

# 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:

	<b>Male</b>			<b>Female</b>		
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
<b>Male</b>							
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
<b>Female</b>							
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

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

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		Male				Female			
<b>#All Organs:</b>									
<b>Benign Tumors</b>									
			40/50 (80%)			43/52 (83%)	40/50 (80%)		
<b>Overall Incidence</b>	Total	40/50 (80%)	Mean 80%	SD 0%	Total	83/102 (81.37%)	Mean 81.35%	SD 1.9%	
.....									
<b>#All Organs:</b>									
<b>Malignant Tumors</b>									
			9/50 (18%)			15/52 (29%)	13/50 (26%)		
<b>Overall Incidence</b>	Total	9/50 (18%)	Mean 18%	SD 0%	Total	28/102 (27.45%)	Mean 27.42%	SD 2.01%	
.....									
<b>#All Organs:</b>									
<b>Malignant and Benign Tumors</b>									
			44/50 (88%)			48/52 (92%)	44/50 (88%)		
<b>Overall Incidence</b>	Total	44/50 (88%)	Mean 88%	SD 0%	Total	92/102 (90.2%)	Mean 90.15%	SD 3.05%	
.....									
<b>#All Organs:</b>									
<b>Hemangiosarcoma</b>									
			1/50 (2%)			1/52 (2%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%	
.....									
<b>#All Organs:</b>									
<b>Hemangiosarcoma or Hemangioma</b>									
			1/50 (2%)			1/52 (2%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%	
.....									
<b>#All Organs:</b>									
<b>Histiocytic Sarcoma</b>									
			0/50 (0%)			1/52 (2%)	1/50 (2%)		
<b>Overall Incidence</b>	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

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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  
 Vehicle: ALL VEHICLES

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

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

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

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

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

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

#: Denominator is number of animals necropsied

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 Strain: Harlan Sprague-Dawley  
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**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
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		Male			Female		
<b>*Liver:</b>							
<b>Hepatocellular Carcinoma or Hepatocellular Adenoma</b>							
		0/50 (0%)	Mean 0%	SD 0%	0/52 (0%)	2/50 (4%)	Mean 2%
<b>Overall Incidence</b>	Total	0/50 (0%)			Total 2/102 (1.96%)		SD 2.83%
.....							
<b>*Liver:</b>							
<b>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma</b>							
		0/50 (0%)	Mean 0%	SD 0%	0/52 (0%)	2/50 (4%)	Mean 2%
<b>Overall Incidence</b>	Total	0/50 (0%)			Total 2/102 (1.96%)		SD 2.83%
.....							
<b>*Lung:</b>							
<b>Alveolar/Bronchiolar Adenoma</b>							
		1/50 (2%)	Mean 2%	SD 0%	0/51 (0%)	0/50 (0%)	Mean 0%
<b>Overall Incidence</b>	Total	1/50 (2%)			Total 0/101 (0%)		SD 0%
.....							
<b>*Lung:</b>							
<b>Alveolar/Bronchiolar Carcinoma</b>							
		1/50 (2%)	Mean 2%	SD 0%	0/51 (0%)	0/50 (0%)	Mean 0%
<b>Overall Incidence</b>	Total	1/50 (2%)			Total 0/101 (0%)		SD 0%
.....							
<b>*Lung:</b>							
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>							
		2/50 (4%)	Mean 4%	SD 0%	0/51 (0%)	0/50 (0%)	Mean 0%
<b>Overall Incidence</b>	Total	2/50 (4%)			Total 0/101 (0%)		SD 0%
.....							
<b>#Mammary Gland:</b>							
<b>Adenoma</b>							
		0/50 (0%)	Mean 0%	SD 0%	0/52 (0%)	1/50 (2%)	Mean 1%
<b>Overall Incidence</b>	Total	0/50 (0%)			Total 1/102 (0.98%)		SD 1.41%

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



Version: May2011  
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**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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		Male			Female		
<b>#Mammary Gland: Carcinoma</b>							
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%
<b>#Mammary Gland: Carcinoma or Adenoma</b>							
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%
<b>#Mammary Gland: Fibroadenoma</b>							
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%
<b>#Mammary Gland: Fibroma, Fibroadenoma or Adenoma</b>							
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%
<b>#Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>							
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%
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma</b>							
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

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 Contract/Lab: All Laboratories  
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Male					Female				
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma</b>									
			1/50 (2%)			0/52 (0%)		0/50 (0%)	
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%	
.....									
<b>#Oral Mucosa: Squamous Cell Carcinoma</b>									
			1/50 (2%)			0/52 (0%)		0/50 (0%)	
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%	
.....									
<b>*Ovary: Granulosa Cell Tumor Malignant</b>									
						0/52 (0%)		1/50 (2%)	
<b>Overall Incidence</b>					Total	1/102 (0.98%)	Mean 1%	SD 1.41%	
.....									
<b>*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS</b>									
						0/52 (0%)		1/50 (2%)	
<b>Overall Incidence</b>					Total	1/102 (0.98%)	Mean 1%	SD 1.41%	
.....									
<b>*Ovary: Luteoma</b>									
						1/52 (2%)		0/50 (0%)	
<b>Overall Incidence</b>					Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%	
.....									
<b>*Pancreas: Adenoma</b>									
			9/50 (18%)			0/52 (0%)		0/50 (0%)	
<b>Overall Incidence</b>	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		
<b>*Pancreas:</b>							
<b>  Carcinoma</b>							
			0/50 (0%)		0/52 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1% SD 1.41%
.....							
<b>*Pancreas:</b>							
<b>  Carcinoma or Adenoma</b>							
			9/50 (18%)		0/52 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	9/50 (18%)	Mean 18%	SD 0%	Total	1/102 (0.98%)	Mean 1% SD 1.41%
.....							
<b>*Parathyroid Gland:</b>							
<b>  Adenoma</b>							
			1/43 (2%)		0/47 (0%)	0/46 (0%)	
<b>Overall Incidence</b>	Total	1/43 (2.33%)	Mean 2.33%	SD 0%	Total	0/93 (0%)	Mean 0% SD 0%
.....							
<b>#Peripheral Nerve:</b>							
<b>  Schwannoma Malignant</b>							
			0/50 (0%)		0/52 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1% SD 1.41%
.....							
<b>#Peripheral Nerve:</b>							
<b>  Schwannoma: Benign, Malignant, NOS</b>							
			0/50 (0%)		0/52 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1% SD 1.41%
.....							
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>							
<b>  Adenoma</b>							
			13/50 (26%)		17/52 (33%)	13/50 (26%)	
<b>Overall Incidence</b>	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

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 Strain: Harlan Sprague-Dawley  
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**Toxicology Data Management System**  
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Male					Female				
<b>*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma</b>									
			0/50 (0%)			2/52 (4%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 1.92%	SD 2.72%	
.....									
<b>*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma</b>									
			13/50 (26%)			19/52 (37%)	13/50 (26%)		
<b>Overall Incidence</b>	Total	13/50 (26%)	Mean 26%	SD 0%	Total	32/102 (31.37%)	Mean 31.27%	SD 7.45%	
.....									
<b>*Pituitary Gland: Pars Intermedia: Adenoma</b>									
			0/50 (0%)			0/52 (0%)	1/50 (2%)		
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%	
.....									
<b>*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma</b>									
			0/50 (0%)			0/52 (0%)	1/50 (2%)		
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%	
.....									
<b>*Prostate: Adenoma</b>									
			5/50 (10%)						
<b>Overall Incidence</b>	Total	5/50 (10%)	Mean 10%	SD 0%					
.....									
<b>*Prostate: Carcinoma or Adenoma</b>									
			5/50 (10%)						
<b>Overall Incidence</b>	Total	5/50 (10%)	Mean 10%	SD 0%					

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

#: Denominator is number of animals necropsied

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**Toxicology Data Management System**  
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**Route: ALL ROUTES**  
**Vehicle: ALL VEHICLES**

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		Male			Female		
<b>*Salivary Glands:</b>							
<b>Schwannoma Malignant</b>							
			1/50 (2%)		0/51 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/101 (0%)	Mean 0% SD 0%
.....							
<b>#Skeletal Muscle:</b>							
<b>Rhabdomyosarcoma</b>							
			0/50 (0%)		0/52 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1% SD 1.41%
.....							
<b>#Skeletal Muscle:</b>							
<b>Rhabdomyosarcoma or Rhabdomyoma</b>							
			0/50 (0%)		0/52 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1% SD 1.41%
.....							
<b>#Skin:</b>							
<b>Basal Cell Adenoma</b>							
			1/50 (2%)		0/52 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0% SD 0%
.....							
<b>#Skin:</b>							
<b>Basal Cell Adenoma or Basosquamous Tumor Benign</b>							
			1/50 (2%)		0/52 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0% SD 0%
.....							
<b>#Skin:</b>							
<b>Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma</b>							
			1/50 (2%)		0/52 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	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					
<b>#Skin:</b>										
<b>Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma</b>										
<b>Overall Incidence</b>	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%)			
<b>#Skin:</b>										
<b>Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma</b>										
<b>Overall Incidence</b>	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%)			
<b>#Skin:</b>										
<b>Fibroma</b>										
<b>Overall Incidence</b>	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%)			
<b>#Skin:</b>										
<b>Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma</b>										
<b>Overall Incidence</b>	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%)			
<b>#Skin:</b>										
<b>Hemangiosarcoma</b>										
<b>Overall Incidence</b>	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%)			
<b>#Skin:</b>										
<b>Keratoacanthoma</b>										
<b>Overall Incidence</b>	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				
<b>#Skin:</b>									
<b>Neural Crest Tumor</b>									
			1/50 (2%)			0/52 (0%)		0/50 (0%)	
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Neurofibrosarcoma or Schwannoma (malignant or NOS)</b>									
			0/50 (0%)			1/52 (2%)		0/50 (0%)	
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%	
.....									
<b>#Skin:</b>									
<b>Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)</b>									
			0/50 (0%)			1/52 (2%)		0/50 (0%)	
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%	
.....									
<b>#Skin:</b>									
<b>Schwannoma Malignant</b>									
			0/50 (0%)			1/52 (2%)		0/50 (0%)	
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%	
.....									
<b>#Skin:</b>									
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>									
			2/50 (4%)			1/52 (2%)		0/50 (0%)	
<b>Overall Incidence</b>	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%	
.....									
<b>#Skin:</b>									
<b>Squamous Cell Papilloma, Papilloma, or Keratoacanthoma</b>									
			2/50 (4%)			1/52 (2%)		0/50 (0%)	
<b>Overall Incidence</b>	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			
<b>*Testes:</b>								
<b>Adenoma</b>								
			2/50 (4%)					
<b>Overall Incidence</b>	Total	2/50 (4%)	Mean 4%	SD 0%				
.....								
<b>*Thyroid Gland: C-Cell:</b>								
<b>Adenoma</b>								
			13/50 (26%)		9/51 (18%)	10/50 (20%)		
<b>Overall Incidence</b>	Total	13/50 (26%)	Mean 26%	SD 0%	Total 19/101 (18.81%)	Mean 18.82%	SD 1.66%	
.....								
<b>*Thyroid Gland: C-Cell:</b>								
<b>Carcinoma</b>								
			1/50 (2%)		2/51 (4%)	1/50 (2%)		
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total 3/101 (2.97%)	Mean 2.96%	SD 1.36%	
.....								
<b>*Thyroid Gland: C-Cell:</b>								
<b>Carcinoma or Adenoma</b>								
			13/50 (26%)		11/51 (22%)	11/50 (22%)		
<b>Overall Incidence</b>	Total	13/50 (26%)	Mean 26%	SD 0%	Total 22/101 (21.78%)	Mean 21.78%	SD 0.31%	
.....								
<b>*Thyroid Gland: Follicular Cell:</b>								
<b>Adenoma</b>								
			0/50 (0%)		1/51 (2%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total 1/101 (0.99%)	Mean 0.98%	SD 1.39%	
.....								
<b>*Thyroid Gland: Follicular Cell:</b>								
<b>Carcinoma or Adenoma</b>								
			0/50 (0%)		1/51 (2%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total 1/101 (0.99%)	Mean 0.98%	SD 1.39%	
.....								

\*: 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			
<b>#Tooth:</b>								
<b>Odontoma</b>								
			0/50 (0%)			1/52 (2%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%
.....								
<b>#Uterus:</b>								
<b>Carcinoma</b>								
					2/52 (4%)	1/50 (2%)		
<b>Overall Incidence</b>	Total				3/102 (2.94%)	Mean 2.92%		SD 1.31%
.....								
<b>#Uterus:</b>								
<b>Polyp Stromal</b>								
					3/52 (6%)	8/50 (16%)		
<b>Overall Incidence</b>	Total				11/102 (10.78%)	Mean 10.88%		SD 7.23%
.....								
<b>#Uterus:</b>								
<b>Sarcoma Stromal or Polyp Stromal</b>								
					3/52 (6%)	8/50 (16%)		
<b>Overall Incidence</b>	Total				11/102 (10.78%)	Mean 10.88%		SD 7.23%
.....								
<b>#Uterus:</b>								
<b>Schwannoma Malignant</b>								
					1/52 (2%)	0/50 (0%)		
<b>Overall Incidence</b>	Total				1/102 (0.98%)	Mean 0.96%		SD 1.36%
.....								
<b>#Uterus:</b>								
<b>Squamous Cell Carcinoma</b>								
					0/52 (0%)	1/50 (2%)		
<b>Overall Incidence</b>	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						
<b>#Vagina:</b>												
<b>Polyp</b>												
				1/52 (2%)		0/50 (0%)						
<b>Overall Incidence</b>				Total	1/102 (0.98%)	Mean	0.96%	SD	1.36%			
.....												
<b>#Vagina:</b>												
<b>Squamous Cell Carcinoma</b>												
				1/52 (2%)		0/50 (0%)						
<b>Overall Incidence</b>				Total	1/102 (0.98%)	Mean	0.96%	SD	1.36%			
.....												
<b>#Zymbal's Gland:</b>												
<b>Carcinoma</b>												
		1/50 (2%)		0/52 (0%)		0/50 (0%)						
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean	2%	SD	0%	Total	0/102 (0%)	Mean	0%	SD	0%
.....												
<b>#Zymbal's Gland:</b>												
<b>Carcinoma or Adenoma</b>												
		1/50 (2%)		0/52 (0%)		0/50 (0%)						
<b>Overall Incidence</b>	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