

NTP Historical Controls Report

All Routes and Vehicles

F 344/N Tac RATS

June 2013

REPORT DESCRIPTION

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

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

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

Male
M1
M2
М3
M4
M5
Female
Female F1
F1
F1 F2

the data would be shown as:

	Male		Female				
M1	M2	М3	F1	F2	F3		
M4	M5		F4	F5			

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

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

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 06/12/2013

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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 Battelle Columbus Laboratory	056031105 059601405	05/08/06 10/26/06	729 726	50(5) 50(3)	17(663) 19(658)	532.6 528.0	Cobalt Water disinfection byproducts (Bromodichloroacetic acid)
					Female		
Battelle Northwest Battelle Columbus Laboratory	056031105 059601405	05/08/06 10/27/06	730 727	50(5) 50(5)	35(688) 34(694)	350.7 352.8	Cobalt Water disinfection byproducts (Bromodichloroacetic acid)

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

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: Benign Tumors									
		47/50 (94%)	46/50 (92%)			44/50 (88%)	41/50 (82%)		
Overall Incidence	Total	93/100 (93%)	Mean 93%	SD 1.41%	Total	85/100 (85%)	Mean 85%	SD 4.24%	
#All Organs: Malignant Tumors		31/50 (62%)	24/50 (48%)			25/50 (50%)	23/50 (46%)		
Overall Incidence	Total	55/100 (55%)	Mean 55%	SD 9.9%	Total	48/100 (48%)	Mean 48%	SD 2.83%	
#All Organs: Malignant and Benign Tur	mors	50/50 (100%)	49/50 (98%)			48/50 (96%)	47/50 (94%)		
Overall Incidence	Total	99/100 (99%)	Mean 99%	SD 1.41%	Total	95/100 (95%)	Mean 95%	SD 1.41%	
#All Organs: Hemangioma		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: Hemangiosarcoma									
	.	0/50 (0%)	0/50 (0%)	00.00/	-	1/50 (2%)	0/50 (0%)	00 4 440/	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
#All Organs: Hemangiosarcoma or Her	nangioma								
Overall Insidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	1/50 (2%)	1/50 (2%)	CD 00/	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES Species: RATS Strain: F 344/N Tac Vehicle: ALL VEHICLES

Length of Study: CHRONIC

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			Male				Female						
#All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated													
		21/50 (42%)	15/50 (30%)			16/50 (32%)	19/50 (38%)						
Overall Incidence	Total	36/100 (36%)	Mean 36%	SD 8.49%	Total	35/100 (35%)	Mean 35%	SD 4.24%					
#All Organs: Mesothelioma: Benign, Ma	alignant, NOS	S 2/50 (4%)	1/50 (2%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%					
#All Organs: Mesothelioma: Malignant		2/50 (40/)	4/50 /20/			0/50 (00/)	0/50 /09/\						
Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%					
#All Organs: Osteoma		0/50 (00()	4/50 (00/)			0/50 (00()	0/50 (00/)						
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%					
#All Organs: Osteosarcoma or Osteoma	a												
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%					
*Adrenal Cortex: Adenoma													
		0/50 (0%)	2/50 (4%)			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%					

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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		Male				Female							
Adrenal Medulla: Pheochromocytoma Benign													
	15/50 (30%)	10/50 (20%)			6/50 (12%)	1/50 (2%)							
Total	25/100 (25%)	Mean 25%	SD 7.07%	Total	7/100 (7%)	Mean 7%	SD 7.07%						
lignant													
	2/50 (4%)	0/50 (0%)			0/50 (0%)	1/50 (2%)							
Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%						
Total	17/50 (34%) 27/100 (27%)	10/50 (20%) Mean 27%	SD 9.9%	Total	6/50 (12%) 8/100 (8%)	2/50 (4%) Mean 8%	SD 5.66%						
	0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)							
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%						
ma													
	` ,	` '			` ,	` ,							
	` '				` ,		SD 0%						
Total	1/100 (1%)	0/30 (0 <i>%)</i> Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%						
	Total lignant Total nign, Complex Total Total	15/50 (30%) Total 25/100 (25%) lignant 2/50 (4%) Total 2/100 (2%) nign, Complex, Malignant, NOS 17/50 (34%) Total 27/100 (27%) O/50 (0%) Total 1/100 (1%) ma O/50 (0%) Total 1/100 (1%)	15/50 (30%) 10/50 (20%) Total 25/100 (25%) Mean 25% lignant 2/50 (4%) 0/50 (0%) Total 2/100 (2%) Mean 2% nign, Complex, Malignant, NOS 17/50 (34%) 10/50 (20%) Total 27/100 (27%) Mean 27% 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% ma 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1%	Total 15/50 (30%) 10/50 (20%) Total 25/100 (25%) Mean 25% SD 7.07% lignant 2/50 (4%) 0/50 (0%) Total 2/100 (2%) Mean 2% SD 2.83% nign, Complex, Malignant, NOS 17/50 (34%) 10/50 (20%) Total 27/100 (27%) Mean 27% SD 9.9% Total 1/100 (1%) Mean 1% SD 1.41% ma 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41%	15/50 (30%) 10/50 (20%) Total 25/100 (25%) Mean 25% SD 7.07% Total lignant 2/50 (4%) 0/50 (0%) Total 2/100 (2%) Mean 2% SD 2.83% Total nign, Complex, Malignant, NOS 17/50 (34%) 10/50 (20%) Total 27/100 (27%) Mean 27% SD 9.9% Total 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41% Total ma 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41% Total	15/50 (30%) 10/50 (20%) 6/50 (12%) Total 25/100 (25%) Mean 25% SD 7.07% Total 7/100 (7%) lignant 2/50 (4%) 0/50 (0%) Total 2/100 (2%) Mean 2% SD 2.83% Total 1/100 (1%) nign, Complex, Malignant, NOS 17/50 (34%) 10/50 (20%) Total 27/100 (27%) Mean 27% SD 9.9% Total 8/100 (8%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) ma 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%)	hign 15/50 (30%) 10/50 (20%) Total 25/100 (25%) Mean 25% SD 7.07% Total 7/100 (7%) Mean 7% lignant 2/50 (4%) 0/50 (0%) Total 2/100 (2%) Mean 2% SD 2.83% Total 1/100 (1%) Mean 1% nign, Complex, Malignant, NOS 17/50 (34%) 10/50 (20%) Total 27/100 (27%) Mean 27% SD 9.9% Total 8/100 (8%) Mean 8% 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% ma 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0%						

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male				Female					
*Brain: Fibrous Histiocytoma 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)												
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Brain: Glioma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
*Brain: Granular Cell Tumor Benig	n	0/50 (00/)	0/50 (40)			0/50 (00)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Brain: Oligodendroglioma, Glioma	a, or Astrocy											
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Clitoral/Preputial Gland: Adenoma												
Overall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	2/49 (4%) 10/99 (10.1%)	8/50 (16%) Mean 10.04%	SD 8.43%				
*Clitoral/Preputial Gland: Carcinoma												
Overall Incidence	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%	Total	4/49 (8%) 5/99 (5.05%)	1/50 (2%) Mean 5.08%	SD 4.36%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male				Female	
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		3/50 (6%)	4/50 (8%)			6/49 (12%)	8/50 (16%)	
Overall Incidence	Total	7/100 (7%)	Mean 7%	SD 1.41%	Total	14/99 (14.14%)	Mean 14.12%	SD 2.66%
#Ear: Neural Crest Tumor								
		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%
#Harderian Gland: Carcinoma								
		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%
#Harderian Gland: Carcinoma or Adenoma		0/50 (001)	4/50 (00/)			0/50 (00)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Heart: Schwannoma Malignant								
		1/50 (2%)	0/50 (0%)			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%
#Intestine Large: Colon/Rect								
		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%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male				Female						
#Intestine Large: Colon/Rectum: Carcinoma or 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%					
#Intestine Small: Ileum: Carcinoma													
		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%					
#Intestine Small: Jejunum: Carcinoma													
		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%					
#Intestine Small: Site Unspec Carcinoma													
		0/50 (0%)	0/50 (0%)			2/50 (4%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%					
#Intestine Small: Site Unspec Carcinoma or Adenoma													
		0/50 (0%)	0/50 (0%)			2/50 (4%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%					
*Islets, Pancreatic: 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%					

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male				Female	
*Islets, Pancreatic: Carcinoma								
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Islets, Pancreatic: Carcinoma or Adenoma								
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
*Kidney: Renal Tubule: Adenoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma						0/50 /00/\	0/50 (/0//)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Fibrous Histiocytoma		0/50 (00/)	4/50 (00)			0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male	Female							
*Liver: Hemangioma 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%)											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%			
*Lung: Alveolar/Bronchiolar Ade	noma										
Overall Incidence	Total	2/50 (4%) 5/100 (5%)	3/50 (6%) Mean 5%	SD 1.41%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%			
*Lung: Alveolar/Bronchiolar Card						2/50 (4%)	0/50 (0%)				
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%			
*Lung: Fibrous Histiocytoma		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%			
*Lung: Squamous Cell Carcinom	а	0/50 (00/)	4/50 (00)			0/50 (00/)	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Lymph Node: Fibrous Histiocytoma											
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male				Female	
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
#Mammary Gland: Carcinoma								
		1/50 (2%)	0/50 (0%)			2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Mammary Gland: Carcinoma or Adenoma								
		1/50 (2%)	0/50 (0%)			3/50 (6%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	4/100 (4%)	Mean 4%	SD 2.83%
#Mammary Gland: Fibroadenoma		4/50 (004)	0/50 (00/)			40/50 (000/)	00(50 (500))	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	18/50 (36%) 46/100 (46%)	28/50 (56%) Mean 46%	SD 14.14%
#Mammary Gland: Fibroma, Fibroadenoma	or Adenoma							
		1/50 (2%)	0/50 (0%)			19/50 (38%)	28/50 (56%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	47/100 (47%)	Mean 47%	SD 12.73%
#Mammary Gland: Fibroma, Fibroadenoma	, Carcinoma, or	Adenoma 2/50 (4%)	0/50 (0%)			20/50 (40%)	28/50 (56%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	48/100 (48%)	Mean 48%	SD 11.31%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

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): Papilloma Squamous or Papilloma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%				
#Oral Cavity (Oral Mucos Squamous Cell Carcino		ynx, Tooth, Gingiva):										
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Oral Cavity (Oral Mucos	a, Tongue, Phary	ynx, Tooth, Gingiva): Gquamous, or Papilloma 0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%				
#Oral Mucosa: Squamous Cell Carcino	oma	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%				
*Pancreas: Adenoma		•••••										
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Pancreas: Carcinoma or Adenoma	a					(201)	0/50 (00)					
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)					

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

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: Mixed Tumor Malignant								
		1/50 (2%)	0/50 (0%)			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%
*Pituitary Gland: Pars Distali Adenoma								
		27/50 (54%)	26/50 (52%)			29/50 (58%)	23/50 (46%)	
Overall Incidence	Total	53/100 (53%)	Mean 53%	SD 1.41%	Total	52/100 (52%)	Mean 52%	SD 8.49%
*Pituitary Gland: Pars Distali Carcinoma or Adenoma	is or Unspec	ified Site: 27/50 (54%)	26/50 (52%)			29/50 (58%)	23/50 (46%)	
Overall Incidence	Total	53/100 (53%)	Mean 53%	SD 1.41%	Total	52/100 (52%)	Mean 52%	SD 8.49%
*Prostate: Adenoma		4/50 (00)	4/50 (004)					
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%				
*Prostate: Carcinoma or Adenoma								
		1/50 (2%)	1/50 (2%)					
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%				
*Salivary Glands: Adenoma								
		1/50 (2%)	0/50 (0%)	00		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

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: Carcinoma or Adenoma								
		1/50 (2%)	0/50 (0%)			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%
#Skeletal Muscle: Fibrous Histiocytoma								
		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								
		2/50 (4%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Basal Cell Adenoma or I		Tumor Benign					•••••	
	•	2/50 (4%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Basal Cell Adenoma. Ba	sosquamous T	umor Benign, or Trichoep	oithelioma					
,,,		4/50 (8%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 5.66%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Basal Cell Carcinoma, B NOS), or Trichoepithelio	asal Cell Adend	oma, Basosquamous Tur	nor (benign, maligna	nt or				
•		4/50 (8%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 5.66%	Total	1/100 (1%)	Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES

Report Date: 06/12/2013

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Species: RATS Strain: F 344/N Tac

Vehicle: ALL VEHICLES

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												
		8/50 (16%)	9/50 (18%)			2/50 (4%)	0/50 (0%)					
Overall Incidence	Total	17/100 (17%)	Mean 17%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%				
#Skin: Fibroma		2/50 (4%)	4/50 (8%)			2/50 (4%)	2/50 (4%)					
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 2.83%	Total	4/100 (4%)	Mean 4%	SD 0%				
#Skin: Fibroma, Fibrosarcoma,	Sarcoma, Myx	coma, Myxosarcoma, or Fib	rous Histiocytoma 6/50 (12%)			3/50 (6%)	2/50 (4%)					
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 5.66%	Total	5/100 (5%)	Mean 5%	SD 1.41%				
#Skin: Fibrosarcoma		0/50 (00/)	1/50 (20/)			0/50 (00/)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Fibrosarcoma, Sarcoma,	, Myxosarcoma	a, or Fibrous Histiocytoma										
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%				
#Skin: Fibrous Histiocytoma		0/50 (00)	4/50 (05)			4/50 (000)	0/50 (00)					
Overell Incidence	Total	0/50 (0%)	1/50 (2%)	CD 4 440/	Total	1/50 (2%)	0/50 (0%)	CD 4 440/				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male			Female				
#Skin: Hamartoma										
		1/50 (2%)	0/50 (0%)			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: Keratoacanthoma										
		4/50 (8%)	7/50 (14%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Lipoma										
		2/50 (4%)	1/50 (2%)			1/50 (2%)	2/50 (4%)			
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	3/100 (3%)	Mean 3%	SD 1.41%		
#Skin: Neurofibrosarcoma or Sch	nwannoma (n	nalignant or NOS) 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%		
#Skin: Neurofibrosarcoma, Neuro						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%		
#Skin: Schwannoma Malignant		2(22)	(00)			(00)	0.77			
	.	0/50 (0%)	0/50 (0%)	OD 00/	-	1/50 (2%)	0/50 (0%)	00 4 440/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male				Female	
#Skin: Squamous Cell Carcinon	na			,				
		1/50 (2%)	0/50 (0%)			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:								
Squamous Cell Carcinon or Carcinoma	na, Basal Cell (Carcinoma, Basosquamo	us Tumor (malignant	or NOS),				
		1/50 (2%)	0/50 (0%)			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: Squamous Cell Papillom						•••••		
		0/50 (0%)	3/50 (6%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Squamous Cell Papillom	a or Papilloma					•••••	•••••	
		0/50 (0%)	3/50 (6%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Squamous Cell Papillom						1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	14/100 (14%)	Mean 14%	SD 5.66%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Squamous Cell Papillom	a, Papilloma, o	or Keratoacanthoma 4/50 (8%)	9/50 (18%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	13/100 (13%)	Mean 13%	SD 7.07%	Total	1/100 (1%)	Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

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: Trichoepithelioma								
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Forestomach:								
Squamous Cell Carcinoma	a or Papillom	a Squamous 0/50 (0%)	1/50 (2%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)	1/50 (2%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Testes: Adenoma								
Overall Incidence	Total	35/50 (70%) 69/100 (69%)	34/50 (68%) Mean 69%	SD 1.41%				
*Thymus: Thymoma Malignant								
		0/46 (0%)	0/48 (0%)	OD 00/		0/47 (0%)	1/48 (2%)	05 4 470/
Overall Incidence	Total	0/94 (0%)	Mean 0%	SD 0%	Total	1/95 (1.05%)	Mean 1.04%	SD 1.47%
*Thymus: Thymoma: Benign, Malign	ant, NOS							
Overall Incidence	Total	0/46 (0%) 0/94 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 1/95 (1.05%)	1/48 (2%) Mean 1.04%	SD 1.47%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N Tac

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
*Thyroid Gland: C-Cell: Adenoma						,		
		4/49 (8%)	7/50 (14%)			8/50 (16%)	11/50 (22%)	
Overall Incidence	Total	11/99 (11.11%)	Mean 11.08%	SD 4.13%	Total	19/100 (19%)	Mean 19%	SD 4.24%
*Thyroid Gland: C-Cell: Carcinoma								
Overall Incidence	Total	1/49 (2%) 2/99 (2.02%)	1/50 (2%) Mean 2.02%	SD 0.03%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		5/49 (10%)	8/50 (16%)			9/50 (18%)	11/50 (22%)	
Overall Incidence	Total	13/99 (13.13%)	Mean 13.1%	SD 4.1%	Total	20/100 (20%)	Mean 20%	SD 2.83%
*Thyroid Gland: Follicular Cel Adenoma		0/49 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cel Carcinoma						•••••		
		2/49 (4%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2.04%	SD 2.89%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Thyroid Gland: Follicular Cel Carcinoma or Adenoma								
Overall Incidence	Total	2/49 (4%)	1/50 (2%)	CD 4 470/	Total	1/50 (2%)	0/50 (0%)	CD 4 440/
Overall Incidence	Total	3/99 (3.03%)	Mean 3.04%	SD 1.47%	Total	1/100 (1%)	Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male				Female	Female				
#Tongue: Squamous Cell Carcinoma or Papilloma Squamous												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%				
#Tongue: Squamous Cell Papillo	ma											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%				
#Uterus: Deciduoma NOS												
Overall Incidence					Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
#Uterus: Fibrous Histiocytoma						0/50 (0%)	4/50 /00/					
Overall Incidence					Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
#Uterus: Hemangiosarcoma												
Overall Incidence					Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%				
#Uterus: Leiomyoma												
Overall Incidence					Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F 344/N Tac

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Mean 0%

SD 0%

Report Date: 06/12/2013

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus:** Leiomyosarcoma 0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% #Uterus: **Polyp Stromal** 10/50 (20%)4/50 (8%) **Overall Incidence** Total 14/100 (14%) Mean 14% SD 8.49% #Uterus: Sarcoma Stromal 0/50 (0%)1/50 (2%) **Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% #Uterus: Sarcoma Stromal or Polyp Stromal 10/50 (20%)5/50 (10%) **Overall Incidence** Total 15/100 (15%) SD 7.07% Mean 15% #Zymbal's Gland: Adenoma 1/50 (2%)0/50 (0%)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% #Zymbal's Gland: Carcinoma 3/50 (6%)1/50 (2%)0/50 (0%)0/50 (0%)

SD 2.83%

0/100 (0%)

Total

Mean 4%

Total

4/100 (4%)

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

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			
#Zymbal's Gland: Carcinoma or Adenoma		1/20 (001)	./=-			2(22)	2(72 (224)		
Overall Incidence	Total	4/50 (8%) 5/100 (5%)	1/50 (2%) Mean 5%	SD 4.24%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied