

NTP Historical Controls Report

By Route and Vehicle

F 344/N RATS

2006

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.

This report is broken up into sections based on the route and vehicle used to deliver the chemical. The Table of Contents on Page 3 shows the different Route/Vehicle combinations. To see the data from all routes and vehicles combined into one set, you must run the "All Routes" report.

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

Male
M1
M2
M3
M4
M5
Female
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.

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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: CORN OIL Page: 4

Report Date: 06/03/2022

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				
Southern Research Institute	059302306	07/11/97	729	50(3)	37(693)	510.6	2,4-Hexadienal		
	Female								
Southern Research Institute	059302306	07/11/97	732	50(5)	37(699)	314.6	2,4-Hexadienal		

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: CORN OIL Page: 5

			Male				Female	
#All Organs: Benign Tumors								
		48/50 (96%)				45/50 (90%)		
Overall Incidence	Total	48/50 (96%)	Mean 96%	SD 0%	Total	45/50 (90%)	Mean 90%	SD 0%
#All Organs: Malignant Tumors								
		21/50 (42%)				18/50 (36%)		
Overall Incidence	Total	21/50 (42%)	Mean 42%	SD 0%	Total	18/50 (36%)	Mean 36%	SD 0%
#All Organs: Malignant and Benign Tu		50/50 (100%)				48/50 (96%)		
Overall Incidence	Total	50/50 (100%)	Mean 100%	SD 0%	Total	48/50 (96%)	Mean 96%	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 Her								
Overell Insidence	Tatal	0/50 (0%)	Mana 00/	CD 00/	Total	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%

^{*:} 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

Page: 6

Report Date: 06/03/2022

Route: GAVAGE

Vehicle: CORN OIL

			Male	Female				
#All Organs: Histiocytic Sarcoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic,	Monocytic, Mo					10/50 (20%)		
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	10/50 (20%)	Mean 20%	SD 0%
#All Organs: Malignant Lymphoma: Hi Overall Incidence	stiocytic, Lym Total	phocytic, Mixed, NOS, or 0/50 (0%) 0/50 (0%)	Undifferentiated Ce	II Type SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: 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%
#All Organs: Mesothelioma: Benign, M						1/50 (2%)		
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#All Organs: Mesothelioma: Malignant		4/50 (8%)				1/50 (2%)		
		4/50 (8%)				1/00 (2/0)		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: CORN OIL Page: 7

			Male				Female			
#All Organs: Osteoma										
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: 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										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Adrenal Cortex: 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%		
*Adrenal Cortex: 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%		
*Adrenal Medulla: Ganglioneuroma										
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

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL Page: 8

			Male			Female							
*Adrenal Medulla: Pheochromocytoma Benign 7/50 (14%) 1/50 (2%)													
·	J	7/50 (14%)				1/50 (2%)							
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%					
*Adrenal Medulla: Pheochromocytoma C	Complex	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%					
*Adrenal Medulla: Pheochromocytoma N	/lalignant		•••••										
		0/50 (0%)				1/50 (2%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%					
*Adrenal Medulla: Pheochromocytoma: I	Benign, Complex					2/50 (4%)							
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%					
#Blood Vessel: 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%					
#Bone: Chordoma													
Overall Incidence	Total	0/50 (0%)	Moon 09/	SD 0%	Total	0/50 (0%)	Moon 09/	SD 0%					
Overali incidence	Total	0/50 (0%)	Mean 0%	3D 0%	Total	0/50 (0%)	Mean 0%	2D 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: CORN OIL **Page**: 9

				Male			Female			
#Bone: Osteoma			()							
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma		0.70	(004)							
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma or Osteoma			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Astrocytoma Malignant			(0%)				2/50 (4%)			
Overall Incidence	Total	0/50 (0%)	` ′	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Brain: Glioma Malignant										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Granular Cell Tumor Benign	······	0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(0 /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: CORN OIL **Page:** 10

			Male				Female					
*Brain: Granular Cell Tumor Malignant 0/50 (0%) 0/50 (0%) 0/50 (0%) OVERALL Incidence of the control of the												
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Brain: Medulloblastoma Mal		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%				
*Brain: Meningioma 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: Meningioma: Benign, Mali	gnant, NOS	0/50 (0%	o)			0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Brain: Oligodendroglioma Benigr		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 Malign		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: CORN OIL Page: 11

			Male			Female			
*Brain: Oligodendroglioma, Glion	na, or Astrocy	rtoma							
		0/50 (0%)				2/50 (4%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Brain: 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%	
*Clitoral/Preputial Gland: Adenoma									
		1/49 (2%)				5/50 (10%)			
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%	
*Clitoral/Preputial Gland: Carcinoma		3/49 (6%)				2/50 (4%)			
Overall Incidence	Total	3/49 (6.12%)	Mean 6.12%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Clitoral/Preputial Gland: Carcinoma or Adenoma									
Occupation of days as	T-1-1	4/49 (8%)	M 0.400/	00.00/	T-1-1	7/50 (14%)	M 4 40/	OD 00/	
Overall Incidence	Total	4/49 (8.16%)	Mean 8.16%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%	
*Clitoral/Preputial Gland: Fibrosarcoma		0/49 (0%)				0/50 (0%)			
Overall Incidence	Total	0/49 (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: CORN OIL **Page:** 12

			Male				Female	
*Clitoral/Preputial Gland: Hemangiosarcoma		0/40 (00/)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Sarcoma		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Schwannoma Malignant		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Papilloma Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 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%
#Eye: Amelanotic Melanoma, Ben	ign	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: CORN OIL **Page:** 13 Report Date: 06/03/2022

			Male				Female	
#Eye: Melanoma 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%
#Eye: Melanoma Malignant						0/20 (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%
#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		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 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%
*Heart: 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%

^{*:} 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: CORN OIL Page: 14

			Male				Female				
*Heart: Schwannoma Malignant 0/50 (0%) 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%			
#Intestine Large: Colon/Rect	um:										
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/Rect Carcinoma						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%			
#Intestine Large: Colon/Rect Carcinoma or Adenoma						0/50 (09/)					
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/Rect 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 Large: Colon/Rect Polyp Adenomatous						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%			

^{*:} 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: CORN OIL **Page:** 15

				Male			Female			
#Intestine Small: Jejunum: Carcinoma										
			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Leiomyoma										
			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Sarcoma										
			(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 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%	
#Intestine Small: Site Unspec 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%	
#Intestine Small: Site Unspec Leiomyoma			(00/)				0/50 /00/			
Overall Incidence	Total		(0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan 00/	CD 00/	
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: CORN OIL **Page:** 16

			Male			Female			
#Intestine Small: Site Unspe Sarcoma	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%	
*Islets, Pancreatic: Adenoma				•••••					
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Islets, Pancreatic: Carcinoma		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%	
*Islets, Pancreatic: Carcinoma or Adenoma		4/50 (8%)				1/50 (2%)			
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Kidney: Pelvis and Transition									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Pelvis and Transition Carcinoma or Adenoma						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%	

^{*:} 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: CORN OIL Page: 17

			Male				Female				
*Kidney: Pelvis and Transitional Epithelium: 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%			
*Kidney: Renal Tubule: 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%			
*Kidney: Renal Tubule: Carcinoma		0/50 (004)				4/50 (004)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
*Kidney: Renal Tubule: 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: Renal Tubule: Lipoma	••••										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: 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%			

^{*:} 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: CORN OIL **Page:** 18

			Male				Female		
*Kidney: Renal Tubule: 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%	
*Kidney: Renal Tubule: Stromal Nephroma		0/50 (00/)				0/50 (09/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Liver: Cholangiocarcinoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: 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%	
*Liver: Hepatocellular Adenoma		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%	
*Liver: Hepatocellular Carcinoma		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

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: CORN OIL **Page:** 19

		Male						Female			
*Liver: Hepatocellular Carcinoma or Hepatoblastoma											
•	•	0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
Liver:	was an Hamata call	lulan A dan ama									
Hepatocellular Carcino	ma or Hepatocei	0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(076)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Liver:											
Hepatocellular Carcino	ma, Hepatocellul	lar Adenoma, or	Hepatob	lastoma							
		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 A	denoma	1/50	(20/)				2/50 (60/)				
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%		
*Lung:											
Alveolar/Bronchiolar C	arcinoma										
		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 C	arcinoma or Alve	olar/Bronchiola	ır Adenor	ma							
Aiveolai/Biolicillolai C	archioma of Aive	1/50	(2%)	IIG			3/50 (6%)				
		., 55	_, _,				5,55 (5,5)				

^{*:} 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: CORN OIL Page: 20

		Male				Female			
	` '				0/50 (0%)				
Total	, ,	Mean 0%	SD 0%	Total	, ,	Mean 0%	SD 0%		
	` '				0/50 (0%)				
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
	0/50 (09/)				0/50 (09/)				
Total	` '		SD 0%	Total	` '	Mean 0%	SD 0%		
Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	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 (00/)				0/50 (09/)				
Total	, ,		SD 0%	Total	` '	Mean 0%	SD 0%		
	Total Total	Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) 0/50 (0%)	O/50 (0%) Total O/50 (0%) Mean 0% O/50 (0%) Total O/50 (0%) Mean 0% O/50 (0%) Total O/50 (0%) Mean 0% O/50 (0%) Total O/50 (0%) Mean 0% O/50 (0%) Mean 0% O/50 (0%) Mean 0%	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%	Total 0/50 (0%) Mean 0% SD 0% Total Total 0/50 (0%)	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 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 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 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 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: CORN OIL **Page:** 21

			Male			Female			
#Lymph Node, Mesenteric: 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%	
#Mammary Gland: 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: Carcinoma						0/50 /40/			
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	
#Mammary Gland: Carcinoma or Adenoma		2/50 (4%)				3/50 (6%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
#Mammary Gland: Fibroadenoma									
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	22/50 (44%) 22/50 (44%)	Mean 44%	SD 0%	
#Mammary Gland: Fibroma		0/50 /6513				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%	

^{*:} 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: CORN OIL Page: 22

			Male		Female						
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma 3/50 (6%) Overall Incidence Total 3/50 (6%) Mean 6% SD 0% Total 23/50 (46%) Mean 46% SD 0%											
·····		3/30 (0/0)	······			25/50 (40/0)					
#Mammary Gland: Fibroma, Fibroadenoma	a, Carcinoma, or										
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	24/50 (48%) 24/50 (48%)	Mean 48%	SD 0%			
#Mammary Gland: 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%			
#Mammary Gland: Myoepithelioma		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Mesentery: 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%			
#Mesentery: 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%			

^{*:} 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: CORN OIL **Page:** 23

			Male				Female			
#Mesentery: Lipoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Mesentery: 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%		
#Mesentery: 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%		
#Mesentery: Rhabdomyosarcoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Mesentery: Sarcoma		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%		
*Nose: Adenoma		0/50 (0%)				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%		

^{*:} 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: CORN OIL Page: 24

			Male				Female	
*Nose: Chondroma								
		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: 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%
*Nose: Squamous Cell Carcin	oma	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 Papilloma Squamous o	sa, Tongue, Phary	ynx, Tooth, Gingiva):				4/50 (001)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
Oral Cavity (Oral Mucos						•••••		
04		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		/nx, Tooth, Gingiva): Squamous, or Papilloma				(201)		
Squamous Cell Carcin	,	1/50 (2%)				1/50 (2%)		

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

^{#:} Denominator is number of animals necropsied

Version: 2006 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Page: 25

			Male			Female			
#Oral Mucosa: Squamous Cell Carcinom	a								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Oral Mucosa: Squamous Cell Papilloma	 I			•••••		•••••			
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Ovary: Cystadenoma						(201)			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor Be						0/50 (00/)			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor Ma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor: Be	enign, Maligna	ant, NOS				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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 26

			Male			Female			
*Ovary: Granulosa-Theca Tumor	· Malignant								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Luteoma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Sarcoma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Thecoma Malignant						0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Adenoma									
Overall Incidence	Total	10/50 (20%) 10/50 (20%)	Mean 20%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
Overall incluence	1 Ulai	10/30 (20%)	IVIEdII 20%	JU U%	1 Ulai	1/30 (2%)	IVIEAN 270	0% עכ	
*Pancreas: 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%	

^{*:} 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: CORN OIL Page: 27

			Male			Female			
*Pancreas: Carcinoma or Adenoma									
Overall Incidence	Total	10/50 (20%) 10/50 (20%)	Mean 20%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Pancreas: Fibroma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Mixed Tumor Benign		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%	
*Parathyroid Gland: 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%	
#Peripheral Nerve: 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%	
#Peripheral Nerve: 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

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

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

VAGE

Page: 28

			Male			Female				
#Peripheral Nerve: Schwannoma: Benign, Ma	lignant, 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%		
*Pituitary Gland: Pars Distali Adenoma	is or Unspeci	fied Site:								
		12/50 (24%)				19/50 (38%)				
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	19/50 (38%)	Mean 38%	SD 0%		
*Pituitary Gland: Pars Distali Carcinoma	is or Unspeci									
		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 Distali Carcinoma or Adenoma	is or Unspeci	fied Site:								
		12/50 (24%)				19/50 (38%)				
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	19/50 (38%)	Mean 38%	SD 0%		
*Pituitary Gland: Pars Interm Adenoma	nedia:									
		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Pituitary Gland: Pars Interm 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%		

^{*:} 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

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

> Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Page: 29

			Male			Female			
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:								
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Prostate: Adenoma		2/49 (4%)							
Overall Incidence	Total	2/49 (4.08%)	Mean 4.08%	SD 0%					
*Prostate: Carcinoma or Adenoma									
	.	2/49 (4%)	1 000/	OD 00/					
Overall Incidence	Total	2/49 (4.08%)	Mean 4.08%	SD 0%					
*Salivary Glands: 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%	
*Salivary Glands: 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%	
*Salivary Glands: 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%	

^{*:} 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: CORN OIL **Page:** 30

			Male				Female			
*Salivary Glands: Schwannoma Malignant										
_		1/50 (2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skeletal Muscle: 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%		
#Skeletal Muscle: Hemangioma		0/50 (00()				0/50 (00/)				
	-	0/50 (0%)		OD 00/	-	0/50 (0%)		00.00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skeletal Muscle: 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%		
#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%		
#Skeletal Muscle: Rhabdomyosarcoma										
		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: CORN OIL **Page:** 31

				Male			Female			
#Skeletal Muscle: Rhabdomyosarcoma or	Rhabdomyoma									
-	-	0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skeletal Muscle: 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: Basal Cell Adenoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Basal Cell Adenoma or Overall Incidence		umor Benign	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Basal Cell Adenoma, Ba							0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	(= / - /	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Basal Cell Carcinoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(070)	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 Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 32 Report Date: 06/03/2022

SD 0%

SD 0%

Mean 4%

Mean 0%

Length of Study: CHRON	iiC								
			Male				Female		
	-	s Tumor (malignant or N 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 Carcinoma, NOS), or Trichoepitheli	Basal Cell Adenc	oma, Basosquamous Tur 1/50 (2%)	mor (benign, maligna	ant or		0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Basal or Sq. Cell Carcii Adenoma, Papilloma, S	noma, Carcinoma Sq Papilloma, Ker	a, Basosq. Tumor (M or I ratoacanthoma, Trichoep 5/50 (10%)	3), Basal Cell Adeno ithelioma	ma,		1/50 (2%)			
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Skin: Fibroma		4/50 (8%)				2/50 (4%)			
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myxo	oma, Myxosarcoma, or F 7/50 (14%)	ibrous Histiocytoma			2/50 (4%)			

SD 0%

SD 0%

Mean 14%

Mean 6%

Total

Total

2/50 (4%)

0/50

0/50 (0%)

(0%)

Total

Total

7/50 (14%)

3/50

3/50 (6%)

(6%)

Overall Incidence

Fibrosarcoma

Overall Incidence

#Skin:

^{*:} 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: CORN OIL **Page:** 33

			Male			Female					
#Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 3/50 (6%)											
Overall Incidence	Total	3/50 (6%) 3/50 (6%)) Mean 6%	SD 0%	Total	0/50 (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	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Skin: 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%			
#Skin: Hemangiopericytoma		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: 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%			
#Skin: Keratoacanthoma		2/50 /22/				4/50 (00/)					
Overall Incidence	Total	3/50 (6%) 3/50 (6%)) Mean 6%	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

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: CORN OIL Page: 34

			Male			Female			
#Skin: Lipoma 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: 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: Melanoma 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%	
#Skin: Myxoma 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: Myxosarcoma 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	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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Aboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Route: GAVAGE
Vehicle: CORN OIL

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Report Date: 06/03/2022

Length of Study: CHRONIC

	Male				Female				
#Skin: Neurofibroma or Schwa	annoma 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: Neurofibrosarcoma or \$						0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin:	urofibroma, or S	6chwannoma (benign, ma 0/50 (0%) 0/50 (0%)	alignant or NOS)		Total	0/50 (0%) 0/50 (0%)		SD 0%	
Overall incidence	Total	` '	Mean 0%	SD 0%		(/	Mean 0%		
#Skin: 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%	
#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%	

^{*:} 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 Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

I Animal Groups

Report Date: 06/03/2022

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			Male			Female			
#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%	
#Skin: Squamous 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: Squamous Cell Carcinoma, or Carcinoma	Basal Cell C	Carcinoma, Basosquan	nous Tumor (malignar	nt or NOS),		0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
/Skin: Squamous Cell Papilloma		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: Squamous Cell Papilloma o		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: Squamous Cell Papilloma, I	Papilloma, S		ma or Keratoacanthor			1/50 (2%)			
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (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

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 37

			Male				Female		
#Skin: Squamous Cell Papilloma,	, Papilloma, o	r Keratoacanthoma 4/50 (8%)				1/50 (2%)			
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Skin: Trichoepithelioma		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: 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 Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
						0/30 (0 /6)			
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	M 00/	OD 00/		0/50 (0%)		00.00	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Spleen: Hemangioma		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%	

^{*:} 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: CORN OIL **Page:** 38

				Male				Female	
*Spleen: Hemangiosarcoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Spleen: Leiomyosarcoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(0 %)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: 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%
#Stomach, Forestomach: Lipoma		1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Schwannoma Malignant									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papilloma		(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: CORN OIL **Page:** 39

			Male				Female	
#Stomach, Forestomach: 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%
#Stomach, Glandular: 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%
#Stomach, Glandular: Carcinoma or Adenoma		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%
#Stomach, Glandular: Leiomyosarcoma								
Occupation of James	T-1-1	0/50 (0%)	M 00/	OD 00/	T-1-1	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%
#Stomach, Glandular: 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%
*Testes: Adenoma								
		41/50 (82%)	••	05.00/				
Overall Incidence	Total	41/50 (82%)	Mean 82%	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: CORN OIL **Page:** 40

			Male				Female	
*Thymus: Sarcoma								
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 Benign								
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%)				0/48 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malig		0/50 (0%)				0/48 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma								
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma		4/50 (00)				4/50 (00()		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	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

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: CORN OIL Page: 41

			Male				Female		
*Thyroid Gland: C-Cell: Carcinoma or Adenoma	Total	5/50 (10%)	Maan 100/	SD 00/	Total	13/50 (26%)	Magn 269/	CD 00/	
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	13/50 (26%)	Mean 26%	SD 0%	
*Thyroid Gland: Follicular Cell: Adenoma		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%	
*Thyroid Gland: Follicular Cell: Carcinoma						4/50 (00/)			
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: Follicular Cell: Carcinoma or 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%	
#Tissue NOS: 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%	
·····			IVICALI U/0	JD 0/0	1 Otal		IVIGAII U/0		
#Tissue NOS: Leiomyoma		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: CORN OIL Page: 42

			Male				Female	
#Tissue NOS: Paraganglioma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: 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%
#Tissue NOS: Schwannoma Malignant		0/50 (0%)				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%
		, ,						
#Tongue: Liposarcoma		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%
		` '				` '		
#Tongue: Squamous 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%
#Tongue: Squamous Cell Carcinoma	or 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

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: CORN OIL Page: 43

				Male				Female	
#Tongue: Squamous Cell Papilloma		,							
Overell Insidence	Tatal		(0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Maan 00/	CD 00/
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tooth: Odontogenic Tumor		0/50	(00()				4/50 (00()		
Overall Incidence	Total		(0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
Overall incidence	Total	0/50 (0%)					1/50 (2%)		
*Urinary Bladder: Carcinoma		0/50	(00)				2(72)		
O	T-1-1		(0%)	M 00/	OD 00/	T-1-1	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%
*Urinary Bladder: Carcinoma or Papilloma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma		- /							
			(0%)		05 00/		0/50 (0%)	••	25. 22/
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Papilloma									
			(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 Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
*Urinary Bladder: 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%
#Uterus: Adenoma		•••••						
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Uterus: Hemangioma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma		•••••	•••••					
Loidinyodarooma						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
*· Denominator is number of a								

^{*:} 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: CORN OIL **Page:** 45

	Male			Female	
#Uterus: Polyp Stromal					
Overall Incidence		Total	14/50 (28%) 14/50 (28%)	Mean 28%	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	14/50 (28%) 14/50 (28%)	Mean 28%	SD 0%
#Uterus: Schwannoma Malignant		•••••			
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Leiomyoma					
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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

> Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

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			Male				Female	
#Vagina: Leiomyosarcoma								
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%
#Vagina: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: 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%
#Zymbal's 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%
#Zymbal's Gland: Carcinoma or Adenoma								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

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		
Southern Research Institute	059100507	06/26/00	730	50(3)	30(693)	520.6	Methylene blue trihydrate
					Female		
Southern Research Institute	059100507	06/26/00	733	50(5)	35(699)	335.9	Methylene blue trihydrate

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: METHYLCELLULOSE

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			Male				Female	
#All Organs: Benign Tumors								
•		47/50 (94%)				47/50 (94%)		
Overall Incidence	Total	47/50 (94%)	Mean 94%	SD 0%	Total	47/50 (94%)	Mean 94%	SD 0%
#All Organs: Malignant Tumors								
		30/50 (60%)				19/50 (38%)		
Overall Incidence	Total	30/50 (60%)	Mean 60%	SD 0%	Total	19/50 (38%)	Mean 38%	SD 0%
#All Organs: Malignant and Benign To	umors							
		49/50 (98%)				50/50 (100%)		
Overall Incidence	Total	49/50 (98%)	Mean 98%	SD 0%	Total	50/50 (100%)	Mean 100%	SD 0%
#All Organs: Hemangioma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
		1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#All Organs: Hemangiosarcoma or He	emangioma							
		2/50 (4%)				1/50 (2%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	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: METHYLCELLULOSE

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			Male			Female			
#All Organs: Histiocytic Sarcoma									
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#All Organs:									
Leukemia: Lymphocytic, I	Monocytic, Mo	•	ntiated						
		23/50 (46%)				12/50 (24%)			
Overall Incidence	Total	23/50 (46%)	Mean 46%	SD 0%	Total	12/50 (24%)	Mean 24%	SD 0%	
#All Organs:									
Malignant Lymphoma: His	stiocytic, Lym	phocytic, Mixed, NOS, o	r Undifferentiated Ce	ell Type					
		0/50 (0%)				0/50 (0%)			
	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Overall Incidence #All Organs: Mesothelioma: Benign								SD 0%	
#All Organs: Mesothelioma: Benign		, ,				0/50 (0%)		SD 0%	
#All Organs: Mesothelioma: Benign								SD 0%	
#All Organs: Mesothelioma: Benign Overall Incidence		0/50 (0%)				0/50 (0%)			
#All Organs: Mesothelioma: Benign Overall Incidence	Total	0/50 (0%) 0/50 (0%)				0/50 (0%)			
#All Organs: Mesothelioma: Benign Overall Incidence #All Organs:	Total	0/50 (0%) 0/50 (0%)				0/50 (0%)			
#All Organs: Mesothelioma: Benign Overall Incidence #All Organs: Mesothelioma: Benign, Ma	Total	0/50 (0%) 0/50 (0%)				0/50 (0%) 0/50 (0%)			
#All Organs: Mesothelioma: Benign Overall Incidence #All Organs: Mesothelioma: Benign, Ma	Total alignant, NOS	0/50 (0%) 0/50 (0%) 3/50 (6%)	Mean 0%	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: Benign, Material Incidence #All Organs:	Total alignant, NOS	0/50 (0%) 0/50 (0%) 3/50 (6%)	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

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: METHYLCELLULOSE

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			Ma	ale			Female			
#All Organs: Osteoma										
		0/50 (0%	6)			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%		Total	0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Osteosarcoma										
		0/50 (0%	6)			1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#All Organs: Osteosarcoma or Osteoma		0/50 (0%	()			1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	% Mean 0	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
······		, ,				, ,				
*Adrenal Cortex: Adenoma										
		1/50 (2%	•			1/50 (2%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%		Total	1/50 (2%)	Mean 2%	SD 0%		
*Adrenal Cortex: Carcinoma										
		0/50 (0%	6)			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Ganglioneuroma										
		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: METHYLCELLULOSE

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			Male			Female			
*Adrenal Medulla: Pheochromocytoma Benign 9/50 (18%) Overall Incidence Total 9/50 (18%) Mean 18% SD 0% Total 2/50 (4%) Mean 4% SD 0%									
*Adrenal Medulla: Pheochromocytoma Cor	mplex	4/50 (004)				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%	
*Adrenal Medulla: Pheochromocytoma Mal	lignant	1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma: Be Overall Incidence	nign, Complex	, Malignant, NOS 11/50 (22%) 11/50 (22%)	Mean 22%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	
#Blood Vessel: 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%	
#Bone: Chordoma		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: METHYLCELLULOSE

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				Male			Female			
#Bone: Osteoma										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma		0/-0	(004)				(00)			
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Bone: Osteosarcoma or Osteoma			(0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Brain: Astrocytoma Malignant			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	` ′	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Glioma Malignant										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Granular Cell Tumor Benign		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(070)	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: METHYLCELLULOSE

Page: 53

			Male				Female			
*Brain: Granular Cell Tumor Ma	alignant									
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: Medulloblastoma Mal										
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: Meningioma 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: Meningioma: Benign, M	lalignant, 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%		
*Brain: Oligodendroglioma Ber	nign	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%		
*Brain: Oligodendroglioma Mal	ignant	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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Vehicle: METHYLCELLULOSE

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

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			Male			Female			
*Brain: Oligodendroglioma, Glioma	a, 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: 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%	
*Clitoral/Preputial Gland: Adenoma		1/50 (2%)				7/50 (14%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%	
Clitoral/Preputial Gland: Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
Clitoral/Preputial Gland:			Wear 070						
Carcinoma or Adenoma Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%	
*Clitoral/Preputial Gland: 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%	

^{*:} 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: METHYLCELLULOSE

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			Male			Female			
	,	,		05 00/		0/50 (0%)	• • • • • • • • • • • • • • • • • • • •	05.00/	
lotai	` '		ean 0%	SD 0%	l otal	0/50 (0%)	Mean 0%	SD 0%	
	,	,		00.00/		` '		05 00/	
Total	0/50 (0%)	M:	ean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	0/50 ((0%)				0/50 (0%)			
Total	0/50 (0%)	,	ean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	0/50 ((0%)				0/50 (0%)			
Total	0/50 (0%)	,	ean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	0/50 (0%)				0/50 (0%)			
Total	0/50 (0%)	M	ean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
ign	0/50 //	00()				0/50 (09/)			
Total	,	,	aan 0%	SD 0%	Total	, ,	Moan 0%	SD 0%	
	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%) O/50 (0%) O/50 (0%)	Total 0/50 (0%) Me 0/50 (0%) Total 0/50 (0%) Me 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Me 0/50 (0%) Total 0/50 (0%) Me 0/50 (0%) Me 0/50 (0%)	0/50 (0%) Total 0/50 (0%) Mean 0% ign 0/50 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%	Total 0/50 (0%) Mean 0% SD 0% Total Total 0/50 (0%)	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 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 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 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 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 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female			
#Eye: Melanoma 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%		
#Eye: Melanoma 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%		
#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										
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 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%		
*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%		

^{*:} 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: METHYLCELLULOSE

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			Male			Female			
*Heart: 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%	
					·····				
#Intestine Large: Colon/Rectu Adenoma	ım:								
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/Rectu Carcinoma	ım:	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 Large: Colon/Rectu 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%	
#Intestine Large: Colon/Rectu 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%	
		` '			TOLAI	0/30 (0 /8)			
#Intestine Large: Colon/Rectu Polyp Adenomatous	ım:								
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

Toxicology Data Management System

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Report Date: 06/03/2022

SD 0%

Mean 0%

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Intestine Small: Jejunum: Carcinoma Overall Incidence Intestine Small: Jejunum: Leiomyoma	Total Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyoma		0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyoma		0/50 (0%)	iviean 076	JD 0/8	Total		iviean 076	
Leiomyoma	Total	` '						
	Total	` '						
	Total	0/50 /00/)				0/50 (0%)		
verall Incidence		0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Sarcoma								
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
ntestine Small: Site Unspec Carcinoma								
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
ntestine Small: Site Unspec Carcinoma or Adenoma	ified:							
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
ntestine Small: Site Unspec Leiomyoma	ified:							
		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

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: METHYLCELLULOSE

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			Male				Female				
#Intestine Small: Site Unspecified: Sarcoma 0/50 (0%)											
		0/50 (0%)		05.00		0/50 (0%)		05.00/			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Islets, Pancreatic: Adenoma											
Overell Insidence	Tatal	4/50 (8%)	Maan 00/	CD 00/	Tatal	2/49 (4%)	Mana 4.000/	CD 00/			
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	2/49 (4.08%)	Mean 4.08%	SD 0%			
*Islets, Pancreatic: Carcinoma											
		0/50 (0%)				0/49 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			
*Islets, Pancreatic: Carcinoma or Adenoma		4/50 (8%)				2/49 (4%)					
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	2/49 (4.08%)	Mean 4.08%	SD 0%			
*Kidney: Pelvis and Transitio	onal Epitheliu	m:				•••••					
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Pelvis and Transition 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: METHYLCELLULOSE

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				Male				Female	
*Kidney: Pelvis and Transition Papilloma	onal Epitheliu	m:					,		
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) Mea	n 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma		0.7-0					(00)		
Overall Incidence	Total	0/50 (0%)		n 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma									
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) Mea	ın 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma)%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	,	ın 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma									
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) Mea	ın 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma									
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) Mea	ın 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: METHYLCELLULOSE

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			Male			Female		
*Kidney: Renal Tubule: 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%
*Kidney: Renal Tubule: Stromal Nephroma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Cholangiocarcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma		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 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%
*Liver: Hepatocellular 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%

^{*:} 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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Report Date: 06/03/2022

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Mean 0%

SD 0%

Male **Female** *Liver: Hepatocellular Carcinoma or Hepatoblastoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma (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, Hepatocellular Adenoma, or Hepatoblastoma 1/50 (2%)0/50 (0%)Overall Incidence Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Lung: Alveolar/Bronchiolar Adenoma 1/50 (2%)0/50 (0%)

Alveolar/Bronchiolar Carcinoma

0/50 (0%) 0/50 (0%)

SD 0%

Total

0/50 (0%)

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

Mean 2%

*Lung:

*Luna:

Overall Incidence

Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma

Total

1/50 (2%)

1/50 (2%) 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

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: METHYLCELLULOSE

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			Male				Female	
*Lung: Carcinoma		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%
*Lung: 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%
*Lung: Squamous 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%
#Lymph Node, Mesenteric: 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%
#Lymph Node, Mesenteric: 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%
#Lymph Node, Mesenteric: 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%

^{*:} 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: METHYLCELLULOSE

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			Male				Female	
#Lymph Node, Mesenteric: 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%
#Mammary 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%
#Mammary 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%
#Mammary Gland: Carcinoma or Adenoma		0/50 (00/)				0/50 (400)		
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%)				28/50 (56%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	28/50 (56%)	Mean 56%	SD 0%
#Mammary Gland: Fibroma		0/50 (004)				0/50 (00)		
Overell Institutes	Tatal	0/50 (0%)	Mana 00/	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%

^{*:} 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: METHYLCELLULOSE

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		Male						Female				
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma												
Overall Incidence	Total	2/50 (- 2/50 (4%)	4%)	Mean 4%	SD 0%	Total	29/50 (58%) 29/50 (58%)	Mean 58%	SD 0%			
#Mammary Gland:												
Fibroma, Fibroadenom	a, Carcinoma, or											
Overall Incidence	Total	2/50 (4%)	4%)	Mean 4%	SD 0%	Total	30/50 (60%) 30/50 (60%)	Mean 60%	SD 0%			
#Mammary Gland: Hemangioma		0/50 /	00()				0/50 (00)					
Overall Incidence	Total	0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Mammary Gland: Myoepithelioma			0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Mesentery: Fibrosarcoma												
Overall Incidence	Total	0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Mesentery: Hemangiosarcoma		4/50 //	20/)				0/50 (00/)					
Overall Incidence	Total	1/50 (2%)	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

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: METHYLCELLULOSE

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			Male				Female	
#Mesentery: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Liposarcoma		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%
#Mesentery: Osteosarcoma		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%
#Mesentery: Rhabdomyosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: 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%
*Nose: Adenoma		0/50 (09/)				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%

^{*:} 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: 67 Report Date: 06/03/2022

Species: RATS Strain: F 344/N

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Nose: Chondroma		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: 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%
*Nose: Squamous Cell Carcin	oma	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 Papilloma Squamous o	sa, Tongue, Phary					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 Squamous Cell Carcin	sa, Tongue, Phary	/nx, Tooth, Gingiva):						
		1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Oral Cavity (Oral Mucos	sa, Tongue, Phary					1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Version: 2006 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male					
#Oral Mucosa: Squamous Cell Carcino	oma							
•		1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Oral Mucosa: Squamous Cell Papillo	ma							
	-	0/50 (0%)		OD 00/	T	0/50 (0%)		OD 00/
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: Granulosa Cell Tumor	Benign							
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor	Malignant			•••••				
	J					0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor:								
						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Version: 2006 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Ovary: Granulosa-Theca Tumo	r Malignant							
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Sarcoma				•••••				
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Thecoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas:								
Additiona		0/50 (0%)				1/49 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/49 (2.04%)	Mean 2.04%	SD 0%
*Pancreas: Carcinoma								
		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (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: METHYLCELLULOSE

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			Male	Female				
*Pancreas: Carcinoma or Adenoma								
		0/50 (0%)				1/49 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/49 (2.04%)	Mean 2.04%	SD 0%
*Pancreas: Fibroma								
		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Pancreas: Mixed Tumor Benign		1/50 (2%)				0/49 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma		0/50 (0%)				0/47 (0%)		OD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: 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%
#Peripheral Nerve: Schwannoma Malignant		1/50 (2%)				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

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: METHYLCELLULOSE

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			Male				Female					
#Peripheral Nerve: Schwannoma: Benign, Malignant, NOS												
_		1/50 (2%)				0/50 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Distali Adenoma												
		25/50 (50%)				36/50 (72%)						
Overall Incidence	Total	25/50 (50%)	Mean 50%	SD 0%	Total	36/50 (72%)	Mean 72%	SD 0%				
*Pituitary Gland: Pars Distali 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 Distali Carcinoma or Adenoma												
		25/50 (50%)				36/50 (72%)						
Overall Incidence	Total	25/50 (50%)	Mean 50%	SD 0%	Total	36/50 (72%)	Mean 72%	SD 0%				
*Pituitary Gland: Pars Interm Adenoma	edia:											
		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 Interm Carcinoma	edia:											
		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 Tumor Incidence for Selected Control Animal Groups

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Length of Study: CHRONIC

Route: GAVAGE Vehicle: METHYLCELLULOSE **Page:** 72

			Male				Female					
*Pituitary Gland: Pars Intermedia: 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%				
*Prostate: Adenoma		1/50 (2%)										
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%								
*Prostate: Carcinoma or Adenoma												
		1/50 (2%)										
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%								
*Salivary Glands: 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%				
*Salivary Glands: 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%				
*Salivary Glands: 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%				

^{*:} 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: METHYLCELLULOSE

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			Male				Female	
*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%
#Skeletal Muscle: 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%
#Skeletal Muscle: Hemangioma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: 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%
#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%
#Skeletal Muscle: Rhabdomyosarcoma		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: METHYLCELLULOSE

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				Male				Female				
#Skeletal Muscle: Rhabdomyosarcoma or Rhabdomyoma												
-			(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skeletal Muscle: Sarcoma												
			(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		0/50	(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Basal Cell Adenoma or		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%			
#Skin: Basal Cell Adenoma, Ba		mor Benign, or					1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	(0,0)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
#Skin: Basal Cell Carcinoma		0/50	(0%)				1/50 (2%)					
Overall Incidence	Total	0/50	(U /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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

#Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0% #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%) Mean 0% SD 0% Total 2/50 (4%) Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 2/50 (4%) Mean 4% SD 0% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 7/50 (14%) Mean 14% SD 0% Total 3/50 (6%) Mean 6% SD 0% #Skin: Fibroma 6/50 (12%) Mean 12% SD 0% Total 1/50 (2%) Mean 2% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 8/50 (16%) Mean 16% SD 0% Total 2/50 (4%) Mean 4% SD 0% Overall Incidence Total 8/50 (16%) Mean 16% SD 0% Total 2/50 (4%) Mean 4% SD 0% Overall Incidence Total 8/50 (16%) Mean 16% SD 0% Total 2/50 (4%) Mean 4% SD 0% Overall Incidence Total 8/50 (16%) Mean 16% SD 0% Total 2/50 (4%) Mean 4% SD 0%	
Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0% Mean 1/50 (2%) Mean 2% SD 0% Mean 2% S	
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma	1
Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 2/50 (4%) Mean 4% SD 0% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Keratoacanthoma, Trichoepithelioma 3/50 (6%) Mean 6% SD 0% Overall Incidence Total 7/50 (14%) Mean 14% SD 0% Total 3/50 (6%) Mean 6% SD 0% #Skin: Fibroma 6/50 (12%) Mean 12% SD 0% Total 1/50 (2%) Mean 2% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 8/50 (16%) 2/50 (4%) 2/50 (4%)	
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 7/50 (14%) Overall Incidence Total 7/50 (14%) #Skin: Fibroma 6/50 (12%) Overall Incidence Total 6/50 (12%) Mean 12% SD 0% Total 1/50 (2%) Mean 2% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 8/50 (16%) #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 8/50 (16%)	
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 7/50 (14%) Overall Incidence Total 7/50 (14%) #Skin: Fibroma 6/50 (12%) Overall Incidence Total 6/50 (12%) Mean 12% SD 0% Total 1/50 (2%) Mean 2% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 8/50 (16%) #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 8/50 (16%) #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma	1
#Skin: Fibroma 6/50 (12%) Overall Incidence Total 6/50 (12%) Mean 12% SD 0% Total 1/50 (2%) Mean 2% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 8/50 (16%) 2/50 (4%)	
#Skin: Fibroma 6/50 (12%) Overall Incidence Total 6/50 (12%) Mean 12% SD 0% Total 1/50 (2%) Mean 2% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 8/50 (16%) 2/50 (4%)	ı
Overall Incidence Total 6/50 (12%) Mean 12% SD 0% Total 1/50 (2%) Mean 2% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 8/50 (16%) 2/50 (4%)	
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 8/50 (16%) 2/50 (4%)	ı
10tal 0/30 (10/0) Wealt 10/0 3D 0/0 10tal 2/30 (4/0) Wealt 4/0 3D 0/0	,
#Skin: Fibrosarcoma 3/50 (6%) 1/50 (2%)	
Overall Incidence Total 3/50 (6%) Mean 6% SD 0% Total 1/50 (2%) Mean 2% SD 0%	1

^{*:} 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: METHYLCELLULOSE

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				Male				Female				
#Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 3/50 (6%) 1/50 (2%)												
Overall Incidence	Total	3/50 (6%)	Mea	an 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
#Skin: Fibrous Histiocytoma		0/50 ((00/)				0/50 /00/					
Overall Incidence	Total	0/50 (0%)	(0%) Mea	an 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Skin: Hemangioma		0/50 ((0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mea	an 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Hemangiopericytoma			(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mea	an 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Hemangiosarcoma												
Overall Incidence	Total	0/50 (0/50 (0%)	(0%) Mea	an 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
#Skin: Keratoacanthoma		3/50 ((6%)				0/50 (0%)					
Overall Incidence	Total	3/50 (6%)	` '	an 6%	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: METHYLCELLULOSE

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			Male		Female			
#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		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: 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%
#Skin: Myxoma		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: Myxosarcoma								
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		1/50 (2%)				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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Skin: Neurofibroma or Schwa	annoma 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: Neurofibrosarcoma or	Schwannoma (m	•						
		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, Ne	eurofibroma, or S	Schwannoma (benign, ma 0/50 (0%)	alignant or NOS)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: 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%
#Skin: Sarcoma		0/50 (00/)						
O	T-1-1	0/50 (0%)	M 00/	OD 00/	T-1-1	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%
#Skin: Schwannoma Benign		0/50 (0%)				0/50 (0%)		
		3,33 (370)				0,00 (0,0)		

^{*:} 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: METHYLCELLULOSE

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			Male				Female	
#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%
#Skin: Squamous 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: Squamous Cell Carcinoma, or Carcinoma		Carcinoma, Basosquam				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Squamous Cell Papilloma Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
Overall incluence		4/30 (6%)			10tai		iviean 270	30 0%
#Skin: Squamous Cell Papilloma o	r Papilloma	4/50 (8%)				1/50 (2%)		
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Squamous Cell Papilloma, F	Papilloma, S	quamous Cell Carcinor 7/50 (14%)	na or Keratoacanthor	ma		1/50 (2%)		
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	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

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Report Date: 06/03/2022

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

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Female	Male	Male										
#Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma												
0 (2%)		7/50 (14%)										
(2%) Mean 2% SD 0%	Mean 14% SD 0% Tota	verall Incidence Total 7/50 (14%) Mean 14%										
0 (0%)		Skin: Trichoepithelioma										
0 (2%) 0 (2%)	Mean 0% SD 0% Total											
		Skin: Sebaceous Gland: Adenoma										
0 (0%)		0/50 (0%)										
0 (0%) Mean 0% SD 0%	Mean 0% SD 0% Tota	,										
		Skin: Sebaceous Gland: Carcinoma										
0 (0%) 0 (0%)	Mean 0% SD 0% Tota	(-,-)										
		Skin: Sebaceous Gland: Carcinoma or Adenoma										
0 (0%)	Mana 00/	0/50 (0%)										
0 (0%) Mean 0% SD 0%	iviean u% SD U% Tota	verail incidence 10tal 0/50 (0%) Mean 0%										
9 (0%)		Spleen: Hemangioma										
` '	Mean 0% SD 0% Tota	,										
9 (0%) Mean 0% SI	Mean 0% SD 0% Tota Mean 0% SD 0% Tota	Spleen: Hemangioma O/50 (0%) Mean 0% Mean 0% O/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: METHYLCELLULOSE

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			Male	Female				
*Spleen: Hemangiosarcoma								
	T-1-1	1/50 (2%	<i>'</i>	00, 00/	Tatal	0/49 (0%)	Maran 00/	OD 00/
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Spleen: Leiomyosarcoma								
		0/50 (0%	<i>'</i>			0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: 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%
#Stomach, Forestomach: Lipoma		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%
#Stomach, Forestomach: 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%
#Stomach, Forestomach: Squamous Cell Carcinom	a or Papilloma		```			1/50 (2%)		
Overall Incidence	Total	0/50 (0% 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (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

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: GAVAGE

Vehicle: METHYLCELLULOSE

			Male		Female			
#Stomach, Forestomach: Squamous Cell Papilloma		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						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%
#Stomach, Glandular: Carcinoma or Adenoma	T-1-1	0/50 (0%)	Mars 200	OD 004	T-1-1	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%
#Stomach, Glandular: 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%
#Stomach, Glandular: 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%
*Testes: Adenoma		41/50 (82%)						
Overall Incidence	Total	41/50 (82%)	Mean 82%	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: METHYLCELLULOSE

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			Male				Female	
*Thymus: Sarcoma								
		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign								
		0/49 (0%)				1/50 (2%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Thymus: Thymoma Malignant		0/40 (00/)				0/50 (00/)		
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		, ,						
*Thymus: Thymoma: Benign, Malign	ant, NOS	0/49 (0%)				1/50 (2%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Thyroid Gland: C-Cell: Adenoma								
		6/50 (12%)				7/50 (14%)		
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
Occupation of the second	T-1-1	2/50 (4%)	Maria 40/	00 00/	T-1-1	0/50 (0%)	M 00/	OD 00/
Overall Incidence	Total	2/50 (4%)	Mean 4%	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: METHYLCELLULOSE

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			Male				Female	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		8/50 (16%)				7/50 (14%)		
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%
*Thyroid Gland: Follicular Cell: 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%
*Thyroid Gland: Follicular Cell: 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%
*Thyroid Gland: Follicular Cell: 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%
#Tissue NOS: Fibrosarcoma		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%
#Tissue NOS: 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%

^{*:} 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: METHYLCELLULOSE

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			Male				Female	
#Tissue NOS: Paraganglioma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: 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%
#Tissue NOS: 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%
#Tongue: 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%
#Tongue: Squamous 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%
#Tongue: Squamous Cell Carcinoma	or Papilloma	a Squamous 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: METHYLCELLULOSE

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			Male				Female	
#Tongue: 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%
#Tooth: Odontogenic 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%
*Urinary Bladder: 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%
*Urinary Bladder: Carcinoma or 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%
*Urinary Bladder: Leiomyosarcoma		0/50 (0%)				0/50 (09/)		
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		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%

^{*:} 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

Contract/Lab: All Laboratories Tumor Incidence for Selection

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Urinary Bladder: 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%
#Uterus: Adenoma								
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: Hemangioma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma								
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

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: METHYLCELLULOSE

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	Male			Female	
#Uterus: Polyp Stromal					
Overall Incidence		Total	13/50 (26%) 13/50 (26%)	Mean 26%	SD 0%
#Uterus: Sarcoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal					
Overall Incidence		Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					
Overall Incidence		Total	15/50 (30%) 15/50 (30%)	Mean 30%	SD 0%
#Uterus: Schwannoma Malignant					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Leiomyoma					
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

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Report Date: 06/03/2022

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

			Male				Female	
#Vagina: Leiomyosarcoma								
,						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Vagina: Polyp								
						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Vagina: Sarcoma								
						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Zymbal's 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%
#Zymbal's Gland: 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%
#Zymbal's 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%

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

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

2006

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 90

Report Date: 06/03/2022

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	058812206	06/25/97	727	50(3)	26(667)	483.6	Elmiron (sodium pentosanpolysulfate)
Battelle Columbus Laboratory	058812305	03/21/01	727	50(3)	26(673)	509.7	Formamide
Battelle Columbus Laboratory	058805005	10/30/95	729	50(3)	25(665)	488.4	Methacrylonitrile
Southern Research Institute	050516105	03/06/96	N/A	0(0)	0(0)	N/A	Riddelliine
					Female		
Battelle Columbus Laboratory	058812206	06/26/97	728	50(5)	30(672)	327.2	Elmiron (sodium pentosanpolysulfate)
Battelle Columbus Laboratory	058812305	03/20/01	730	50(5)	38(703)	358.3	Formamide
Battelle Columbus Laboratory	058805005	10/31/95	731	50(5)	38(710)	315.4	Methacrylonitrile
Southern Research Institute	050516105	03/06/96	729	50(5)	33(683)	322.1	Riddelliine

Strain: F 344/N

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 91

			Male				Female	
#All Organs: Benign Tumors								
		49/50 (98%)	45/50 (90%)	47/50 (94%)		37/50 (74%) 45/50 (90%)	43/50 (86%)	35/50 (70%)
Overall Incidence	Total	141/150 (94%)	Mean 94%	SD 4%	Total	160/200 (80%)	Mean 80%	SD 9.52%
#All Organs: Malignant Tumors								
		29/50 (58%)	25/50 (50%)	29/50 (58%)		12/50 (24%) 20/50 (40%)	15/50 (30%)	26/50 (52%)
Overall Incidence	Total	83/150 (55.33%)	Mean 55.33%	SD 4.62%	Total	73/200 (36.5%)	Mean 36.5%	SD 12.26%
#All Organs: Malignant and Benign T	umors	49/50 (98%)	48/50 (96%)	49/50 (98%)		42/50 (84%)	49/50 (98%)	45/50 (90%)
Overall Incidence	Total	146/150 (97.33%)	Mean 97.33%	SD 1.15%	Total	47/50 (94%) 183/200 (91.5%)	Mean 91.5%	SD 5.97%
#All Organs: Hemangioma	•••••							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} 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: 92

			Male				Female	
#All Organs: Hemangiosarcoma or Hen	nangioma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#All Organs: Histiocytic Sarcoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
#All Organs:								
Leukemia: Lymphocytic, N	Monocytic, N Total	fononuclear, or Undiffere 15/50 (30%) 50/150 (33.33%)	ntiated 15/50 (30%) Mean 33.33%	20/50 (40%) SD 5.77%	Total	7/50 (14%) 12/50 (24%) 50/200 (25%)	10/50 (20%) Mean 25%	21/50 (42%) SD 12.06%
•	Total	15/50 (30%) 50/150 (33.33%)	15/50 (30%) Mean 33.33%	SD 5.77%	Total	12/50 (24%) 50/200 (25%) 0/50 (0%)	,	,
Leukemia: Lymphocytic, N Overall Incidence #All Organs: Malignant Lymphoma: His	Total	15/50 (30%) 50/150 (33.33%) mphocytic, Mixed, NOS, o	15/50 (30%) Mean 33.33% r Undifferentiated Cel	SD 5.77%	Total Total	12/50 (24%) 50/200 (25%)	Mean 25%	SD 12.06%
Leukemia: Lymphocytic, Noverall Incidence #All Organs: Malignant Lymphoma: His	Total stiocytic, Lyr	15/50 (30%) 50/150 (33.33%) mphocytic, Mixed, NOS, o 0/50 (0%) 0/150 (0%)	15/50 (30%) Mean 33.33% T Undifferentiated Cel	SD 5.77% I Type 0/50 (0%) SD 0%		12/50 (24%) 50/200 (25%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	Mean 25% 0/50 (0%) Mean 0%	SD 12.06% 0/50 (0%) SD 0%
Leukemia: Lymphocytic, Noverall Incidence #All Organs: Malignant Lymphoma: His	Total stiocytic, Lyr	15/50 (30%) 50/150 (33.33%) mphocytic, Mixed, NOS, o 0/50 (0%)	15/50 (30%) Mean 33.33% r Undifferentiated Cel	SD 5.77% I Type 0/50 (0%)		12/50 (24%) 50/200 (25%) 0/50 (0%) 0/50 (0%)	Mean 25% 0/50 (0%)	SD 12.06% 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: 93

			Male				Female	
#All Organs: Mesothelioma: Benign, Mal	ignant, NOS							
		2/50 (4%)	2/50 (4%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	2/200 (1%)	Mean 1%	SD 2%
#All Organs: Mesothelioma: Malignant								
		2/50 (4%)	2/50 (4%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	2/200 (1%)	Mean 1%	SD 2%
¢All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma or Osteoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (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: 94

			Male				Female	
*Adrenal Cortex: Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
*Adrenal Cortex: Carcinoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Ganglioneuroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benign								
		7/50 (14%)	9/50 (18%)	3/50 (6%)		2/50 (4%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	19/150 (12.67%)	Mean 12.67%	SD 6.11%	Total	4/200 (2%)	Mean 2%	SD 1.63%
*Adrenal Medulla: Pheochromocytoma Comple	ex							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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:** 95

			Male				Female	
Adrenal Medulla: Pheochromocytoma M	lalignant							
		1/50 (2%)	0/50 (0%)	1/50 (2%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Adrenal Medulla: Pheochromocytoma: E								
		7/50 (14%)	9/50 (18%)	4/50 (8%)		3/50 (6%) 2/50 (4%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	20/150 (13.33%)	Mean 13.33%	SD 5.03%	Total	6/200 (3%)	Mean 3%	SD 2.58%
#Blood Vessel: Osteosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Bone: Chordoma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
Bone: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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:** 96

			Male				Female	
#Bone: Osteosarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Astrocytoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Glioma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Benign								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} 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

			Male	Female
*Brain: Granular Cell Tumor Ma	llignant			
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
*Brain: Medulloblastoma Mal				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
*Brain: Meningioma Malignant				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
*Brain: Meningioma: Benign, M	alignant, NOS			
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
*Brain: Oligodendroglioma Ben				
-		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 1/200 (0.5%) Mean 0.5% SD 1%

^{*:} 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 n age. 50

			Male				Female	
Brain: Oligodendroglioma Maliç	gnant							
	_	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma, Glio	ma, or Astroc							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Brain: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma								
		1/50 (2%)	1/50 (2%)	2/50 (4%)		3/50 (6%) 7/49 (14%)	2/50 (4%)	2/49 (4%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%	Total	14/198 (7.07%)	Mean 7.09%	SD 4.88%
Clitoral/Preputial Gland: Carcinoma								
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 3/49 (6%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	4/198 (2.02%)	Mean 2.04%	SD 2.89%

^{*:} 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	
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		2/50 (4%)	2/50 (4%)	3/50 (6%)		3/50 (6%) 10/49 (20%)	2/50 (4%)	3/49 (6%)
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 1.15%	Total	18/198 (9.09%)	Mean 9.13%	SD 7.58%
*Clitoral/Preputial Gland: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
*Clitoral/Preputial Gland: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Schwannoma Malignant								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/198 (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:** 100

			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
#Ear: Neural Crest Tumor								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Eye: Amelanotic Melanoma, Be								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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: 101

			Male			Female	
#Harderian Gland: Adenoma							
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 09	% To	tal 0/200 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma							
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 09		()	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma							
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 09	% To	tal 0/200 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Benign							
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 09		()	Mean 0%	SD 0%
Heart: Schwannoma Malignant							
•		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 09	% To	tal 0/200 (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: 102

			Male				Female	
#Intestine Large: Colon/R Adenoma	lectum:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/R Carcinoma	lectum:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/R Carcinoma or Adenoma	lectum:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/R Leiomyosarcoma	lectum:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/R Polyp Adenomatous	lectum:							
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} 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: 103

			Male				Female	
#Intestine Small: Jejunum: Carcinoma	:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Sarcoma	:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
fintestine Small: Site Unsp Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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: 104

			Male				Female	
#Intestine Small: Site Unspec	cified:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		1/50 (2%)	2/50 (4%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
*Islets, Pancreatic: Carcinoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
lslets, Pancreatic: Carcinoma or Adenoma								
		1/50 (2%)	3/50 (6%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%

^{*:} 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: 105

			Male				Female	
*Kidney: Pelvis and Trans Carcinoma	sitional Epitheli	um:						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Trans Carcinoma or Adenoma	sitional Epitheli	um:						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Pelvis and Trans Papilloma			0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/30 (0/0)	0/30 (0/0)	0/30 (0/0)		0/50 (0%)	0/00 (0/0)	0/00 (0/0)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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: 106

			Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Stromal Nephroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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: 107

			Male				Female	
*Liver: Cholangiocarcinoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	4/200 (2%)	Mean 2%	SD 1.63%
*Liver: Hepatocellular Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Liver: Hepatocellular Carcinoma o	r Hepatobl	astoma						
-	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} 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: 108

Report Date: 06/03/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

		Male			Female			
*Liver: Hepatocellular Carcino	oma or Hepatoce	ellular Adenoma						
·	·	0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%) 1/50 (2%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	5/200 (2.5%)	Mean 2.5%	SD 1%
*Liver: Hepatocellular Carcino	oma, Hepatocellı	ular Adenoma, or Hepatob	olastoma					
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%) 1/50 (2%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	5/200 (2.5%)	Mean 2.5%	SD 1%
*Lung: Alveolar/Bronchiolar A	denoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
*Lung: Alveolar/Bronchiolar C	arcinoma							
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Lung: Alveolar/Bronchiolar C	arcinoma or Alv	/eolar/Bronchiolar Adeno	ma					
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	4/200 (2%)	Mean 2%	SD 2.31%

^{*:} 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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 109

			Male				Female	
Lung: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lung: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lung: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/30 (0/0)	0/30 (0/0)	0/30 (0/0)		0/50 (0%)	0/30 (0/0)	0/30 (0/0)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Carcinoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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: 110

			Male				Female	
Lymph Node, Mesenteric: Hemangiosarcoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	2/200 (1%)	Mean 1%	SD 1.15%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 2/50 (4%)	2/50 (4%)	3/50 (6%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	8/200 (4%)	Mean 4%	SD 1.63%
#Mammary Gland: Carcinoma or Adenoma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%) 3/50 (6%)	2/50 (4%)	3/50 (6%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	9/200 (4.5%)	Mean 4.5%	SD 1.91%

^{*:} 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: 111

			Male				Female	
#Mammary Gland: Fibroadenoma								
		2/50 (4%)	2/50 (4%)	2/50 (4%)		15/50 (30%) 28/50 (56%)	33/50 (66%)	21/50 (42%)
Overall Incidence	Total	6/150 (4%)	Mean 4%	SD 0%	Total	97/200 (48.5%)	Mean 48.5%	SD 15.78%
#Mammary Gland: Fibroma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Mammary Gland: Fibroma, Fibroadenom		4/50 (8%)	4/50 (8%)	2/50 (4%)		15/50 (30%) 28/50 (56%)	33/50 (66%)	21/50 (42%)
Overall Incidence	Total	10/150 (6.67%)	Mean 6.67%	SD 2.31%	Total	97/200 (48.5%)	Mean 48.5%	SD 15.78%
#Mammary Gland: Fibroma, Fibroadenom	a, Carcinoma, o	r Adenoma 4/50 (8%)	4/50 (8%)	2/50 (4%)		16/50 (32%) 30/50 (60%)	35/50 (70%)	23/50 (46%)
Overall Incidence	Total	10/150 (6.67%)	Mean 6.67%	SD 2.31%	Total	104/200 (52%)	Mean 52%	SD 16.57%
#Mammary Gland: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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: 112

			Male				Female	
#Mammary Gland: Myoepithelioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mesentery: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mesentery: Liposarcoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} 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: 113 Report Date: 06/03/2022

			Male				Female	
#Mesentery: Osteosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Rhabdomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
*Nose: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Nose: Chondroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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: 114

			Male				Female	
Nose: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Nose: Squamous Cell Carcin	oma	0/50 (00/)	0/50 /00/	0/50 (00/)		0/50 (00/)	0/50 (00/)	0(50 (00())
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
			Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucos) Squamous Cell Carcin		ynx, 100th, Gingiva):						
·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Oral Cavity (Oral Mucos	sa, Tongue, Phar	ynx, Tooth, Gingiva): Squamous, or Papilloma						
•	, .u	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
						0/30 (0/0)		

^{*:} 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: 115

			Male				Female	
#Oral Mucosa: Squamous Cell Carcinom	na							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Oral Mucosa: Squamous Cell Papilloma	a							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
Ovary: Granulosa Cell Tumor Be	enign							
	_					0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
'Ovary: Granulosa Cell Tumor Ma	alignant							
	-					0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence					Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} 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 Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

red Control Animal Groups Report Date: 06/03/2022 GAVAGE

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	Male		Female	
Ovary:				
Granulosa Cell Tumor: Benign, Malignant, NOS				
		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)		
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Ovary: Granulosa-Theca Tumor Malignant				
3 a a a a a a a a a a a a a a a a a a a		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	, ,	, ,
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
		•••••		
Ovary: Luteoma				
Luteoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/30 (0/0)	0/30 (0/0)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Ovary:				
Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/30 (0 /8)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
Ovary: Thecoma Malignant				
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)		
Overall Incidence	Total	0/200 (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: 117 Report Date: 06/03/2022

			Male				Female	
Pancreas: Adenoma								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Pancreas: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Pancreas: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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

*Parathyroid Gland: Adenoma

Overall Incidence

#Peripheral Nerve: Sarcoma

Overall Incidence

#Peripheral Nerve:

Overall Incidence

#Peripheral Nerve:

Overall Incidence

Overall Incidence

Adenoma

Schwannoma Malignant

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Male **Female** (0%)0/48 (0%)0/46 (0%)1/46 (2%)0/46 (0%)1/48 (2%)0/48 (0%)Mean 0% 2/188 (1.06%) SD 0% Total Mean 1.06% SD 1.23% (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

21/50

27/50

82/200 (41%)

Total

(42%)

(54%)

22/50

(44%)

Mean 41%

(24%)

SD 12.49%

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*.	Danaminatar	ia mumahan	of online old	ith ticoco	avaminad	microscopically

Total

Total

Total

Total

Total

0/46

0/140 (0%)

0/50

0/150 (0%)

0/50

0/150 (0%)

0/50

0/150 (0%)

19/50

47/150 (31.33%)

(38%)

11/50

Mean 31.33%

(22%)

17/50

SD 8.33%

(34%)

......

Schwannoma: Benign, Malignant, NOS

*Pituitary Gland: Pars Distalis or Unspecified Site:

^{#:} 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

Report Date: 06/03/2022

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			Male				Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma												
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%				
*Pituitary Gland: Pars Dis Carcinoma or Adenoma	stalis or Unspec											
		20/50 (40%)	11/50 (22%)	17/50 (34%)		21/50 (42%) 27/50 (54%)	24/50 (48%)	13/50 (26%)				
Overall Incidence	Total	48/150 (32%)	Mean 32%	SD 9.17%	Total	85/200 (42.5%)	Mean 42.5%	SD 12.04%				
*Pituitary Gland: Pars Int Adenoma	ermedia:	4/50 (00()	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)				
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Into	ermedia:											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Int Carcinoma or Adenoma	ermedia:											
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (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

Control Animal Groups Report Date: 06/03/2022

Page: 120

			Male				Female	
*Prostate: Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
*Prostate: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
*Salivary Glands: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Salivary Glands: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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: 121

			Male			Female	
*Salivary Glands: Schwannoma Malignant							
		1/50 (2%)	0/50 (0%) 2/50	(4%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2% SD 2	% То	otal 0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Fibrosarcoma							
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0		otal 0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangioma							
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0	% To	otal 0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma							
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0		otal 0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Lipoma							
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0	% То	otal 0/200 (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: 122

			Male				Female	
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or R	Rhabdomyoma							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
∜Skin: Basal Cell Adenoma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
#Skin: Basal Cell Adenoma or B	asosquamous	s Tumor Benign						
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%

^{*:} 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

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Report Date: 06/03/2022

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male				Female	
#Skin:	_							
Basal Cell Adenoma, B	asosquamous 1	Tumor Benign, or Trichoe		0/50 (00/)		4/50 (00/)	0/50 (40/)	4/50 (00/)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	4/200 (2%)	Mean 2%	SD 1.63%
#Skin: Basal Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Basal Cell Carcinoma c	or Basosquamo	us Tumor (malignant or N 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		noma, Basosquamous Tu		nt or				
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	5/200 (2.5%)	Mean 2.5%	SD 1%
#Skin: Basal or Sq. Cell Carcii	noma, Carcinon	na, Basosq. Tumor (M or eratoacanthoma, Trichoe	B), Basal Cell Adenon					
• •		4/50 (8%)	10/50 (20%)	2/50 (4%)		1/50 (2%) 1/50 (2%)	4/50 (8%)	2/50 (4%)

^{*:} 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 Report Date: 06/03/2022

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			Male				Female	
#Skin: Fibroma								
		1/50 (2%)	6/50 (12%)	3/50 (6%)		1/50 (2%) 1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	10/150 (6.67%)	Mean 6.67%	SD 5.03%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
#Skin:		xoma, Myxosarcoma, or Fl 3/50 (6%)		3/50 (6%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	13/150 (8.67%)	Mean 8.67%	SD 4.62%	Total	3/50 (6%) 5/200 (2.5%)	Mean 2.5%	SD 2.52%
/Skin: Fibrosarcoma		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/50 (2%) 1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Fibrosarcoma, Sarcoma		a, or Fibrous Histiocytoma 2/50 (4%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	2/50 (4%) 2/200 (1%)	Mean 1%	SD 2%
#Skin: Fibrous Histiocytoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/50 (0%) 0/200 (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: 125

			Male				Female	
≄Skin: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Hemangiopericytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Keratoacanthoma								
		2/50 (4%)	8/50 (16%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	2/50 (4%)	0/50 (0%)
verall Incidence	Total	11/150 (7.33%)	Mean 7.33%	SD 7.57%	Total	2/200 (1%)	Mean 1%	SD 2%
Skin: Lipoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	2/200 (1%)	Mean 1%	SD 1.15%

^{*:} 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: 126

			Male				Female	
έSkin: Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Melanoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Myxoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Myxosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Skin: Neural Crest Tumor								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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: 127

			Male				Female	
#Skin: Neurofibroma or Schwar	nnoma benign							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or S	chwannoma (n	nalignant or NOS)						
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Neurofibrosarcoma, Neu Overall Incidence	rofibroma, or s	Schwannoma (benign, ma 0/50 (0%) 1/150 (0.67%)	alignant or NOS) 1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/50 (2%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	0/50 (0%) SD 1%
#Skin: Osteosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma		0/50 /00/	0/50 (00/)	0/50 (00/)		0/50 (09/)	0/50 (09/)	0/50 (00/)
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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: 128
Report Date: 06/03/2022

			Male				Female	
#Skin: Schwannoma Benign								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignant								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Squamous Cell Carcinoma								
•		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell	Carcinoma, Basosquamo	ous Tumor (malignant	or NOS),				
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Squamous Cell Papilloma								
-		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} 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: 129 Report Date: 06/03/2022

			Male				Female	
#Skin: Squamous Cell Papillom	a or Papilloma							
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Squamous Cell Papilloma		quamous Cell Carcinom		a				
		3/50 (6%)	9/50 (18%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	14/150 (9.33%)	Mean 9.33%	SD 7.57%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
#Skin: Squamous Cell Papilloma Overall Incidence	a, Papilloma, or Total	Keratoacanthoma 3/50 (6%) 13/150 (8.67%)	9/50 (18%) Mean 8.67%	1/50 (2%) SD 8.33%	Total	0/50 (0%) 0/50 (0%) 3/200 (1.5%)	2/50 (4%) Mean 1.5%	1/50 (2%) SD 1.91%
Skin: Trichoepithelioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
≴Skin: Sebaceous Gland: Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (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: 130

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
'Spleen: Leiomyosarcoma				•••••				
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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: 131

			Male				Female	
#Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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: 132

			Male				Female	
#Stomach, Glandular: Carcinoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Leiomyosarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Testes: Adenoma					•••••			
		44/50 (88%)	44/50 (88%)	40/50 (80%)				
Overall Incidence	Total	128/150 (85.33%)	Mean 85.33%	SD 4.62%				

^{*:} 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: 133

			Male				Female	
*Thymus: Sarcoma								
		0/45 (0%)	0/49 (0%)	0/49 (0%)		0/45 (0%) 0/48 (0%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/143 (0%)	Mean 0%	SD 0%	Total	0/189 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign								
		0/45 (0%)	0/49 (0%)	0/49 (0%)		0/45 (0%) 0/48 (0%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/143 (0%)	Mean 0%	SD 0%	Total	0/189 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
		0/45 (0%)	0/49 (0%)	0/49 (0%)		0/45 (0%) 1/48 (2%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/143 (0%)	Mean 0%	SD 0%	Total	1/189 (0.53%)	Mean 0.52%	SD 1.04%
Thymus: Thymoma: Benign, Malign	ant, NOS							
		0/45 (0%)	0/49 (0%)	0/49 (0%)		0/45 (0%) 1/48 (2%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/143 (0%)	Mean 0%	SD 0%	Total	1/189 (0.53%)	Mean 0.52%	SD 1.04%
Thyroid Gland: C-Cell:								
		8/50 (16%)	6/50 (12%)	9/50 (18%)		11/50 (22%) 2/49 (4%)	5/50 (10%)	3/50 (6%)
Overall Incidence	Total	23/150 (15.33%)	Mean 15.33%	SD 3.06%	Total	21/199 (10.55%)	Mean 10.52%	SD 8.04%

^{*:} 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 Female

Page: 134

			Male			Female	
*Thyroid Gland: C-Cell: Carcinoma							
		2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0% 1/49 (2%		2/50 (4%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total 3/199 (1.51%)	Mean 1.51%	SD 1.92%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma							
		10/50 (20%)	6/50 (12%)	10/50 (20%)	11/50 (22% 3/49 (6%	,	5/50 (10%)
Overall Incidence	Total	26/150 (17.33%)	Mean 17.33%	SD 4.62%	Total 24/199 (12.06%)	Mean 12.03%	SD 6.89%
*Thyroid Gland: Follicular Cel Adenoma	II:						
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0% 0/49 (0%	,	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total 0/199 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Ce Carcinoma	II:						
		2/50 (4%)	1/50 (2%)	0/50 (0%)	1/50 (2% 0/49 (0%	,	1/50 (2%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total 2/199 (1.01%)	Mean 1%	SD 1.15%
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma	II:						
		2/50 (4%)	1/50 (2%)	1/50 (2%)	1/50 (2% 0/49 (0%	,	1/50 (2%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%	Total 2/199 (1.01%)	Mean 1%	SD 1.15%

^{*:} 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: 135

			Male				Female	
#Tissue NOS: Fibrosarcoma								
		0/50 (0%)	0/50 (0%) 0/	50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD	0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tissue NOS: Leiomyoma								
		0/50 (0%)	0/50 (0%) 0/	50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)		0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tissue NOS: Paraganglioma								
		0/50 (0%)	0/50 (0%) 0/	50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD	0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tissue NOS: Sarcoma								
		0/50 (0%)	0/50 (0%) 0/	50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)		0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant								
-		0/50 (0%)	0/50 (0%) 0/	50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD	0%	Total	0/200 (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:** 136

			Male				Female	
#Tongue: Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Squamous Cell Carcinoma o	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
#Tooth: Odontogenic Tumor								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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: 137

			Male				Female	
'Urinary Bladder: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Urinary Bladder: Carcinoma or Papilloma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Urinary Bladder: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Urinary Bladder: Papilloma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Urinary Bladder: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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 Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 138

	Male			Female	
#Uterus: Adenoma					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma					
			0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Uterus: Hemangioma					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyoma					
			0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Uterus: Leiomyosarcoma					
			1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} 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 Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 06/03/2022

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	Male			Female	
#Uterus: Polyp Stromal					
			7/50 (14%) 11/50 (22%)	7/50 (14%)	7/50 (14%)
Overall Incidence		Total	32/200 (16%)	Mean 16%	SD 4%
#Uterus: Sarcoma					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					
			7/50 (14%) 11/50 (22%)	7/50 (14%)	7/50 (14%)
Overall Incidence		Total	32/200 (16%)	Mean 16%	SD 4%
#Uterus: Schwannoma Malignant					
			0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence		Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} 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 Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
#Vagina: Leiomyoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
#Vagina: Leiomyosarcoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
#Vagina: Polyp								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
#Vagina: Sarcoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} 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: 141

			Male				Female	
#Zymbal's Gland: Carcinoma		0/50 (00)	0/50 (00/)	0/50 (00)	o les	2 (00)	-0 (00()	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 0/50	` '	50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total 0/200	0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 0/50	` '	50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total 1/200	` '	Mean 0.5%	SD 1%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Strain: F 344/N Length of Study: CHRONIC

Contract/Lab: All Laboratories

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	059601105	06/04/01	729	50(5)	26(676)	540.9	Cumene
Battelle Northwest	059302607	08/14/97	733	50(5)	28(684)	509.1	Decalin
Battelle Northwest	058800405	09/13/99	729	50(5)	31(686)	519.5	Divinylbenzene
Battelle Northwest	058812403	01/18/96	733	50(5)	27(667)	502.3	Indium phosphide
Battelle Northwest	059700601	05/25/00	726	50(5)	32(693)	529.7	Methyl isobutyl ketone
Battelle Northwest	058800603	08/06/01	729	50(5)	27(680)	537.2	alpha-Methylstyrene
Battelle Northwest	050511002	03/28/96	733	49(5)	24(681)	507.1	Naphthalene
Battelle Northwest	059000407	10/06/97	729	50(5)	27(675)	540.5	Propylene glycol mono-t-butyl ether
Battelle Northwest	059600105	01/18/99	729	50(5)	29(701)	534.2	Stoddard solvent (type IIC)
Battelle Northwest	056142707	01/06/97	729	50(5)	20(668)	521.5	Vanadium pentoxide
					Female		
Battelle Northwest	059601105	06/04/01	731	50(5)	21(674)	356.9	Cumene
Battelle Northwest	059302607	08/14/97	734	50(5)	32(700)	346.6	Decalin
Battelle Northwest	058800405	09/13/99	731	50(5)	33(679)	355.3	Divinylbenzene
Battelle Northwest	058812403	01/18/96	735	50(5)	34(682)	337.2	Indium phosphide
Battelle Northwest	059700601	05/25/00	727	50(5)	35(694)	365.6	Methyl isobutyl ketone
Battelle Northwest	058800603	08/06/01	730	50(5)	27(647)	351.9	alpha-Methylstyrene
Battelle Northwest	050511002	03/28/96	734	49(5)	28(700)	325.2	Naphthalene
Battelle Northwest	059000407	10/06/97	730	50(5)	33(675)	366.9	Propylene glycol mono-t-butyl ether
Battelle Northwest	059600105	01/18/99	730	50(5)	36(696)	363.6	Stoddard solvent (type IIC)
Battelle Northwest	056142707	01/06/97	731	50(5)	33(688)	351.1	Vanadium pentoxide

Toxicology

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

			Male				Female	
All Organs: Benign Tumors								
		48/50 (96%)	47/50 (94%)	49/50 (98%)		44/50 (88%)	46/50 (92%)	43/50 (86%)
		47/50 (94%)	50/50 (100%)	48/50 (96%)		44/50 (88%)	44/50 (88%)	43/50 (86%)
		46/49 (94%)	50/50 (100%)	50/50 (100%)		38/49 (78%)	41/50 (82%)	37/50 (74%)
		48/50 (96%)				41/50 (82%)		
verall Incidence	Total	483/499 (96.79%)	Mean 96.79%	SD 2.55%	Total	421/499 (84.37%)	Mean 84.36%	SD 5.46%
All Organs: Malignant Tumors								
		36/50 (72%)	27/50 (54%)	29/50 (58%)		24/50 (48%)	25/50 (50%)	17/50 (34%)
		26/50 (52%)	31/50 (62%)	32/50 (64%)		25/50 (50%)	22/50 (44%)	25/50 (50%)
		34/49 (69%)	35/50 (70%)	33/50 (66%)		26/49 (53%)	33/50 (66%)	30/50 (60%)
		28/50 (56%)				28/50 (56%)		
verall Incidence	Total	311/499 (62.32%)	Mean 62.34%	SD 7.1%	Total	255/499 (51.1%)	Mean 51.11%	SD 8.73%
All Organs: Malignant and Benign 1								
		50/50 (100%)	49/50 (98%)	50/50 (100%)		50/50 (100%)	49/50 (98%)	46/50 (92%)
		49/50 (98%)	50/50 (100%)	50/50 (100%)		49/50 (98%)	46/50 (92%)	46/50 (92%)
		48/49 (98%)	50/50 (100%)	50/50 (100%)		44/49 (90%)	49/50 (98%)	44/50 (88%)
		50/50 (100%)				47/50 (94%)		
verall Incidence	Total	496/499 (99.4%)	Mean 99.4%	SD 0.97%	Total	470/499 (94.19%)	Mean 94.18%	SD 4.07%
All Organs: Hemangioma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%	Total	2/499 (0.4%)	Mean 0.4%	SD 0.85%

^{*:} 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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

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Report Date: 06/03/2022

Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#All Organs: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%	Total	2/499 (0.4%)	Mean 0.4%	SD 0.85%
All Organs: Hemangiosarcoma or H	emangioma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		2/49 (4%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	2/499 (0.4%)	Mean 0.4%	SD 0.84%	Total	4/499 (0.8%)	Mean 0.81%	SD 1.42%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	2/499 (0.4%)	Mean 0.4%	SD 0.84%	Total	5/499 (1%)	Mean 1%	SD 1.7%
#All Organs: Leukemia: Lymphocytic	, Monocytic, M	lononuclear, or Undiffere	ntiated					
, ,,		26/50 (52%)	19/50 (38%)	22/50 (44%)		12/50 (24%)	11/50 (22%)	10/50 (20%)
		16/50 (32%)	25/50 (50%)	26/50 (52%)		14/50 (28%)	14/50 (28%)	18/50 (36%)
		' '	` '	, ,		` ,	, ,	, ,
		26/49 (53%)	33/50 (66%)	25/50 (50%)		16/49 (33%)	24/50 (48%)	26/50 (52%)
		26/49 (53%) 22/50 (44%)	33/50 (66%)	25/50 (50%)		16/49 (33%) 21/50 (42%)	24/50 (48%)	26/50 (52%)

^{*:} 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

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Report Date: 06/03/2022

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

Route: INHALATION Vehicle: AIR

			Male			Female	
#All Organs:				_			
Malignant Lymphoma: I	Histiocytic, Lyn	nphocytic, Mixed, NOS, or		• •	-4	- ()	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	` ,	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	` ,	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)			0/50 (0%)	••	05 00/
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total 0/499 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/49 (4%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)			0/50 (0%)		
Overall Incidence	Total	2/499 (0.4%)	Mean 0.41%	SD 1.29%	Total 0/499 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign,		s					
		3/50 (6%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/49 (4%)	2/50 (4%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)			0/50 (0%)		
Overall Incidence	Total	14/499 (2.81%)	Mean 2.81%	SD 1.94%	Total 0/499 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Maligna							
		3/50 (6%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	` ,	0/50 (0%)
		0/49 (0%)	2/50 (4%)	0/50 (0%)	0/49 (0%)	` ,	0/50 (0%)
		1/50 (2%)	(-7	` '	0/50 (0%)	` '	, ,
Overall Incidence	Total	12/499 (2.4%)	Mean 2.4%	SD 2.07%	Total 0/499 (0%)	Mean 0%	SD 0%
	· otal	. =, (2. 170)	2.170	02 2.0.70	. 5.5 6/ 100 (0/0)		02 0.0

^{*:} 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: INHALATION Vehicle: AIR

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					Male						F	emale		
#All Organs: Osteoma							,							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/499 (0%	,	Mean		SD 0%		Total	0/499 (,		n 0%	SD	
#All Organs: Osteosarcoma														
		0/50	(0%)	0/50	(0%)	1/50	(2%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		3/50	(6%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/49	(2%)	1/50	(2%)	2/50	(4%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)						0/50	(0%)				
Overall Incidence	Total	9/499 (1.89	,	Mean 1		SD 1.99		Total	1/499 (0	.2%)	Mear	0.2%	SD 0.	.63%
#All Organs: Osteosarcoma or Osteo														
		0/50	(0%)	0/50	(0%)	1/50	(2%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		3/50	(6%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/49	(2%)	1/50	(2%)	2/50	(4%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)		, ,		, ,		0/50	(0%)		` '		, ,
Overall Incidence	Total	9/499 (1.89	,	Mean 1		SD 1.99		Total	1/499 (0	,		0.2%	SD 0.	
*Adrenal Cortex: Adenoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		1/49	(2%)	0/50	(0%)	2/50	(4%)
		2/49	(4%)	0/50	(0%)	0/50	(0%)		1/49	(2%)	2/49	(4%)	0/50	(0%)
		0/50	(0%)		(-)		/		0/49	(0%)		` '		, , , ,
			(/				%			21%)				

^{*:} 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

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
*Adrenal Cortex: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50	(0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/49	(2%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)	0/49	(0%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)			0/49	(0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total 2/496 (0.	,	Mean 0.4%	SD 0.85%
*Adrenal Medulla: Ganglioneuroma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50	` '	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50	(0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)	0/48	` '	0/49 (0%)	0/50 (0%)
		0/50 (0%)			0/49	(0%)		
Overall Incidence	Total	0/498 (0%)	Mean 0%	SD 0%	Total 0/495 (0	,	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma B								
		7/50 (14%)	7/49 (14%)	12/50 (24%)	1/50	(2%)	1/50 (2%)	2/50 (4%)
		10/50 (20%)	8/50 (16%)	8/50 (16%)	2/50	(4%)	3/50 (6%)	1/49 (2%)
		4/49 (8%)	12/50 (24%)	5/50 (10%)	3/48	(6%)	2/49 (4%)	2/50 (4%)
		4/50 (8%)			2/49	(4%)		
Overall Incidence	Total	77/498 (15.46%)	Mean 15.44%	SD 5.86%	Total 19/495 (3.	,	Mean 3.85%	SD 1.52%
*Adrenal Medulla:			•••••	•••••	•			
Pheochromocytoma C	Complex							
•	•	0/50 (0%)	0/49 (0%)	0/50 (0%)	1/50	(2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50	(0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)	0/48	(0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	, ,	, ,	0/49	(0%)	, ,	• •
Overall Incidence	Total	0/498 (0%)	Mean 0%	SD 0%	Total 1/495 (0.	2%)	Mean 0.2%	SD 0.63%
		()	***********			,		-=

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

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^{#:} 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: INHALATION Vehicle: AIR

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			Male				Female	
Adrenal Medulla: Pheochromocytoma M	lalignant							
		1/50 (2%)	2/49 (4%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		1/49 (2%)	2/50 (4%)	1/50 (2%)		0/48 (0%)	0/49 (0%)	1/50 (2%)
		1/50 (2%)				0/49 (0%)		
verall Incidence	Total	11/498 (2.21%)	Mean 2.21%	SD 1.49%	Total	2/495 (0.4%)	Mean 0.4%	SD 0.84%
Adrenal Medulla:								
Pheochromocytoma: E	Benign, Complex	x, Malignant, NOS						
-	- •	7/50 (14%)	8/49 (16%)	13/50 (26%)		3/50 (6%)	1/50 (2%)	2/50 (4%)
		10/50 (20%)	8/50 (16%)	10/50 (20%)		2/50 (4%)	3/50 (6%)	1/49 (2%)
		5/49 (10%)	14/50 (28%)	6/50 (12%)		3/48 (6%)	2/49 (4%)	3/50 (6%)
		5/50 (10%)				2/49 (4%)		
Overall Incidence	Total	86/498 (17.27%)	Mean 17.25%	SD 6.24%	Total	22/495 (4.44%)	Mean 4.45%	SD 1.6%
#Blood Vessel: Osteosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%
Bone: Chordoma								
Onordonia		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/30 (0/8)	0/30 (0/0)		0/50 (0%)	0/30 (0/0)	0/30 (0/0)
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%
Jverail illeluelle	i Ulai	0/433 (0/0)	IVICALI U/0	30 0/0	TOTAL	0/499 (0/0)	IVICALI U/0	30 0/0

^{*:} 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: INHALATION Vehicle: AIR

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					Male						F	emale		
#Bone: Osteoma														,
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/499 (0%	,	Mean		SD 0%		Total	0/499 (,		n 0%	SD	
#Bone: Osteosarcoma											•••••			
		0/50	(0%)	0/50	(0%)	1/50	(2%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		3/50	(6%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/49	(2%)	1/50	(2%)	2/50	(4%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)						0/50	(0%)				
Overall Incidence	Total	9/499 (1.8%	•	Mean '		SD 1.999		Total	1/499 (0			0.2%	SD 0	
#Bone: Osteosarcoma or Osteon														
		0/50	(0%)	0/50	(0%)	1/50	(2%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		3/50	(6%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/49	(2%)	1/50	(2%)	2/50	(4%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)						0/50	(0%)				
Overall Incidence	Total	9/499 (1.8%	,	Mean 1		SD 1.999		Total	1/499 (0	,		0.2%	SD 0	.63%
Brain: Astrocytoma Malignant	•••••													
, ,		0/50	(0%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/49	(0%)	0/50	(0%)	1/50	(2%)		0/49	(0%)	0/49	(0%)	0/49	(0%)
		0/50	(0%)		, , , ,		` '/		0/50	(0%)		` '		` '
Overall Incidence	Total	1/498 (0.29		Mean (20/	SD 0.639	1/	Total	1/497 (0		N4	0.2%	SD 0	620/

^{*:} 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: INHALATION Vehicle: AIR

Page: 150

*Brain: Glioma Malignant										
Glioma Malignant										
		,	,	/50 (0%)	0/49	(0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		,	,	/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		,	,	/50 (0%)	0/50	(0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		•	0%)					0/50 (0%)		
Overall Incidence	Total	0/498 (0%)		ean 0%	SD 0%		Total	2/497 (0.4%)	Mean 0.4%	SD 0.84%
*Brain:										
Granular Cell Tumor Ber	nign									
	_	0/50 (0	0%) 0	/50 (0%)	0/49	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0	0%) 0	/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0	0%) 0	/50 (0%)	0/50	(0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0	0%)					0/50 (0%)		
Overall Incidence	Total	0/498 (0%)		ean 0%	SD 0%		Total	0/497 (0%)	Mean 0%	SD 0%
*Brain:					•••••					
Granular Cell Tumor Mal	lignant									
	3	0/50 (0	0%) 0	/50 (0%)	0/49	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		,	,	/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0	0%) 0	/50 (0%)	0/50	(0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0)%)	, ,		, ,		0/50 (0%)	` ,	, ,
Overall Incidence	Total	0/498 (0%)		ean 0%	SD 0%		Total	0/497 (0%)	Mean 0%	SD 0%
*Brain:										
Medulloblastoma Mal										
		0/50 (0	0%) 0	/50 (0%)	0/49	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		(,	/50 (0%)	1/50	(2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		,	,	/50 (0%)	0/50	(0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		,	0%)	(070)	3,30	(0 /0)		0/50 (0%)	5, 10 (070)	3, 10 (0,0)
Overall Incidence	Total	1/498 (0.2%)		ean 0.2%	SD 0.639	%	Total	0/497 (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: INHALATION Vehicle: AIR

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					Male						F	emale		
Brain: Meningioma Malignant														
		0/50	(0%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/49	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/498 (0%	,	Mean		SD 0%		Total	0/497 (0%)	Mea	n 0%	SD	0%
*Brain:														
Meningioma: Benign, N	Malignant, NOS													
		0/50	(0%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/49	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/498 (0%	,	Mean		SD 0%		Total	0/497 (n 0%	SD	
*Brain: Oligodendroglioma Ber	nign													
	_	0/50	(0%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/49	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/498 (0%	,	Mean		SD 0%		Total	0/497 (,		n 0%	SD	
*Brain:														
Oligodendroglioma Mal	lignant													
- -	-	0/50	(0%)	0/50	(0%)	0/49	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/49	(0%)
		0/50	(0%)		, ,				0/50	(0%)				•
Overall Incidence	Total	0/498 (0%	١	Mean	0%	SD 0%		Total	2/497 (0		Mear	0.4%	SD 0	84%

^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
Brain:								
Oligodendroglioma, Glior	ma, or Astroc							
		0/50 (0%)	0/50 (0%)	0/49 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
		0/49 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/50 (0%) 1/498 (0.2%)	Mean 0.2%	SD 0.63%	Total	0/50 (0%) 5/497 (1.01%)	Mean 1%	SD 1.7%
Di					•••••			
Brain: Sarcoma								
Gardonia		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/00 (0/0)	0/00 (0/0)		0/50 (0%)	0/10 (0/0)	0/10 (0/0)
Overall Incidence	Total	0/498 (0%)	Mean 0%	SD 0%	Total	0/497 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/48 (0%)		1/50 (2%)	8/48 (17%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		5/49 (10%)	0/50 (0%)	0/50 (0%)
		3/48 (6%)	1/50 (2%)	0/50 (0%)		4/49 (8%)	1/50 (2%)	0/49 (0%)
		0/50 (0%)				2/50 (4%)		
verall Incidence	Total	5/496 (1.01%)	Mean 1.03%	SD 2.02%	Total	21/495 (4.24%)	Mean 4.3%	SD 5.65%
Clitoral/Preputial Gland:								•••••
		0/50 (0%)	0/50 (0%)	0/48 (0%)		2/50 (4%)	1/48 (2%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	2/50 (4%)		0/49 (0%)	1/50 (2%)	1/50 (2%)
		3/48 (6%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	2/50 (4%)	1/49 (2%)
		0/50 (0%)		()		0/50 (0%)	(/	- (/
verall Incidence	Total	9/496 (1.81%)	Mean 1.82%	SD 2.25%	Total	8/495 (1.62%)	Mean 1.61%	SD 1.58%

^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/48 (0%)		3/50 (6%)	9/48 (19%)	0/50 (0%)
		3/50 (6%)	1/50 (2%)	2/50 (4%)		5/49 (10%)	1/50 (2%)	1/50 (2%)
		6/48 (13%) 0/50 (0%)	2/50 (4%)	0/50 (0%)		4/49 (8%) 2/50 (4%)	3/50 (6%)	1/49 (2%)
overall Incidence	Total	14/496 (2.82%)	Mean 2.85%	SD 4.04%	Total	29/495 (5.86%)	Mean 5.92%	SD 5.5%
Clitoral/Preputial Gland: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	1/50 (2%)
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	0/496 (0%)	Mean 0%	SD 0%	Total	1/495 (0.2%)	Mean 0.2%	SD 0.63%
Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	0/496 (0%)	Mean 0%	SD 0%	Total	0/495 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	, ,	, ,		0/50 (0%)	, ,	, ,
verall Incidence	Total	0/496 (0%)	Mean 0%	SD 0%	Total	0/495 (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: INHALATION Vehicle: AIR

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			Male				Female	
*Clitoral/Preputial Gland: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/496 (0%)	Mean 0%	SD 0%	Total	0/495 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/496 (0%)	Mean 0%	SD 0%	Total	0/495 (0%)	Mean 0%	SD 0%
#Ear: Neural Crest Tumor								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%
#Eye:	iam							
Amelanotic Melanoma, Ben	ign	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		` '	0/50 (0%)	0/50 (0%)		` '	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Occupation of James	T-1-1	0/50 (0%)	M 00/	OD 00/	T-1-1	0/50 (0%)	M 00/	OD 00/
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (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: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Eye: Melanoma Benign 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/499 (0%) Mean 0% SD 0% 0/499 (0%) Mean 0% SD 0% Total #Eye: **Melanoma Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/49 0/49 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/499 (0%) SD 0% 0/499 (0%) Mean 0% SD 0% Total Mean 0% Total #Harderian Gland: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 0/50 (0%)(0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence 0/499 (0%) Mean 0% SD 0% 0/499 (0%) Mean 0% SD 0% Total Total #Harderian Gland: Carcinoma 0/50 0/50 (0%)0/50 (0%) 0/50 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/49 0/49 0/50 0/50 0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/499 (0%) Mean 0% SD 0% Total 0/499 (0%) Mean 0% SD 0%

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^{*:} 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: INHALATION Vehicle: AIR

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					Male						F	emale		
#Harderian Gland: Carcinoma or Adenoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/499 (0%)	Mean	0%	SD 0%		Total	0/499 (0%)	Mea	n 0%	SD	0%
Heart: Schwannoma Benign														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/49	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/499 (0.2%	•	Mean (SD 0.639		Total	0/498 (,		n 0%	SD	
'Heart: Schwannoma Malignant														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/49	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/499 (0.2%	•	Mean (SD 0.639		Total	0/498 (,		n 0%	SD	
#Intestine Large: Colon/Red Adenoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	2.20	(-,-,	-, - 0	(= / = /		0/50	(0%)		(- / - /	2, 20	(-,-)
		0,00	(3,3)	Mean		SD 0%			0/499 (` '	Mea			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: INHALATION Vehicle: AIR

Page: 157

					Male						F	emale		
#Intestine Large: Colon/Re Carcinoma	ectum:						,		,					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/499 (0%	, ,	Mean	0%	SD 0%		Total	0/499 (0%)	Mea	n 0%	SD	0%
#Intestine Large: Colon/Re Carcinoma or Adenoma	ectum:													
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/499 (0%		Mean		SD 0%		Total	0/499 (n 0%	SD	- / -
#Intestine Large: Colon/Re Leiomyosarcoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		, ,		` ,		0/50	(0%)		` ,		` ,
Overall Incidence	Total	0/499 (0%	•	Mean		SD 0%		Total	0/499 (n 0%	SD	0%
#Intestine Large: Colon/Re														
- 4		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	1/50	(2%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		(/		(/		0/50	(0%)		()		()
Overall Incidence	Total	1/499 (0.29	. ,	Mean (20/	SD 0.639	1/	Total	0/499 (` ,		n 0%	SD	00/

^{*:} 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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR Page: 158

Report Date: 06/03/2022

#Intestine Small: Jejunum:				Female				
Carcinoma								
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
	1/50 (2%)				0/50 (0%)			
Overall Incidence Tota	1/499 (0.2%)	Mean 0.2%	SD 0.63%	Total	0/499 (0%)	Mean 0%	SD 0%	
Intestine Small: Jejunum: Leiomyoma								
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
	0/50 (0%)				0/50 (0%)			
Overall Incidence Tota	()	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%	
Intestine Small: Jejunum: Sarcoma								
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
	0/50 (0%)				0/50 (0%)			
verall Incidence Tota	()	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%	
Intestine Small: Site Unspecified: Carcinoma								
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
	1/50 (2%)	(-70)	(0)		0/50 (0%)	2,22 (2,3)	(-,-)	
Overall Incidence Tota	` '	Mean 0.2%	SD 0.63%	Total	0/499 (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

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

Report Date: 06/03/2022

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Species: RATS Strain: F 344/N

Vehicle: AIR

			Male			Female					
#Intestine Small: Site Uns Carcinoma or Adenoma	•										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)			
S II I ! . !	T-1-1	1/50 (2%)	M 0 00/	OD 0.000/	T-1-1	0/50 (0%)	M 00/	OD 00/			
Overall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%	Total	0/499 (0%)	Mean 0%	SD 0%			
#Intestine Small: Site Uns Leiomyoma	specified:										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%			
#Intestine Small: Site Uns Sarcoma				•••••							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%			
Islets, Pancreatic:											
		1/50 (2%)	3/50 (6%)	5/50 (10%)		1/50 (2%)	1/50 (2%)	1/50 (2%)			
		1/50 (2%)	3/50 (6%)	3/50 (6%)		1/50 (2%)	0/50 (0%)	3/50 (6%)			
		2/49 (4%)	4/50 (8%)	3/50 (6%)		1/49 (2%)	0/49 (0%)	1/49 (2%)			
		1/50 (2%)	(-/-)	(-)		1/49 (2%)	()	- (/			
Overall Incidence	Total	26/499 (5.21%)	Mean 5.21%	SD 2.7%	Total	10/496 (2.02%)	Mean 2.01%	SD 1.63%			

^{*:} 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**

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

Vehicle: AIR

Page: 160

Report Date: 06/03/2022

			Male				Female	
*Islets, Pancreatic: Carcinoma								
		2/50 (4%)	4/50 (8%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)	4/50 (8%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		4/49 (8%)	0/50 (0%)	1/50 (2%)		1/49 (2%)	1/49 (2%)	0/49 (0%)
		1/50 (2%)				1/49 (2%)		
Overall Incidence	Total	20/499 (4.01%)	Mean 4.02%	SD 3.01%	Total	5/496 (1.01%)	Mean 1.01%	SD 1.07%
Islets, Pancreatic: Carcinoma or Adenoma								
		3/50 (6%)	7/50 (14%)	6/50 (12%)		2/50 (4%)	2/50 (4%)	1/50 (2%)
		3/50 (6%)	7/50 (14%)	4/50 (8%)		1/50 (2%)	0/50 (0%)	3/50 (6%)
		6/49 (12%)	4/50 (8%)	4/50 (8%)		2/49 (4%)	1/49 (2%)	1/49 (2%)
		2/50 (4%)				2/49 (4%)		
Overall Incidence	Total	46/499 (9.22%)	Mean 9.22%	SD 3.57%	Total	15/496 (3.02%)	Mean 3.02%	SD 1.71%
Kidney: Pelvis and Transiti Carcinoma								
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	3/499 (0.6%)	Mean 0.6%	SD 0.97%	Total	0/495 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transiti Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	3/499 (0.6%)	Mean 0.6%	SD 0.97%	Total	0/495 (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**

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: AIR

Route: INHALATION

Length of Study: CHRONIC

Report Date: 06/03/2022

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			Male				Female	
*Kidney: Pelvis and Transition	onal Epitheliu	um:						
·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/49 (0%)	0/49 (0%)
	-	0/50 (0%)		00.00/	-	0/50 (0%)		00.00/
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/495 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Adenoma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	1/50 (2%)	0/50 (0%)		0/48 (0%)	0/49 (0%)	0/49 (0%)
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	4/499 (0.8%)	Mean 0.8%	SD 1.03%	Total	0/495 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	0/50 (0%)	1/50 (2%)		1/48 (2%)	0/49 (0%)	0/49 (0%)
Overell Incidence	Tatal	0/50 (0%)	Mana 0 40/	CD 0.040/	Tatal	0/50 (0%)	Maara 0 040/	CD 0.000/
Overall Incidence	Total	2/499 (0.4%)	Mean 0.4%	SD 0.84%	Total	1/495 (0.2%)	Mean 0.21%	SD 0.66%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	1/50 (2%)	1/50 (2%)		1/48 (2%)	0/49 (0%)	0/49 (0%)
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	6/499 (1.2%)	Mean 1.2%	SD 1.4%	Total	1/495 (0.2%)	Mean 0.21%	SD 0.66%

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^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
*Kidney: Renal Tubule: Lipoma								
		1/50 (2%)	0/50 (0%)	0/50 (0	0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0	0%)	1/50 (2%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0	0%)	0/48 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%	Total	1/495 (0.2%)	Mean 0.2%	SD 0.63%
*Kidney: Renal Tubule: Liposarcoma								
		0/50 (0%)	0/50 (0%)	,	2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	,	0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0	0%)	0/48 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%	Total	0/495 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0	0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0	0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0	0%)	0/48 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/495 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Stromal Nephroma								
-		0/50 (0%)	0/50 (0%)	0/50 (0	0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0	0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0	0%)	0/48 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/495 (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: INHALATION Vehicle: AIR

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			Male				Female	
*Liver:								,
Cholangiocarcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/497 (0%)	Mean 0%	SD 0%
*Liver:								
Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/497 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma								
riopatoconaia. Ataonoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	3/50 (6%)	0/50 (0%)		0/49 (0%)	1/49 (2%)	0/49 (0%)
		0/50 (0%)	(273)	(171)		1/50 (2%)	(=70)	(0,10)
Overall Incidence	Total	5/499 (1%)	Mean 1%	SD 1.95%	Total	2/497 (0.4%)	Mean 0.4%	SD 0.85%
*Liver:								
Hepatocellular Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	3/33 (3/0)	0,00 (0,70)		0/50 (0%)	3/ 10 (0/0)	3, 10 (070)
Overall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.65%	Total	0/497 (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

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

Report Date: 06/03/2022

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Species: RATS Strain: F 344/N

Vehicle: AIR

			Male				Female	
*Liver: Hepatocellular Carcino	oma or Henatobl	astoma						
riopatoconaiai caronic	oma or moparous	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	(171)	(575)		0/50 (0%)	(0,0)	(575)
Overall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.65%	Total	0/497 (0%)	Mean 0%	SD 0%
*Liver:								
Hepatocellular Carcino	oma or Hepatoce	ellular Adenoma						
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/49 (4%)	3/50 (6%)	0/50 (0%)		0/49 (0%)	1/49 (2%)	0/49 (0%)
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	6/499 (1.2%)	Mean 1.21%	SD 2.16%	Total	2/497 (0.4%)	Mean 0.4%	SD 0.85%
*Liver:								
Hepatocellular Carcino	oma, Hepatocellu	ular Adenoma, or Hepatob						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/49 (4%)	3/50 (6%)	0/50 (0%)		0/49 (0%)	1/49 (2%)	0/49 (0%)
	-	0/50 (0%)	1 0 4 0 4 0 4 0 4	00.0400/	-	1/50 (2%)		OD 0.050/
Overall Incidence	Total	6/499 (1.2%)	Mean 1.21%	SD 2.16%	Total	2/497 (0.4%)	Mean 0.4%	SD 0.85%
*Lung: Alveolar/Bronchiolar A	\ danama							
Aiveolai/Dronchiolar A	Auenoma	1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		6/50 (12%)	0/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		2/49 (4%)	0/50 (0%)	1/50 (2%)		1/49 (2%)	0/50 (2%)	0/49 (0%)
		4/50 (8%)	0/00 (0/0)	1/50 (2/0)		0/49 (0%)	0/00 (0/0)	0/40 (0/0)
Overall Incidence	Total	15/499 (3.01%)	Mean 3.01%	SD 4.03%	Total	3/497 (0.6%)	Mean 0.6%	SD 0.97%
overall includince	Total	13/433 (3.0170)	WEATT 3.0176	3D 4.03/0	i olai	3/43/ (0.070)	IVICALI 0.070	JD 0.31/0

^{*:} 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

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** *Lung: Alveolar/Bronchiolar Carcinoma 1/50 (2%)1/50 (2%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/49 (0%)1/50 (2%)1/50 (2%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)Overall Incidence Total 6/499 (1.2%) Mean 1.2% SD 1.03% 3/497 (0.6%) Mean 0.6% SD 0.97% Total *Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 2/50 (4%)2/50 (4%)1/50 (2%)1/50 (2%)2/50 (4%)0/50 (0%)0/50 (0%)7/50 (14%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)2/49 (4%)1/50 (2%)2/50 (4%)1/49 (2%)0/50 (0%)0/49 (0%)4/50 (8%) 0/49 (0%)**Overall Incidence** 21/499 (4.21%) Mean 4.21% SD 4.16% 6/497 (1.21%) Mean 1.2% SD 1.4% Total Total *Lung: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 0/50 (0%)(0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%) 0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)Overall Incidence 0/499 (0%) Mean 0% SD 0% 0/497 (0%) Mean 0% SD 0% Total Total *Lung: Sarcoma 0/50 0/50 (0%)0/50 (0%) 0/50 0/50 (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 0/49 (0%)0/49 0/50 (0%)0/50 (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/49(0%)Overall Incidence Total 0/499 (0%) Mean 0% SD 0% Total 0/497 (0%) Mean 0% SD 0%

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^{*:} 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: INHALATION Vehicle: AIR

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*Lung: Squamous Cell Carcinoma	0/50 (0%)	0/50 (00/)					
	()	0/50 (00/)					
	0/50 (00/)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
	0/50 (0%)				0/49 (0%)		
Overall Incidence Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%	Total	0/497 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Carcinoma							
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)				0/50 (0%)		
Overall Incidence Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangioma							
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)				0/50 (0%)		
Overall Incidence Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma							
•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
	0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	(-,-)	(4,4)		0/50 (0%)	(-7-)	(-,-)
Overall Incidence Total	0/499 (0%)	Mean 0%	SD 0%	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%

^{*:} 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

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Lymph Node, Mesenteric: Sarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%	Total	0/499 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%
#Mammary Gland: Carcinoma								
		2/50 (4%)	1/50 (2%)	1/50 (2%)		10/50 (20%)	5/50 (10%)	3/50 (6%)
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	5/50 (10%)	3/50 (6%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)		3/49 (6%)	5/50 (10%)	4/50 (8%)
		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	7/499 (1.4%)	Mean 1.4%	SD 1.65%	Total	40/499 (8.02%)	Mean 8.01%	SD 5.24%
#Mammary Gland: Carcinoma or Adenoma								
		2/50 (4%)	2/50 (4%)	1/50 (2%)		10/50 (20%)	5/50 (10%)	3/50 (6%)
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	5/50 (10%)	3/50 (6%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)		3/49 (6%)	5/50 (10%)	4/50 (8%)
		0/50 (0%)	, ,	. ,		3/50 (6%)	, ,	. ,
Overall Incidence	Total	8/499 (1.6%)	Mean 1.6%	SD 1.84%	Total	41/499 (8.22%)	Mean 8.21%	SD 5.11%

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

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^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 06/03/2022

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC Male **Female** #Mammary Gland: Fibroadenoma 0/50 (0%)2/50 (4%)1/50 (2%)24/50 (48%)25/50 (50%)20/50 (40%)(44%)2/50 (4%)2/50 (4%)1/50 (2%)20/50 (40%)22/50 22/50 (44%)0/49 (0%)2/50 (4%)3/50 (6%)17/49 (35%)25/50 (50%)19/50 (38%)2/50 (4%)16/50 (32%)Overall Incidence 15/499 (3.01%) Mean 3% SD 1.94% 210/499 (42.08%) Mean 42.07% SD 6.23% Total Total #Mammary Gland: **Fibroma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/499 (0%) SD 0% 0/499 (0%) SD 0% Total Mean 0% Total Mean 0% #Mammary Gland: Fibroma, Fibroadenoma or Adenoma 3/50 1/50 (2%)24/50 0/50 (0%)(6%)(48%)25/50 (50%)20/50 (40%)2/50 (4%)2/50 (4%)1/50 (2%)20/50 (40%)22/50 (44%)22/50 (44%)0/49 (0%)2/50 (4%)3/50 (6%)17/49 (35%)25/50 (50%)19/50 (38%)2/50 (4%)17/50 (34%)Overall Incidence Total 16/499 (3.21%) Mean 3.2% SD 2.15% 211/499 (42.28%) Mean 42.27% SD 5.89% Total

(2%)

(2%)

(6%)

31/50

20/50

18/49

19/50

239/499 (47.9%)

Total

(62%)

(40%)

(37%)

(38%)

29/50

26/50

27/50

(58%)

(52%)

(54%)

Mean 47.87%

22/50

24/50

23/50

SD 8.56%

(44%)

(48%)

(46%)

1/50

1/50

3/50

SD 2.27%

Total

2/50

2/50

1/49

2/50

22/499 (4.41%)

(4%)

(4%)

(2%)

(4%)

4/50

4/50

2/50

Mean 4.4%

(8%)

(8%)

(4%)

Fibroma, Fibroadenoma, Carcinoma, or Adenoma

#Mammary Gland:

Overall Incidence

^{......} *: 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

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

				Male						F	emale		
#Mammary Gland: Hemangioma													
		0/50 (0%	6) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	6) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49 (0%	6) 0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	%)					0/50	(0%)				
verall Incidence	Total	0/499 (0%)	Mean		SD 0%		Total	0/499 (•		ın 0%	SD (
Mammary Gland: Myoepithelioma													
		0/50 (0%	6) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	6) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49 (0%	6) 0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	%)					0/50	(0%)				
verall Incidence	Total	0/499 (0%)	Mean	0%	SD 0%		Total	0/499 (0%)	Mea	ın 0%	SD (0%
Mesentery:		•••••											
		0/50 (0%	6) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	,	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49 (0%	,	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	,	,		()		0/50	(0%)		` ,		` ,
verall Incidence	Total	0/499 (0%)	Mean	0%	SD 0%		Total	0/499 (0%)	Mea	ın 0%	SD (0%
Mesentery: Hemangiosarcoma		•••••											
_		0/50 (0%	6) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	,	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49 (0%	(a) 0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	,	` '	-	` '		0/50	(0%)		` '	-	` ,
			,						` -/				

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

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^{#:} 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: INHALATION Vehicle: AIR

Page: 170

			Male			Female				
#Mesentery:										
Lipoma		2/22 (22/)	0/50 (00/)	2/22 (22/)		2/=2 (22/)	2/22 (22/)	0/=0 (00/)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%		
#Mesentery: Liposarcoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%		
#Mesentery: Osteosarcoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%		
#Mesentery: Rhabdomyosarcoma										
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	` '	, ,		0/50 (0%)	, ,	, ,		
		0/499 (0%)	Mean 0%	SD 0%		0/499 (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: INHALATION Vehicle: AIR

Page: 171

			Male		Female				
#Mesentery: Sarcoma									
		0/50 (0%	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/49 (2%	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%	1			0/50 (0%)			
Overall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.65%	Total	0/499 (0%)	Mean 0%	SD 0%	
Nose: Adenoma									
		0/50 (0%)	, ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/49 (0%	0/50 (0%)	1/50 (2%)		0/49 (0%)	0/49 (0%)	0/49 (0%)	
		0/49 (0%	1			0/50 (0%)			
Overall Incidence	Total	1/497 (0.2%)	Mean 0.2%	SD 0.63%	Total	0/496 (0%)	Mean 0%	SD 0%	
*Nose: Chondroma									
		0/50 (0%	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/49 (0%	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)	
		0/49 (0%)			1/50 (2%)			
Overall Incidence	Total	1/497 (0.2%)	Mean 0.2%	SD 0.63%	Total	2/496 (0.4%)	Mean 0.4%	SD 0.84%	
*Nose: Sarcoma									
		0/50 (0%	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/49 (0%	` ,	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)	
		0/49 (0%	` ,	(-,-)		0/50 (0%)	(7)	(-,-)	

^{*:} 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: INHALATION Vehicle: AIR

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					Male						F	emale		
*Nose: Squamous Cell Carcino	oma													
oquamous con caronic	Ja	0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/49	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/49	(0%)
		0/49	(0%)	0,00	(070)	0,00	(070)		0/50	(0%)	0, 10	(070)	0, 10	(070)
Overall Incidence	Total	0/497 (0%	` ,	Mean	0%	SD 0%		Total	0/496 (` '	Mea	n 0%	SD	0%
#Oral Cavity (Oral Mucos Papilloma Squamous o														
	•	0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	2/499 (0.4	•	Mean ().4%	SD 0.849	%	Total	1/499 (0	.2%)	Mear	0.2%	SD 0.	.63%
#Oral Cavity (Oral Mucos Squamous Cell Carcino	a, Tongue, Phar													
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	2/50	(4%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		` ,		` ,		0/50	(0%)		` ,		` ,
Overall Incidence	Total	1/499 (0.2	%)	Mean ().2%	SD 0.639	%	Total	2/499 (0	` '	Mear	0.4%	SD 1.	.26%
#Oral Cavity (Oral Mucos														
Squamous Cell Carcino	. •		• ,											
	,	0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	3/50	(6%)	0/50	(0%)
		1/50	(2%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0,00	(370)	0,00	(0,0)		0/50	(0%)	3,00	(373)	3/00	(370)
Overall Incidence	Total		` ,	Mean (0.6%	SD 0.979	0/_	Total	3/499 (0	` '	Moor	0.6%	SD 1	Q0/_
Overail Incidence	Total	3/499 (0.6	%)	Mean ().6%	SD 0.979	%	Total	3/499 (0	.6%)	Mear	0.6%	SD 1	.9%

^{*:} 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: INHALATION Vehicle: AIR

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					Male						F	emale		
#Oral Mucosa: Squamous Cell Carcinoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/499 (0.2%	•	Mean 0		SD 0.639		Total	1/499 (0	,		0.2%	SD 0.	63%
[‡] Oral Mucosa: Squamous Cell Papilloma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/499 (0.2%	6)	Mean ().2%	SD 0.639	%	Total	0/499 (0%)	Mea	n 0%	SD	0%
*Ovary: Cystadenoma														
•									0/50	(0%)	0/50	(0%)	0/50	(0%)
									0/50	(0%)	0/50	(0%)	0/50	(0%)
									0/49	(0%)	0/50	(0%)	0/50	(0%)
									0/50	(0%)		, ,		` ,
Overall Incidence								Total	0/499 (,		n 0%	SD	0%
	ign													
'Ovary: Granulosa Cell Tumor Ben	ign								0/50	(0%)	0/50	(0%)	0/50	(0%)
	ign								0/50 1/50	` '	0/50 0/50	` '		
*Ovary: Granulosa Cell Tumor Ben	ign									(2%)	0/50	(0%) (0%) (0%)	0/50	(0%)
	ign								1/50	` '		(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

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Report Date: 06/03/2022

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: **Granulosa Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)2/49 (4%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 3/499 (0.6%) Mean 0.61% SD 1.37% *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)2/49 (4%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 4/499 (0.8%) Mean 0.81% SD 1.42% Total *Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)0/50 0/50 (0%)(0%)(2%)(0%)0/50 (0%)1/50 0/50 1/49 (2%)1/50 (2%)0/50 (0%)0/50 (0%)SD 0.97% **Overall Incidence** 3/499 (0.6%) Mean 0.6% Total *Ovary: Luteoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 0/49 (0%)(0%)(0%)0/50 (0%)**Overall Incidence** Total 0/499 (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: INHALATION Vehicle: AIR

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					Male						F	emale		
*Ovary: Sarcoma														
									0/50	(0%)	0/50	(0%)	0/50	(0%)
									0/50	(0%)	0/50	(0%)	0/50	(0%)
									0/49	(0%)	0/50	(0%)	0/50	(0%)
									0/50	(0%)				
Overall Incidence								Total	0/499 (n 0%	SD	
*Ovary: Thecoma Malignant														
									0/50	(0%)	1/50	(2%)	0/50	(0%)
									0/50	(0%)	0/50	(0%)	0/50	(0%)
									0/49	(0%)	0/50	(0%)	0/50	(0%)
									0/50	(0%)				
Overall Incidence								Total	1/499 (0	•		າ 0.2%	SD 0	
*Pancreas: Adenoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/49	(2%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/49	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	2/499 (0.4%	•	Mean (SD 0.859		Total	0/497 (•		n 0%	SD	
*Pancreas: Carcinoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/49	(0%)
		0/50	(0%)	2, 20	()	2, 20	(- / - /		0/50	(0%)		(-,-)	50	(-,-)
Overall Incidence	Total	0/499 (0%)	` ,	Mean	0%	SD 0%		Total	0/497 (Mea	ın 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: INHALATION Vehicle: AIR

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			Male				Female	
*Pancreas: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	,	,		0/50 (0%)	,	,
Overall Incidence	Total	2/499 (0.4%)	Mean 0.4%	SD 0.85%	Total	0/497 (0%)	Mean 0%	SD 0%
Pancreas: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/497 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/497 (0%)	Mean 0%	SD 0%
Parathyroid Gland: Adenoma								
		0/45 (0%)	0/49 (0%)	0/46 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		1/44 (2%)	0/49 (0%)	0/47 (0%)		0/40 (0%)	0/46 (0%)	0/43 (0%)
		0/45 (0%)	0/49 (0%)	0/50 (0%)		0/42 (0%)	0/49 (0%)	0/49 (0%)
		0/49 (0%)				0/45 (0%)		
Overall Incidence	Total	1/473 (0.21%)	Mean 0.23%	SD 0.72%	Total	0/461 (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: INHALATION Vehicle: AIR

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Report Date: 06/03/2022

			Male				Female	
#Peripheral Nerve: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma Malignar	nt							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign,	, Malignant, NO	s						•••••
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Adenoma		cified Site:						
		36/50 (72%)	27/50 (54%)	36/50 (72%)		35/50 (70%)	34/50 (68%)	37/50 (74%)
		36/49 (73%)	35/50 (70%)	34/49 (69%)		30/50 (60%)	24/49 (49%)	35/50 (70%)
		31/49 (63%)	35/50 (70%)	38/50 (76%)		23/49 (47%)	30/49 (61%)	27/49 (55%)
		35/50 (70%)	30,00 (1070)	30,00 (10,0)		31/49 (63%)	33/10 (01/0)	
Overall Incidence	Total	343/497 (69.01%)	Mean 69.01%	SD 6.22%	Total	306/495 (61.82%)	Mean 61.75%	SD 9.17%
Trei aii iiiciueiice	i Uldi	J43/43/ (U3.U1/0)	IVICALI 03.01/0	JD 0.22/0	i Ulai	300/493 (01.02%)	Weall 01.73%	3D 3.11/0

^{*:} 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: INHALATION

Report Date: 06/03/2022

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Species: RATS Strain: F 344/N

Vehicle: AIR

			Male		Female						
Pituitary Gland: Pars Dista Carcinoma	alis or Unspe	cified Site:									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)			
		1/49 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%)	0/49 (0%)	0/49 (0%)			
		0/50 (0%)				0/49 (0%)					
verall Incidence	Total	2/497 (0.4%)	Mean 0.4%	SD 0.85%	Total	1/495 (0.2%)	Mean 0.2%	SD 0.63%			
Pituitary Gland: Pars Dista Carcinoma or Adenoma		cified Site:									
		36/50 (72%)	27/50 (54%)	36/50 (72%)		36/50 (72%)	34/50 (68%)	37/50 (74%)			
		37/49 (76%)	35/50 (70%)	34/49 (69%)		30/50 (60%)	24/49 (49%)	35/50 (70%)			
		31/49 (63%)	35/50 (70%)	39/50 (78%)		23/49 (47%)	30/49 (61%)	27/49 (55%)			
		35/50 (70%)				31/49 (63%)					
Overall Incidence	Total	345/497 (69.42%)	Mean 69.42%	SD 6.67%	Total	307/495 (62.02%)	Mean 61.95%	SD 9.39%			
Pituitary Gland: Pars Inter Adenoma											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)			
		0/50 (0%)				0/49 (0%)					
verall Incidence	Total	0/497 (0%)	Mean 0%	SD 0%	Total	0/495 (0%)	Mean 0%	SD 0%			
Pituitary Gland: Pars Inter Carcinoma							•••••	•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)			
		0/50 (0%)	()	(-,-)		0/49 (0%)	(-,-)	(() ()			
Overall Incidence	Total	0/497 (0%)	Mean 0%	SD 0%	Total	0/495 (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: INHALATION Vehicle: AIR

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					Male						F	emale		
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:						,							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/49	(0%)
		0/50	(0%)						0/49	(0%)				
Overall Incidence	Total	0/497 (0%	•	Mean		SD 0%		Total	0/495 (,		n 0%	SD	
*Prostate: Adenoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)							
		1/50	(2%)	0/50	(0%)	0/50	(0%)							
		0/49	(0%)	0/50	(0%)	0/50	(0%)							
		0/50	(0%)											
Overall Incidence	Total	1/499 (0.29	•	Mean (SD 0.639								
*Prostate: Carcinoma or Adenoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)							
		1/50	(2%)	0/50	(0%)	0/50	(0%)							
		0/49	(0%)	0/50	(0%)	0/50	(0%)							
		0/50	(0%)											
Overall Incidence	Total	1/499 (0.29	,	Mean (SD 0.639								
*Salivary Glands: Carcinoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/49	(0%)
		0/49	(0%)						0/50	(0%)				
Overall Incidence	Total	0/498 (0%	6)	Mean	0%	SD 0%		Total	0/498 (0%)	Mea	n 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: INHALATION Vehicle: AIR

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Report Date: 06/03/2022

			Male				Female	
*Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/498 (0%)	Mean 0%	SD 0%	Total	0/498 (0%)	Mean 0%	SD 0%
Salivary Glands:								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/498 (0%)	Mean 0%	SD 0%	Total	0/498 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
	.	0/49 (0%)		00.00/	-	0/50 (0%)		OD 00/
Overall Incidence	Total	0/498 (0%)	Mean 0%	SD 0%	Total	0/498 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%

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^{*:} 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

Report Date: 06/03/2022

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Species: RATS Strain: F 344/N Route: INHALATION Vehicle: AIR

			Male				Female	
#Skeletal Muscle: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overell besidence	Tatal	0/50 (0%)	Mann 00/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
O	T-1-1	0/50 (0%)	M 00/	OD 00/	T-1-1	0/50 (0%)	M 00/	OD 00/
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma								
·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	2/499 (0.4%)	Mean 0.4%	SD 0.84%

^{*:} 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: INHALATION Vehicle: AIR

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					Male						F	emale		
#Skeletal Muscle:														
Rhabdomyosarcoma or Rhabdo	omyoma													
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence To	otal	0/499 (0%	•	Mean		SD 0%		Total	2/499 (0	,		0.4%	SD 0.	
#Skeletal Muscle: Sarcoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence To	otal	0/499 (0%	•	Mean		SD 0%		Total	0/499 (•		n 0%	SD	
#Skin: Basal Cell Adenoma														
		1/50	(2%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		, ,		, ,		0/50	(0%)		, ,		, ,
Overall Incidence To	otal	3/499 (0.69	%)	Mean (0.6%	SD 0.979	6	Total	0/499 (0%) ´	Mea	n 0%	SD	0%
#Skin:														
Basal Cell Adenoma or Basosq	liamolie	Tumor Renian												
Basar Sen Adenoma or Basosqu	aamous	1/50	(2%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	1/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(2%)		0/30	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/30	(0 /0)	0/30	(0 /0)		0/49	(0%)	0/30	(0 /0)	0/30	(0 /0)
Overell Incidence	-4-1		` ,	Maar	2.00/	OD 0.070	,	Tatal		` '	N.4	- 00/	0.5	00/
Overall Incidence Te	otal	3/499 (0.69	%)	Mean (J. 0 %	SD 0.979	′ o	Total	0/499 (U%)	ivlea	n 0%	SD	U%

^{*:} 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**

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: AIR

Route: INHALATION

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Report Date: 06/03/2022

Length of Study: CHRONIC

Male **Female** #Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma 1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence 4/499 (0.8%) Mean 0.8% SD 1.03% 0/499 (0%) SD 0% Total Total Mean 0% #Skin: **Basal Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)0/50 (0%)1/50 (0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 **Overall Incidence** 0/499 (0%) SD 0% 1/499 (0.2%) Mean 0.2% SD 0.63% Total Mean 0% Total #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 0/50 (0%)(0%)0/50 0/50 (0%)(0%)0/50 1/50 (2%)(0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 0/50 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence 0/499 (0%) Mean 0% SD 0% 1/499 (0.2%) Mean 0.2% SD 0.63% Total Total #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 4/499 (0.8%) Mean 0.8% SD 1.03% Total 1/499 (0.2%) Mean 0.2% SD 0.63%

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^{*:} 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: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
Skin: Basal or Sq. Cell Carc Adenoma, Papilloma,	inoma, Carcinon Sq Papilloma, Ko	na, Basosq. Tumor (M or eratoacanthoma, Trichoe	B), Basal Cell Adenom pithelioma	na,				
		5/50 (10%)	3/50 (6%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		4/49 (8%)	2/50 (4%)	1/50 (2%)		1/49 (2%)	0/50 (0%)	1/50 (2%)
	T	5/50 (10%)		00.0040/	T	0/50 (0%)		00 4 0 407
verall Incidence	Total	26/499 (5.21%)	Mean 5.22%	SD 3.31%	Total	4/499 (0.8%)	Mean 0.8%	SD 1.04%
Skin: Fibroma								
		3/50 (6%)	2/50 (4%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	4/50 (8%)	4/50 (8%)		3/50 (6%)	0/50 (0%)	1/50 (2%)
		5/49 (10%)	2/50 (4%)	2/50 (4%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)				1/50 (2%)		
verall Incidence	Total	30/499 (6.01%)	Mean 6.02%	SD 2.86%	Total	6/499 (1.2%)	Mean 1.2%	SD 1.93%
Skin:		coma, Myxosarcoma, or F						
,,	,,,,,	3/50 (6%)	4/50 (8%)	6/50 (12%)		1/50 (2%)	2/50 (4%)	0/50 (0%)
		2/50 (4%)	5/50 (10%)	5/50 (10%)		3/50 (6%)	0/50 (0%)	1/50 (2%)
		7/49 (14%)	3/50 (6%)	3/50 (6%)		1/49 (2%)	3/50 (6%)	0/50 (0%)
		6/50 (12%)	` '	,		1/50 (2%)	` '	,
verall Incidence	Total	44/499 (8.82%)	Mean 8.83%	SD 3.34%	Total	12/499 (2.4%)	Mean 2.4%	SD 2.27%
Skin: Fibrosarcoma								
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/49 (4%)	1/50 (2%)	1/50 (2%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	. ,	• •		0/50 (0%)		
		1/30 (2/0)				0/30 (0/8)		

^{*:} 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: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 (0%)2/50 (4%)1/50 (2%)1/50 (2%)2/50 (4%)0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)2/49 (4%)1/50 (2%)1/50 (2%)1/49 (2%)2/50 (4%)0/50 (0%)4/50 (8%)0/50 (0%)Overall Incidence 14/499 (2.81%) Mean 2.81% SD 2.16% 6/499 (1.2%) Mean 1.2% SD 1.69% Total Total #Skin: **Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)1/50 (2%)0/50 (0%)2/50 (4%)0/50 (0%)**Overall Incidence** 3/499 (0.6%) Mean 0.6% SD 1.35% 2/499 (0.4%) Mean 0.4% SD 0.84% Total Total #Skin: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 0/50 (0%)(0%)0/49 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence 0/499 (0%) Mean 0% SD 0% 1/499 (0.2%) Mean 0.2% SD 0.65% Total Total #Skin: Hemangiopericytoma 0/50 (0%)0/50 (0%) 0/50 0/50 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 0/49 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/499 (0%) Mean 0% SD 0% Total 0/499 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

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

Route: INHALATION Vehicle: AIR

Strain: F 344/N Length of Study: CHRONIC

			Male				Female	
#Skin: Hemangiosarcoma								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%	Total	0/499 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma								
		4/50 (8%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		4/49 (8%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	1/50 (2%)
		4/50 (8%)				0/50 (0%)		
Overall Incidence	Total	17/499 (3.41%)	Mean 3.42%	SD 3.43%	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%
#Skin: Lipoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	1/50 (2%)	2/50 (4%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	9/499 (1.8%)	Mean 1.8%	SD 1.48%	Total	0/499 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	(/	()		0/50 (0%)	, ,	` '
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%

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

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^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 06/03/2022

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Species: RATS Strain: F 344/N Route: INHALATION Vehicle: AIR

				Male						F	emale		
#Skin: Melanoma Malignant													
		0/50 (09	,	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (09	,	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49 (0	,	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (09	,					0/50	(0%)				
verall Incidence	Total	0/499 (0%)	Mean		SD 0%		Total	0/499 (. ,		n 0%	SD	
Skin: Myxoma													
-		0/50 (09	%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (09	%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49 (09	%) 0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (09	%)					0/50	(0%)				
Overall Incidence	Total	0/499 (0%)	Mean		SD 0%		Total	0/499 (. ,		n 0%	SD	
Skin: Myxosarcoma													
		0/50 (09	%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (09	%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49 (09	%) 0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (09	%)					0/50	(0%)				
Overall Incidence	Total	0/499 (0%)	Mean		SD 0%		Total	0/499 (,		n 0%	SD	
∜Skin: Neural Crest Tumor													
		0/50 (09	%) 1/50	(2%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50 (0	,	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49 (0	%) 0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (09	%)	, ,				0/50	(0%)				
Overall Incidence	Total	1/499 (0.2%)	Mean	0.2%	SD 0.63%	6	Total	1/499 (0).2%)	Mear	0.2%	SD 0.	.63%

^{*:} 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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

Control Animal Groups Report Date: 06/03/2022
ATION

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				Male						F	emale		
#Skin:													
Neurofibroma or Schw	annoma benign												
		0/50 (0%	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	,	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49 (0%	,	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	1/50	(2%)
		0/50 (0%	o)					0/50	(0%)				
Overall Incidence	Total	0/499 (0%)	Mean		SD 0%		Total	1/499 (0	,		0.2%	SD 0.	
Skin:													
Neurofibrosarcoma or	Schwannoma (m	nalignant or NOS)											
		0/50 (0%) 1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49 (0%	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%))					0/50	(0%)				
Overall Incidence	Total	1/499 (0.2%)	Mean		SD 0.63%		Total	0/499 (,		n 0%	SD (0%
#Skin:													
Neurofibrosarcoma, N	eurofibroma, or \$	Schwannoma (benig	n, malignant or	NOS)									
•	,	0/50 (0%	. •	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	,	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49 (0%	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	1/50	(2%)
		0/50 (0%	s)	,		(0/50	(0%)		,		,
Overall Incidence	Total	1/499 (0.2%)	Mean	0.2%	SD 0.63%	6	Total	1/499 (0	.2%)	Mean	0.2%	SD 0.	63%
Skin:													
Osteosarcoma													
- Coloodii ooma		0/50 (0%	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	,	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49 (0%	,	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	,	(070)	0/30	(0 /0)		0/49	(0%)	0/30	(0 /0)	0/30	(070)
Overall Incidence	Total	`	Mean	00/	SD 0%		Total		` '	Maa	n 0%	SD (00/
veran incluence	างเลเ	0/499 (0%)	iviean	U%	3D 0%		าบเลเ	0/499 (U70)	iviea	II U%	2D (U 7/0

^{*:} 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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

ute: INHALATION

Vehicle: AIR

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Report Date: 06/03/2022

			Male				Female	
#Skin:								
Sarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	4/50 (20/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		1/50 (2%)	0/30 (0 /8)	0/30 (0 /6)		0/50 (0%)	0/30 (0 /0)	0/30 (0 /8)
Overall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%	Total	2/499 (0.4%)	Mean 0.4%	SD 0.85%
#Skin: Schwannoma Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%
#Skin: Schwannoma Malignant								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%	Total	0/499 (0%)	Mean 0%	SD 0%
≄Skin: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	(270)	(-,0)		0/50 (0%)	(-,-)	(-,-)
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%

^{*:} 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: INHALATION

Report Date: 06/03/2022

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Species: RATS Strain: F 344/N

Vehicle: AIR

			Male				Female	
#Skin: Squamous Cell Carcin or Carcinoma	oma, Basal Cell	Carcinoma, Basosquamo	ous Tumor (malignant	or NOS),				
or Garcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	2/499 (0.4%)	Mean 0.4%	SD 0.84%
#Skin: Squamous Cell Papillo								
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	1/50 (2%)	1/50 (2%)		1/49 (2%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	5/499 (1%)	Mean 1%	SD 1.05%	Total	1/499 (0.2%)	Mean 0.2%	SD 0.65%
#Skin: Squamous Cell Papillo	ma or Papilloma	1						
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	1/50 (2%)	1/50 (2%)		1/49 (2%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	5/499 (1%)	Mean 1%	SD 1.05%	Total	1/499 (0.2%)	Mean 0.2%	SD 0.65%
#Skin:		Squamous Cell Carcinom					•••••	•••••
Squamous Gen Fapino	ilia, Fapiliollia, s	4/50 (8%)	2/50 (4%)	a 1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		4/49 (8%)	2/50 (4%)	1/50 (2%)		1/49 (2%)	0/50 (0%)	1/50 (2%)
		5/50 (10%)	2/00 (4/0)	1700 (270)		0/50 (0%)	0/00 (0/0)	1,00 (2,70)
Overall Incidence	Total	22/499 (4.41%)	Mean 4.42%	SD 3.26%	Total	3/499 (0.6%)	Mean 0.6%	SD 0.97%

^{*:} 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: INHALATION

Page: 191 Report Date: 06/03/2022

Species: RATS Strain: F 344/N

Vehicle: AIR

					Male						F	emale		
#Skin:														,
Squamous Cell Papilloma	ı, Papilloma,	or Keratoacanthom	na											
		4/50 (8	8%)	2/50	(4%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50 (4	4%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		4/49 (8	8%)	2/50	(4%)	1/50	(2%)		1/49	(2%)	0/50	(0%)	1/50	(2%)
		5/50 (10	0%)						0/50	(0%)				
Overall Incidence	Total	22/499 (4.41%)	•	Mean 4.		SD 3.26%		Total	2/499 (0	,		0.4%	SD 0.	
Skin:														
Trichoepithelioma		0/=0 //	201)	a /= a	(00()	. /= 0	(221)		0/=0	(00()		(001)	0/=0	(001)
		,	0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		,	0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		,	0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0	0%)						0/50	(0%)				
verall Incidence	Total	1/499 (0.2%)		Mean 0	.2%	SD 0.63%	%	Total	0/499 ((0%)	Mea	n 0%	SD	0%
Skin: Sebaceous Gland: Adenoma														
		1/50 (2	2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50 (2	2%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/49 (2	2%)	1/50	(2%)	3/50	(6%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0	0%)		, ,		` ,		0/50	(0%)		` ,		` ,
Overall Incidence	Total	8/499 (1.6%)	,	Mean 1		SD 1.849		Total	0/499 ((0%)		n 0%	SD	
Skin: Sebaceous Gland:														
		0/50 (0	0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		,	0%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		,	0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		,	0%) 0%)	0/30	(070)	0/30	(0 /0)		0/49	(0%)	0/30	(0 /0)	0/30	(0 /0)
Overall Incidence	Total	•	0 /0)	Moon	00/	SD 00/		Total		` '	Maan	0.20/	SD 0.	620/
overali incidence	Total	0/499 (0%)		Mean	U-70	SD 0%		Total	1/499 (0	J. Z 70)	iviear	0.2%	3D 0.	.03%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

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Report Date: 06/03/2022

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

Route: INHALATION Vehicle: AIR

Strain: F 344/N Length of Study: CHRONIC

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	1/50 (2%)	3/50 (6%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	8/499 (1.6%)	Mean 1.6%	SD 1.84%	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%
Spleen: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%	Total	0/497 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	1/497 (0.2%)	Mean 0.2%	SD 0.65%
Spleen: Leiomyosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	()	(0.0)		0/50 (0%)	()	(-/-/
Overall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%	Total	0/497 (0%)	Mean 0%	SD 0%
		17433 (0.270)						OD 070

^{*:} 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: INHALATION Vehicle: AIR

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					Male						F	emale		
#Stomach, Forestomach: Leiomyosarcoma		,												
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/499 (0%	o)	Mean		SD 0%		Total	0/499 (0%)	Mea	n 0%	SD	0%
#Stomach, Forestomach: Lipoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/499 (0%	•	Mean		SD 0%		Total	0/499 (n 0%	SD	
#Stomach, Forestomach: Schwannoma Malignant														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/499 (0%	,	Mean		SD 0%		Total	0/499 (,		n 0%	SD	
#Stomach, Forestomach:														
Squamous Cell Carcinoma	or Papilloma	a Squamous												
-	•	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		` '		` '		0/50	(0%)	•	` '	-	` '
Overall Incidence	Total	0/499 (0%	` '	Mean	Λ0/	SD 0%		Total	0/499 (` '	Moo	n 0%	SD	00/

^{*:} 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: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Stomach**, Forestomach: **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/499 (0%) Mean 0% SD 0% 0/499 (0%) Mean 0% SD 0% Total #Stomach, Glandular: Carcinoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/499 (0%) Mean 0% SD 0% 0/499 (0%) Mean 0% SD 0% Total Total #Stomach, Glandular: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)0/50 (0%)(0%)(0%)(0%)0/50 (0%)0/50 0/50 0/50 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence 0/499 (0%) Mean 0% SD 0% 0/499 (0%) Mean 0% SD 0% Total Total #Stomach, Glandular: Leiomyosarcoma 0/50 0/50 (0%)1/50 (2%) (0%)0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 0/49 (0%)0/50 0/50 0/50 (0%)(0%)(0%)(0%)0/50 (0%)0/50 (0%)Overall Incidence Total 1/499 (0.2%) Mean 0.2% SD 0.63% Total 0/499 (0%) Mean 0% SD 0%

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^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
#Stomach, Glandular: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/499 (0.2%)	Mean 0.2%	SD 0.63%	Total	0/499 (0%)	Mean 0%	SD 0%
*Testes: Adenoma								
		36/50 (72%)	40/50 (80%)	38/50 (76%)				
		40/50 (80%)	42/50 (84%)	33/50 (66%)				
		38/49 (78%)	41/50 (82%)	41/50 (82%)				
		36/50 (72%)						
Overall Incidence	Total	385/499 (77.15%)	Mean 77.16%	SD 5.67%				
*Thymus: Sarcoma								
		0/49 (0%)	0/50 (0%)	0/48 (0%)		0/48 (0%)	0/48 (0%)	0/45 (0%)
		0/47 (0%)	0/49 (0%)	0/42 (0%)		0/45 (0%)	0/47 (0%)	0/50 (0%)
		0/47 (0%)	0/47 (0%)	0/49 (0%)		0/46 (0%)	0/45 (0%)	0/47 (0%)
		0/49 (0%)				0/49 (0%)		
Overall Incidence	Total	0/477 (0%)	Mean 0%	SD 0%	Total	0/470 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign								
		0/49 (0%)	0/50 (0%)	0/48 (0%)		0/48 (0%)	0/48 (0%)	0/45 (0%)
		0/47 (0%)	0/49 (0%)	0/42 (0%)		0/45 (0%)	0/47 (0%)	1/50 (2%)
		0/47 (0%)	0/47 (0%)	0/49 (0%)		0/46 (0%)	0/45 (0%)	0/47 (0%)
		0/49 (0%)		. ,		0/49 (0%)	. ,	
Overall Incidence	Total	0/477 (0%)	Mean 0%	SD 0%	Total	1/470 (0.21%)	Mean 0.2%	SD 0.63%

^{*:} 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

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male Female *Thymus: **Thymoma Malignant** 0/49 (0%)0/50 (0%)0/48 (0%)0/48 (0%)0/48 (0%)0/45 (0%)0/47 (0%)0/49(0%)0/42 (0%)0/45 (0%)0/47 (0%)0/50 (0%)0/47 (0%)0/47 (0%)1/49 (2%)0/46 (0%)0/45 (0%)0/47 (0%)0/49 (0%)0/49 (0%)Overall Incidence Total 1/477 (0.21%) Mean 0.2% SD 0.65% 0/470 (0%) Mean 0% SD 0% Total *Thymus: Thymoma: Benign, Malignant, NOS 0/49 (0%)0/50 (0%)0/48 (0%)0/48 (0%)0/48 (0%)0/45 (0%)0/47 (0%)(0%)(0%)1/50 0/49 0/42 0/45 (0%)0/47 (0%)(2%)0/47 (0%)0/47 (0%)1/49 (2%)0/46 (0%)0/45 (0%)0/47 (0%)0/49 (0%)0/49 (0%)**Overall Incidence** 1/477 (0.21%) Mean 0.2% SD 0.65% 1/470 (0.21%) Mean 0.2% SD 0.63% Total Total *Thyroid Gland: C-Cell: Adenoma 3/50 7/50 (14%)2/50 (4%)(10%)0/50 (0%)(6%)3/50 (6%)5/50 5/49 (10%)3/49 (6%) 2/50 (4%)1/50 (2%)6/47 (13%)3/50 (6%)9/46 (20%)3/50 (6%)7/50 (14%)4/47 (9%)8/49 (16%)3/49 (6%)1/50 (2%)2/50 (4%)Overall Incidence 41/494 (8.3%) Mean 8.39% SD 5.86% 36/492 (7.32%) Mean 7.37% SD 4.71% Total Total *Thyroid Gland: C-Cell: Carcinoma 1/50 0/50 (0%)1/50 (2%)3/50 (2%)(2%)0/50 (0%)(6%)1/50 1/49 (2%)2/50 (4%)0/49 (0%)3/47 (6%)1/50 (2%)1/50 (2%)2/50 3/47 1/49 1/46 (2%)1/50 (2%)(4%)(6%)2/49 (4%)(2%)(0%)0/50 1/50 (2%)Overall Incidence Total 9/494 (1.82%) Mean 1.82% SD 1.48% Total 16/492 (3.25%) Mean 3.29% SD 2.26%

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^{*:} 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

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male Female *Thyroid Gland: C-Cell: Carcinoma or Adenoma 3/50 (6%)7/50 (14%)3/50 (6%)3/50 (6%)8/50 (16%)1/50 (2%)6/49 (12%)3/50 (6%)3/49 (6%)8/47 (17%)4/50 (8%)3/50 (6%)10/46 (22%)4/50 (8%) 9/50 (18%)7/47 (15%)9/49 (18%)4/49 (8%)3/50 1/50 (2%)(6%)Overall Incidence 49/494 (9.92%) Mean 10.01% SD 6.27% 50/492 (10.16%) Mean 10.24% SD 5.75% Total Total *Thyroid Gland: Follicular Cell: Adenoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)(0%)0/49 (0%)0/50 0/47 (0%)1/50 (2%)0/50 (0%)0/46 (0%)0/50 (0%)0/50 (0%)0/47 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/50 (0%)Overall Incidence 1/494 (0.2%) Mean 0.2% SD 0.63% 1/492 (0.2%) Mean 0.2% SD 0.63% Total Total *Thyroid Gland: Follicular Cell: Carcinoma 2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)0/49 (0%)(2%)(0%)(2%)0/50 1/50 0/49 1/47 0/50 (0%)(0%)0/46 (0%)1/50 (2%)1/50 (2%)1/47 (2%)0/49 (0%)0/49 (0%)0/50 (0%)2/50 (4%)Overall Incidence Total 5/494 (1.01%) Mean 1% SD 1.41% 4/492 (0.81%) Mean 0.83% SD 1.42% Total *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma 0/50 (0%)(2%)(0%)0/50 0/50 2/50 (4%)1/50 0/50 (0%)(0%)0/49(0%)1/50 (2%)0/49 (0%)1/47 (2%)1/50 (2%)0/50 (0%)0/46 1/50 0/49 (0%)1/50 (2%)(2%)1/47 (2%)0/49 (0%)(0%)0/50 (0%)2/50 (4%)Overall Incidence Total 6/494 (1.21%) Mean 1.2% SD 1.4% Total 5/492 (1.02%) Mean 1.03% SD 1.44%

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^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
#Tissue NOS: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%
#Tissue NOS: Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%
#Tissue NOS: Paraganglioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%
#Tissue NOS: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (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: INHALATION Vehicle: AIR

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					Male						F	emale		
#Tissue NOS: Schwannoma Malignant														
_		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/499 (0%)	•	Mean		SD 0%		Total	0/499 (•		n 0%	SD	
#Tongue: Liposarcoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/499 (0%)		Mean		SD 0%		Total	0/499 (0%)	Mea	n 0%	SD	0%
#Tongue: Squamous Cell Carcinoma														
-		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		, ,		, ,		0/50	(0%)		, ,		, ,
Overall Incidence	Total	0/499 (0%)) ` ´	Mean	0%	SD 0%		Total	1/499 (0	.2%)	Mear	0.2%	SD 0.	.63%
#Tongue:														
Squamous Cell Carcinoma	or Papillom	•												
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	2/50	(4%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/499 (0.2%	6)	Mean ().2%	SD 0.639	%	Total	2/499 (0	.4%)	Mear	0.4%	SD 1.	.26%

^{*:} 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: INHALATION Vehicle: AIR

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					Male				Female					
#Tongue: Squamous Cell Papilloma														
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/499 (0.29	%)	Mean (0.2%	SD 0.639	%	Total	1/499 (0	.2%)	Mear	0.2%	SD 0.	.63%
#Tooth: Odontogenic Tumor														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/499 (0%	•	Mean		SD 0%		Total	0/499 (,		n 0%	SD	
*Urinary Bladder: Carcinoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/48	(0%)	0/50	(0%)	0/50	(0%)		0/48	(0%)	0/49	(0%)	0/49	(0%)
		0/49	(0%)		` ,		• ,		1/50	(2%)		. ,		` ,
Overall Incidence	Total	0/497 (0%	,	Mean		SD 0%		Total	1/495 (0	,		0.2%	SD 0.	
*Urinary Bladder: Carcinoma or Papilloma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		1/48	(2%)	0/50	(0%)	0/50	(0%)		1/48	(2%)	0/49	(0%)	1/49	(2%)
		0/49	(0%)		` ,		. ,		1/50	(2%)		. ,		` '
			,	Mean 0		SD 0.869				61%)		0.61%		.99%

^{*:} 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: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/49 (0%)1/49 (2%)(0%)0/49 0/50 (0%)Overall Incidence Total 0/497 (0%) Mean 0% SD 0% Total 2/495 (0.4%) Mean 0.4% SD 0.85% *Urinary Bladder: **Papilloma** 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(2%)(0%)(0%)0/50 (0%)0/50 1/50 0/50 0/49 0/50 (0%)1/48 (2%)0/50 (0%)0/50 (0%)1/48 (2%)0/49 (0%)1/49 (2%)0/49 (0%)0/50 (0%)**Overall Incidence** 2/497 (0.4%) Mean 0.41% SD 0.86% 2/495 (0.4%) Mean 0.41% SD 0.87% Total Total *Urinary Bladder: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)(0%)0/50 (0%)0/50 0/48 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/49 (0%)0/49 (0%)0/49 (0%)0/50 (0%)Overall Incidence Total 0/497 (0%) Mean 0% SD 0% Total 0/495 (0%) Mean 0% SD 0% #Uterus: Adenoma (0%)0/50 (0%)1/50 (2%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 0/50 (0%)(0%)0/50 (0%)**Overall Incidence** Total 1/499 (0.2%) Mean 0.2% SD 0.63%

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^{*:} 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: INHALATION Vehicle: AIR

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r	flale			F	emale		
EUterus: Carcinoma							
our office and office		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		()		()
Overall Incidence	Total	0/499 (Mea	n 0%	SD	0%
Uterus:							
Hemangioma							
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0,00	(0,0)	0,00	(0,0)
Overall Incidence	Total	1/499 (0	. ,	Mear	0.2%	SD 0	63%
		•					
Uterus:							
Leiomyoma							
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)				
Overall Incidence	Total	0/499 (•		n 0%	SD	
Uterus:							
Leiomyosarcoma							
•		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	1/50	(2%)	0/50	(0%)
		0/73					
		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: INHALATION Vehicle: AIR

Page: 203

	Male		Female	
#Uterus: Polyp Stromal				
		13/50 (26%)	7/50 (14%)	9/50 (18%)
		10/50 (20%)	12/50 (24%)	6/50 (12%)
		15/49 (31%)	5/50 (10%)	10/50 (20%)
		6/50 (12%)		
Overall Incidence	Total	93/499 (18.64%)	Mean 18.66%	SD 6.79%
#Uterus: Sarcoma				
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal				
		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	` ,	` '
Overall Incidence	Total	3/499 (0.6%)	Mean 0.6%	SD 0.97%
#Uterus: Sarcoma Stromal or Polyp Stromal				
outonia of ottorial		14/50 (28%)	7/50 (14%)	9/50 (18%)
		10/50 (20%)	13/50 (26%)	6/50 (12%)
		15/49 (31%)	5/50 (10%)	11/50 (22%)
		6/50 (12%)	0/00 (10/0)	11/00 (22/0)
Overall Incidence	Total	, ,	Mean 19.26%	SD 7.3%
overall illulative	Total	96/499 (19.24%)	WEATT 19.20%	3D 1.3%

^{*:} 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: INHALATION Vehicle: AIR

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Male				F	emale		
Uterus: Schwannoma Malignant							
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)				
Overall Incidence	Total	0/499 (•		n 0%	SD	
Vagina: Leiomyoma							
•		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)		. ,		` ,
Overall Incidence	Total	0/499 (Mea	n 0%	SD	0%
Vagina: Leiomyosarcoma							
•		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)				, ,
Overall Incidence	Total	1/499 (0	.2%)		0.2%	SD 0.	.63%
Vagina: Polyp				• • • • • • • • • • • • • • • • • • • •			
. M.		2/50	(4%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/30	(0/0)	0/00	(0/0)
		0/49 0/50	(0%) (0%)	0/30	(070)	0/30	(076)

^{*:} 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: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Vagina: Sarcoma								
						0/50 (0%)	1/50 (2%)	0/50 (0%)
						0/50 (0%)	1/50 (2%)	0/50 (0%)
						0/49 (0%)	1/50 (2%)	0/50 (0%)
						0/50 (0%)		
Overall Incidence					Total	3/499 (0.6%)	Mean 0.6%	SD 0.97%
#Zymbal's Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/499 (0%)	Mean 0%	SD 0%	Total	0/499 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	1/50 (2%)	0/50 (0%)		2/49 (4%)	2/50 (4%)	1/50 (2%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	3/499 (0.6%)	Mean 0.6%	SD 0.97%	Total	8/499 (1.6%)	Mean 1.61%	SD 1.59%
#Zymbal's Gland: Carcinoma or Adenoma			•••••	•••••				•••••
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	1/50 (2%)	0/50 (0%)		2/49 (4%)	2/50 (4%)	1/50 (2%)
		0/50 (0%)	(=70)	3,33 (3,0)		0/50 (0%)	_, ~~ (. , ~)	30 (= /0)
Overall Incidence	Total	3/499 (0.6%)	Mean 0.6%	SD 0.97%	Total	8/499 (1.6%)	Mean 1.61%	SD 1.59%
veran incluence	i Olai	3/433 (0.070)	1VICALL 0.070	OD 0.31 /0	i Olai	0/400 (1.070)	MEAN 1.01/0	0/ פני.ו סי

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

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^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Strain: F 344/N Length of Study: CHRONIC

Contract/Lab: All Laboratories

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	058813803	08/16/99	729	50(3)	22(681)	501.7	Benzophenone
Battelle Columbus Laboratory	055611103	09/08/97	731	100(3)	60(689)	487.9	trans-Cinnamaldehyde
Battelle Columbus Laboratory	055634803	06/06/96	726	100(3)	52(681)	491.2	Citral
Battelle Columbus Laboratory	058812003	12/18/95	729	50(3)	24(659)	496.8	p,p'-Dichlorodiphenyl sulfone
Southern Research Institute	059201205	07/15/98	729	50(3)	35(704)	446.9	2-Methylimidazole
Southern Research Institute	059201305	01/20/00	730	50(3)	31(702)	448.0	4-Methylimidazole
Southern Research Institute	050520308	02/08/96	729	60(3)	39(698)	447.3	o-Nitrotoluene
Southern Research Institute	050520507	11/28/95	729	50(3)	31(697)	443.8	p-Nitrotoluene
					Female		
Battelle Columbus Laboratory	058813803	08/17/99	729	50(5)	32(688)	348.7	Benzophenone
Battelle Columbus Laboratory	055611103	09/09/97	735	100(5)	70(706)	337.8	trans-Cinnamaldehyde
Battelle Columbus Laboratory	055634803	06/07/96	732	100(5)	75(705)	335.0	Citral
Battelle Columbus Laboratory	058812003	12/19/95	730	50(5)	36(694)	330.5	p,p'-Dichlorodiphenyl sulfone
Southern Research Institute	059201205	07/15/98	734	50(5)	40(707)	320.6	2-Methylimidazole
Southern Research Institute	059201305	01/20/00	735	50(5)	40(702)	311.3	4-Methylimidazole
Southern Research Institute	050520308	02/08/96	730	60(5)	47(713)	299.3	o-Nitrotoluene
Southern Research Institute	050520507	11/28/95	729	50(5)	39(702)	295.2	p-Nitrotoluene

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: **Benign Tumors** 49/50 (98%)99/100 (99%)97/100 (97%)42/50 (84%)78/100 (78%)78/100 (78%)42/50 (84%)49/50 (98%)50/50 (100%) 37/50 (74%)43/50 (86%)(96%)60/60 (100%) 49/50 (98%)47/60 (78%)33/50 (66%)Mean 96.75% **Overall Incidence** Total 495/510 (97.06%) SD 5.26% Total 406/510 (79.61%) Mean 80.04% SD 8.87% #All Organs: **Malignant Tumors** 33/50 (66%)57/100 (57%)76/100 (76%)20/50 (40%)39/100 (39%)30/100 (30%)(68%)19/50 (38%)34/50 22/50 (44%)22/50 (44%)16/50 (32%)19/50 (38%)37/60 (62%)33/50 (66%)24/60 (40%)22/50 (44%)**Overall Incidence** Total 314/510 (61.57%) Mean 60.33% SD 11.43% Total 189/510 (37.06%) Mean 37.62% SD 4.53% #All Organs: **Malignant and Benign Tumors** (99%)50/50 (100%) 100/100 (100%) 99/100 46/50 (92%)92/100 (92%)92/100 (92%)49/50 (98%)50/50 (100%) 50/50 (100%) 43/50 (86%)45/50 (90%)48/50 (96%)60/60 (100%) 50/50 (100%) (90%)43/50 54/60 (86%)**Overall Incidence** 508/510 (99.61%) Mean 99.63% SD 0.74% 463/510 (90.78%) Mean 90.5% SD 3.34% Total Total **#All Organs:** Hemangioma 0/50 (0%)0/100 (0%)1/100 (1%)0/100 (0%)2/100 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)2/50 (4%)0/60 (0%)1/50 (2%)**Overall Incidence** Total 3/510 (0.59%) Mean 0.62% SD 1.41% Total 3/510 (0.59%) Mean 0.5% SD 0.93%

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^{*:} 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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: Hemangiosarcoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)(0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)1/60 (2%)0/50 (0%)0/60 (0%)0/50 (0%)Mean 0.71% Mean 0% **Overall Incidence** Total 3/510 (0.59%) SD 0.98% Total 0/510 (0%) SD 0% **#All Organs:** Hemangiosarcoma or Hemangioma 0/50 (0%)0/100 (0%)1/100 (1%)0/50 (0%)0/100 (0%)2/100 (2%)(2%)(2%)0/50 0/50 1/50 1/50 (0%)0/50 (0%)0/50 (0%)(0%)1/60 (2%)2/50 (4%)0/60 (0%)1/50 (2%)Mean 0.5% **Overall Incidence** Total 6/510 (1.18%) Mean 1.33% SD 1.39% Total 3/510 (0.59%) SD 0.93% #All Organs: **Histiocytic Sarcoma** 0/50 0/100 0/100 0/100 (0%)(0%)(0%)0/50 (0%)0/100 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)(2%)(0%)1/60 0/50 (0%)0/60 0/50 (0%)**Overall Incidence** Total 1/510 (0.2%) Mean 0.21% SD 0.59% 2/510 (0.39%) Mean 0.5% SD 1.41% Total **#All Organs:** Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated (54%)(40%)(68%)(21%)(24%)27/50 40/100 68/100 19/50 (38%)21/100 24/100 27/50 (54%)15/50 (30%)15/50 (30%)8/50 (16%)6/50 (12%)9/50 (18%)30/60 (50%)24/50 (48%)21/60 (35%)13/50 (26%)**Overall Incidence** Total 246/510 (48.24%) Mean 46.75% SD 12.96% Total 121/510 (23.73%) Mean 23.75% SD 9.05%

^{*:} 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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)1/100 (1%)1/100 (1%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)2/50 (4%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 2/510 (0.39%) Mean 0.5% SD 1.41% Total 2/510 (0.39%) Mean 0.25% SD 0.46% #All Organs: Mesothelioma: Benign 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/60 (0%)0/50 0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/510 (0%) Mean 0% SD 0% #All Organs: Mesothelioma: Benign, Malignant, NOS 2/50 4/100 0/100 (4%)5/100 (5%)(4%)0/50 (0%)0/100 (0%)(0%)2/50 (4%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/60 (3%)(0%)5/50 (10%)0/60 0/50 (0%)**Overall Incidence** 22/510 (4.31%) Mean 4.29% SD 2.75% Total 0/510 (0%) Mean 0% SD 0% Total **#All Organs:** Mesothelioma: Malignant 2/50 (4%)5/100 (5%)4/100 (4%)0/50 (0%)0/100 (0%)0/100 (0%)2/50 (4%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/60 (3%)5/50 (10%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 22/510 (4.31%) Mean 4.29% SD 2.75% Total 0/510 (0%) Mean 0% SD 0%

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^{*:} 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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Control Animal Groups Report Date: 06/03/2022 RAL

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			Male			Female				
#All Organs: Osteoma										
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 2/50 (4%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		
Overall Incidence	Total	2/510 (0.39%)	0/50 (0%) Mean 0.5%	SD 1.41%	Total	0/510 (0%)	0/50 (0%) Mean 0%	SD 0%		
#All Organs: Osteosarcoma										
		1/50 (2%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	1/100 (1%)	0/100 (0%)		
		0/50 (0%) 1/60 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/60 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	2/510 (0.39%)	Mean 0.46%	SD 0.85%	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%		
#All Organs: Osteosarcoma or Osteor	ma	•••••								
		1/50 (2%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	1/100 (1%)	0/100 (0%)		
		0/50 (0%) 1/60 (2%)	2/50 (4%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/60 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	4/510 (0.78%)	Mean 0.96%	SD 1.48%	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%		
*Adrenal Cortex: Adenoma		•••••				•••••				
		0/50 (0%)	0/100 (0%)	2/100 (2%)		0/50 (0%)	1/100 (1%)	2/100 (2%)		
		0/50 (0%) 0/60 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		2/50 (4%) 2/60 (3%)	5/50 (10%) 0/50 (0%)	1/49 (2%)		
Overall Incidence	Total	3/510 (0.59%)	Mean 0.5%	SD 0.93%	Total	13/509 (2.55%)	Mean 2.8%	SD 3.24%		

^{*:} 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

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Report Date: 06/03/2022

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

Length of Study: CHRONIC

			Male				Female	
*Adrenal Cortex: Carcinoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/60 (0%)	0/50 (0%)	00.00/	-	0/60 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Ganglioneuroma								
		0/50 (0%)	1/100 (1%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/48 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/49 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%	Total	0/505 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Ben	nign							
-		8/50 (16%)	5/100 (5%)	10/100 (10%)		0/50 (0%)	1/100 (1%)	3/99 (3%)
		4/50 (8%)	8/50 (16%)	8/50 (16%)		2/50 (4%)	0/49 (0%)	2/48 (4%)
		2/60 (3%)	3/50 (6%)			2/60 (3%)	2/49 (4%)	
Overall Incidence	Total	48/510 (9.41%)	Mean 10.04%	SD 5.31%	Total	12/505 (2.38%)	Mean 2.45%	SD 1.82%
*Adrenal Medulla: Pheochromocytoma Con								
·		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	1/100 (1%) 2/50 (4%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	1/100 (1%) 0/49 (0%) 0/49 (0%)	0/99 (0%) 0/48 (0%)
Overall Incidence	Total	3/510 (0.59%)	Mean 0.62%	SD 1.41%	Total	1/505 (0.2%)	Mean 0.12%	SD 0.35%

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^{*:} 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**

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: FEED

Route: ORAL

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Report Date: 06/03/2022

Length of Study: CHRONIC

Male **Female** *Adrenal Medulla: **Pheochromocytoma Malignant** 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)2/100 (2%)0/99 (0%)(4%)2/50 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)(2%)2/60 (3%)0/50 (0%)0/60 (0%)0/49 (0%)**Overall Incidence** Total 4/510 (0.78%) Mean 0.92% SD 1.71% Total 3/505 (0.59%) Mean 0.51% SD 0.95% *Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 5/100 (5%)11/100 (11%)0/50 (0%)4/100 (4%)3/99 (3%)(16%)6/50 (12%)8/50 (16%)10/50 (20%)2/50 (4%)0/49 (0%)3/48 (6%)4/60 (7%)3/50 (6%)2/60 (3%)2/49 (4%)**Overall Incidence** Total 55/510 (10.78%) Mean 11.58% SD 5.46% Total 16/505 (3.17%) Mean 3.09% SD 2.13% #Blood Vessel: Osteosarcoma 0/50 0/100 0/100 (0%)(0%)(0%)0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/60 0/50 (0%)0/60 0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% 0/510 (0%) Mean 0% SD 0% Total #Bone: Chordoma 1/50 (2%)0/100 (0%)0/100 (0%)0/100 0/100 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** 1/510 (0.2%) Mean 0.25% SD 0.71% Total 0/510 (0%) Mean 0% SD 0% Total

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^{*:} 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: ORAL Vehicle: FEED

: ORAL

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			Male				Female	
#Bone: Osteoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%) 0/60 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/60 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/510 (0.39%)	0/50 (0%) Mean 0.5%	SD 1.41%	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%
#Bone: Osteosarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	1/100 (1%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/60 (2%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.21%	SD 0.59%	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%
#Bone: Osteosarcoma or Osteoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	1/100 (1%)	0/100 (0%)
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/60 (2%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	3/510 (0.59%)	Mean 0.71%	SD 1.45%	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%
*Brain: Astrocytoma Malignant								
, -		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	1/100 (1%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	1/50 (2%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	3/510 (0.59%)	Mean 0.62%	SD 0.92%

^{*:} 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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Brain: **Glioma Malignant** 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)(0%) 1/50 (2%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 1/510 (0.2%) Mean 0.25% SD 0.71% Total 0/510 (0%) SD 0% *Brain: **Granular Cell Tumor Benign** 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/510 (0%) Mean 0% SD 0% *Brain: **Granular Cell Tumor Malignant** 0/100 0/100 0/50 (0%)0/100 (0%)(0%)0/50 (0%)0/100 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/60 1/50 (2%)0/60 0/50 (0%)**Overall Incidence** Total 1/510 (0.2%) Mean 0.25% SD 0.71% 0/510 (0%) Mean 0% SD 0% Total *Brain: Medulloblastoma Mal 0/50 (0%)0/100 (0%)0/100 (0%)0/100 0/100 0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/510 (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: ORAL Vehicle: FEED Report Date: 06/03/2022

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			Male				Female	
*Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	1/100 (1%) 0/50 (0%)
		0/60 (0%)	0/50 (0%)	0/00 (0/0)		0/60 (0%)	0/50 (0%)	0/30 (0/0)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%
*Brain:							•••••	
Meningioma: Benign, Ma	lignant, NOS							
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	1/100 (1%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	-	0/60 (0%)	0/50 (0%)	OD 00/	-	0/60 (0%)	0/50 (0%)	00.0050/
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%
*Brain:								
Oligodendroglioma Benig	gn							
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
*Brain:								
Oligodendroglioma Malig	Juani	0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	0,00 (0,70)		0/60 (0%)	0/50 (0%)	3,33 (370)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%

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^{*:} 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: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Brain: Oligodendroglioma, Glioma, or Astrocytoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)1/100 (1%)0/100 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)1/50 (2%)**Overall Incidence** Total 1/510 (0.2%) Mean 0.25% SD 0.71% Total 3/510 (0.59%) Mean 0.62% SD 0.92% *Brain: Sarcoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/510 (0%) Mean 0% SD 0% *Clitoral/Preputial Gland: Adenoma 0/50 7/100 7/100 (0%)(7%)(7%)3/50 (6%)4/99 (4%)15/98 (15%)3/50 (6%)0/50 (0%)2/50 (4%)1/47 (2%)5/50 (10%)8/50 (16%)(3%)(20%)2/60 2/50 (4%)12/59 7/50 (14%)**Overall Incidence** 23/510 (4.51%) Mean 3.92% SD 2.79% 55/503 (10.93%) Mean 10.98% SD 6.47% Total Total *Clitoral/Preputial Gland: Carcinoma 1/50 (2%)4/100 (4%)1/100 (1%)(2%)9/99 (9%)1/98 (1%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)0/47 (0%)3/50 (6%)2/50 (4%)2/60 (3%)2/50 (4%)2/59 (3%)2/50 (4%)SD 2.89% **Overall Incidence** Total 10/510 (1.96%) Mean 1.79% SD 1.79% Total 20/503 (3.98%) Mean 3.69%

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^{*:} 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: ORAL Vehicle: FEED **Page:** 217

Report Date: 06/03/2022

			Male				Female	
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		1/50 (2%)	11/100 (11%)	8/100 (8%)		4/50 (8%)	13/99 (13%)	16/98 (16%)
		3/50 (6%)	0/50 (0%)	2/50 (4%)		1/47 (2%)	8/50 (16%)	10/50 (20%)
		4/60 (7%)	4/50 (8%)			14/59 (24%)	8/50 (16%)	
Overall Incidence	Total	33/510 (6.47%)	Mean 5.71%	SD 3.56%	Total	74/503 (14.71%)	Mean 14.41%	SD 6.77%
Clitoral/Preputial Gland: Fibrosarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/98 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/59 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/503 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/98 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/59 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/503 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Sarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/98 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/59 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/503 (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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Clitoral/Preputial Gland: Schwannoma Malignant								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/98 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/60 (0%) 1/510 (0.2%)	1/50 (2%) Mean 0.25%	SD 0.71%	Total	0/59 (0%) 0/503 (0%)	0/50 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		1/50 (2%)	0/99 (0%)	0/98 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	1/50 (2%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/59 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	2/503 (0.4%)	Mean 0.5%	SD 0.93%
#Ear: Neural Crest Tumor								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
#Eye: Amelanotic Melanoma, Ben								
,	-	0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

#Eye:

#Eye:

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Melanoma Benign

Melanoma Malignant

Overall Incidence

Overall Incidence

#Harderian Gland: Adenoma

Overall Incidence

#Harderian Gland: Carcinoma

Overall Incidence

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** 0/50 (0%)0/100 (0%)0/100 (0%)1/50 (2%)0/100 (0%)0/100 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/510 (0%) Mean 0% SD 0% Total 1/510 (0.2%) Mean 0.25% SD 0.71% 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/60 (0%)1/50 (2%)0/60 (0%)0/50 (0%)Mean 0.25% 1/510 (0.2%) SD 0.71% Total 0/510 (0%) Mean 0% SD 0% 0/50 0/100 0/100 0/100 (0%)(0%)(0%)0/50 (0%)0/100 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/60 0/50 (0%)0/60 0/50 (0%)0/510 (0%) Mean 0% SD 0% 0/510 (0%) Mean 0% SD 0% Total

Total

0/50

0/50

0/60

0/510 (0%)

(0%)

(0%)

(0%)

Page: 219

0/100

0/50

0/50

(0%)

(0%)

(0%)

Mean 0%

0/100

0/50

SD 0%

(0%)

(0%)

Report Date: 06/03/2022

Total

Total

Total

Total

0/50

0/50

0/60

0/510 (0%)

(0%)

(0%)

(0%)

0/100

0/50

0/50

Mean 0%

(0%)

(0%)

(0%)

0/100

0/50

SD 0%

(0%)

(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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Harderian Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%
*Heart: Schwannoma Benign								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%
*Heart: Schwannoma Malignant								
•		1/50 (2%)	2/100 (2%)	0/100 (0%)		1/50 (2%)	0/100 (0%)	1/100 (1%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	1/50 (2%)	
Overall Incidence	Total	3/510 (0.59%)	Mean 0.5%	SD 0.93%	Total	3/510 (0.59%)	Mean 0.62%	SD 0.92%
#Intestine Large: Colon/Rect Adenoma				•••••			•••••	
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Intestine Large: Colon/R Carcinoma	lectum:							
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	1/100 (1%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%	Total	0/510 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/R Carcinoma or Adenoma	lectum:							
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	1/100 (1%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%	Total	0/510 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/R Leiomyosarcoma								
·		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/R Polyp Adenomatous	lectum:							
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%)	1/100 (1%) 0/50 (0%)
Overall Incidence	Total	1/60 (2%) 1/510 (0.2%)	0/50 (0%) Mean 0.21%	SD 0.59%	Total	0/60 (0%) 1/510 (0.2%)	0/50 (0%) Mean 0.12%	SD 0.35%

^{*:} 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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male				Female	
#Intestine Small: Jejunum: Carcinoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma								
		0/50 (0%)	0/100 (0%)	1/100 (1%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%	Total	0/510 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Sarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	1/100 (1%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%
#Intestine Small: Site Unspec Carcinoma	cified:							
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Small: Site Unspecified: Carcinoma or Adenoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/510 (0%) SD 0% #Intestine Small: Site Unspecified: Leiomyoma 0/50 (0%)0/100 (0%)1/100 (1%)0/50 (0%)0/100 (0%)0/100 (0%)(0%)0/50 0/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)(0%)0/60 (0%)0/50 0/60 (0%)0/50 (0%)**Overall Incidence** Total 1/510 (0.2%) Mean 0.12% SD 0.35% Total 0/510 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Sarcoma 0/50 0/100 0/100 (0%)(0%)(0%)0/50 (0%)0/100 (0%)1/100 (1%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/60 0/50 (0%)0/60 0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% 1/510 (0.2%) Mean 0.12% SD 0.35% Total *Islets, Pancreatic: Adenoma 1/50 (2%)2/100 (2%)3/99 (3%)(0%)0/100 (0%)0/100 (0%)0/50 0/50 (0%)0/50 (0%) 3/50 (6%)0/50 (0%)0/50 (0%)0/49 (0%)2/60 (3%)3/50 (6%)1/60 (2%)0/50 (0%)SD 0.59% **Overall Incidence** Total 14/509 (2.75%) Mean 2.8% SD 2.32% Total 1/509 (0.2%) Mean 0.21%

^{*:} 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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
'Islets, Pancreatic: Carcinoma								
		0/50 (0%) 1/50 (2%)	0/100 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	2/100 (2%) 2/50 (4%)	0/100 (0%) 0/49 (0%)
Overall Incidence	Total	0/60 (0%) 3/509 (0.59%)	2/50 (4%) Mean 0.75%	SD 1.49%	Total	0/60 (0%) 4/509 (0.79%)	0/50 (0%) Mean 0.75%	SD 1.49%
Islets, Pancreatic: Carcinoma or Adenoma						•••••		
		1/50 (2%) 1/50 (2%) 2/60 (3%)	2/100 (2%) 0/50 (0%) 5/50 (10%)	3/99 (3%) 3/50 (6%)		0/50 (0%) 0/50 (0%) 1/60 (2%)	2/100 (2%) 2/50 (4%) 0/50 (0%)	0/100 (0%) 0/49 (0%)
Overall Incidence	Total	17/509 (3.34%)	Mean 3.55%	SD 3.11%	Total	5/509 (0.98%)	Mean 0.96%	SD 1.48%
Kidney: Pelvis and Trans Carcinoma		um:						
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/49 (0%) 0/50 (0%)	0/100 (0%) 0/48 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/48 (0%)
Overall Incidence	Total	0/507 (0%)	Mean 0%	SD 0%	Total	0/508 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Trans Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/49 (0%)	0/100 (0%) 0/48 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/48 (0%)
Overall Incidence	Total	0/60 (0%) 0/507 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/508 (0%)	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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Kidney: Pelvis and Transiti Papilloma	ional Epitheliu	ım:						
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/49 (0%) 0/50 (0%)	0/100 (0%) 0/48 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 1/48 (2%)
Overall Incidence	Total	0/507 (0%)	Mean 0%	SD 0%	Total	1/508 (0.2%)	Mean 0.26%	SD 0.74%
*Kidney: Renal Tubule: Adenoma								
		1/50 (2%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/49 (0%) 0/50 (0%)	0/100 (0%) 0/48 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	1/100 (1%) 0/48 (0%)
Overall Incidence	Total	1/507 (0.2%)	Mean 0.25%	SD 0.71%	Total	1/508 (0.2%)	Mean 0.12%	SD 0.35%
'Kidney: Renal Tubule: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/49 (0%) 0/50 (0%)	0/100 (0%) 0/48 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	1/100 (1%) 0/48 (0%)
Overall Incidence	Total	0/507 (0%)	Mean 0%	SD 0%	Total	1/508 (0.2%)	Mean 0.12%	SD 0.35%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	0/100 (0%) 0/49 (0%)	0/100 (0%) 0/48 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	2/100 (2%) 0/48 (0%)
Overall Incidence	Total	0/60 (0%) 1/507 (0.2%)	0/50 (0%) Mean 0.25%	SD 0.71%	Total	0/60 (0%) 2/508 (0.39%)	0/50 (0%) Mean 0.25%	SD 0.71%

^{*:} 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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL
Vehicle: FEED

Length of Study: CHRONIC

Male **Female** *Kidney: Renal Tubule: Lipoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)(0%) 0/50 (0%)0/49 (0%)0/48 (0%)0/50 (0%)0/50 0/48 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/507 (0%) Mean 0% SD 0% Total 0/508 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Liposarcoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/49 (0%)0/48 0/48 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/60 (0%)0/50 0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/507 (0%) Mean 0% SD 0% Total 0/508 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Sarcoma 0/50 0/100 0/100 0/100 (0%)(0%)(0%)0/50 (0%)0/100 (0%)(0%)0/50 (0%)0/49 (0%)1/48 (2%)0/50 (0%)0/50 (0%)0/48 (0%)0/60 (0%)(0%)0/50 0/50 (0%)0/60 (0%)**Overall Incidence** Total 1/507 (0.2%) Mean 0.26% SD 0.74% Total 0/508 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: **Stromal Nephroma** 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)

0/48

SD 0%

(0%)

0/50

0/60

0/508 (0%)

Total

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0%

0/48

SD 0%

(0%)

Total

0/50

0/60

0/507 (0%)

(0%)

(0%)

.....

0/49

0/50

Mean 0%

(0%)

(0%)

Overall Incidence

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Report Date: 06/03/2022

^{*:} 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: ORAL Vehicle: FEED

Control Animal Groups Report Date: 06/03/2022

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			Male				Female	
*Liver: Cholangiocarcinoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	1/100 (1%) 1/50 (2%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 1/50 (2%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%
*Liver: Hemangiosarcoma				•••••			•••••	
·		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma					•			
		2/50 (4%) 0/50 (0%) 2/60 (3%)	2/100 (2%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 1/60 (2%)	0/100 (0%) 1/50 (2%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	6/510 (1.18%)	Mean 1.17%	SD 1.7%	Total	2/510 (0.39%)	Mean 0.46%	SD 0.85%
*Liver: Hepatocellular Carcinoma				•••••	•••••			
•		0/50 (0%) 2/50 (4%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	1/60 (2%) 4/510 (0.78%)	1/50 (2%) Mean 0.96%	SD 1.48%	Total	0/60 (0%) 0/510 (0%)	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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Liver: Hepatocellular Carcino	oma or Hepatobl	astoma						
•	•	0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/60 (2%)	1/50 (2%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	4/510 (0.78%)	Mean 0.96%	SD 1.48%	Total	0/510 (0%)	Mean 0%	SD 0%
*Liver:								
Hepatocellular Carcino	ma or Hepatoce	ellular Adenoma						
		2/50 (4%)	2/100 (2%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		3/60 (5%)	1/50 (2%)			1/60 (2%)	0/50 (0%)	
Overall Incidence	Total	10/510 (1.96%)	Mean 2.12%	SD 2.03%	Total	2/510 (0.39%)	Mean 0.46%	SD 0.85%
*Liver:								
	ma, Hepatocell	ular Adenoma, or Hepatol	olastoma					
•	•	2/50 (4%)	2/100 (2%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		3/60 (5%)	1/50 (2%)			1/60 (2%)	0/50 (0%)	
Overall Incidence	Total	10/510 (1.96%)	Mean 2.12%	SD 2.03%	Total	2/510 (0.39%)	Mean 0.46%	SD 0.85%
*Lung:								•••••
Alveolar/Bronchiolar A	denoma							
		4/50 (8%)	4/100 (4%)	3/100 (3%)		4/50 (8%)	6/100 (6%)	2/100 (2%)
		2/50 (4%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/60 (2%)	1/50 (2%)	()		1/60 (2%)	0/50 (0%)	(-,-,
Overall Incidence	Total	17/510 (3.33%)	Mean 3.33%	SD 2.36%	Total	13/510 (2.55%)	Mean 2.21%	SD 3.11%
		177010 (0.0070)				,	11.04.1 2.2.170	35 3.1170

^{*:} 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

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Report Date: 06/03/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male				Female	
Lung: Alveolar/Bronchiolar C	Carcinoma							
		0/50 (0%) 0/50 (0%)	1/100 (1%) 2/50 (4%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	1/100 (1%) 0/50 (0%)	1/100 (1%) 0/50 (0%)
Overall Incidence	Total	1/60 (2%) 4/510 (0.78%)	0/50 (0%) Mean 0.83%	SD 1.43%	Total	0/60 (0%) 2/510 (0.39%)	0/50 (0%) Mean 0.25%	SD 0.46%
Lung:	`arainama ar Alı	roolor/Propobiolor Adopo						
Aiveolar/Bronchiolar C	arcinoma or Aiv	veolar/Bronchiolar Adeno 4/50 (8%)		2/400 (20/)		4/EO (99/)	7/100 (70/)	2/400 /20/\
		4/50 (8%) 2/50 (4%)	5/100 (5%) 4/50 (8%)	3/100 (3%) 0/50 (0%)		4/50 (8%) 0/50 (0%)	7/100 (7%) 0/50 (0%)	3/100 (3%) 0/50 (0%)
		2/60 (3%)	1/50 (2%)	0/30 (0 /6)		1/60 (2%)	0/50 (0%)	0/30 (0 /8)
Overall Incidence	Total	21/510 (4.12%)	Mean 4.17%	SD 2.78%	Total	15/510 (2.94%)	Mean 2.46%	SD 3.3%
Lung: Carcinoma								
		0/50 (0%)	0/100 (0%)	1/100 (1%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%	Total	0/510 (0%)	Mean 0%	SD 0%
Lung: Sarcoma			•••••	•••••				
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	, ,		0/60 (0%)	0/50 (0%)	. ,
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 230

Report Date: 06/03/2022

			Male				Female	
*Lung: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	1/100 (1%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 1/510 (0.2%)	0/50 (0%) Mean 0.12%	SD 0.35%
#Lymph Node, Mesenteric: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangioma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	1/100 (1%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%	Total	0/510 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/510 (0%)	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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Lymph Node, Mesenteric: Sarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%) 0/60 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%)	0/100 (0%)	1/100 (1%)		2/50 (4%)	1/100 (1%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%	Total	4/510 (0.78%)	Mean 0.88%	SD 1.46%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/100 (0%)	2/100 (2%)		0/50 (0%)	1/100 (1%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	4/50 (8%)	2/50 (4%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	1/50 (2%)	
Overall Incidence	Total	2/510 (0.39%)	Mean 0.25%	SD 0.71%	Total	9/510 (1.76%)	Mean 2.12%	SD 2.75%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/100 (0%)	3/100 (3%)		2/50 (4%)	2/100 (2%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	4/50 (8%)	2/50 (4%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	1/50 (2%)	
Overall Incidence	Total	3/510 (0.59%)	Mean 0.38%	SD 1.06%	Total	13/510 (2.55%)	Mean 3%	SD 2.62%

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^{*:} 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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Mammary Gland: Fibroadenoma 2/50 (4%)3/100 (3%)8/100 (8%)27/50 (54%)55/100 (55%)53/100 (53%)3/50 (6%)0/50 (0%)3/50 (6%)15/50 (30%)26/50 (52%)(48%)0/60 (0%)0/50 (0%)23/60 (38%)14/50 (28%)**Overall Incidence** Total 19/510 (3.73%) Mean 3.38% SD 3.16% Total 237/510 (46.47%) Mean 44.79% SD 11.09% **#Mammary Gland: Fibroma** 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/510 (0%) Mean 0% SD 0% #Mammary Gland: Fibroma, Fibroadenoma or Adenoma 9/100 2/50 (4%)3/100 (3%)(9%)28/50 (56%)55/100 (55%)53/100 (53%)3/50 (6%)0/50 (0%)3/50 (6%)16/50 (32%)26/50 (52%)24/50 (48%)(0%)23/60 (38%)(28%)0/60 0/50 (0%)14/50 **Overall Incidence** 20/510 (3.92%) Mean 3.5% SD 3.38% 239/510 (46.86%) Mean 45.29% SD 10.99% Total Total **#Mammary Gland:** Fibroma, Fibroadenoma, Carcinoma, or Adenoma (4%)3/100 (3%)(11%)(53%)11/100 28/50 (56%)56/100 (56%)53/100 2/50 3/50 (6%)0/50 (0%)3/50 (6%)16/50 (32%)28/50 (56%)25/50 (50%)0/60 (0%)0/50 (0%)23/60 (38%)14/50 (28%)**Overall Incidence** Total 22/510 (4.31%) Mean 3.75% SD 3.88% Total 243/510 (47.65%) Mean 46.17% SD 11.61%

^{*:} 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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Mammary Gland: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	1/100 (1%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 1/510 (0.2%)	0/50 (0%) Mean 0.12%	SD 0.35%
#Mammary Gland: Myoepithelioma			•••••					
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 1/50 (2%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%
Mesentery: Fibrosarcoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 1/50 (2%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%
Mesentery: Hemangiosarcoma			•••••					
-		0/50 (0%) 0/50 (0%)	0/100 (0%) 1/50 (2%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 1/510 (0.2%)	0/50 (0%) Mean 0.25%	SD 0.71%	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Version: 2006 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

			Male		Female	
#Mesentery: Lipoma						
		0/50 (0%) 0/50 (0%) 0/60 (0%)	1/100 (1%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/60 (0%)	` ,	(0%) (0%)
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12% SD 0.35%	Total 0/510 (0%)	Mean 0% SD 0%	
#Mesentery: Liposarcoma						
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/60 (0%)	` ,	(0%) (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0% SD 0%	Total 0/510 (0%)	Mean 0% SD 0%)
#Mesentery: Osteosarcoma						
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/60 (0%)	` ,	(0%) (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0% SD 0%	Total 0/510 (0%)	Mean 0% SD 0%	,
#Mesentery: Rhabdomyosarcoma						
-		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/60 (0%)	` ,	(0%) (0%)
Overall Incidence	Total	0/510 (0%)	0/50 (0%) Mean 0% SD 0%	Total 0/510 (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

Tumor Incidence for Selected Control Animal Groups

Report Date: 06/03/2022

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

			Male				Female	
#Mesentery: Sarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
S	T-1-1	0/60 (0%)	0/50 (0%)	00.00/	T-1-1	0/60 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
Nose: Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	1/100 (1%)
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/509 (0.2%)	Mean 0.25%	SD 0.71%	Total	1/509 (0.2%)	Mean 0.12%	SD 0.35%
Nose: Chondroma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/509 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
Nose: Sarcoma								•••••
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/60 (0%)	0/50 (0%)	, ,		0/60 (0%)	0/50 (0%)	, ,
Overall Incidence	Total	0/509 (0%)	Mean 0%	SD 0%	Total	0/509 (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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

			Male				Female	
*Nose: Squamous Cell Carcin	oma							
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
	+	0/60 (0%)	0/50 (0%)	OD 00/	-	0/60 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/509 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o	-	ynx, Tooth, Gingiva):						
	•	1/50 (2%)	1/100 (1%)	1/100 (1%)		0/50 (0%)	0/100 (0%)	1/100 (1%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	1/50 (2%)	
Overall Incidence	Total	3/510 (0.59%)	Mean 0.5%	SD 0.76%	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%
Oral Cavity (Oral Mucos	sa, Tongue, Phar							
•		0/50 (0%)	1/100 (1%)	1/100 (1%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	1/50 (2%)	
Overall Incidence	Total	2/510 (0.39%)	Mean 0.25%	SD 0.46%	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%
Oral Cavity (Oral Mucos Squamous Cell Carcin	-	ynx, Tooth, Gingiva): Squamous, or Papilloma	······					
		1/50 (2%)	2/100 (2%)	2/100 (2%)		0/50 (0%)	0/100 (0%)	1/100 (1%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	2/50 (4%)	
		5/510 (0.98%)	Mean 0.75%	SD 1.04%	Total	3/510 (0.59%)	Mean 0.62%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Version: 2006 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

			Male				Female	
#Oral Mucosa: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	1/100 (1%) 0/50 (0%) 0/50 (0%)	1/100 (1%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	2/510 (0.39%)	Mean 0.25%	SD 0.46%	Total	0/510 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 1/50 (2%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%
Ovary: Cystadenoma								
						0/50 (0%) 0/50 (0%) 0/60 (0%)	1/100 (1%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence					Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%
Ovary: Granulosa Cell Tumor Ben								
	-					0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence					Total	0/60 (0%) 0/510 (0%)	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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: **Granulosa Cell Tumor Malignant** 0/50 (0%)0/100 (0%)0/100 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/510 (0%) SD 0% *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)0/100 (0%)0/100 (0%)0/50 0/50 (0%)0/50 (0%)(0%)(0%)0/60 (0%)0/50 **Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% **Granulosa-Theca Tumor Malignant** 0/100 0/100 0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/60 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% *Ovary: Luteoma 0/50 0/100 (0%)0/100 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0%

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^{*:} 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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: Sarcoma 0/50 (0%)0/100 (0%)0/100 (0%)(0%) 0/50 (0%)0/50 0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% *Ovary: **Thecoma Malignant** 0/50 (0%)0/100 (0%)0/100 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% *Pancreas: Adenoma 0/50 2/100 0/100 0/100 (0%)1/100 (1%)(2%)0/50 (0%)(0%)(0%)0/50 (0%)1/49 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/49 (0%)(2%)(0%)1/60 0/50 (0%)0/60 0/50 (0%)**Overall Incidence** Total 6/509 (1.18%) Mean 1.09% SD 0.96% Total 0/509 (0%) Mean 0% SD 0% *Pancreas: Carcinoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/49 (0%) 0/50 (0%) 0/50 (0%)0/50 (0%)0/49 (0%)0/60 (0%)1/50 (2%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 1/509 (0.2%) Mean 0.25% SD 0.71% Total 0/509 (0%) Mean 0% SD 0%

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^{*:} 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

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Report Date: 06/03/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: FEED

Route: ORAL

			Male				Female	
Pancreas: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%) 1/60 (2%)	1/100 (1%) 1/49 (2%) 1/50 (2%)	2/100 (2%) 1/50 (2%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/49 (0%)
Overall Incidence	Total	7/509 (1.38%)	Mean 1.34%	SD 0.9%	Total	0/509 (0%)	Mean 0%	SD 0%
*Pancreas: Fibroma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/49 (0%) 0/50 (0%)	1/100 (1%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/49 (0%)
Overall Incidence	Total	1/509 (0.2%)	Mean 0.12%	SD 0.35%	Total	0/509 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Benign								
		1/50 (2%) 0/50 (0%) 0/60 (0%)	1/100 (1%) 0/49 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/49 (0%)
Overall Incidence	Total	2/509 (0.39%)	Mean 0.38%	SD 0.74%	Total	0/509 (0%)	Mean 0%	SD 0%
Parathyroid Gland:								
		0/49 (0%) 0/46 (0%)	0/92 (0%) 0/47 (0%)	0/93 (0%) 1/48 (2%)		0/47 (0%) 0/45 (0%)	0/90 (0%) 0/49 (0%)	2/86 (2%) 0/50 (0%)
Overall Incidence	Total	0/58 (0%) 1/481 (0.21%)	0/48 (0%) Mean 0.26%	SD 0.74%	Total	0/57 (0%) 2/470 (0.43%)	0/46 (0%) Mean 0.29%	SD 0.82%

^{*:} 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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Peripheral Nerve:** Sarcoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/510 (0%) SD 0% **#Peripheral Nerve:** Schwannoma Malignant 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/510 (0%) Mean 0% SD 0% **#Peripheral Nerve:** Schwannoma: Benign, Malignant, NOS 0/100 0/100 0/100 0/50 (0%)(0%)(0%)0/50 (0%)0/100 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/60 0/50 (0%)0/60 0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% 0/510 (0%) Mean 0% SD 0% Total *Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma (20%)21/100 (21%)(17%)(34%)35/100 (35%)(29%)10/50 17/100 17/50 29/100 11/50 (22%)9/50 (18%)16/49 (33%)23/50 (46%)23/50 (46%)29/48 (60%)11/59 (19%)15/48 (31%)19/59 (32%)15/50 (30%)**Overall Incidence** Total 110/506 (21.74%) Mean 22.57% SD 6.02% Total 190/507 (37.48%) Mean 39.08% SD 10.86%

^{*:} 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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Pituitary Gland: Pars Dis Carcinoma	stalis or Unspec	cified Site:						
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 2/50 (4%)	0/100 (0%) 0/48 (0%)
overall Incidence	Total	0/59 (0%) 1/506 (0.2%)	1/48 (2%) Mean 0.26%	SD 0.74%	Total	0/59 (0%) 2/507 (0.39%)	0/50 (0%) Mean 0.5%	SD 1.41%
Pituitary Gland: Pars Dis Carcinoma or Adenoma	stalis or Unspec	cified Site:						
		10/50 (20%) 11/50 (22%) 11/59 (19%)	21/100 (21%) 9/50 (18%) 16/48 (33%)	17/100 (17%) 16/49 (33%)		17/50 (34%) 23/50 (46%) 19/59 (32%)	35/100 (35%) 25/50 (50%) 15/50 (30%)	29/100 (29%) 29/48 (60%)
Overall Incidence	Total	111/506 (21.94%)	Mean 22.83%	SD 6.48%	Total	192/507 (37.87%)	Mean 39.58%	SD 11.3%
Pituitary Gland: Pars Into								
		0/50 (0%) 0/50 (0%) 0/59 (0%)	0/100 (0%) 1/50 (2%) 0/48 (0%)	1/100 (1%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 1/59 (2%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	2/100 (2%) 0/48 (0%)
Overall Incidence	Total	2/506 (0.4%)	Mean 0.38%	SD 0.74%	Total	3/507 (0.59%)	Mean 0.46%	SD 0.86%
Pituitary Gland: Pars Inte								
		0/50 (0%) 0/50 (0%) 0/59 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/59 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/48 (0%)
Overall Incidence	Total	0/59 (0%) 0/506 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/59 (0%) 0/507 (0%)	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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	nedia:						
		0/50 (0%) 0/50 (0%) 0/59 (0%)	0/100 (0%) 1/50 (2%) 0/48 (0%)	1/100 (1%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 1/59 (2%)	0/100 (0%) 2/100 (2%) 0/50 (0%) 0/48 (0%) 0/50 (0%)
Overall Incidence	Total	2/506 (0.4%)	Mean 0.38%	SD 0.74%	Total	3/507 (0.59%)	Mean 0.46% SD 0.86%
*Prostate: Adenoma							
		0/49 (0%) 0/50 (0%)	4/100 (4%) 0/50 (0%)	0/100 (0%) 0/50 (0%)			
Overall Incidence	Total	2/60 (3%) 8/509 (1.57%)	2/50 (4%) Mean 1.42%	SD 1.97%			
*Prostate: Carcinoma or Adenoma							
		0/49 (0%) 0/50 (0%)	4/100 (4%) 0/50 (0%)	0/100 (0%) 0/50 (0%)			
Overall Incidence	Total	2/60 (3%) 8/509 (1.57%)	2/50 (4%) Mean 1.42%	SD 1.97%			
*Salivary Glands: Carcinoma							
		0/49 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 1/50 (2%)	0/100 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/509 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 1/510 (0.2%)	0/50 (0%) Mean 0.25% SD 0.71%

^{*:} 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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Salivary Glands: Carcinoma or Adenoma 0/49 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/509 (0%) Mean 0% SD 0% Total 1/510 (0.2%) Mean 0.25% SD 0.71% *Salivary Glands: Sarcoma 0/49 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/60 (0%)0/50 0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/509 (0%) Mean 0% SD 0% Total 0/510 (0%) Mean 0% SD 0% *Salivary Glands: Schwannoma Malignant 0/100 0/100 0/100 1/49 (2%)(0%)(0%)0/50 (0%)0/100 (0%)(0%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)(0%)1/50 (2%)0/60 0/50 (0%)**Overall Incidence** Total 4/509 (0.79%) Mean 1.01% SD 1.52% Total 0/510 (0%) Mean 0% SD 0% **#Skeletal Muscle: Fibrosarcoma** 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/510 (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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Skeletal Muscle: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%
Skeletal Muscle: Hemangiosarcoma								
•		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 1/50 (2%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%	Total	0/510 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Lipoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 1/60 (2%)	1/100 (1%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	2/510 (0.39%)	Mean 0.33%	SD 0.64%
Skeletal Muscle: Rhabdomyosarcoma								
·		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/510 (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: ORAL Vehicle: FEED Report Date: 06/03/2022

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			Male				Female	Female				
#Skeletal Muscle: Rhabdomyosarcoma or Rhabdomyoma												
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)				
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Sarcoma				•••••								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)				
		0/50 (0%) 0/60 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/60 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%				
#Skin: Basal Cell Adenoma												
		0/50 (0%)	1/100 (1%)	1/100 (1%)		0/50 (0%)	0/100 (0%)	0/100 (0%)				
		1/50 (2%) 2/60 (3%)	0/50 (0%) 1/50 (2%)	1/50 (2%)		0/50 (0%) 0/60 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	7/510 (1.37%)	Mean 1.42%	SD 1.14%	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%				
#Skin: Basal Cell Adenoma or I												
	1	0/50 (0%) 1/50 (2%) 2/60 (3%)	1/100 (1%) 0/50 (0%) 1/50 (2%)	1/100 (1%) 1/50 (2%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 1/50 (2%) 0/50 (0%)	0/100 (0%) 0/50 (0%)				
Overall Incidence	Total	7/510 (1.37%)	Mean 1.42%	SD 1.14%	Total	1/510 (0.2%)	0/50 (0%) Mean 0.25%	SD 0.71%				

^{*:} 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

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Mean 0.75%

SD 1.49%

Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma 0/50 (0%)2/100 (2%)2/100 (2%)0/50 (0%)0/100 (0%)0/100 (0%)2/50 (4%)1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)2/60 (3%)1/50 (2%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 11/510 (2.16%) Mean 2.17% SD 1.17% Total 2/510 (0.39%) Mean 0.5% SD 0.93% #Skin: **Basal Cell Carcinoma** 0/50 (0%)1/100 (1%)0/100 (0%)0/50 (0%)0/100 0/100 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 1/510 (0.2%) Mean 0.12% SD 0.35% Total 1/510 (0.2%) Mean 0.25% SD 0.71% #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 (0%)1/100 (1%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)1/510 (0.2%) Mean 0.12% Mean 0.25% **Overall Incidence** Total SD 0.35% Total 1/510 (0.2%) SD 0.71% #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%)3/100 (3%)2/100 (2%)0/50 (0%)0/100 (0%)0/100 (0%)(2%)2/50 (4%)1/50 1/50 (2%)0/50 (0%)2/50 (4%)1/50 (2%)2/60 (3%)1/50 (2%)0/60 (0%)0/50 (0%)

SD 1.2%

Total

3/510 (0.59%)

Total

12/510 (2.35%)

Mean 2.29%

Overall Incidence

^{*:} 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: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

hicle: FEED

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Report Date: 06/03/2022

			Male				Female	
#Skin: Basal or Sq. Cell Carcir Adenoma, Papilloma, S	noma, Carcinon og Papilloma, Ko	na, Basosq. Tumor (M or l eratoacanthoma, Trichoe	B), Basal Cell Adenom	na,				
		11/50 (22%) 6/50 (12%) 7/60 (12%)	8/100 (8%) 2/50 (4%) 4/50 (8%)	11/100 (11%) 3/50 (6%)		3/50 (6%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 2/50 (4%) 0/50 (0%)	1/100 (1%) 2/50 (4%)
Overall Incidence	Total	52/510 (10.2%)	Mean 10.33%	SD 5.49%	Total	8/510 (1.57%)	Mean 1.88%	SD 2.42%
#Skin: Fibroma				•••••	•			
		5/50 (10%) 2/50 (4%) 5/60 (8%)	7/100 (7%) 2/50 (4%) 1/50 (2%)	2/100 (2%) 8/50 (16%)		3/50 (6%) 0/50 (0%) 3/60 (5%)	1/100 (1%) 1/50 (2%) 0/50 (0%)	1/100 (1%) 1/50 (2%)
Overall Incidence	Total	32/510 (6.27%)	Mean 6.67%	SD 4.76%	Total	10/510 (1.96%)	Mean 2.12%	SD 2.23%
#Skin:								
Fibroma, Fibrosarcoma	i, Sarcoma, Myx	xoma, Myxosarcoma, or F 6/50 (12%) 4/50 (8%) 5/60 (8%)	12/100 (12%) 2/50 (4%) 2/50 (4%)	8/100 (8%) 8/50 (16%)		4/50 (8%) 1/50 (2%) 3/60 (5%)	1/100 (1%) 1/50 (2%) 2/50 (4%)	1/100 (1%) 1/50 (2%)
Overall Incidence	Total	47/510 (9.22%)	Mean 9.04%	SD 4.13%	Total	14/510 (2.75%)	Mean 3.12%	SD 2.42%
#Skin: Fibrosarcoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	6/100 (6%) 0/50 (0%) 0/50 (0%)	2/100 (2%) 0/50 (0%)		1/50 (2%) 1/50 (2%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 1/50 (2%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	8/510 (1.57%)	Mean 1%	SD 2.14%	Total	3/510 (0.59%)	Mean 0.75%	SD 1.04%

^{*:} 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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	Female				
#Skin:												
Fibrosarcoma, Sarcoma,	Myxosarcom	a, or Fibrous Histiocytoma	a									
		1/50 (2%) 2/50 (4%) 0/60 (0%)	6/100 (6%) 0/50 (0%) 1/50 (2%)	5/100 (5%) 0/50 (0%)		1/50 (2%) 1/50 (2%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 2/50 (4%)	0/100 (0%) 0/50 (0%)				
Overall Incidence	Total	15/510 (2.94%)	Mean 2.38%	SD 2.39%	Total	4/510 (0.78%)	Mean 1%	SD 1.51%				
#Skin: Fibrous Histiocytoma												
·		1/50 (2%) 1/50 (2%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 1/50 (2%)	2/100 (2%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)				
Overall Incidence	Total	5/510 (0.98%)	Mean 1%	SD 1.07%	Total	0/510 (0%)	Mean 0%	SD 0%				
tSkin: Hemangioma				•••••								
-		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 2/50 (4%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)				
Overall Incidence	Total	2/510 (0.39%)	Mean 0.5%	SD 1.41%	Total	0/510 (0%)	Mean 0%	SD 0%				
#Skin: Hemangiopericytoma												
5		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)				
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/510 (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: ORAL Vehicle: FEED

Control Animal Groups Report Date: 06/03/2022

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			Male				Female	
#Skin: Hemangiosarcoma								
		0/50 (0%) 1/50 (2%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	1/60 (2%) 2/510 (0.39%)	0/50 (0%) Mean 0.46%	SD 0.85%	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Keratoacanthoma				•••••				
		10/50 (20%) 3/50 (6%) 5/60 (8%)	5/100 (5%) 1/50 (2%) 2/50 (4%)	8/100 (8%) 1/50 (2%)		3/50 (6%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	35/510 (6.86%)	Mean 6.92%	SD 5.8%	Total	3/510 (0.59%)	Mean 0.75%	SD 2.12%
≇Skin: Lipoma								
		0/50 (0%) 1/50 (2%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 1/50 (2%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 1/50 (2%)	2/100 (2%) 0/50 (0%)
Overall Incidence	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%	Total	4/510 (0.78%)	Mean 0.75%	SD 1.04%
#Skin: Liposarcoma								
-		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/510 (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

Tumor Incidence for Selected Control Animal Groups

Report Date: 06/03/2022

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

		Male				Female			
#Skin: Melanoma Malignant									
		0/50 (0%)	0/100 (0%)	1/100 (1%)		0/50 (0%)	0/100 (0%)	0/100 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overell Incidence	Total	0/60 (0%)	0/50 (0%)	CD 0.250/	Total	0/60 (0%)	0/50 (0%)	CD 00/	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%	Total	0/510 (0%)	Mean 0%	SD 0%	
#Skin: Myxoma									
		0/50 (0%)	0/100 (0%)	1/100 (1%)		0/50 (0%)	0/100 (0%)	0/100 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)		
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%	Total	0/510 (0%)	Mean 0%	SD 0%	
#Skin: Myxosarcoma									
-		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)		
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%	
#Skin: Neural Crest Tumor				•••••					
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	1/100 (1%)	0/100 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)		
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%	

^{*:} 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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Skin: Neurofibroma or Schw	annoma benign							
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
#Skin:	•••••							
Neurofibrosarcoma or	Schwannoma (m	alignant or NOS)						
		0/50 (0%)	0/100 (0%)	2/100 (2%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	3/510 (0.59%)	Mean 0.5%	SD 0.93%	Total	0/510 (0%)	Mean 0%	SD 0%
#Skin:								
Neurofibrosarcoma, Ne	eurofibroma, or S	Schwannoma (benign, ma	alignant or NOS)					
		0/50 (0%)	0/100 (0%)	2/100 (2%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	3/510 (0.59%)	Mean 0.5%	SD 0.93%	Total	0/510 (0%)	Mean 0%	SD 0%
#Skin: Osteosarcoma								
		1/50 (2%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	0,00 (0,0)		0/60 (0%)	0/50 (0%)	2.00 (0.0)
Overall Incidence	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%	Total	0/510 (0%)	Mean 0%	SD 0%
		1/310 (0.270)				` '		OD 070

^{*:} 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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

to: ODAL

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

			Male				Female	
#Skin: Sarcoma								
		0/50 (0%) 1/50 (2%)	0/100 (0%) 0/50 (0%)	1/100 (1%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	1/50 (2%)	
Overall Incidence	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%
#Skin: Schwannoma Benign								
•		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignant								
		0/50 (0%)	0/100 (0%)	2/100 (2%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	3/510 (0.59%)	Mean 0.5%	SD 0.93%	Total	0/510 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma								
-		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%	Total	0/510 (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: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

icle: FEED

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			Male				Female	
#Skin: Squamous Cell Carcino or Carcinoma	oma, Basal Cell	Carcinoma, Basosquamo	ous Tumor (malignant	or NOS),				
		0/50 (0%) 0/50 (0%) 0/60 (0%)	1/100 (1%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 1/50 (2%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%
#Skin: Squamous Cell Papillo		1/50 (2%)	0/100 (0%)	1/100 (1%)		0/50 (0%)	0/100 (0%)	1/100 (1%)
		1/50 (2%) 1/50 (2%) 0/60 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	4/510 (0.78%)	Mean 0.88%	SD 0.99%	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%
#Skin: Squamous Cell Papillo	ma or Papilloma	a						
		1/50 (2%) 1/50 (2%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 1/50 (2%)	1/100 (1%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	1/100 (1%) 1/50 (2%)
Overall Incidence	Total	4/510 (0.78%)	Mean 0.88%	SD 0.99%	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%
#Skin:		Squamous Cell Carcinon		a				•••••
	, , ,	11/50 (22%) 4/50 (8%) 5/60 (8%)	5/100 (5%) 1/50 (2%) 3/50 (6%)	9/100 (9%) 2/50 (4%)		3/50 (6%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	1/100 (1%) 1/50 (2%)
Overall Incidence	Total	40/510 (7.84%)	Mean 8.04%	SD 6.12%	Total	5/510 (0.98%)	Mean 1.12%	SD 2.1%

^{*:} 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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin:								
Squamous Cell Papilloma	a, Papilloma,	or Keratoacanthoma						
		11/50 (22%)	5/100 (5%)	9/100 (9%)		3/50 (6%)	0/100 (0%)	1/100 (1%)
		4/50 (8%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		5/60 (8%)	3/50 (6%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	39/510 (7.65%)	Mean 7.79%	SD 6.34%	Total	5/510 (0.98%)	Mean 1.12%	SD 2.1%
#Skin: Trichoepithelioma								
·		0/50 (0%)	1/100 (1%)	1/100 (1%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	4/510 (0.78%)	Mean 0.75%	SD 0.89%	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	, ,		0/60 (0%)	0/50 (0%)	, ,
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

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

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%
*Spleen: Hemangioma								
g		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/49 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/49 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/509 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/49 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/49 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/509 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
*Spleen: Leiomyosarcoma		•••••	•••••	•••••				
•		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/49 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/49 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/509 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/509 (0%)	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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	1/100 (1%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
		0/60 (0%)	0/50 (0%)	(***)		0/60 (0%)	0/50 (0%)	(,
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%	Total	0/510 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Lipoma								
•		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Schwannoma Malignant								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
-	•	0/50 (0%)	1/100 (1%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%	Total	0/510 (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: ORAL Vehicle: FEED Report Date: 06/03/2022

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			Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	1/100 (1%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%	Total	0/510 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Leiomyosarcoma								
-		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (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

Tumor Incidence for Selected Control Animal Groups

Report Date: 06/03/2022

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

			Male				Female	
#Stomach, Glandular: Lipoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%
Testes:								
		45/50 (90%)	91/100 (91%)	96/100 (96%)				
		41/50 (82%)	48/50 (96%)	46/50 (92%)				
		55/60 (92%)	49/50 (98%)					
Overall Incidence	Total	471/510 (92.35%)	Mean 92.08%	SD 4.97%				
Thymus: Sarcoma								
		0/48 (0%)	0/87 (0%)	0/97 (0%)		0/50 (0%)	0/92 (0%)	0/96 (0%)
		0/46 (0%)	0/48 (0%)	0/48 (0%)		0/46 (0%)	0/48 (0%)	0/47 (0%)
		0/56 (0%)	0/49 (0%)			0/57 (0%)	0/48 (0%)	
Overall Incidence	Total	0/479 (0%)	Mean 0%	SD 0%	Total	0/484 (0%)	Mean 0%	SD 0%
Thymus: Thymoma Benign								
-		0/48 (0%)	1/87 (1%)	0/97 (0%)		0/50 (0%)	0/92 (0%)	0/96 (0%)
		0/46 (0%)	0/48 (0%)	0/48 (0%)		0/46 (0%)	0/48 (0%)	0/47 (0%)
		0/56 (0%)	0/49 (0%)			0/57 (0%)	0/48 (0%)	
Overall Incidence	Total	1/479 (0.21%)	Mean 0.14%	SD 0.41%	Total	0/484 (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

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Mean 1.35%

SD 1.59%

Report Date: 06/03/2022

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** *Thymus: **Thymoma Malignant** 0/48 (0%)0/87 (0%)0/97 (0%)0/50 (0%)1/92 (1%)0/96 (0%)0/46 (0%)0/48 (0%)0/48 (0%)0/46 (0%)0/48 (0%)(0%)0/56 (0%)0/49 (0%)0/57 (0%)0/48 (0%)Mean 0.14% **Overall Incidence** Total 0/479 (0%) Mean 0% SD 0% Total 1/484 (0.21%) SD 0.38% *Thymus: Thymoma: Benign, Malignant, NOS 0/48 (0%)1/87 (1%)0/97 (0%)0/50 (0%)1/92 (1%)0/96 (0%)(0%)0/46 0/48 (0%)0/48 (0%)0/46 (0%)0/48 (0%)0/47 (0%)0/56 (0%)0/49 (0%)0/57 (0%)0/48 (0%)Mean 0.14% **Overall Incidence** Total 1/479 (0.21%) Mean 0.14% SD 0.41% Total 1/484 (0.21%) SD 0.38% *Thyroid Gland: C-Cell: Adenoma 10/50 (20%)12/100 (12%)12/100 (12%)4/50 (8%)11/100 (11%)21/100 (21%)8/50 (16%)9/48 (19%)11/47 (23%)5/50 (10%)9/49 (18%)10/47 (21%)(17%)10/59 11/50 (22%)9/60 (15%)6/50 (12%)**Overall Incidence** 83/504 (16.47%) Mean 17.64% SD 4.24% Total 75/506 (14.82%) Mean 14.58% SD 5.13% Total *Thyroid Gland: C-Cell: Carcinoma 1/50 (2%)3/100 (3%)4/100 (4%)0/50 (0%)3/100 (3%)0/100 (0%)0/50 (0%)1/48 (2%)0/47 (0%)2/50 (4%)0/49 (0%)1/47 (2%)0/59 (0%)0/50 (0%)1/60 (2%)0/50 (0%)

SD 1.6%

Total

7/506 (1.38%)

Total

9/504 (1.79%)

Mean 1.39%

.....

Overall Incidence

^{*:} 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

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Report Date: 06/03/2022

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

			Male				Female	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		11/50 (22%)	15/100 (15%)	16/100 (16%)		4/50 (8%)	14/100 (14%)	21/100 (21%)
		8/50 (16%)	10/48 (21%)	11/47 (23%)		7/50 (14%)	9/49 (18%)	11/47 (23%)
		10/59 (17%)	11/50 (22%)			10/60 (17%)	6/50 (12%)	
Overall Incidence	Total	92/504 (18.25%)	Mean 19.02%	SD 3.36%	Total	82/506 (16.21%)	Mean 15.93%	SD 4.98%
*Thyroid Gland: Follicular Cell Adenoma	l :							
		2/50 (4%)	1/100 (1%)	3/100 (3%)		0/50 (0%)	1/100 (1%)	0/100 (0%)
		0/50 (0%)	1/48 (2%)	0/47 (0%)		1/50 (2%)	0/49 (0%)	2/47 (4%)
		0/59 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	7/504 (1.39%)	Mean 1.26%	SD 1.59%	Total	4/506 (0.79%)	Mean 0.91%	SD 1.54%
Thyroid Gland: Follicular Cell Carcinoma								
		0/50 (0%)	3/100 (3%)	1/100 (1%)		0/50 (0%)	0/100 (0%)	1/100 (1%)
		0/50 (0%)	0/48 (0%)	0/47 (0%)		0/50 (0%)	1/49 (2%)	0/47 (0%)
		1/59 (2%)	0/50 (0%)			0/60 (0%)	1/50 (2%)	
Overall Incidence	Total	5/504 (0.99%)	Mean 0.71%	SD 1.12%	Total	3/506 (0.59%)	Mean 0.63%	SD 0.92%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	l:							
		2/50 (4%)	4/100 (4%)	4/100 (4%)		0/50 (0%)	1/100 (1%)	1/100 (1%)
		0/50 (0%)	1/48 (2%)	0/47 (0%)		1/50 (2%)	1/49 (2%)	2/47 (4%)
		1/59 (2%)	0/50 (0%)			0/60 (0%)	1/50 (2%)	
Overall Incidence	Total	12/504 (2.38%)	Mean 1.97%	SD 1.86%	Total	7/506 (1.38%)	Mean 1.54%	SD 1.38%

^{*:} 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

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Report Date: 06/03/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Vehicle: FEED

			Male				Female	
#Tissue NOS: Fibrosarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
verall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%
Tissue NOS: Leiomyoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
Tissue NOS: Paraganglioma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
verall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
Tissue NOS: Sarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%	Total	0/510 (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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

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

			Male				Female	
#Tissue NOS: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 1/50 (2%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%
#Tongue: Liposarcoma								
-		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%
#Tongue: Squamous Cell Carcinoma	ı							
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	05 00/		0/60 (0%)	1/50 (2%)	00 0000
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%
#Tongue:	or Panillam	a Saucmouc						
Squamous Cell Carcinoma	гог Раршош	1/50 (2%)	1/100 (1%)	1/100 (1%)		0/50 (0%)	0/100 (0%)	1/100 (1%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	3,00 (0,0)		0/60 (0%)	1/50 (2%)	2.00 (0.0)
Overall Incidence	Total	3/510 (0.59%)	Mean 0.5%	SD 0.76%	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%

^{*:} 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

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Report Date: 06/03/2022

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

			Male				Female	
#Tongue: Squamous Cell Papilloma								
		1/50 (2%) 0/50 (0%)	1/100 (1%) 0/50 (0%)	1/100 (1%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	1/100 (1%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 3/510 (0.59%)	0/50 (0%) Mean 0.5%	SD 0.76%	Total	0/60 (0%) 1/510 (0.2%)	0/50 (0%) Mean 0.12%	SD 0.35%
#Tooth: Odontogenic Tumor								
-		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/510 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/49 (0%)
Overall Incidence	Total	0/509 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma								
·		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/49 (0%)		0/50 (0%) 1/50 (2%)	0/100 (0%) 1/50 (2%)	0/100 (0%) 0/49 (0%)
Overall Incidence	Total	1/60 (2%) 1/509 (0.2%)	0/50 (0%) Mean 0.21%	SD 0.59%	Total	0/60 (0%) 2/509 (0.39%)	0/50 (0%) Mean 0.5%	SD 0.93%

^{*:} 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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: Leiomyosarcoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)(0%) 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 0/49 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/509 (0%) Mean 0% SD 0% Total 0/509 (0%) Mean 0% SD 0% *Urinary Bladder: **Papilloma** 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/49 0/49 0/50 (0%)(0%)1/50 (2%)1/50 (2%)(0%)(0%)1/60 (2%)0/50 0/60 (0%)0/50 (0%)**Overall Incidence** Total 1/509 (0.2%) Mean 0.21% SD 0.59% Total 2/509 (0.39%) Mean 0.5% SD 0.93% *Urinary Bladder: Sarcoma 0/50 0/100 0/100 0/100 0/100 (0%)(0%)(0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)(0%)(0%)0/50 0/60 0/50 (0%)0/60 (0%)**Overall Incidence** Total 0/509 (0%) Mean 0% SD 0% Total 0/509 (0%) Mean 0% SD 0% **#Uterus:** Adenoma 0/50 (0%)0/100 (0%)1/100 (1%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** SD 0.35% Total 1/510 (0.2%) Mean 0.12%

^{*:} 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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

#Uterus: Carcinoma 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/60 (0%) 0/50 (0%) 0/60 (0%) 0/50 (0%) 0/60 (0%) 0/50 (0%) 0/60 (0%) 0/60 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/60 (0%) 1/50 (2%) 0/60 (0%)
Overall Incidence Total 0/50 (0%) 0/50
Overall Incidence Total 0/60 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0% #Uterus: Hemangioma 0/50 (0%) 0/50 (0%
Overall Incidence Total 0/510 (0%) Mean 0% SD 0% #Uterus: Hemangioma 0/50 (0%) 0/100 (0%) 1/100 (1%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/60 (0%) 1/50 (2%) 0/50 (0%) Nean 0.38% SD 0.74%
#Uterus: Hemangioma \[\begin{array}{cccccccccccccccccccccccccccccccccccc
#Uterus: Hemangioma \[\begin{array}{c ccccccccccccccccccccccccccccccccccc
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$
0/60 (0%) 1/50 (2%) Overall Incidence Total 2/510 (0.39%) Mean 0.38% SD 0.74%
Overall Incidence Total 2/510 (0.39%) Mean 0.38% SD 0.74%
#Uterus: Leiomyoma
0/50 (0%) 0/100 (0%) 0/100 (0%)
0/50 (0%) 0/50 (0%) 0/50 (0%)
0/60 (0%) 0/50 (0%)
Overall Incidence Total 0/510 (0%) Mean 0% SD 0%
#Uterus: Leiomyosarcoma
0/50 (0%) 0/100 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
0/60 (0%) 0/50 (0%)
Overall Incidence Total 0/510 (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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

	Male		Female	
fUterus: Polyp Stromal				
		6/50 (12%) 10/50 (20%)	14/100 (14%) 8/50 (16%)	19/100 (19%) 16/50 (32%)
		11/60 (18%)	6/50 (12%)	10/30 (32/0)
Overall Incidence	Tota	al 90/510 (17.65%)	Mean 17.92%	SD 6.47%
EUterus: Sarcoma				
		0/50 (0%)	0/100 (0%)	0/100 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)
	- .	0/60 (0%)	0/50 (0%)	00.0740/
Overall Incidence	Tota	` '	Mean 0.25%	SD 0.71%
fUterus: Sarcoma Stromal				
		0/50 (0%)	0/100 (0%)	0/100 (0%)
		1/50 (2%)	0/50 (0%)	1/50 (2%)
Normall Institutes	Т	0/60 (0%)	0/50 (0%)	CD 0.000/
Overall Incidence	Tota	,	Mean 0.5%	SD 0.93%
tUterus: Sarcoma Stromal or Polyp Stromal				
•		6/50 (12%)	14/100 (14%)	19/100 (19%)
		11/50 (22%)	8/50 (16%)	17/50 (34%)
		11/60 (18%)	6/50 (12%)	
Overall Incidence	Tota	al 92/510 (18.04%)	Mean 18.42%	SD 7.21%

^{*:} 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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

	Male	Female	
#Uterus: Schwannoma Malignant			
-			0%)
		0/50 (0%) 0/50 (0%) 0/50 (0 0/60 (0%) 1/50 (2%)	0%)
Overall Incidence	Total	1/510 (0.2%) Mean 0.25% SD 0.71%	
#Vagina: Leiomyoma			
·			0%)
			0%)
Overall Incidence	Total	1/60 (2%) 0/50 (0%) 1/510 (0.2%) Mean 0.21% SD 0.59%	/ _
	ισια		
#Vagina: Leiomyosarcoma			
·			0%)
			0%)
Overall Incidence	Total	0/60 (0%) 0/50 (0%) 0/510 (0%) Mean 0% SD 0%	
	TOTAL	,	
≇Vagina: Polyp			
21		0/50 (0%) 0/100 (0%) 0/100 (0	0%)
		()	0%)
Overell Insidence	Tatal	0/60 (0%) 0/50 (0%)	
Overall Incidence	Total	0/510 (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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

			Male				Female	
#Vagina: Sarcoma								
						0/50 (0%)	0/100 (0%)	0/100 (0%)
						0/50 (0%) 0/60 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/510 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma				•••••				
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	1/100 (1%)	0/100 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/60 (2%) 2/510 (0.39%)	0/50 (0%) Mean 0.33%	SD 0.64%
		, ,				, ,		
#Zymbal's Gland: Carcinoma								
		0/50 (0%)	0/100 (0%)	1/100 (1%)		0/50 (0%)	0/100 (0%)	0/100 (0%)
		1/50 (2%) 0/60 (0%)	0/50 (0%) 2/50 (4%)	3/50 (6%)		0/50 (0%) 1/60 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	7/510 (1.37%)	2/30 (4%) Mean 1.62%	SD 2.26%	Total	1/510 (0.2%)	Mean 0.21%	SD 0.59%
		,				,		
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/100 (0%)	1/100 (1%)		0/50 (0%)	1/100 (1%)	0/100 (0%)
		1/50 (2%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/60 (0%)	2/50 (4%) Mean 1.62%	SD 2.26%	Total	2/60 (3%) 3/510 (0.59%)	0/50 (0%) Mean 0.54%	SD 1.18%
Overali incidence		7/510 (1.37%)				, ,		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Route: ORAL

Vehicle: WATER

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

Report Date: 06/03/2022

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Species: RATS Strain: F 344/N

Length of Study: CHRONIC

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	058803105	03/31/97	729	50(3)	23(662)	519.6	Dipropylene glycol
Battelle Columbus Laboratory	058800705	08/14/95	729	50(3)	29(665)	502.2	Sodium nitrite
Southern Research Institute	059601803	12/15/98	729	50(3)	29(682)	511.6	Water disinfection byproducts (Bromodichloromethane)
Southern Research Institute	059601705	03/08/00	729	50(3)	34(683)	522.9	Water disinfection byproducts (Dibromoacetic acid)
Southern Research Institute	059601003	09/16/98	729	50(3)	36(687)	514.1	Water disinfection byproducts (Sodium chlorate)
					Female		
Battelle Columbus Laboratory	058803105	04/01/97	729	50(5)	30(683)	350.8	Dipropylene glycol
Battelle Columbus Laboratory	058800705	08/15/95	730	50(5)	33(695)	350.1	Sodium nitrite
Southern Research Institute	059601803	N/A	N/A	0(0)	0(0)	N/A	Water disinfection byproducts (Bromodichloromethane)
Southern Research Institute	059601705	03/08/00	734	50(5)	35(693)	350.5	Water disinfection byproducts (Dibromoacetic acid)
Southern Research Institute	059601003	09/16/98	734	50(5)	37(699)	341.7	Water disinfection byproducts (Sodium chlorate)

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: 271

			Male				Female	
#All Organs: Benign Tumors								
		47/50 (94%) 47/50 (94%)	47/50 (94%) 48/50 (96%)	49/50 (98%)		44/50 (88%) 42/50 (84%)	42/50 (84%) 46/50 (92%)	
Overall Incidence	Total	238/250 (95.2%)	Mean 95.2%	SD 1.79%	Total	174/200 (87%)	Mean 87%	SD 3.83%
#All Organs: Malignant Tumors								
		35/50 (70%) 29/50 (58%)	30/50 (60%) 27/50 (54%)	28/50 (56%)		25/50 (50%) 16/50 (32%)	23/50 (46%) 21/50 (42%)	
Overall Incidence	Total	149/250 (59.6%)	Mean 59.6%	SD 6.23%	Total	85/200 (42.5%)	Mean 42.5%	SD 7.72%
#All Organs: Malignant and Benign T	umors							
		49/50 (98%)	49/50 (98%)	50/50 (100%)		50/50 (100%) 45/50 (90%)	45/50 (90%) 49/50 (98%)	
Overall Incidence	Total	50/50 (100%) 247/250 (98.8%)	49/50 (98%) Mean 98.8%	SD 1.1%	Total	189/200 (94.5%)	49/50 (98%) Mean 94.5%	SD 5.26%
#All Organs: Hemangioma						•••••		•••••
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: Hemangiosarcoma or Hemangioma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/200 (0%) **Overall Incidence** Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total Mean 0% SD 0% #All Organs: **Histiocytic Sarcoma** (0%) (0%)(0%) 0/50 (0%)0/50 0/50 (0%)0/50 0/50 2/50 (4%)1/50 (2%)0/50 (0%)0/50 (0%)Overall Incidence Total 3/250 (1.2%) Mean 1.2% SD 1.79% Total 0/200 (0%) Mean 0% SD 0% #All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated 16/50 (32%)17/50 (34%)16/50 (32%)10/50 (20%)15/50 (30%)17/50 (34%)13/50 (26%)11/50 (22%)11/50 (22%)**Overall Incidence** Total 79/250 (31.6%) Mean 31.6% SD 3.29% Total 47/200 (23.5%) Mean 23.5% SD 4.43% **#All Organs:** Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%)1/50 (2%)(0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)Overall Incidence Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total 0/200 (0%) Mean 0% SD 0% **#All Organs:** Mesothelioma: Benign 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 0/200 (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: ORAL Vehicle: WATER Page: 273

			Male				Female	
#All Organs: Mesothelioma: Benign, Mali	ignant, NOS	3						
		6/50 (12%) 3/50 (6%)	3/50 (6%) 0/50 (0%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	15/250 (6%)	Mean 6%	SD 4.24%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant								
		6/50 (12%) 3/50 (6%)	3/50 (6%) 0/50 (0%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	15/250 (6%)	Mean 6%	SD 4.24%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteoma			•••••			•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Normall In aideman	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/250 (1.6%)	3/50 (6%) Mean 1.6%	SD 2.61%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
All Organs: Osteosarcoma or Osteoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 4/250 (1.6%)	3/50 (6%) Mean 1.6%	SD 2.61%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Jveran mondence	ıvıaı	4/200 (1.0/0)	IVICALI 1.0 /0	۷۵ ۵.0۱/۵	ı Ulai	0/200 (0/0)	IVICALI U/0	0 /0 م

^{*:} 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: ORAL Vehicle: WATER Page: 274

			Male				Female	
*Adrenal Cortex: Adenoma								
		0/47 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%)	1/50 (2%)	
Overall Incidence	Total	0/49 (0%) 0/245 (0%)	0/49 (0%)	CD 00/	Total	1/49 (2%)	0/50 (0%)	CD 4.040/
Overali incidence	Total	0/245 (0%)	Mean 0%	SD 0%	Total	3/198 (1.52%)	Mean 1.52%	SD 1.01%
*Adrenal Cortex: Carcinoma								
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	
Occupation of decision	T-(-1	0/49 (0%)	0/49 (0%)	OD 00/	T-1-1	0/49 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Ganglioneuroma								
		1/47 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	
		0/49 (0%)	0/49 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	1/245 (0.41%)	Mean 0.43%	SD 0.95%	Total	0/198 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benign								
-		4/47 (9%)	6/50 (12%)	8/50 (16%)		0/49 (0%)	4/50 (8%)	
		7/49 (14%)	6/49 (12%)			1/49 (2%)	2/50 (4%)	
Overall Incidence	Total	31/245 (12.65%)	Mean 12.61%	SD 2.81%	Total	7/198 (3.54%)	Mean 3.51%	SD 3.41%
*Adrenal Medulla: Pheochromocytoma Comple	ex							
•		0/47 (0%)	0/50 (0%)	2/50 (4%)		0/49 (0%)	0/50 (0%)	
		0/49 (0%)	0/49 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	2/245 (0.82%)	Mean 0.8%	SD 1.79%	Total	0/198 (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: ORAL Vehicle: WATER

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Report Date: 06/03/2022

			Male				Female	
*Adrenal Medulla: Pheochromocytoma M	lalignant	547 (440)	4/50 (001)	4/52 (00)		0/40 (/0/)	0/50 (00/)	
		5/47 (11%) 0/49 (0%)	1/50 (2%) 3/49 (6%)	1/50 (2%)		2/49 (4%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	10/245 (4.08%)	Mean 4.15%	SD 4.26%	Total	2/198 (1.01%)	Mean 1.02%	SD 2.04%
*Adrenal Medulla: Pheochromocytoma: E	Benign, Comple	x, Malignant, NOS						
		9/47 (19%) 7/49 (14%)	7/50 (14%) 9/49 (18%)	11/50 (22%)		2/49 (4%) 1/49 (2%)	4/50 (8%) 2/50 (4%)	
Overall Incidence	Total	43/245 (17.55%)	Mean 17.56%	SD 3.4%	Total	9/198 (4.55%)	Mean 4.53%	SD 2.5%
#Blood Vessel: Osteosarcoma		0/50 (00/)	0/50 (00/)	2/52 (224)		0/50 (00/)	0/50 (00/)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Chordoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male				Female	
#Bone: Osteosarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	1/50 (2%)	CD 4.40/	Total	0/50 (0%)	0/50 (0%)	CD 00/
	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Insidence	Tatal	0/50 (0%)	1/50 (2%)	CD 4.40/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Astrocytoma Malignant								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/199 (0%)	Mean 0%	SD 0%
*Brain: Glioma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/199 (0%)	0/49 (0%) Mean 0%	SD 0%
	10tai	1/250 (0.4%)	wiean 0.4%	SD 0.69%	ı olal		wiean 0%	
*Brain: Granular Cell Tumor Benign	ı							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/49 (0%)	CD 00/
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/199 (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: ORAL Vehicle: WATER Page: 277

			Male			Female
*Brain: Granular Cell Tumor Ma	lignant					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0/50 (0%)	(0%)	` '	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total	0/199 (0%)	Mean 0% SD 0%
*Brain: Medulloblastoma Mal						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0/50 (0%)	(0%)	` '	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total	0/199 (0%)	Mean 0% SD 0%
*Brain: Meningioma Malignant						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0/50 (0%)	(0%)	` '	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total	1/199 (0.5%)	Mean 0.5% SD 1%
*Brain: Meningioma: Benign, M	alignant, NOS					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0/50 (0%)	(0%)	` ,	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total	1/199 (0.5%)	Mean 0.5% SD 1%
*Brain: Oligodendroglioma Ben	ign					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (0/50 (0%)	(2%)	` '	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.89%	Total	0/199 (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

Toxicology Data Management System

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male				Female	
*Brain: Oligodendroglioma Malig	gnant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma, Glio	ma or Astroc	vtoma						
Ongodenarognoma, Ono	ma, or Astroo	0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	,		0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	0/199 (0%)	Mean 0%	SD 0%
Brain: Sarcoma	T-1-1	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	Taral	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	OD 004
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/199 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma		0/50 (00)	2/22 (221)	2/22 (121)		242 4424	242 4220	
		3/50 (6%) 3/50 (6%)	0/50 (0%) 1/48 (2%)	2/50 (4%)		6/48 (13%) 8/50 (16%)	8/46 (17%) 11/49 (22%)	
Overall Incidence	Total	9/248 (3.63%)	Mean 3.62%	SD 2.6%	Total	33/193 (17.1%)	Mean 17.09%	SD 4.13%
		` ,				` ,		
Clitoral/Preputial Gland: Carcinoma								
		3/50 (6%)	5/50 (10%)	1/50 (2%)		5/48 (10%)	2/46 (4%)	
Overell Incidence	Total	0/50 (0%)	3/48 (6%)	CD 2.020/	Total	1/50 (2%)	3/49 (6%)	CD 2 F60/
Overall Incidence	Total	12/248 (4.84%)	Mean 4.85%	SD 3.92%	Total	11/193 (5.7%)	Mean 5.72%	SD 3.56%

^{*:} 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: ORAL Vehicle: WATER Page: 279

			Male				Female	
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		6/50 (12%)	5/50 (10%)	3/50 (6%)		10/48 (21%)	10/46 (22%)	
Overall Incidence	Total	3/50 (6%) 21/248 (8.47%)	4/48 (8%) Mean 8.47%	SD 2.6%	Total	9/50 (18%) 43/193 (22.28%)	14/49 (29%) Mean 22.29%	SD 4.48%
*Clitoral/Preputial Gland: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/46 (0%)	
Overall Incidence	Total	0/50 (0%) 0/248 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/193 (0%)	0/49 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/46 (0%)	
Overall Incidence	Total	0/50 (0%) 0/248 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/193 (0%)	0/49 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Sarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/46 (0%)	
Overall Incidence	Total	0/50 (0%) 1/248 (0.4%)	0/48 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/193 (0%)	0/49 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Schwannoma Malignant								
3		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/46 (0%)	
Overall Incidence	Total	0/50 (0%) 0/248 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/193 (0%)	0/49 (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: ORAL Vehicle: WATER Page: 280

			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Papilloma	1							
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/48 (0%)	0/50 (0%)		0/48 (0%) 0/50 (0%)	0/46 (0%) 0/49 (0%)	
Overall Incidence	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/193 (0%)	Mean 0%	SD 0%
#Ear: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Eye: Amelanotic Melanoma, B	enign							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
#Eye: Melanoma Benign								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
#Eye: Melanoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (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

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: 281

			Male				Female	
#Harderian Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0.4%	CD 0.000/	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
overali incidence	Total	1/250 (0.4%)		SD 0.89%		` '		
#Harderian Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	1/50 (2%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
	10tai	1/230 (0.476)			TOtal			
#Harderian Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	00.00
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/200 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Benign								
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 3/250 (1.2%)	0/50 (0%) Mean 1.2%	SD 1.79%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Heart: Schwannoma Malignant								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/200 (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: ORAL Vehicle: WATER Page: 282

			Male				Female	
#Intestine Large: Colon/R Adenoma	Rectum:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Large: Colon/R								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/R	Rectum:							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/R Leiomyosarcoma	Rectum:							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Large: Colon/R	Rectum:							
- •		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (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: ORAL Vehicle: WATER Page: 283

			Male				Female	
#Intestine Small: Jejunum Carcinoma	:							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum Leiomyoma	:							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Carcinoma	pecified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Carcinoma or Adenoma	•							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Route: ORAL

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Species: RATS Strain: F 344/N Vehicle: WATER

Length of Study: CHRONIC

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			Male				Female	
#Intestine Small: Site Unspe Leiomyoma	cified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		2/44 (5%) 5/48 (10%)	4/50 (8%) 3/50 (6%)	3/49 (6%)		0/47 (0%) 0/47 (0%)	0/50 (0%) 2/50 (4%)	
Overall Incidence	Total	17/241 (7.05%)	Mean 7.02%	SD 2.26%	Total	2/194 (1.03%)	Mean 1%	SD 2%
*Islets, Pancreatic: Carcinoma								
		0/44 (0%) 0/48 (0%)	1/50 (2%) 2/50 (4%)	0/49 (0%)		0/47 (0%) 0/47 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	3/241 (1.24%)	Mean 1.2%	SD 1.79%	Total	1/194 (0.52%)	Mean 0.5%	SD 1%
*Islets, Pancreatic: Carcinoma or Adenoma								
		2/44 (5%) 5/48 (10%)	5/50 (10%) 5/50 (10%)	3/49 (6%)		0/47 (0%) 0/47 (0%)	0/50 (0%) 3/50 (6%)	
Overall Incidence	Total	20/241 (8.3%)	Mean 8.22%	SD 2.7%	Total	3/194 (1.55%)	Mean 1.5%	SD 3%

^{*:} 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

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Report Date: 06/03/2022

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Kidney: Pelvis and Transitional Epithelium: Carcinoma 0/47 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/47 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/242 (0%) Mean 0% SD 0% Total 0/199 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma (0%) (0%) 0/49 (0%) 0/47 0/50 (0%)0/49(0%)0/50 0/49 (0%)0/47 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/242 (0%) Mean 0% SD 0% Total 0/199 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: **Papilloma** 0/47 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/47 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/242 (0%) Mean 0% SD 0% Total 0/199 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Adenoma 1/47 (2%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)1/49 (2%)0/47 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 2/242 (0.83%) Mean 0.83% SD 1.14% Total 0/199 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma 0/47 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/47 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/242 (0%) Mean 0% SD 0% Total 0/199 (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: ORAL Vehicle: WATER Page: 286

			Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		1/47 (2%) 1/49 (2%)	0/50 (0%) 0/47 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	2/242 (0.83%)	Mean 0.83%	SD 1.14%	Total	0/199 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma								
		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/47 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/242 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma								
		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/47 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/242 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma								
		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/47 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/242 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Stromal Nephroma								
-		1/47 (2%) 0/49 (0%)	0/50 (0%) 0/47 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/242 (0.41%)	Mean 0.43%	SD 0.95%	Total	0/199 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

*Liver:

*Liver:

*Liver:

*Liver:

*Liver:

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Cholangiocarcinoma

Hemangiosarcoma

Hepatocellular Adenoma

Hepatocellular Carcinoma

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

SD 0%

0/50

SD 0%

......

(0%)

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Mean 0%

Mean 0%

(0%)

(0%)

0/50

0/50

SD 0%

SD 0%

	Male				Female	
(0%) (0%) %)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%
(0%) (0%) %)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%
(0%) (2%) %)	0/50 (0%) 0/50 (0%) Mean 0.8%	1/50 (2%) SD 1.1%	Total	0/50 (0%) 2/50 (4%) 2/200 (1%)	0/50 (0%) 0/50 (0%) Mean 1%	SD 2%
(0%) (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	

0/200 (0%)

0/50

0/50

0/200 (0%)

(0%)

(0%)

Total

Total

Total

Total

Total

Total

Total

0/50

0/250 (0%)

0/50

0/50

0/250 (0%)

0/50 1/50

2/250 (0.8%)

0/50

0/50

0/250 (0%)

0/50

0/50

0/250 (0%)

(0%)

(0%)

Mean 0%

0/50

0/50

Mean 0%

(0%)

(0%)

Hepatocellular Carcinoma or Hepatoblastoma

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^{*:} 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

Report Date: 06/03/2022

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

			Male				Female	
*Liver:								
Hepatocellular Carcino	oma or Hepatoce							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)			2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	2/200 (1%)	Mean 1%	SD 2%
*Liver:								
Hepatocellular Carcino	ma, Hepatocellu	ular Adenoma, or Hepatol						
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)			2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	2/200 (1%)	Mean 1%	SD 2%
*Lung: Alveolar/Bronchiolar A	denoma							
		2/50 (4%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	
		2/50 (4%)	1/50 (2%)	(5,5)		1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	7/250 (2.8%)	Mean 2.8%	SD 1.79%	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%
*Lung:								
Alveolar/Bronchiolar C	arcinoma							
		1/50 (2%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	
		0/50 (0%)	3/50 (6%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.45%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
*Lung:	arcinoma or Alv	veolar/Bronchiolar Adeno	ma					
		3/50 (6%)	2/50 (4%)	1/50 (2%)		1/50 (2%)	3/50 (6%)	
		2/50 (4%)	4/50 (8%)	(=,0)		2/50 (4%)	2/50 (4%)	
Overall Incidence	Total	12/250 (4.8%)	Mean 4.8%	SD 2.28%	Total	8/200 (4%)	Mean 4%	SD 1.63%

^{*:} 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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male				Female	
*Lung: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
		0/250 (0%)		3D 0%	10tai	0/200 (0%)		JD 0%
*Lung: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Occupation of James	T-1-1	1/50 (2%)	0/50 (0%)	00.000/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
*Lung: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangioma								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (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: ORAL Vehicle: WATER Page: 290

			Male				Female	
#Lymph Node, Mesenteric: Hemangiosarcoma								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
#Lymph Node, Mesenteric: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 5/200 (2.5%)	3/50 (6%) Mean 2.5%	SD 3%
#Mammary Gland: Carcinoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		4/50 (8%) 3/50 (6%)	1/50 (2%) 3/50 (6%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	11/200 (5.5%)	Mean 5.5%	SD 2.52%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		4/50 (8%)	2/50 (4%)	
Overall Incidence	Total	1/50 (2%) 2/250 (0.8%)	0/50 (0%) Mean 0.8%	SD 1.1%	Total	3/50 (6%) 15/200 (7.5%)	6/50 (12%) Mean 7.5%	SD 3.42%

^{*:} 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**

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male				Female	
#Mammary Gland: Fibroadenoma								
		1/50 (2%) 4/50 (8%)	3/50 (6%) 2/50 (4%)	1/50 (2%)		36/50 (72%) 32/50 (64%)	21/50 (42%) 33/50 (66%)	
Overall Incidence	Total	11/250 (4.4%)	Mean 4.4%	SD 2.61%	Total	122/200 (61%)	Mean 61%	SD 13.11%
#Mammary Gland: Fibroma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenom								
		1/50 (2%) 4/50 (8%)	3/50 (6%) 2/50 (4%)	2/50 (4%)		36/50 (72%) 32/50 (64%)	23/50 (46%) 35/50 (70%)	
Overall Incidence	Total	12/250 (4.8%)	Mean 4.8%	SD 2.28%	Total	126/200 (63%)	Mean 63%	SD 11.83%
#Mammary Gland: Fibroma, Fibroadenom	na, Carcinoma, o	r Adenoma						
		1/50 (2%) 5/50 (10%)	3/50 (6%) 2/50 (4%)	2/50 (4%)		37/50 (74%) 32/50 (64%)	23/50 (46%) 37/50 (74%)	
Overall Incidence	Total	13/250 (5.2%)	Mean 5.2%	SD 3.03%	Total	129/200 (64.5%)	Mean 64.5%	SD 13.2%
#Mammary Gland: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (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: ORAL Vehicle: WATER Page: 292

			Male				Female	
#Mammary Gland: Myoepithelioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mesentery: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma						•••••		
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mesentery: Lipoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mesentery: Liposarcoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (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: ORAL Vehicle: WATER Page: 293

			Male				Female	
#Mesentery: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Rhabdomyosarcoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma						•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
*Nose: Adenoma								
		0/46 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/49 (0%) 0/244 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/198 (0%)	0/50 (0%) Mean 0%	SD 0%
*Nose: Chondroma								
		0/46 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/49 (0%) 0/244 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/198 (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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male				Female	
*Nose: Sarcoma								
		0/46 (0%)	0/50 (0%)	1/50 (2%)		0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/49 (0%) 1/244 (0.41%)	0/49 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/198 (0%)	0/50 (0%) Mean 0%	SD 0%
*Nose: Squamous Cell Carcin	oma		•••••					
		0/46 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)		0/48 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/244 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o	sa, Tongue, Phar	ynx, Tooth, Gingiva):						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Phar							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%
#Oral Cavity (Oral Mucos Squamous Cell Carcin		ynx, Tooth, Gingiva): Squamous, or Papilloma	•••••					
	,	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	2/200 (1%)	Mean 1%	SD 1.15%

^{*:} 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: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male					Female	
#Oral Mucosa: Squamous Cell Carcinoma									
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50	(0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%		Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Oral Mucosa: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/30	(0 78)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%		Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma							0/50 (0%)	0/50 (0%)	
Overall Incidence						Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Ovary: Granulosa Cell Tumor Beni	gn							0/50 (00/)	
							0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence						Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Ovary: Granulosa Cell Tumor Maliç									
							0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence						Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Version: 2006 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

	Male				F	emale	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS							
			0/50	(0%)	0/50	(0%)	
			0/50	(0%)	1/50	(2%)	
Overall Incidence			•	0.5%)		0.5%	SD 1%
*Ovary: Granulosa-Theca Tumor Malignant							
-			0/50	(0%)	0/50	(0%)	
			0/50	(0%)	0/50	(0%)	
Overall Incidence	To		/200	. ,		n 0%	SD 0%
*Ovary: Luteoma							
			0/50	(0%)	0/50	(0%)	
			0/50	(0%)	0/50	(0%)	
Overall Incidence	Tı	otal 0.	/200	(0%)	Mea	n 0%	SD 0%
*Ovary: Sarcoma							
ou. oonid			1/50	(2%)	0/50	(0%)	
			0/50	(0%)	0/50	(0%)	
Overall Incidence			,	0.5%)		0.5%	SD 1%
*Ovary: Thecoma Malignant							
•			0/50	(0%)	0/50	(0%)	
			0/50	(0%)	0/50	(0%)	
Overall Incidence	T	otal 0	/200	(0%)	Mea	n 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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date: 06/03/2022

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Species: RATS Strain: F 344/N

Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Pancreas: Adenoma								
		0/44 (0%) 0/48 (0%)	0/50 (0%) 0/49 (0%)	3/49 (6%)		1/47 (2%) 0/47 (0%)	0/50 (0%) 2/50 (4%)	
Overall Incidence	Total	3/240 (1.25%)	Mean 1.22%	SD 2.74%	Total	3/194 (1.55%)	Mean 1.53%	SD 1.93%
Pancreas: Carcinoma								
		1/44 (2%) 0/48 (0%)	0/50 (0%) 0/49 (0%)	0/49 (0%)		0/47 (0%) 0/47 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/240 (0.42%)	Mean 0.45%	SD 1.02%	Total	0/194 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma								
		1/44 (2%) 0/48 (0%)	0/50 (0%) 0/49 (0%)	3/49 (6%)		1/47 (2%) 0/47 (0%)	0/50 (0%) 2/50 (4%)	
Overall Incidence	Total	4/240 (1.67%)	Mean 1.68%	SD 2.67%	Total	3/194 (1.55%)	Mean 1.53%	SD 1.93%
Pancreas: Fibroma								
		0/44 (0%) 0/48 (0%)	0/50 (0%) 0/49 (0%)	0/49 (0%)		0/47 (0%) 0/47 (0%)	0/50 (0%) 0/50 (0%)	
verall Incidence	Total	0/240 (0%)	Mean 0%	SD 0%	Total	0/194 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Benign								
		2/44 (5%) 0/48 (0%)	0/50 (0%) 0/49 (0%)	0/49 (0%)		0/47 (0%) 0/47 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	2/240 (0.83%)	Mean 0.91%	SD 2.03%	Total	0/47 (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: ORAL Vehicle: WATER Page: 298

			Male				Female	
*Parathyroid Gland: Adenoma								
		1/45 (2%) 0/50 (0%)	0/45 (0%) 0/49 (0%)	0/48 (0%)		0/49 (0%) 0/50 (0%)	0/46 (0%) 0/47 (0%)	
Overall Incidence	Total	1/237 (0.42%)	Mean 0.44%	SD 0.99%	Total	0/192 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Sarcoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma Malignar	nt							
_		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign,	, Malignant, NOS	3						
_		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Adenoma		cified Site:						
		15/47 (32%) 23/50 (46%)	13/50 (26%) 16/48 (33%)	22/49 (45%)		20/48 (42%) 26/50 (52%)	24/50 (48%) 23/49 (47%)	
Overall Incidence	Total	89/244 (36.48%)	Mean 36.43%	SD 8.69%	Total	93/197 (47.21%)	Mean 47.15%	SD 4.26%

^{*:} 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: ORAL Vehicle: WATER Report Date: 06/03/2022

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			Male				Female	
Pituitary Gland: Pars Dis	talis or Unspec	cified Site:						
		0/47 (0%) 0/50 (0%)	0/50 (0%) 0/48 (0%)	0/49 (0%)		1/48 (2%) 0/50 (0%)	0/50 (0%) 1/49 (2%)	
Overall Incidence	Total	0/244 (0%)	Mean 0%	SD 0%	Total	2/197 (1.02%)	Mean 1.03%	SD 1.19%
Pituitary Gland: Pars Dis	talis or Unspec							
		15/47 (32%) 23/50 (46%)	13/50 (26%) 16/48 (33%)	22/49 (45%)		21/48 (44%) 26/50 (52%)	24/50 (48%) 24/49 (49%)	
Overall Incidence	Total	89/244 (36.48%)	Mean 36.43%	SD 8.69%	Total	95/197 (48.22%)	Mean 48.18%	SD 3.41%
*Pituitary Gland: Pars Inte Adenoma								
		0/47 (0%) 0/50 (0%)	0/50 (0%) 0/48 (0%)	0/49 (0%)		0/48 (0%) 1/50 (2%)	0/50 (0%) 1/49 (2%)	
Overall Incidence	Total	0/244 (0%)	Mean 0%	SD 0%	Total	2/197 (1.02%)	Mean 1.01%	SD 1.17%
Pituitary Gland: Pars Inte								
		0/47 (0%) 0/50 (0%)	0/50 (0%) 0/48 (0%)	0/49 (0%)		0/48 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	
Overall Incidence	Total	0/244 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Inte Carcinoma or Adenoma	ermedia:							
		0/47 (0%) 0/50 (0%)	0/50 (0%) 0/48 (0%)	0/49 (0%)		0/48 (0%) 1/50 (2%)	0/50 (0%) 1/49 (2%)	
Overall Incidence	Total	0/244 (0%)	Mean 0%	SD 0%	Total	2/197 (1.02%)	Mean 1.01%	SD 1.17%

^{*:} 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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Prostate: Adenoma 1/48 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/248 (0.4%) Mean 0.42% SD 0.93% *Prostate: Carcinoma or Adenoma (0%) 1/48 (2%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/248 (0.4%) Mean 0.42% SD 0.93% *Salivary Glands: Carcinoma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% Total 0/198 (0%) Mean 0% SD 0% *Salivary Glands: Carcinoma or Adenoma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% Total 0/198 (0%) Mean 0% SD 0% *Salivary Glands: Sarcoma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% Total 0/198 (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: ORAL Vehicle: WATER Page: 301

			Male				Female	
*Salivary Glands: Schwannoma Malignant								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangioma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Lipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (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: ORAL Vehicle: WATER **Page:** 302

			Male				Female	
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma or I				•••••				
•	•	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								•••••
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%) 2/250 (0.8%)	0/50 (0%) Mean 0.8%	SD 1.1%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Skin: Basal Cell Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or B	Basosquamous	Tumor Benign						
	•	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (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: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

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			Male				Female	
Skin:		Compan Danism on Telebrary	aldh all a ma					
Basai Celi Adenoma, Ba	sosquamous i	Tumor Benign, or Trichoe 0/50 (0%)		1/50 (2%)		0/50 (00/)	1/50 (00/)	
		0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 2/50 (4%)	
verall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
					1 Ulai			
Skin: Basal Cell Carcinoma								
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
verall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Skin: Basal Cell Carcinoma or	Basosquamou	us Tumor (malignant or N 0/50 (0%) 1/50 (2%)	0S) 1/50 (2%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	
verall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Skin: Basal Cell Carcinoma, B NOS), or Trichoepithelio	asal Cell Aden ma	oma, Basosquamous Tur	nor (benign, malignar 1/50 (2%)	nt or 2/50 (4%)		0/50 (0%)	2/50 (4%)	
		2/50 (4%)	1/50 (2%)	2/00 (4/0)		0/50 (0%)	3/50 (6%)	
verall Incidence	Total	6/250 (2.4%)	Mean 2.4%	SD 1.67%	Total	5/200 (2.5%)	Mean 2.5%	SD 3%
Skin: Basal or Sq. Cell Carcino	oma, Carcinom	na, Basosq. Tumor (M or E eratoacanthoma, Trichoep	8), Basal Cell Adenom ithelioma	na,		0/50 (0%)	3/50 (6%)	
Adenoma, Papilloma, Sq	•	1/50 (2%) 7/50 (14%)	3/50 (6%) 5/50 (10%)	4/50 (8%)		1/50 (2%)	3/50 (6%)	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Mean 0%

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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Mean 0%

SD 0%

Report Date: 06/03/2022

Route: ORAL Vehicle: WATER

Male **Female** #Skin: **Fibroma** 1/50 6/50 (12%)0/50 (0%)6/50 (12%)1/50 (2%)(2%)5/50 (10%)9/50 (18%)1/50 (2%)4/50 (8%)Overall Incidence Total 26/250 (10.4%) Mean 10.4% SD 6.54% Total 7/200 (3.5%) Mean 3.5% SD 3% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 9/50 (18%)1/50 (2%)7/50 (14%)1/50 (2%)1/50 (2%)6/50 (12%) 10/50 (20%)1/50 (2%)4/50 (8%)**Overall Incidence** Total 33/250 (13.2%) Mean 13.2% SD 7.01% Total 7/200 (3.5%) Mean 3.5% SD 3% #Skin: **Fibrosarcoma** 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total 0/200 (0%) Mean 0% SD 0% #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma (6%)1/50 (2%)1/50 0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 7/250 (2.8%) Mean 2.8% SD 1.79% Total 0/200 (0%) Mean 0% SD 0% #Skin: **Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

0/200 (0%)

Total

0/250 (0%)

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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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 305

			Male				Female	
#Skin: Hemangioma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Hemangiopericytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma								
		1/50 (2%) 3/50 (6%)	2/50 (4%) 4/50 (8%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	13/250 (5.2%)	Mean 5.2%	SD 2.28%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Lipoma								
		1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} 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: ORAL Vehicle: WATER Page: 306

			Male				Female	
#Skin: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Myxoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Myxosarcoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} 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: ORAL Vehicle: WATER Report Date: 06/03/2022

Page: 307

			Male				Female	
#Skin: Neurofibroma or Schw	vannoma benign							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin:								
Neurofibrosarcoma or	Schwannoma (m	alignant or NOS) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Overall Incidence	Total	6 chwannoma (benign, ma 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%
#Skin:	·····	0/200 (0/0)	Wican 078				Wican 070	
Osteosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
		3/50 (6%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
	Total	5/250 (2%)	` '	SD 2.45%	Total	0/200 (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: ORAL Vehicle: WATER Page: 308

			Male				Female	
#Skin: Schwannoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignant		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 /00/\	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma								
·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/50 (2%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%
		, ,						
#Skin: Squamous Cell Carcinoma or Carcinoma	a, Basal Cell	Carcinoma, Basosquamo	ous Tumor (malignant	or NOS),				
		0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	2/50 (4%) 1/50 (2%)	
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
#Skin: Squamous Cell Papilloma								
•		0/50 (0%) 2/50 (4%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	
		= (. / 0)	(-70)			(=)		

^{*:} 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: ORAL Vehicle: WATER Page: 309

			Male				Female	
#Skin: Squamous Cell Papillon	na or Papilloma							
		0/50 (0%) 2/50 (4%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Squamous Cell Papillon		Squamous Cell Carcinom 1/50 (2%)		a 3/50 (6%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	6/50 (12%) 16/250 (6.4%)	4/50 (8%) Mean 6.4%	SD 3.85%	Total	1/50 (2%) 2/200 (1%)	0/50 (0%) Mean 1%	SD 1.15%
Squamous Cell Papillon Overall Incidence	na, Papilloma, c Total	or Keratoacanthoma 1/50 (2%) 5/50 (10%) 15/250 (6%)	2/50 (4%) 4/50 (8%) Mean 6%	3/50 (6%) SD 3.16%	Total	0/50 (0%) 1/50 (2%) 1/200 (0.5%)	0/50 (0%) 0/50 (0%) Mean 0.5%	SD 1%
#Skin: Trichoepithelioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/50 (2%) 2/250 (0.8%)	1/50 (2%) Mean 0.8%	SD 1.1%	Total	0/50 (0%) 3/200 (1.5%)	2/50 (4%) Mean 1.5%	SD 1.91%
#Skin: Sebaceous Gland: Adenoma		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
		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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 310

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	00.007		0/50 (0%)	0/50 (0%)	00.00
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
	-	0/50 (0%)	0/50 (0%)	OD 0.000/	-	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma								
_		0/43 (0%)	0/50 (0%)	0/48 (0%)		0/48 (0%)	0/50 (0%)	
		0/50 (0%)	0/48 (0%)			0/47 (0%)	0/50 (0%)	
Overall Incidence	Total	0/239 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
_		0/43 (0%)	0/50 (0%)	1/48 (2%)		0/48 (0%)	0/50 (0%)	
		0/50 (0%)	0/48 (0%)			0/47 (0%)	0/50 (0%)	
Overall Incidence	Total	1/239 (0.42%)	Mean 0.42%	SD 0.93%	Total	0/195 (0%)	Mean 0%	SD 0%
*Spleen: Leiomyosarcoma								
•		0/43 (0%)	0/50 (0%)	0/48 (0%)		0/48 (0%)	0/50 (0%)	
		0/50 (0%)	0/48 (0%)			0/47 (0%)	0/50 (0%)	
Overall Incidence	Total	0/239 (0%)	Mean 0%	SD 0%	Total	0/195 (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: ORAL Vehicle: WATER **Page:** 311

			Male				Female	
#Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
			······					
#Stomach, Forestomach: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
	.	0/50 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	00.007
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinon	na or Papillom	a Squamous						
	-	0/50 (0%)	1/50 (2%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
#Stomach, Forestomach: Squamous Cell Papillom	ıa							
•		0/50 (0%)	1/50 (2%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%

^{*:} 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

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Report Date: 06/03/2022

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

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Stomach, Glandular: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	22 22/		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Leiomyosarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Testes: Adenoma								
		45/50 (90%) 41/50 (82%)	47/50 (94%) 45/50 (90%)	45/50 (90%)				
Overall Incidence	Total	223/250 (89.2%)	Mean 89.2%	SD 4.38%				

^{*:} 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: ORAL Vehicle: WATER Report Date: 06/03/2022

Page: 313

			Male				Female	
*Thymus: Sarcoma								
		0/39 (0%) 1/49 (2%)	0/50 (0%) 0/48 (0%)	0/48 (0%)		0/48 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	
Overall Incidence	Total	1/234 (0.43%)	Mean 0.41%	SD 0.91%	Total	0/195 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign								
		0/39 (0%) 1/49 (2%)	0/50 (0%) 0/48 (0%)	0/48 (0%)		1/48 (2%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	
Overall Incidence	Total	1/234 (0.43%)	Mean 0.41%	SD 0.91%	Total	1/195 (0.51%)	Mean 0.52%	SD 1.04%
*Thymus: Thymoma Malignant								
		0/39 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/48 (0%)		0/48 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	
Overall Incidence	Total	0/234 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligi								
		0/39 (0%) 1/49 (2%)	0/50 (0%) 0/48 (0%)	0/48 (0%)		1/48 (2%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	
Overall Incidence	Total	1/234 (0.43%)	Mean 0.41%	SD 0.91%	Total	1/195 (0.51%)	Mean 0.52%	SD 1.04%
*Thyroid Gland: C-Cell: Adenoma								
		4/42 (10%) 6/50 (12%)	12/50 (24%) 9/47 (19%)	8/46 (17%)		6/45 (13%) 6/50 (12%)	7/50 (14%) 12/47 (26%)	
Overall Incidence	Total	39/235 (16.6%)	Mean 16.41%	SD 5.76%	Total	31/192 (16.15%)	Mean 16.22%	SD 6.27%

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^{*:} 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: ORAL Vehicle: WATER Report Date: 06/03/2022

Page: 314

			Male				Female	
*Thyroid Gland: C-Cell: Carcinoma								
		2/42 (5%)	2/50 (4%)	1/46 (2%)		1/45 (2%)	2/50 (4%)	
		1/50 (2%)	2/47 (4%)			0/50 (0%)	1/47 (2%)	
Overall Incidence	Total	8/235 (3.4%)	Mean 3.44%	SD 1.27%	Total	4/192 (2.08%)	Mean 2.09%	SD 1.64%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		6/42 (14%)	14/50 (28%)	9/46 (20%)		7/45 (16%)	9/50 (18%)	
		7/50 (14%)	11/47 (23%)			6/50 (12%)	13/47 (28%)	
Overall Incidence	Total	47/235 (20%)	Mean 19.85%	SD 6.01%	Total	35/192 (18.23%)	Mean 18.3%	SD 6.71%
*Thyroid Gland: Follicular Ce Adenoma	II:							
		1/42 (2%)	1/50 (2%)	0/46 (0%)		0/45 (0%)	1/50 (2%)	
		1/50 (2%)	1/47 (2%)			0/50 (0%)	0/47 (0%)	
Overall Incidence	Total	4/235 (1.7%)	Mean 1.7%	SD 0.96%	Total	1/192 (0.52%)	Mean 0.5%	SD 1%
*Thyroid Gland: Follicular Ce Carcinoma	II:							
		0/42 (0%)	1/50 (2%)	0/46 (0%)		1/45 (2%)	1/50 (2%)	
		0/50 (0%)	0/47 (0%)			0/50 (0%)	1/47 (2%)	
Overall Incidence	Total	1/235 (0.43%)	Mean 0.4%	SD 0.89%	Total	3/192 (1.56%)	Mean 1.59%	SD 1.06%
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma	II:							
		1/42 (2%)	2/50 (4%)	0/46 (0%)		1/45 (2%)	2/50 (4%)	
		1/50 (2%)	1/47 (2%)			0/50 (0%)	1/47 (2%)	
Overall Incidence	Total	5/235 (2.13%)	Mean 2.1%	SD 1.42%	Total	4/192 (2.08%)	Mean 2.09%	SD 1.64%

^{*:} 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: ORAL Vehicle: WATER Page: 315 Report Date: 06/03/2022

			Male				Female	
#Tissue NOS: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tissue NOS: Leiomyoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tissue NOS: Paraganglioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	1/50 (2%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tissue NOS: Sarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant					•••••			
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (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: ORAL Vehicle: WATER Page: 316

			Male				Female	
#Tongue: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Tongue: Squamous Cell Carcinoma of Overall Incidence	or Papillom Total	a Squamous 0/50 (0%) 0/50 (0%) 1/250 (0.4%)	0/50 (0%) 0/50 (0%) Mean 0.4%	1/50 (2%) SD 0.89%	Total	1/50 (2%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) 0/50 (0%) Mean 0.5%	SD 1%
#Tongue: Squamous Cell Papilloma						-/		
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tooth: Odontogenic Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (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: ORAL Vehicle: WATER Page: 317

			Male				Female	
*Urinary Bladder: Carcinoma								
		0/46 (0%) 1/50 (2%)	0/49 (0%) 0/48 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/242 (0.41%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma								
		0/46 (0%) 1/50 (2%)	1/49 (2%) 0/48 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	2/242 (0.83%)	Mean 0.81%	SD 1.11%	Total	0/200 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma				•••••				
-		0/46 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/242 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Papilloma								
		0/46 (0%) 0/50 (0%)	1/49 (2%) 0/48 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/242 (0.41%)	Mean 0.41%	SD 0.91%	Total	0/200 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Sarcoma								
		1/46 (2%) 0/50 (0%)	0/49 (0%) 0/48 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/242 (0.41%)	Mean 0.43%	SD 0.97%	Total	0/200 (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

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Report Date: 06/03/2022

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus:** Adenoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% **#Uterus:** Carcinoma 0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/200 (1%) Mean 1% SD 2% #Uterus: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Uterus: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Uterus: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (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: ORAL Vehicle: WATER Page: 319

Report Date: 06/03/2022

	Male		Female	
#Uterus:				
Polyp Stromal		8/50 (16%)	7/50 (14%)	
		4/50 (8%)	9/50 (18%)	
Overall Incidence	Total	28/200 (14%)	Mean 14%	SD 4.32%
#Uterus: Sarcoma				
Garconia		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal				
		1/50 (2%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%
#Uterus: Sarcoma Stromal or Polyp Stromal				
our comarcinarion i cripp culcimar		9/50 (18%)	7/50 (14%)	
		4/50 (8%)	10/50 (20%)	
Overall Incidence	Total	30/200 (15%)	Mean 15%	SD 5.29%
#Uterus: Schwannoma Malignant				
		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Version: 2006 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female** #Vagina: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Vagina: Leiomyosarcoma 0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Vagina: Polyp 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Vagina: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Zymbal's Gland: Adenoma 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 0/200 (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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date: 06/03/2022

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Species: RATS Strain: F 344/N

Vehicle: WATER Length of Study: CHRONIC

			Male			Female			
#Zymbal's Gland: Carcinoma									
		3/50 (6%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.45%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
#Zymbal's Gland: Carcinoma or Adenoma									
		3/50 (6%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		
Overall Incidence	Total	6/250 (2.4%)	Mean 2.4%	SD 2.19%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

^{*:} 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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

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								
Southern Research Institute	059302007	04/24/00	729	50(1)	20(670)	484.2	Diisopropylcarbodiimide		
Female									
Southern Research Institute	059302007	04/24/00	731	50(1)	30(672)	319.5	Diisopropylcarbodiimide		

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male					Female				
#All Organs: Benign Tumors										
•		47/50 (94%)				44/50 (88%)				
Overall Incidence	Total	47/50 (94%)	Mean 94%	SD 0%	Total	44/50 (88%)	Mean 88%	SD 0%		
#All Organs: Malignant Tumors		34/50 (68%)				22/50 (44%)				
Overall Incidence	Total	34/50 (68%)	Mean 68%	SD 0%	Total	22/50 (44%)	Mean 44%	SD 0%		
#All Organs: Malignant and Benign T										
		50/50 (100%)				48/50 (96%)				
Overall Incidence	Total	50/50 (100%)	Mean 100%	SD 0%	Total	48/50 (96%)	Mean 96%	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%		

^{*:} 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

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

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

Page: 324

#All Organs: Histiocytic Sarcoma O/50 (0 Overall Incidence Total 0/50 (0%) #All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Und	Male					
Overall Incidence Total 0/50 (0%) #All Organs:						
#All Organs:	0%)			0/50 (0%)		
#All Organs:	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
, , , , , , , , , , , , , , , , , , ,						
13/50 (26	6%)			9/50 (18%)		
Overall Incidence Total 13/50 (26%)	Mean 26%	SD 0%	Total	9/50 (18%)	Mean 18%	SD 0%
#All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, N 2/50 (4 Overall Incidence Total 2/50 (4%)	NOS, or Undifferentiated Ce 4%) Mean 4%	ell Type	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall incidence Total 2/30 (470)						
#All Organs: Mesothelioma: Benign 0/50 (0	D%)			0/50 (0%)		
Overall Incidence Total 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign, Malignant, NOS			•••••	•••••		
	2%)			0/50 (0%)		
Overall Incidence Total 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant	20(1)			0/50 (00/)		
1/50 (2 Overall Incidence Total 1/50 (2%)	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

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: SKIN Vehicle: ETHANOL Page: 325

			Male			Female			
#All Organs: 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%	
#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	a	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		0/50 (0%)				3/50 (6%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
*Adrenal Cortex: 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%	
*Adrenal Medulla: Ganglioneuroma		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (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 Tumor Incidence for Se

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 326

			Male			Female					
*Adrenal Medulla: Pheochromocytoma Benign											
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%			
*Adrenal Medulla: Pheochromocytoma Co	omplex					•••••					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%			
*Adrenal Medulla: Pheochromocytoma Ma	alignant	4/50 (8%)				0/49 (0%)					
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			
*Adrenal Medulla: Pheochromocytoma: B	enign, Complex,	, Malignant, NOS 6/50 (12%)			Total	0/49 (0%)	Mean 0%	SD 0%			
	Total	6/50 (12%)	Mean 12%	SD 0%	Total	0/49 (0%)		SD 0%			
#Blood Vessel: 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%			
#Bone: Chordoma		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%			

^{*:} 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: SKIN Vehicle: ETHANOL Page: 327

			Male			Female				
#Bone: Osteoma										
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: Osteosarcoma										
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: 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: Astrocytoma Malignant		1/50 (2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Brain: 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%		
*Brain: Granular Cell Tumor Benigr		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: SKIN Vehicle: ETHANOL **Page:** 328

			Male				Female				
*Brain: Granular Cell Tumor 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%			
*Brain: Medulloblastoma Mal		2/20 (201)				0/20 (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%			
*Brain: Meningioma 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: Meningioma: Benign, Mal	lignant, NOS	0/50 (0%)				0/50 (0%)		OD 00			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Brain: Oligodendroglioma Benig	jn	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%			
*Brain: Oligodendroglioma Malig	nant	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: SKIN Vehicle: ETHANOL

Control Animal Groups Report Date: 06/03/2022 KIN

Page: 329

			Male			Female					
*Brain: Oligodendroglioma, Glioma, or Astrocytoma 1/50 (2%) 0/50 (0%)											
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: 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%			
*Clitoral/Preputial Gland: Adenoma		4/50 (001)				0/50 (40)					
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%			
*Clitoral/Preputial Gland: Carcinoma		1/50 (2%)				2/50 (4%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%			
*Clitoral/Preputial Gland: Carcinoma or Adenoma	••••										
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%			
*Clitoral/Preputial Gland: Fibrosarcoma		0/00 /5-13									
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

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: SKIN Vehicle: ETHANOL Page: 330

			Male				Female	
*Clitoral/Preputial Gland: Hemangiosarcoma		272 (221)				2/22 (221)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	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%
*Clitoral/Preputial Gland: 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%
*Clitoral/Preputial Gland: 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%
		0/30 (0%)		3D 0%	i Olai	0/30 (0%)	iviean 0%	
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: Amelanotic Melanoma, Ben	ign	0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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

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Report Date: 06/03/2022

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

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
#Eye: Melanoma 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%
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								
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		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 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%
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%

^{*:} 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: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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Report Date: 06/03/2022

SD 0%

Mean 0%

				Male				Female	
*Heart: Schwannoma Malignant									
		1/50	(2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Intestine Large: Colon/Rectu Adenoma									
			(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Carcinoma	um:								
		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 Large: Colon/Rectu Carcinoma or Adenoma									
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Leiomyosarcoma	um:								
•		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 Large: Colon/Rectu Polyp Adenomatous							•••••		
		0/50	(0%)				0/50 (0%)		

SD 0%

Total

0/50 (0%)

Total

0/50 (0%)

Mean 0%

Overall Incidence

^{*:} 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: 333

Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#Intestine Small: Jejunum: 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%
#Intestine Small: Jejunum: Leiomyoma								
		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: Jejunum: Sarcoma		0/50 (00()				0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan 00/	CD 00/
Overall incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma	cified:							
		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 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%
#Intestine Small: Site Unspec								
•		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

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

> Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

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			Male				Female			
#Intestine Small: Site Unspec	cified:									
		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										
		5/50 (10%)				0/50 (0%)				
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Islets, Pancreatic: 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%		
*Islets, Pancreatic: Carcinoma or Adenoma		7/50 (14%)				0/50 (0%)				
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Kidney: Pelvis and Transitio										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Kidney: Pelvis and Transitio Carcinoma or Adenoma	nal Epitheliu									
		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

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

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

Page: 335

			Male				Female					
*Kidney: Pelvis and Transitional Epithelium: 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%				
*Kidney: Renal Tubule: 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%				
*Kidney: Renal Tubule: 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%				
*Kidney: Renal Tubule: Carcinoma or Adenoma						0/50 (09/)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Kidney: Renal Tubule: Lipoma	••••											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Kidney: Renal Tubule: 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%				

^{*:} 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: SKIN Vehicle: ETHANOL Page: 336

			Male				Female			
*Kidney: Renal Tubule: 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%		
*Kidney: Renal Tubule: Stromal Nephroma										
	-	0/50 (0%)		OD 00/	-	0/50 (0%)		OD 00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Liver: Cholangiocarcinoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Liver: 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%		
Overall incidence		` '				` '				
*Liver: Hepatocellular Adenoma						-4				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%		
		` '				` ,				
*Liver: Hepatocellular 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%		

^{*:} 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

Report Date: 06/03/2022

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Species: RATS Strain: F 344/N Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
*Liver: Hepatocellular Carcino	oma or Hepatobla	stoma						
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcino	ma or Hepatocel	lular Adenoma						
•	•	0/50 (0%)				6/50 (12%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%
*Liver:		lar Adenoma, or Hepatob				6/50 (12%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%
*Lung: Alveolar/Bronchiolar A	denoma							
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar C								
		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 C	arcinoma or Alve	eolar/Bronchiolar Adenor	na					
		1/50 (2%)				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: SKIN Vehicle: ETHANOL Page: 338

			Male	Female Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0%		Female		
*Lung: Carcinoma		0/50 (09/)				0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%
*Lung: Sarcoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Lung: Squamous Cell Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Carcinoma		0/50 (0%)				` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	(,	Mean 0%	SD 0%
#Lymph Node, Mesenteric: 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%

^{*:} 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: 339

Report Date: 06/03/2022

SD 0%

Mean 0%

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Male **Female #Lymph Node, Mesenteric:** 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% #Mammary 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% #Mammary Gland: Carcinoma 0/50 (0%)4/50 (8%) **Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 4/50 (8%) Mean 8% SD 0% #Mammary Gland: Carcinoma or Adenoma 0/50 (0%)4/50 (8%) **Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 8% SD 0% 4/50 (8%) **#Mammary Gland:** Fibroadenoma 0/50 (0%)12/50 (24%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 12/50 (24%) Mean 24% SD 0% #Mammary Gland: **Fibroma** 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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma	a or Adenoma	0/50 (0%)				12/50 (24%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	12/50 (24%)	Mean 24%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma	a, Carcinoma, or A	Adenoma 0/50 (0%)				14/50 (28%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	14/50 (28%)	Mean 28%	SD 0%
#Mammary Gland: 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%
#Mammary Gland: Myoepithelioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: 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%
#Mesentery: 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%

^{*:} 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: SKIN Vehicle: ETHANOL

ol Animal Groups Report Date: 06/03/2022

Page: 341

			Male			0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%		
#Mesentery: Lipoma		(201)				(20)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)		
#Mesentery: Liposarcoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Mesentery: Osteosarcoma		0/50 (00()				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Mesentery: Rhabdomyosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Mesentery: Sarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Nose: Adenoma		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%

^{*:} 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

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Report Date: 06/03/2022

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

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

			Male	Male Female				
*Nose: Chondroma		0/50 (0%)				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%
*Nose: 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%
*Nose: Squamous Cell Carcino	oma			•••••				
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o		nx, Tooth, Gingiva):						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
Oral Cavity (Oral Mucos Squamous Cell Carcino		nx, Tooth, Gingiva):						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Oral Cavity (Oral Mucos		vnx, Tooth, Gingiva): iquamous, or Papilloma				0/50 /00/		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%) 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: SKIN Vehicle: ETHANOL Page: 343

			Male			Female			
#Oral Mucosa: Squamous Cell Carcinom	a								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Oral Mucosa: Squamous Cell Papilloma	ı								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Cystadenoma						0/50 (00)			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor Be						0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor Ma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor: Be	enign, Maligna	ant, NOS				(201)			
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

Version: 2006 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 344 Report Date: 06/03/2022

SD 0%

Mean 0%

			Male				Female	
*Ovary: Granulosa-Theca Tumo	r Malignant							
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Thecoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma				•••••		•••••		
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma								
		0/50 (0%)				0/50 (0%)		

SD 0%

Total

0/50 (0%)

Total

0/50 (0%)

Mean 0%

Overall Incidence

^{*:} 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: SKIN Vehicle: ETHANOL Page: 345

			Male			0/50 (0%) otal 0/50 (0%) Mean 0% SD 0% 0/50 (0%) otal 0/50 (0%) Mean 0% SD 0% 0/45 (0%) otal 0/45 (0%) Mean 0% SD 0%			Female		
*Pancreas: Carcinoma or Adenoma		3/50 (6%)				` '					
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Pancreas: Fibroma		0/50 (00/)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	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	` '	Mean 0%	SD 0%			
*Parathyroid Gland: Adenoma		0/49 (0%)				0/45 (0%)					
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/45 (0%)					
#Peripheral Nerve: Sarcoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%			
#Peripheral Nerve: 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

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

ontrol Animal Groups Report Date: 06/03/2022
N

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			Male				Female	
#Peripheral Nerve: Schwannoma: Benign, N	Malignant, 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%
*Pituitary Gland: Pars Dist	alis or Unspeci	fied Site:						
Overall Incidence	Total	29/50 (58%) 29/50 (58%)	Mean 58%	SD 0%	Total	33/50 (66%) 33/50 (66%)	Mean 66%	SD 0%
*Pituitary Gland: Pars Dist Carcinoma	alis or Unspeci					2/52 /69()		
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
*Pituitary Gland: Pars Dist Carcinoma or Adenoma	talis or Unspeci					36/50 (72%)		
Overall Incidence	Total	34/50 (68%)	Mean 68%	SD 0%	Total	36/50 (72%)	Mean 72%	SD 0%
*Pituitary Gland: Pars Inte Adenoma								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Inte Carcinoma	rmedia:							
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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male				Female	
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:							
		3/50 (6%)				0/50 (0%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma		4/50 (00)						
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
*Prostate: Carcinoma or Adenoma								
		1/50 (2%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%				
*Salivary Glands: Carcinoma		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma								
		0/49 (0%)		00.00		0/50 (0%)		00.00/
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Sarcoma						2/22 (224)		
Overall Incidence	Total	1/49 (2%)	Maon 2.040/	CD 00/	Total	0/50 (0%)	Maan 00/	CD 00/
Overall incidence	Total	1/49 (2.04%)	Mean 2.04%	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: SKIN Vehicle: ETHANOL Page: 348 Report Date: 06/03/2022

			Male		Female 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% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0%			
*Salivary Glands: Schwannoma Malignant								
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%
#Skeletal Muscle: Fibrosarcoma		2/-2 (221)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
#Skeletal Muscle: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
#Skeletal Muscle: Lipoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	, ,	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skeletal Muscle: Rhabdomyosarcoma or Ri	habdomyoma							
-	-		0%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		1/50 (2	2%)			0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
∜Skin: Basal 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%
∜Skin: Basal Cell Adenoma or Ba		Tumor Benign	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, Baso								
	-	_	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 Carcinoma			0%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
overali incidence		` ,				` '		

^{*:} 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: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

roups Report Date: 06/03/2022

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			Male			Female 0/50 (0%) 0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%) SD 0% 1/50 (2%) Mean 2% SD 0%				
#Skin:	_									
Basal Cell Carcinoma	or Basosquamou	s Tumor (malignant or N	OS)			0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%		
#Skin: Basal Cell Carcinoma	Basal Cell Adend	oma, Basosquamous Tur	nor (henian malians	ant or						
NOS), or Trichoepitheli		•	nor (berngil, mangile							
Overall Instidence	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	` '	Mana 00/	CD 00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
Adenoma, Papilloma, S Overall Incidence	Sq Papilloma, Ke	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 4/50 (8%) 4/50 (8%)	nithelioma Mean 8%	ma, SD 0%	Total	` '	Mean 2%	SD 0%		
#Skin: Fibroma										
		5/50 (10%)				0/50 (0%)				
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myxo	oma, Myxosarcoma, or Fi	ibrous Histiocytoma			0.50				
	-	5/50 (10%)	100/	OD 00/	T	0/50 (0%)		OD 00/		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Fibrosarcoma		0.170 (004)				0.750 (001)				
O	T-1-1	0/50 (0%)	M 00/	00.00/	T-1-1	0/50 (0%)	Maran 00/	00.00/		
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: SKIN Vehicle: ETHANOL Page: 351

			Male		Female 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Mean 0% SD 0%			
#Skin: Fibrosarcoma, Sarcoma	, Myxosarcoma		cytoma			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)		
#Skin: Fibrous Histiocytoma								
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) Mean 0%	SD 0%	Total	(,	Mean 0%	SD 0%
#Skin: Hemangioma			0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
#Skin: Hemangiopericytoma			0%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)		
#Skin: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%)	0%) Mean 0%	SD 0%	Total	0/50 (0%)		
#Skin: Keratoacanthoma								
Overall Incidence	Total	3/50 (6%)	5%) Mean 6%	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

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: SKIN Vehicle: ETHANOL Page: 352

			Male		0/50 (0%) Total 0/50 (0%) Mean 0% SD 0 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0			Female			
#Skin: Lipoma		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%			
#Skin: Liposarcoma		0/50 (0%)									
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%			
#Skin: Melanoma Malignant		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%			
#Skin: Myxoma	Tatal	0/50 (0%)	Mars 00/	CD 00/	Total	` '	M 00/	CD 004			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	l otal	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Myxosarcoma		0/50 /00/				0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	(,	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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Control Animal Groups Report Date: 06/03/2022

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			Male				Female	
#Skin: Neurofibroma or Schwa	nnoma benign Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
	10tai	0/50 (0%)			10lai	0/50 (0%)		3D 0%
#Skin: Neurofibrosarcoma or S	chwannoma (m	•				2/50 (4%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Skin: Neurofibrosarcoma, Neu						2/50 (4%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Skin: 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%
#Skin: 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%
#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%

^{*:} 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: 354

Report Date: 06/03/2022

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

#Skin: Squamous Cell Carcinoma Overall Incidence Total 0 #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma or Carcinoma	0/50 (0%) 0/50 (0%)	Mean 4%	SD 0%	Total	Female 2/50 (4%) 2/50 (4%) Mean 4% SD 0% 0/50 (0%) 0/50 (0%) Mean 0% SD 0%				
#Skin: Squamous Cell Carcinoma Overall Incidence Total 0 #Skin: Squamous Cell Carcinoma, Basal Cell Carcino or Carcinoma Overall Incidence Total 0	0/50 (4%) 0/50 (0%) 0/50 (0%)				2/50 (4%)		SD 0%		
#Skin: Squamous Cell Carcinoma Overall Incidence Total 0 #Skin: Squamous Cell Carcinoma, Basal Cell Carcino or Carcinoma Overall Incidence Total 0	0/50 (0%) 0/50 (0%)				` '		SD 0%		
#Skin: Squamous Cell Carcinoma Overall Incidence Total 0. #Skin: Squamous Cell Carcinoma, Basal Cell Carcino or Carcinoma Overall Incidence Total 0.	0/50 (0%) 0/50 (0%)								
#Skin: Squamous Cell Carcinoma, Basal Cell Carcino or Carcinoma Overall Incidence Total 0)/50 (0%)				0/50 (0%)				
#Skin: Squamous Cell Carcinoma, Basal Cell Carcino or Carcinoma Overall Incidence Total 0.		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
	oma, Basosquamous								
)/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
Squamous Cell Papilloma	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: Squamous Cell Papilloma or Papilloma	4/50 (00/)				0/50 (00/)				
Overall Incidence Total 1.	1/50 (2%) /50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Skin: Squamous Cell Papilloma, Papilloma, Squamo	ous Cell Carcinoma o	or Keratoacanthom	a		1/50 (2%)				
Overall Incidence Total 4	1/50 (8%)	Mean 8%	SD 0%	Total	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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Male **Female** #Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 4/50 (8%)1/50 (2%)**Overall Incidence** Total 4/50 (8%) Mean 8% SD 0% Total 1/50 (2%) Mean 2% SD 0% #Skin: Trichoepithelioma 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 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: Carcinoma 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total Mean 0% SD 0% 0/50 (0%) **#Skin: Sebaceous 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% *Spleen: Hemangioma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Mean 0% SD 0% Total 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

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Report Date: 06/03/2022

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female		
*Spleen: 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%
*Spleen: 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%
#Stomach, Forestomach: 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%
#Stomach, Forestomach: 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%
#Stomach, Forestomach: 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%
#Stomach, Forestomach: Squamous Cell Carcinoma						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: SKIN Vehicle: ETHANOL **Page**: 357

			Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma		2/22 (224)				2(72 (221)		
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%
#Stomach, Glandular: 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%
#Stomach, Glandular: 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%
*Testes: Adenoma		00/50 (700)						
Overall Incidence	Total	36/50 (72%) 36/50 (72%)	Mean 72%	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: SKIN Vehicle: ETHANOL Page: 358

			Male Female				O/50 (0%) Total O/50 (0%) Mean 0% SD 0 O/50 (0%) Total O/50 (0%) Mean 0% SD 0 O/50 (0%) Total O/50 (0%) Mean 0% SD 0 O/50 (0%) Total O/50 (0%) Mean 0% SD 0 3/50 (6%)		
*Thymus: Sarcoma									
		0/49 (0%)		05.00/		` '		00.004	
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	I otal	0/50 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma Benign									
		0/49 (0%)				` ,			
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma Malignant		0/49 (0%)				0/50 (0%)			
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%	
*Thymus: Thymoma: Benign, Malign		0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	` '	Moon 0%	SD 0%	
Overall incluence		` '				, ,		JD 0%	
*Thyroid Gland: C-Cell: Adenoma		5/50 (10%)				3/50 (69/)			
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	(,	Mean 6%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma		E/E0 /40%\				2/50 /49/			
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		10/50 (20%)				5/50 (10%)		
Overall Incidence	Total	10/50 (20%)	Mean 20%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%
*Thyroid Gland: Follicular Cell: 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%
*Thyroid Gland: Follicular Cell: Carcinoma								
		0/50 (0%)		25.00/		1/50 (2%)		00.004
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or 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%
#Tissue NOS: 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%
#Tissue NOS: Leiomyoma								
		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: SKIN Vehicle: ETHANOL Page: 360

			Male Female				Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%		
#Tissue NOS: Paraganglioma									
	T	0/50 (0%)	NA 00/	OD 00/	-	` '		05.00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	ı otal	0/50 (0%)	Mean 0%	SD 0%	
#Tissue NOS: Sarcoma									
		0/50 (0%)				` '			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tissue NOS: Schwannoma Malignant		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%	
#Tongue: Liposarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		, ,		SD 0%	
#Tongue: Squamous Cell Carcinom									
		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	a or Papilloma	a Squamous 0/50 (0%)				2/50 (4%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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: SKIN Vehicle: ETHANOL Page: 361

			Male Female				2/50 (4%) Mean 4% SD 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0/50 (0%) Total 0/50 (0%) Mean 0% SD		
#Tongue: Squamous Cell Papilloma									
		0/50 (0%)				2/50 (4%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
#Tooth: Odontogenic Tumor									
		0/50 (0%)				` '			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Carcinoma		- (((((((((((70)			
O	T-1-1	0/50 (0%)	M 00/	OD 00/	Tatal	` '	Maran 00/	OD 00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		, ,		SD 0%	
*Urinary Bladder: Carcinoma or Papilloma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%	
*Urinary Bladder: Leiomyosarcoma									
		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%)			
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: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

d Control Animal Groups Report Date: 06/03/2022 KIN

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		Male					Female	
*Urinary Bladder: 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%
#Uterus: Adenoma								
						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
Overell Incidence					Tatal	0/50 (0%)	Mana 00/	CD 00/
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Hemangioma						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyoma								
•						1/50 (2%)		
Overall Incidence					Total	1/50 (2%)	Mean 2%	SD 0%
#Uterus: Leiomyosarcoma								
						0/50 (0%)		
Overall Incidence					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: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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Page: 363

	Male			Female			
#Uterus: Polyp Stromal							
Overall Incidence		Total	10/50 (20%) 10/50 (20%)	Mean 20%	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	10/50 (20%) 10/50 (20%)	Mean 20%	SD 0%		
#Uterus: Schwannoma Malignant							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Vagina: Leiomyoma							
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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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