Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 143

Report Date: 06/05/2013

## **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	052000903	11/18/04	726	50(3)	33(668)	516.1	beta-Picoline
					Female		
Battelle Columbus Laboratory	052000903	11/19/04	727	50(5)	30(688)	352.7	beta-Picoline

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 144

			Male			Female			
#All Organs: Benign Tumors									
		45/50 (90%)				47/50 (94%)			
Overall Incidence	Total	45/50 (90%)	Mean 90%	SD 0%	Total	47/50 (94%)	Mean 94%	SD 0%	
#All Organs: Malignant Tumors		00/50 (4004)				47/50 (0.40())			
	<b>-</b>	23/50 (46%)	14 4007	00.00/	<b>.</b>	17/50 (34%)		00.00/	
Overall Incidence	Total	23/50 (46%)	Mean 46%	SD 0%	Total	17/50 (34%)	Mean 34%	SD 0%	
#All Organs: Malignant and Benign T	umors								
		48/50 (96%)				49/50 (98%)			
Overall Incidence	Total	48/50 (96%)	Mean 96%	SD 0%	Total	49/50 (98%)	Mean 98%	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									
		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 H	emangioma								
		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:** 145

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Contract/Lab: All Laboratories

Strain: F 344/N Length of Study: CHRONIC

#All Organs:				Male	Female				
Mean 0	•								
#All Organs: Leukemia: Lymphocytic, Monocytic, Monocyti	•		0/50 (0%)				0/50 (0%)		
Leukemia: Lymphocytic, Monotuclear, or Undifferentiated   14/50   (28%)   Mean 28%   SD 0%   Total   12/50   (24%)   Mean 24%   SD 0%	Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
14/50 (28%)   Mean 28%   SD 0%   Total   12/50 (24%)   Mean 24%   SD 0%	#All Organs:								
Overall Incidence         Total         14/50 (28%)         Mean 28%         SD 0%         Total         12/50 (24%)         Mean 24%         SD 0%           #All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type         0/50 (0%)         0/50 (0%)         Mean 0%         SD 0%         Total 0/50 (0%)         Mean 0%         SD 0%         Total 0/50 (0%)         Mean 0%         SD 0%           #All Organs: Mesothelioma: Malignant: Mesothelioma: Malignant: Mesothelioma: Malignant: Mesothelioma: Malignant: Mesothelioma: Malignant: Mesothelioma: Malignant: Mesothelioma: Mesotheli	Leukemia: Lymphocytic	c, Monocytic, Mo		ntiated			12/50 (24%)		
#All Organs:     Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type			14/50 (28%)				12/50 (24%)		SD 0%
Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%  #All Organs:									
Overall Incidence         Total         0/50 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)         Mean 0%         SD 0%           #All Organs:	Malignant Lymphoma: I	Histiocytic, Lym		r Undifferentiated Ce	II Type		0/50 (00/)		
#All Organs:		<b>-</b>	, ,		05.00/	<b>-</b>	` '		00.007
Mesothelioma: Benign, Malignant, NOS           4/50 (8%)         Mean 8%         SD 0%         Total         0/50 (0%)         Mean 0%         SD 0%           #All Organs: Mesothelioma: Malignant           4/50 (8%)         Mean 8%         SD 0%         Total         0/50 (0%)         Mean 0%         SD 0%           Overall Incidence         Total         4/50 (8%)         Mean 8%         SD 0%         Total         0/50 (0%)         Mean 0%         SD 0%           #All Organs: Osteoma	Overali incidence	ıotaı	0/50 (0%)	iviean 0%	SD 0%	ı otal	0/50 (0%)	wean 0%	SD 0%
Overall Incidence         Total         4/50 (8%)         Mean 8%         SD 0%         Total         0/50 (0%)         Mean 0%         SD 0%           #All Organs: Mesothelioma: Malignant           4/50 (8%)         Mean 8%         SD 0%         Total         0/50 (0%)         Mean 0%         SD 0%           Overall Incidence         Total         4/50 (8%)         Mean 8%         SD 0%         Total         0/50 (0%)         Mean 0%         SD 0%           #All Organs: Osteoma	•	Malian and NOO							
Overall Incidence         Total         4/50 (8%)         Mean 8%         SD 0%         Total         0/50 (0%)         Mean 0%         SD 0%              4/50 (8%)         Mean 8%         SD 0%         Total         0/50 (0%)         Mean 0%         SD 0%            Osteoma         Osteoma <t< td=""><td>Mesotnelloma: Benign,</td><td>Malignant, NOS</td><td></td><td></td><td></td><td></td><td>0/50 (0%)</td><td></td><td></td></t<>	Mesotnelloma: Benign,	Malignant, NOS					0/50 (0%)		
Mesothelioma: Malignant           4/50 (8%)         0/50 (0%)           Overall Incidence         Total         4/50 (8%)         Mean 8%         SD 0%         Total         0/50 (0%)         Mean 0%         SD 0%           #All Organs: Osteoma         Osteoma         Osteoma <td>Overall Incidence</td> <td>Total</td> <td>` '</td> <td>Mean 8%</td> <td>SD 0%</td> <td>Total</td> <td>` '</td> <td>Mean 0%</td> <td>SD 0%</td>	Overall Incidence	Total	` '	Mean 8%	SD 0%	Total	` '	Mean 0%	SD 0%
4/50 (8%)  Overall Incidence Total 4/50 (8%)  Mean 8% SD 0% Total 0/50 (0%)  #All Organs: Osteoma	#All Organs:								
Overall Incidence         Total         4/50 (8%)         Mean 8%         SD 0%         Total         0/50 (0%)         Mean 0%         SD 0%           #All Organs:         Osteoma	Mesothelioma: Maligna	nt							
#All Organs: Osteoma			4/50 (8%)				0/50 (0%)		
Osteoma	Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
0 (= 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%	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: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 146

			Male			Female			
#All Organs: Osteosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Osteosarcoma or Osteoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Cortex: Adenoma		1/50 (2%)				2/50 (4%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	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: Pheochromocytoma Benign		5/50 (10%)				2/50 (4%)			
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Comple	ex	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

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 147

			Male				Female			
*Adrenal Medulla: Pheochromocytoma Ma	alignant									
•	-	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: B										
	og, oop.o,	6/50 (12%)				2/50 (4%)				
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
#Blood Vessel: Leiomyosarcoma	•••••	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%		
#Bone: Chordoma		, ,				, ,				
Overall Incidence	Tatal	0/50 (0%)	Mann 00/	CD 00/	Tatal	0/50 (0%)	Maan 00/	SD 0%		
Overali incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%			
#Bone: 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%		
#Bone: Osteosarcoma		2/20 (201)				(201)				
	<b>-</b>	0/50 (0%)		00.00/	<b>-</b>	0/50 (0%)	NA 00/	05.00/		
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

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 148

			Male			Female			
#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%	
*Brain: Glioma									
		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: Glioma Benign		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
		, ,				, ,			
*Brain: Glioma 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%	
*Brain: Oligodendroglioma, Glioma									
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Brain: Osteosarcoma									
Occupation of the second	Tatal	0/50 (0%)	Mara 00/	00.00/	Tatal	0/50 (0%)	Marana 00/	OD 00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<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: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 149

			Male			Female			
*Clitoral/Preputial Gland: Adenoma									
		0/50 (0%)				7/50 (14%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%	
*Clitoral/Preputial Gland: Carcinoma									
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Carcinoma or Adenoma		2/50 / 40/				7/50 (4.40/)			
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%	
		, ,				, ,			
*Clitoral/Preputial Gland: Sarcoma		0/50 (00/)				(70 (70)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Ear: Neural Crest Tumor									
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Eye: Melanoma Benign		0.75							
Overell Incidence	Tatal	0/50 (0%)		CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date: 06/05/2013

Page: 150

Species: RATS Strain: F 344/N

Vehicle: WATER

Length of Study: CHRONIC

			Male		Female			
#Eye: Melanoma 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%
#Harderian Gland: Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Harderian 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%
*Heart: Schwannoma Benign								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Heart: 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%

<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: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 151

		·	Male			Female			
#Intestine Large: Colon/Recti Adenoma	um:								
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 Large: Colon/Recti	um:			•••••					
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: Duodenum: Leiomyoma									
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: Duodenum: Schwannoma Malignant						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: Ileum: 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%	
#Intestine Small: Jejunum: 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%	

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

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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female			
#Intestine Small: Jejunum: Leiomyoma		0/50 (00/)				0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#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 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%		
#Intestine Small: Site Unspec 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%		
#Intestine Small: Site Unspec Carcinoma or Adenoma	cified:									
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 Leiomyoma										
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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 153

			Male	•			Female	Female	
#Intestine Small: Site Unspe Leiomyosarcoma	ecified:								
Overall Incidence	Total	0/50 (09 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspe Schwannoma Malignant	ecified:								
Overall Incidence	Total	0/50 (09 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Adenoma		4/50 (8 <sup>s</sup>	27.)			0/50 (0%)			
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Carcinoma		0/50 /05				0/50 (00/)			
Overall Incidence	Total	0/50 (09 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Carcinoma or Adenoma	•••••								
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Pelvis and Transiti Papilloma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/49 (0%) 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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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

Route: ORAL

Length of Study: CHRONIC

Vehicle: WATER

Page: 154

			Male			Female			
*Kidney: Renal Tubule: Adenoma	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma		0/50 (00/)							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: 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%	
*Kidney: Renal Tubule: Lipoma		0/50 (0%)		OD 00/	<del>-</del>	0/49 (0%)		00.00	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Mesenchymal Tumor Malig	gnant	0/50 (00/)				0/40 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Sarcoma						0/40 (09/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 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: F 344/N

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 155

				Male			O/50 (0%)  Total O/50 (0%)  Mean 0% SD 0%  O/50 (0%)  Total O/50 (0%)  Mean 0% SD 0%  SD 0%  Total 2/50 (4%)  Total 2/50 (4%)  Mean 4% SD 0%			Female			
*Liver: Hepatocellular Adenoma	ı												
Overall Incidence	Total	3/50 3/50 (6%)	(6%)	Mean 6%	SD 0%	Total	` '	Mean 4%	SD 0%				
*Liver: Hepatocellular Carcinom	ıa												
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%				
*Liver: Hepatocellular Carcinom	a or Hepatobla		(0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%				
*Liver: Hepatocellular Carcinom	a or Hepatocel	lular Adenoma 3/50	(6%)		<b>OD</b> 000	<del>-</del>	` '		00.00				
Overall Incidence	Total	3/50 (6%)		Mean 6%	SD 0%		` '						
*Liver: Hepatocellular Carcinom	a, Hepatocellul	•	Hepatobl	astoma			2/50 (4%)						
Overall Incidence	Total	3/50 (6%)	()	Mean 6%	SD 0%	Total	` '	Mean 4%	SD 0%				
*Liver: Ito Cell Tumor Benign		0/5	(201)				(20)						
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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 156

Report Date: 06/05/2013

Species: RATS Strain: F 344/N Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

		Male				Female				
*Lung: Alveolar/Bronchiolar A	denoma									
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
	Total	3/30 (6%)			10lai	0/50 (0%)				
*Lung: Alveolar/Bronchiolar C	arcinoma									
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:		eolar/Bronchiolar Adenon 3/50 (6%)				0/50 (0%)				
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Lung: 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%		
#Mammary Gland: Adenolipoma										
Occupati la abdance	Tatal	0/50 (0%)	M 00/	00,007	Taral	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%		
#Mammary 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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 157

Male						2/50 (4%) Total 2/50 (4%) Mean 4% SD 0%  34/50 (68%) Total 34/50 (68%) Mean 68% SD 0%  0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%			Female				
		(0%)				` ,							
Total	0/50 (0%)		Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%					
		(0%)				` ,							
	0/50 (0%)		Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%					
		(001)											
Tatal		(2%)	Mana 20/	CD 00/	Tatal	, ,	Mann C00/	CD 00/					
	, ,				1 Otal	34/50 (68%)	wean 68%	5D 0%					
	0/50	(00/.)				0/50 (00/)							
Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)		SD 0%					
	1/50	(2%)				34/50 (68%)							
Total	1/50 (2%)		Mean 2%	SD 0%	Total	34/50 (68%)	Mean 68%	SD 0%					
Carcinoma, or		(00/)				24/50 (000)							
Total		(2%)	Moon 29/	SD 0%	Total	` ,	Moon 68%	SD 0%					
	Total <b>or Adenoma</b> Total	Total 0/50 (0%)  0/50 Total 0/50 (0%)  1/50 Total 1/50 (2%)  Total 0/50 (0%)  Or Adenoma 1/50 Total 1/50 (2%)  Carcinoma, or Adenoma 1/50	Total 0/50 (0%)  0/50 (0%)  Total 0/50 (0%)  1/50 (2%)  Total 1/50 (2%)  Total 0/50 (0%)  Total 0/50 (0%)  or Adenoma  1/50 (2%)  Total 1/50 (2%)  Carcinoma, or Adenoma  1/50 (2%)	0/50 (0%) Total 0/50 (0%) Mean 0%  0/50 (0%) Total 0/50 (0%) Mean 0%  1/50 (2%) Total 1/50 (2%) Mean 2%  0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0%  or Adenoma 1/50 (2%) Total 1/50 (2%) Mean 2%  Carcinoma, or Adenoma 1/50 (2%)	0/50 (0%)           Total         0/50 (0%)         Mean 0%         SD 0%           Total         0/50 (0%)         Mean 0%         SD 0%           1/50 (2%)           Total         1/50 (2%)         Mean 2%         SD 0%           Total         0/50 (0%)         Mean 0%         SD 0%           Or Adenoma           1/50 (2%)         Mean 2%         SD 0%	Total 0/50 (0%) Mean 0% SD 0% Total  0/50 (0%) Mean 0% SD 0% Total  1/50 (2%) Mean 2% SD 0% Total  1/50 (0%) Mean 0% SD 0% Total  1/50 (0%) Mean 0% SD 0% Total  0/50 (0%) Mean 0% SD 0% Total  0/50 (0%) Mean 0% SD 0% Total  or Adenoma  1/50 (2%) Mean 2% SD 0% Total  Carcinoma, or Adenoma  1/50 (2%)	Total 0/50 (0%) Mean 0% SD 0% Total 2/50 (4%)  Total 0/50 (0%) Mean 0% SD 0% Total 2/50 (4%)  Total 0/50 (0%) Mean 0% SD 0% Total 2/50 (4%)  Total 1/50 (2%) Mean 2% SD 0% Total 34/50 (68%)  Total 0/50 (0%) Mean 0% SD 0% Total 34/50 (68%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 1/50 (2%) Mean 0% SD 0% Total 0/50 (68%)  Carcinoma, or Adenoma  1/50 (2%) Mean 2% SD 0% Total 34/50 (68%)	Total 0/50 (0%) Mean 0% SD 0% Total 2/50 (4%) Mean 4%    0/50 (0%)					

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 158

			Male		Female           0/50 (0%)         Mean 0%         SD 0%           0/50 (0%)         Mean 0%         SD 0%			Female			
#Mesentery: Fibrous Histiocytoma											
	<b>+</b>	0/50 (0%)		<b>OD</b> 00/	<b></b>	` '		05.00/			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Mesentery: Schwannoma Malignar	nt										
		0/50 (0%)				` '					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Nose: Adenoma		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%			
#Oral Cavity (Oral Mucos Papilloma Squamous o Overall Incidence	sa, Tongue, Phary or Papilloma Total	vnx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%			
#Oral Cavity (Oral Mucos Squamous Cell Carcine				•••••		•••••					
		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	a, Tongue, Phary					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

Strain: F 344/N

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 159

			Male		0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%  0/50 (0%)			
#Oral Mucosa: Squamous Cell Carcino	ma							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Moon 0%	SD 0%
		0/30 (0/8)						
#Oral Mucosa: Squamous Cell Papillon	na	0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Ovary: Cystadenoma						0/50 (00)		
Overall Incidence					Total	` ,	Mean 0%	SD 0%
*Ovary: Fibrosarcoma						0/50 (00/)		
Overall Incidence						0/50 (0%)		SD 0%
*Ovary: Granulosa Cell Tumor B								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor N	<i>l</i> lalignant					(201)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

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

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 160

			Male				Female	
*Ovary: Granulosa Cell Tumor: B	enign, Malign	ant, NOS				0.750 (001)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor	Malignant					0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Schwannoma Malignant								
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Sertoli Cell Tumor Maligi								
Overall Incidence					Total	, ,	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma	ı							
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma						(00)		
Overall Incidence	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

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

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 161

Report Date: 06/05/2013

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male				Female		
*Pancreas: Carcinoma or Adenoma	1								
		1/49 (2%)				0/50 (0%)			
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Mixed Tumor Benign									
		0/49 (0%)				0/50 (0%)			
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Parathyroid Gland: Adenoma		2/-2 (22)				-/			
		0/50 (0%)				0/47 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%	
*Pituitary Gland: Pars Dis Adenoma	talis or Unspeci	ified Site:							
		28/50 (56%)				30/50 (60%)			
Overall Incidence	Total	28/50 (56%)	Mean 56%	SD 0%	Total	30/50 (60%)	Mean 60%	SD 0%	
*Pituitary Gland: Pars Dis									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Pituitary Gland: Pars Dis Carcinoma or Adenoma	talis or Unspeci								
	=	28/50 (56%)				30/50 (60%)			
Overall Incidence	Total	28/50 (56%)	Mean 56%	SD 0%	Total	30/50 (60%)	Mean 60%	SD 0%	
		(/				( /			

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

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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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

Route: ORAL

Length of Study: CHRONIC

Vehicle: WATER

Page: 162

	Male						Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Ganglioneuroma												
Overall Incidence	Total	0/50 (0 0/50 (0%)	%) Mean	0% SD 0%	6 Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Intern	media:											
Overall Incidence	Total	0/50 (0 0/50 (0%)	%) Mean	0% SD 0%	6 Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Interr Carcinoma or Adenoma	nedia:	0/50 (0	%)			0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean	0% SD 0%	6 Total	0/50 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Nervo Craniopharyngioma						0/50 (00/)						
Overall Incidence	Total	0/50 (0%)	%) Mean			0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Prostate: Adenoma												
Overall Incidence	Total	0/49 (0%)	%) Mean	0% SD 0%	6							
*Prostate: Carcinoma or Adenoma			%)									
Overall Incidence	Total	0/49 (0%)	Mean									

<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: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 163

			Male			0/50 (0%) otal 0/50 (0%) Mean 0% SD 0%				
*Salivary Glands: Carcinoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%		
*Salivary Glands: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%		
*Salivary Glands: Sarcoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,	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: Adenoma		0/50 (0%)								
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%						
#Skeletal Muscle: Fibrous Histiocytoma		0/50 (00()				0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 164

				Male		Female       0/50 (0%)     Mean 0%     SD 0%       1/50 (2%)     Mean 2%     SD 0%       0/50 (2%)     Mean 2%     SD 0%			
#Skeletal Muscle: Lipoma									
		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									
		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: Basal Cell Adenoma or E	3asosquamous	Tumor Benign 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: Basal Cell Adenoma, Ba		umor Benign, o					1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	, ,	Mean 2%	SD 0%	Total	1/50 (2%)		SD 0%
#Skin: Basal Cell Carcinoma									
		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		nant or NO	OS)			0/50 (0%)		

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 165 Report Date: 06/05/2013

Species: RATS Strain: F 344/N Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

#Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma													
/50 (2%)				1/50 (2%)									
` '		SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%							
. Tumor (M or B), Ba	sal Cell Adenoma,												
	Oma			1/50 (2%)									
` '	Mean 12%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%							
/50 (6%)				2/50 (4%)									
(6%) I		SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%							
osarcoma, or Fibrous				2/50 (4%)									
(8%)	Mean 8%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%							
/50 (2%)				0/50 (0%)									
(2%)		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%							
us Histiocytoma				0/50 (0%)									
(2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%							
	/50 (2%)  . Tumor (M or B), Bahoma, Trichoepitheli /50 (12%) (12%)  /50 (6%)  /50 (6%)  Desarcoma, or Fibrous /50 (8%)  (8%)  /50 (2%)  us Histiocytoma /50 (2%)	/50 (2%) Mean 2%  . Tumor (M or B), Basal Cell Adenoma, homa, Trichoepithelioma /50 (12%) (12%) Mean 12%  /50 (6%) Mean 6%  Desarcoma, or Fibrous Histiocytoma /50 (8%) Mean 8%  /50 (2%) Mean 2%  us Histiocytoma /50 (2%)	/50 (2%) (2%) Mean 2% SD 0%  Tumor (M or B), Basal Cell Adenoma, homa, Trichoepithelioma /50 (12%) (12%) Mean 12% SD 0%  /50 (6%) (6%) Mean 6% SD 0%  Desarcoma, or Fibrous Histiocytoma /50 (8%) (8%) Mean 8% SD 0%  /50 (2%) (2%) Mean 2% SD 0%	/50 (2%) Mean 2% SD 0% Total  . Tumor (M or B), Basal Cell Adenoma, homa, Trichoepithelioma /50 (12%) (12%) Mean 12% SD 0% Total  /50 (6%) Mean 6% SD 0% Total  . Desarcoma, or Fibrous Histiocytoma /50 (8%) (8%) Mean 8% SD 0% Total  /50 (2%) (2%) Mean 2% SD 0% Total	1/50 (2%)   1/50 (4%)   1/50 (2%)   1/50 (4%)   1/50 (2%)   1/50 (4%)   1/50 (2%)   1/50 (4%)   1/50 (2%)   1/50 (2%)   1/50 (2%)   1/50 (0%)   1/50 (0%)   1/50 (0%)   1/50 (2%)   1/50 (2%)   1/50 (0%)   1/50 (0%)   1/50 (2%)   1/50 (2%)   1/50 (2%)   1/50 (0%)   1/50 (0%)   1/50 (0%)   1/50 (2%)   1/50 (2%)   1/50 (2%)   1/50 (0%)   1/50 (0%)   1/50 (0%)   1/50 (0%)   1/50 (2%)   1/50 (2%)   1/50 (2%)   1/50 (0%)   1/50	1/50 (2%)   Mean 2%   SD 0%   Total   1/50 (2%)   Mean 2%							

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 166

			Male			Female           0/50 (0%)         0/50 (0%)         Mean 0%         SD 0%           0/50 (0%)         Mean 0%         SD 0%		
#Skin: Fibrous Histiocytoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
#Skin: Hemangiosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
#Skin: Keratoacanthoma Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	` '	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%	
#Skin: 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%
#Skin: Neural Crest Tumor 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

Species: RATS

Strain: F 344/N

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

.....

Schwannoma Benign

**Schwannoma Malignant** 

#Skin:

#Skin:

#Skin:

#Skin: Sarcoma

#Skin:

#Skin:

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Total

Total

Total

Total

Total

Total

Neurofibrosarcoma or Schwannoma (malignant or NOS)

0/50

0/50 (0%)

0/50

0/50 (0%)

0/50

0/50 (0%)

0/50

0/50 (0%)

0/50

0/50 (0%)

0/50

0/50 (0%)

(0%)

(0%)

(0%)

(0%)

(0%)

Mean 0%

Mean 0%

Length of Study: CHRONIC

Neurofibroma or Schwannoma benign

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

SD 0%

SD 0%

Male **Female** 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%)

0/50

0/50

0/50 (0%)

0/50 (0%)

Total

Total

(0%)

(0%)

Mean 0%

Mean 0%

SD 0%

SD 0%

Page: 167

*: Denominator is number	r 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: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 168

			Male	Female				
#Skin: Squamous Cell Carcinoma Overall Incidence	a 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 or Carcinoma	a, Basal Cell C	Carcinoma, Basosquamo	us Tumor (malignan	t 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: Squamous Cell Papilloma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma		0/50 (0%)				0/50 (0%)		
	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 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 Papilloma,	, 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%

<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: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 169

			Male	Female				
#Skin: Trichoepithelioma 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: 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%
#Skin: Sebaceous Gland: Carcinoma or Adenoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Spinal Cord: Glioma 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%
#Stomach, Glandular: 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, Glandular: 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%

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

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

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 170

#Stomach, Glandular: Sarcoma			Male			Female			
	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Testes: Adenoma		35/50 (70%)							
Overall Incidence	Total	35/50 (70%)	Mean 70%	SD 0%					
*Testes: Hemangioma		0/50 (0%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%					
*Thymus: Thymoma Benign Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma Malignant		0/49 (0%)				0/49 (0%)			
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma NOS		0/49 (0%)				0/49 (0%)			
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 171

					Female				
*Thymus: Thymoma: Benign, Malignant, NOS  0/49 (0%)  0/49 (0%)									
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Adenoma									
Overall Incidence	Total	12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%	Total	10/50 (20%) 10/50 (20%)	Mean 20%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		13/50 (26%)				11/50 (22%)			
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	11/50 (22%)	Mean 22%	SD 0%	
*Thyroid Gland: Follicular C									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: Follicular C Carcinoma						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: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 172

			Male		Female			
*Thyroid Gland: Follicular C Carcinoma or Adenoma	Cell:							
		1/50 (2%	,			0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom	na							
		0/50 (0%	,			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom	-	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 Papilloma				SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue:				SD 0% SD 0%	Total Total		Mean 0%  Mean 0%	SD 0% SD 0%
#Tongue: Squamous Cell Papilloma	<b>a</b> Total	0/50 (0% 0/50 (0%)	%) Mean 0%			0/50 (0%) 0/50 (0%)		
#Tongue: Squamous Cell Papilloma Overall Incidence  #Tooth: Adamantinoma Malignan	Total	0/50 (0% 0/50 (0%) 0/50 (0%	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma Overall Incidence #Tooth:	<b>a</b> Total	0/50 (0% 0/50 (0%)	%) Mean 0%			0/50 (0%) 0/50 (0%)		
#Tongue: Squamous Cell Papilloma Overall Incidence  #Tooth: Adamantinoma Malignan	Total	0/50 (0% 0/50 (0%) 0/50 (0%	%) Mean 0% %) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Page: 173

Report Date: 06/05/2013

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

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female** \*Urinary Bladder: Carcinoma or Papilloma 0/50 (0%)0/50 (0%)0/50 (0%) SD 0% SD 0% **Overall Incidence** Total Mean 0% Total 0/50 (0%) Mean 0% \*Urinary Bladder: 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% \*Urinary Bladder: **Papilloma** 0/50 (0%)0/50 (0%)SD 0% **Overall Incidence** Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% ..... #Uterus: Adenoma 0/50 (0%)**Overall Incidence** SD 0% Total 0/50 (0%) Mean 0% #Uterus: Carcinoma 1/50 (2%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% **#Uterus:** Leiomyosarcoma 1/50 (2%)

Total

1/50 (2%)

Mean 2%

SD 0%

**Overall Incidence** 

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

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

Species: RATS

Strain: F 344/N

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

Tumor Incidence for Selected Control Animal Groups

Page: 174

Report Date: 06/05/2013

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus: Polyp Stromal** 8/50 (16%) **Overall Incidence** Total 8/50 (16%) Mean 16% SD 0% **#Uterus:** Sarcoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% #Uterus: Sarcoma Stromal 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% ..... #Uterus: Sarcoma Stromal or Polyp Stromal 8/50 (16%) **Overall Incidence** SD 0% Total 8/50 (16%) Mean 16% #Uterus: **Schwannoma Malignant** 

0/50

0/50 (0%)

Total

(0%)

Mean 0%

SD 0%

Polyp 1/50 (2%)

 Overall Incidence
 Total
 1/50 (2%)
 Mean 2%
 SD 0%

**Overall Incidence** 

#Vagina:

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

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

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 175

			Male				Female	
#Vagina: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Schwannoma Malignant								
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Zymbal's 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%
#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		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