

# NTP Historical Controls Report

By Route and Vehicle

Harlan Sprague-Dawley RATS

November 2019

# REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

This report is broken up into sections based on the route and vehicle used to deliver the chemical. The Table of Contents on Page 3 shows the different Route/Vehicle combinations. To see the data from all routes and vehicles combined into one set, you must run the "All Routes" report.

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

Male
M1
M2
M3
M4
M5
Female
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.

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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: GAVAGE Vehicle: CORN OIL Page: 4

Report Date: 02/17/2020

# **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	052000603	03/14/07	727	50(3)	20(644)	584.8	Indole-3-carbinol
					Female		
Battelle Columbus Laboratory	052000603	03/15/07	729	50(5)	21(637)	353.0	Indole-3-carbinol

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: GAVAGE Vehicle: CORN OIL **Page**: 5

			Male				Female	
#All Organs: Benign Tumors								
		27/50 (54%)				40/50 (80%)		
Overall Incidence	Total	27/50 (54%)	Mean 54%	SD 0%	Total	40/50 (80%)	Mean 80%	SD 0%
#All Organs: Malignant Tumors								
		12/50 (24%)				19/50 (38%)		
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	19/50 (38%)	Mean 38%	SD 0%
#All Organs: Malignant and Benign Tu	umors	33/50 (66%)				46/50 (92%)		
Overall Incidence	Total	33/50 (66%)	Mean 66%	SD 0%	Total	46/50 (92%)	Mean 92%	SD 0%
		, ,						
#All Organs: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
_		1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#All Organs: Hemangiosarcoma or He	emangioma							
		1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	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: GAVAGE Vehicle: CORN OIL Page: 6

			Male				Female	
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#All Organs: Leukemia: Granulocytic								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic, M Overall Incidence	onocytic, Mo	nonuclear, or Undifference 0/50 (0%) 0/50 (0%)	ntiated  Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Malignant Lymphoma: Hist Overall Incidence		0/50 (0%) 0/50 (0%)			Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		0/30 (0/0)			1 Otal			30 0%
#All Organs: Malignant Schwannoma								
		2/50 (4%)				2/50 (4%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#All Organs: Mesothelioma: Benign, Mal	ignant, NOS	4/50 (631)				0/50 (00/)	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Overell Insidence	Tatal	1/50 (2%)	Maan 20/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (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: GAVAGE Vehicle: CORN OIL Page: 7

				Male				Female	
#All Organs: Mesothelioma: Malignant									
			(2%)		25.22		0/50 (0%)		25
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma		- 1							
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
·····							0,00 (0,70)		
#All Organs: Osteosarcoma or Osteoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Carcinoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Ganglioneuroma		0/50	(09/)				0/50 (09/)		
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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: GAVAGE Vehicle: CORN OIL Page: 8

			Male				Female	
Adrenal Medulla: Pheochromocytoma Be	nign							
	_	5/50 (10%)				0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Co								
•	•	1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Ma	llignant	2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma: Be						0/50 (0%)		
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteo	oma	0/50 (09/)				0/50 (0%)		
Overall Incidence	Total	` '	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 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

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 9

	Male	Female
*Brain: Glioma Malignant		
Overall Incidence		
*Brain: Granular Cell Tumor Benign		
Overall Incidence		
*Brain: Granular Cell Tumor Malignant		
Overall Incidence		
*Brain: Meningioma Benign		
Overall Incidence		
*Brain: Meningioma Malignant		
Overall Incidence		
*Brain: Meningioma: Benign, Malignant, NOS		
Overall Incidence		

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: GAVAGE Vehicle: CORN OIL **Page:** 10

			Male				Female	
*Brain: Oligodendroglioma, Glioma,	, or Astrocy	toma						
Overall Incidence								
*Brain: Schwannoma Malignant								
Overall Incidence								
*Clitoral/Preputial Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma	• • • • • • • • • • • • • • • • • • • •							
	Total	0/50 (0%)	Maan 00/	SD 00/	Total	0/50 (0%)	Maan 00/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: GAVAGE Vehicle: CORN OIL Page: 11

			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Epididymis: Sarcoma								
		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
#Eye: Leiomyoma								
	<b>T</b>	0/50 (0%)		<b>OD</b> 00/	<b>T</b>	0/50 (0%)		00.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant								
		1/50 (2%)		05.00/		0/50 (0%)		25. 22/
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Granular Cell Tumor Benigi								
_		0/50 (0%)	)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Leiomyoma	ım:							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: GAVAGE Vehicle: CORN OIL **Page:** 12

0/50 (0%) 0/50 (0%)  0/50 (0%)  0/50 (0%)  0/50 (0%)  0/50 (0%)	Mean 0%  Mean 0%  Mean 0%	SD 0% SD 0% SD 0%	Total Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0% Mean 0%	SD 0% SD 0%
0/50 (0%)  0/50 (0%)  0/50 (0%)  0/50 (0%)  0/50 (0%)	Mean 0%	SD 0%		0/50 (0%) 0/50 (0%) 0/50 (0%)		
0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		0/50 (0%) 0/50 (0%)		
0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%		Total	0/50 (0%)	Mean 0%	SD 0%
0/50 (0%) 0/50 (0%) 0/50 (0%)			Total	0/50 (0%)	Mean 0%	SD 0%
0/50 (0%) 0/50 (0%)			Total		Mean 0%	SD 0%
0/50 (0%)	Mean 0%	SD 09/		0/50 (0%)		
0/50 (0%)	Mean 0%	SD 00/		0/50 (0%)		
` '	Mean 0%			2/=2 /22/)		05.00/
		טע עפ	Total	0/50 (0%)	Mean 0%	SD 0%
0/50 (0%)				0/50 (0%)		
0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
0/50 (0%)				0/50 (0%)		
0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
0/50 /40/)				0/50 (00/)		
2/50 (4%)		CD 00/	Total	, ,	Maan 00/	SD 0%
	0/50 (0%) 2/50 (4%)	0/50 (0%) Mean 0% 2/50 (4%)	0/50 (0%) Mean 0% SD 0% 2/50 (4%)	0/50 (0%) Mean 0% SD 0% Total	0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 2/50 (4%) 0/50 (0%)	0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 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: GAVAGE Vehicle: CORN OIL Page: 13

				Male				Female	
*Islets, Pancreatic: Carcinoma									
		0/50 (	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma									
		2/50 (	(4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Pelvis and Transitio Papilloma	nal Epitheliu		(004)				0(50 (00))		
			(0%)	••	05.00/		0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma									
		1/50 (	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma									
		0/50 (	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma									
			(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (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: GAVAGE Vehicle: CORN OIL Page: 14

			Male				Female	
*Kidney: Renal Tubule: Lipoma		0/50 (0%)				0/50 /00/		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Oncocytoma Benign	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Polyp Adenomatous		, ,				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lacrimal Gland: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: GAVAGE Vehicle: CORN OIL **Page:** 15 Report Date: 02/17/2020

			Male			Female			
*Liver: Cholangiocarcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Liver: Cholangioma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hemangioma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Adenoma		1/50 (2%)				2/50 (4%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Liver: Hepatocellular Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Carcinoma o		stoma							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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: GAVAGE Vehicle: CORN OIL **Page:** 16

				Male			Female				
*Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma  1/50 (2%) 2/50 (4%)											
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	ean 2%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%		
	10tai	, ,				10lai	2/50 (4%)	IVIEAII 470	3D 0%		
*Liver: Hepatocellular Carcino	ma, Hepatocellul	ar Adenoma, or	Hepatoblastom	ıa							
·	•	1/50	(2%)				2/50 (4%)				
Overall Incidence	Total	1/50 (2%)	M	ean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
*Lung: Alveolar/Bronchiolar A	denoma	0/49	(0%)				1/50 (2%)				
Overall Incidence	Total	0/49 (0%)	M	ean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Lung: Alveolar/Bronchiolar C	arcinoma	0/49	(0%)				0/50 (0%)				
Overall Incidence	Total	0/49 (0%)	M	ean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Lung: Alveolar/Bronchiolar C	arcinoma or Alve	olar/Bronchiola					1/50 (2%)				
Overall Incidence	Total	0/49 (0%)	` '	ean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Lung: Sarcoma		0/40	(00()				4/50 (20/)				
Overall Incidence	Total	0/49 0/49 (0%)	(0%)	ean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	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: GAVAGE Vehicle: CORN OIL Page: 17

				Male			Female			
*Lung: Squamous Cell Carcinoma										
Overall Incidence	Total	0/49 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Hemangiosarcoma										
Overall Incidence	Total	1/50 ( 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Adenolipoma		0/50 (	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(076)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Adenoma			(0%)				3/50 (6%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
#Mammary Gland: Carcinoma										
Overall Incidence	Total	0/50 ( 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	
#Mammary Gland: Carcinoma or Adenoma		0/50	(0%)				6/50 (12%)			
Overall Incidence	Total	0/50 (0%)	(U /U)	Mean 0%	SD 0%	Total	6/50 (12%)	Mean 12%	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: GAVAGE Vehicle: CORN OIL **Page:** 18

				Male				Female				
#Mammary Gland: Fibroadenoma												
Overall Incidence	Total	1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	29/50 (58%) 29/50 (58%)	Mean 58%	SD 0%			
#Mammary Gland: Fibroma, Fibroadenom												
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	30/50 (60%) 30/50 (60%)	Mean 60%	SD 0%			
#Mammary Gland: Fibroma, Fibroadenom	a, Carcinoma, or		(2%)				32/50 (64%)					
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	32/50 (64%)	Mean 64%	SD 0%			
#Mammary Gland: Myoepithelioma Overall Incidence	Total		(0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
*Nose: Carcinoma												
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%			
#Oral Cavity (Oral Mucos Squamous Cell Carcino		nx, Tooth, Ging	iva):				0/50 (00/)					
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			

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

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

**Toxicology Data Management System** 

**Page:** 19

Report Date: 02/17/2020

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male			Female				
#Oral Cavity (Oral Mucos Squamous Cell Carcin		/nx, Tooth, Gingiva): Equamous, or Papilloma 1/50 (2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Oral Mucosa: Squamous Cell Carcin						0/50 (0%)				
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Cystadenoma						0/50 (00/)				
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Granulosa Cell Tumor	Benign					0/50 (09/)				
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Granulosa Cell Tumor	Malignant	•••••		•••••						
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Granulosa Cell Tumor:	: Benign, Maligna	nt, NOS				0/50 (00/)				
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

<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: GAVAGE Vehicle: CORN OIL Page: 20

	Male		Female				
*Ovary: Granulosa-Theca Tumor Benign							
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
*Ovary: Granulosa-Theca Tumor Malignant							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Luteoma							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Schwannoma Malignant							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Sertoli Cell Tumor Benign		•••••	•••••	•••••			
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Thecoma Benign							
Overall Incidence		Total	0/50 (0%) 0/50 (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: GAVAGE Vehicle: CORN OIL **Page:** 21

			Male			Female			
*Ovary: Tubulostromal Carcinoma									
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Pancreas: Adenoma		•••••							
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Carcinoma or Adenoma		5/50 (10%)							
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Parathyroid Gland: Adenoma									
Overall Incidence	Total	0/43 (0%) 0/43 (0%)	Mean 0%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%	
#Peripheral Nerve: Paraganglioma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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: GAVAGE Vehicle: CORN OIL Page: 22

			Male				Female	
#Peripheral Nerve: Schwannoma Malignan	ıt							
_		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign,	Malignant, NOS							
•		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Adenoma								
		5/50 (10%)				18/50 (36%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	18/50 (36%)	Mean 36%	SD 0%
*Pituitary Gland: Pars Dis Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis		fied Site:						•••••
		5/50 (10%)				18/50 (36%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	18/50 (36%)	Mean 36%	SD 0%
*Pituitary Gland: Pars Into Adenoma	ermedia:							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: GAVAGE Vehicle: CORN OIL **Page:** 23

				Male				Female			
*Pituitary Gland: Pars Interr Carcinoma or Adenoma	media:										
		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Pituitary Gland: Pars Nervo Schwannoma Malignant											
		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Prostate: Adenoma		0/50	(0%)								
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%						
*Prostate: Carcinoma or Adenoma		0/50	(0%)								
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%						
*Salivary Glands: Schwannoma Malignant											
		1/50	(2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Seminal Vesicle: Hemangiosarcoma											
Overall Incidence	Total	0/50 0/50 (0%)	(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: GAVAGE Vehicle: CORN OIL Page: 24 Report Date: 02/17/2020

			Male				Female			
#Skeletal Muscle: Hemangioma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skeletal Muscle: Liposarcoma						0.750				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Skeletal Muscle: Sarcoma	•••••	0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Skin: Basal Cell Adenoma	•••••	0/50 (00/)				0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Skin: Basal Cell Adenoma or I		Tumor Benign								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Skin: Basal Cell Adenoma, Ba						0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: GAVAGE Vehicle: CORN OIL Page: 25

			Male				Female	
#Skin: Basal Cell Carcinoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma o	or Basosquamou		los)					
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		ma, Basosquamous Tu	mor (benign, maligna	nt or		0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal or Sq. Cell Carcii Adenoma, Papilloma, S	noma, Carcinoma oq Papilloma, Ker Total	a, Basosq. Tumor (M or latoacanthoma, Trichoel 6/50 (12%) 6/50 (12%)	B), Basal Cell Adenoi oithelioma Mean 12%	ma, SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibroma								GD 0%
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Fibroma, Fibrosarcoma Hemangiopericytoma	a, Sarcoma, Myxc	, •	ignant Fibrous Histio	cytoma, or				
Overall Incidence	Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	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: GAVAGE Vehicle: CORN OIL **Page:** 26

			Male				Female				
#Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma  7/50 (14%)  Overall Incidence  Total  7/50 (14%)  Mean 14%  SD 0%  Total  7/50 (4%)  Mean 4%  SD 0%											
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%			
#Skin: Fibrosarcoma											
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
#Skin: Fibrosarcoma, Sarcoma	, Myxosarcoma	, or Malignant Fibrous Hi	istiocytoma			1/50 (2%)					
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
#Skin: Hemangioma		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Hemangiopericytoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Skin: Hemangiosarcoma		0/50 (0%)				1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	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: GAVAGE Vehicle: CORN OIL Page: 27

				Male				Female	
#Skin: Keratoacanthoma									
		4/50	(8%)				0/50 (0%)		
Overall Incidence	Total	4/50 (8%)		Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma		0/50	(00()				0/50 (00/)		
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		` '				TOTAL			
#Skin: Malignant Fibrous Histi	ocytoma								
Overall Incidence	Total	1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin:									
Neurofibrosarcoma or	Schwannoma (ma	alignant or NOS	)						
		0/50	(0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Neurofibrosarcoma, Ne	urofibroma, or S		nign, ma	lignant or NOS)			1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	/	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	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: GAVAGE Vehicle: CORN OIL Page: 28

				Male				Female	
#Skin: Osteosarcoma									
Overall Incidence	Total	0/50 ( 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Pilomatrixoma									
Overall Incidence	Total	0/50 ( 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin:									
Sarcoma Overall Incidence	Total	0/50 ( 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin:									
Schwannoma Malignant		0/50	(0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	, ,	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Squamous Cell Carcinom	a								
Overall Incidence	Total	1/50 ( 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinom: or Carcinoma									
			(4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	0/50 (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: GAVAGE Vehicle: CORN OIL Page: 29

			Male				Female	
#Skin: Squamous Cell Papillom	a							
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillom	a or Panilloma							
oquamous con r apmom	a or r apmoma	1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Squamous Cell Papillom  Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall Incidence #Skin:	Total	` '	Mean 10%	SD 0%	Total	` ,	Mean 0%	SD 0%
Squamous Cell Papillom	a, Papilloma, o					2/22 (22/)		
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Trichoepithelioma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland:								
Adenoma								
Adenoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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: GAVAGE Vehicle: CORN OIL **Page:** 30

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Malignant								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma		0/50 /00/)				0/50 (00)		
Occupati la si dan sa	T-1-1	0/50 (0%)	Maran 00/	OD 00/	T-1-1	0/50 (0%)	M 00/	00.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma o		ı Squamous						
	-	1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	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: GAVAGE Vehicle: CORN OIL **Page:** 31

			Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Testis: Adenoma		3/49 (6%)						
Overall Incidence	Total	3/49 (6%) 3/49 (6.12%)	Mean 6.12%	SD 0%				
*Thymus: Thymoma Benign		4/40 (00)				0/47 (00/)		
Overall Incidence	Total	1/46 (2%) 1/46 (2.17%)	Mean 2.17%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/46 (0%)				0/47 (0%)		
Overall Incidence	Total	0/46 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligna								
Overall Incidence	Total	1/46 (2%) 1/46 (2.17%)	Mean 2.17%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma	••••••					44/40 (0000)		
Overall Incidence	Total	13/50 (26%) 13/50 (26%)	Mean 26%	SD 0%	Total	11/49 (22%) 11/49 (22.45%)	Mean 22.45%	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: GAVAGE Vehicle: CORN OIL **Page:** 32

			Male				Female	
*Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		13/50 (26%)				11/49 (22%)		
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	11/49 (22.45%)	Mean 22.45%	SD 0%
*Thyroid Gland: Follicular Cel Adenoma	l:							
		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cel Carcinoma								
		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cel Carcinoma or Adenoma								
		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: GAVAGE Vehicle: CORN OIL **Page:** 33

				Male				Female		
#Tongue: Squamous Cell Carcinoma  0/50 (0%)  0/50 (0%)										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Tongue:	or Donilloma	Samana								
Squamous Cell Carcinoma	or Papilloma		(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(0,0)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tooth: Odontoma		0/50	(00()				0/50 (0%)			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Leiomyosarcoma										
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	
#Uterus: Adenocarcinoma										
Overall Incidence						Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	
#Uterus: Adenocarcinoma or Adeno	oma									
Overall Incidence						Total	5/50 (10%) 5/50 (10%)	Mean 10%	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: GAVAGE Vehicle: CORN OIL **Page:** 34

	Male		Female				
#Uterus: Adenoma							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Deciduoma Benign							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Granular Cell Tumor Benign							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Polyp Stromal							
Overall Incidence		Total	10/50 (20%) 10/50 (20%)	Mean 20%	SD 0%		
#Uterus: Sarcoma							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Sarcoma Stromal							
Overall Incidence		Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 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** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page:** 35

Report Date: 02/17/2020

Route: GAVAGE Vehicle: CORN OIL

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

	Male			Female	
#Uterus: Sarcoma Stromal or Polyp Stromal					
carcoma caromar or r cryp caromar			12/50 (24%)		
Overall Incidence		Total	12/50 (24%)	Mean 24%	SD 0%
#Uterus:					
Schwannoma Malignant			2/52 (22/)		
			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus:					
Squamous Cell Carcinoma					
•			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#M =2					
#Vagina: Granular Cell Tumor Benign					
Grandial Cell Fullion Belligh			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Vagina:					
Polyp			4/50 (00/)		
Occupation of the second		T-1-1	1/50 (2%)	M 00/	OD 00/
Overall Incidence		Total	1/50 (2%)	Mean 2%	SD 0%
#Vagina:					
Schwannoma Malignant					
-			1/50 (2%)		
Overall Incidence		Total	1/50 (2%)	Mean 2%	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: GAVAGE Vehicle: CORN OIL **Page:** 36

			Male				Female	
#Zymbal's Gland: Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: INHALATION Vehicle: AIR

**Page:** 37

Report Date: 02/17/2020

## **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 Northwest	051047203	01/17/11	729	50(5)	25(661)	609.4	p-Chloro-a,a,a-trifluorotoluene
					Female		
Battelle Northwest	051047203	01/17/11	731	50(5)	22(626)	377.3	p-Chloro-a,a,a-trifluorotoluene

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: INHALATION Vehicle: AIR

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			Male				Female				
#All Organs: Benign Tumors											
_		30/50 (60%)				39/50 (78%)					
Overall Incidence	Total	30/50 (60%)	Mean 60%	SD 0%	Total	39/50 (78%)	Mean 78%	SD 0%			
#All Organs: Malignant Tumors											
Overall Incidence	Total	12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%	Total	11/50 (22%) 11/50 (22%)	Mean 22%	SD 0%			
#All Organs: Malignant and Benign T	umors	37/50 (74%)				41/50 (82%)					
Overall Incidence	Total	37/50 (74%)	Mean 74%	SD 0%	Total	41/50 (82%)	Mean 82%	SD 0%			
#All Organs: Hemangioma		1/50 (2%)				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#All Organs: Hemangiosarcoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#All Organs: Hemangiosarcoma or H	emangioma	1/50 (2%)				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (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: INHALATION Vehicle: AIR

**Page:** 39

			Male		Female			
#All Organs: Histiocytic Sarcoma								
-		0/50 (0	0%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Granulocytic								
Overall Incidence	Total	1/50 (2 1/50 (2%)	2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall incidence	Total	1/50 (2%)	iviean 2%	SD 0%	TOTAL	0/50 (0%)	wean 0%	3D 0%
			*0/ \			0/50 (0%)		
Overall Incidence	Total	3/50 (6 3/50 (6%)	%) Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs:		3/50 (6%)	,		Total Total	` '	Mean 0%  Mean 0%	SD 0%
#All Organs: Malignant Lymphoma: H	istiocytic, Lymp	3/50 (6%) chocytic, Mixed, N 0/50 (0 0/50 (0%)	Mean 6%  IOS, or Undifferentiated Co  )%)  Mean 0%	ell Type		0/50 (0%) 0/50 (0%) 0/50 (0%)		
#All Organs: Malignant Lymphoma: H Overall Incidence  #All Organs: Malignant Schwannoma	istiocytic, Lymp	3/50 (6%)  Chocytic, Mixed, N 0/50 (0 0/50 (0%)	Mean 6%  OS, or Undifferentiated Comment  Mean 0%  Mean 0%	ell Type SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 2/50 (4%)	Mean 0%	SD 0%
#All Organs: Malignant Lymphoma: Hi Overall Incidence #All Organs:	istiocytic, Lymp	3/50 (6%) chocytic, Mixed, N 0/50 (0 0/50 (0%)	Mean 6%  IOS, or Undifferentiated Co  )%)  Mean 0%	ell Type		0/50 (0%) 0/50 (0%) 0/50 (0%)		
#All Organs: Malignant Lymphoma: H Overall Incidence  #All Organs: Malignant Schwannoma	istiocytic, Lymp Total Total	3/50 (6%)  chocytic, Mixed, N 0/50 (0 0/50 (0%)  0/50 (0%)	Mean 6%  OS, or Undifferentiated Comment  Mean 0%  Mean 0%	ell Type SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 2/50 (4%)	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

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

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Ma	le			Female			
#All Organs: Mesothelioma: Malignant										
Overall Incidence	Total	1/50 (2 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Osteosarcoma		0/50 (0				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Osteosarcoma or Osteoma		0/50 (0	%)			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Adrenal Cortex: Adenoma		3/50 (6	%)		Total	0/50 (0%)	Magn 09/	SD 0%		
Overall Incidence	Total	3/50 (6%)	Mean 6%		Total	0/50 (0%)	Mean 0%	SD 0%		
*Adrenal Cortex: Carcinoma		0/50 (0	0/)			0/50 (00/)				
Overall Incidence	Total	0/50 (0 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Ganglioneuroma		0/50 (0	%)			0/49 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (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: INHALATION Vehicle: AIR

Page: 41

		Male	Female									
*Adrenal Medulla: Pheochromocytoma Benign												
_	12/50 (24%)				0/49 (0%)							
Total	12/50 (24%)	Mean 24%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%					
mplex												
	0/50 (0%)				0/49 (0%)							
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%					
lignant	2/50 (4%)				0/49 (0%)							
Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%					
	, Malignant, NOS				0/49 (0%)							
Total	14/50 (28%)	Mean 28%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%					
	0/50 (0%)				0/50 (0%)							
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%					
ma	0/50 (00/)				0/50 (00/)							
Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%					
	Total  mplex  Total  ignant  Total  nign, Complex,  Total  Total	12/50 (24%) Total 12/50 (24%)  mplex  0/50 (0%)  Total 0/50 (0%)  ignant  2/50 (4%)  Total 2/50 (4%)  nign, Complex, Malignant, NOS  14/50 (28%)  Total 14/50 (28%)  Total 0/50 (0%)  Total 0/50 (0%)	12/50 (24%) Total 12/50 (24%) Mean 24%  mplex  0/50 (0%) Total 0/50 (0%) Mean 0%  ignant  2/50 (4%) Total 2/50 (4%) Mean 4%  nign, Complex, Malignant, NOS 14/50 (28%) Total 14/50 (28%) Mean 28%   0/50 (0%)  Total 0/50 (0%)  Mean 0%	12/50 (24%) Total 12/50 (24%) Mean 24% SD 0%  mplex  0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%  ignant  2/50 (4%) Total 2/50 (4%) Mean 4% SD 0%  nign, Complex, Malignant, NOS 14/50 (28%) Total 14/50 (28%) Mean 28% SD 0%  Total 0/50 (0%) Mean 0% SD 0%	12/50 (24%)  Total 12/50 (24%) Mean 24% SD 0% Total  nplex  0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total  ignant  2/50 (4%)  Total 2/50 (4%) Mean 4% SD 0% Total  nign, Complex, Malignant, NOS 14/50 (28%)  Total 14/50 (28%) Mean 28% SD 0% Total  0/50 (0%) Mean 0% SD 0% Total	12/50 (24%) Mean 24% SD 0% Total 0/49 (0%) Total 12/50 (24%) Mean 24% SD 0% Total 0/49 (0%)  mplex  0/50 (0%) Mean 0% SD 0% Total 0/49 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%)  ignant  2/50 (4%) Mean 4% SD 0% Total 0/49 (0%)  Total 2/50 (4%) Mean 4% SD 0% Total 0/49 (0%)  nign, Complex, Malignant, NOS 14/50 (28%) Mean 28% SD 0% Total 0/49 (0%)  Total 14/50 (28%) Mean 28% SD 0% Total 0/49 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)	Total 12/50 (24%) Mean 24% SD 0% Total 0/49 (0%) Mean 0%  mplex  0/50 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0%  ignant  2/50 (4%) Mean 4% SD 0% Total 0/49 (0%) Mean 0%  Total 2/50 (4%) Mean 4% SD 0% Total 0/49 (0%) Mean 0%  nign, Complex, Malignant, NOS  14/50 (28%) Mean 28% SD 0% Total 0/49 (0%) Mean 0%  Total 14/50 (28%) Mean 28% SD 0% Total 0/49 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 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: INHALATION Vehicle: AIR

Page: 42

				Male			Female				
*Brain: Glioma Malignant											
Overall Incidence	Total	2/50 2/50 (4%)	(4%)	Mean 4%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
*Brain: Granular Cell Tumor Benigi	า										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Brain: Granular Cell Tumor Malign	ant	0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Brain: Meningioma Benign			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Brain: Meningioma Malignant											
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Brain: Meningioma: Benign, Malig	nant, NOS	0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50	(U <sup>7</sup> 0)	Mean 0%	SD 0%	Total	0/50 (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: INHALATION Vehicle: AIR

**Page:** 43

				Male				Female				
*Brain: Oligodendroglioma, Glioma, or Astrocytoma												
2/50 (4%) 1/50 (2%)  Diversit Insidence Total 2/50 (4%) Moon 4% SD 0% Total 1/50 (2%) Moon 3% SD 0%												
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
*Brain: Schwannoma Malignant												
		0/50	(0%)				1/50 (2%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
*Clitoral/Preputial Gland: Adenoma		- /										
	<b>-</b>	0/50	(0%)	NA 00/	<b>OD</b> 00/	<b>+</b>	0/50 (0%)		OD 00/			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Clitoral/Preputial Gland: Carcinoma												
			(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Clitoral/Preputial Gland: Carcinoma or Adenoma												
		0/50	(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Clitoral/Preputial Gland: Squamous Cell Carcinoma			4									
		0/50	(0%)		05.00/		0/50 (0%)		00.007			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (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: INHALATION Vehicle: AIR

Page: 44

			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Epididymis: Sarcoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
#Eye: Leiomyoma		4/50 (00/)				0/50 /00/		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rect Granular Cell Tumor Benig	um:							
	•	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rect Leiomyoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (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: INHALATION Vehicle: AIR

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		Male	Female				
	0/50 (0%)				0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Tatal	` '	Mana 20/	CD 00/	Tatal	` '	Maan 00/	CD 00/
1 Otal	1/50 (2%)	wean 2%	SD 0%	notai	0/50 (0%)	wean 0%	SD 0%
ecified:							
Total	` ,	Maan 00/	CD 00/	Total	` '	Maan Oo/	SD 0%
	, ,	iviean 0%	3D 0%		0/50 (0%)	wiean 0%	3D 0%
ecified:	0/50 (0%)				0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
ecified:							
	1/50 (2%)				0/50 (0%)		
Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	9/50 (469/)				4/50 (20/)		
Total	, ,	Mean 16%	SD 0%	Total	` '	Mean 2%	SD 0%
	Total  Total  Total  ecified:  Total  Total	0/50 (0%) Total 0/50 (0%)  1/50 (2%)  Total 1/50 (2%)  Pecified:  0/50 (0%)  Total 0/50 (0%)  Pecified:  1/50 (2%)  Total 1/50 (2%)  Total 1/50 (2%)  Total 1/50 (2%)  8/50 (16%)	0/50 (0%) Total 0/50 (0%) Mean 0%  1/50 (2%) Total 1/50 (2%) Mean 2%  Decified:  0/50 (0%) Total 0/50 (0%) Mean 0%  Decified:  1/50 (0%) Total 0/50 (0%) Mean 0%  Decified:  1/50 (2%) Total 1/50 (2%) Mean 2%	0/50 (0%)       Total     0/50 (0%)     Mean 0%     SD 0%       1/50 (2%)       Total     1/50 (2%)     Mean 2%     SD 0%       Decified:       0/50 (0%)       Total     0/50 (0%)     Mean 0%     SD 0%       Decified:       1/50 (0%)       Total     1/50 (2%)     Mean 2%     SD 0%       8/50 (16%)	Total 0/50 (0%) Mean 0% SD 0% Total  1/50 (2%) Mean 2% SD 0% Total  1/50 (2%) Mean 2% SD 0% Total  Pecified:  0/50 (0%) Mean 0% SD 0% Total  Pecified:  1/50 (2%) Mean 0% SD 0% Total  Pecified:  1/50 (0%) Mean 0% SD 0% Total  Pecified:  1/50 (2%) Mean 0% SD 0% Total  Pecified:  1/50 (2%) Mean 0% SD 0% Total	Total 0/50 (0%)  Total 0/50 (0%)  Mean 0% SD 0% Total 0/50 (0%)  Total 1/50 (2%)  Mean 2% SD 0% Total 0/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)  Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)  Mean 0% SD 0% Total 0/50 (0%)  Pecified:  Total 0/50 (0%)  Mean 0% SD 0% Total 0/50 (0%)  Pecified:  1/50 (2%)  Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)  Mean 0% SD 0% Total 0/50 (0%)  Pecified:  1/50 (2%)  Mean 2% SD 0% Total 0/50 (0%)  Total 1/50 (2%)  Mean 2% SD 0% Total 0/50 (0%)  Pecified:	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0%  Pecified:  0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Pecified:  1/50 (2%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Pecified:  1/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Pecified:  1/50 (2%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Pecified:  1/50 (2%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Pecified:  1/50 (2%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Pecified:  1/50 (2%) Mean 0% SD 0% Total 0/50 (0%) Mean 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: INHALATION Vehicle: AIR

Page: 46

			Male				Female			
*Islets, Pancreatic: Carcinoma										
		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Islets, Pancreatic: Carcinoma or Adenoma										
		8/50 (16%)				2/50 (4%)				
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
*Kidney: Pelvis and Transitio Papilloma	nal Epitheliu									
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Adenoma										
		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Kidney: Renal Tubule: Carcinoma										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Carcinoma or Adenoma										
		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	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: INHALATION Vehicle: AIR

Page: 47

			Male				Female	
*Kidney: Renal Tubule: Lipoma								
Occupation of the second	Tatal	0/50 (0%)	M 00/	00.00/	Tatal	0/50 (0%)	Marana 00/	OD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma		2/52 (221)				2/22 (22)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		0/50 (0%)		SD 0%	ı Olal	0/30 (0%)	Weall 0%	3D 0%
*Kidney: Renal Tubule: Nephroblastoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Oncocytoma Benign		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Polyp Adenomatous			•••••	•••••				
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lacrimal Gland: Carcinoma		0/50 (0%)				0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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: INHALATION Vehicle: AIR

Page: 48

				Male				Female	
*Liver: Cholangiocarcinoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	` '	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Cholangioma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		0/50	(0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Liver: Hepatocellular Carcinoma		0/50	(004)				0/50 (00/)		
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma c	or Hepatobla		(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(0 /0)	Mean 0%	SD 0%	Total	0/50 (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: INHALATION Vehicle: AIR

**Page:** 49

			Male				Female	
*Liver: Hepatocellular Carcino	ma or Hepatocel	lular Adenoma						
	-	0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Liver: Hepatocellular Carcino								
	.,	0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Lung: Alveolar/Bronchiolar A	denoma	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar C		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar C						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma		0/50 (22/)				0/50 (0%)		
O	Tatal	0/50 (0%)	M 00/	OD 00/	T-1-1	0/50 (0%)	Maran 00/	00.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: INHALATION Vehicle: AIR

**Page:** 50

				Male				Female	
*Lung: Squamous Cell Carcinoma									
Overall Incidence	Total	0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma									
Overall Incidence	Total	0/50 ( 0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenolipoma		0/50 (	0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	076)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma		0/50 (	0%)				4/50 (8%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%
#Mammary Gland: Carcinoma									
Overall Incidence	Total	0/50 ( 0/50 (0%)	0%)	Mean 0%	SD 0%	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%
#Mammary Gland: Carcinoma or Adenoma		0/50 (	0%)				9/50 (18%)		
Overall Incidence	Total	0/50 (0%)	0 70)	Mean 0%	SD 0%	Total	9/50 (18%)	Mean 18%	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: INHALATION Vehicle: AIR

**Page:** 51

			Male				Female	
#Mammary Gland: Fibroadenoma								
		2/50 (4%)				20/50 (40%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	20/50 (40%)	Mean 40%	SD 0%
#Mammary Gland: Fibroma, Fibroadenon								
		2/50 (4%)				23/50 (46%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	23/50 (46%)	Mean 46%	SD 0%
#Mammary Gland: Fibroma, Fibroadenon Overall Incidence	na, Carcinoma, or Total	Adenoma 2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	27/50 (54%) 27/50 (54%)	Mean 54%	SD 0%
		` ,			Total	27/50 (54%)	Mean 5476	3D 078
#Mammary Gland: Myoepithelioma		` ,			Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland:		0/50 (0%) 0/50 (0%)				0/50 (0%) 0/50 (0%)		
#Mammary Gland: Myoepithelioma  Overall Incidence  *Nose:		0/50 (0%)				0/50 (0%)		
#Mammary Gland: Myoepithelioma  Overall Incidence  *Nose: Carcinoma  Overall Incidence	Total Total sa, Tongue, Phary	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0% Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (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: INHALATION Vehicle: AIR

Page: 52

			Male				Female	
#Oral Cavity (Oral Mucos Squamous Cell Carcino		/nx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcino		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor	Benign					3/50 (6%)		
Overall Incidence					Total	3/50 (6%)	Mean 6%	SD 0%
*Ovary: Granulosa Cell Tumor	Malignant							
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor:	Benign, Maligna	nt, NOS				3/50 (6%)		
Overall Incidence					Total	3/50 (6%)	Mean 6%	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: INHALATION Vehicle: AIR **Page:** 53

	Male			Female	
*Ovary: Granulosa-Theca Tumor Benign					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Schwannoma Malignant			•••••		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Sertoli Cell Tumor Benign					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Thecoma Benign					
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	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: INHALATION Vehicle: AIR

Page: 54

			Male				Female		
*Ovary: Tubulostromal Carcinoma						0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Carcinoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Parathyroid Gland: Adenoma	•••••			•••••					
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%	
#Peripheral Nerve: Paraganglioma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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: INHALATION Vehicle: AIR

**Page:** 55

			Male				Female	
#Peripheral Nerve: Schwannoma Malignan	t							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign,	Malignant, NOS							
-		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Adenoma		fied Site:				18/50 (36%)		
Overall Incidence	Total	11/50 (22%) 11/50 (22%)	Mean 22%	SD 0%	Total	18/50 (36%) 18/50 (36%)	Mean 36%	SD 0%
*Pituitary Gland: Pars Dis Carcinoma						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Carcinoma or Adenoma	talis or Unspeci					•••••		
		11/50 (22%)				18/50 (36%)		
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	18/50 (36%)	Mean 36%	SD 0%
*Pituitary Gland: Pars Inte Adenoma	ermedia:							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: INHALATION Vehicle: AIR

**Page:** 56

			Male				Female	
*Pituitary Gland: Pars Interme Carcinoma or Adenoma	edia:					,		
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Nervos Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Schwannoma Malignant								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Hemangiosarcoma		0/50 (0%)						
Overall Incidence	Total	0/50 (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: INHALATION Vehicle: AIR

**Page:** 57

			Male				Female	
#Skeletal Muscle: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Liposarcoma		0.70				(201)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skeletal Muscle: Sarcoma		0/50 (00/)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or E		Tumor Benign 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Bas	sosquamous Tu	umor Benign, or Tricho 0/50 (0%)	pepithelioma			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: INHALATION Vehicle: AIR

**Page:** 58

			Male				Female	Female			
#Skin: Basal Cell Carcinoma											
		0/50 (0%)				1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
#Skin:	• • • • • • • • • • • • • • • • • • • •	•••••									
Basal Cell Carcinoma	or Basosquamous	s Tumor (malignant or N	IOS)								
		0/50 (0%)				1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
#Skin:											
Basal Cell Carcinoma, NOS), or Trichoepithel	Basal Cell Adeno ioma	oma, Basosquamous Tu	mor (benign, maligna	ant or							
		0/50 (0%)				1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
Overall illicidence											
#Skin: Basal or Sq. Cell Carci	noma, Carcinoma	a, Basosq. Tumor (M or ratoacanthoma, Trichoe 4/50 (8%)	B), Basal Cell Adeno			1/50 (2%)					
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	noma, Carcinoma	a, Basosq. Tumor (M or ratoacanthoma, Trichoe	B), Basal Cell Adeno		Total		Mean 2%	SD 0%			
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence	noma, Carcinoma Sq Papilloma, Ker	a, Basosq. Tumor (M or ratoacanthoma, Trichoe 4/50 (8%) 4/50 (8%)	B), Basal Cell Adeno oithelioma	ma,		1/50 (2%) 1/50 (2%)		SD 0%			
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence  #Skin: Fibroma	noma, Carcinoma Sq Papilloma, Ker	a, Basosq. Tumor (M or ratoacanthoma, Trichoe 4/50 (8%)	B), Basal Cell Adeno oithelioma	ma,		1/50 (2%)		SD 0%			
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence  #Skin: Fibroma Overall Incidence	noma, Carcinoma Sq Papilloma, Ker Total Total	a, Basosq. Tumor (M or ratoacanthoma, Trichoe) 4/50 (8%) 4/50 (8%)	B), Basal Cell Adeno oithelioma Mean 8% Mean 0%	ma, SD 0%	Total Total	1/50 (2%) 1/50 (2%) 0/50 (0%)	Mean 2%				
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence  #Skin: Fibroma Overall Incidence  #Skin: Fibroma Fibroma, Fibrosarcom	noma, Carcinoma Sq Papilloma, Ker Total Total	a, Basosq. Tumor (M or ratoacanthoma, Trichoe) 4/50 (8%) 4/50 (8%)  0/50 (0%)	B), Basal Cell Adeno oithelioma Mean 8% Mean 0%	ma, SD 0% SD 0%	Total Total	1/50 (2%) 1/50 (2%) 0/50 (0%)	Mean 2%				
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence  #Skin: Fibroma Overall Incidence	noma, Carcinoma Sq Papilloma, Ker Total Total	a, Basosq. Tumor (M or ratoacanthoma, Trichoe 4/50 (8%) 4/50 (8%) 0/50 (0%)	B), Basal Cell Adeno oithelioma Mean 8% Mean 0%	ma, SD 0% SD 0%	Total Total	1/50 (2%) 1/50 (2%) 0/50 (0%)	Mean 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: INHALATION Vehicle: AIR

**Page:** 59

#Skin: Fibroma, Fibrosarcoma, Sarcoma,  Overall Incidence Tota  #Skin: Fibrosarcoma  Overall Incidence Tota  #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, Myxosarcoma,	1/50 1/50 0/50 al 0/50	(50 (2%) (2%) (50 (0%) (0%)	Mean 2%	SD 0%	Total Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)		SD 0%
#Skin: Fibrosarcoma  Overall Incidence Tota  #Skin:	0/2al 0/50 al 0/50 coma, or Malign	(2%) /50 (0%) (0%)				0/50 (0%)		
#Skin: Fibrosarcoma  Overall Incidence Tota  #Skin:	0/: al 0/50 coma, or Malign	/50 (0%) (0%)				0/50 (0%)		
#Skin: Fibrosarcoma  Overall Incidence Tota  #Skin:	0/al 0/50 coma, or Malign	(50 (0%) (0%)				0/50 (0%)		
#Skin:	coma, or Malign	(0%)	Mean 0%	SD 0%	Total	` '		
#Skin:	coma, or Malign		Mean 0%	SD 0%	Total	0/50 (0%)		
_		ant Fibraria Ui				0/30 (0/0)	Mean 0%	SD 0%
Overall Incidence Total		(50 (2%) (2%)	istiocytoma  Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma						0/50 (0%)		
Overall Incidence Total	al 1/50	(2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangiopericytoma								
Overall Insidence Tate		(50 (0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/
Overall Incidence Tota	aı 0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma	0/	/50 (0%)				0/50 (09/)		
Overall Incidence Tota		(50 (0%) (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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: INHALATION Vehicle: AIR

**Page:** 60

			Male				Female	
#Skin: Keratoacanthoma								
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Malignant Fibrous Histi	iocytoma	1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or		alignant or NOS) 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Ne		chwannoma (benign, m 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: INHALATION Vehicle: AIR

Page: 61

			Male			Female			
#Skin: Osteosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Pilomatrixoma						(201)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Sarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Schwannoma Malignan	t								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Carcino	oma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Carcino or Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		1/50 (2%) 1/50 (2%)		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: INHALATION Vehicle: AIR

Page: 62

				Male				Female	
#Skin: Squamous Cell Papillom	a								
		1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillom	a or Panilloma								
oquamous och i upmom	a or r apmoma	1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	, ,	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Squamous Cell Papillom  Overall Incidence	Total	4/50 4/50 (8%)	(8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
	-	4/50	(8%)			Total	` '	Mean 0%	SD 0%
#Skin: Squamous Cell Papillom	a, Papilloma, or	r Keratoacantho	oma (8%)				0/50 (0%)		
Overall Incidence	Total	4/50 (8%)		Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Trichoepithelioma					•••••				
•		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma									
		1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	` ,	Mean 2%	SD 0%	Total	0/50 (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: INHALATION Vehicle: AIR

Page: 63

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Malignant								
		0/50 (0%)		00.00/		0/50 (0%)		05.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma		0/50 (00/)				0/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		` '			ı olal		iviean 0%	3D 0%
#Stomach, Forestomach: Sarcoma								
		0/50 (0%)		00.00/		0/50 (0%)		05.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma o		a Squamous						
	-	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: INHALATION Vehicle: AIR

**Page:** 64

				Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma									
Overall Incidence	Total	0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Testis: Adenoma		0/50							
Overall Incidence	Total	0/50 (0%)	0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Benign		0/48 ((	0%)				0/50 (0%)		
Overall Incidence	Total	0/48 (0%)	070)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/48 ((	0%)				0/50 (0%)		
Overall Incidence	Total	0/48 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligna	nt, NOS		•••						
Overall Incidence	Total	0/48 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma			40()				0/50 /40/)		
Overall Incidence	Total	2/50 (4%)	4%)	Mean 4%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	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: INHALATION Vehicle: AIR

**Page:** 65

				Male				Female	
*Thyroid Gland: C-Cell: Carcinoma									
		1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
Overell Insidence	Tatal	3/50	(6%)	Mana C0/	CD 00/	Tatal	2/50 (4%)	Mann 40/	CD 00/
Overall Incidence	Total	3/50 (6%)		Mean 6%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Thyroid Gland: Follicular Cell: Adenoma	:	0/70	(221)				(201)		
Overall Incidence	Total	0/50	(0%)	Maan 00/	SD 0%	Total	0/50 (0%)	Maan 00/	SD 0%
Overall incidence	Total	0/50 (0%)		Mean 0%	3D 0%	Total	0/50 (0%)	Mean 0%	
*Thyroid Gland: Follicular Cell: Carcinoma	:	0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(0 /0)	Mean 0%	SD 0%	Total	0/50 (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

#: Denominator is number of animals necropsied

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 66

				Male				Female	
#Tongue: Squamous Cell Carcinoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	()	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma of	or Papilloma	a Squamous							
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	(270)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Adenocarcinoma									
Overall Incidence									
#Uterus: Adenocarcinoma or Adenon	na								
Overall Incidence									
*: Denominator is number of animals	with tissues e	xamined microscop	cally						

Contract/Lab: All Laboratories

Species: RATS

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

#: Denominator is number of animals necropsied

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 67

	Male	Female
#Uterus: Adenoma		
Overall Incidence		
#Uterus: Deciduoma Benign		
Overall Incidence		
#Uterus: Granular Cell Tumor Benign		
Overall Incidence		
#Uterus: Polyp Stromal		
Overall Incidence		
#Uterus: Sarcoma		
Overall Incidence		
#Uterus: Sarcoma Stromal		
Overall Incidence		
*: Denominator is number of animals with tissues examined		

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: INHALATION Vehicle: AIR

Page: 68

	Male			Female	
#Uterus: Sarcoma Stromal or Polyp Stromal					
Overall Incidence					
#Uterus: Schwannoma Malignant					
Overall Incidence					
#Uterus: Squamous Cell Carcinoma					
Overall Incidence					
#Vagina: Granular Cell Tumor Benign			1/50 (2%)		
Overall Incidence		Total	1/50 (2%)	Mean 2%	SD 0%
#Vagina:					•••••
Polyp Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Schwannoma Malignant					
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	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: INHALATION Vehicle: AIR

**Page:** 69

			Male				Female	
#Zymbal's Gland: Carcinoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (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: ORAL Vehicle: FEED **Page:** 70

Report Date: 02/17/2020

## **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	051018801	02/17/11	733	50(2)	32(675)	525.8	Di(2-ethylhexyl) Phthalate
					Female		
Battelle Columbus Laboratory	051018801	02/18/11	736	50(4)	33(691)	329.5	Di(2-ethylhexyl) Phthalate

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: ORAL Vehicle: FEED Page: 71 Report Date: 02/17/2020

			Male				Female	
#All Organs: Benign Tumors								
		27/50 (54%)				37/50 (74%)		
Overall Incidence	Total	27/50 (54%)	Mean 54%	SD 0%	Total	37/50 (74%)	Mean 74%	SD 0%
#All Organs: Malignant Tumors								
		13/50 (26%)				16/50 (32%)		
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	16/50 (32%)	Mean 32%	SD 0%
#All Organs: Malignant and Benign Tu	umors	20/50 (0.40/)				44/50 (000()		
Overall Incidence	Total	32/50 (64%) 32/50 (64%)	Mean 64%	SD 0%	Total	41/50 (82%) 41/50 (82%)	Mean 82%	SD 0%
		` ,		070 U%	ı Olal	41/30 (62%)		3D 0%
#All Organs: Hemangioma		(70)				2(72 (22))		
O	T-1-1	1/50 (2%)	M 00/	OD 00/	Taral	0/50 (0%)	Maran 00/	OD 00/
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma or He	emangioma							
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (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: ORAL Vehicle: FEED **Page:** 72

			Male				Female	
#All Organs: Histiocytic Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Granulocytic								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic, M Overall Incidence	onocytic, Mo	ononuclear, or Undiffere 0/50 (0%) 0/50 (0%)	ntiated  Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Malignant Lymphoma: Hist Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#All Organs: Malignant Schwannoma		3/50 (6%)				1/50 (2%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#All Organs: Mesothelioma: Benign, Mal	ignant, NOS	2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (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: ORAL Vehicle: FEED Page: 73

			Male	•			Female	
#All Organs: Mesothelioma: Malignant								
Overall Incidence	Total	2/50 (4° 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma		0/50 (0'				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma		0/50 (0'	%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma		1/50 (2'	%)		Tatal	0/50 (0%)	Mars 20%	CD 00/
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Carcinoma								
Overall Incidence	Total	0/50 (0° 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Ganglioneuroma		0/50 (0'	%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: ORAL Vehicle: FEED Page: 74

			Male				Female					
*Adrenal Medulla: Pheochromocytoma Benign												
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
*Adrenal Medulla: Pheochromocytoma Com												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma Mali	gnant	1/50 (2%)				0/50 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma: Ben	ign, Complex,	Malignant, NOS 5/50 (10%)				1/50 (2%)						
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
#Bone: Osteosarcoma												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Bone: Osteosarcoma or Osteom	na	0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: ORAL Vehicle: FEED **Page:** 75

			Male				Female	
*Brain: Glioma Malignant								
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Be	nign							
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
*Brain: Granular Cell Tumor Ma	lignant	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Benign		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Malignant								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, M	alignant, NOS	0/50 /(00)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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: ORAL Vehicle: FEED Page: 76

			Male				Female				
*Brain: Oligodendroglioma, Glioma, or Astrocytoma											
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Brain: Schwannoma Malignant		······									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Clitoral/Preputial Gland: Adenoma		0/40 (00/)				0/40 /00/)					
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%			
*Clitoral/Preputial Gland: Carcinoma		1/49 (2%)		05.00	Total	0/49 (0%)	M 00/	OD 00			
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			
*Clitoral/Preputial Gland: Carcinoma or Adenoma		1/49 (2%)				0/49 (0%)					
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			
*Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/49 (0%)				0/49 (0%)					
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (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: ORAL Vehicle: FEED Page: 77

			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Papilloma		0/49 (0%)				1/49 (2%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/49 (2.04%)	Mean 2.04%	SD 0%
*Epididymis: Sarcoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
#Eye: Leiomyoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant		3/50 (6%)				1/50 (2%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Intestine Large: Colon/Rectu Granular Cell Tumor Benigr	ım:							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Leiomyoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: ORAL Vehicle: FEED **Page:** 78

				Male				Female	
#Intestine Small: Jejunum: Carcinoma									
			(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma									
			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspeci Carcinoma	fied:								
	<b>.</b>		(2%)		OD 00/	<b>+</b>	0/50 (0%)		OD 00/
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspeci Carcinoma or Adenoma	fied:	1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	(270)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspeci Leiomyosarcoma									
			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma		0/40	(00()				4/50 (00/)		
Overall Incidence	Total	3/49 3/49 (6.12%)	(6%)	Mean 6.12%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
Overall incidence		,					( ,		

<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: ORAL Vehicle: FEED **Page:** 79

			Male				Female	
*Islets, Pancreatic: Carcinoma								
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma						······································		
Overall Incidence	Total	3/49 (6%) 3/49 (6.12%)	Mean 6.12%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Kidney: Pelvis and Transitio Papilloma	nal Epitheliu							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
						3,00 (070)		
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: ORAL Vehicle: FEED **Page:** 80

			Male				Female	
*Kidney: Renal Tubule: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Oncocytoma Benign	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Polyp Adenomatous		1/50 (2%)		GD 070	·····	0/50 (0%)	incari 070	GD 0/8
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lacrimal Gland: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: ORAL Vehicle: FEED Page: 81

			Male				Female	
*Liver: Cholangiocarcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Cholangioma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Liver: Hemangioma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma  Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma		` '				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma o	or Hepatobla	stoma 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: ORAL Vehicle: FEED Page: 82

			Male			Female						
*Liver:  Hepatocellular Carcinoma or Hepatocellular Adenoma  0/50 (0%)  Overall Incidence  Total 0/50 (0%)  Mean 0%  SD 0%  Total 0/50 (0%)  Mean 0%  SD 0%												
Overall incidence		` '				` '						
*Liver: Hepatocellular Carcino	ma, Hepatocellul	ar Adenoma, or Hepatol 0/50 (0%)	olastoma			0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Lung: Alveolar/Bronchiolar Ad		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Lung: Alveolar/Bronchiolar Ca		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Lung: Alveolar/Bronchiolar Ca						0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Lung: Sarcoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: ORAL Vehicle: FEED Page: 83

				Male			Female			
*Lung: Squamous Cell Carcinoma										
		•	%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mear		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Hemangiosarcoma										
		•	<b>1%</b> )				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mear		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Adenolipoma										
Overall Incidence	Total	0/50 (0 0/50 (0%)	l%) Mear	. 00/.	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		` '					0/30 (0 /6)	Wiedii 076		
#Mammary Gland: Adenoma		0/50 (0	.07)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%)	%) Mear		SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Carcinoma										
		0/50 (0	%)				8/50 (16%)			
Overall Incidence	Total	0/50 (0%)	Mear		SD 0%	Total	8/50 (16%)	Mean 16%	SD 0%	
#Mammary Gland: Carcinoma or Adenoma										
		,	%)				8/50 (16%)			
Overall Incidence	Total	0/50 (0%)	Mean		SD 0%	Total	8/50 (16%)	Mean 16%	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: ORAL Vehicle: FEED Page: 84

			Male				Female					
#Mammary Gland: Fibroadenoma												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	25/50 (50%) 25/50 (50%)	Mean 50%	SD 0%				
#Mammary Gland: Fibroma, Fibroadenom												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	25/50 (50%) 25/50 (50%)	Mean 50%	SD 0%				
#Mammary Gland: Fibroma, Fibroadenom	a, Carcinoma, or	Adenoma 0/50 (0%)				29/50 (58%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	29/50 (58%)	Mean 58%	SD 0%				
#Mammary Gland: Myoepithelioma  Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Nose: Carcinoma												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Oral Cavity (Oral Mucos Squamous Cell Carcine		nx, Tooth, Gingiva):				0/50 (00/)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 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: 02/17/2020

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: ORAL Vehicle: FEED

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

Male Female **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):** Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Oral Mucosa: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% \*Ovary: Cystadenoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% ..... \*Ovary: **Granulosa Cell Tumor Benign** 1/50 (2%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% \*Ovarv: **Granulosa Cell Tumor Malignant** 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Granulosa Cell Tumor: Benign, Malignant, NOS 1/50 (2%)**Overall Incidence** Total Mean 2% SD 0% 1/50 (2%)

<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: ORAL Vehicle: FEED

Report Date: 02/17/2020

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	Male	Female			
*Ovary: Granulosa-Theca Tumor Benign			0/50 (00/)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant					
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma					
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Schwannoma Malignant			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Sertoli Cell Tumor Benign					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Thecoma Benign					
Overall Incidence		Total	0/50 (0%) 0/50 (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: ORAL Vehicle: FEED Page: 87

			Male			Female			
*Ovary: Tubulostromal Carcinoma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Adenoma									
Overall Incidence	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Carcinoma									
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Carcinoma or Adenoma		4/40 /20/				0/50 (0%)			
Overall Incidence	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Parathyroid Gland: Adenoma									
Overall Incidence	Total	0/43 (0%) 0/43 (0%)	Mean 0%	SD 0%	Total	0/42 (0%) 0/42 (0%)	Mean 0%	SD 0%	
#Peripheral Nerve: Paraganglioma						-/			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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: ORAL Vehicle: FEED Page: 88

				Male				Female	
#Peripheral Nerve: Schwannoma Malignant									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign, M									
ochwannoma. Denign, w	angham, NOS	0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dista Adenoma		ied Site:							
Overall Incidence	Total	3/50 3/50 (6%)	(6%)	Mean 6%	SD 0%	Total	13/49 (27%) 13/49 (26.53%)	Mean 26.53%	SD 0%
*Pituitary Gland: Pars Dista Carcinoma									
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dista Carcinoma or Adenoma									
		3/50	(6%)				13/49 (27%)		
Overall Incidence	Total	3/50 (6%)		Mean 6%	SD 0%	Total	13/49 (26.53%)	Mean 26.53%	SD 0%
*Pituitary Gland: Pars Inter Adenoma	media:								
	<b>T</b>	1/50	(2%)	N. 00/	05.00/	<b>-</b>	0/49 (0%)		05.00/
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/49 (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

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

......

Carcinoma or Adenoma

......

\*Prostate: Adenoma

\*Prostate:

..... \*Pituitary Gland: Pars Nervosa: **Schwannoma Malignant** 

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

\*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** 0/49 (0%)Mean 2% SD 0% Total 0/49 (0%) Mean 0% SD 0% 0/49 (0%)Mean 0% SD 0% Total 0/49 (0%) Mean 0% SD 0% Mean 2% SD 0% Mean 2% SD 0%

**Overall Incidence** \*Salivary Glands:

**Schwannoma Malignant** 

Total

Total

Total

Total

Total

0/50

1/50

1/50 (2%)

0/50

0/50 (0%)

1/50

1/50 (2%)

1/50

1/50 (2%)

0/50 (0%)

(2%)

(0%)

(2%)

(2%)

(0%)

Mean 0%

Mean 0%

SD 0%

SD 0%

Total

0/49 (0%)

(0%)

0/49

Mean 0%

Page: 89

Report Date: 02/17/2020

SD 0%

**#Seminal Vesicle:** Hemangiosarcoma

**Overall Incidence** 

0/50 (0%)

**Overall Incidence** Total 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: ORAL Vehicle: FEED **Page:** 90

			Male				Female	
#Skeletal Muscle: Hemangioma		0/50 (00)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Liposarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or E						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Bas		umor Benign, or Tricl 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

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

Species: RATS

Contract/Lab: All Laboratories

**Toxicology Data Management System** Tumor Incidence for Selected Control Animal Groups

**Page:** 91

Report Date: 02/17/2020

Route: ORAL Vehicle: FEED

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

			Male				Female			
#Skin: Basal Cell Carcinoma										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Basal Cell Carcinoma or	· Rasosquamou	s Tumor (malignant or N	OS)							
Basar och oaromoma or	Dasosquamou	0/50 (0%)	00,			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Basal Cell Carcinoma, B NOS), or Trichoepithelio	asal Cell Adend	oma, Basosquamous Tur	nor (benign, maligna	ant or						
1100), or Trionocpiaicine	····u	0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, Sc				ma,		0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Fibroma										
		3/50 (6%)				0/50 (0%)				
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Fibroma, Fibrosarcoma, Hemangiopericytoma	Sarcoma, Myxo	oma, Myxosarcoma, Mali	gnant Fibrous Histic	ocytoma, or						
		3/50 (6%)				1/50 (2%)				
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	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: ORAL Vehicle: FEED Page: 92

			Male				Female	
#Skin: Fibroma, Fibrosarcoma,	Sarcoma, Myxc	oma, Myxosarcoma, or M 3/50 (6%)	lalignant Fibrous His	stiocytoma		1/50 (2%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcoma,	Myxosarcoma	0/50 (0%)	-			1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Hemangioma		0/50 (0%)				0/50 (0%)		22
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangiopericytoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: ORAL Vehicle: FEED Page: 93

				Male			Female			
#Skin: Keratoacanthoma										
		1/50	(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Lipoma										
•		3/50	(6%)				0/50 (0%)			
Overall Incidence	Total	3/50 (6%)		Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Liposarcoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	, ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Malignant Fibrous Hist										
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Neurofibrosarcoma or										
	`	-	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Neurofibrosarcoma, Ne		chwannoma (be					0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	` '	Mean 0%	SD 0%	Total	0/50 (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: ORAL Vehicle: FEED **Page:** 94

			Male				Female	
#Skin: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Pilomatrixoma								
		0/50 (0%)		00.00		0/50 (0%)	••	05.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Schwannoma Malignant			•••••					
G		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma								
oquamous oen ouromoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma, or Carcinoma		≎arcinoma, Basosquan						
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: ORAL Vehicle: FEED **Page:** 95

				Male			Female			
#Skin: Squamous Cell Papillom	ıa									
Overall Incidence	Total	0/50 (0%)	(0%) Mear		SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Papillon	a or Panilloma								•••••	
Overall Incidence	Total	0/50 ( 0/50 (0%)	(0%) Mear	n 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Papillon	na, Papilloma, So	-	arcinoma or Kerat (2%) Mear		SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Papillon Overall Incidence	na, Papilloma, or	Keratoacanthon	na (2%) Mear	n 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Trichoepithelioma		,	(0%)				0/50 (0%)			
•	Total	0/50 (0%)	Mear	າ 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Overall Incidence					<b> </b>					
#Skin: Sebaceous Gland: Adenoma			(0%)				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** 

**Page:** 96

Report Date: 02/17/2020

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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

Route: ORAL Vehicle: FEED

			Male			Female			
#Skin: Sebaceous Gland: Carcinoma or Adenoma		2/22 (221)				(201)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Spinal Cord: Astrocytoma Malignant									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Spleen: Hemangiosarcoma		0/50 (00/)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Sarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Carcinoma o		a <b>Squamous</b> 0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<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

Species: RATS

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED **Page:** 97

			Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma								
Occupation of demand	Taral	0/50 (0%)	Mara 2007	00,007	Tatal	0/50 (0%)	Maran 00/	OD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Testis: Adenoma								
		7/50 (14%)						
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%				
*Thymus: Thymoma Benign								
		0/48 (0%)				0/49 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/48 (0%)				0/49 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligna								
		0/48 (0%)				0/49 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma						10/50 (0.10)		
O	T-1-1	13/50 (26%)	M 000/	00.00/	Tatal	12/50 (24%)	Maran 040/	OD 00/
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	12/50 (24%)	Mean 24%	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: ORAL Vehicle: FEED Page: 98

			Male				Female			
*Thyroid Gland: C-Cell: Carcinoma										
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%		
*Thyroid Gland: C-Cell: Carcinoma or Adenoma						( /				
Overall Incidence	Total	14/50 (28%) 14/50 (28%)	Mean 28%	SD 0%	Total	14/50 (28%) 14/50 (28%)	Mean 28%	SD 0%		
*Thyroid Gland: Follicular Cell: Adenoma		2/22 (201)				(20)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Thyroid Gland: Follicular Cell: Carcinoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Tissue NOS: Schwannoma Malignant		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: ORAL Vehicle: FEED **Page:** 99

				Male			Female					
#Tongue: Squamous Cell Carcinoma												
Overall Incidence	Total	0/50 (0%)		an 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Tongue: Squamous Cell Carcino												
Overall Incidence	Total		(0%) Me	an 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Tooth: Odontoma		0/50 (	(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	,	an 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Urinary Bladder: Leiomyosarcoma			(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Me	an 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Uterus: Adenocarcinoma												
Overall Incidence						Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%			
#Uterus: Adenocarcinoma or Ade	enoma	••••••										
Overall Incidence						Total	2/50 (4%) 2/50 (4%)	Mean 4%	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: ORAL Vehicle: FEED Page: 100

	Male			Female	
#Uterus: Adenoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Deciduoma Benign			•••••		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Granular Cell Tumor Benign					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal					
Overall Incidence		Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%
#Uterus: Sarcoma			•••••		
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Uterus: Sarcoma Stromal					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 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: 02/17/2020

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

Route: ORAL Vehicle: FEED

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

Male **Female #Uterus:** Sarcoma Stromal or Polyp Stromal 5/50 (10%) **Overall Incidence** Total 5/50 (10%) Mean 10% SD 0% ..... **#Uterus: Schwannoma Malignant** 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% #Uterus: **Squamous Cell Carcinoma** 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% ..... #Vagina: **Granular Cell Tumor Benign** 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% #Vagina: Polyp 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% #Vagina: **Schwannoma Malignant** 0/50 (0%)**Overall Incidence** Total Mean 0% SD 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: ORAL Vehicle: FEED Page: 102

			Male			Female			
#Zymbal's Gland: Carcinoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma or Adenoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: PERINATAL AND POSTNATAL

Vehicle: FEED

#### Page: 103

Report Date: 02/17/2020

#### **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 Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	051018802 051098701 051026001 052061401 052061402	06/27/11 08/30/10 11/08/10 10/27/08 07/27/09	729 729 729 N/A 743	50(2) 49(2) 50(2) 0(0) 50(2)	25(648) 27(672) 30(706) 0(0) 36(684)	593.4 628.3 615.3 N/A 609.5	Di(2-ethylhexyl) Phthalate Dibutyl Phthalate 2-Hydroxy-4-methoxybenzophenone Perfluorooctanoic Acid Perfluorooctanoic Acid
					Female		
Battelle Columbus Laboratory	051018802 051098701 051026001 052061401 052061402	06/28/11 08/31/10 11/09/10 10/28/08 N/A	732 730 730 744 N/A	50(4) 50(4) 50(4) 50(4) 0(0)	31(684) 29(668) 30(657) 23(649) 0(0)	376.1 397.3 379.6 385.9 N/A	Di(2-ethylhexyl) Phthalate Dibutyl Phthalate 2-Hydroxy-4-methoxybenzophenone Perfluorooctanoic Acid Perfluorooctanoic Acid

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: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 104

			Male				Female	
#All Organs: Benign Tumors								
		28/50 (56%)	35/49 (71%) 32/50 (64%)	38/50 (76%)		41/50 (82%) 39/50 (78%)	40/50 (80%)	41/50 (82%)
Overall Incidence	Total	133/199 (66.83%)	Mean 66.86%	SD 8.77%	Total	161/200 (80.5%)	Mean 80.5%	SD 1.91%
#All Organs: Malignant Tumors								
		15/50 (30%)	14/49 (29%) 9/50 (18%)	11/50 (22%)		14/50 (28%) 14/50 (28%)	13/50 (26%)	15/50 (30%)
Overall Incidence	Total	49/199 (24.62%)	Mean 24.64%	SD 5.63%	Total	56/200 (28%)	Mean 28%	SD 1.63%
#All Organs: Malignant and Benign To	umors	36/50 (72%)	41/49 (84%)	42/50 (84%)		44/50 (88%)	44/50 (88%)	47/50 (94%)
		30/30 (72/8)	37/50 (74%)	42/30 (84 %)		47/50 (86%)	44/30 (88/8)	47/30 (94%)
Overall Incidence	Total	156/199 (78.39%)	Mean 78.42%	SD 6.31%	Total	182/200 (91%)	Mean 91%	SD 3.46%
#All Organs: Hemangioma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#All Organs: Hemangiosarcoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female						
#All Organs: Hemangiosarcoma or Hemangioma													
-		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%					
#All Organs: Histiocytic Sarcoma													
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%					
#All Organs: Leukemia: Granulocytic	c												
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%					
#All Organs: Leukemia: Lymphocytic	c, Monocytic, M	ononuclear, or Undifferer	ntiated										
		0/50 (0%)	0/49 (0%) 3/50 (6%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 3%	Total	2/200 (1%)	Mean 1%	SD 1.15%					
#All Organs:	Histiocytic Lym	nphocytic, Mixed, NOS, or	Undifferentiated Cell	Type									
gayp.lollia.		0/50 (0%)	1/49 (2%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	2/200 (1%)	Mean 1%	SD 1.15%					

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male	Female
#All Organs: Malignant Schwannoma				
		6/50 (12%)	3/49 (6%) 1/50 (2%) 1/50 (2%)	3/50 (6%) 2/50 (4%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	11/199 (5.53%)	Mean 5.53% SD 4.73%	Total 5/200 (2.5%) Mean 2.5% SD 3%
#All Organs: Mesothelioma: Benign, Mali	ignant, NOS			
		1/50 (2%)	1/49 (2%) 1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01% SD 0.02%	Total 0/200 (0%) Mean 0% SD 0%
#All Organs: Mesothelioma: Malignant				
		1/50 (2%)	1/49 (2%) 1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01% SD 0.02%	Total 0/200 (0%) Mean 0% SD 0%
#All Organs: Osteosarcoma				
		0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD 0%	Total 1/200 (0.5%) Mean 0.5% SD 1%
#All Organs: Osteosarcoma or Osteoma				
		0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD 0%	Total 1/200 (0.5%) Mean 0.5% SD 1%

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
*Adrenal Cortex: Adenoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	3/50 (6%)		0/50 (0%) 2/50 (4%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 3%	Total	5/200 (2.5%)	Mean 2.5%	SD 3%
*Adrenal Cortex: Carcinoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Ganglioneuroma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Adrenal Medulla: Pheochromocytoma Benig	jn							
		5/50 (10%)	7/49 (14%) 8/50 (16%)	9/50 (18%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	29/199 (14.57%)	Mean 14.57%	SD 3.4%	Total	4/200 (2%)	Mean 2%	SD 2.83%
*Adrenal Medulla: Pheochromocytoma Comp								
		1/50 (2%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female						
*Adrenal Medulla: Pheochromocytoma Malignant													
		0/50 (0%)	1/49 (2%) 0/50 (0%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)					
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 2.83%	Total	2/200 (1%)	Mean 1%	SD 2%					
*Adrenal Medulla: Pheochromocytoma: Ben		x, Malignant, NOS											
		6/50 (12%)	8/49 (16%) 8/50 (16%)	12/50 (24%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	5/50 (10%)					
Overall Incidence	Total	34/199 (17.09%)	Mean 17.08%	SD 5.01%	Total	6/200 (3%)	Mean 3%	SD 4.76%					
#Bone: Osteosarcoma													
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%					
#Bone: Osteosarcoma or Osteom	na												
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%					
*Brain: Glioma Malignant													
		0/50 (0%)	2/49 (4%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	3/199 (1.51%)	Mean 1.52%	SD 1.95%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%					

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
*Brain: Granular Cell Tumor Bei	nign							
		0/50 (0%)	0/49 (0%) 2/50 (4%)	2/50 (4%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2%	SD 2.31%	Total	2/200 (1%)	Mean 1%	SD 1.15%
*Brain: Granular Cell Tumor Ma	lignant							
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Benign								
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Malignant								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Brain: Meningioma: Benign, Ma	alignant, NOS							
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
Brain: Oligodendroglioma, Gliom	a, or Astroc	ytoma						
		0/50 (0%)	2/49 (4%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.52%	SD 1.95%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Brain: Schwannoma Malignant								
		0/50 (0%)	0/49 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma								
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/197 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	1/49 (2%)		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	1/197 (0.51%)	Mean 0.5%	SD 1%
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%)	1/49 (2%) 0/50 (0%)	1/49 (2%)		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	2/198 (1.01%)	Mean 1.02%	SD 1.18%	Total	1/197 (0.51%)	Mean 0.5%	SD 1%

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
Clitoral/Preputial Gland: Squamous Cell Carcinoma								
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/197 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Papilloma								
		1/50 (2%)	0/49 (0%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.5%	SD 1%	Total	0/197 (0%)	Mean 0%	SD 0%
Epididymis: Sarcoma								
		0/49 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%				
∉Eye: Leiomyoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
'Heart: Schwannoma Malignant								
		2/50 (4%)	2/49 (4%) 0/50 (0%)	1/50 (2%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.52%	SD 1.94%	Total	0/198 (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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Intestine Large: Colon/Red Granular Cell Tumor Ben								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Red Leiomyoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		2/50 (4%)	0/49 (0%) 1/50 (2%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2%	SD 1.63%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Carcinoma								
		2/50 (4%)	0/49 (0%) 1/50 (2%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2%	SD 1.63%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Intestine Small: Site Unspec Carcinoma or Adenoma	cified:							
		2/50 (4%)	0/49 (0%) 1/50 (2%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2%	SD 1.63%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Small: Site Unspec Leiomyosarcoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		2/50 (4%)	4/49 (8%) 5/50 (10%)	3/50 (6%)		3/49 (6%) 1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	14/199 (7.04%)	Mean 7.04%	SD 2.6%	Total	5/199 (2.51%)	Mean 2.53%	SD 2.57%
*Islets, Pancreatic: Carcinoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
*Islets, Pancreatic: Carcinoma or Adenoma								
		2/50 (4%)	4/49 (8%) 5/50 (10%)	3/50 (6%)		3/49 (6%) 1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	14/199 (7.04%)	Mean 7.04%	SD 2.6%	Total	6/199 (3.02%)	Mean 3.03%	SD 2.06%

<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

Species: RATS

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

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
*Kidney: Pelvis and Transitio Papilloma	onal Epitheli	um:						
		0/50 (0%)	0/49 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma								
		1/50 (2%)	1/49 (2%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		1/50 (2%)	1/49 (2%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

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

Vehicle: FEED

**Page:** 115

			Male				Female	
*Kidney: Renal Tubule: Liposarcoma								
		0/50 (0%)	0/49 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma								
		0/50 (0%)	0/49 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Oncocytoma Benign								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Polyp Adenomatous								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lacrimal Gland: Carcinoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
*Liver: Cholangiocarcinoma								
		0/50 (0%)	0/49 (0%) 1/50 (2%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/199 (0%)	Mean 0%	SD 0%
<sup>t</sup> Liver: Cholangioma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%
*Liver: Hemangioma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/199 (1.51%)	Mean 1.51%	SD 1.92%
Liver: Hepatocellular Carcinoma								
		1/50 (2%)	1/49 (2%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
Liver: Hepatocellular Carcino	oma or Hepatobl	astoma						
·	·	1/50 (2%)	1/49 (2%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
*Liver: Hepatocellular Carcino		ellular Adenoma		- 1				
		1/50 (2%)	1/49 (2%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 3/50 (6%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	4/199 (2.01%)	Mean 2.01%	SD 2.83%
*Liver: Hepatocellular Carcino Overall Incidence	oma, Hepatocellu Total	ular Adenoma, or Hepatok 1/50 (2%) 2/199 (1.01%)	0lastoma 1/49 (2%) 0/50 (0%) Mean 1.01%	0/50 (0%) SD 1.17%	Total	1/49 (2%) 3/50 (6%) 4/199 (2.01%)	0/50 (0%) Mean 2.01%	0/50 (0%) SD 2.83%
*Lung: Alveolar/Bronchiolar A	denoma	0/50 (0%)	1/49 (2%)	0/50 (0%)	•••••	0/49 (0%)	0/50 (0%)	0/49 (0%)
*Lung: Alveolar/Bronchiolar A  Overall Incidence	Adenoma Total	0/50 (0%) 1/199 (0.5%)	1/49 (2%) 0/50 (0%) Mean 0.51%	0/50 (0%) SD 1.02%	Total	0/49 (0%) 0/50 (0%) 0/198 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Alveolar/Bronchiolar A	Total	,	0/50 (0%)	,	Total	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** 

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
Lung: Alveolar/Bronchiolar Carcin	noma or Alv	veolar/Bronchiolar Adeno	ma					
		0/50 (0%)	1/49 (2%) 0/50 (0%)	1/50 (2%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/198 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
*Lung: Squamous Cell Carcinoma								
		0/50 (0%)	0/49 (0%) 1/50 (2%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/198 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenolipoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Mammary Gland: Adenoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%
#Mammary Gland: Carcinoma								
		1/50 (2%)	0/49 (0%) 0/50 (0%)	2/50 (4%)		1/50 (2%) 3/50 (6%)	4/50 (8%)	7/50 (14%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	15/200 (7.5%)	Mean 7.5%	SD 5%
#Mammary Gland: Carcinoma or Adenoma								
		1/50 (2%)	0/49 (0%) 0/50 (0%)	2/50 (4%)		2/50 (4%) 4/50 (8%)	4/50 (8%)	7/50 (14%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	17/200 (8.5%)	Mean 8.5%	SD 4.12%
#Mammary Gland: Fibroadenoma								
		2/50 (4%)	1/49 (2%) 2/50 (4%)	2/50 (4%)		28/50 (56%) 21/50 (42%)	33/50 (66%)	32/50 (64%)
Overall Incidence	Total	7/199 (3.52%)	Mean 3.51%	SD 0.98%	Total	114/200 (57%)	Mean 57%	SD 10.89%
#Mammary Gland: Fibroma, Fibroadenoma or A								
		2/50 (4%)	1/49 (2%) 2/50 (4%)	2/50 (4%)		29/50 (58%) 22/50 (44%)	33/50 (66%)	32/50 (64%)
Overall Incidence	Total	7/199 (3.52%)	Mean 3.51%	SD 0.98%	Total	116/200 (58%)	Mean 58%	SD 9.93%

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Mammary Gland: Fibroma, Fibroadenom	a, Carcinoma, o	r Adenoma						
·	,	3/50 (6%)	1/49 (2%) 2/50 (4%)	3/50 (6%)		30/50 (60%) 25/50 (50%)	35/50 (70%)	36/50 (72%)
Overall Incidence	Total	9/199 (4.52%)	Mean 4.51%	SD 1.9%	Total	126/200 (63%)	Mean 63%	SD 10.13%
#Mammary Gland: Myoepithelioma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Nose: Carcinoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Oral Cavity (Oral Mucos Squamous Cell Carcing		ynx, Tooth, Gingiva):						
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	sa, Tongue, Phar	ynx, Tooth, Gingiva): Squamous, or Papilloma						
equament our our our	, - <b></b>	0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male					Female	
#Oral Mucosa: Squamous Cell Carcino	oma								
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50	(0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%		Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma									
							0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence						Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor	Benign						1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence						Total	2/200 (1%)	Mean 1%	SD 1.15%
Ovary: Granulosa Cell Tumor	Malignant								
							1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence						Total	1/200 (0.5%)	Mean 0.5%	SD 1%
'Ovary: Granulosa Cell Tumor:	Benign, Maligna	ant, NOS							
							2/50 (4%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence						Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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	Male			Female	
*Ovary: Granulosa-Theca Tumor Benign					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Schwannoma Malignant			•••••	•••••	
			0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence		Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Ovary: Sertoli Cell Tumor Benign					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
Ovary: Thecoma Benign								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
Ovary: Tubulostromal Carcinoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma								
		10/50 (20%)	4/49 (8%) 3/50 (6%)	5/50 (10%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	22/199 (11.06%)	Mean 11.04%	SD 6.19%	Total	0/199 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma								
		0/50 (0%)	2/49 (4%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.02%	SD 2.04%	Total	0/199 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
		10/50 (20%)	6/49 (12%) 3/50 (6%)	5/50 (10%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	24/199 (12.06%)	Mean 12.06%	SD 5.89%	Total	0/199 (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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female		
*Parathyroid Gland: Adenoma									
		0/42 (0%)	0/48 (0%) 0/41 (0%)	0/49 (0%)		0/42 (0%) 0/47 (0%)	0/45 (0%)	1/41 (2%)	
Overall Incidence	Total	0/180 (0%)	Mean 0%	SD 0%	Total	1/175 (0.57%)	Mean 0.61%	SD 1.22%	
#Peripheral Nerve: Paraganglioma									
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%	
#Peripheral Nerve: Schwannoma Malignant									
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%	
#Peripheral Nerve: Schwannoma: Benign, M	lalignant, NOS								
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%	
*Pituitary Gland: Pars Dista Adenoma									
		4/50 (8%)	15/48 (31%) 5/50 (10%)	14/50 (28%)		15/49 (31%) 22/50 (44%)	12/50 (24%)	19/50 (38%)	
Overall Incidence	Total	38/198 (19.19%)	Mean 19.31%	SD 12.01%	Total	68/199 (34.17%)	Mean 34.15%	SD 8.71%	

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female				
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma											
		0/50 (0%)	0/48 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%			
*Pituitary Gland: Pars Dis Carcinoma or Adenoma	talis or Unspec										
		4/50 (8%)	15/48 (31%) 5/50 (10%)	14/50 (28%)		16/49 (33%) 22/50 (44%)	13/50 (26%)	19/50 (38%)			
Overall Incidence	Total	38/198 (19.19%)	Mean 19.31%	SD 12.01%	Total	70/199 (35.18%)	Mean 35.16%	SD 7.67%			
*Pituitary Gland: Pars Inte Adenoma											
		0/50 (0%)	0/48 (0%) 0/50 (0%)	2/50 (4%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/198 (1.01%)	Mean 1%	SD 2%	Total	0/199 (0%)	Mean 0%	SD 0%			
*Pituitary Gland: Pars Inte Carcinoma or Adenoma											
		0/50 (0%)	0/48 (0%) 0/50 (0%)	2/50 (4%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/198 (1.01%)	Mean 1%	SD 2%	Total	0/199 (0%)	Mean 0%	SD 0%			
*Pituitary Gland: Pars Ner Schwannoma Malignan	rvosa:										
		0/50 (0%)	0/48 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
Prostate: Adenoma								
		0/50 (0%)	1/49 (2%) 3/50 (6%)	0/50 (0%)				
Overall Incidence	Total	4/199 (2.01%)		SD 2.83%				
*Prostate: Carcinoma or Adenoma								
		0/50 (0%)	1/49 (2%) 3/50 (6%)	0/50 (0%)				
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 2.83%				
*Salivary Glands: Schwannoma Malignant								
		2/50 (4%)	0/49 (0%) 0/49 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	2/198 (1.01%)	Mean 1%	SD 2%	Total	0/196 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Hemangiosarcoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangioma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Skeletal Muscle: Liposarcoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		1/50 (2%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
		0/50 (0%)	1/49 (2%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or		s Tumor Benign						
		0/50 (0%)	1/49 (2%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin:		Fumor Benign, or Trichoe						
,		1/50 (2%)	1/49 (2%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	0/200 (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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female			
#Skin: Basal Cell Carcinoma										
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%		
∜Skin: Basal Cell Carcinoma o	or Basosquamo	us Tumor (malignant or N 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%		
	Basal Cell Ader	noma, Basosquamous Tui	mor (benign, maligna	nt or						
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		•	, , ,			0/50 (09/)	0/50 (09/)	0/50 (09/)		
Basal Cell Carcinoma, NOS), or Trichoepitheli	ioma	1/50 (2%)	1/49 (2%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		
Basal Cell Carcinoma,		•	1/49 (2%)		Total	` '	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carci	Total	1/50 (2%)	1/49 (2%) 1/50 (2%) Mean 1.51%	0/50 (0%) SD 1.01%	Total	0/50 (0%)	(3.1.)	(-11)		
Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence *Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, S	Total	1/50 (2%) 3/199 (1.51%) na, Basosq. Tumor (M or leratoacanthoma, Trichoe	1/49 (2%) 1/50 (2%) Mean 1.51% B), Basal Cell Adenon pithelioma 9/49 (18%)	0/50 (0%) SD 1.01%	Total Total	0/50 (0%) 0/200 (0%) 1/50 (2%)	Mean 0%	SD 0%		
Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carci	Total Total noma, Carcinon q Papilloma, Ka	1/50 (2%) 3/199 (1.51%)  na, Basosq. Tumor (M or leratoacanthoma, Trichoep 4/50 (8%)	1/49 (2%) 1/50 (2%) Mean 1.51% B), Basal Cell Adenon pithelioma 9/49 (18%) 6/50 (12%)	0/50 (0%) SD 1.01% na, 4/50 (8%)		0/50 (0%) 0/200 (0%) 1/50 (2%) 0/50 (0%)	Mean 0%  0/50 (0%)	SD 0% 0/50 (0%)		
Basal Cell Carcinoma, NOS), or Trichoepitheli  Overall Incidence  #Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, So	Total Total noma, Carcinon q Papilloma, Ka	1/50 (2%) 3/199 (1.51%)  na, Basosq. Tumor (M or leratoacanthoma, Trichoep 4/50 (8%)	1/49 (2%) 1/50 (2%) Mean 1.51% B), Basal Cell Adenon pithelioma 9/49 (18%) 6/50 (12%)	0/50 (0%) SD 1.01% na, 4/50 (8%)		0/50 (0%) 0/200 (0%) 1/50 (2%) 0/50 (0%)	Mean 0%  0/50 (0%)	SD 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

#Skin:

#Skin:

#Skin:

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Hemangiopericytoma

Overall Incidence

**Overall Incidence** 

**Fibrosarcoma** 

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

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Male Female Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, Malignant Fibrous Histiocytoma, or 4/49 (8%)1/50 (2%)(2%)0/50 (0%)(6%)1/50 2/50 (4%)1/50 (2%)Mean 6.04% SD 1.7% Total 3/200 (1.5%) Mean 1.5% SD 1% ..... Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma 4/49 (8%)3/50 (6%)1/50 (2%)1/50 (2%)0/50 (0%)2/50 (4%)1/50 (2%)Mean 6.04% SD 1.7% 3/200 (1.5%) SD 1% Total Mean 1.5%

(2%)

(2%)

(2%)

0/50

1/50

(0%)

(2%)

0/50

0/50

SD 1%

(0%)

(0%)

1/50

1/50

1/50

			1/50 (2%)			0/50 (0%)	
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	1/200 (0.5%)	Mean 0.5%
#Skin:							

(2%)

(2%)

(2%)

1/49

1/50

Fibrosarcoma, Sarcoma, Myxosarcoma, or	Malignant I	Fibrous I	Histiocytoma
	0/50	(0%)	1/49

Total

Total

3/50

12/199 (6.03%)

3/50

12/199 (6.03%)

0/50

(6%)

(6%)

(0%)

Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
#Skin: Hemangioma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

0/50

0/50

(0%)

(0%)

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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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Skin: Hemangiopericytoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma								
		2/50 (4%)	8/49 (16%) 5/50 (10%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	17/199 (8.54%)	Mean 8.58%	SD 5.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Lipoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	2/50 (4%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Liposarcoma								
		1/50 (2%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Skin: Malignant Fibrous Hist	tiocytoma							
C	•	0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Neurofibrosarcoma or								
		2/50 (4%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Overall Incidence	Total	Schwannoma (benign, ma 2/50 (4%) 2/199 (1.01%)	0/49 (0%) 0/50 (0%) Mean 1%	0/50 (0%) SD 2%	Total	1/50 (2%) 0/50 (0%) 2/200 (1%)	1/50 (2%) Mean 1%	0/50 (0%) SD 1.15%
#Skin: Osteosarcoma		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Pilomatrixoma								
		0/50 (0%)	3/49 (6%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.53%	SD 3.06%	Total	0/200 (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: PERINATAL AND POSTNATAL

Vehicle: FEED

**Page:** 132

			Male	Female
≮Skin: Sarcoma				
		0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD 0%	Total 1/200 (0.5%) Mean 0.5% SD 1%
#Skin: Schwannoma Malignant				
		2/50 (4%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1% SD 2%	Total 2/200 (1%) Mean 1% SD 1.15%
#Skin: Squamous Cell Carcinoma				
		1/50 (2%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5% SD 1%	Total 1/200 (0.5%) Mean 0.5% SD 1%
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell	Carcinoma, Basosquamo	ous Tumor (malignant or NOS), 0/49 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5% SD 1%	Total 1/200 (0.5%) Mean 0.5% SD 1%
#Skin: Squamous Cell Papilloma				
- 4		0/50 (0%)	0/49 (0%) 2/50 (4%) 0/50 (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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Skin: Squamous Cell Papilloma	or Papilloma	a						
	·	0/50 (0%)	0/49 (0%) 0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma						1/50 (2%)	0/50 (0%)	0/50 (0%)
		3/30 (0/0)	5/50 (10%)	4/30 (0/0)		0/50 (0%)	0/30 (0/0)	0/30 (0/0)
Overall Incidence	Total	20/199 (10.05%)	Mean 10.08%	SD 4.47%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Squamous Cell Papilloma	, <b>Papilloma</b> , o	or Keratoacanthoma 2/50 (4%) 19/199 (9.55%)	8/49 (16%) 5/50 (10%) Mean 9.58%	4/50 (8%) SD 5.14%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Trichoepithelioma		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		(=,,,	0/50 (0%)	(4,4)		0/50 (0%)	(-7-5)	(575)
								OD 00/
	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
					Total			
#Skin: Sebaceous Gland:		` /		,,	Total	0/200 (0%) 0/50 (0%) 0/50 (0%)	Mean 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: PERINATAL AND POSTNATAL

Vehicle: FEED

**Page**: 134

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Malignant								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Spleen: Hemangiosarcoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%
#Stomach, Forestomach: Sarcoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 135

			Male				Female					
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous												
·	•	0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%				
#Stomach, Forestomach: Squamous Cell Papilloma												
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%				
Testis: Adenoma												
		3/49 (6%)	2/49 (4%) 0/50 (0%)	1/50 (2%)								
Overall Incidence	Total	6/198 (3.03%)	Mean 3.05%	SD 2.64%								
Thymus: Thymoma Benign												
		0/47 (0%)	0/48 (0%) 0/48 (0%)	0/46 (0%)		0/46 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)				
Overall Incidence	Total	0/189 (0%)	Mean 0%	SD 0%	Total	0/193 (0%)	Mean 0%	SD 0%				
Thymus: Thymoma Malignant												
-		0/47 (0%)	0/48 (0%) 0/48 (0%)	0/46 (0%)		0/46 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)				
Overall Incidence	Total	0/189 (0%)	Mean 0%	SD 0%	Total	0/193 (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: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 136

			Male				Female	
*Thymus: Thymoma: Benign, Maligna	ant, NOS							
		0/47 (0%)	0/48 (0%) 0/48 (0%)	0/46 (0%)		0/46 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/189 (0%)	Mean 0%	SD 0%	Total	0/193 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma								
		10/50 (20%)	8/49 (16%) 11/49 (22%)	7/50 (14%)		8/49 (16%) 9/50 (18%)	12/50 (24%)	5/50 (10%)
Overall Incidence	Total	36/198 (18.18%)	Mean 18.19%	SD 3.76%	Total	34/199 (17.09%)	Mean 17.08%	SD 5.76%
*Thyroid Gland: C-Cell: Carcinoma								
		1/50 (2%)	1/49 (2%) 0/49 (0%)	1/50 (2%)		0/49 (0%) 1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	3/198 (1.52%)	Mean 1.51%	SD 1.01%	Total	3/199 (1.51%)	Mean 1.5%	SD 1%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		10/50 (20%)	8/49 (16%) 11/49 (22%)	8/50 (16%)		8/49 (16%) 9/50 (18%)	13/50 (26%)	6/50 (12%)
Overall Incidence	Total	37/198 (18.69%)	Mean 18.69%	SD 3.09%	Total	36/199 (18.09%)	Mean 18.08%	SD 5.85%
*Thyroid Gland: Follicular Ce Adenoma								
		0/50 (0%)	1/49 (2%) 0/49 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/199 (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: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 137

			Male				Female	
*Thyroid Gland: Follicular Cell Carcinoma	:							
		0/50 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma								
		0/50 (0%)	1/49 (2%) 0/49 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/198 (0.51%)		SD 1.02%	Total	0/199 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma o	r Papillom	na Squamous						
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 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: 02/17/2020

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

			Male				Female	
#Tooth: Odontoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Urinary Bladder: Leiomyosarcoma								
		0/50 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
#Uterus: Adenocarcinoma						3/50 (6%)	1/50 (2%)	5/50 (10%)
						1/50 (2%)	1730 (270)	3/30 (10/0)
Overall Incidence					Total	10/200 (5%)	Mean 5%	SD 3.83%
Uterus: Adenocarcinoma or Ad	lenoma							
						3/50 (6%) 2/50 (4%)	1/50 (2%)	5/50 (10%)
Overall Incidence					Total	11/200 (5.5%)	Mean 5.5%	SD 3.42%
#Uterus: Adenoma								
						0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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	Male		Female
#Uterus: Deciduoma Benign			
		1/50 (2%) 0/5 0/50 (0%)	50 (0%) 0/50 (0%)
Overall Incidence	Tota	, ,	Mean 0.5% SD 1%
#Uterus: Granular Cell Tumor Benign			
		1/50 (2%) 0/5 0/50 (0%)	50 (0%) 0/50 (0%)
Overall Incidence	Total	al 1/200 (0.5%) N	Mean 0.5% SD 1%
#Uterus: Polyp Stromal			
		8/50 (16%) 5/5 16/50 (32%)	50 (10%) 8/50 (16%)
Overall Incidence	Tota		Mean 18.5% SD 9.43%
#Uterus: Sarcoma			
		0/50 (0%) 0/5 0/50 (0%)	50 (0%) 0/50 (0%)
Overall Incidence	Tota	` '	Mean 0% SD 0%
#Uterus: Sarcoma Stromal			
		0/50 (0%) 1/5 1/50 (2%)	50 (2%) 0/50 (0%)
Overall Incidence	Tota	• ,	Mean 1% SD 1.15%

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

**Page:** 140

	Male			Female	
#Uterus: Sarcoma Stromal or Polyp Stromal					
			8/50 (16%) 16/50 (32%)	6/50 (12%)	8/50 (16%)
Overall Incidence		Total	38/200 (19%)	Mean 19%	SD 8.87%
Uterus: Schwannoma Malignant					
			1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Uterus: Squamous Cell Carcinoma					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
Vagina: Granular Cell Tumor Benign					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
₹Vagina: Polyp					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
Vagina: Schwannoma Malignant								
						1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Zymbal's Gland: Carcinoma								
		1/50 (2%)	1/49 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/200 (0%)	Mean 0%	SD 0%
≠Zymbal's Gland: Carcinoma or Adenoma								
		1/50 (2%)	1/49 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/200 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

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Report Date: 02/17/2020

#### **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	050303803	01/30/12	729	50(2)	12(621)	610.8	Sodium Tungstate Dihydrate
					Female		
Battelle Columbus Laboratory	050303803	01/31/12	730	50(5)	30(667)	393.3	Sodium Tungstate Dihydrate

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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	Male					Female			
#All Organs: Benign Tumors									
		29/50 (58%)				39/50 (78%)			
Overall Incidence	Total	29/50 (58%)	Mean 58%	SD 0%	Total	39/50 (78%)	Mean 78%	SD 0%	
#All Organs: Malignant Tumors									
		14/50 (28%)				17/50 (34%)			
Overall Incidence	Total	14/50 (28%)	Mean 28%	SD 0%	Total	17/50 (34%)	Mean 34%	SD 0%	
#All Organs: Malignant and Benign To	umors	36/50 (72%)				47/50 (94%)			
Overall Incidence	Total	36/50 (72%)	Mean 72%	SD 0%	Total	47/50 (94%)	Mean 94%	SD 0%	
#All Organs: Hemangioma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma									
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma or He	emangioma	1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

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				Female				
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Granulocytic								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic, M Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Malignant Lymphoma: Hist	iocytic, Lymp					2/50 (4%)		
• " ' ' '		4 (50 (00()		OD 00/	<b>-</b>	0/50 (40/)	10/	00 00/
	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
								SD 0%
#All Organs: Malignant Schwannoma		1/50 (2%)				2/50 (4%)		
#All Organs: Malignant Schwannoma								SD 0% SD 0%
#All Organs: Malignant Schwannoma  Overall Incidence  #All Organs: Mesothelioma: Benign, Mal	Total	1/50 (2%) 1/50 (2%)				2/50 (4%)		
#All Organs: Malignant Schwannoma Overall Incidence #All Organs:	Total	1/50 (2%) 1/50 (2%)				2/50 (4%)		

<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: PERINATAL AND POSTNATAL

Vehicle: WATER

Page: 145

		Male	Female				
	0/50 (0%)				0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
	0/50 (0%)				1/50 (2%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	0/50 (0%)				0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	4/50 (00%)				0/50 (00/)		
Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
	Total  Total  Total	Total 0/50 (0%)  0/50 (0%)  Total 0/50 (0%)  0/50 (0%)  Total 1/50 (2%)	0/50 (0%) Total 0/50 (0%) Mean 0%  0/50 (0%) Total 0/50 (0%) Mean 0%	O/50 (0%)         Mean 0%         SD 0%           Total         0/50 (0%)         Mean 0%         SD 0%	Total 0/50 (0%) Mean 0% SD 0% Total  Total 0/50 (0%) Mean 0% SD 0% Total	O/50 (0%)         Mean 0%         SD 0%         Total         O/50 (0%)           Total         O/50 (0%)         Mean 0%         SD 0%         Total         1/50 (2%)           Total         O/50 (0%)         Mean 0%         SD 0%         Total         1/50 (2%)           Total         O/50 (0%)         Mean 0%         SD 0%         Total         1/50 (2%)           Total         O/50 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)           Total         O/50 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)           Total         O/50 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)           Total         O/50 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%)  Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2%  Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2%  Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2%  Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 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: PERINATAL AND POSTNATAL

Vehicle: WATER

**Page:** 146

		Male		Female				
ign								
_	10/50 (20%)				1/50 (2%)			
Total	10/50 (20%)	Mean 20%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
nplex								
	0/50 (0%)				0/50 (0%)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
ignant	2/50 (4%)				1/50 (2%)			
Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
	Malignant, NOS				2/50 (4%)			
Total	12/50 (24%)	Mean 24%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
	•••••							
	0/50 (0%)				0/50 (0%)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
na	0/50 (00/)				0/50 (00/)			
Total	` ,	Moon 09/	SD 00/	Total	` '	Moon 09/	SD 0%	
	Total  nplex  Total  ignant  Total  nign, Complex,  Total	10/50 (20%) Total 10/50 (20%)  nplex  0/50 (0%)  Total 0/50 (0%)  ignant  2/50 (4%)  Total 2/50 (4%)  nign, Complex, Malignant, NOS 12/50 (24%)  Total 12/50 (24%)  Total 0/50 (0%)  Total 0/50 (0%)	10/50 (20%) Total 10/50 (20%) Mean 20%  nplex  0/50 (0%) Total 0/50 (0%) Mean 0%  ignant  2/50 (4%) Total 2/50 (4%) Mean 4%  nign, Complex, Malignant, NOS 12/50 (24%) Total 12/50 (24%) Mean 24%  0/50 (0%)  Total 0/50 (0%)  Mean 0%	10/50 (20%) Total 10/50 (20%) Mean 20% SD 0%  nplex  0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%  ignant  2/50 (4%) Total 2/50 (4%) Mean 4% SD 0%  nign, Complex, Malignant, NOS 12/50 (24%) Total 12/50 (24%) Mean 24% SD 0%  Total 0/50 (0%)  Total 0/50 (0%)  Mean 0% SD 0%	Total   10/50 (20%)   Mean 20%   SD 0%   Total	10/50 (20%)   Mean 20%   SD 0%   Total   1/50 (2%)   Total   10/50 (20%)   Mean 20%   SD 0%   Total   1/50 (2%)   Mean 20%   SD 0%   Total   1/50 (2%)   Mean 20%   SD 0%   Total   0/50 (0%)   Total   0/50 (0%)   Mean 0%   SD 0%   Total   0/50 (0%)   Mean 20%   SD 0%   Total   1/50 (2%)   Mean 20%   SD 0%   Total   1/50 (4%)   Mean 20%   SD 0%   Total   1/50 (4%)   Mean 20%   SD 0%   Total   1/50 (4%)   Mean 20%   SD 0%   Total   1/50 (0%)   Mean 20%   SD 0%   Total   1/50 (0%)	10 50 (20%)   10 50 (20%)   Mean 20%   SD 0%   Total   1/50 (2%)   Mean 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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female				
*Brain: Glioma Malignant											
_		2/50 (4%	b)			0/50 (0%)					
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Brain: Granular Cell Tumor Benig	gn										
	_	0/50 (0%	b)			0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Brain: Granular Cell Tumor Malig	ınant	1/50 (2%	.)			0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Brain: Meningioma Benign		0/50 (0%				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Brain: Meningioma Malignant											
		0/50 (0%	,	05 00/		0/50 (0%)		05 00/			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Brain: Meningioma: Benign, Mali	gnant, NOS										
Overall Institutes	Tatal	0/50 (0%	,	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

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				Male				Female	
*Brain: Oligodendroglioma, Glioma,	or Astrocy	toma							
			(4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant									
			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma		0/50	(00()				0/50 (00/)		
Overall Incidence	Total		(0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
		0/50 (0%)					0/50 (0%)		3D 0%
*Clitoral/Preputial Gland: Carcinoma		0/50	(00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma									
			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma									
			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Epididymis: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
				35 0/0				
#Eye: Leiomyoma		0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		` '					IVICALI U/0	
*Heart: Schwannoma Malignant		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Intestine Large: Colon/Rec Granular Cell Tumor Beni	tum:							
	_	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rec Leiomyoma	tum:							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#Intestine Small: Jejunum: Carcinoma						,		
Overall Incidence	Total	1/50 (29 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma							•••••	
Overall Incidence	Total	0/50 (09 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Carcinoma								
Overall Incidence	Total	1/50 (29) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Carcinoma or Adenoma						0/50 (00/)		
Overall Incidence	Total	1/50 (29 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Leiomyosarcoma							•••••	
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma		0/50 ///	····			4/50 (004)		
Overall Incidence	Total	2/50 (4%)	%) Mean 4%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male			Female			
*Islets, Pancreatic: Carcinoma									
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Islets, Pancreatic: Carcinoma or Adenoma									
		3/50 (6%)				2/50 (4%)			
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Kidney: Pelvis and Transitio Papilloma	nal Epitheliu								
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Adenoma									
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma or Adenoma									
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
*Kidney: Renal Tubule: Lipoma		0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Oncocytoma Benign		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Polyp Adenomatous		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lacrimal Gland: Carcinoma		0/50 (001)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

**Page:** 153

				Male			Female			
*Liver: Cholangiocarcinoma										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		` ,								
*Liver: Cholangioma										
			(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hemangioma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver:  Hepatocellular Adenoma  Overall Incidence	Total		(2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Liver: Hepatocellular Carcinoma			(0%)				` '			
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Carcinoma o	r Hepatobla		(224)				(00)			
Overall Incidence	Total		(0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan 00/	CD 00/	
	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

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				Male			Female				
*Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma  1/50 (2%)  1/50 (2%)											
Overall Incidence	Total	1/50 1/50 (2%)	` ,	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
*Liver: Hepatocellular Carcino	ma, Hepatocellul	•	•	lastoma			4/50 (00)				
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
*Lung: Alveolar/Bronchiolar Ad		1/50	(2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	(270)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Lung: Alveolar/Bronchiolar Ca		1/50	(2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	` '	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Lung: Alveolar/Bronchiolar Ca	arcinoma or Alve	eolar/Bronchiola 2/50	ar Adenon (4%)	na			0/50 (0%)				
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Lung: Sarcoma											
Overall Incidence	Total	0/50 0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male			Female			
*Lung: Squamous Cell Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Hemangiosarcoma		•••••				•••••			
Tiemangiosarooma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Adenolipoma		0/50 (00)				0/50			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Adenoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	
#Mammary Gland: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	
#Mammary Gland: Carcinoma or Adenoma		0/50 (0%)				5/50 (10%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	5/50 (10%)	Mean 10%	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: PERINATAL AND POSTNATAL

Vehicle: WATER

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				Male			Female					
#Mammary Gland: Fibroadenoma												
		0/50 (0	1%)			30/50 (60%)						
Overall Incidence	Total	0/50 (0%)	Mean		5 Total	30/50 (60%)	Mean 60%	SD 0%				
#Mammary Gland: Fibroma, Fibroadenon	na or Adenoma											
•		0/50 (0	%)			32/50 (64%)						
Overall Incidence	Total	0/50 (0%)	Mean	0% SD 0%	5 Total	32/50 (64%)	Mean 64%	SD 0%				
#Mammary Gland: Fibroma, Fibroadenon	,	0/50 (0	%)			34/50 (68%)						
Overall Incidence	Total	0/50 (0%)	Mean			34/50 (68%)	Mean 68%	SD 0%				
#Mammary Gland: Myoepithelioma						0/50 (00/)						
Overall Incidence	Total	0/50 (0 0/50 (0%)	Mean			()	Mean 0%	SD 0%				
*Nose: Carcinoma												
		0/50 (0	1%)			0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean	0% SD 0%	6 Total	0/50 (0%)	Mean 0%	SD 0%				
#Oral Cavity (Oral Muco		nx, Tooth, Gingiva	a):									
Squamous Cell Carcin												
Squamous Cell Carcin		0/50 (0	l%)			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** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

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

Vehicle: WATER

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			Male				Female	
#Oral Cavity (Oral Mucos Squamous Cell Carcino		/nx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcino		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor	Benign					0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor	Malignant							
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Granulosa Cell Tumor:	Benign, Maligna	nt, NOS				1/50 (2%)		
Overall Incidence					Total	1/50 (2%)	Mean 2%	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: PERINATAL AND POSTNATAL

Vehicle: WATER

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	Male			Female	
*Ovary: Granulosa-Theca Tumor Benign					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant					
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Luteoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Schwannoma Malignant					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Sertoli Cell Tumor Benign					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Thecoma Benign					
Overall Incidence		Total	0/50 (0%) 0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
*Ovary: Tubulostromal Carcinoma						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma								
	<b>.</b>	14/50 (28%)		00.00/	<b>-</b>	0/50 (0%)		<b>OD</b> 00/
Overall Incidence	Total	14/50 (28%)	Mean 28%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	14/50 (28%) 14/50 (28%)	Mean 28%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
		0/43 (0%)				0/46 (0%)		
Overall Incidence	Total	0/43 (0%)	Mean 0%	SD 0%	Total	0/46 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Paraganglioma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#Peripheral Nerve: Schwannoma Malignan	nt							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign,	Malignant, NOS							
•		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Adenoma	stalis or Unspeci					46/50 (200/)		
Overall Incidence	Total	8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%	Total	16/50 (32%) 16/50 (32%)	Mean 32%	SD 0%
						, ,		
*Pituitary Gland: Pars Dis Carcinoma	stalis or Unspeci	ried Site:						
our official		1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Pituitary Gland: Pars Dis								
Carcinoma or Adenoma	a							
		9/50 (18%)				17/50 (34%)		
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	17/50 (34%)	Mean 34%	SD 0%
*Pituitary Gland: Pars Into Adenoma	ermedia:							
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

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				Male				Female	
*Pituitary Gland: Pars Intermo	edia:								
		1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Nervos Schwannoma Malignant									
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma		0/50	(00/)						
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma		0/50	(0%)						
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%				
*Salivary Glands: Schwannoma Malignant									
_		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Hemangiosarcoma		1/50	(2%)						
Overall Incidence	Total	1/50 (2%)	(~ /0)	Mean 2%	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: PERINATAL AND POSTNATAL

Vehicle: WATER

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				Male				Female	
#Skeletal Muscle: Hemangioma		0/50 (	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Liposarcoma		0/50 (	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma		0/50 //	(00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma		0/50 (	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(0 70)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or E	3asosquamous	_	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Bas		umor Benign, or T					0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	( - · <del>- /</del>	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

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

on: Nov2019

Contract/Lab: All Laboratories

Species: RATS

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

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

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male			Female		
#Skin: Basal Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Carcinoma	or Basosquamou	s Tumor (malignant or N	NOS)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin:	• • • • • • • • • • • • • • • • • • • •		•••••					
Basal Cell Carcinoma, NOS), or Trichoepithel		oma, Basosquamous Tu	mor (benign, maligna	ant or				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Adenoma, Papilloma, S		a, Basosq. Tumor (M or ratoacanthoma, Trichoe 1/50 (2%)	pithelioma	·		0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:								
Fibroma								
Fibroma Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
Overall Incidence #Skin:	•••••	3/50 (6%)			Total	1/50 (2%)	Mean 2%	SD 0%
Overall Incidence #Skin: Fibroma, Fibrosarcom	•••••	3/50 (6%)			Total Total	` ,	Mean 2%  Mean 6%	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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male			Female		
#Skin: Fibroma, Fibrosarcoma, \$	Sarcoma, Myxc	oma, Myxosarcoma, or M 3/50 (6%)	Malignant Fibrous His	stiocytoma		2/50 (4%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Skin: Fibrosarcoma						(20)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Fibrosarcoma, Sarcoma,						1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangiopericytoma		0/50 (00/)				4/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

**Page:** 165

			Male Female					
#Skin: Keratoacanthoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Malignant Fibrous Hist		0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
						( ,		
#Skin: Neurofibrosarcoma or	Schwannoma (m	alignant or NOS) 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Ne	eurofibroma, or S	chwannoma (benign, m	alignant or NOS)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#Skin: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Pilomatrixoma								
		0/50 (0%)		<b>OD</b> 40/		0/50 (0%)	••	25. 22/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignant								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma								
·		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma,	Basal Cell (	Parcinoma Basosquam	nous Tumor (malignar	ot or NOS)				
or Carcinoma			iouo ruilloi (munghai	,,				
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

Page: 167

			Male				Female	
#Skin: Squamous Cell Papillor	ma							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillor	ma or Papilloma							
oquamous con r apmon	na or r apmoma	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillor Overall Incidence	ma, Papilloma, So Total	quamous Cell Carcinom 1/50 (2%) 1/50 (2%)	a or Keratoacanthor  Mean 2%	na SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillor Overall Incidence		r Keratoacanthoma 1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Trichoepithelioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

Page: 168

				Male			Female			
#Skin: Sebaceous Gland: Carcinoma or Adenoma										
	<b>-</b>		(0%)		<b>OD</b> 00/	<b></b>	0/50 (0%)		<b>OD</b> 00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Spinal Cord: Astrocytoma Malignant		0.770	(224)				2/22 (22)			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Spleen: Hemangiosarcoma		0/50	(00/)				0/50 (00/)			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
				······				······		
#Stomach, Forestomach: Sarcoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Carcinoma										
•		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papilloma		(09/)				0/50 (0%)			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

Page: 169

			Male				Female		
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Testis: Adenoma		1/50 (2%)							
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%					
*Thymus: Thymoma Benign		0/48 (0%)				0/47 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma Malignant		0/48 (0%)				0/47 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma: Benign, Malignar	nt, NOS	0/48 (0%)				0/47 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Adenoma		4/50 (8%)				5/50 (10%)			
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	5/50 (10%) 5/50 (10%)	Mean 10%	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: PERINATAL AND POSTNATAL

Vehicle: WATER

Page: 170

				Male				Female	
*Thyroid Gland: C-Cell: Carcinoma									
		0/50	(0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
		4/50	(8%)		05 00/		7/50 (14%)		05.00/
Overall Incidence	Total	4/50 (8%)		Mean 8%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%
*Thyroid Gland: Follicular Cell Adenoma	:	0/50	(00()				0/50 (00/)		
Overall Incidence	Total	0/50	(0%)	Maan OO/	SD 0%	Total	0/50 (0%)	Maan 00/	SD 0%
	Total	0/50 (0%)		Mean 0%	3D 0%	Total	0/50 (0%)	Mean 0%	טיי עכ
*Thyroid Gland: Follicular Cell Carcinoma	:	0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

Page: 171

			Male				Female	
#Tongue: Squamous Cell Carcinon	na					,		
·		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinon		a Squamous		•••••		•••••		
oquamous cen caromon	na or r apmome	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		0/50 (00)				0/50 (00/)		
	<b>-</b>	0/50 (0%)		<b>OD</b> 00/	<b>-</b>	0/50 (0%)		<b>OD</b> 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Adenocarcinoma								
						3/50 (6%)		
Overall Incidence					Total	3/50 (6%)	Mean 6%	SD 0%
#Uterus: Adenocarcinoma or Ade	noma							
						3/50 (6%)		
Overall Incidence					Total	3/50 (6%)	Mean 6%	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: PERINATAL AND POSTNATAL

Vehicle: WATER

Page: 172

	Male			Female	
#Uterus: Adenoma			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Deciduoma Benign			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Granular Cell Tumor Benign			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal			5/50 (10%)		
Overall Incidence		Total	5/50 (10%)	Mean 10%	SD 0%
#Uterus: Sarcoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal			1/50 (2%)		
Overall Incidence		Total	1/50 (2%)	Mean 2%	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: PERINATAL AND POSTNATAL

Vehicle: WATER

**Page:** 173

	Male			Female	
#Uterus: Sarcoma Stromal or Polyp Stromal			0/50 /400/		
Overall Incidence		Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%
#Uterus: Schwannoma Malignant			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Squamous Cell Carcinoma			2/50 (4%)		
Overall Incidence		Total	2/50 (4%)	Mean 4%	SD 0%
#Vagina: Granular Cell Tumor Benign			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Vagina: Polyp					
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Vagina: Schwannoma Malignant			0/50 (00/)		
Overall Incidence		Total	0/50 (0%) 0/50 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

Page: 174

			Male				Female	
#Zymbal's Gland: Carcinoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (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: Whole Body Exposure

Vehicle: AIR

# **Page:** 175

Report Date: 02/17/2020

### **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		
I. I. T. Research Institute	052010556	09/16/12	730	90(1)	25(642)	658.1	Radiofrequency Radiation
					Female		
I. I. T. Research Institute	052010556	09/16/12	737	90(1)	48(659)	462.4	Radiofrequency Radiation

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: Whole Body Exposure

Vehicle: AIR

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			Male			Female			
#All Organs: Benign Tumors									
· ·		49/90 (54%)				82/90 (91%)			
Overall Incidence	Total	49/90 (54.44%)	Mean 54.44%	SD 0%	Total	82/90 (91.11%)	Mean 91.11%	SD 0%	
#All Organs: Malignant Tumors									
		24/90 (27%)				37/90 (41%)			
Overall Incidence	Total	24/90 (26.67%)	Mean 26.67%	SD 0%	Total	37/90 (41.11%)	Mean 41.11%	SD 0%	
#All Organs: Malignant and Benign To	umors	57/90 (63%)				89/90 (99%)			
Overall Incidence	Total	57/90 (63.33%)	Mean 63.33%	SD 0%	Total	89/90 (98.89%)	Mean 98.89%	SD 0%	
#All Organs: Hemangioma		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma									
		3/90 (3%)				3/90 (3%)			
Overall Incidence	Total	3/90 (3.33%)	Mean 3.33%	SD 0%	Total	3/90 (3.33%)	Mean 3.33%	SD 0%	
#All Organs: Hemangiosarcoma or He	emangioma	3/90 (3%)				3/90 (3%)			
Overall Incidence	Total	3/90 (3.33%)	Mean 3.33%	SD 0%	Total	3/90 (3.33%)	Mean 3.33%	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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
#All Organs: Histiocytic Sarcoma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Granulocytic								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic, N	lonocytic, Mo	ononuclear, or Undiffere	ntiated			0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#All Organs: Malignant Lymphoma: His						5/90 (6%)		
						0/00 (0/0)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	5/90 (5.56%)	Mean 5.56%	SD 0%
Overall Incidence #All Organs: Malignant Schwannoma	Total		Mean 2.22%	SD 0%	Total	5/90 (5.56%)	Mean 5.56%	SD 0%
#All Organs: Malignant Schwannoma		3/90 (3%)				5/90 (5.56%) 4/90 (4%)		
#All Organs: Malignant Schwannoma	Total  Total		Mean 2.22% Mean 3.33%	SD 0%	Total Total	5/90 (5.56%)	Mean 5.56% Mean 4.44%	SD 0%
#All Organs:	Total	3/90 (3%) 3/90 (3.33%)				5/90 (5.56%) 4/90 (4%)		
#All Organs: Malignant Schwannoma Overall Incidence #All Organs:	Total	3/90 (3%) 3/90 (3.33%)				5/90 (5.56%) 4/90 (4%)		

<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: Whole Body Exposure

Vehicle: AIR

**Page:** 178

		Male				Female	
	2/90 (2%)				0/90 (0%)		
	,				` '		SD 0%
Total	` '	Moon 00/	SD 00/	Total	` '	Moon 00/	SD 0%
	0/90 (0%)				0/90 (0%)	wiean 0%	טט ט% 
	0/00 (0%)				0/90 (0%)		
Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
					1/00 (10/)		
Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
	0/90 (0%)				1/90 (1%)		
Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
	0/88 (09/)				0/86 (00/)		
Total	` '	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
	Total Total	Total 2/90 (2.22%)  O/90 (0%)  Total 0/90 (0%)  O/90 (0%)  Total 0/90 (0%)  Total 1/90 (1.11%)  Total 0/90 (0%)  Total 0/90 (0%)  O/88 (0%)	2/90 (2%) Total 2/90 (2.22%) Mean 2.22%  0/90 (0%) Total 0/90 (0%) Mean 0%  0/90 (0%) Total 0/90 (0%) Mean 0%  1/90 (1%) Total 1/90 (1.11%) Mean 1.11%  0/90 (0%) Total 0/90 (0%) Mean 0%	7/90 (2%) Total 2/90 (2.22%) Mean 2.22% SD 0%    O/90 (0%)	Total 2/90 (2%) Total 2/90 (2.22%) Mean 2.22% SD 0% Total  O/90 (0%) Total 0/90 (0%) Mean 0% SD 0% Total  O/90 (0%) Total 0/90 (0%) Mean 0% SD 0% Total  1/90 (1%) Total 1/90 (1.11%) Mean 1.11% SD 0% Total  O/90 (0%) Total 0/90 (0%) Mean 0% SD 0% Total	2/90 (2%)         Mean 2.22%         SD 0%         Total 0/90 (0%)           0/90 (0.22%)         Mean 2.22%         SD 0%         Total 0/90 (0%)           0/90 (0%)         Mean 0%         SD 0%         Total 0/90 (0%)           0/90 (0%)         Mean 0%         SD 0%         Total 0/90 (0%)           0/90 (0%)         Mean 0%         SD 0%         Total 0/90 (0%)           1/90 (1%)         Mean 1.11%         SD 0%         Total 1/90 (1.11%)           0/90 (0%)         Mean 1.11%         SD 0%         Total 1/90 (1.11%)           0/90 (0%)         Mean 0%         SD 0%         Total 1/90 (1.11%)           0/90 (0%)         Mean 0%         SD 0%         Total 1/90 (1.11%)	Total 2/90 (2%) Total 2/90 (2.22%) Mean 2.22% SD 0% Total 0/90 (0%) Mean 0%  Total 0/90 (0%) Mean 0% SD 0% Total 0/90 (0%) Mean 0%  Total 0/90 (0%) Mean 0% SD 0% Total 0/90 (0%) Mean 0%  Total 0/90 (0%) Mean 0% SD 0% Total 0/90 (0%) Mean 0%  Total 0/90 (0%) Mean 0% SD 0% Total 0/90 (0%) Mean 0%  Total 1/90 (1%) Mean 1.11% SD 0% Total 1/90 (1.11%) Mean 1.11%  Total 0/90 (0%) Mean 0% SD 0% Total 1/90 (1.11%) Mean 1.11%  O/90 (0%) Mean 0% SD 0% Total 1/90 (1.11%) Mean 1.11%

<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: Whole Body Exposure

Vehicle: AIR

**Page:** 179

			Male				Female		
*Adrenal Medulla: Pheochromocytoma Be	nign								
-		10/88 (11%)				1/86 (1%)			
Overall Incidence	Total	10/88 (11.36%)	Mean 11.36%	SD 0%	Total	1/86 (1.16%)	Mean 1.16%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Co									
-	•	1/88 (1%)				0/86 (0%)			
Overall Incidence	Total	1/88 (1.14%)	Mean 1.14%	SD 0%	Total	0/86 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Ma	llignant	4/00 (40/)				0/86 (0%)			
Overall Incidence	Total	1/88 (1%) 1/88 (1.14%)	Mean 1.14%	SD 0%	Total	0/86 (0%) 0/86 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma: Be						1/86 (1%)			
Overall Incidence	Total	11/88 (12.5%)	Mean 12.5%	SD 0%	Total	1/86 (1.16%)	Mean 1.16%	SD 0%	
#Bone: Osteosarcoma									
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma or Osteo	oma	0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (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: Whole Body Exposure

Vehicle: AIR

Page: 180

			Male				Female		
*Brain: Glioma Malignant		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	
Brain: Granular Cell Tumor Benig	n								
Overall Incidence	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	
Brain: Granular Cell Tumor Malig		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%	
Brain: Meningioma Benign		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%	
Brain: Meningioma Malignant		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%	
Brain: Meningioma: Benign, Maliç	nant, NOS								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
*Brain: Oligodendroglioma, Glioma	a, or Astrocy	toma						
	•	0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma		0/88 (0%)				0/87 (0%)		
Overall Incidence	Total	0/88 (0%)	Mean 0%	SD 0%	Total	0/87 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma	Total	0/88 (0%) 0/88 (0%)	Mean 0%	SD 0%	Total	0/87 (0%) 0/87 (0%)	Mean 0%	SD 0%
		` '				0/07 (0/0)		
*Clitoral/Preputial Gland: Carcinoma or Adenoma		0/88 (0%)				0/87 (0%)		
Overall Incidence	Total	0/88 (0%)	Mean 0%	SD 0%	Total	0/87 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/88 (0%)				0/87 (0%)		
Overall Incidence	Total	0/88 (0%)	Mean 0%	SD 0%	Total	0/87 (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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/88 (0%)				0/87 (0%)		
Overall Incidence	Total	0/88 (0%)	Mean 0%	SD 0%	Total	0/87 (0%)	Mean 0%	SD 0%
*Epididymis: Sarcoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%				
#Eye: Leiomyoma		0/00 (00)				0/00 (00)		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rect Granular Cell Tumor Benig	um:							
•		0/90 (0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Intestine Large: Colon/Rect Leiomyoma	um:							
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (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**

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Report Date: 02/17/2020

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Male **Female** #Intestine Small: Jejunum: Carcinoma 2/90 (2%)0/90 (0%)**Overall Incidence** Total 2/90 (2.22%) Mean 2.22% SD 0% Total 0/90 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyosarcoma 0/90 (0%)1/90 (1%)**Overall Incidence** Total 0/90 (0%) Mean 0% SD 0% Total 1/90 (1.11%) Mean 1.11% SD 0% #Intestine Small: Site Unspecified: Carcinoma 2/90 (2%)0/90 (0%)**Overall Incidence** Total 2/90 (2.22%) Mean 2.22% SD 0% Total 0/90 (0%) Mean 0% SD 0% ..... #Intestine Small: Site Unspecified: Carcinoma or Adenoma 2/90 (2%)0/90 (0%)**Overall Incidence** Total 2/90 (2.22%) Mean 2.22% SD 0% Total Mean 0% SD 0% 0/90 (0%) #Intestine Small: Site Unspecified: Leiomyosarcoma 0/90 (0%)1/90 (1%)**Overall Incidence** Total 0/90 (0%) Mean 0% SD 0% Total 1/90 (1.11%) Mean 1.11% SD 0% \*Islets, Pancreatic: Adenoma

SD 0%

5/90

Total

5/90 (5.56%)

(6%)

Mean 5.56%

SD 0%

Total

5/90

5/90 (5.56%)

(6%)

Mean 5.56%

**Overall Incidence** 

<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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
*Islets, Pancreatic: Carcinoma								
		8/90 (9%)				2/90 (2%)		
Overall Incidence	Total	8/90 (8.89%)	Mean 8.89%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
		13/90 (14%)				7/90 (8%)		
Overall Incidence	Total	13/90 (14.44%)	Mean 14.44%	SD 0%	Total	7/90 (7.78%)	Mean 7.78%	SD 0%
*Kidney: Pelvis and Transitio Papilloma	nal Epitheli							
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma		3/90 (3%)				1/90 (1%)		
Overall Incidence	Total	3/90 (3.33%)	Mean 3.33%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
		1/90 (1%)				1/90 (1%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		3/90 (3%)				2/90 (2%)		
Overall Incidence	Total	3/90 (3.33%)	Mean 3.33%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
*Kidney: Renal Tubule: Lipoma								
•		1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma								
	<b>-</b>	0/90 (0%)		<b>OD</b> 00/	<b>T</b>	0/90 (0%)		05.00/
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
		, ,						
*Kidney: Renal Tubule: Oncocytoma Benign		1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Polyp Adenomatous								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Lacrimal Gland: Carcinoma		0/00 (00/)				0/00 /09/		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
Overall incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
*Liver: Cholangiocarcinoma Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
					10tai			
*Liver: Cholangioma		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		0/90 (0%)				7/90 (8%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	7/90 (7.78%)	Mean 7.78%	SD 0%
*Liver: Hepatocellular Carcinoma		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma	or Hepatobla					0/90 (0%)		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (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**

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Report Date: 02/17/2020

SD 0%

Mean 0%

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Male **Female** \*Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 0/90 (0%)7/90 (8%) **Overall Incidence** Total 0/90 (0%) Mean 0% SD 0% Total 7/90 (7.78%) Mean 7.78% SD 0% \*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 7/90 (8%) **Overall Incidence** Total 0/90 (0%) Mean 0% SD 0% Total 7/90 (7.78%) Mean 7.78% SD 0% \*Lung: Alveolar/Bronchiolar Adenoma 1/90 (1%)0/90 (0%)**Overall Incidence** Total 1/90 (1.11%) Mean 1.11% SD 0% Total 0/90 (0%) Mean 0% SD 0% ..... \*Lung: Alveolar/Bronchiolar Carcinoma 0/90 (0%)0/90 (0%)**Overall Incidence** Total 0/90 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/90 (0%) \*Luna: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 1/90 (1%) 0/90 (0%)**Overall Incidence** Total 1/90 (1.11%) Mean 1.11% SD 0% Total 0/90 (0%) Mean 0% SD 0% \*Lung: Sarcoma (0%) 0/90 (0%)0/90

SD 0%

Total

0/90 (0%)

Total

0/90 (0%)

Mean 0%

**Overall Incidence** 

<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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
*Lung: Squamous Cell Carcinoma		0/00 (00/)				0/00 (00%)		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenolipoma		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma		0/90 (0%)				8/90 (9%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	8/90 (8.89%)	Mean 8.89%	SD 0%
#Mammary Gland: Carcinoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	10/90 (11%) 10/90 (11.11%)	Mean 11.11%	SD 0%
#Mammary Gland: Carcinoma or Adenoma		0/90 (0%)				16/00 /199/\		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	16/90 (18%) 16/90 (17.78%)	Mean 17.78%	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: Whole Body Exposure

Vehicle: AIR

**Page:** 189

			Male				Female	
#Mammary Gland: Fibroadenoma								
		2/90 (2%)				63/90 (70%)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	63/90 (70%)	Mean 70%	SD 0%
#Mammary Gland: Fibroma, Fibroadenom								
•		2/90 (2%)				64/90 (71%)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	64/90 (71.11%)	Mean 71.11%	SD 0%
#Mammary Gland: Fibroma, Fibroadenom		2/90 (2%)				66/90 (73%)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	66/90 (73.33%)	Mean 73.33%	SD 0%
#Mammary Gland: Myoepithelioma		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
<b></b>					•••••			
*Nose: Carcinoma								
		0/89 (0%)				0/90 (0%)		
Carcinoma	Total	0/89 (0%) 0/89 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
	sa, Tongue, Phar	0/89 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
Carcinoma  Overall Incidence  #Oral Cavity (Oral Mucos	sa, Tongue, Phar	0/89 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%

<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

Route: Whole Body Exposure

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

Vehicle: AIR

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				Male				Female	
#Oral Cavity (Oral Mucos Squamous Cell Carcino		Squamous, or Pa					2/90 (2%)		
Overall Incidence	Total	0/90 (0%)	M	ean 0%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	SD 0%
#Oral Mucosa: Squamous Cell Carcino	oma	0/90	(0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	` '	ean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
*Ovary: Cystadenoma							1/90 (1%)		
Overall Incidence						Total	1/90 (1.11%)	Mean 1.11%	SD 0%
*Ovary: Granulosa Cell Tumor	Benign						1/90 (1%)		
Overall Incidence						Total	1/90 (1.11%)	Mean 1.11%	SD 0%
*Ovary: Granulosa Cell Tumor	Malignant								
Overall Incidence						Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%
*Ovary: Granulosa Cell Tumor:	Benign, Maligna	nt, NOS					3/90 (3%)		
Overall Incidence						Total	3/90 (3%)	Mean 3.33%	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: Whole Body Exposure

Vehicle: AIR

**Page:** 191

	Male			Female	
*Ovary: Granulosa-Theca Tumor Benign			0/90 (0%)		
Overall Incidence		Total	0/90 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant			2(22)		
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma			0/00 /00/)		
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Ovary: Schwannoma Malignant					
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Ovary: Sertoli Cell Tumor Benign			4/00 (40())		
Overall Incidence		Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%
*Ovary: Thecoma Benign					
Overall Incidence		Total	0/90 (0%) 0/90 (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: Whole Body Exposure

Vehicle: AIR

**Page:** 192

			Male				Female	
*Ovary: Tubulostromal Carcinoma								
Overall Incidence					Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	18/90 (20%) 18/90 (20%)	Mean 20%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma		4/00 (401)				0.00 (0.00)		
Overall Incidence	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma		49/00 (200/)				0/00 (09/)		
Overall Incidence	Total	18/90 (20%) 18/90 (20%)	Mean 20%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma				•••••				
Overall Incidence	Total	1/83 (1%) 1/83 (1.2%)	Mean 1.2%	SD 0%	Total	0/87 (0%) 0/87 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Paraganglioma		0/00 (00/)				0/00 (00/)		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (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: Whole Body Exposure

Vehicle: AIR

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			Male				Female		
#Peripheral Nerve: Schwannoma Malignant		0/00 /(0%)				0/90 (0%)			
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%	
#Peripheral Nerve: Schwannoma: Benign, Ma	lignant, NOS								
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%	
Pituitary Gland: Pars Distali Adenoma									
		17/89 (19%)				43/90 (48%)			
Overall Incidence	Total	17/89 (19.1%)	Mean 19.1%	SD 0%	Total	43/90 (47.78%)	Mean 47.78%	SD 0%	
Pituitary Gland: Pars Distali Carcinoma									
		0/89 (0%)				1/90 (1%)			
Overall Incidence	Total	0/89 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	
Pituitary Gland: Pars Distali Carcinoma or Adenoma									
		17/89 (19%)				44/90 (49%)			
Overall Incidence	Total	17/89 (19.1%)	Mean 19.1%	SD 0%	Total	44/90 (48.89%)	Mean 48.89%	SD 0%	
Pituitary Gland: Pars Interm Adenoma									
		0/89 (0%)				0/90 (0%)			
Overall Incidence	Total	0/89 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%	

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

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

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

\*Salivary Glands:

\*Prostate: Adenoma

\*Prostate:

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: Whole Body Exposure

Vehicle: AIR

Male **Female** \*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 0/89 (0%)0/90 (0%)0/89 (0%) Total Mean 0% SD 0% Total 0/90 (0%) Mean 0% SD 0% ...... \*Pituitary Gland: Pars Nervosa: **Schwannoma Malignant** 0/89 (0%)0/90 (0%)Total 0/89 (0%) Mean 0% SD 0% Total 0/90 (0%) Mean 0% SD 0% 2/90 (2%)Total 2/90 (2.22%) Mean 2.22% SD 0% ...... Carcinoma or Adenoma 2/90 (2%)Total 2/90 (2.22%) Mean 2.22% SD 0% ..... **Schwannoma Malignant** 0/90 (0%)0/90 (0%)Total 0/90 (0%) Mean 0% SD 0% Total 0/90 (0%) Mean 0% SD 0%

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Report Date: 02/17/2020

**#Seminal Vesicle:** 

**Overall Incidence** 

Hemangiosarcoma

0/90

(0%)

**Overall Incidence** Total 0/90 (0%) Mean 0% SD 0%

\*: Denominator is number of animals with tissues examined microscopically

#: 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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
#Skeletal Muscle: Hemangioma								
_		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Liposarcoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma	•••••							
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma		1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Adenoma or	Basosquamous	Tumor Benign 1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Ba	sosquamous T	umor Benign, or Trichoe	pithelioma			0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 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

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

Route: Whole Body Exposure

Vehicle: AIR

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Report Date: 02/17/2020

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

		·	Male				Female	
#Skin: Basal Cell Carcinoma								
Busur och Garomoma		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Carcinoma	or Basosquamou	us Tumor (malignant or N	IOS)					
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Carcinoma, NOS), or Trichoepithel	Basal Cell Aden	oma, Basosquamous Tu	mor (benign, maligna	nt or				
		1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin:								
		ia, Basosq. Tumor (M or l eratoacanthoma, Trichoej		na,				
Auenoma, Fapinoma,	oq rapiliollia, Re	8/90 (9%)	pitnenoma			0/90 (0%)		
Overall Incidence	Total	8/90 (8.89%)	Mean 8.89%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin:								
Fibroma		2/90 (2%)				2/00 (20/)		
Overell Insidence	Tatal	( ,	Mana 0 000/	CD 00/	Tatal	2/90 (2%)	Maan 0.000/	CD 00/
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	SD 0%
#Skin:								
	a, Sarcoma, Myx	oma, Myxosarcoma, Mali	ignant Fibrous Histio	cytoma, or				
Hemangiopericytoma		<b>=</b> / <b>a</b> · <b>a</b> ··/•				<b>-</b> (00 (00))		
O	T-1-1	5/90 (6%)	Mara 5 500′	OD 00/	T-1-1	5/90 (6%)	Maria 5 5001	OD 00/
Overall Incidence	Total	5/90 (5.56%)	Mean 5.56%	SD 0%	Total	5/90 (5.56%)	Mean 5.56%	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: Whole Body Exposure

Vehicle: AIR

**Page:** 197

		Male				Female	
Sarcoma, Myx	oma, Myxosarcoma, or N	Malignant Fibrous His	tiocytoma				
	5/90 (6%)				5/90 (6%)		
Total	5/90 (5.56%)	Mean 5.56%	SD 0%	Total	5/90 (5.56%)	Mean 5.56%	SD 0%
	1/90 (1%)				0/90 (0%)		
Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
Total	3/90 (3%) 3/90 (3.33%)	Mean 3.33%	SD 0%	Total	3/90 (3%) 3/90 (3.33%)	Mean 3.33%	SD 0%
Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
	0/00 (09/)				0/00 (0%)		
Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
	Total  Total  Myxosarcoma  Total  Total	5/90 (6%) Total 5/90 (5.56%)  1/90 (1%) Total 1/90 (1.11%)  Myxosarcoma, or Malignant Fibrous H 3/90 (3%) Total 3/90 (3.33%)  0/90 (0%)  Total 0/90 (0%)  Total 0/90 (0%)  Total 0/90 (0%)	Sarcoma, Myxoma, Myxosarcoma, or Malignant Fibrous His 5/90 (6%)  Total 5/90 (5.56%) Mean 5.56%   1/90 (1%)  Total 1/90 (1.11%) Mean 1.11%  Myxosarcoma, or Malignant Fibrous Histiocytoma 3/90 (3%)  Total 3/90 (3.33%) Mean 3.33%   0/90 (0%)  Total 0/90 (0%)  Mean 0%  0/90 (0%)  Total 0/90 (0%)  Mean 0%	Sarcoma, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma           5/90 (6%)         Total         5/90 (5.56%)         Mean 5.56%         SD 0%           1/90 (1%)           Total         1/90 (1.11%)         Mean 1.11%         SD 0%           Myxosarcoma, or Malignant Fibrous Histiocytoma           3/90 (3%)         Total         3/90 (3.33%)         Mean 3.33%         SD 0%           Total         0/90 (0%)         Mean 0%         SD 0%           Total         0/90 (0%)         Mean 0%         SD 0%           O/90 (0%)         Mean 0%         SD 0%	Sarcoma, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma           5/90 (6%)         Total         5/90 (5.56%)         Mean 5.56%         SD 0%         Total           Myxosarcoma, or Malignant Fibrous Histiocytoma         3/90 (3%)         Total         3/90 (3.33%)         Mean 3.33%         SD 0%         Total           Total         0/90 (0%)         Mean 0%         SD 0%         Total           0/90 (0%)         Total         SD 0%         Total	Sarcoma, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma   5/90 (6%)   5/90 (6%)   5/90 (5.56%)	Sarcoma, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma   5/90 (6%)   Total   5/90 (5.56%)   Mean 5.56%   SD 0%   Total   5/90 (5.56%)   Mean 5.56%   SD 0%   Total   5/90 (5.56%)   Mean 5.56%   Mean 5.56%      1/90 (1%)

<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: Whole Body Exposure

Vehicle: AIR

**Page:** 198

			Male				Female	
#Skin: Keratoacanthoma								
		5/90 (6%)				0/90 (0%)		
Overall Incidence	Total	5/90 (5.56%)	Mean 5.56%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Lipoma								
		2/90 (2%)				0/90 (0%)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
		` '			10tai			
#Skin: Malignant Fibrous Histi	ocytoma							
		0/90 (0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Skin: Neurofibrosarcoma or								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Ne		Schwannoma (benign, m 0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (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: Whole Body Exposure

Vehicle: AIR

**Page:** 199

			Male				Female	
#Skin: Osteosarcoma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Pilomatrixoma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
		2/90 (2%)				2/90 (2%)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	SD 0%
#Skin: Schwannoma Malignant								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma								
·		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell (	Carcinoma, Basosquamo	ous Tumor (malignan	t or NOS),				
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (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: Whole Body Exposure

Vehicle: AIR

Page: 200

			Male				Female	
#Skin: Squamous Cell Papillor	ma							
·		2/90 (2%)				0/90 (0%)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillor	na or Panilloma							
oquamous och i apmoi	na or r apmoma	2/90 (2%)				0/90 (0%)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillor	na. Papilloma. S	Squamous Cell Carcinon	na or Keratoacanthom	a				
oquaouo oo apo.	, . up, .	7/90 (8%)		-		0/90 (0%)		
Overall Incidence	Total	7/90 (7.78%)	Mean 7.78%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillor						0/90 (0%)		
Overall Incidence	Total	7/90 (7.78%)	Mean 7.78%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Trichoepithelioma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
Aucilollia		4/00 (40/)				0/90 (0%)		
Overall Incidence		1/90 (1%)	Mean 1.11%			0/90 (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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Malignant								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
		3/90 (3%)				1/90 (1%)		
Overall Incidence	Total	3/90 (3.33%)	Mean 3.33%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Stomach, Forestomach: Sarcoma								
		0/90 (0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papillom	=				0/90 (0%)		
Overell Incidence	Total	` '	Maan 1 110/	CD 00/	Total	` ,	Maan OO/	CD 00/
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (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: Whole Body Exposure

Vehicle: AIR

Page: 202

			Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma								
		1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Testis: Adenoma								
		2/90 (2%)						
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%				
*Thymus: Thymoma Benign								
		0/88 (0%)				1/87 (1%)		
Overall Incidence	Total	0/88 (0%)	Mean 0%	SD 0%	Total	1/87 (1.15%)	Mean 1.15%	SD 0%
*Thymus: Thymoma Malignant								
Overall Incidence	Total	0/88 (0%) 0/88 (0%)	Mean 0%	SD 0%	Total	1/87 (1%) 1/87 (1.15%)	Mean 1.15%	SD 0%
*Thymus: Thymoma: Benign, Maligna								
	•	0/88 (0%)				2/87 (2%)		
Overall Incidence	Total	0/88 (0%)	Mean 0%	SD 0%	Total	2/87 (2.3%)	Mean 2.3%	SD 0%
*Thyroid Gland: C-Cell: Adenoma								
		8/89 (9%)				6/90 (7%)		
Overall Incidence	Total	8/89 (8.99%)	Mean 8.99%	SD 0%	Total	6/90 (6.67%)	Mean 6.67%	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: Whole Body Exposure

Vehicle: AIR

Page: 203

			Male				Female	
*Thyroid Gland: C-Cell: Carcinoma								
		2/89 (2%)				0/90 (0%)		
Overall Incidence	Total	2/89 (2.25%)	Mean 2.25%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
Overall Incidence	Total	10/89 (11%) 10/89 (11.24%)	Mean 11.24%	SD 0%	Total	6/90 (7%) 6/90 (6.67%)	Mean 6.67%	SD 0%
*Thyroid Gland: Follicular Cell: Adenoma	:							
Overall Incidence	Total	0/89 (0%) 0/89 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma		0/89 (0%)				1/90 (1%)		
Overall Incidence	Total	0/89 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		0/89 (0%)				1/90 (1%)		
Overall Incidence	Total	0/89 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Tissue NOS: Schwannoma Malignant						400		
	<b>T</b>	1/90 (1%)		00.00/	<b>-</b>	1/90 (1%)		05.00/
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	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

#: Denominator is number of animals necropsied

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Page: 204

				Male				Female	
#Tongue: Squamous Cell Carcinoma									
		0/90	(0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)		Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Tongue: Squamous Cell Carcinoma o	or Papillom	a Squamous							
	•	0/90	(0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)		Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Tooth: Odontoma	•••••	0/90	(0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	(0,0)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma		0/89	(0%)				1/88 (1%)		
Overall Incidence	Total	0/89 (0%)	(0,0)	Mean 0%	SD 0%	Total	1/88 (1.14%)	Mean 1.14%	SD 0%
#Uterus: Adenocarcinoma									
Overall Incidence									
#Uterus: Adenocarcinoma or Adenon									
Overall Incidence									
*: Denominator is number of animals	with tissues e	examined microscop	ically						

Contract/Lab: All Laboratories

Species: RATS

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

#: Denominator is number of animals necropsied

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

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	Male	Female
#Uterus: Adenoma		
Overall Incidence		
#Uterus: Deciduoma Benign		
Overall Incidence		
#Uterus: Granular Cell Tumor Benign		
Overall Incidence		
#Uterus: Polyp Stromal		
Overall Incidence		
#Uterus: Sarcoma		
Overall Incidence		
#Uterus: Sarcoma Stromal		
Overall Incidence		
* Denominator is number of animals with tissues examined n		

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: Whole Body Exposure

Vehicle: AIR

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	Male			Female		
#Uterus: Sarcoma Stromal or Polyp Stromal						
Overall Incidence						
#Uterus: Schwannoma Malignant						
Overall Incidence						
#Uterus: Squamous Cell Carcinoma						
Overall Incidence						
#Vagina: Granular Cell Tumor Benign			0/00 /00/			
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	
#Vagina: Polyp						
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	
#Vagina: Schwannoma Malignant						
Overall Incidence		Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	
*: Denominator is number of animals with tissues examined microsco						

<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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
#Zymbal's Gland: Carcinoma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%

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

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