

# NTP Historical Controls Report

By Route and Vehicle

Harlan Sprague-Dawley RATS

**April 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	M3	F1	F2	F3		
M4	M5		F4	F5			

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

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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: 07/01/2019

# **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		

Species: RATS

**Toxicology Data Management System** 

Page: 5

Report Date: 07/01/2019

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Vehicle: CORN OIL

		Male				Female	
Total	27/50 (54%)	Mean 54%	SD 0%	Total	40/50 (80%)	Mean 80%	SD 0%
	` '				` '		
	12/50 (24%)				10/50 (38%)		
Total	12/50 (24%)	Mean 24%	SD 0%	Total	19/50 (38%)	Mean 38%	SD 0%
umors							
Total	33/50 (66%)	Mean 66%	SD 0%	Total	46/50 (92%)	Mean 92%	SD 0%
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	1/50 (2%)				1/50 (2%)		
Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
emangioma							
Total	` '	Mean 2%	SD 0%	Total	, ,	Mean 2%	SD 0%
	Total  umors  Total  Total	Total 27/50 (54%)  12/50 (24%)  Total 12/50 (24%)  umors  33/50 (66%)  Total 33/50 (66%)   0/50 (0%)  Total 0/50 (0%)  Total 1/50 (2%)  Total 1/50 (2%)  emangioma  1/50 (2%)	27/50 (54%) Total 27/50 (54%) Mean 54%  12/50 (24%) Total 12/50 (24%) Mean 24%  umors  33/50 (66%) Total 33/50 (66%) Mean 66%  Total 0/50 (0%) Mean 0%  1/50 (2%) Total 1/50 (2%) Mean 2%  emangioma  1/50 (2%)	Total 27/50 (54%)  Total 27/50 (54%) Mean 54% SD 0%  12/50 (24%)  Total 12/50 (24%) Mean 24% SD 0%  umors  33/50 (66%)  Total 33/50 (66%) Mean 66% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 1/50 (2%) Mean 2% SD 0%  emangioma  1/50 (2%)	Total 27/50 (54%) Total 27/50 (54%) Mean 54% SD 0% Total  12/50 (24%) Total 12/50 (24%) Mean 24% SD 0% Total  umors  33/50 (66%) Total 33/50 (66%) Mean 66% SD 0% Total  7 Total 0/50 (0%) Mean 0% SD 0% Total  1/50 (2%) Mean 2% SD 0% Total  1/50 (2%)	Total 27/50 (54%) Mean 54% SD 0% Total 40/50 (80%)  12/50 (24%) Mean 24% SD 0% Total 19/50 (38%)  Total 12/50 (24%) Mean 24% SD 0% Total 19/50 (38%)  Umors  33/50 (66%) Mean 66% SD 0% Total 46/50 (92%)  Total 33/50 (66%) Mean 66% SD 0% Total 46/50 (92%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%)  Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%)	Total 27/50 (54%) Mean 54% SD 0% Total 40/50 (80%) Mean 80%    12/50 (24%)

<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 Incidence	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

Toxicology

Contract/Lab: 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		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%
#All Organs: 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%
#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  Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Overall incidence		` /	wean 0%			0/50 (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 (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: 8

			Male				Female					
*Adrenal Medulla: Pheochromocytoma Benign												
	_	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 Com												
		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 Malig	ynant	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: Beni						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 Osteom												
Occupation and the second	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%				

<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:** 9

			Male				Female	
*Brain: Glioma Malignant								
Overall Incidence								
*Brain: Granular Cell Tumor Beniç	jn							
Overall Incidence								
*Brain: Granular Cell Tumor Malig	nant							
Overall Incidence								
*Brain: Oligodendroglioma, Gliom	a, or Astrocyt	oma						
Overall Incidence								
*Brain: Schwannoma Malignant								
Overall Incidence								
*Clitoral/Preputial Gland: 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%

<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:** 10

			Male				Female	
*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%
*Epididymis: Sarcoma								
		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
#Eye: Leiomyoma								
O	T-1-1	0/50 (0%)	Maran 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%
*Heart: Schwannoma Malignant								
		1/50 (2%)		05.00/		0/50 (0%)		05 00/
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 Benig								
-		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: 11

			Male				Female			
#Intestine Small: Jejunum: 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%		
#Intestine Small: Jejunum: 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%		
#Intestine Small: Site Unspec Carcinoma						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%		
#Intestine Small: Site Unspec 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%		
#Intestine Small: Site Unspec 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		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: GAVAGE Vehicle: CORN OIL Page: 12

			Male				Female	
*Islets, Pancreatic: 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%
*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					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: 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								
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: 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: GAVAGE Vehicle: CORN OIL **Page:** 13

			Male		0/50 (0%) Total 0/50 (0%) Mean 0% S  0/50 (0%) Total 0/50 (0%) Mean 0% S			
*Kidney: Renal Tubule: Lipoma		0/50 (09/)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%
*Kidney: Renal Tubule: Liposarcoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,	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	` '	Mean 0%	SD 0%
*Kidney: Renal Tubule: Oncocytoma Benign	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Liver: Cholangiocarcinoma		, ,				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%)	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: 14 Report Date: 07/01/2019

			Male			Female       2/50 (4%)     Mean 4%     SD 0%       0/50 (0%)     0/50 (0%)     Mean 0%     SD 0%       0/50 (0%)     Mean 0%     SD 0%       0/50 (0%)     Mean 0%     SD 0%       2/50 (4%)     Mean 4%     SD 0%       2/50 (4%)     Mean 4%     SD 0%		
*Liver: Hepatocellular Adenoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	` '	Mean 4%	SD 0%
		` '				` ,		
*Liver: Hepatocellular Carcinoma		0/50 (0%)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)		
*Liver: Hepatocellular Carcinoma		astoma						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Liver:								
Hepatocellular Carcinoma	or Hepatocei	1/50 (2%)				2/50 (4%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	` '	Mean 4%	SD 0%
*Liver:								
Hepatocellular Carcinoma,	ператосени	1/50 (2%)	tobiastoma			2/50 (4%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)		02 070
*Lung: Alveolar/Bronchiolar Aden								
		0/49 (0%)				1/50 (2%)		
Overall Incidence	Total	0/49 (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:** 15

				Male		1/50 (2%) Total 1/50 (2%) Mean 2% S  1/50 (2%) Total 1/50 (2%) Mean 2% S  0/50 (0%) Total 0/50 (0%) Mean 0% S			
*Lung: Alveolar/Bronchiolar Car	cinoma	,							
		0/49	(0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	М	ean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Car	cinoma or Alve				•••••		•••••		
		0/49	(0%)				1/50 (2%)		
Overall Incidence	Total	0/49 (0%)	` '	ean 0%	SD 0%	Total	` ,	Mean 2%	SD 0%
*Lung: Sarcoma		0/49	(00/)				4/50 (20/)		
Overall Incidence	Total	0/49	(0%)	ean 0%	SD 0%	Total	` ,	Mean 2%	SD 0%
		0/40 (0/0)							
*Lung: Squamous Cell Carcinon	na	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%
#Lymph Node, Mesenteric: Hemangiosarcoma									
•		1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	М	ean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenolipoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	` '	ean 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:** 16

				Male		29/50 (58%)			
#Mammary Gland: Adenoma									
			(0%)				( ,		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	, ,		SD 0%
#Mammary Gland: Carcinoma									
			(0%)		05.00/		( ,		05.00/
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	l otal	3/50 (6%)	Mean 6%	SD 0%
#Mammary Gland: Carcinoma or Adenoma		0/50	(0%)				6/50 (12%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	` ,	Mean 12%	SD 0%
#Mammary Gland: Fibroadenoma		1/50	(2%)				20/50 (58%)		
Overall Incidence	Total	1/50 (2%)	` ,	Mean 2%	SD 0%	Total	` ,	Mean 58%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma o									
			(2%)				30/50 (60%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	30/50 (60%)	Mean 60%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma,	Carcinoma, or		(2%)				32/50 (64%)		
Overall Incidence	Total	1/50 (2%)	(270)	Mean 2%	SD 0%	Total	32/50 (64%)	Mean 64%	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		Total 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0%  O/49 (0%) Total 0/49 (0%) Mean 0% SD 0%  O/50 (0%) Total 0/50 (0%) Mean 0% SD 0%				
#Mammary Gland: Myoepithelioma									
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Nose: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%	
#Oral Cavity (Oral Mucosa Squamous Cell Carcino		vnx, Tooth, Gingiva): 1/50 (2%)				` '			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Oral Cavity (Oral Mucosa Squamous Cell Carcino	a, Tongue, Phary	/nx, Tooth, Gingiva): Squamous, or Papilloma				0/50 (00/)			
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Overall Incidence #Oral Mucosa: Squamous Cell Carcino		1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Oral Mucosa: Squamous Cell Carcino	ma	1/50 (2%)				0/50 (0%)			
#Oral Mucosa:		1/50 (2%)	Mean 2% Mean 2%	SD 0% SD 0%	Total Total	0/50 (0%)	Mean 0% Mean 0%	SD 0% SD 0%	
#Oral Mucosa: Squamous Cell Carcino	ma	1/50 (2%)				0/50 (0%)			

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

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

Contract/Lab: 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	
*Ovary: Granulosa Cell Tumor Benign					
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, Malignant, NOS			0/50 (00/)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*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: Sertoli Cell Tumor 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:** 19

			Male				Female	
*Ovary: Thecoma Benign								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*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		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								
		5/50 (10%)				0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
Occupation and desired	Tatal	0/43 (0%)	M 00/	00.00/	Tarat	0/47 (0%)	Maria 00/	OD 00/
Overall Incidence	Total	0/43 (0%)	Mean 0%	SD 0%	Total	0/47 (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: 20

			Male				Female	
*Pituitary Gland: Pars Distal Adenoma	is or Unspecif	ied 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 Distal Carcinoma	is or Unspecif	ied Site:						
		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 Distal Carcinoma or Adenoma	is or Unspecif	ied 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 Intern 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%
*Pituitary Gland: Pars Interm 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%
*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%

<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		0/50 (0%)			
*Prostate: Adenoma 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								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	` ,	Mean 0%	SD 0%
#Seminal Vesicle: Hemangiosarcoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Liposarcoma								
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								
Overall Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	1/50 (2%)	Maan 20/	CD 00/
Overali 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:** 22

			Male			Female           0/50 (0%)           Total         0/50 (0%)           Mean 0%           Total         0/50 (0%)           Mean 0%           Total         0/50 (0%)           Mean 0%		
#Skin: Basal Cell Adenoma								
		0/50 (09	%)			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	Rasosquamous	Tumor Benjan						
Dasai Ocii Adeiloilla Oi	Dasosquamous	0/50 (0°	%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin:								
Basal Cell Adenoma, Ba	isosquamous ri	0/50 (0°				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin:								
Basal Cell Carcinoma		4/50 /0/	2/1			0/50 (00/)		
Overell Incidence	Total	1/50 (29	,	CD 00/	Total	` '	Maan 00/	SD 0%
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	ı Olal		wean 0%	טט עא U%
#Skin:								
Basal Cell Carcinoma o	r Basosquamou	s Tumor (malignan	t or NOS)					
		1/50 (29	,			0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:								
_		oma, Basosquamou	us Tumor (benign, maligna	ant or				
•		1/50 (29	%)			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

Species: RATS

**Toxicology Data Management System** 

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

ol Animal Groups

**Page:** 23

Report Date: 07/01/2019

Route: GAVAGE Vehicle: CORN OIL

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

			Male			Female				
#Skin: Basal or Sq. Cell Carcin Adenoma. Papilloma. S	noma, Carcinoma g Papilloma, Ke	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep	3), Basal Cell Adenoi ithelioma	ma,						
	, ,	6/50 (12%)				0/50 (0%)				
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Fibroma										
		5/50 (10%)				1/50 (2%)				
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Skin: Fibroma, Fibrosarcoma Hemangiopericytoma	, Sarcoma, Myxo	oma, Myxosarcoma, Mali	gnant Fibrous Histio	cytoma, or		2/50 (4%)				
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
#Skin:		oma, Myxosarcoma, or M 7/50 (14%) 7/50 (14%)			Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%		
	·····					2/30 (4/8)				
#Skin: Fibrosarcoma		1/50 (2%)				1/50 (2%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Skin: Fibrosarcoma, Sarcoma	a, Myxosarcoma	, or Malignant Fibrous Hi	stiocytoma			1/50 (2%)				
Overall Incidence	Total	2/50 (4%)	Mean 4%	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: 24 Report Date: 07/01/2019

			Male		0/50 (0%) Total 0/50 (0%) Mean 0% SD 0  1/50 (2%) Total 1/50 (2%) Mean 2% SD 0  0/50 (0%) Total 0/50 (0%) Mean 0% SD 0			
#Skin: Hemangioma		0/50 (0%)				0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin: Hemangiopericytoma		2/20 (201)				(201)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin: Hemangiosarcoma		0/50 (0%)				4/50 (29/)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 2%	SD 0%
#Skin: Keratoacanthoma		4/50 (8%)				0/50 (0%)		
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	, ,	Mean 0%	SD 0%
#Skin: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin: Malignant Fibrous Histion	cytoma							
Overall Incidence	Total	1/50 (2%) 1/50 (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

Species: RATS

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

**Page: 25** 

Report Date: 07/01/2019

Vehicle: CORN OIL

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Male **Female** #Skin: Neurofibrosarcoma or Schwannoma (malignant 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, Neurofibroma, or Schwannoma (benign, malignant or NOS) 1/50 (2%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0% #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: Sarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (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:

SD 0%

0/50

0/50 (0%)

Total

(0%)

Mean 0%

SD 0%

Total

1/50

1/50 (2%)

(2%)

Mean 2%

**Squamous Cell Carcinoma** 

**Overall Incidence** 

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

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

Species: RATS

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

Tumor Incidence for Selected Control Animal Groups

**Page:** 26

Report Date: 07/01/2019

Route: GAVAGE

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

			Male				Female	
#Skin: Squamous Cell Carcin or Carcinoma	oma, Basal Cell C	Carcinoma, Basosquamo	us Tumor (malignan	t or 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%
#Skin: Squamous Cell Papillo	oma	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 Papillo	oma 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%
#Skin: Squamous Cell Papillo	oma, Papilloma, S	Equamous Cell Carcinom 5/50 (10%)	a or Keratoacanthon	na		0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	oma, Papilloma, o	r Keratoacanthoma 5/50 (10%)				0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous 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%

<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: Sebaceous Gland: Carcinoma or Adenoma		0/50 /5	2007.)			0/50 (00/)				
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) Mean			0/50 (0%) 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 (0	)%)			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean	0% SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Stomach, Forestomach: Sarcoma		0/50 (0	)%)	0D 00		0/50 (0%)		07 00		
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	1/50 (2%)	2%) Mean	2% SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Stomach, Forestomach: Squamous Cell Carcinoma c		a Squamous	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: 28

			Male			Female						
#Stomach, Forestomach: Squamous Cell Papilloma												
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
Overall incidence	10181	0/50 (0%)				0/50 (0%)						
*Testis: Adenoma		0/40 (004)										
Overall Incidence	Total	3/49 (6%) 3/49 (6.12%)	Mean 6.12%	SD 0%								
*Thymus: Thymoma Benign												
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 Overall Incidence	Total	0/46 (0%) 0/46 (0%)	Mean 0%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma: Benign, Maligr		1/46 (2%)				0/47 (0%)						
Overall Incidence	Total	1/46 (2.17%)	Mean 2.17%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%				
*Thyroid Gland: C-Cell: Adenoma						44/40 (220)						
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**: 29

			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 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: Follicular Cell: 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%		
#Tongue: Squamous Cell Carcinoma		0/50 (004)				0/50 (00/)				
		0/50 (0%)				0/50 (0%)		22. 22/		
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

**Toxicology Data Management System** 

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

Route: GAVAGE Vehicle: CORN OIL

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

**Page:** 30

				Male			Female					
#Tongue: Squamous Cell Carcinoma or Papilloma 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		0/-0	(224)				(201)					
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		0/50	(00/)				0/49 (0%)					
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%			
#Uterus: Standard or Exte Adenocarcinoma Overall Incidence						Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%			
#Uterus: Standard or Exte Adenocarcinoma or Ad		ns (Combined):					5/50 (10%)					
Overall Incidence						Total	5/50 (10%)	Mean 10%	SD 0%			
#Uterus: Standard or Exte Adenoma	ended Evaluation	ns (Combined):										
Overall Incidence						Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
	imala with tiasuas a											

<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

mor incidence for Selected Control Animal Route: GAVAGE

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

Route: GAVAGE
Vehicle: CORN OIL

**Page:** 31

	Male			Female				
#Uterus: Standard or Extended Evaluations (Combined): Polyp Stromal								
			10/50 (20%)					
Overall Incidence		Total	10/50 (20%)	Mean 20%	SD 0%			
#Uterus: Standard or Extended Evaluations (Combined): Sarcoma Stromal								
			2/50 (4%)					
Overall Incidence		Total	2/50 (4%)	Mean 4%	SD 0%			
#Uterus: Standard or Extended Evaluations (Combined): Sarcoma Stromal or Polyp Stromal			40/50 (040())					
Overall Incidence		Total	12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%			
#Vagina: Granular Cell Tumor Benign			0/50 /00/)					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Vagina: Polyp								
			1/50 (2%)					
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: 32

			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:** 33

Report Date: 07/01/2019

# **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		

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page: 34** 

Report Date: 07/01/2019

Species: RATS

Route: INHALATION Vehicle: AIR

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

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** 12/50 (24%)11/50 (22%)**Overall Incidence** Total 12/50 (24%) Mean 24% SD 0% Total 11/50 (22%) Mean 22% SD 0% #All Organs: **Malignant and Benign Tumors** 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** SD 0% Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 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 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%

<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:** 35

			Male				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										
		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: Leukemia: Lymphocytic, M Overall Incidence	onocytic, Mo	ononuclear, or Undifferen 3/50 (6%) 3/50 (6%)	ntiated  Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#All Organs:  Malignant Lymphoma: Hist Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
		0/50 (0%)				2/50 (4%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
#AII O										
#All Organs: Mesothelioma: Benign, Ma	ignant, NOS					0/50 (00/)				
•	lignant, NOS Total	1/50 (2%) 1/50 (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** 

Contract/Lab: All Laboratories

Species: RATS

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 36

			Male				Female			
#All Organs: Mesothelioma: 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%		
#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 Osteom	a	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 Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%) 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 (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:** 37

			Male				Female					
*Adrenal Medulla: Pheochromocytoma Benign  12/50 (24%)  0/49 (0%)												
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma Comp		0/50 (0%)				0/49 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma Maligr		2/50 (4%)				0/49 (0%)						
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma: Benig Overall Incidence			Mean 28%	SD 0%	Total	0/49 (0%) 0/49 (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 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%				

<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: 38

				Male				Female	
*Brain: Glioma Malignant									
Overall Incidence	Total	2/50 (4%)	(4%)	Mean 4%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Brain: Granular Cell Tumor Benign									
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 Maligna	ant	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%
*Brain: Oligodendroglioma, Glioma,	, or Astrocy		(4%)				1/50 (2%)		
Overall Incidence	Total	2/50 (4%)	(470)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Brain: Schwannoma Malignant									
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Clitoral/Preputial Gland: Carcinoma									
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: INHALATION Vehicle: AIR

**Page:** 39

			Male				Female	
*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%
*Epididymis: Sarcoma								
Overell Incidence	Tatal	1/50 (2%)	Mana 200/	CD 00/				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%				
#Eye: Leiomyoma								
Occupation of the sec	T-1-1	1/50 (2%)	M 00/	OD 00/	T-1-1	0/50 (0%)	M 00/	OD 00/
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant								
Overall Incidence	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Mann 00/	SD 0%
Overali incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 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:							
		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: 40

			Male				Female						
#Intestine Small: Jejunum: Carcinoma  0/50 (0%)  0/50 (0%)													
		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 Small: Jejunum: Leiomyosarcoma						(201)							
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%					
#Intestine Small: Site Unspeci Carcinoma	fied:												
		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 Small: Site Unspeci 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%					
#Intestine Small: Site Unspeci Leiomyosarcoma													
		1/50 (2%)				0/50 (0%)							
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%					
*Islets, Pancreatic: Adenoma													
Overall Incidence	Total	8/50 (16%)	Mean 16%	CD 00/	Total	1/50 (2%)	Mean 2%	CD 00/					
Overali incidence	Total	8/50 (16%)		SD 0%	Total	1/50 (2%)		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: INHALATION

Page: 41

Report Date: 07/01/2019

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

Vehicle: AIR

*Islets, Pancreatic: Carcinoma			Male				Female	
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
		` '				1/30 (2/0)	Wiedii 270	
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 Transit Papilloma		o/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%)		
							Mean 0%	SD 0%

SD 0%

1/50

1/50 (2%)

Total

(2%)

Mean 2%

SD 0%

Total

0/50

0/50 (0%)

(0%)

Mean 0%

Carcinoma or Adenoma

**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: INHALATION Vehicle: AIR

Page: 42

			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								
<b>P</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%
*Kidney: Renal Tubule: Nephroblastoma		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: 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%
*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 (09/)				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%

<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: INHALATION Vehicle: AIR

Page: 43

				Male				Female				
*Liver: Hepatocellular Adenoma  0/50 (0%)  2/50 (4%)												
Overall Incidence	Total	0/50 0/50 (0%)	,	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%			
*Liver: Hepatocellular Carcinoma							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	or Hepatobla	<b>stoma</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%			
*Liver: Hepatocellular Carcinoma Overall Incidence	or Hepatocel	lular Adenoma 0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%			
*Liver: Hepatocellular Carcinoma,		ar Adenoma, or					2/50 (4%)					
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%			
*Lung: Alveolar/Bronchiolar Aden	oma	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

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 44

			Male		0/50 (0%) Total 0/50 (0%) Mea  0/50 (0%)  Total 0/50 (0%) Mea  0/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)			
*Lung: Alveolar/Bronchiolar C	arcinoma							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 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: Sarcoma								
		0/50 (0%)				` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Squamous Cell Carcine	oma	0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteri 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%
#Mammary Gland: Adenolipoma								
		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

**Toxicology Data Management System** 

**Page:** 45

Report Date: 07/01/2019

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

Route: INHALATION Vehicle: AIR

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

		Male				Female	
	0/50 (0%)				4/50 (8%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%
	` '				` '		
	` '				5/50 (10%)	Mean 10%	SD 0%
	` '				` '		
	` '			l otal	9/50 (18%)	Mean 18%	SD 0%
	2/50 (4%)				20/50 (40%)		
Total	2/50 (4%)	Mean 4%	SD 0%	Total	20/50 (40%)	Mean 40%	SD 0%
r Adenoma							
	` '				` '		
	( /		SD 0%	Total	23/50 (46%)	Mean 46%	SD 0%
,	2/50 (4%)				27/50 (54%)		
Total	2/50 (4%)	Mean 4%	SD 0%	Total	27/50 (54%)	Mean 54%	SD 0%
	Total  Total  Total  Total  Total  Carcinoma, or	Total 0/50 (0%)  0/50 (0%)  Total 0/50 (0%)  0/50 (0%)  0/50 (0%)  Total 0/50 (0%)  2/50 (4%)  Total 2/50 (4%)  r Adenoma 2/50 (4%)  Carcinoma, or Adenoma 2/50 (4%)	0/50 (0%) Total 0/50 (0%) Mean 0%  0/50 (0%) Total 0/50 (0%) Mean 0%  0/50 (0%) Total 0/50 (0%) Mean 0%  2/50 (4%) Total 2/50 (4%) Mean 4%  r Adenoma 2/50 (4%) Total 2/50 (4%) Mean 4%  Carcinoma, or Adenoma 2/50 (4%)	0/50 (0%)       Total     0/50 (0%)     Mean 0%     SD 0%       0/50 (0%)       Total     0/50 (0%)     Mean 0%     SD 0%       Total     0/50 (0%)     Mean 0%     SD 0%       2/50 (4%)       Total     2/50 (4%)     Mean 4%     SD 0%       Total     2/50 (4%)       Total     2/50 (4%)     Mean 4%     SD 0%       Carcinoma, or Adenoma       2/50 (4%)	Total 0/50 (0%) Mean 0% SD 0% Total    Total 0/50 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 4/50 (8%)    Total 0/50 (0%) Mean 0% SD 0% Total 4/50 (8%)   Total 0/50 (0%) Mean 0% SD 0% Total 5/50 (10%)   Total 0/50 (0%) Mean 0% SD 0% Total 5/50 (10%)   Total 0/50 (0%) Mean 0% SD 0% Total 9/50 (18%)   Total 0/50 (0%) Mean 0% SD 0% Total 9/50 (18%)   Total 2/50 (4%) Mean 4% SD 0% Total 20/50 (40%)   Total 2/50 (4%) Mean 4% SD 0% Total 23/50 (46%)   Total 2/50 (4%) Mean 4% SD 0% Total 23/50 (46%)   Total 2/50 (4%) Mean 4% SD 0% Total 23/50 (46%)   Total 2/50 (4%) Mean 4% SD 0% Total 23/50 (46%)   Total 2/50 (4%) Mean 4% SD 0% Total 23/50 (46%)   Total 2/50 (4%) Mean 4% SD 0% Total 23/50 (46%)   Total 2/50 (4%) Mean 4% SD 0% Total 23/50 (46%)   Total 2/50 (4%) Mean 4% SD 0% Total 23/50 (46%)	Total 0/50 (0%) Mean 0% SD 0% Total 4/50 (8%) Mean 8%    O/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: INHALATION Vehicle: AIR

**Page:** 46

			Male				Female					
#Mammary Gland: Myoepithelioma  0/50 (0%)  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%				
*Nose: Carcinoma		2/22 (221)				2/22 (221)						
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 Mucosa, Squamous Cell Carcinoma		vnx, Tooth, Gingiva): 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 Cavity (Oral Mucosa, Squamous Cell Carcinoma						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 Carcinoma	a											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	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%				

<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	
*Ovary: Granulosa Cell Tumor Benign					
Overall Incidence		Total	3/50 (6%) 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, Malignant, NOS			0/50 (00)		
Overall Incidence		Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
*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: Sertoli Cell Tumor 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: INHALATION Vehicle: AIR

Page: 48

			Male				Female	
*Ovary: Thecoma Benign								
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Tubulostromal Carcinoma								
Overall Incidence					Total	0/50 (0%) 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		(20)				(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%
*Pancreas: 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%
*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%

<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				
*Pituitary Gland: Pars Distali Adenoma	s or Unspeci	ified Site:								
		11/50 (22%)		05.00/		18/50 (36%)		00.004		
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	18/50 (36%)	Mean 36%	SD 0%		
*Pituitary Gland: Pars Distali Carcinoma	s or Unspeci	ified Site:								
		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 Distali Carcinoma or Adenoma										
		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 Interm 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%		
*Pituitary Gland: Pars Interm 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%		
*Pituitary Gland: Pars Nervos Schwannoma Malignant	sa:									
	<b>-</b>	0/50 (0%)		00.00/	<b>-</b>	0/50 (0%)		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	
*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		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%
		, ,				' '		
#Seminal Vesicle: Hemangiosarcoma								
Occupil to all towards	T-1-1	0/50 (0%)	M 00/	OD 00/				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Liposarcoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	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%)	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:** 51

				Male	Female				
#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	Basosquamous	_	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:									
Basal Cell Adenoma, Ba	asosquamous Tu	_	-	thelioma					
			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:									
<b>Basal Cell Carcinoma</b>									
			(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 o	r Basosquamou	s Tumor (malign	ant or NO	S)					
		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, E NOS), or Trichoepithelio		ma, Basosquam	nous Tumo	or (benign, maligna	ant or				
,,		0/50	(0%)				1/50 (2%)		
		0/50 (0%)					1/50 (2%)		

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

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

Species: RATS

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

Tumor Incidence for Selected Control Animal Groups

Page: 52

Report Date: 07/01/2019

Route: INHALATION Vehicle: AIR

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

Contract/Lab: All Laboratories

Male **Female** #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma (8%)4/50 1/50 (2%)SD 0% **Overall Incidence** Total 4/50 (8%) Mean 8% SD 0% Total 1/50 (2%) Mean 2% #Skin: **Fibroma** 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: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, Malignant Fibrous Histiocytoma, or Hemangiopericytoma 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: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma 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: **Fibrosarcoma** 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: Fibrosarcoma, Sarcoma, Myxosarcoma, or Malignant Fibrous Histiocytoma (2%)0/50 (0%)**Overall Incidence** Total 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:** 53

			Male				Female	
#Skin: Hemangioma								
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: Hemangiopericytoma		0/50 (0%	۷)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma		0/50 (0%	<i>د</i>			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma		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: Lipoma		4/50 (00	<i>.</i>			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%
#Skin: Malignant Fibrous Histion	cytoma	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%

<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: INHALATION Vehicle: AIR

**Page:** 54

			Male			Female			
#Skin: Neurofibrosarcoma or Schwannoma (malignant 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, Neuro	fibroma, or S		nalignant or 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: 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: 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									
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 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

Species: RATS

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

Tumor Incidence for Selected Control Animal Groups

**Page:** 55

Report Date: 07/01/2019

Route: INHALATION Vehicle: AIR

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

Contract/Lab: All Laboratories

Male **Female** #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 0/50 (0%)1/50 (2%)0/50 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0% ..... **Squamous Cell 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% #Skin: **Squamous Cell Papilloma or Papilloma** (2%) 1/50 0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% ..... #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma (8%)0/50 (0%)4/50 (8%) **Overall Incidence** Total Mean 8% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Skin: Squamous Cell Papilloma, Papilloma, or 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: Sebaceous Gland: Adenoma 1/50 (2%)0/50 (0%)Mean 0% **Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (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	
#Skin: Sebaceous Gland: Carcinoma or Adenoma									
Overall Insidence	Tatal	1/50	(2%)	Mana 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%
#Spinal Cord: Astrocytoma Malignant		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%
*Spleen: Hemangiosarcoma		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%
#Stomach, Forestomach: Sarcoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(078)	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	a Squamous 0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(370)	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:** 57

				Male				Female		
#Stomach, Forestomach: Squamous Cell Papilloma										
O	Tatal		(0%)	M 00/	00.00/	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%	
*Testis: Adenoma		0/50	(0%)							
Overall Incidence	Total	0/50 (0%)	(070)	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%)	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, Malign										
Overall Incidence	Tatal		(0%)	Maan 00/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/	
Overall incidence	Total	0/48 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Adenoma		0/50	(40/)				0/50 (40%)			
Overall Incidence	Total	2/50 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

Species: RATS

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 58

				Male				Female	
*Thyroid Gland: C-Cell: Carcinoma									
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		3/50	(6%)				2/50 (4%)		
Overall Incidence	Total	3/50 (6%)	(070)	Mean 6%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma		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%
*Thyroid Gland: Follicular Cell: 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%
#Tissue NOS: Schwannoma Malignant							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%
#Tongue: Squamous Cell Carcinoma		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:** 59

	Male						Female				
#Tongue: Squamous Cell Carcino	oma or Papilloma		(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	. ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Tooth: Odontoma			··								
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Urinary Bladder: Leiomyosarcoma		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%		
#Uterus: Standard or Ext Adenocarcinoma	ended Evaluatio	ns (Combined):									
Overall Incidence											
#Uterus: Standard or Ext Adenocarcinoma or Ad		ns (Combined):									
Overall Incidence											
#Uterus: Standard or Ext Adenoma	ended Evaluatio	ns (Combined):									
Overall Incidence											
*: Denominator is number of ar	nimals with tissues e	xamined microscopio	cally					• • • • • • • • • • • • • • • • • • • •			

Contract/Lab: 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		
#Uterus: Standard or Extended Evaluations (Combined): Polyp Stromal						
Overall Incidence						
#Uterus: Standard or Extended Evaluations (Combined): Sarcoma Stromal						
Overall Incidence						
#Uterus: Standard or Extended Evaluations (Combined): Sarcoma Stromal or Polyp Stromal						
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%	
* Denominator in number of animals with tipours avaning distinguishing						

<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	
#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: PERINATAL AND POSTNATAL

Vehicle: FEED

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Report Date: 07/01/2019

# **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	051026001	11/08/10	729	50(2)	30(706)	615.3	2-Hydroxy-4-methoxybenzophenone
Battelle Columbus Laboratory	052061401	10/27/08	N/A	0(0)	0(0)	N/A	Perfluorooctanoic Acid
Battelle Columbus Laboratory	052061402	07/27/09	743	50(2)	36(684)	609.5	Perfluorooctanoic Acid
					Female		
Battelle Columbus Laboratory	051026001	11/09/10	730	50(4)	30(657)	379.6	2-Hydroxy-4-methoxybenzophenone
Battelle Columbus Laboratory	052061401	10/28/08	744	50(4)	23(649)	385.9	Perfluorooctanoic Acid
Battelle Columbus Laboratory	052061402	N/A	N/A	0(0)	0(0)	N/A	Perfluorooctanoic Acid

Contract/Lab: 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: Benign Tumors										
•		38/50 (76%)		32/50 (64%)		41/50 (82%)	39/50 (78%)			
Overall Incidence	Total	70/100 (70%)	Mean 70%	SD 8.49%	Total	80/100 (80%)	Mean 80%	SD 2.83%		
#All Organs: Malignant Tumors										
		11/50 (22%)		9/50 (18%)		15/50 (30%)	14/50 (28%)			
Overall Incidence	Total	20/100 (20%)	Mean 20%	SD 2.83%	Total	29/100 (29%)	Mean 29%	SD 1.41%		
#All Organs: Malignant and Benign Tu	ımors									
		42/50 (84%)		37/50 (74%)		47/50 (94%)	47/50 (94%)			
Overall Incidence	Total	79/100 (79%)	Mean 79%	SD 7.07%	Total	94/100 (94%)	Mean 94%	SD 0%		
#All Organs: Hemangioma						0/50 /00/)	0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#All Organs: Hemangiosarcoma	•••••									
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#All Organs: Hemangiosarcoma or He	mangioma									
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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			
#All Organs: Histiocytic Sarcoma									
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#All Organs: Leukemia: Granulocytic									
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
Leukemia: Lymphocytic, Mo	Total	0/50 (0%) 3/100 (3%)	Mean 3%	3/50 (6%) SD 4.24%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	
#All Organs: Malignant Lymphoma: Histi						0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
#All Organs: Malignant Schwannoma									
		1/50 (2%)		1/50 (2%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#All Organs: Mesothelioma: Benign, Mal						0/50 (00/)	0/50 (00/)		
Overall Institutes	Tatal	1/50 (2%)	Maan 20/	1/50 (2%)	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (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				
#All Organs: Mesothelioma: Malignant										
		1/50 (2%)		1/50 (2%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#All Organs: Osteosarcoma										
		0/50 (0%)		0/50 (0%)		0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
#All Organs: Osteosarcoma or Osteoma		0/50 (00/)		0/50 /00/		0/50 (00/)	4/50 (20/)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%		
*Adrenal Cortex: Adenoma		3/50 (6%)		0/50 (0%)		3/50 (6%)	2/50 (4%)			
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	5/100 (5%)	Mean 5%	SD 1.41%		
*Adrenal Cortex: Carcinoma										
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Ganglioneuroma		0(50 (00))		0(50 (00))		0/50 (00)	0/50 (00/)			
Overell Incidence	Tatal	0/50 (0%)	Mana 00/	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	CD 00/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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 Benign													
	9/50 (18%)		8/50 (16%)		3/50 (6%)	1/50 (2%)							
Total	17/100 (17%)	Mean 17%	SD 1.41%	Total	4/100 (4%)	Mean 4%	SD 2.83%						
mplex													
	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)							
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%						
lignant	2/50 (60/)		0/50 (00/)		2/50 (40/)	0/50 (00()							
Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%						
	, Malignant, NOS		8/50 (16%)		5/50 (10%)	1/50 (2%)							
Total	20/100 (20%)	Mean 20%	SD 5.66%	Total	6/100 (6%)	Mean 6%	SD 5.66%						
							•••••						
	0/50 (0%)		0/50 (0%)		0/50 (0%)	1/50 (2%)							
Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%						
ma	0/50 (0%)		0/50 (0%)		0/50 (0%)	1/50 (29/)							
Total	0/100 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%						
	Total  mplex  Total  lignant  Total  enign, Complex  Total	9/50 (18%) Total 17/100 (17%)  mplex  0/50 (0%) Total 0/100 (0%)  lignant  3/50 (6%) Total 3/100 (3%)  enign, Complex, Malignant, NOS 12/50 (24%) Total 20/100 (20%)  Total 0/100 (0%)  Total 0/100 (0%)	Note	Note	Note	nign  9/50 (18%)  Total 17/100 (17%)  Mean 17%  SD 1.41%  Total 4/100 (4%)  mplex  0/50 (0%)  Total 0/100 (0%)  Mean 0%  SD 0%  Total 0/100 (0%)  Mean 3%  SD 4.24%  Total 2/100 (2%)  mign, Complex, Malignant, NOS 12/50 (24%)  Total 20/100 (20%)  Mean 20%  SD 5.66%  Total 6/100 (6%)  Total 0/100 (0%)  Mean 20%  SD 5.66%  Total 1/100 (1%)  Total 0/100 (0%)  Mean 0%  SD 0/50 (0%)  Total 1/100 (1%)  Total 0/100 (0%)  Mean 20%  SD 5.66%  Total 1/100 (1%)  Total 0/100 (0%)  Mean 0%  SD 0/50 (0%)  Total 0/50 (0%)  Total 0/100 (0%)  Mean 0%  SD 0/50 (0%)  Total 0/100 (0%)  Total 0/100 (0%)  Mean 0%  SD 0/50 (0%)  Total 0/100 (1%)	nign  9/50 (18%) Total 17/100 (17%) Mean 17% SD 1.41% Total 4/100 (4%) Mean 4%  mplex  0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  serign, Complex, Malignant, NOS 12/50 (24%) Total 20/100 (20%) Mean 20% SD 5.66% Total 6/100 (6%) Mean 6%  ma  0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 1/100 (1%) Mean 0% Total 20/100 (20%) Mean 20% SD 5.66% Total 1/100 (1%) Mean 6%  ma  0/50 (0%) 0/50 (0%) 0/50 (0%) Total 1/100 (1%) Mean 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

**Page:** 67

			Male				Female					
*Brain: Glioma Malignant  0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%)												
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Brain: Granular Cell Tumor Benign		2/50 (4%)		2/50 (4%)		1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Brain: Granular Cell Tumor Maligna	ınt	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Brain: Oligodendroglioma, Glioma,	or Astrocy	ytoma 0/50 (0%)		1/50 (2%)		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Brain: Schwannoma Malignant		0/50 (0%)		1/50 (2%)		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Clitoral/Preputial Gland: Carcinoma		1/49 (2%)		0/50 (0%)		0/48 (0%)	1/50 (2%)					
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	1/98 (1.02%)	Mean 1%	SD 1.41%				

<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: 68

			Male				Female	
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		1/49 (2%)		0/50 (0%)		0/48 (0%)	1/50 (2%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	1/98 (1.02%)	Mean 1%	SD 1.41%
*Epididymis: Sarcoma								
		0/50 (0%)		0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
#Eye: Leiomyoma								
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant		4/50 /00/		0/50 (0%)		0/40 (00/)	0/50 (00()	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	Mean 1%	0/50 (0%) SD 1.41%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Large: Colon/Rect Granular Cell Tumor Benig	um:							
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rect	ım:							
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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:** 69

			Male				Female	
#Intestine Small: Jejunum: Carcinoma	:							
		1/50 (2%)		1/50 (2%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Carcinoma								
		1/50 (2%)		1/50 (2%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Site Unsp Carcinoma or Adenoma								
		1/50 (2%)		1/50 (2%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Site Unsp Leiomyosarcoma								
•		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		3/50 (6%)		5/50 (10%)	_	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%

<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				
	0/50 (0%)		0/50 (0%)		1/50 (2%)	0/50 (0%)	
Total	, ,	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
			-/ //>		(70)	(201)	
Total	3/50 (6%) 8/100 (8%)	Mean 8%	5/50 (10%) SD 2.83%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
al Epitheliu	m:						•••••
	1/50 (2%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)		1/50 (29/)		0/50 (0%)	0/50 (0%)	
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (02/)		4/50 (201)		0/50 (09/)	0/50 (00/)	
Total	` ,	Moon 19/	* *	Total	` '	` ,	SD 0%
	Total  al Epitheliu  Total  Total	Total 0/100 (0%)  3/50 (6%) Total 8/100 (8%)  al Epithelium:  1/50 (2%) Total 1/100 (1%)  Total 0/50 (0%)  Total 0/100 (0%)  Total 0/100 (0%)	Total 0/100 (0%) Mean 0%  3/50 (6%) Total 8/100 (8%) Mean 8%  al Epithelium:  1/50 (2%) Total 1/100 (1%) Mean 1%  0/50 (0%)  Total 0/100 (0%) Mean 0%  0/50 (0%)	Total 0/100 (0%) Mean 0% SD 0%  3/50 (6%) 5/50 (10%)  Total 8/100 (8%) Mean 8% SD 2.83%  al Epithelium:  1/50 (2%) 0/50 (0%)  Total 1/100 (1%) Mean 1% SD 1.41%  0/50 (0%)  Total 1/100 (1%) Mean 1% SD 1.41%  0/50 (0%)  Total 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0%	Total 0/100 (0%) Mean 0% SD 0% Total  3/50 (6%) 5/50 (10%) Total 8/100 (8%) Mean 8% SD 2.83% Total  al Epithelium:  1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total  0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41% Total  Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total	Total 0/100 (0%) Mean 0% SD 0% Total 1/100 (1%)  3/50 (6%) 5/50 (10%) 1/50 (2%)  Total 8/100 (8%) Mean 8% SD 2.83% Total 2/100 (2%)  al Epithelium:  1/50 (2%) 0/50 (0%) 0/50 (0%)  Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%)  Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%)  Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%)  Total 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)	Total 0/100 (0%) Mean 0% SD 0% Total 1/100 (1%) Mean 1%  3/50 (6%) 5/50 (10%) 1/50 (2%) 1/50 (2%)  Total 8/100 (8%) Mean 8% SD 2.83% Total 2/100 (2%) Mean 2%  al Epithelium:  1/50 (2%) Mean 1%  0/50 (0%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0%  Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0%  Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 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: FEED

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			Male			Female				
*Kidney: Renal Tubule: Lipoma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
		, ,				, ,				
*Kidney: Renal Tubule: Liposarcoma		0/50 (0%)		1/50 (2%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Nephroblastoma		0/50 (0%)		4/50 (00)		0/50 (00/)	0/50 (09())			
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	Mean 1%	1/50 (2%) SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Kidney: Renal Tubule: Oncocytoma Benign		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Liver: Cholangiocarcinoma		•••••								
		0/50 (0%)		1/50 (2%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Liver: Cholangioma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%		

<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 Adenoma  0/50 (0%) 0/50 (0%) 0/50 (0%) 2/50 (4%)												
		0/50	(0%)		0/50	(0%)		0/50 (0%)	2/50 (4%)			
Overall Incidence	Total	0/100 (0%)		Mean 0%	SD 0%		Total	2/100 (2%)	Mean 2%	SD 2.83%		
*Liver: Hepatocellular Carcinoma	1											
			(0%)		0/50	(0%)		0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	0/100 (0%)		Mean 0%	SD 0%		Total	1/100 (1%)	Mean 1%	SD 1.41%		
*Liver: Hepatocellular Carcinoma	or Hepatobla		(0%)		0/50	(0%)		0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	0/100 (0%)	` ,	Mean 0%	SD 0%	,	Total	1/100 (1%)	Mean 1%	SD 1.41%		
*Liver: Hepatocellular Carcinoma	or Hepatoce		(0%)		0/50	(0%)		0/50 (0%)	3/50 (6%)			
Overall Incidence	Total	0/100 (0%)	` ,	Mean 0%	SD 0%	` ,	Total	3/100 (3%)	Mean 3%	SD 4.24%		
*Liver: Hepatocellular Carcinoma	ı, Hepatocellu	•	•	astoma								
			(0%)		0/50	(0%)		0/50 (0%)	3/50 (6%)			
Overall Incidence	Total	0/100 (0%)		Mean 0%	SD 0%		Total	3/100 (3%)	Mean 3%	SD 4.24%		
*Lung: Alveolar/Bronchiolar Ade	noma											
			(0%)		0/50	(0%)		0/49 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)		Mean 0%	SD 0%		Total	0/99 (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:** 73

			Male				Female				
Lung: Alveolar/Bronchiolar Carcinoma											
		1/50 (2%)		0/50 (0%)		0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%			
*Lung: Alveolar/Bronchiolar Ca											
		1/50 (2%)		0/50 (0%)		0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%			
*Lung: Sarcoma											
		0/50 (0%)		0/50 (0%)		0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%			
*Lung: Squamous Cell Carcinor	ma	0/50 (0%)		1/50 (2%)		0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%			
#Lymph Node, Mesenteric Hemangiosarcoma											
•		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Mammary Gland: Adenolipoma											
		0/50 (0%)		0/50 (0%)		1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			

<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%)		0/50 (0%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Mammary Gland: Carcinoma								
		2/50 (4%)		0/50 (0%)		7/50 (14%)	3/50 (6%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	10/100 (10%)	Mean 10%	SD 5.66%
#Mammary Gland: Carcinoma or Adenoma								
		2/50 (4%)		0/50 (0%)		7/50 (14%)	4/50 (8%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	11/100 (11%)	Mean 11%	SD 4.24%
#Mammary Gland: Fibroadenoma		2/22 (42)		2/22 (121)		22/22 (2.42)		
		2/50 (4%)	••	2/50 (4%)		32/50 (64%)	21/50 (42%)	05 45 5007
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	53/100 (53%)	Mean 53%	SD 15.56%
#Mammary Gland: Fibroma, Fibroadenoma or A	denoma							
		2/50 (4%)		2/50 (4%)		32/50 (64%)	22/50 (44%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	54/100 (54%)	Mean 54%	SD 14.14%
#Mammary Gland: Fibroma, Fibroadenoma, Card				2/50 (4%)		36/50 (72%)	25/50 (50%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	61/100 (61%)	Mean 61%	SD 15.56%
Total moldence	iotai	3/100 (3/0)	MCGII 370	35 1.41/0	iotai	31/100 (01/0)	Wicaii 01/0	GD 10.0070

<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: Myoepithelioma									
		0/50 (0%)		0/50	(0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Carcinoma									
		0/50 (0%)		0/50	(0%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		Total	1/100 (1%)	Mean 1%	SD 1.41%
#Oral Cavity (Oral Mucosa, Squamous Cell Carcinom	•	ynx, Tooth, Gingiva): 0/50 (0%)		0/50	(0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	(575)	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, Squamous Cell Carcinom			Mean 0%	0/50 SD 0%	(0%)	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
							0/100 (0/8)		
#Oral Mucosa: Squamous Cell Carcinom	ıa								
		0/50 (0%)		0/50	(0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma							0/50 (00)	0/50 /00/	
Overall Incidence						Total	0/50 (0%) 0/100 (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: FEED

**Page:** 76

r	Male		Female	
*Ovary: Granulosa Cell Tumor Benign		0/50 (00()	4/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Ovary: Granulosa Cell Tumor Malignant		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Ovary: Granulosa-Theca Tumor Benign		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant		0(50 (00))	0(50 (00))	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Sertoli Cell Tumor Benign		0/50 /02/	0/50 /00/	
Overall Incidence	Total	0/50 (0%) 0/100 (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: FEED

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			Male				Female	
*Ovary: Thecoma Benign								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Tubulostromal Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	5/50 (10%) 8/100 (8%)	Mean 8%	3/50 (6%) SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	5/50 (10%) 8/100 (8%)	Mean 8%	3/50 (6%) SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
Overall Incidence	Total	0/49 (0%) 0/90 (0%)	Mean 0%	0/41 (0%) SD 0%	Total	1/41 (2%) 1/88 (1.14%)	0/47 (0%) Mean 1.22%	SD 1.72%

<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:** 78

			Male				Female			
*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma										
		14/50 (28%)		5/50 (10%)		19/50 (38%)	22/50 (44%)			
Overall Incidence	Total	19/100 (19%)	Mean 19%	SD 12.73%	Total	41/100 (41%)	Mean 41%	SD 4.24%		
Pituitary Gland: Pars Dis Carcinoma										
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
Pituitary Gland: Pars Dis Carcinoma or Adenoma	•									
		14/50 (28%)		5/50 (10%)		19/50 (38%)	22/50 (44%)			
Overall Incidence	Total	19/100 (19%)	Mean 19%	SD 12.73%	Total	41/100 (41%)	Mean 41%	SD 4.24%		
Pituitary Gland: Pars Inte Adenoma										
		2/50 (4%)		0/50 (0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%		
Pituitary Gland: Pars Inte Carcinoma or Adenoma										
		2/50 (4%)		0/50 (0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%		
Pituitary Gland: Pars Ner Schwannoma Malignant										
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

**Page**: 79

Report Date: 07/01/2019

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

			Male				Female	
*Prostate: Adenoma								
Overall Incidence	Total	0/50 (0%) 3/100 (3%)	Mean 3%	3/50 (6 <sup>o</sup> SD 4.24%	%)			
*Prostate: Carcinoma or Adenoma		0/50 (0%)		3/50 (6'	0/)			
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	76)			
*Salivary Glands: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	Mean 0%	0/49 (0 <sup>0</sup> SD 0%	%) Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%
#Seminal Vesicle: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	0/50 (0 <sup>0</sup> SD 0%	,			
#Skeletal Muscle: Liposarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	0/50 (0 <sup>o</sup> SD 0%	%) Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	0/50 (0 <sup>0</sup> SD 0%	%) Total	0/50 (0%) 0/100 (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: FEED

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			Male				Female	
#Skin: Basal Cell Adenoma								
		0/50 (0%)		1/50 (2%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or	Basosquamous	Tumor Benign						
	•	0/50 (0%)		1/50 (2%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Ba	asosquamous T	umor Benign, or Trichoe 0/50 (0%)	pithelioma	1/50 (2%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma o	r Basosquamou	s Tumor (malignant or N	os)					
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin:	Basal Cell Adend	oma, Basosquamous Tun						
,,		0/50 (0%)		1/50 (2%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (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: 07/01/2019

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			
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma										
Overall Incidence	Total	4/50 (8%) 10/100 (10%)	Mean 10%	6/50 (12%) SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Skin: Fibroma		3/50 (6%)		1/50 (2%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	3/50 (6%) 4/100 (4%)	Mean 4%	SD 2.83%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
Fibroma, Fibrosarcoma Hemangiopericytoma Overall Incidence	a, Sarcoma, Myx	oma, Myxosarcoma, Mali 3/50 (6%) 5/100 (5%)	gnant Fibrous Histi	2/50 (4%) SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%		
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myx	oma, Myxosarcoma, or M	alignant Fibrous Hi	stiocytoma						
Overall Incidence	Total	3/50 (6%) 5/100 (5%)	Mean 5%	2/50 (4%) SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%		
#Skin: Fibrosarcoma		0/50 (0%)		1/50 (2%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Fibrosarcoma, Sarcom	na, Myxosarcoma	a, or Malignant Fibrous H	stiocytoma	1/50 (2%)		0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%		

<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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0/50 (0%) % SD 0%  0/50 (0%) % SD 0%  0/50 (0%) SD 0%	Total Total Total	0/50 (0%) 0/100 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%  0/50 (0%) Mean 0%  0/50 (0%)  Mean 0%	SD 0%
% SD 0%  0/50 (0%)  % SD 0%  0/50 (0%)	Total	0/100 (0%)  0/50 (0%)  0/100 (0%)  0/50 (0%)	Mean 0%  0/50 (0%)  Mean 0%  0/50 (0%)	SD 0%
0/50 (0%) % SD 0% 0/50 (0%)	Total	0/50 (0%) 0/100 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%
% SD 0% 0/50 (0%)	Total	0/50 (0%) 0/100 (0%) 0/50 (0%)	Mean 0% 00 00 00 00 00 00 00 00 00 00 00 00	
% SD 0% 0/50 (0%)		0/100 (0%)	Mean 0% 00 00 00 00 00 00 00 00 00 00 00 00	
0/50 (0%)		0/50 (0%)	0/50 (0%)	
, ,		` ,	( /	
, ,		` ,	( /	
% SD 0%	lotal	(1/1()() (()%)		
			ivieari u%	SD 0%
5/50 (10%)		0/50 (0%)	0/50 (0%)	
% SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%
0/50 (0%)		0/50 (0%)	0/50 (0%)	
% SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
0/50 /09/\		0/50 (09/)	0/50 (09/)	
U/SU (U%)		, ,	` ,	SD 0%
	0/50 (0%) % SD 2.83%	0/50 (0%) % SD 2.83% Total 0/50 (0%)	0/50 (0%) 0/50 (0%) 2% SD 2.83% Total 0/100 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) % SD 2.83% Total 0/100 (0%) Mean 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: Neurofibrosarcoma or Schwannoma (malignant or NOS)											
		0/50 (0%)		0/50	(0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Neurofibrosarcoma, Neu											
Neuronbrosarcoma, Neu	ironbronia, or s	0/50 (0%)	iligilatit of NO3)	0/50	(0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	` '	Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Osteosarcoma											
		0/50 (0%)		0/50	(0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Sarcoma											
		0/50 (0%)		0/50	(0%)		0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		Total	1/100 (1%)	Mean 1%	SD 1.41%		
#Skin: Schwannoma Malignant											
· ·		0/50 (0%)		0/50	(0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	. ,	Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Squamous Cell Carcino	ma					•••••					
		0/50 (0%)		0/50	(0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		Total	0/100 (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

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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Report Date: 07/01/2019

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma										
0%										
0%										
0%										
0 0%										
0%										
0%										

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

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

Contract/Lab: All Laboratories

Species: RATS

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

### **Toxicology Data Management System**

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

Vehicle: FEED

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			Male					Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma									
		0/50 (0%)		0/50	(0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		Total	0/100 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Malignant									
		0/50 (0%)		0/50	(0%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		Total	1/100 (1%)	Mean 1%	SD 1.41%
*Spleen: Hemangiosarcoma				- /					
	<b>-</b>	0/50 (0%)		0/50	(0%)	<b>.</b>	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Sarcoma		0/50 (00/)		0/50	(00()		0/50 (001)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	0/50 SD 0%	(0%)	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	10lai		Wiedii 0%			10tai	0/100 (0%)	Weatt 076	
#Stomach, Forestomach: Squamous Cell Carcinoma									
		0/50 (0%)		0/50	(0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma		=				•••••			
		0/50 (0%)		0/50	(0%)		0/50 (0%)	0/50 (0%)	22.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		Total	0/100 (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	
#Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Testis: Adenoma								
		1/50 (2%)		0/50 (0%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Thymus: Thymoma Benign								
		0/46 (0%)		0/48 (0%)		0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
		0/46 (0%)		0/48 (0%)		0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malignan	t, NOS							
3	•	0/46 (0%)		0/48 (0%)		0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma								
		7/50 (14%)		11/49 (22%)		5/50 (10%)	9/50 (18%)	
Overall Incidence	Total	18/99 (18.18%)	Mean 18.22%	SD 5.97%	Total	14/100 (14%)	Mean 14%	SD 5.66%

<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: 87

			Male				Female		
*Thyroid Gland: C-Cell: Carcinoma									
		1/50 (2%)		0/49 (0%)		1/50 (2%)	1/50 (2%)		
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
		8/50 (16%)		11/49 (22%)		6/50 (12%)	9/50 (18%)		
Overall Incidence	Total	19/99 (19.19%)	Mean 19.22%	SD 4.56%	Total	15/100 (15%)	Mean 15%	SD 4.24%	
*Thyroid Gland: Follicular Cell: Carcinoma									
		0/50 (0%)		0/49 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		0/50 (00/)		0/40 (00/)		0/50 (00/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Tissue NOS: Schwannoma Malignant									
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Carcinoma		0/50 (0%)		0/50 (/0%)		0/50 (09/)	0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	
Jveran incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	3D 0%	

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

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

**Toxicology Data Management System** 

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	
#Tongue: Squamous Cell Carcino	ma or Papilloma	a Squamous						
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma								
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma								
		0/50 (0%)		0/49 (0%)		0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Uterus: Standard or Exte Adenocarcinoma	ended Evaluation	ns (Combined):				5/50 (10%)	1/50 (2%)	
Overall Incidence					Total	6/100 (6%)	Mean 6%	SD 5.66%
#Uterus: Standard or Exte		ns (Combined):						
						5/50 (10%)	2/50 (4%)	
Overall Incidence					Total	7/100 (7%)	Mean 7%	SD 4.24%
#Uterus: Standard or Exte	ended Evaluation	ns (Combined):						
Owner Haller at James					T-1-1	0/50 (0%)	1/50 (2%)	OD 4 440/
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%

<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

Strain: Harlan Sprague-Dawley

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

**Page:** 89

Male			Female	
#Uterus: Standard or Extended Evaluations (Combined): Polyp Stromal				
Overall Incidence	Total	8/50 (16%) 24/100 (24%)	16/50 (32%) Mean 24%	SD 11.31%
#Uterus: Standard or Extended Evaluations (Combined): Sarcoma Stromal				
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Uterus: Standard or Extended Evaluations (Combined): Sarcoma Stromal or Polyp Stromal				
Overall Incidence	Total	8/50 (16%) 24/100 (24%)	16/50 (32%) Mean 24%	SD 11.31%
#Vagina: Granular Cell Tumor Benign		2(72)	(00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Polyp				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Schwannoma Malignant				
Overall Incidence	Total	0/50 (0%) 0/100 (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: FEED

**Page:** 90

			Male			Female			
#Zymbal's Gland: Carcinoma									
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma or Adenoma									
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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: 07/01/2019

### **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

**Page:** 92

			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

**Page:** 93

			Male				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		phocytic, Mixed, NOS, o 1/50 (2%)	r Undifferentiated Ce	ell Type		2/50 (4%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
#All Organs:									
Malignant Schwannoma		( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( (							
Malignant Schwannoma		1/50 (2%)				2/50 (4%)			
Malignant Schwannoma	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	
•		1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
Malignant Schwannoma  Overall Incidence  #All Organs:		1/50 (2%)	Mean 2%	SD 0%	Total	` '	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: PERINATAL AND POSTNATAL

Vehicle: WATER

**Page:** 94

			Male				Female	
#All Organs: Mesothelioma: 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%
#All Organs: Osteosarcoma								
		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: Osteosarcoma or Osteom	a	0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Adrenal Cortex: 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%
*Adrenal Cortex: Carcinoma		` '				( ,		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Ganglioneuroma		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

**Page:** 95

			Male				Female					
*Adrenal Medulla: Pheochromocytoma Benign  10/50 (20%)  1/50 (2%)												
, ,		10/50 (20%)				1/50 (2%)						
Overall Incidence	Total	10/50 (20%)	Mean 20%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
*Adrenal Medulla: Pheochromocytoma Comp												
		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: Pheochromocytoma Maligr	nant	2/50 (4%)				1/50 (2%)						
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
*Adrenal Medulla: Pheochromocytoma: Beniç	ın, Complex	, <b>Malignant, NOS</b> 12/50 (24%)				2/50 (4%)		OD 004				
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%				
#Bone: Osteosarcoma		0/50 (00/)				0/50 (00/)						
Overell Incidence	T-4-1	0/50 (0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Mann 00/	CD 00/				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Bone: 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%				

<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:** 96

				Male				Female	
*Brain: Glioma Malignant									
_			(4%)				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	n								
_		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: Granular Cell Tumor Maligr	nant	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: Oligodendroglioma, Glioma		toma							
Overall Incidence	Total	2/50 (4%)	(4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant									
			(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%
*Clitoral/Preputial Gland: Carcinoma		0/-0	(224)				2/52 (224)		
Overall Insidence	Tatal		(0%)	Mann 00/	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

**Page:** 97

			Male				Female	
*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%
*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								
		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/Rectu Granular Cell Tumor Benig	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%
#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: PERINATAL AND POSTNATAL

Vehicle: WATER

**Page:** 98

			Male				Female	
#Intestine Small: Jejunum: Carcinoma								
		1/50 (2%	6)			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								
Overall Incidence	Total	0/50 (0%)	•	CD 00/	Total	0/50 (0%)	Maan 00/	SD 0%
Overall incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma	cified:	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%
		` '			10tai	0/50 (0%)		JD 0%
#Intestine Small: Site Unspec Carcinoma or Adenoma	cified:	1/50 (2%	6)			0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec								
•		0/50 (0%	(o)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		2/50 (4%	,	05.00/		1/50 (2%)		00.007
Overall Incidence	Total	2/50 (4%)	Mean 4%	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: PERINATAL AND POSTNATAL

Vehicle: WATER

**Page:** 99

			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 Transition Papilloma	onal 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		2/52 (124)				2(22)		
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 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		0/50 (40)				0/50 (00/)		
	<b>.</b>	2/50 (4%)	10/	<b>OD</b> 00/	<b>-</b>	0/50 (0%)	NA 00/	00.00/
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

Page: 100

			Male				Female	
*Kidney: Renal Tubule: 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%
*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%
*Liver: Cholangiocarcinoma		` '				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Cholangioma		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

Page: 101

1/50 1/50 (2%) 0/50 0/50 (0%)	(0%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
1/50 (2%) 0/50	(0%)	Mean 2%	SD 0%	Total	` '	Mean 2%	SD 0%
0/50	(0%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
	, ,						
	, ,						
0/50 (0%)	)				0/50 (0%)		
		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
blastoma 0/50	(0%)				0/50 (0%)		
` '	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
cellular Adenoma					1/50 (2%)		
1/50 (2%)	) ` ´	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
						•••••	
					1/50 (2%)		
` ,	,		SD 0%	Total	` '	Mean 2%	SD 0%
	. ,	Mean 2%	SD 0%	Total	` '	Mean 0%	SD 0%
ec	0/50 0/50 (0%) cellular Adenoma 1/50 1/50 (2%) llular Adenoma, o 1/50 1/50 (2%)	0/50 (0%) 0/50 (0%)  cellular Adenoma 1/50 (2%) 1/50 (2%)  Illular Adenoma, or Hepatob 1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%) Mean 0%  cellular Adenoma 1/50 (2%) 1/50 (2%) Mean 2%  Illular Adenoma, or Hepatoblastoma 1/50 (2%) 1/50 (2%) Mean 2%	0/50 (0%) 0/50 (0%) Mean 0% SD 0%  cellular Adenoma 1/50 (2%) 1/50 (2%) Mean 2% SD 0%  llular Adenoma, or Hepatoblastoma 1/50 (2%) 1/50 (2%) Mean 2% SD 0%	0/50 (0%)  0/50 (0%)  Mean 0%  SD 0%  Total  cellular Adenoma  1/50 (2%)  1/50 (2%)  Mean 2%  SD 0%  Total  Illular Adenoma, or Hepatoblastoma  1/50 (2%)  1/50 (2%)  Mean 2%  SD 0%  Total	0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Cellular Adenoma 1/50 (2%) 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%)  Illular Adenoma, or Hepatoblastoma 1/50 (2%) 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Cellular Adenoma 1/50 (2%) 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2%  Illular Adenoma, or Hepatoblastoma 1/50 (2%) 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2%  Illular Adenoma, or Hepatoblastoma 1/50 (2%) 1/50 (2%) Mean 2%  Illular Adenoma, or Hepatoblastoma 1/50 (2%) Mean 2%  O/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: WATER

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			Male				Female	
*Lung: Alveolar/Bronchiolar Car	rcinoma							
		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 Car								
		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: 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%
*Lung: Squamous Cell Carcinor 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		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 (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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#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%
#Mammary Gland: Fibroadenoma		0/50 (0%)				30/50 (60%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	30/50 (60%)	Mean 60%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma or								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	32/50 (64%) 32/50 (64%)	Mean 64%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, C	arcinoma, or	Adenoma 0/50 (0%)				34/50 (68%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	34/50 (68%)	Mean 68%	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: Myoepithelioma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Nose: 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%
#Oral Cavity (Oral Mucos Squamous Cell Carcino	a, Tongue, Phary					0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcino	a, Tongue, Phary					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	oma							
oquanious cen 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%
·	Total	` ,	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	
*Ovary: Granulosa Cell Tumor Benign					
Overall Incidence		Total	0/50 (0%) 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, Malignant, NOS			4/50 (00)		
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*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: Sertoli Cell Tumor 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: Thecoma Benign								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: 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%
Overall incluence		, ,				` '		
*Pancreas: Carcinoma		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%
*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%

<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		

			Male				Female	
*Pituitary Gland: Pars Distalis Adenoma	or Unspeci	fied Site:						
		8/50 (16%)				16/50 (32%)		
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	16/50 (32%)	Mean 32%	SD 0%
*Pituitary Gland: Pars Distalis 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%
*Pituitary Gland: Pars Distalis Carcinoma or Adenoma								
		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 Interme Adenoma								
	<b>-</b>	1/50 (2%)		<b>OD</b> 00/	<b>T</b>	0/50 (0%)		OD 00/
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Interme Carcinoma or Adenoma	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 Nervosa Schwannoma Malignant								
Overall Incidence	Total	1/50 (2%)	Moon 20/	SD 00/	Total	0/50 (0%)	Moon 09/	SD 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: PERINATAL AND POSTNATAL

Vehicle: WATER

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		Male					Female			
*Prostate: Adenoma		,								
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%					
*Prostate: Carcinoma or Adenoma										
Overall Incidence	Total	0/50 0/50 (0%)	(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										
Overall Incidence	Total	1/50 (2%)	(2%)	Mean 2%	SD 0%					
#Skeletal Muscle: Liposarcoma										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skeletal Muscle: 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%	

<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:** 109

			Male				Female			
#Skin: Basal Cell Adenoma										
		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%		
#Skin:		• • • • • • • • • • • • • • • • • • • •								
Basal Cell Adenoma or	· Basosquamous	_								
		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, B	asosquamous Ti	umor Benign, or Tric	choepithelioma							
		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%		
#Skin:										
<b>Basal Cell Carcinoma</b>										
		0/50 (0%	o)			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 Basosquamou	s Tumor (malignant	or NOS)							
		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%		
#Skin:										
-		oma, Basosquamous	s Tumor (benign, malign	ant or						
<b>/,</b>	<del>-</del>	0/50 (0%	s)			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: 110

			Male				Female				
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma  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: Fibroma		3/50 (6%)				1/50 (2%)					
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
#Skin: Fibroma, Fibrosarcoma Hemangiopericytoma	a, Sarcoma, Myxo	3/50 (6%)		ocytoma, or	Total	3/50 (6%)	Moon 6%	SD 0%			
Overall Incidence		3/50 (6%)	Mean 6%		Total	3/50 (6%)	Mean 6%	SD 0%			
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myxo	oma, Myxosarcoma, or 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		0/50 (00/)				1/50 (2%)					
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, Sarcom	a, Myxosarcoma,	or Malignant Fibrous	Histiocytoma			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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#Skin: Hemangioma		0/20 (553)				(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: Hemangiopericytoma		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: 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%
#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								
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: Malignant Fibrous Histion	cytoma	0/50 (0%)				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%

<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			0/50 (0%) Total 0/50 (0%) Mean 0% SD  1/50 (2%) Total 1/50 (2%) Mean 2% SD  0/50 (0%) Total 0/50 (0%) Mean 0% SD  0/50 (0%) Total 0/50 (0%) Mean 0% SD		
Overall Incidence	Total	0/50 (0%)		Mean	0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Neurof	ibroma, or S	•	enign, maligr (0%)	nant or N	ios)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean	0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin: Osteosarcoma			(0%)					1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean	0%	SD 0%	Total	` '	Mean 2%	SD 0%
#Skin: Sarcoma			(0%)							
Overall Incidence	Total	0/50 (0%)	` '	Mean	0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin: Schwannoma Malignant		0/50	(0%)					0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean	0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma		0/50	(00()					0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean		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

Species: RATS

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 07/01/2019

Route: PERINATAL AND POSTNATAL

Vehicle: WATER

Strain: Harlan Sprague-Dawley

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female			
#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or 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 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%		
#Skin: Squamous Cell Papilloma	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%		
#Skin: Squamous Cell Papilloma,	, Papilloma, S	quamous Cell Carcinoma 1/50 (2%)	a or Keratoacanthon	na		0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Squamous Cell Papilloma,	, Papilloma, o	r 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: Sebaceous Gland: Adenoma						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: 114

			Male					
#Skin: Sebaceous Gland: Carcinoma or 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%
#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 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Sarcoma		0/50 (0%)	Magr. 00/	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%
#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						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					
#Stomach, Forestomach: Squamous Cell Papilloma Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Overall incidence	10tai	0/50 (0%)		3D 0%		0/50 (0%)	wiean 0%	3D 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, Maligna								
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma								
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

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				Male			Female		
*Thyroid Gland: C-Cell: Carcinoma			4						
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma			(8%)				7/50 (14%)		
Overall Incidence	Total	4/50 (8%)	(070)	Mean 8%	SD 0%	Total	7/50 (14%)	Mean 14%	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		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	(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%
#Tongue: Squamous Cell Carcinoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(370)	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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female				
#Tongue: Squamous Cell Carcinoma or Papilloma Squamous  0/50 (0%)											
Occupation at damps	T-1-1	0/50 (0%)	M 00/	05.00/	T-1-1	0/50 (0%)	Mara 2007	00.00/			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Tooth: Odontoma		2(22)				2(72)					
Overall Institutes	Tatal	0/50 (0%)	Mann 00/	CD 00/	Tatal	0/50 (0%)	Maga 00/	CD 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: Standard or Exte	ended Evaluation	ns (Combined):									
Overall Incidence											
#Uterus: Standard or Exte Adenocarcinoma or Ad		ns (Combined):					•••••				
Overall Incidence											
#Uterus: Standard or Exte	ended Evaluation	ns (Combined):					•••••				
Overall Incidence											
*: Denominator is number of an		xamined microscopically									

Contract/Lab: 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	
#Uterus: Standard or Extended Evaluations (Combined): Polyp Stromal					
Overall Incidence					
#Uterus: Standard or Extended Evaluations (Combined): Sarcoma Stromal					
Overall Incidence					
#Uterus: Standard or Extended Evaluations (Combined): Sarcoma Stromal or Polyp Stromal					
Overall Incidence					
#Vagina: Granular Cell Tumor Benign			0/50 (00/)		
Overall Incidence		Total	0/50 (0%) 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					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*: Denominator is number of animals with tissues examined microscopically					

<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		0/50 (0%)			
#Zymbal's Gland: Carcinoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 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

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Report Date: 07

Report Date: 07/01/2019

## **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

**Toxicology Data Management System** 

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Report Date: 07/01/2019

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

			Male				Female	
#All Organs: Benign Tumors Overall Incidence	Total	49/90 (54%) 49/90 (54.44%)	Mean 54.44%	SD 0%	Total	82/90 (91%) 82/90 (91.11%)	Mean 91.11%	SD 0%
Overall incluence		49/90 (34.4470)						
#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 T	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								
Overall Incidence	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%
#All Organs: Hemangiosarcoma or He						2/00 (20/)		
Overall Incidence	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%

<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

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Report Date: 07/01/2019

Route: Whole Body Exposure

Vehicle: AIR

			Male			Female           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         5/90 (6%) 0/90 (5.56%)         Mean 5.56%         SD 0%           Total         4/90 (4%) 0/90 (4.44%)         Mean 4.44%         SD 0%		Female		
#All Organs: Histiocytic Sarcoma		0/90 (0%)				0/00 (09/)	0/90 (0%) 90 (0%) Mean 0% SD 0% 0/90 (0%) 90 (0%) Mean 0% SD 0% 0/90 (0%) 0/90 (0%) Mean 0% SD 0% 5/90 (6%) 0 (5.56%) Mean 5.56% SD 0%			
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%		
All Organs: Leukemia: Granulocytic		0/00 /00/				0/00 (00/)				
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	()	Mean 0%	SD 0%		
#All Organs: Leukemia: Lymphocytic, I  Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%		
All Organs: Malignant Lymphoma: His	stiocytic, Lym	nphocytic, Mixed, NOS, o 2/90 (2%)	r Undifferentiated Ce	II Туре		5/90 (6%)				
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	5/90 (5.56%)	Mean 5.56%	SD 0%		
All Organs: Malignant Schwannoma		3/90 (3%)				4/90 (4%)				
Overall Incidence	Total	3/90 (3.33%)	Mean 3.33%	SD 0%	Total	4/90 (4.44%)	Mean 4.44%	SD 0%		
#All Organs: Mesothelioma: Benign, Ma	alignant, NOS	<b>S</b> 2/90 (2%)				0/90 (0%)				
		2/00 (2/0)				0,00 (0,0)				

SD 0%

Total

0/90 (0%)

Mean 0%

SD 0%

Total

2/90 (2.22%)

Mean 2.22%

**Overall Incidence** 

<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: Whole Body Exposure

Vehicle: AIR

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			Male		0/90 (0%) D 0% Total 0/90 (0%) Mean 0%  0/90 (0%) D 0% Total 0/90 (0%) Mean 0%			
#All Organs: Mesothelioma: Malignant								
_		2/90 (2%)				0/90 (0%)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%		` '		SD 0%
#All Organs: 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%
#All Organs: Osteosarcoma or Osteoma		0/90 (0%)				0/00 (00/)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
		, ,				, ,		
*Adrenal Cortex: Adenoma		4/00 (40)				4/00 (40()		
Overall Incidence	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	Total	, ,	Mean 1.11%	SD 0%
*Adrenal Cortex: 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%
*Adrenal Medulla: Ganglioneuroma								
		0/88 (0%)				0/86 (0%)		
Overall Incidence	Total	0/88 (0%)	Mean 0%	SD 0%	Total	0/86 (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

**Report Date:** 07/01/2019

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			Male				Female	
*Adrenal Medulla: Pheochromocytoma Benig	n							
Overall Incidence	Total	10/88 (11%) 10/88 (11.36%)	Mean 11.36%	SD 0%	Total	1/86 (1%) 1/86 (1.16%)	Mean 1.16%	SD 0%
*Adrenal Medulla: Pheochromocytoma Comp								
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 Maligi								
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: Benig						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								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma								
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				0/90 (0%) 0% Total 0/90 (0%) Mean 0% SD  1/90 (1%) 0% Total 1/90 (1.11%) Mean 1.11% SD  0/90 (0%) 0% Total 0/90 (0%) Mean 0% SD  0/90 (0%) 0% Total 0/90 (0%) 0% Total 0/90 (0%) 0% SD					
*Brain: Glioma Malignant											
•		0/90 (0%)				0/90 (0%)					
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%		, ,		SD 0%			
*Brain: Granular Cell Tumor Ber	ign										
	•	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%			
*Brain: Granular Cell Tumor Mal	ignant	0/00 /00/				0/00 (00/)					
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	` '	Maan 00/	SD 0%			
		0/90 (0%)				, ,		3D 0%			
*Brain: Oligodendroglioma, Glio	ma, or Astrocy	rtoma									
		0/90 (0%)				0/90 (0%)					
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 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: 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: Carcinoma or Adenoma								
Overall Incidence	Total	0/88 (0%) 0/88 (0%)	Mean 0%	SD 0%	Total	0/87 (0%) 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:							
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%
#Intestine Large: Colon/Rect Leiomyoma						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**

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Report Date: 07/01/2019

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

			Male			Female           Total         0/90 (0%)         Mean 0%         SD 0%           1/90 (1%)         Total 1/90 (0%)         Mean 1.11%         SD 0%           Total 0/90 (0%)         Mean 0%         SD 0%           Total 0/90 (0%)         Mean 0%         SD 0%           Total 1/90 (1.11%)         Mean 1.11%         SD 0%			
#Intestine Small: Jejunum: Carcinoma		2/90 (2%)				0/90 (0%)			
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	, ,	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Leiomyosarcoma		0/00 /00/				4/00 (48%)			
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%		1/90 (1.11%)		SD 0%	
#Intestine Small: Site Unsp Carcinoma									
Overall Incidence	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%	Total	` ,	Mean 0%	SD 0%	
#Intestine Small: Site Unsp Carcinoma or Adenoma		2/90 (2%)				0/00 /0%			
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	()	Mean 0%	SD 0%	
#Intestine Small: Site Unsp Leiomyosarcoma	ecified:								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 1.11%	SD 0%	
*Islets, Pancreatic: Adenoma									
Overall Incidence	Total	5/90 (6%) 5/90 (5.56%)	Mean 5.56%	SD 0%	Total	5/90 (6%) 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

Species: RATS

**Toxicology Data Management System** 

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Report Date: 07/01/2019

Contract/Lab: All Laboratories

Strain: Harlan Sprague-Dawley

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Length of Study: CHRONIC 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 Transitional Epithelium: **Papilloma** 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 Mean 3.33% SD 0% Total Mean 1.11% SD 0% 3/90 (3.33%) 1/90 (1.11%) \*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%)

SD 0%

2/90 (2.22%)

Total

Mean 2.22%

SD 0%

Total

3/90 (3.33%)

Mean 3.33%

**Overall Incidence** 

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

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

Species: RATS

**Toxicology Data Management System** 

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

Route: Whole Body Exposure

Vehicle: AIR

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Report Date: 07/01/2019

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

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

<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: Hepatocellular Adenoma								
Overall Incidence	Total	0/90 (0 0/90 (0%)	%) Mean 0%	SD 0%	Total	7/90 (8%) 7/90 (7.78%)	Mean 7.78%	SD 0%
*Liver: Hepatocellular Carcinoma								
Overall Incidence	Total	0/90 (0 0/90 (0%)	%) Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	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 Overall Incidence	or Hepatoce	llular Adenoma 0/90 (0 0/90 (0%)	%) Mean 0%	SD 0%	Total	7/90 (8%) 7/90 (7.78%)	Mean 7.78%	SD 0%
*Liver: Hepatocellular Carcinoma,			•			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 Aden		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%

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

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

Species: RATS

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Page: 131

Report Date: 07/01/2019

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

Contract/Lab: All Laboratories

		Male					Female	
*Lung: Alveolar/Bronchiolar Card	inoma							
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Lung:		a alau/Duamahialau A dana						
Alveolar/Bronchiolar Carc	inoma or Aiv	eolar/Bronchiolar Adend 1/90 (1%)	oma			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								
		0/90 (0%)		05.00/		0/90 (0%)		<b>25</b> /
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Lung: Squamous Cell Carcinoma	a	0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma								
·		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: Adenolipoma								
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

**Toxicology Data Management System** 

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Report Date: 07/01/2019

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

			Male			Female				
#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										
		0/90 (0%)				10/90 (11%)				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	10/90 (11.11%)	Mean 11.11%	SD 0%		
#Mammary Gland: Carcinoma or Adenoma										
		0/90 (0%)				16/90 (18%)				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	16/90 (17.78%)	Mean 17.78%	SD 0%		
#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, Fibroadenoma or	r Adenoma									
		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, Fibroadenoma, C	Carcinoma, o	r Adenoma								
		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%		

<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	
#Mammary Gland: Myoepithelioma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Nose: Carcinoma								
Overall Incidence	Total	0/89 (0%) 0/89 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcino		vnx, Tooth, Gingiva):  0/90 (0%)				2/90 (2%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	SD 0%
	a, Tongue, Phary oma, Papilloma S	rnx, Tooth, Gingiva): quamous, or Papilloma 0/90 (0%)		OD 00/	<b>T</b> -1-1	2/90 (2%)	M 0.000/	<b>OD</b> 007
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	SD 0%
#Oral Mucosa: Squamous Cell Carcino	oma	0/00 (00/)				4/00 (40)		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%
*Ovary: Cystadenoma						4/00 (40)		
						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

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	Male			Female	
*Ovary: Granulosa Cell Tumor Benign					
Overall Incidence		Total	1/90 (1%) 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, Malignant, NOS					
Overall Incidence		Total	3/90 (3%) 3/90 (3.33%)	Mean 3.33%	SD 0%
*Ovary: Granulosa-Theca Tumor Benign					
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant					
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Ovary: Sertoli Cell Tumor Benign					
Overall Incidence		Total	1/90 (1%) 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

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: Whole Body Exposure

Vehicle: AIR

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			Male				Female			
*Ovary: Thecoma Benign										
Overall Incidence					Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%		
*Ovary: Tubulostromal Carcinom	na									
Overall Incidence					Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%		
*Pancreas: Adenoma		10/00 (0531)				0/00 (00)				
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						0/00 (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										
		18/90 (20%)				0/90 (0%)				
Overall Incidence	Total	18/90 (20%)	Mean 20%	SD 0%	Total	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%		

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

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

Species: RATS

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

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

**Page:** 136

Report Date: 07/01/2019

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

Contract/Lab: All Laboratories

			Male				Female	
Pituitary Gland: Pars Dista Adenoma	alis or Unspec	ified Site:						
		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 Dista 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 Dista 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 Inter 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%
Pituitary Gland: Pars Inter Carcinoma or Adenoma	media:							
		0/89 (0%)				0/90 (0%)		
Overall Incidence	Total	0/89 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Nerv Schwannoma Malignant	osa:							
		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

Contract/Lab: 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	
*Prostate: Adenoma Overall Incidence	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%				
*Prostate: Carcinoma or Adenoma		2/90 (2%)						
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%				
*Salivary Glands: 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%
#Seminal Vesicle: Hemangiosarcoma		0/90 (0%)						
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Liposarcoma		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: 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%

<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: 07/01/2019

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley
Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

			Male		Female			
#Skin:		,						
Basal Cell Adenoma								
	<b>-</b>	1/90 (1%)		00.00/	<b></b>	0/90 (0%)		OD 00/
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	s 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:		Frimas Banian as Triabaa	uithaliama					
basai Celi Adenoma, ba	asosquamous i	Fumor Benign, or Trichoe 1/90 (1%)	pitnelloma			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 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:								
-	r Basosquamoi	us Tumor (malignant or N	IOS)					
Busar Sen Suromonia S	, Basosquamot	0/90 (0%)	100)			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, E	Basal Cell Aden	oma, Basosquamous Tu	mor (benign, maligna	int or				
NOS), or Trichoepithelic	oma	1/00 (40/)				0/00 (00/)		
		1/90 (1%)				0/90 (0%)		

SD 0%

Total

0/90 (0%)

Mean 0%

SD 0%

Total

1/90 (1.11%)

Mean 1.11%

**Overall Incidence** 

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

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

Species: RATS

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

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

**Page:** 139

Report Date: 07/01/2019

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

Contract/Lab: All Laboratories

			Male				Female	
		a, Basosq. Tumor (M or ratoacanthoma, Trichoe		na,				
, ,	• • •	8/90 (9%)	•			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								
Overall Incidence	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%
#Skin: Fibroma, Fibrosarcoma Hemangiopericytoma  Overall Incidence	a, Sarcoma, Myx Total	oma, Myxosarcoma, Mal 5/90 (6%) 5/90 (5.56%)	ignant Fibrous Histion Mean 5.56%	cytoma, or	Total	5/90 (6%) 5/90 (5.56%)	Mean 5.56%	SD 0%
#Skin:		oma, Myxosarcoma, or N 5/90 (6%)			7044	5/90 (6%)		02 0/0
Overall Incidence	Total	5/90 (5.56%)	Mean 5.56%	SD 0%	Total	5/90 (5.56%)	Mean 5.56%	SD 0%
#Skin: Fibrosarcoma		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: Fibrosarcoma, Sarcom	a, Myxosarcoma	ı, or Malignant Fibrous H 3/90 (3%)	listiocytoma			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	
#Skin: 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%
#Skin: Hemangiopericytoma		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: Hemangiosarcoma		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: 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								
Overall Incidence	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Skin: Malignant Fibrous Histion	cytoma	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%

<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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
#Skin: Neurofibrosarcoma or Sch	wannoma (n					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%
#Skin: Neurofibrosarcoma, Neuro	fibroma, or S	Schwannoma (benign, ma	alignant or NOS)			0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Osteosarcoma		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%
#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								
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: 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%

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

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

Version: Apr2019 Contract/Lab: All Laboratories

Species: RATS

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

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Report Date: 07/01/2019

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

			Male				Female	
#Skin: Squamous Cell Carcinoma or Carcinoma	a, Basal Cell	Carcinoma, Basosquamo	ous Tumor (malignant	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%
#Skin: Squamous Cell Papilloma		0/00 (00/)				0/00 /00/		
Overall Incidence	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma		ı						
		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 Papilloma	, Papilloma, \$	Squamous Cell Carcinom 7/90 (8%)	a or Keratoacanthom	a		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 Papilloma						0/90 (0%)		
Overall Incidence	Total	7/90 (7.78%)	Mean 7.78%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma		4/00 /40/						
Overall Incidence	Total	1/90 (1.41%)	Mean 1.11%	CD 00/	Total	0/90 (0%)	Maan 00/	CD 00/
Overall incluence	Total	1/90 (1.11%)	iviean 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

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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

\*Testis: Adenoma

\*Thymus:

\*Thymus:

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

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

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Mean 6.67%

SD 0%

Report Date: 07/01/2019

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

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% 2/90 (2%)**Overall Incidence** Total 2/90 (2.22%) Mean 2.22% SD 0% 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% ...... **Thymoma Malignant** 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: Benign, Malignant, NOS

> 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

**Overall Incidence** 

8/89 (9%)6/90 (7%)Total 8/89 (8.99%) Mean 8.99% SD 0% Total 6/90 (6.67%)

\*: 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

Page: 145

			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									
		10/89 (11%)				6/90 (7%)			
Overall Incidence	Total	10/89 (11.24%)	Mean 11.24%	SD 0%	Total	6/90 (6.67%)	Mean 6.67%	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									
Overall Incidence	Total	0/89 (0%) 0/89 (0%)	Mean 0%	SD 0%	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	
#Tissue NOS: Schwannoma Malignant									
		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%	
#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%	

<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

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				Male				Female	
#Tongue: Squamous Cell Carcino	ma or Papilloma	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%)	` ,	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma	Total	0/89 0/89 (0%)	(0%)	Mean 0%	SD 0%	Total	1/88 (1%) 1/88 (1.14%)	Mean 1.14%	SD 0%
#Uterus: Standard or Exte	ended Evaluation	ns (Combined):							
#Uterus: Standard or Exte Adenocarcinoma or Ade		ns (Combined):							
Overall Incidence									
#Uterus: Standard or Exte	ended Evaluation	ns (Combined):							
Overall Incidence									
*: Denominator is number of an		xamined microscop	oically				•••••		

Contract/Lab: 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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		Female			
#Uterus: Standard or Extended Evaluations (Combined): Polyp Stromal					
Overall Incidence					
#Uterus: Standard or Extended Evaluations (Combined): Sarcoma Stromal					
Overall Incidence					
#Uterus: Standard or Extended Evaluations (Combined): Sarcoma Stromal or Polyp Stromal					
Overall Incidence					
#Vagina: Granular Cell Tumor Benign			0/00 (0%)		
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 microscopically					

<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