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/00 (0/0)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/00 (0/0)	
		1/90 (1%)	0/50 (0%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/00 (0/0)	1700 (270)		0/49 (0%)	0/00 (0/0)	0/00 (0/0)	
Overall Incidence	Total	5/638 (0.78%)	Mean 0.77%	SD 1.31%	Total	0/638 (0%)	Mean 0%	SD 0%	
Pancreas:									
Carcinoma or Adenoma									
		7/50 (14%)	1/49 (2%)	10/50 (20%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		6/49 (12%)	5/50 (10%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	, ,	3/50 (6%)		0/50 (0%)	0/50 (0%)	, ,	
		18/90 (20%)	8/50 (16%)	14/50 (28%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		9/50 (18%)				0/49 (0%)			
Overall Incidence	Total	86/638 (13.48%)	Mean 13.02%	SD 8.06%	Total	0/638 (0%)	Mean 0%	SD 0%	
Parathyroid Gland: Adenoma									
		0/49 (0%)	0/43 (0%)	0/42 (0%)		0/46 (0%)	0/42 (0%)	0/42 (0%)	
		0/48 (0%)	0/49 (0%)	0/43 (0%)		0/45 (0%)	1/41 (2%)	0/47 (0%)	
		0/48 (0%)		0/41 (0%)		0/45 (0%)	0/47 (0%)		
		1/83 (1%)	1/49 (2%)	0/43 (0%)		0/87 (0%)	0/48 (0%)	0/46 (0%)	
		0/49 (0%)				0/44 (0%)			
Overall Incidence	Total	2/587 (0.34%)	Mean 0.27%	SD 0.66%	Total	1/580 (0.17%)	Mean 0.2%	SD 0.7%	
Peripheral Nerve: Paraganglioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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%)	. ,	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	, ,	, ,		0/50 (0%)	, ,	. ,	
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.59%	Total	0/640 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES **Page:** 30 Report Date: 12/30/2020

		Male						Female						
#Peripheral Nerve: Schwannoma Malignant	t	,												
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	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%)		
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/639 (0.16	6%)	Mean C	).17%	SD 0.59	%	Total	0/640	(0%)	Mea	an 0%	SD	0%
Peripheral Nerve: Schwannoma: Benign, N	Walignant, NOS	6												
	<b>g</b> ,	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	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%)		()
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		` ,		, ,		0/50	(0%)		, ,		,
Overall Incidence	Total	1/620 /0.10	. ,	Mean C	170/	CD 0.50	0/	Tatal	0/040	, ,		an 0%	SD	Λ0/
		1/639 (0.16	•			SD 0.59		Total	0/640				_	
Pituitary Gland: Pars Dist			•										_	
Pituitary Gland: Pars Dist			•										_	
Pituitary Gland: Pars Dist		cified Site:										•••••		
Pituitary Gland: Pars Dist		cified Site:	(24%)	3/50	(6%)	4/50	(8%)		20/50	(40%)	13/49	(27%)	15/49	(31%)
Pituitary Gland: Pars Dist		2/50 15/48	(24%) (31%)	3/50	(6%)	4/50 5/50	(8%) (10%)		20/50 12/50	(40%) (24%)	13/49 19/50	(27%) (38%)	15/49	(31%)
Pituitary Gland: Pars Dist		12/50 15/48 11/50	(24%) (31%) (22%)	3/50 14/50	(6%) (28%)	4/50 5/50 5/50	(8%) (10%) (10%)		20/50 12/50 18/50	(40%) (24%) (36%)	13/49 19/50 22/50	(27%) (38%) (44%)	15/49 18/50	(31%) (36%)
Pituitary Gland: Pars Dist Adenoma Overall Incidence	talis or Unspec	2/50 12/50 15/48 11/50 17/89	(24%) (31%) (22%) (19%) (14%)	3/50 14/50 10/50 Mean 1	(6%) (28%) (20%) 7.36%	4/50 5/50 5/50 8/50 8/50	(8%) (10%) (10%) (16%)	Total	20/50 12/50 18/50 43/90	(40%) (24%) (36%) (48%) (22%)	13/49 19/50 22/50 21/50	(27%) (38%) (44%)	15/49 18/50	(31%) (36%) (32%)
Pituitary Gland: Pars Dist	talis or Unspec	12/50 15/48 11/50 17/89 7/50 111/637 (17.	(24%) (31%) (22%) (19%) (14%)	3/50 14/50 10/50 Mean 1	(6%) (28%) (20%) 7.36%	4/50 5/50 5/50 8/50	(8%) (10%) (10%) (16%)	Total	20/50 12/50 18/50 43/90 11/50	(40%) (24%) (36%) (48%) (22%)	13/49 19/50 22/50 21/50	(27%) (38%) (44%) (42%)	15/49 18/50 16/50	(31%) (36%) (32%)
Pituitary Gland: Pars Dist Adenoma Dverall Incidence	talis or Unspec	12/50 15/48 11/50 17/89 7/50 111/637 (17.	(24%) (31%) (22%) (19%) (14%)	3/50 14/50 10/50 Mean 1	(6%) (28%) (20%) 7.36%	4/50 5/50 5/50 8/50 8/50	(8%) (10%) (10%) (16%)	Total	20/50 12/50 18/50 43/90 11/50	(40%) (24%) (36%) (48%) (22%)	13/49 19/50 22/50 21/50	(27%) (38%) (44%) (42%)	15/49 18/50 16/50	(31%) (36%) (32%)
Pituitary Gland: Pars Dist Adenoma Overall Incidence	talis or Unspec	2/50 15/48 11/50 17/89 7/50 111/637 (17.	(24%) (31%) (22%) (19%) (14%) 43%)	3/50 14/50 10/50 Mean 1	(6%) (28%) (20%) 7.36%	4/50 5/50 5/50 8/50 8/50 SD 8.09	(8%) (10%) (10%) (16%)	Total	20/50 12/50 18/50 43/90 11/50 228/638 (3	(40%) (24%) (36%) (48%) (22%) 35.74%)	13/49 19/50 22/50 21/50 Mean	(27%) (38%) (44%) (42%) 34.91%	15/49 18/50 16/50 SD 8	(31%) (36%) (32%) .09%
Pituitary Gland: Pars Dist Adenoma Dverall Incidence	talis or Unspec	2/50 15/48 11/50 17/89 7/50 111/637 (17.	(24%) (31%) (22%) (19%) (14%) 43%) (0%)	3/50 14/50 10/50 Mean 1	(6%) (28%) (20%) 7.36%	4/50 5/50 5/50 8/50 8/50 SD 8.09	(8%) (10%) (10%) (16%) (16%)	Total	20/50 12/50 18/50 43/90 11/50 228/638 (3	(40%) (24%) (36%) (48%) (22%) 35.74%)	13/49 19/50 22/50 21/50 Mean	(27%) (38%) (44%) (42%) 34.91%	15/49 18/50 16/50 SD 8	(31%) (36%) (32%) .09%
Pituitary Gland: Pars Dist Adenoma Dverall Incidence Pituitary Gland: Pars Dist	talis or Unspec	12/50 15/48 11/50 17/89 7/50 111/637 (17.	(24%) (31%) (22%) (19%) (14%) 43%) (0%) (0%) (0%)	3/50 14/50 10/50 Mean 1	(6%) (28%) (20%) 7.36% (0%) (0%)	4/50 5/50 5/50 8/50 8/50 SD 8.09 0/50 0/50	(8%) (10%) (10%) (16%) (16%) (0%) (0%) (0%)	Total	20/50 12/50 18/50 43/90 11/50 228/638 (3	(40%) (24%) (36%) (48%) (22%) 35.74%) (0%) (2%) (0%)	13/49 19/50 22/50 21/50 Mean 0/49 0/50 0/50	(27%) (38%) (44%) (42%) 34.91% (0%) (0%) (0%)	15/49 18/50 16/50 SD 8	(31%) (36%) (32%) .09% (2%) (0%)
Pituitary Gland: Pars Dist Adenoma Dverall Incidence	talis or Unspec	2/50 15/48 11/50 17/89 7/50 111/637 (17. 2:ified Site:	(24%) (31%) (22%) (19%) (14%) 43%) 	3/50 14/50 10/50 Mean 1 0/50 0/50	(6%) (28%) (20%) 7.36%	4/50 5/50 5/50 8/50 8/50 SD 8.09 0/50 0/50 0/50	(8%) (10%) (10%) (16%) (16%)	Total	20/50 12/50 18/50 43/90 11/50 228/638 (3 0/50 1/50 0/50	(40%) (24%) (36%) (48%) (22%) 35.74%) (0%) (2%)	13/49 19/50 22/50 21/50 Mean 0/49 0/50	(27%) (38%) (44%) (42%) 34.91% (0%) (0%)	15/49 18/50 16/50 SD 8	(31%) (36%) (32%) .09%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

**Strain:** Harlan Sprague-Dawley **Length of Study:** CHRONIC

			Male				Female	
Pituitary Gland: Pars Dis Carcinoma or Adenoma	•	cified Site:						
		12/50 (24%) 15/48 (31%) 11/50 (22%)	3/50 (6%) 14/50 (28%)	4/50 (8%) 5/50 (10%) 5/50 (10%)		20/50 (40%) 13/50 (26%) 18/50 (36%)	13/49 (27%) 19/50 (38%) 22/50 (44%)	16/49 (33%) 18/50 (36%)
		17/89 (19%) 7/50 (14%)	10/50 (20%)	9/50 (18%)		44/90 (49%) 11/50 (22%)	21/50 (42%)	17/50 (34%)
Overall Incidence	Total	112/637 (17.58%)	Mean 17.53%	SD 8.08%	Total	232/638 (36.36%)	Mean 35.51%	SD 7.89%
Pituitary Gland: Pars Inte Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/48 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/89 (0%)	1/50 (2%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/90 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
		0/50 (0%)	1/30 (2/0)	1/30 (2/0)		0/50 (0%)	1/30 (2/0)	0/30 (0 /0)
Overall Incidence	Total	5/637 (0.78%)	Mean 0.83%	SD 1.34%	Total	1/638 (0.16%)	Mean 0.17%	SD 0.58%
Pituitary Gland: Pars Inte Carcinoma or Adenoma	ermedia:							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/48 (0%)	2/50 (4%)	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 (70 (00))
		0/89 (0%)	1/50 (2%)	1/50 (2%)		0/90 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 5/637 (0.78%)	Mean 0.83%	SD 1.34%	Total	0/50 (0%) 1/638 (0.16%)	Mean 0.17%	SD 0.58%
		, ,				` ,		
Pituitary Gland: Pars Ner Schwannoma Malignan								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (001)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
		0/89 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/90 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/637 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/638 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: ALL ROUTES
Vehicle: ALL VEHICLES

**Strain:** Harlan Sprague-Dawley **Length of Study:** CHRONIC

			Male		Female
*Prostate: Adenoma					
		0/50 (0%)	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%)	0/50 (0%)	
		0/50 (0%)			
Overall Incidence	Total	7/639 (1.1%)	Mean 1.02%	SD 1.82%	
*Prostate: Carcinoma or Adenoma					
		0/50 (0%)	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%)	0/50 (0%)	
		0/50 (0%)			
Overall Incidence	Total	7/639 (1.1%)	Mean 1.02%	SD 1.82%	
*Salivary Glands: Schwannoma Malignant					
		0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%) 0/49 (0%) 0/49 (0%)
		0/49 (0%)	0/50 (0%)	1/50 (2%)	0/49 (0%) 0/49 (0%) 0/50 (0%)
		0/50 (0%)		0/49 (0%)	0/50 (0%) 0/49 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)			0/50 (0%)
Overall Incidence	Total	3/638 (0.47%)	Mean 0.5%	SD 1.24%	Total 0/635 (0%) Mean 0% SD 0%
#Seminal Vesicle: Hemangiosarcoma					
		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)		0/50 (0%)	
		0/90 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)			
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

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						F	emale		
#Skeletal Muscle: Hemangioma														
<b></b>		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	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%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/639 (0%)		Mean		SD 0%		Total	1/640 (0.	,		0.17%	SD 0	
#Skeletal Muscle: Liposarcoma														
		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%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		1/50	(2%)	0/50	(0%)		
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
			(0%)						0/50	(0%)				
Overall Incidence	Total	0/639 (0%)		Mean		SD 0%		Total	1/640 (0.			0.17%	SD 0	
#Skeletal Muscle: Sarcoma														
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	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%)		
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/639 (0.16%	•	Mean 0		SD 0.589		Total	1/640 (0.	,		0.17%	SD 0	.58%
#Skin: Basal Cell Adenoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	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%)		` '	1/50	(2%)		0/50	(0%)	0/50	(0%)		` ,
		1/90	(1%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)		` '		. ,		0/50	(0%)		. ,		` ,
			6)	Mean 0		SD 0.819			1/640 (0.			0.17%		.58%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

**Page:** 34

Report Date: 12/30/2020

			Male			Female					
#Skin:											
Basal Cell Adenoma or E	Basosquamous	s Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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%)		1/50 (2%)		0/50 (0%)	0/50 (0%)				
		1/90 (1%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	1/50 (2%)	0/50 (0%)			
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	3/639 (0.47%)	Mean 0.43%	SD 0.81%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%			
#Skin:											
Basal Cell Adenoma, Ba	sosquamous 1	Γumor Benign, or Tricho	epithelioma								
	-	0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	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%)		1/50 (2%)		0/50 (0%)	0/50 (0%)				
		1/90 (1%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	1/50 (2%)	0/50 (0%)			
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	4/639 (0.63%)	Mean 0.6%	SD 0.91%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%			
#Skin: Basal Cell Carcinoma											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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%)		1/50 (2%)	0/50 (0%)	, ,			
		0/90 (0%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	2/50 (4%)	0/50 (0%)			
		0/50 (0%)	, ,	, ,		0/50 (0%)	, ,	, ,			
Overall Incidence	Total	2/639 (0.31%)	Mean 0.33%	SD 0.78%	Total	3/640 (0.47%)	Mean 0.5%	SD 1.24%			
#Skin:			•••••								
Basal Cell Carcinoma or	Basosquamoi	us Tumor (malignant or	NOS)								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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%)	0,00 (0,0)	0/50 (0%)		1/50 (2%)	0/50 (0%)	3/00 (0/0)			
		0/90 (0%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	2/50 (4%)	0/50 (0%)			
		0/50 (0%)	1/50 (2/0)	0/30 (0/0)		0/50 (0%)	2/30 (4/0)	0/00 (0/0)			
Overall Incidence	Total	` '	Moon 0.339/	SD 0.799/	Total		Moon 0.5%	SD 1.24%			
Overall incluence	Total	2/639 (0.31%)	Mean 0.33%	SD 0.78%	างเลเ	3/640 (0.47%)	Mean 0.5%	SD 1.24%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

**Page:** 35

Report Date: 12/30/2020

Route: ALL ROUTES
Vehicle: ALL VEHICLES

**Strain:** Harlan Sprague-Dawley **Length of Study:** CHRONIC

Contract/Lab: All Laboratories

#Skin: Basal Cell Carcinoma, Basa NOS), or Trichoepithelioma	I Call Adam	·						
	I Call Adam							
	ii Celi Adeli	oma, Basosquamous Tu	ımor (benign, malign	ant or				
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	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%)		1/50 (2%)		1/50 (2%)	0/50 (0%)	
		1/90 (1%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	3/50 (6%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	6/639 (0.94%)	Mean 0.93%	SD 1%	Total	4/640 (0.62%)	Mean 0.67%	SD 1.78%
∙Skin:								
Basal or Sq. Cell Carcinoma Adenoma, Papilloma, Sq Pa	a, Carcinom pilloma. Ke	a, Basosq. Tumor (M or	B), Basal Cell Adend	oma,				
		1/50 (2%)	1/50 (2%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		9/49 (18%)	4/50 (8%)	6/50 (12%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		4/50 (8%)	()	6/50 (12%)		1/50 (2%)	0/50 (0%)	(,
		8/90 (9%)	5/50 (10%)	1/50 (2%)		0/90 (0%)	3/50 (6%)	0/50 (0%)
		3/50 (6%)	,	( ,		0/50 (0%)	, ,	,
Overall Incidence	Total	52/639 (8.14%)	Mean 8.1%	SD 4.83%	Total	5/640 (0.78%)	Mean 0.83%	SD 1.8%
≄Skin: Fibroma								
		4/50 (8%)	3/50 (6%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/49 (6%)	3/50 (6%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)		1/50 (2%)		0/50 (0%)	0/50 (0%)	
		2/90 (2%)	2/50 (4%)	3/50 (6%)		2/90 (2%)	0/50 (0%)	1/50 (2%)
		4/50 (8%)				1/50 (2%)		
Overall Incidence	Total	33/639 (5.16%)	Mean 5.36%	SD 2.85%	Total	5/640 (0.78%)	Mean 0.69%	SD 1.01%
					•••••			
#Skin: Fibroma, Fibrosarcoma, Sa Hemangiopericytoma	rcoma, Myx	oma, Myxosarcoma, Ma	lignant Fibrous Histi	ocytoma, or				
g.epeey.ea		6/50 (12%)	3/50 (6%)	3/50 (6%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		4/49 (8%)	3/50 (6%)	7/50 (14%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
		1/50 (2%)	3,33 (070)	2/50 (4%)		0/50 (0%)	1/50 (2%)	_, 00 (.,0)
		5/90 (6%)	3/50 (6%)	3/50 (6%)		5/90 (6%)	0/50 (0%)	3/50 (6%)
		4/50 (8%)	3,33 (070)	3,33 (370)		2/50 (4%)	2,00 (0,0)	2,00 (0,0)
	Total	44/639 (6.89%)	Mean 6.98%	SD 3.27%	Total	16/640 (2.5%)	Mean 2.3%	SD 2.17%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

Vehicle: ALL VEHICLES

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

ce for Selected Control Animal Groups

Route: ALL ROUTES

**Page:** 36

Report Date: 12/30/2020

**Strain:** Harlan Sprague-Dawley **Length of Study:** CHRONIC

			Male				Female	
#Skin:								
Fibroma, Fibrosarcoma	a, Sarcoma, My	koma, Myxosarcoma, or l	Malignant Fibrous His	tiocytoma				
		6/50 (12%)	3/50 (6%)	3/50 (6%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		4/49 (8%)	3/50 (6%)	7/50 (14%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
		1/50 (2%)		2/50 (4%)		0/50 (0%)	1/50 (2%)	
		5/90 (6%)	3/50 (6%)	3/50 (6%)		5/90 (6%)	0/50 (0%)	2/50 (4%)
		4/50 (8%)				2/50 (4%)		
overall Incidence	Total	44/639 (6.89%)	Mean 6.98%	SD 3.27%	Total	15/640 (2.34%)	Mean 2.13%	SD 1.92%
Skin:								
Fibrosarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/49 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)		1/50 (2%)		0/50 (0%)	0/50 (0%)	
		1/90 (1%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	6/639 (0.94%)	Mean 0.93%	SD 1%	Total	4/640 (0.62%)	Mean 0.67%	SD 0.98%
:Skin:								
Fibrosarcoma, Sarcom	a, Myxosarcom	a, or Malignant Fibrous I	Histiocytoma					
	-	2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		1/49 (2%)	0/50 (0%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)		1/50 (2%)		0/50 (0%)	1/50 (2%)	
		3/90 (3%)	1/50 (2%)	0/50 (0%)		3/90 (3%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	11/639 (1.72%)	Mean 1.61%	SD 1.6%	Total	10/640 (1.56%)	Mean 1.44%	SD 1.13%
∜Skin: Hemangioma							•••••	
· •		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%)	0/50 (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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	3,22 (3,70)	(-,0)		0/50 (0%)	()	(2.3)
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/640 (0%)	Mean 0%	SD 0%

.....

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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:** 37

					Male						F	emale		
#Skin:		·					<u> </u>		<u> </u>					<u> </u>
Hemangiopericytoma														
		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%)	0/50	(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%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/639 (0%	•	Mean		SD 0%		Total	1/640 (0.	,		0.17%	SD 0	
#Skin:														
Hemangiosarcoma														
5		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%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)		, ,	0/50	(0%)		0/50	(0%)	0/50	(0%)		, ,
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/639 (0%		Mean		SD 0%		Total	1/640 (0.	,		0.17%	SD 0	
#Skin: Keratoacanthoma														
		1/50	(2%)	1/50	(2%)	2/50	(4%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		8/49	(16%)	2/50	(4%)	4/50	(8%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		3/50	(6%)		` ,	5/50	(10%)		0/50	(0%)	0/50	(0%)		,
		5/90	(6%)	2/50	(4%)	1/50	(2%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)		` ,		` ,		0/50	(0%)		. ,		` ,
Overall Incidence	Total	36/639 (5.63	3%)	Mean 5		SD 4.15		Total	0/640 (	,		ın 0%	SD	
#Skin:														
Lipoma														
-		2/50	(4%)	3/50	(6%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	1/50	(2%)
		0/49	(0%)	2/50	(4%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)			0/50	(0%)		0/50	(0%)	0/50	(0%)		, ,
		2/90	(2%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)		, ,				0/50	(0%)				, ,
		10/639 (1.5		Mean 1		SD 2.12		Total	3/640 (0.			0.5%	SD (	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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:** 38 Report Date: 12/30/2020

			Male				Female	
#Skin:								
Liposarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	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%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/640 (0%)	Mean 0%	SD 0%
Skin:						•••••		
Malignant Fibrous Hist	tiocytoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	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%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	2/639 (0.31%)	Mean 0.33%	SD 0.78%	Total	2/640 (0.31%)	Mean 0.26%	SD 0.63%
#Skin:				•••••	•••••	•••••		
Neurofibrosarcoma or	Schwannoma (r	malignant or NOS)						
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	2/639 (0.31%)	Mean 0.33%	SD 1.15%	Total	3/640 (0.47%)	Mean 0.5%	SD 0.9%
#Skin:	aurafibrama ar	Caburannama /banian m	aliament or NOC)					
neurotibrosarcoma, N	euronbroma, or	Schwannoma (benign, m	•	0/50 (40/)		0/50 (00/)	0/50 (00/)	1/FO (20/)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (00/)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		0/50 (0%)				0/50 (0%)		
	Total	2/639 (0.31%)	Mean 0.33%	SD 1.15%	Total	3/640 (0.47%)	Mean 0.5%	SD 0.9%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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:** 39

					Male						F	emale		
#Skin:														
Osteosarcoma														
		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%)	0/50	(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%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/639 (0%	,	Mean		SD 0%		Total	1/640 (0.	,		0.17%	SD 0.	
#Skin:														
Pilomatrixoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	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%)		
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	3/639 (0.47		Mean 0		SD 1.779		Total	0/640 (			n 0%	SD	
#Skin: Sarcoma														
		1/50	(2%)	0/50	(0%)	0/50	(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%)	0/50	(0%)
		0/50	(0%)		` ,	0/50	(0%)		0/50	(0%)	1/50	(2%)		, ,
		2/90	(2%)	0/50	(0%)	0/50	(0%)		2/90	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		, ,		, ,		0/50	(0%)				, ,
Overall Incidence	Total	3/639 (0.47		Mean 0		SD 0.829		Total	4/640 (0.	,		0.52%	SD 0.	
#Skin:														
Schwannoma Malignant														
3		0/50	(0%)	0/50	(0%)	2/50	(4%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)		` '	0/50	(0%)		0/50	(0%)	0/50	(0%)		` '
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		` '		` '		0/50	(0%)		` '		` '
		0/30	(0/0)						0,00	(0,0)				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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: 40

					Male						F	emale		
#Skin:							·							
Squamous Cell Carcino	ma													
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		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%)		
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	2/639 (0.3		Mean 0		SD 0.78		Total	1/640 (0			0.17%	SD 0	
#Skin:														
Squamous Cell Carcino or Carcinoma	ma, Basal Cell (	Carcinoma, Ba	isosquamo	ous Tumor (	malignant	or NOS),								
or our our our		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/49	(0%)	0/50	(0%)	2/50	(4%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		` ,	0/50	(0%)		1/50	(2%)	0/50	(0%)		,
		0/90	(0%)	1/50	(2%)	0/50	(0%)		0/90	(0%)	2/50	(4%)	0/50	(0%)
		0/50	(0%)		` ,		` ,		0/50	(0%)		` ,		, ,
Overall Incidence	Total	4/639 (0.63		Mean 0	.67%	SD 1.3%	6	Total	4/640 (0	.62%)	Mean	0.67%	SD 1	.3%
#Skin: Squamous Cell Papillon														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	2/50	(4%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)			0/50	(0%)		0/50	(0%)	0/50	(0%)		
		2/90	(2%)	2/50	(4%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)						0/50	(0%)				
Overall Incidence	Total	9/639 (1.4	,	Mean 1		SD 1.57		Total	0/640 (	•		n 0%	SD	
#Skin:														
Squamous Cell Papillon	na or Papilloma													
•	-	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	2/50	(4%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)			0/50	(0%)		0/50	(0%)	0/50	(0%)		
		2/90	(2%)	2/50	(4%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)						0/50	(0%)				
	Total	9/639 (1.41		Mean 1		SD 1.57		Total	0/640 (			ın 0%	SD	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

**Strain:** Harlan Sprague-Dawley **Length of Study:** CHRONIC

			Male				Female	
#Skin:		,						
Squamous Cell Papillon	na, Papilloma, S	Squamous Cell Carcinom	na or Keratoacanthom	a				
		1/50 (2%)	1/50 (2%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		8/49 (16%)	4/50 (8%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		4/50 (8%)		5/50 (10%)		0/50 (0%)	0/50 (0%)	
		7/90 (8%)	4/50 (8%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)				0/50 (0%)		
Overall Incidence	Total	46/639 (7.2%)	Mean 7.18%	SD 4.1%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%
#Skin:								
Squamous Cell Papillon	na, Papilloma, d	or Keratoacanthoma						
		1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		8/49 (16%)	4/50 (8%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		4/50 (8%)		5/50 (10%)		0/50 (0%)	0/50 (0%)	
		7/90 (8%)	4/50 (8%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)				0/50 (0%)		
Overall Incidence	Total	45/639 (7.04%)	Mean 7.01%	SD 4.2%	Total	0/640 (0%)	Mean 0%	SD 0%
#Skin: Trichoepithelioma								
•		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	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%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/640 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
		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%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/90 (1%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	. ,	. ,		0/50 (0%)		
Overall Incidence	Total	2/639 (0.31%)	Mean 0.26%	SD 0.63%	Total	0/640 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

**Strain:** Harlan Sprague-Dawley **Length of Study:** CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		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%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/90 (1%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	2/639 (0.31%)	Mean 0.26%	SD 0.63%	Total	0/640 (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%)
		0/49 (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%)	,
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	, ,	, ,		0/50 (0%)	, ,	, ,
Overall Incidence	Total	0/639 (0%)	Mean 0%	SD 0%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%
Spleen: Hemangiosarcoma						•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/49 (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%)	
		3/90 (3%)	0/50 (0%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	3/639 (0.47%)	Mean 0.28%	SD 0.96%	Total	2/638 (0.31%)	Mean 0.26%	SD 0.64%
Stomach, Forestomach:								
		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%)	0/50 (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%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
		` '	` '	` '		` '	` '	` '
		0/50 (0%)				0/50 (0%)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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						F	emale		
#Stomach, Forestomach:														
Squamous Cell Carcinoma	a													
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	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	(00()	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(00()
		0/90 0/50	(0%)	0/50	(0%)	0/50	(0%)		0/90 0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/639 (0.16	(0%)	Mean 0	170/	SD 0.589	0/	Total	1/640 (0.	(0%)	Moon	0.17%	SD 0	E00/
		`	,					Total	,	,		0.17%	o	
#Stomach, Forestomach:														
Squamous Cell Carcinoma	a or Papillom	a Squamous												
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	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%)		0/50	(0%)	0/50	(0%)		
		1/90	(1%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	2/639 (0.31		Mean 0		SD 0.63		Total	1/640 (0.	,		0.17%	SD 0	.58%
#Stomach, Forestomach: Squamous Cell Papilloma														
		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%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		,	0/50	(0%)		0/50	(0%)	0/50	(0%)		,
		1/90	(1%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		, ,				0/50	(0%)				
Overall Incidence	Total	1/639 (0.16	,	Mean 0		SD 0.329		Total	0/640 (	,		ın 0%	SD	
*Testis:														
Adenoma														
		1/50	(2%)	7/50	(14%)	3/49	(6%)							
		2/49	(4%)	1/50	(2%)	3/49	(6%)							
		0/50	(0%)		\ /	0/50	(0%)							
		2/90	(2%)	0/50	(0%)	1/50	(2%)							
		0/50	(0%)	-: -: <del>-</del>	(/		( /							
			4%)		3.21%	SD 4.059								

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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: 12/30/2020

			Male				Female	
*Thymus: Thymoma Benign								
		0/46 (0%)	0/48 (0%)	0/47 (0%)		0/49 (0%)	0/49 (0%)	0/46 (0%)
		0/48 (0%)	0/46 (0%)	1/46 (2%)		0/49 (0%)	0/49 (0%)	0/47 (0%)
		0/48 (0%)		0/48 (0%)		0/50 (0%)	0/49 (0%)	
		0/88 (0%) 0/49 (0%)	0/48 (0%)	0/48 (0%)		1/87 (1%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	1/610 (0.16%)	Mean 0.18%	SD 0.63%	Total	1/622 (0.16%)	Mean 0.1%	SD 0.33%
Thymus:								
Thymoma Malignant								
		0/46 (0%)	0/48 (0%)	0/47 (0%)		0/49 (0%)	0/49 (0%)	0/46 (0%)
		0/48 (0%)	0/46 (0%)	0/46 (0%)		0/49 (0%)	0/49 (0%)	0/47 (0%)
		0/48 (0%)		0/48 (0%)		0/50 (0%)	0/49 (0%)	
		0/88 (0%)	0/48 (0%)	0/48 (0%)		1/87 (1%)	0/50 (0%)	0/47 (0%)
		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/610 (0%)	Mean 0%	SD 0%	Total	1/622 (0.16%)	Mean 0.1%	SD 0.33%
*Thymus: Thymoma: Benign, Malig	nant. NOS							
<b>,</b>	,	0/46 (0%)	0/48 (0%)	0/47 (0%)		0/49 (0%)	0/49 (0%)	0/46 (0%)
		0/48 (0%)	0/46 (0%)	1/46 (2%)		0/49 (0%)	0/49 (0%)	0/47 (0%)
		0/48 (0%)	0, 10 (0,0)	0/48 (0%)		0/50 (0%)	0/49 (0%)	o, (o,o)
		0/88 (0%)	0/48 (0%)	0/48 (0%)		2/87 (2%)	0/50 (0%)	0/47 (0%)
		0/49 (0%)	(***)	()		0/50 (0%)	(***)	(2.2.7)
Overall Incidence	Total	1/610 (0.16%)	Mean 0.18%	SD 0.63%	Total	2/622 (0.32%)	Mean 0.19%	SD 0.66%
Thyroid Gland: C-Cell:								
Adenoma								
		11/50 (22%)	13/50 (26%)	10/50 (20%)		9/50 (18%)	12/50 (24%)	8/49 (16%)
		8/49 (16%)	7/50 (14%)	13/50 (26%)		12/50 (24%)	5/50 (10%)	11/49 (22%)
		2/50 (4%)		11/49 (22%)		2/50 (4%)	9/50 (18%)	
						0/00 (70/)	40/50 (000/)	E/EO /400/\
		8/89 (9%)	8/50 (16%)	4/50 (8%)		6/90 (7%)	16/50 (32%)	5/50 (10%)
		8/89 (9%) 9/50 (18%)	8/50 (16%)	4/50 (8%)		6/90 (7%) 10/50 (20%)	16/50 (32%)	5/50 (10%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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

Vehicle: ALL VEHICLES

**Page:** 45 Report Date: 12/30/2020 Route: ALL ROUTES

			Male		Female
*Thyroid Gland: C-Cell: Carcinoma					
		1/50 (2%)	2/50 (4%)	1/50 (2%)	0/50 (0%) 2/50 (4%) 0/49 (0%)
		1/49 (2%)	1/50 (2%)	0/50 (0%)	1/50 (2%) 1/50 (2%) 0/49 (0%)
		1/50 (2%)		0/49 (0%)	0/50 (0%) 1/50 (2%)
		2/89 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%) 0/50 (0%) 2/50 (4%) 2/50 (4%)
Overall Incidence	Total	9/637 (1.41%)	Mean 1.36%	SD 1.32%	Total 9/638 (1.41%) Mean 1.5% SD 1.73%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma					
		11/50 (22%)	14/50 (28%)	10/50 (20%)	9/50 (18%) 14/50 (28%) 8/49 (16%)
		8/49 (16%)	8/50 (16%)	13/50 (26%)	13/50 (26%) 6/50 (12%) 11/49 (22%)
		3/50 (6%)		11/49 (22%)	2/50 (4%) 9/50 (18%)
		10/89 (11%)	8/50 (16%)	4/50 (8%)	6/90 (7%) 16/50 (32%) 7/50 (14%)
		9/50 (18%)			12/50 (24%)
Overall Incidence	Total	109/637 (17.11%)	Mean 17.5%	SD 6.75%	Total 113/638 (17.71%) Mean 18.45% SD 8.49%
*Thyroid Gland: Follicular C Adenoma	Cell:				
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)
		0/50 (0%)		0/49 (0%)	0/50 (0%) 0/50 (0%)
		0/89 (0%)	2/50 (4%)	0/50 (0%)	0/90 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)			1/50 (2%)
Overall Incidence	Total	3/637 (0.47%)	Mean 0.5%	SD 1.25%	Total 1/638 (0.16%) Mean 0.17% SD 0.58%
*Thyroid Gland: Follicular C Carcinoma	Cell:				
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)
		0/50 (0%)		0/49 (0%)	0/50 (0%) 0/50 (0%)
		0/89 (0%)	0/50 (0%)	0/50 (0%)	1/90 (1%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)			0/50 (0%)
Overall Incidence	Total	0/637 (0%)	Mean 0%	SD 0%	Total 1/638 (0.16%) Mean 0.09% SD 0.32%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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						F	emale		
*Thyroid Gland: Follicular Co Carcinoma or Adenoma	ell:						,		,					
			(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/49	(0%)
			(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/49	(0%)
			(0%)			0/49	(0%)		0/50	(0%)	0/50	(0%)		
			(0%) (0%)	2/50	(4%)	0/50	(0%)		1/90 1/50	(1%) (2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	3/637 (0.47%	,	Mean (		SD 1.259		Total	2/638 (0	,		0.26%	SD 0.	
#Tissue NOS: Schwannoma Malignant														
•		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%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		0/50	(0%)	0/50	(0%)		
		1/90	(1%)	0/50	(0%)	0/50	(0%)		1/90	(1%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/639 (0.16%		Mean 0	.09%	SD 0.329	%	Total	1/640 (0	.16%)	Mean	0.09%	SD 0.	32%
#Tongue: Squamous Cell Carcinoma														
•		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%)	0/50	(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%)		1/90	(1%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/639 (0%)		Mean		SD 0%		Total	1/640 (0	,		0.09%	SD 0.	32%
#Tongue: Squamous Cell Carcinoma														
24	upo	•	(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%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	5,50	(0,0)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0,00	(3,0)
		0/90	(0%)	0/50	(0%)	0/50	(0%)		1/90	(1%)	0/50	(0%)	0/50	(0%)
			(0%)	0,00	(070)	0,00	(0 /0)		0/50	(0%)	0,00	(0 /0)	0,00	(370)
Overall Incidence	Total		` '	Mean	O°/-	SD 0%		Total	1/640 (0	, ,	Mean	0.09%	SD 0.	32%
veran incluence	i Olai	0/639 (0%)		iviean	U /0	3D 0%		TUlai	1/040 (0	. 1070)	iviean	0.0970	3D 0.	JZ 70

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

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Report Date: 12/30/2020

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

**Strain:** Harlan Sprague-Dawley **Length of Study:** CHRONIC

			Male				Female	
fTooth: Odontoma								
		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%)	0/50 (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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/640 (0%)	Mean 0%	SD 0%
Urinary Bladder: Leiomyosarcoma								
		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%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)		0/49 (0%)		0/50 (0%)	0/50 (0%)	
		0/89 (0%)	0/50 (0%)	0/50 (0%)		1/88 (1%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	0/637 (0%)	Mean 0%	SD 0%	Total	1/635 (0.16%)	Mean 0.09%	SD 0.33%
Uterus: Adenocarcinoma								
						2/50 (4%)	2/50 (4%) 5/50 (10%)	3/50 (6%) 5/50 (10%)
						1/50 (2%)	1/50 (2%)	( ,
						,	2/50 (4%)	3/50 (6%)
						3/50 (6%)	` '	, ,
verall Incidence					Total	27/500 (5.4%)	Mean 5.4%	SD 2.84%
Uterus: Adenocarcinoma or Ade	enoma							
						2/50 (4%)	2/50 (4%) 5/50 (10%)	3/50 (6%) 5/50 (10%)
						1/50 (2%)	2/50 (4%)	0/50 (00:)
						0.50	4/50 (8%)	3/50 (6%)
						3/50 (6%)		
Overall Incidence					Total	30/500 (6%)	Mean 6%	SD 2.67%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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: 48

Male			Female	
#Uterus:				
Adenoma				
		0/50 (0%	6) 0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/50 (0%)
		0/50 (0%	5) 1/50 (2%)	
			2/50 (4%)	0/50 (0%)
		0/50 (0%	b)	
Overall Incidence	Total	3/500 (0.6%)	Mean 0.6%	SD 1.35%
#Uterus:				
Adenoma, Adenocarcinoma, Sq Cell Carcinoma, or Sq Cell Papilloma				
		4/50 (8%	2/50 (4%)	3/50 (6%)
			5/50 (10%)	5/50 (10%)
		2/50 (4%	5) 2/50 (4%)	
			4/50 (8%)	5/50 (10%)
		3/50 (6%	b)	
Overall Incidence	Total	35/500 (7%)	Mean 7%	SD 2.54%
#Uterus:				
Deciduoma Benign				
		0/50 (0%	6) 0/50 (0%)	1/50 (2%)
			0/50 (0%)	0/50 (0%)
		0/50 (0%	6) 0/50 (0%)	
			0/50 (0%)	0/50 (0%)
		0/50 (0%	b)	
Overall Incidence	Total	1/500 (0.2%)	Mean 0.2%	SD 0.63%
#Uterus:				
Granular Cell Tumor Benign				
		0/50 (0%	6) 0/50 (0%)	1/50 (2%)
		•	0/50 (0%)	0/50 (0%)
		0/50 (0%	6) 0/50 (0%)	. ,
		•	0/50 (0%)	0/50 (0%)
				. ,
		0/50 (0%	o)	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Report Date: 12/30/2020

**Strain:** Harlan Sprague-Dawley **Length of Study:** CHRONIC

Route: ALL ROUTES
Vehicle: ALL VEHICLES

	Male		Female	
#Uterus:				
Hemangioma				
		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%)		
verall Incidence	Total	( /	Mean 0.2%	SD 0.63%
Uterus:				
Papilloma				
		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%)		
overall Incidence	Total	` ,	Mean 0.2%	SD 0.63%
Uterus:		•••••		
Polyp Stromal				
••		9/50 (18%)	5/50 (10%)	8/50 (16%)
			8/50 (16%)	10/50 (20%)
		7/50 (14%)	16/50 (32%)	
			2/50 (4%)	5/50 (10%)
		5/50 (10%)		
verall Incidence	Total	` '	Mean 15%	SD 7.62%
Uterus:				•••••
Sarcoma				
our oomu		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/00 (0/6)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	3,00 (0,70)
		0/00 (0/6)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/30 (0/0)	0/00 (0/0)
verall Incidence	Total	, ,	Mean 0.2%	SD 0.63%
verall incluence	rotal	1/500 (0.2%)	iviean 0.2%	SD 0.03%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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				
		0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	2/50 (4%)
		0/50 (0%)	1/50 (2%)	
			0/50 (0%)	1/50 (2%)
		0/50 (0%)		
Overall Incidence	Total 4	/500 (0.8%)	Mean 0.8%	SD 1.4%
#Uterus:				
Sarcoma Stromal or Polyp Stromal				
		9/50 (18%)	5/50 (10%)	8/50 (16%)
		(1270)	8/50 (16%)	12/50 (24%)
		7/50 (14%)	16/50 (32%)	(= 170)
		(* 1,75)	2/50 (4%)	6/50 (12%)
		5/50 (10%)	_, _, ( , , , ,	(1=70)
Overall Incidence	Total 78	/500 (15.6%)	Mean 15.6%	SD 7.88%
#! Name = .				
#Uterus: Schwannoma Malignant				
Sommaniona manghant		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/00 (0/0)	0/50 (0%)	0/50 (0%)
			0/00 (0/0)	
		0/50 (0%)	0/50 (0%)	(2.2.7)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	
		, ,	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total 1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		, ,	` '	
		0/50 (0%)	0/50 (0%)	0/50 (0%)
#Uterus:		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) Mean 0.2%	0/50 (0%) SD 0.63%
#Uterus:		0/50 (0%) /500 (0.2%)	0/50 (0%)  Mean 0.2%  0/50 (0%)	0/50 (0%) SD 0.63%  0/50 (0%)
#Uterus:		0/50 (0%) /500 (0.2%) 2/50 (4%)	0/50 (0%)  Mean 0.2%  0/50 (0%)  0/50 (0%)  0/50 (0%)	0/50 (0%) SD 0.63%
#Uterus:		0/50 (0%) /500 (0.2%) 2/50 (4%)	0/50 (0%)  Mean 0.2%  0/50 (0%)  0/50 (0%)  0/50 (0%)  0/50 (0%)	0/50 (0%) SD 0.63%  0/50 (0%) 0/50 (0%)
#Uterus:		0/50 (0%) /500 (0.2%) 2/50 (4%)	0/50 (0%)  Mean 0.2%  0/50 (0%)  0/50 (0%)  0/50 (0%)	0/50 (0%) SD 0.63%  0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

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Report Date: 12/30/2020

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: ALL ROUTES
Vehicle: ALL VEHICLES

**Strain:** Harlan Sprague-Dawley **Length of Study:** CHRONIC

Male		Female					
#Uterus: Squamous Cell Carcinoma							,
		1/50 (	(2%)	0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)
		1/50 (	(2%)	0/50	(0%)		, ,
		0/50 (	(0%)	0/50	(0%)	2/50	(4%)
Overall Incidence	Total	4/500 (0.8%	%)	Mear	0.8%	SD 1	
#Vagina: Granular Cell Tumor Benign							
orandial deli rumoi benign		0/50 (	(0%)	0/50	(0%)	0/50	(0%)
			(0%)	0/50	(0%)	0/50	(0%)
			(2%)	0/50	(0%)		
		,	(0%)	0/50	(0%)	0/50	(0%)
• " "	<del>-</del>		(0%)		0.470/	00.0	500/
Overall Incidence	Total	1/640 (0.169			0.17%	SD 0.	
#Vagina: Polyp							
		0/50 (	(0%)	0/50	(0%)	0/50	(0%)
			(0%)	0/50	(0%)	1/50	(2%)
		,	(0%)	0/50	(0%)		
		,	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/50 ( 2/640 (0.319	(0%) %)	Mean	0.33%	SD 0.	78%
#Vagina: Sarcoma							
		,	(0%)	0/50	(0%)	0/50	(0%)
		,	(0%)	0/50	(0%)	0/50	(0%)
		,	(0%)	0/50	(0%)	0.475	(00)
			(0%) (2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/640 (0.169	%)	Mean	0.17%	SD 0.	58%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

**Page:** 52

Report Date: 12/30/2020

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: ALL ROUTES
Vehicle: ALL VEHICLES

**Strain:** Harlan Sprague-Dawley **Length of Study:** CHRONIC

			Male			Female		
#Vagina: Schwannoma Malignant								
						0/50 (0%)	0/50 (0%)	1/50 (2%)
						0/50 (0%)	0/50 (0%)	1/50 (2%)
						1/50 (2%)	0/50 (0%)	
						1/90 (1%)	1/50 (2%)	0/50 (0%)
						0/50 (0%)		
verall Incidence					Total	5/640 (0.78%)	Mean 0.76%	SD 0.97%
Zymbal's Gland: Adenoma								
		1/50 (2%)	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%)	0/50 (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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	,	,		0/50 (0%)	` ,	,
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/640 (0%)	Mean 0%	SD 0%
Zymbal's Gland: Carcinoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	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%)	
		0/90 (0%)	1/50 (2%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	6/639 (0.94%)	Mean 1%	SD 1.05%	Total	0/640 (0%)	Mean 0%	SD 0%
Zymbal's Gland: Carcinoma or Adenoma								
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	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%)	` '
		0/90 (0%)	1/50 (2%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)	(/	(/
						0/30 (0/0)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied