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: GAVAGE Vehicle: WATER **Page:** 70

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	052000505	01/21/04	727	50(3)	30(679)	498.5	Ginseng		
Female Female									
Battelle Columbus Laboratory	052000505	01/22/04	728	50(5)	36(700)	355.0	Ginseng		

Species: RATS

Toxicology Data Management System

Page: 71

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Strain: F 344/N Vehicle: WATER

			Male				Female	
#All Organs: Benign Tumors		40/E0 (000/)				42/50 (049/)		
Overall Incidence	Total	49/50 (98%) 49/50 (98%)	Mean 98%	SD 0%	Total	42/50 (84%) 42/50 (84%)	Mean 84%	SD 0%
#All Organs: Malignant Tumors								
Overall Incidence	Total	26/50 (52%) 26/50 (52%)	Mean 52%	SD 0%	Total	10/50 (20%) 10/50 (20%)	Mean 20%	SD 0%
		, ,				` '		
#All Organs: Malignant and Benign Tui	mors	49/50 (98%)				45/50 (90%)		
Overall Incidence	Total	49/50 (98%)	Mean 98%	SD 0%	Total	45/50 (90%)	Mean 90%	SD 0%
#All Organs: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: 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 Her	nangioma							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Mana

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: GAVAGE Vehicle: WATER Page: 72

			Male	Female								
#All Organs: Histiocytic Sarcoma												
•		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#All Organs:												
Leukemia: Lymphocyti	c, Monocytic, Mo	ononuclear, or Undifferer	ntiated			0/50 (1001)						
		18/50 (36%)				6/50 (12%)						
Overall Incidence	Total	18/50 (36%)	Mean 36%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%				
#All Organs:												
•	Histiocytic, Lym	phocytic, Mixed, NOS, or	Undifferentiated Ce	II Type								
		0/50 (0%)		• •		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
		` ,				0/50 (0%)	Mean 0%	SD 0%				
#All Organs:		0/50 (0%)				0/50 (0%)	Mean 0%	SD 0%				
		0/50 (0%)				0/50 (0%)	Mean 0%	SD 0%				
#All Organs:		0/50 (0%)					Mean 0% Mean 0%	SD 0% SD 0%				
#All Organs: Mesothelioma: Benign	, Malignant, NOS	0/50 (0%) 2/50 (4%)				0/50 (0%)						
#All Organs: Mesothelioma: Benign Overall Incidence #All Organs:	, Malignant, NOS Total	0/50 (0%) 2/50 (4%)				0/50 (0%)						
#All Organs: Mesothelioma: Benign	, Malignant, NOS Total	0/50 (0%) 2/50 (4%) 2/50 (4%)				0/50 (0%) 0/50 (0%)						
#All Organs: Mesothelioma: Benign Overall Incidence #All Organs: Mesothelioma: Maligna	, Malignant, NOS Total	0/50 (0%) 2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#All Organs: Mesothelioma: Benign Overall Incidence #All Organs:	, Malignant, NOS Total	0/50 (0%) 2/50 (4%) 2/50 (4%)				0/50 (0%) 0/50 (0%)						
#All Organs: Mesothelioma: Benign Overall Incidence #All Organs: Mesothelioma: Maligna	, Malignant, NOS Total	0/50 (0%) 2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#All Organs: Mesothelioma: Benign Overall Incidence #All Organs: Mesothelioma: Maligna Overall Incidence #All Organs:	, Malignant, NOS Total	0/50 (0%) 2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 73

				Male			Female			
#All Organs: Osteosarcoma										
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Osteosarcoma or Osteoma		1/50	(20/)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Cortex: Adenoma		0/50	(00()				0/50 (00/)			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*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										
Overall Incidence	Total	4/50 4/50 (8%)	(8%)	Mean 8%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Comple	ex	0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 74

				Male				Female				
*Adrenal Medulla: Pheochromocytoma 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%			
*Adrenal Medulla: Pheochromocytoma: B												
	J., J., J.,		8%)				1/50 (2%)					
Overall Incidence	Total	4/50 (8%)	,,	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
#Blood Vessel: Leiomyosarcoma		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	U70)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Bone: Chordoma			0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 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		4/50	201)				0/50 (00/)					
Overell Insidence	Tatal		2%)	Mana 20/	CD 00/	Tatal	0/50 (0%)	Mann 00/	CD 00/			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 75

			Ma	le			Female			
#Bone: Osteosarcoma or Osteoma										
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	%) Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Brain: Glioma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	6) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Brain: Glioma Benign		0/50 (00	·····			0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Brain: Glioma Malignant		0/50 (0%				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%		Total	0/50 (0%)	Mean 0%	SD 0%		
*Brain: Oligodendroglioma, Glioma	, or Astrocy									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Brain: Osteosarcoma		0/50 (0%	۷)			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} 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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 76

			Male				Female			
*Clitoral/Preputial Gland: Adenoma										
		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Clitoral/Preputial Gland: Carcinoma										
		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Clitoral/Preputial Gland: Carcinoma or Adenoma		2/-2 (224)				2/-2 (194)				
	.	0/50 (0%)		00.00/	-	2/50 (4%)	10/	00.00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
*Clitoral/Preputial Gland: Sarcoma										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Ear: Neural Crest Tumor										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Eye: Melanoma Benign										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} 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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 77

			Male			Female			
#Eye: Melanoma Malignant		0/50 (00)				4/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Harderian 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%	
#Harderian Gland: Carcinoma		4/50 (20/)				0/50 (09/)			
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 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 78

			Male			Female						
#Intestine Large: Colon/Rectum: 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 Large: Colon/Rec 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%				
#Intestine Small: Duodenur Leiomyoma						1/50 (20/)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
#Intestine Small: Duodenur 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%				
#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		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%				

^{*:} 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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page**: 79

			Male			Female			
#Intestine Small: Jejunum: 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: Jejunum: Leiomyosarcoma	•••••								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspe 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 Unspe 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%	
#Intestine Small: Site Unspe Carcinoma or Adenoma				•••••					
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspe Leiomyoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 80

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: WATER

Route: GAVAGE

Length of Study: CHRONIC

Male **Female** #Intestine Small: Site Unspecified: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: **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% *Islets, Pancreatic: Adenoma 0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0% *Islets, Pancreatic: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) *Islets, Pancreatic: Carcinoma or Adenoma 0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0% *Kidney: Pelvis and Transitional Epithelium: **Papilloma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%

^{*:} 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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 81

				Male			Female			
*Kidney: Renal Tubule: Adenoma										
Overall Incidence	Total	1/50 (2%)	2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma										
Overall Incidence	Total	1/50 (2%)	2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma or Adenoma		2/50 (-	4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	,	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Lipoma		0/50 (0%)			Total	0/50 (0%)	M 00/	OD 00	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Mesenchymal Tumor Malig	jnant									
Overall Incidence	Total	0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Sarcoma		0/50 //	00()				0/50 /09/			
Overall Incidence	Total	0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 82

			Male			Female					
*Liver: Hepatocellular Adenoma 0/50 (0%) 0/50 (0%) Overall heidenes Total 0/50 (0%) Overall heidenes 0/50 (0%) Overall heidenes											
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Carcinoma	a	1/50 (2%)				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Carcinoma						0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Carcinoma						0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Carcinoma						0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Ito Cell Tumor Benign		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			

^{*:} 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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 83

			Male		Female						
*Lung: Alveolar/Bronchiolar Adenoma 0/50 (0%) 1/50 (2%)											
		0/50 (0%)				1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
*Lung: Alveolar/Bronchiolar Car	cinoma										
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Lung: Alveolar/Bronchiolar Car		0/50 (0%)		00.00		1/50 (2%)		35 30			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	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											
		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: Adenoma		0/50 (00/)				0/50 (40/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 84

			Male				Female	
#Mammary Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Mammary Gland: Fibroadenoma		2/50 (4%)				22/50 (649/)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	32/50 (64%) 32/50 (64%)	Mean 64%	SD 0%
#Mammary Gland: Fibroma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma or								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	33/50 (66%) 33/50 (66%)	Mean 66%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, C	arcinoma, or	Adenoma 2/50 (4%)				33/50 (66%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	33/50 (66%)	Mean 66%	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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 85

			Male				Female	
#Mesentery: Fibrous Histiocytoma								
	+	0/50 (0%)		05 , 00/	T	0/50 (0%)		00.004
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%)				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%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o Overall Incidence	a, Tongue, Phary		Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcine								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phary					0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 86

Report Date: 06/05/2013

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Oral Mucosa: Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%) SD 0% **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% **#Oral Mucosa: Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Ovary: Cystadenoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Ovary: Fibrosarcoma 0/50 (0%)SD 0% **Overall Incidence** Total 0/50 (0%) Mean 0% *Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% **Granulosa Cell Tumor Malignant** 0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/50 (0%)

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 87

Report Date: 06/05/2013

SD 0%

Mean 0%

		Female	
Total	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%
	0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%
Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
	Total Total Total	Total 0/50 (0%) O/50 (0%) Total 0/50 (0%) O/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%)	0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)

SD 0%

0/50 (0%)

Total

Total

0/50 (0%)

Mean 0%

Overall Incidence

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

^{#:} 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: GAVAGE Vehicle: WATER Page: 88

			Male				Female	
*Pancreas: Carcinoma or Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Mixed Tumor Benign								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma		0/50 (00)				0/40 (00)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
Overall incluence		0/50 (0%)				0/48 (0%)		3D 0%
*Pituitary Gland: Pars Dista Adenoma	is or Unspeci	ified Site:						
		20/50 (40%)				16/50 (32%)		
Overall Incidence	Total	20/50 (40%)	Mean 40%	SD 0%	Total	16/50 (32%)	Mean 32%	SD 0%
*Pituitary Gland: Pars Dista 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%
*Pituitary Gland: Pars Dista Carcinoma or Adenoma		ified Site:						
		20/50 (40%)				16/50 (32%)		
Overall Incidence	Total	20/50 (40%)	Mean 40%	SD 0%	Total	16/50 (32%)	Mean 32%	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: GAVAGE

Page: 89

Report Date: 06/05/2013

Species: RATS **Strain:** F 344/N

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

		Male				Female	
is or Unspecif	ied Site:						
	0/50 (0%)				0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
nedia:							
	` '				` '		
	` '	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
nedia:	0/50 (09/)				0/50 (09/)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
sa:	0/50 (00/)				0/50 (00/)		
Total	` ,	Moon 0%	SD 0%	Total	` '	Moan 0%	SD 0%
	, ,						
	` '						
	` '						
Total	` ,	Mean 2%	SD 0%				
1	Total nedia: Total nedia: Total ssa: Total Total	Total 0/50 (0%) nedia: 0/50 (0%) Total 0/50 (0%) nedia: 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 1/50 (2%) Total 1/50 (2%)	is or Unspecified Site: 0/50 (0%)	is or Unspecified Site: 0/50 (0%)	is or Unspecified Site: 10/50	is or Unspecified Site: O/50 (0%)	is or Unspecified Site: 0/50 (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

Page: 90 Report Date: 06/05/2013

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

Length of Study: CHRONIC

			Male	-			Female	
*Salivary Glands: Carcinoma	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		` ,				` ,	ivican 076	
*Salivary Glands: Sarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
			iviean 0%			0/30 (0%)	iviean 0%	
#Seminal Vesicle: Adenoma Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
#Skeletal Muscle: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} 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: GAVAGE Vehicle: WATER **Page:** 91

				Male				Female	
#Skeletal Muscle: Lipoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#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 I	3asosquamous	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%)	Mean 2%	SD 0%
#Skin: Basal Cell Carcinoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:			nont or N	ne)					
Basal Cell Carcinoma or	Basosquamou	s Tumor (malig	(0%)) 3)			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 Length of Study: CHRONIC

Toxicology Data Management System

Page: 92

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

			Male				Female				
#Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 1/50 (2%) 1/50 (2%)											
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
≭Skin: Basal or Sq. Cell Carcir Adenoma, Papilloma, S	noma, Carcinoma oq Papilloma, Ker	a, Basosq. Tumor (M or atoacanthoma, Trichoe	B), Basal Cell Adeno pithelioma	ma,							
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%			
#Skin: Fibroma Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
Skin: Fibroma, Fibrosarcoma overall Incidence	a, Sarcoma, Myx o	oma, Myxosarcoma, or I 3/50 (6%) 3/50 (6%)	Fibrous Histiocytoma Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
Skin: Fibrosarcoma 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: Fibrosarcoma, Sarcom						0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 93

			Male				Female	
#Skin: Fibrous Histiocytoma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma		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%
#Skin: Keratoacanthoma		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Skin: Lipoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#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		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 94

			Male			Female						
#Skin: Neurofibroma or Schwannoma benign 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%				
#Skin: Neurofibrosarcoma or Sc	hwannoma (m	alignant or NOS)										
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Neurofibrosarcoma, Neur						0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
Skin: Sarcoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
≄Skin: Schwannoma Benign		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
Skin: 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%				

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 95

			Male				Female	
#Skin: Squamous Cell Carcinor	ma							
•		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:		Carcinoma, Basosquamo						
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillom	na	0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Squamous Cell Papillom	na or Papilloma							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Squamous Cell Papillom	na, Papilloma, S	quamous Cell Carcinoma	or Keratoacanthon	na		3/50 (6%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
#Skin: Squamous Cell Papillom	na, Papilloma, o	r Keratoacanthoma 0/50 (0%)				3/50 (6%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 96

#Skin: Trichoepithelioma			Male	Female				
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma						(201)		
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		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Spinal Cord: Glioma Malignant		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#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		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 97

#Stomach, Glandular: Sarcoma			Male			Female			
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Testes: Adenoma									
		45/50 (90%)							
Overall Incidence	Total	45/50 (90%)	Mean 90%	SD 0%					
*Testes: Hemangioma		0/50 (00)							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%					
		, ,							
*Thymus: Thymoma Benign		0/50 (00/)				0/40 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma Malignant									
		0/50 (0%)				1/48 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/48 (2.08%)	Mean 2.08%	SD 0%	
*Thymus: Thymoma NOS		0/50 (00/)				0/49 /09/			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 98

Mean 0%

Report Date: 06/05/2013

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

> Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Male Female *Thymus: Thymoma: Benign, Malignant, NOS 0/50 (0%)1/48 (2%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 1/48 (2.08%) Mean 2.08% SD 0% *Thyroid Gland: C-Cell: Adenoma 11/50 (22%)6/50 (12%) **Overall Incidence** Total 11/50 (22%) Mean 22% SD 0% Total 6/50 (12%) Mean 12% SD 0% *Thyroid Gland: C-Cell: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Thyroid Gland: C-Cell: Carcinoma or Adenoma 11/50 (22%)6/50 (12%) **Overall Incidence** Total 11/50 (22%) Mean 22% SD 0% Total 6/50 (12%) Mean 12% SD 0% *Thyroid Gland: Follicular Cell: Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Thyroid Gland: Follicular Cell: Carcinoma 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total SD 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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 99

			Male	Female							
Thyroid Gland: Follicular Cell: 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%			
#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	a 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:	a 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%			

^{*:} 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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 100

			Male	Female				
*Urinary Bladder: Carcinoma or 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%
*Urinary Bladder: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: 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%
#Uterus: Adenoma						0/50 (09/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma						0/50 /00/		
Overall Incidence					Total	0/50 (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 Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: WATER

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Page: 101

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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 102

			Male				Female	
#Vagina: Sarcoma						2(72)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Schwannoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma		0/50 (00/)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's 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%

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

^{#:} Denominator is number of animals necropsied