

NTP Historical Controls Report

All Routes and Vehicles

Harlan Sprague-Dawley RATS

May 2011

REPORT DESCRIPTION

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

The report combines all the data from all of the historical control studies into one section. To see this data broken up by route and vehicle you must run the "By Route And Vehicle" report.

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

Male

M1
M2
M3
M4
M5

Female

F1
F2
F3
F4
F5

the data would be shown as:

	Male			Female		
M1	M2	M3	F1	F2	F3	
M4	M5		F4	F5		

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

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

Version: May2011
Contract/Lab: All Laboratories
Species: RATS
Strain: Harlan Sprague-Dawley
Length of Study: CHRONIC

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

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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	052030401	N/A	N/A	0(0)	0(0)	N/A	TEF evaluation (PCB 118)
Battelle Columbus Laboratory	058814806	01/29/03	727	50(3)	28(665)	606.4	3,3',4,4'-Tetrachloroazobenzene
Female							
Battelle Columbus Laboratory	052030401	03/26/04	733	52(5)	21(616)	383.5	TEF evaluation (PCB 118)
Battelle Columbus Laboratory	058814806	01/30/03	727	50(5)	25(652)	385.7	3,3',4,4'-Tetrachloroazobenzene

Version: May2011
 Contract/Lab: All Laboratories
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 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
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		Male				Female			
#All Organs:									
Benign Tumors									
			40/50 (80%)			43/52 (83%)	40/50 (80%)		
Overall Incidence	Total	40/50 (80%)	Mean 80%	SD 0%	Total	83/102 (81.37%)	Mean 81.35%	SD 1.9%	
.....									
#All Organs:									
Malignant Tumors									
			9/50 (18%)			15/52 (29%)	13/50 (26%)		
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	28/102 (27.45%)	Mean 27.42%	SD 2.01%	
.....									
#All Organs:									
Malignant and Benign Tumors									
			44/50 (88%)			48/52 (92%)	44/50 (88%)		
Overall Incidence	Total	44/50 (88%)	Mean 88%	SD 0%	Total	92/102 (90.2%)	Mean 90.15%	SD 3.05%	
.....									
#All Organs:									
Hemangiosarcoma									
			1/50 (2%)			1/52 (2%)	0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%	
.....									
#All Organs:									
Hemangiosarcoma or Hemangioma									
			1/50 (2%)			1/52 (2%)	0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%	
.....									
#All Organs:									
Histiocytic Sarcoma									
			0/50 (0%)			1/52 (2%)	1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 1.96%	SD 0.05%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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	Male				Female			
#All Organs:								
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated								
			1/50 (2%)			0/52 (0%)	1/50 (2%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%
.....								
#All Organs:								
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type								
			1/50 (2%)			2/52 (4%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/102 (1.96%)	Mean 1.92%	SD 2.72%
.....								
*Adrenal Cortex:								
Adenoma								
			1/50 (2%)			2/52 (4%)	1/50 (2%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	3/102 (2.94%)	Mean 2.92%	SD 1.31%
.....								
*Adrenal Cortex:								
Carcinoma								
			0/50 (0%)			1/52 (2%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%
.....								
*Adrenal Medulla:								
Pheochromocytoma Benign								
			5/50 (10%)			3/52 (6%)	3/50 (6%)	
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	6/102 (5.88%)	Mean 5.88%	SD 0.16%
.....								
*Adrenal Medulla:								
Pheochromocytoma: Benign, Complex, Malignant, NOS								
			5/50 (10%)			3/52 (6%)	3/50 (6%)	
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	6/102 (5.88%)	Mean 5.88%	SD 0.16%

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

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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		Male			Female		
*Brain:							
Astrocytoma Benign							
		1/50	(2%)		0/52	(0%)	0/50 (0%)
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/102 (0%)
							Mean 0%
							SD 0%
.....							
*Brain:							
Oligodendroglioma, Glioma, or Astrocytoma							
		1/50	(2%)		0/52	(0%)	0/50 (0%)
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/102 (0%)
							Mean 0%
							SD 0%
.....							
#Eye:							
Schwannoma Malignant							
		1/50	(2%)		0/52	(0%)	0/50 (0%)
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/102 (0%)
							Mean 0%
							SD 0%
.....							
#Intestine Small: Duodenum:							
Carcinoma							
		0/50	(0%)		0/52	(0%)	1/50 (2%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)
							Mean 1%
							SD 1.41%
.....							
#Intestine Small: Site Unspecified:							
Carcinoma							
		0/50	(0%)		0/52	(0%)	1/50 (2%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)
							Mean 1%
							SD 1.41%
.....							
#Intestine Small: Site Unspecified:							
Carcinoma or Adenoma							
		0/50	(0%)		0/52	(0%)	1/50 (2%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)
							Mean 1%
							SD 1.41%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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		Male			Female		
*Islets, Pancreatic:							
Adenoma							
		2/50 (4%)	Mean 4%	SD 0%	0/52 (0%)	0/50 (0%)	Mean 0%
Overall Incidence	Total	2/50 (4%)			0/102 (0%)		SD 0%
.....							
*Islets, Pancreatic:							
Carcinoma or Adenoma							
		2/50 (4%)	Mean 4%	SD 0%	0/52 (0%)	0/50 (0%)	Mean 0%
Overall Incidence	Total	2/50 (4%)			0/102 (0%)		SD 0%
.....							
*Kidney: Renal Tubule:							
Lipoma							
		0/50 (0%)	Mean 0%	SD 0%	0/52 (0%)	1/50 (2%)	Mean 1%
Overall Incidence	Total	0/50 (0%)			1/102 (0.98%)		SD 1.41%
.....							
*Liver:							
Cholangiocarcinoma							
		0/50 (0%)	Mean 0%	SD 0%	0/52 (0%)	1/50 (2%)	Mean 1%
Overall Incidence	Total	0/50 (0%)			1/102 (0.98%)		SD 1.41%
.....							
*Liver:							
Cholangioma							
		0/50 (0%)	Mean 0%	SD 0%	1/52 (2%)	0/50 (0%)	Mean 0.96%
Overall Incidence	Total	0/50 (0%)			1/102 (0.98%)		SD 1.36%
.....							
*Liver:							
Hepatocellular Adenoma							
		0/50 (0%)	Mean 0%	SD 0%	0/52 (0%)	2/50 (4%)	Mean 2%
Overall Incidence	Total	0/50 (0%)			2/102 (1.96%)		SD 2.83%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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	Male				Female			
*Liver:								
Hepatocellular Carcinoma or Hepatocellular Adenoma								
			0/50 (0%)			0/52 (0%)	2/50 (4%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 2%	SD 2.83%
.....								
*Liver:								
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma								
			0/50 (0%)			0/52 (0%)	2/50 (4%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 2%	SD 2.83%
.....								
*Lung:								
Alveolar/Bronchiolar Adenoma								
			1/50 (2%)			0/51 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/101 (0%)	Mean 0%	SD 0%
.....								
*Lung:								
Alveolar/Bronchiolar Carcinoma								
			1/50 (2%)			0/51 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/101 (0%)	Mean 0%	SD 0%
.....								
*Lung:								
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma								
			2/50 (4%)			0/51 (0%)	0/50 (0%)	
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/101 (0%)	Mean 0%	SD 0%
.....								
#Mammary Gland:								
Adenoma								
			0/50 (0%)			0/52 (0%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%

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

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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 Report Date: 05/17/2011

		Male			Female		
#Mammary Gland: Carcinoma							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/52 (4%) 6/102 (5.88%)	4/50 (8%) Mean 5.92% SD 2.94%
#Mammary Gland: Carcinoma or Adenoma							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/52 (4%) 7/102 (6.86%)	5/50 (10%) Mean 6.92% SD 4.35%
#Mammary Gland: Fibroadenoma							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	25/52 (48%) 56/102 (54.9%)	31/50 (62%) Mean 55.04% SD 9.85%
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	25/52 (48%) 56/102 (54.9%)	31/50 (62%) Mean 55.04% SD 9.85%
#Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	27/52 (52%) 59/102 (57.84%)	32/50 (64%) Mean 57.96% SD 8.54%
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma							
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/52 (0%) 0/102 (0%)	0/50 (0%) Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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Male					Female				
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma									
			1/50 (2%)			0/52 (0%)		0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%	
.....									
#Oral Mucosa: Squamous Cell Carcinoma									
			1/50 (2%)			0/52 (0%)		0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%	
.....									
*Ovary: Granulosa Cell Tumor Malignant									
						0/52 (0%)		1/50 (2%)	
Overall Incidence					Total	1/102 (0.98%)	Mean 1%	SD 1.41%	
.....									
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS									
						0/52 (0%)		1/50 (2%)	
Overall Incidence					Total	1/102 (0.98%)	Mean 1%	SD 1.41%	
.....									
*Ovary: Luteoma									
						1/52 (2%)		0/50 (0%)	
Overall Incidence					Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%	
.....									
*Pancreas: Adenoma									
			9/50 (18%)			0/52 (0%)		0/50 (0%)	
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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		Male			Female		
*Pancreas:							
 Carcinoma							
			0/50 (0%)		0/52 (0%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1% SD 1.41%
.....							
*Pancreas:							
 Carcinoma or Adenoma							
			9/50 (18%)		0/52 (0%)	1/50 (2%)	
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	1/102 (0.98%)	Mean 1% SD 1.41%
.....							
*Parathyroid Gland:							
 Adenoma							
			1/43 (2%)		0/47 (0%)	0/46 (0%)	
Overall Incidence	Total	1/43 (2.33%)	Mean 2.33%	SD 0%	Total	0/93 (0%)	Mean 0% SD 0%
.....							
#Peripheral Nerve:							
 Schwannoma Malignant							
			0/50 (0%)		0/52 (0%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1% SD 1.41%
.....							
#Peripheral Nerve:							
 Schwannoma: Benign, Malignant, NOS							
			0/50 (0%)		0/52 (0%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1% SD 1.41%
.....							
*Pituitary Gland: Pars Distalis or Unspecified Site:							
 Adenoma							
			13/50 (26%)		17/52 (33%)	13/50 (26%)	
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	30/102 (29.41%)	Mean 29.35% SD 4.73%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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Male					Female				
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma									
			0/50 (0%)			2/52 (4%)		0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 1.92%	SD 2.72%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma									
			13/50 (26%)			19/52 (37%)		13/50 (26%)	
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	32/102 (31.37%)	Mean 31.27%	SD 7.45%	
.....									
*Pituitary Gland: Pars Intermedia: Adenoma									
			0/50 (0%)			0/52 (0%)		1/50 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%	
.....									
*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma									
			0/50 (0%)			0/52 (0%)		1/50 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%	
.....									
*Prostate: Adenoma									
			5/50 (10%)						
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%					
.....									
*Prostate: Carcinoma or Adenoma									
			5/50 (10%)						
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%					

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

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
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 Length of Study: CHRONIC

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

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		Male			Female		
*Salivary Glands:							
Schwannoma Malignant							
			1/50 (2%)		0/51 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/101 (0%)	Mean 0% SD 0%
.....							
#Skeletal Muscle:							
Rhabdomyosarcoma							
			0/50 (0%)		0/52 (0%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1% SD 1.41%
.....							
#Skeletal Muscle:							
Rhabdomyosarcoma or Rhabdomyoma							
			0/50 (0%)		0/52 (0%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1% SD 1.41%
.....							
#Skin:							
Basal Cell Adenoma							
			1/50 (2%)		0/52 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Basal Cell Adenoma or Basosquamous Tumor Benign							
			1/50 (2%)		0/52 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma							
			1/50 (2%)		0/52 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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	Male				Female					
#Skin:										
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma										
Overall Incidence	Total	1/50 (2%)	1/50 (2%)	Mean 2%	SD 0%	Total	0/52 (0%)	0/50 (0%)	Mean 0%	SD 0%
							0/102 (0%)			
#Skin:										
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma										
Overall Incidence	Total	3/50 (6%)	3/50 (6%)	Mean 6%	SD 0%	Total	1/52 (2%)	0/50 (0%)	Mean 0.96%	SD 1.36%
							1/102 (0.98%)			
#Skin:										
Fibroma										
Overall Incidence	Total	5/50 (10%)	5/50 (10%)	Mean 10%	SD 0%	Total	2/52 (4%)	0/50 (0%)	Mean 1.92%	SD 2.72%
							2/102 (1.96%)			
#Skin:										
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma										
Overall Incidence	Total	5/50 (10%)	5/50 (10%)	Mean 10%	SD 0%	Total	2/52 (4%)	0/50 (0%)	Mean 1.92%	SD 2.72%
							2/102 (1.96%)			
#Skin:										
Hemangiosarcoma										
Overall Incidence	Total	1/50 (2%)	1/50 (2%)	Mean 2%	SD 0%	Total	1/52 (2%)	0/50 (0%)	Mean 0.96%	SD 1.36%
							1/102 (0.98%)			
#Skin:										
Keratoacanthoma										
Overall Incidence	Total	2/50 (4%)	2/50 (4%)	Mean 4%	SD 0%	Total	1/52 (2%)	0/50 (0%)	Mean 0.96%	SD 1.36%
							1/102 (0.98%)			

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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	Male				Female			
#Skin:								
Neural Crest Tumor								
			1/50 (2%)			0/52 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Neurofibrosarcoma or Schwannoma (malignant or NOS)								
			0/50 (0%)			1/52 (2%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%
.....								
#Skin:								
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)								
			0/50 (0%)			1/52 (2%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%
.....								
#Skin:								
Schwannoma Malignant								
			0/50 (0%)			1/52 (2%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%
.....								
#Skin:								
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma								
			2/50 (4%)			1/52 (2%)	0/50 (0%)	
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%
.....								
#Skin:								
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma								
			2/50 (4%)			1/52 (2%)	0/50 (0%)	
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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		Male			Female		
*Testes:							
Adenoma							
			2/50 (4%)				
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%			
.....							
*Thyroid Gland: C-Cell:							
Adenoma							
			13/50 (26%)		9/51 (18%)	10/50 (20%)	
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total 19/101 (18.81%)	Mean 18.82%	SD 1.66%
.....							
*Thyroid Gland: C-Cell:							
Carcinoma							
			1/50 (2%)		2/51 (4%)	1/50 (2%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total 3/101 (2.97%)	Mean 2.96%	SD 1.36%
.....							
*Thyroid Gland: C-Cell:							
Carcinoma or Adenoma							
			13/50 (26%)		11/51 (22%)	11/50 (22%)	
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total 22/101 (21.78%)	Mean 21.78%	SD 0.31%
.....							
*Thyroid Gland: Follicular Cell:							
Adenoma							
			0/50 (0%)		1/51 (2%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 1/101 (0.99%)	Mean 0.98%	SD 1.39%
.....							
*Thyroid Gland: Follicular Cell:							
Carcinoma or Adenoma							
			0/50 (0%)		1/51 (2%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 1/101 (0.99%)	Mean 0.98%	SD 1.39%

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#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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	Male				Female			
#Tooth:								
Odontoma								
			0/50 (0%)			1/52 (2%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%
.....								
#Uterus:								
Carcinoma								
					2/52 (4%)	1/50 (2%)		
Overall Incidence	Total				3/102 (2.94%)	Mean 2.92%		SD 1.31%
.....								
#Uterus:								
Polyp Stromal								
					3/52 (6%)	8/50 (16%)		
Overall Incidence	Total				11/102 (10.78%)	Mean 10.88%		SD 7.23%
.....								
#Uterus:								
Sarcoma Stromal or Polyp Stromal								
					3/52 (6%)	8/50 (16%)		
Overall Incidence	Total				11/102 (10.78%)	Mean 10.88%		SD 7.23%
.....								
#Uterus:								
Schwannoma Malignant								
					1/52 (2%)	0/50 (0%)		
Overall Incidence	Total				1/102 (0.98%)	Mean 0.96%		SD 1.36%
.....								
#Uterus:								
Squamous Cell Carcinoma								
					0/52 (0%)	1/50 (2%)		
Overall Incidence	Total				1/102 (0.98%)	Mean 1%		SD 1.41%

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#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

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

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				Male		Female						
#Vagina:												
Polyp												
				1/52 (2%)		0/50 (0%)						
Overall Incidence				Total	1/102 (0.98%)	Mean	0.96%	SD	1.36%			
.....												
#Vagina:												
Squamous Cell Carcinoma												
				1/52 (2%)		0/50 (0%)						
Overall Incidence				Total	1/102 (0.98%)	Mean	0.96%	SD	1.36%			
.....												
#Zymbal's Gland:												
Carcinoma												
		1/50 (2%)		0/52 (0%)		0/50 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean	2%	SD	0%	Total	0/102 (0%)	Mean	0%	SD	0%
.....												
#Zymbal's Gland:												
Carcinoma or Adenoma												
		1/50 (2%)		0/52 (0%)		0/50 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean	2%	SD	0%	Total	0/102 (0%)	Mean	0%	SD	0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied