

NTP Historical Controls Report

By Route and Vehicle

F 344/N RATS

October 2007

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: 05/27/2022

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 Battelle Columbus Laboratory	058810503 059902303	04/22/02 03/25/02	729 729	50(3) 50(3)	35(702) 29(683)	521.9 501.9	Isoeugenol beta-Myrcene			
	Female									
Battelle Columbus Laboratory Battelle Columbus Laboratory	058810503 059902303	04/23/02 03/26/02	730 730	50(5) 50(5)	33(699) 31(668)	339.3 323.8	Isoeugenol beta-Myrcene			

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								
		49/50 (98%)	49/50 (98%)			41/50 (82%)	40/50 (80%)	
Overall Incidence	Total	98/100 (98%)	Mean 98%	SD 0%	Total	81/100 (81%)	Mean 81%	SD 1.41%
#All Organs: Malignant Tumors								
		29/50 (58%)	23/50 (46%)			18/50 (36%)	11/50 (22%)	
Overall Incidence	Total	52/100 (52%)	Mean 52%	SD 8.49%	Total	29/100 (29%)	Mean 29%	SD 9.9%
#All Organs: Malignant and Benign Tu	ımors	50/50 (100%)	E0/E0 (4009/)			46/50 (92%)	45/50 (00%)	
Overall Incidence	Total	100/100 (100%)	50/50 (100%) Mean 100%	SD 0%	Total	46/50 (92%) 91/100 (91%)	45/50 (90%) Mean 91%	SD 1.41%
		' '				, ,		
#All Organs: Hemangioma		0/50 (00/)	0/50 (00/)			0/50 (00()	4/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#All Organs: Hemangiosarcoma			•••••			•••••		•••••
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma or He	emangioma							
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

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: 6

			Male				Female	
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic, N	Monocytic. Mo	ononuclear, or Undifferen	itiated					
	,	10/50 (20%)	9/50 (18%)			8/50 (16%)	5/50 (10%)	
Overall Incidence	Total	19/100 (19%)	Mean 19%	SD 1.41%	Total	13/100 (13%)	Mean 13%	SD 4.24%
#All Organs: Malignant Lymphoma: His Overall Incidence	tiocytic, Lym Total	phocytic, Mixed, NOS, or 0/50 (0%) 1/100 (1%)	Undifferentiated Cel 1/50 (2%) Mean 1%	I Type SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overali incidence	rotai	1/100 (1%)	wean 1%	SD 1.41%	rotai	0/100 (0%)	wean 0%	SD 0%
•								
#All Organs: Mesothelioma: Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Mesothelioma: Benign Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall Incidence		0/100 (0%)	Mean 0%			0/100 (0%)	` '	SD 0%
Mesothelioma: Benign Overall Incidence #All Organs:		0/100 (0%)	Mean 0%			0/100 (0%)	` '	SD 0%
Mesothelioma: Benign Overall Incidence #All Organs: Mesothelioma: Benign, Ma		0/100 (0%)	Mean 0%			0/100 (0%)	Mean 0%	SD 0% SD 1.41%
Mesothelioma: Benign Overall Incidence #All Organs:	alignant, NOS	0/100 (0%) 3/50 (6%) 5/100 (5%)	Mean 0% 2/50 (4%) Mean 5%			0/100 (0%) 0/50 (0%) 1/100 (1%)	Mean 0% 1/50 (2%) Mean 1%	
Mesothelioma: Benign Overall Incidence #All Organs: Mesothelioma: Benign, Ma Overall Incidence #All Organs:	alignant, NOS	0/100 (0%) 3/50 (6%)	Mean 0%			0/100 (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: 7

		Male		Female				
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.	` ,	` '	00 4 440/		` ,	` '	OD 00/	
	, ,	Mean 3%	SD 1.41%	l otal	0/100 (0%)	Mean 0%	SD 0%	
	2/50 (40/)	4/50 /20/			0/50 (00/)	0/50 (00/)		
Total		` ,	SD 1./10/	Total	, ,	` '	SD 0%	
	` '				0/100 (0/8)			
	2/22 (221)	(70)			0.75	0.750 (001)		
Total		` '	SD 1 410/	Total	, ,	` '	SD 0%	
	` ,				, ,			
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
	0/50 (00/)	4/50 (20)			0/50 (00/)	0/50 (00/)		
Total	, ,	` '	SD 1.410/	Total	` '	` '	SD 0%	
-	Total Total Total	Total 0/100 (0%) 2/50 (4%) 3/100 (3%) 2/50 (4%) 2/50 (4%) 3/100 (3%) Total 0/50 (0%) Total 1/100 (1%)	Total 0/100 (0%) Mean 0% 2/50 (4%) 1/50 (2%) Total 3/100 (3%) Mean 3% 2/50 (4%) 1/50 (2%) Total 3/100 (3%) Mean 3% 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% 0/50 (0%) 0/50 (0%) Total 0/50 (0%) 1/50 (2%) Total 0/50 (0%) 1/50 (2%) Mean 0%	Total 0/100 (0%) Mean 0% SD 0% 2/50 (4%) 1/50 (2%) Total 3/100 (3%) Mean 3% SD 1.41% 2/50 (4%) 1/50 (2%) Total 3/100 (3%) Mean 3% SD 1.41% 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 1/100 (1%) Mean 1% SD 1.41%	Total 0/100 (0%) Mean 0% SD 0% Total 2/50 (4%) 1/50 (2%) Total Total Total 3/100 (3%) Mean 3% SD 1.41% Total Total 3/100 (3%) 1/50 (2%) SD 1.41% Total Total 1/100 (1%) Mean 1% SD 1.41% Total Total 0/50 (0%) 0/50 (0%) SD 0% Total Total 0/100 (0%) Mean 0% SD 0% Total Total 1/100 (1%) Mean 1% SD 1.41% Total	Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) 2/50 (4%) 1/50 (2%) 0/50 (0%) Total 3/100 (3%) Mean 3% SD 1.41% Total 0/100 (0%) Total 3/100 (3%) Mean 3% SD 1.41% Total 0/50 (0%) Total 1/50 (2%) Total 0/50 (0%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total 0/50 (0%) Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/50 (0%) 1/50 (2%) Total 0/50 (0%) Total 0/50 (0%) 1/50 (2%) Total 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total 0/50 (0%)	Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% 2/50 (4%) 1/50 (2%)	

^{*:} 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: 8

			Male				Female	
*Adrenal Medulla: Hemangioma								
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Adrenal Medulla: Pheochromocytoma Beni	ign							
		5/50 (10%)	11/50 (22%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	16/100 (16%)	Mean 16%	SD 8.49%	Total	3/100 (3%)	Mean 3%	SD 1.41%
*Adrenal Medulla: Pheochromocytoma Com	nplex							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Mali	gnant							
		3/50 (6%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma: Ber								
		7/50 (14%)	13/50 (26%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	20/100 (20%)	Mean 20%	SD 8.49%	Total	3/100 (3%)	Mean 3%	SD 1.41%
#Blood Vessel: Osteosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

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: Chondrosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Chondrosarcoma or Chondrosarcoma	roma							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Chordoma								
O	T-1-1	0/50 (0%)	1/50 (2%)	OD 4 440/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (0%)	0/50 (0%)	05 00/		0/50 (0%)	0/50 (0%)	00.007
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma								
		2/50 (4%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma		- (15°)	(05.1)				(00)	
Overell Incidence	Tatal	2/50 (4%)	1/50 (2%)	CD 4 440/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

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: Astrocytoma Malignant									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Brain: Ependymoma Benign									
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Brain: Glioma Malignant						(20)	0/20 (00)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Brain: Granular Cell Tumor Benig		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Brain: Medulloblastoma Mal		•••••							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Brain: Meningioma Malignant		0/50 (0%)	0/50 (0%)			0/50 (09/)	0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

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: Meningioma: Benign, Malignant, NOS												
	_	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Brain: Oligodendroglioma Benig												
	-	0/50 (0%)	1/50 (2%)	05 4 4407	-	0/50 (0%)	0/50 (0%)	OD 00/				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Brain: Oligodendroglioma Malig	nant	1/50 (2%)	0/50 (0%)			1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Brain: Oligodendroglioma, Glion						•••••						
		1/50 (2%)	1/50 (2%)			1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Clitoral/Preputial Gland: Adenoma												
		2/50 (4%)	5/50 (10%)			3/48 (6%)	7/50 (14%)					
Overall Incidence	Total	7/100 (7%)	Mean 7%	SD 4.24%	Total	10/98 (10.2%)	Mean 10.12%	SD 5.48%				
*Clitoral/Preputial Gland: Carcinoma												
		2/50 (4%)	0/50 (0%)			2/48 (4%)	0/50 (0%)					
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	2/98 (2.04%)	Mean 2.08%	SD 2.95%				

^{*:} 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:** 12

			Male				Female		
*Clitoral/Preputial Gland: Carcinoma or Adenoma									
		4/50 (8%)	5/50 (10%)			5/48 (10%)	7/50 (14%)		
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 1.41%	Total	12/98 (12.24%)	Mean 12.21%	SD 2.53%	
*Clitoral/Preputial Gland: Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	05 00/		0/48 (0%)	0/50 (0%)	00.00	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Squamous Cell Papilloma		0/50 (001)	0(50 (00))			0/40 (00/)	0/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%	
	10lal	0/100 (0%)		3D 0%	10tai	0/96 (0%)	IVIEATI 0%		
#Ear: Neural Crest Tumor		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Esophagus: Fibrosarcoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Eye: Amelanotic Melanoma, Ben	ign	- (ac)	(05)		••••••		(00)		
Overall Institutes	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 13

	Male Female				0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SI 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SI 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SI 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SI 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SI			
#Eye: Melanoma Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	(,	()	SD 0%
#Eye: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` ,	SD 0%
#Harderian Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` '	SD 0%
#Harderian Gland: Carcinoma		0/50 (00/)				0/50 /00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	(,	` '	SD 0%
*Heart: Schwannoma Benign		- (a)	(00)			(201)	0.70	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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: 14

			Male		0/50 (0%) 0/50 (0%) 6 Total 0/100 (0%) Mean 0% 6 Total 0/100 (0%) 0/50 (0%) 6 Total 0/100 (0%) Mean 0% 6 Total 0/100 (0%) 0/50 (0%) 6 Total 0/100 (0%) Mean 0% 7 Total 0/100 (0%) 0/50 (0%)			Female				
*Heart: Schwannoma Malignant												
		0/50 (0%)	0/50 (0%)			` ,	(/					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Intestine Large: Colon/Rectu Adenoma	um:											
		0/50 (0%)	0/50 (0%)			` ,	()					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Intestine Large: Colon/Rectu Carcinoma												
		0/50 (0%)	0/50 (0%)			` ,	()					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Intestine Large: Colon/Rector Carcinoma or Adenoma												
0	Tatal	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	, ,	` '	OD 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		, ,	iviean 0%	SD 0%				
#Intestine Large: Colon/Rectu Leiomyosarcoma	um:											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Intestine Small: Duodenum: Carcinoma		0/50 (00)	0/50 (001)			0(50 (00))	0/50 (00/)					
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 15

		Male Female				0/50 (0%) 0/50 (0%) 7 Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) 1% Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) 7 Total 0/100 (0%) Mean 0% 7 Total 0/100 (0%) 0/50 (0%) 7 Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)		
#Intestine Small: Duodenum: Leiomyoma								
		0/50 (0%)	0/50 (0%)			` '	(/	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma								
		1/50 (2%)	0/50 (0%)			` ,	()	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			` '	()	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma								
		0/50 (0%)	0/50 (0%)			, ,	` '	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Leiomyoma								
	.	1/50 (2%)	0/50 (0%)	05 4 440/	+	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 16

			Male				Female	
#Intestine Small: Site Unspec Leiomyosarcoma	ified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Adenoma								
		4/50 (8%)	2/50 (4%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Islets, Pancreatic: Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Carcinoma or Adenoma								
		4/50 (8%)	3/50 (6%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	7/100 (7%)	Mean 7%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Kidney: Pelvis and Transitio Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transitio Carcinoma or Adenoma	nal Epitheliu							
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} 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: 17

	Male Female						Female Total 0/50 (0%) 0/100 (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 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0%		
*Kidney: Pelvis and Transiti Papilloma	ional Epitheliu								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	, ,	` ,	SD 0%	
*Kidney: Renal Tubule: Adenoma		(00)	(00)				(00)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	, ,	` ,	SD 0%	
*Kidney: Renal Tubule: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` ,	SD 0%	
*Kidney: Renal Tubule: Carcinoma or Adenoma						0/50 /00/	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Hemangiosarcoma									
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%		0/100 (0%)	Mean 0%		
*Kidney: Renal Tubule: Lipoma									
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

^{*:} 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				0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% S 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%						
*Kidney: Renal Tubule: Liposarcoma											
Overall Incidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	` '	()	CD 00/			
Overall incidence	Total	0/100 (0%)	Mean 0%	SD 0%	ı otal	0/100 (0%)	wean 0%	SD 0%			
*Kidney: Renal Tubule: Mesenchymal Tumor Benign											
		0/50 (0%)	0/50 (0%)			` ,	` ,				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Nephroblastoma		2/52 (221)	2/52 (221)			2/52 (224)					
Overell Insidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	` '	` ,	CD 4 440/			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	ı otal	1/100 (1%)	wean 1%	SD 1.41%			
*Kidney: Renal Tubule: Sarcoma											
		0/50 (0%)	0/50 (0%)			, ,	` '				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
*Liver: Cholangiocarcinoma											
		0/50 (0%)	0/50 (0%)			` '	` ,				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
*Liver: Cholangioma		0(50 (00))	0/50 (00/)			0/50 (00/)	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
Overall incluence	ı Ulal	0/100 (076)	IVICALI U70	3D 070	ı Ulai	0/100 (070)	IVICALI U70	3D 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: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma								
		1/50 (2%)	0/50 (0%)	00		0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma								
Overell Incidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma	or Hepatobla	stoma						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma	, Hepatocellu	lar Adenoma, or Hepatob	lastoma 0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} 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	
*Lung: Alveolar/Bronchiolar A	denoma							
		3/50 (6%)	3/50 (6%)			1/50 (2%)	4/50 (8%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 0%	Total	5/100 (5%)	Mean 5%	SD 4.24%
*Lung: Alveolar/Bronchiolar C	arcinoma							
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar C Overall Incidence	arcinoma or Alve	eolar/Bronchiolar Adenon 4/50 (8%) 7/100 (7%)	na 3/50 (6%) Mean 7%	SD 1.41%	Total	1/50 (2%) 5/100 (5%)	4/50 (8%) Mean 5%	SD 4.24%
*Lung: Hemangiosarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma					•••••			
		0/50 (0%)	0/50 (0%) Mean 0%	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overell Incidence	T-4-1			SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Overall Incidence	Total	0/100 (0%)						
Overall Incidence *Lung: Squamous Cell Carcin		0/100 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	

^{*:} 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:** 21

			Male				Female	
#Lymph Node, Mesenteric: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
• " ' '	-	0/50 (0%)	0/50 (0%)	00.00/	+	4/50 (8%)	0/50 (0%)	00 5 000/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	4/100 (4%)	Mean 4%	SD 5.66%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	25 22/		4/50 (8%)	0/50 (0%)	05 - 000/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	4/100 (4%)	Mean 4%	SD 5.66%
#Mammary Gland: Fibroadenoma								
		4/50 (8%)	0/50 (0%)			26/50 (52%)	17/50 (34%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 5.66%	Total	43/100 (43%)	Mean 43%	SD 12.73%
#Mammary Gland: Fibroma		0(50 (00))	0/50 (05.)			0/50 (00.1)	0/50 (00/)	
Overell Incidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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

Page: 22

Report Date: 05/27/2022

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma	or Adenoma							
		4/50 (8%)	0/50 (0%)			26/50 (52%)	17/50 (34%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 5.66%	Total	43/100 (43%)	Mean 43%	SD 12.73%
#Mammary Gland: Fibroma, Fibroadenoma,	Carcinoma, or	· Adenoma						
,	·	4/50 (8%)	0/50 (0%)			28/50 (56%)	17/50 (34%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 5.66%	Total	45/100 (45%)	Mean 45%	SD 15.56%
#Mesentery: Fibrosarcoma								
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: Osteosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: Rhabdomyosarcoma		- (ac.)	(05.1)			0.00		
Occupation of desires	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 23

	Male Female				0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0 0/50 (0%) 1/50 (0%) 0/50 (0%) 1/50 (2%)			
*Nose: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		(,	Mean 0%	SD 0%
'Nose: Chondroma								
		0/50 (0%)	0/50 (0%)			` ,	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Sarcoma								
		0/50 (0%)	0/50 (0%)			` '	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	l otal	0/100 (0%)	Mean 0%	SD 0%
*Nose: Squamous Cell Carcinoma	a	0/50 (00)	0/50 (00/)			0/50 (001)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	, ,	` ,	SD 0%
#Oral Cavity (Oral Mucosa, T Papilloma Squamous or P	Tongue, Phary		1/50 (2%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	` '	` ,	SD 1.41%
#Oral Cavity (Oral Mucosa, T Squamous Cell Carcinoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selection

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	
Oral Cavity (Oral Mucos Squamous Cell Carcing		Squamous, or Papilloma						
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
Oral Mucosa: Squamous Cell Carcing	oma							
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
tOral Mucosa: Squamous Cell Papillo	ma	0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
Ovary: Granulosa Cell Tumor	Benign				Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
Ovary: Granulosa Cell Tumor	Malignant					0/50 (00/)	0/50 (00/)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Ovary: Granulosa Cell Tumor:	Benign, Maligna	ant, NOS				0/50 (00/)	4/50 (00/)	
Overall Incidence					Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 25

			Male				Female	
*Ovary: Granulosa-Theca Tumor B	enign							
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	7/50 (14%) 8/100 (8%)	1/50 (2%) Mean 8%	SD 8.49%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	8/50 (16%) 9/100 (9%)	1/50 (2%) Mean 9%	SD 9.9%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Mixed Tumor Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
Overall Incidence	Total	0/47 (0%) 1/92 (1.09%)	1/45 (2%) Mean 1.11%	SD 1.57%	Total	0/47 (0%) 0/94 (0%)	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: GAVAGE Vehicle: CORN OIL Page: 26

			Male				Female	
#Peripheral Nerve: Schwannoma Malignan	t							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign,	Malignant, NOS							
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Adenoma	talis or Unspeci	fied Site:						
		19/50 (38%)	6/50 (12%)			25/50 (50%)	25/50 (50%)	
Overall Incidence	Total	25/100 (25%)	Mean 25%	SD 18.38%	Total	50/100 (50%)	Mean 50%	SD 0%
*Pituitary Gland: Pars Dis Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Carcinoma or Adenoma	talis or Unspeci							
		19/50 (38%)	6/50 (12%)			25/50 (50%)	25/50 (50%)	
Overall Incidence	Total	25/100 (25%)	Mean 25%	SD 18.38%	Total	50/100 (50%)	Mean 50%	SD 0%
*Pituitary Gland: Pars Inte Adenoma	ermedia:							
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} 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: 27

			Male				Female	
*Pituitary Gland: Pars Interm Carcinoma	edia:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Interm Carcinoma or Adenoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma		- (aa)	2/22 (22)					
	.	0/50 (0%)	0/50 (0%)	OD 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma								
Overell Insidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (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: 28

			Male				Female	
#Skeletal Muscle: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Lipoma								
	-	0/50 (0%)	0/50 (0%)	OD 00/	-	0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or Rh	abdomyoma							
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} 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:** 29

			Male				Female	
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
	-	0/50 (0%)	0/50 (0%)	00.00/	+	0/50 (0%)	1/50 (2%)	05 4 440/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Basal Cell Adenoma or Overall Incidence	Basosquamous Total	Tumor Benign 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
Overall incluence	ı Olai	0/100 (0%)		30 0%	10lai	1/100 (1%)		
#Skin: Basal Cell Adenoma, Ba	asosquamous T	umor Benign, or Trichoep 0/50 (0%)	oithelioma 0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Basal Cell Carcinoma								
O	T-1-1	1/50 (2%)	1/50 (2%)	00 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma o	r Basosquamou	s Tumor (malignant or NO	•			0/50 (00/)	0/50 (00/)	
		1/50 (2%) 2/100 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 30

Report Date: 05/27/2022

Length of Study: CHRONIC

			Male				Female	
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tun	nor (benign, maligna	nt or				
		1/50 (2%)	1/50 (2%)	05.00/		0/50 (0%)	1/50 (2%)	00 4 4404
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	noma, Carcinom oq Papilloma, Ke	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 8/50 (16%)	8), Basal Cell Adenon ithelioma 3/50 (6%)	na,		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 7.07%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Fibroma		5/50 (10%)	3/50 (6%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 2.83%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myx	oma, Myxosarcoma, or Fi 7/50 (14%)	brous Histiocytoma 4/50 (8%)			0/50 (0%)	3/50 (6%)	
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 4.24%	Total	3/100 (3%)	Mean 3%	SD 4.24%
#Skin: Fibrosarcoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
		1/100 (1/0)	ivicali 170	GD 1.4170	i Otal		ivicali 1/0	
#Skin: Fibrosarcoma, Sarcom	a, Myxosarcoma	a, or Fibrous Histiocytoma 2/50 (4%)	a 1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

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:** 31

			Male				Female	
#Skin: Fibrous Histiocytoma								(0%) ean 0% SD 0% (0%) ean 0% SD 0%
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Hemangiosarcoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Keratoacanthoma		7/50 (4.40/)	2/50 (40/)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	7/50 (14%) 9/100 (9%)	2/50 (4%) Mean 9%	SD 7.07%	Total	0/50 (0%) 0/100 (0%)	Mean 0%	
#Skin: Lipoma	•••••							
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Liposarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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:** 32

			Male				Female	
#Skin: Neural Crest Tumor								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Neurofibroma or Schwa	annoma benian							
	9	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or 3 Overall Incidence	Schwannoma (m Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin:		Schwannoma (benign, ma 0/50 (0%) 0/100 (0%)		SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		0/100 (0%)				` '		
#Skin: Osteosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 33

			Male				Female	
#Skin: Schwannoma Benign								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	05.00/		0/50 (0%)	0/50 (0%)	00.007
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma or Carcinoma	, Basal Cell (Carcinoma, Basosquamo	us Tumor (malignant	or NOS),				
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	or Papilloma		2/20 /00:				(20)	
Occupil by althouse	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

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: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma										
Overall Incidence	Total	7/50 (14%) 9/100 (9%)	2/50 (4%) Mean 9%	SD 7.07%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Skin:										
Squamous Cell Papilloma,	, Papilloma, o	7/50 (14%)	2/50 (4%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 7.07%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Trichoepithelioma	•••••									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Sebaceous Gland: Adenoma										
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Sebaceous Gland: Carcinoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Sebaceous Gland: Carcinoma or Adenoma		4/50 (001)	4/50 (051)			0/50 (001)	0/50 (00/)			
Overell Incidence	Total	1/50 (2%)	1/50 (2%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	SD 0%		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	טט עס יייט עס		

^{*:} 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:** 35

			Male				Female	
#Spinal Cord: Astrocytoma Benign						0/50 (0%) 1/50 (2%)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` '	SD 1.41%
	10tai	0/100 (0%)	IVIEATI U%	ال ا	10lai	(170)		
*Spleen: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			` ,	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma		2/22 (221)	-(27-2 (221)	2/22 (224)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	CD 00/
		0/100 (0%)	IVIEATI U%	ال ا	10lai	0/100 (0%)		SD 0%
*Spleen: Hemangiosarcoma		4/50 (20/)	0/50 (0%)			0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%		0/100 (0%)	Mean 0%	SD 0%
*Spleen: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			` '	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 36

			Male				Female	
#Stomach, Forestomach: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 (00/)	0/50 (0%)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma Overall Incidence	or Papilloma	a Squamous 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Glandular: Leiomyosarcoma								
		0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall Incidence	Total	0/100 (0%)						
Overall Incidence #Stomach, Glandular: Lipoma	Total	0/100 (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: GAVAGE Vehicle: CORN OIL **Page:** 37

			Male				Female	
*Testes: Adenoma Overall Incidence	Total	46/50 (92%) 93/100 (93%)	47/50 (94%) Mean 93%	SD 1.41%				
*Thymus: Sarcoma								
Overall Incidence	Total	0/47 (0%) 0/94 (0%)	0/47 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/96 (0%)	0/49 (0%) Mean 0%	SD 0%
*Thymus: Thymoma Benign								
Overall Incidence	Total	0/94 (0%)	0/47 (0%) Mean 0%	SD 0%	Total	0/96 (0%)	0/49 (0%) Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/47 (0%)	0/47 (0%)			0/47 (0%)	0/49 (0%)	
Overall Incidence	Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/96 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malig								
Overall Incidence	Total	0/47 (0%) 0/94 (0%)	0/47 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/96 (0%)	0/49 (0%) Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma								
Overall Incidence	Total	9/50 (18%) 21/100 (21%)	12/50 (24%) Mean 21%	SD 4.24%	Total	7/50 (14%) 12/100 (12%)	5/50 (10%) Mean 12%	SD 2.83%

^{*:} 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:** 38

			Male				Female	
*Thyroid Gland: C-Cell: Carcinoma								
		6/50 (12%)	0/50 (0%)			3/50 (6%)	0/50 (0%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 8.49%	Total	3/100 (3%)	Mean 3%	SD 4.24%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		15/50 (30%)	12/50 (24%)			9/50 (18%)	5/50 (10%)	
Overall Incidence	Total	27/100 (27%)	Mean 27%	SD 4.24%	Total	14/100 (14%)	Mean 14%	SD 5.66%
*Thyroid Gland: Follicular Cell Adenoma								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Carcinoma								
		1/50 (2%)	2/50 (4%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma								
		2/50 (4%)	3/50 (6%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Tissue NOS: Fibrosarcoma		0/50 (05)	0/50 (051)			0/50 (00)	0/50 (00)	
One will be add on a co	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 39

			Male				Female	
#Tissue NOS: Leiomyoma								
Occupation of decree	Taral	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	00,00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Lipoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Paraganglioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Liposarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/27/2022

Species: RATS Strain: F 344/N Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Tongue: Squamous Cell Carcinoma	or Papillom	a Squamous						
		0/50 (0%)	0/50 (0%)	25. 22/		0/50 (0%)	1/50 (2%)	00
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Tongue: Squamous Cell Papilloma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Tooth: Odontoma								
Occupil by althouse	T -4-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma								
•		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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: Papilloma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Adenoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Carcinoma								
Overall Incidence					Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
Uterus: Deciduoma Benign								
Overall Incidence					Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
Uterus: Hemangioma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Uterus: Hemangiosarcoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Denominator is number of an		avaminad migraaganigally						

^{*:} 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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N	lale		Female	
#Uterus: Leiomyoma		(45.3)	0.50	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Polyp Stromal				
Overall Incidence	Total	8/50 (16%) 16/100 (16%)	8/50 (16%) Mean 16%	SD 0%
#Uterus: Sarcoma Stromal		0/50 (631)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal		8/50 (16%)	8/50 (16%)	
Overall Incidence	Total	16/100 (16%)	Mean 16%	SD 0%
#Uterus: Schwannoma Malignant				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Polyp		4/50 (00/)	0/50 /00/	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

#Vagina: Sarcoma

Overall Incidence

#Zymbal's Gland: Adenoma

Overall Incidence

#Zymbal's Gland: Carcinoma

Overall Incidence

#Zymbal's Gland:

Overall Incidence

......

Carcinoma or Adenoma

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

Male **Female** 0/50 (0%)0/50 (0%)SD 0% Total 0/100 (0%) Mean 0% (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% (4%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 2% SD 2.83% Total 0/100 (0%) Mean 0% SD 0%

0/50

0/100 (0%)

Total

(0%)

0/50

(0%)

Mean 0%

SD 0%

Page: 43

Report Date: 05/27/2022

Total

Total

Total

0/50

0/100 (0%)

2/50

2/100 (2%)

2/50

2/100 (2%)

(4%)

0/50

Mean 2%

(0%)

SD 2.83%

^{*:} 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: 05/27/2022

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

Oct2007

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 Tu	ımors	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	mangioma	0/50 (40%)				4/50 /00/			
Overall Incidence	Total	2/50 (4%)	Maan 40/	CD 00/	Total	1/50 (2%)	Maan 20/	CD 00/	
	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

Toxicology Data Ma

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

Species: RATS

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Route: GAVAGE

Strain: F 344/N Length of Study: CHRONIC Vehicle: METHYLCELLULOSE

Page: 47

			Male				Female	
#All Organs: Osteoma								
		0/50 (0%)		05.00/		0/50 (0%)		25
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%)		25 22/		1/50 (2%)		05.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#All Organs: Osteosarcoma or Osteo	ma	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 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	•••••			•••••		•••••		
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: 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

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	
*Adrenal Medulla: 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%
*Adrenal Medulla: Pheochromocytoma Benig	n							
		9/50 (18%)				2/50 (4%)		
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Adrenal Medulla: Pheochromocytoma Comp	lex	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 Malig								
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: Beni								
		11/50 (22%)				2/50 (4%)		
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Blood Vessel: Osteosarcoma								
		0/50 (0%)		05 00/		0/50 (0%)	••	00.007
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: Chondrosarcoma		0/50 ((0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mear	0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Chondrosarcoma or Chond	droma					•••••				
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) Mear	0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Bone: Chordoma		0/50 ((0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mear		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteoma			0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mear		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma						•••••				
Overall Incidence	Total	0/50 (0%)	0%) Mear	0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Bone: Osteosarcoma or Osteoma		0/50 ((0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mear	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

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: 50

			Male				Female	
*Brain: Astrocytoma Malignant		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%
*Brain: Ependymoma 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%
*Brain: Glioma Malignant		0/50 (0%	٨)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Benig		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: 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%	6)			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					
*Brain: Meningioma: Benign, Malignant, 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 Beni	gn	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 Maliç	gnant	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, Glio	ma, or Astrocyt	t 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%				
*Clitoral/Preputial Gland: Adenoma												
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%				
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%)				1/50 (2%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				

^{*:} 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				
*Clitoral/Preputial Gland: Carcinoma or Adenoma										
		1/50 (2%)		05.00		8/50 (16%)		00.00		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	8/50 (16%)	Mean 16%	SD 0%		
*Clitoral/Preputial Gland: 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%		
*Clitoral/Preputial Gland: 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%		
#Ear: Neural Crest Tumor Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Esophagus: Fibrosarcoma		- ()								
Overall Incidence	Total	0/50 (0%)	Maan 00/	SD 0%	Total	0/50 (0%)	Maan OO/	SD 0%		
Overali incidence	Total	0/50 (0%)	Mean 0%	5D 0%	Total	0/50 (0%)	Mean 0%	SU U‰		
#Eye: Amelanotic Melanoma, Ben	ign	2/72 (201)				2/22 (221)				
Overall Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan Oo/	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

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			
#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: 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%	
#Harderian Gland: 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%	
#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 (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	
*Heart: Schwannoma Malignant		0/50 /6	2007				0/50 (00/)		
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) Mear	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%) Mear	0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Carcinoma			20()				0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	0%) Mear		SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Carcinoma or Adenoma)%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mear		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Leiomyosarcoma									
Overall Incidence	Total	0/50 (0%)	0%) Mear	0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma			207.)				0/50 (09/)		
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) Mear	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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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				Male			Female				
#Intestine Small: Duodenum: 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: 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: Leiomyosarcoma											
Overall Incidence	Total	0/50 (0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
		` '					, ,				
#Intestine Small: Site Unspec Carcinoma	cified:										
		,	(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: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

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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									
		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%	
*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									
		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		m:				0/50 (00/)			
Overall Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan Ol/	SD 0%	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	3D 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

Papilloma

Adenoma

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Lipoma

*Kidney: Renal Tubule:

*Kidney: Renal Tubule: Carcinoma

..... *Kidney: Renal Tubule: Carcinoma or Adenoma

...... *Kidney: Renal Tubule: Hemangiosarcoma

*Kidney: Renal Tubule:

Length of Study: CHRONIC

*Kidney: Pelvis and Transitional Epithelium:

Total

Total

Total

Total

Total

Total

0/50

0/50 (0%)

(0%)

Mean 0%

SD 0%

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Male **Female** 0/50 (0%)0/50 (0%)0/50 (0%) SD 0% Mean 0% SD 0% Total 0/50 (0%) Mean 0% 0/50 (0%)0/50 (0%)0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)SD 0% 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% 0/50 (0%)0/50 (0%)0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%

Total

0/50

0/50 (0%)

(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: GAVAGE

Vehicle: METHYLCELLULOSE

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				Male			Female			
*Kidney: Renal Tubule: Liposarcoma										
			(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: Mesenchymal Tumor Benign										
			(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: Nephroblastoma		0.50	(004)				(00)			
Overall Incidence	Total		(0%)	Maan Oll	CD 00/	Total	0/50 (0%)	Maan OO/	SD 0%	
Overall incidence		0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	3D 0%	
*Kidney: Renal Tubule: Sarcoma										
			(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%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Cholangioma										
	.		(0%)		05.00/	+	0/50 (0%)		OD 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: GAVAGE

Vehicle: METHYLCELLULOSE

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				Male	Female				
*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%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma		stoma	(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		lular Adenoma	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	(= / 0)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma,	Hepatocellul	ar Adenoma, or	Hepatob (2%)	lastoma			0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	(=,0)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			M	ale		Female					
*Lung: Alveolar/Bronchiolar Adenoma											
		1/50 (2	,			0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 29	6 SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Lung: Alveolar/Bronchiolar Ca	rcinoma										
		0/50 (0	%)			0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 09		Total	0/50 (0%)	Mean 0%	SD 0%			
*Lung: Alveolar/Bronchiolar Ca			Adenoma			0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 29		Total	0/50 (0%)	Mean 0%	SD 0%			
*Lung: Hemangiosarcoma		0/50 (0				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 09	% SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Lung: Sarcoma											
		0/50 (0	%)			0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 09	% SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Lung: Squamous Cell Carcino	ma										
		0/50 (0	,			0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 09	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

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/27/2022

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Strain: F 344/N Length of Study: CHRONIC

Contract/Lab: All Laboratories

			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%)		OD 00/		1/50 (2%)	NA 00/	05.00/	
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 (0%)				2/50 (4%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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 (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					
#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, Fibroadenoma	a Carcinoma or	Adenoma						•••••				
·		2/50	(4%)				30/50 (60%)					
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	30/50 (60%)	Mean 60%	SD 0%			
#Mesentery: Fibrosarcoma			(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Mesentery: Hemangiosarcoma			(2%)				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	()	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Mesentery: Osteosarcoma												
Overall Incidence	Total	0/50 0/50 (0%)	(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%)	(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: METHYLCELLULOSE

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			Male				Female	
*Nose: 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%
*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 Carcinom						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%
#Oral Cavity (Oral Mucosa, Papilloma Squamous or F		/nx, Tooth, Gingiva):						
		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 Mucosa, Squamous Cell Carcinom	Tongue, Phary							
		1/50 (2%)				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

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					
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma 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 Carcinon	na	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%			
#Oral Mucosa: Squamous Cell Papillom	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%			
*Ovary: Granulosa Cell Tumor Be	enign					0/50 (0%)					
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%			
*Ovary: Granulosa Cell Tumor Ma	alignant										
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Ovary: Granulosa Cell Tumor: B	enign, Maligna	nt, NOS				0/50 (0%)					
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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		Male				Female			
*Ovary: Granulosa-Theca Tumor B	Benign					0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Adenoma		0/50 (0%)				1/49 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%	
*Pancreas: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	
*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: Mixed Tumor Benign									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	
*Parathyroid Gland: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/47 (0%) 0/47 (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					
#Peripheral Nerve: Schwannoma Malignant												
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Peripheral Nerve:	Maliament NOS											
Schwannoma: Benign, N	walignant, 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 Dist Adenoma												
Overall Incidence	Total	25/50 (50%) 25/50 (50%)	Mean 50%	SD 0%	Total	36/50 (72%) 36/50 (72%)	Mean 72%	SD 0%				
*Pituitary Gland: Pars Dist Carcinoma						0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Dist	alis or Unspeci											
Carcinoma or Adenoma		05/50 (500/)				00/50 (700/)						
Overall Incidence	Total	25/50 (50%) 25/50 (50%)	Mean 50%	SD 0%	Total	36/50 (72%) 36/50 (72%)	Mean 72%	SD 0%				
						· · · · · · · · · · · · · · · · · · ·						
*Pituitary Gland: Pars Inte Adenoma	rmedia:											
		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					
*Pituitary Gland: Pars Intermedia: Carcinoma												
		•	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 or Adenoma	edia:											
		•	0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Prostate: Adenoma		4/50	20()									
Overall Incidence	Total	1/50 (2%)	2%)	Mean 2%	SD 0%							
		, ,										
*Prostate: Carcinoma or Adenoma												
Overall Incidence	Total	1/50 (2%)	2%)	Mean 2%	SD 0%							
*Salivary Glands: Sarcoma												
		`	0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Salivary Glands: Schwannoma Malignant												
Occupation at desire	Tatal	,	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: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Skeletal Muscle: 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%
#Skeletal Muscle: Hemangioma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma		0/50 (09/)				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%
#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								
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: Rhabdomyosarcoma or F	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%

^{*:} 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	
#Skeletal Muscle: Sarcoma								
		0/50 (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%
#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	Basosquamous	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, B			ichoepithelioma	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
		` '				` '		
#Skin: Basal Cell Carcinoma		0/50 (0				4/50 (00/)		
Overall Incidence	Total	0/50 (0° 0/50 (0%)	%) Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Carcinoma o	or Basosquamou	s Tumor (malignam 0/50 (0				1/50 (2%)		

^{*:} 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: 05/27/2022

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 2/50 (0%)(4%)**Overall Incidence** 0/50 (0%) SD 0% Mean 4% SD 0% Total Mean 0% Total 2/50 (4%) Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma (14%)3/50 (6%)Mean 14% **Overall Incidence** Total 7/50 (14%) SD 0% Total 3/50 (6%) Mean 6% SD 0% #Skin: **Fibroma** 6/50 (12%)1/50 (2%)**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%)**Overall Incidence** Total 8/50 (16%) Mean 16% SD 0% Total 2/50 (4%) Mean 4% SD 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% #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 3/50 (6%)1/50 (2%)**Overall Incidence** Total 3/50 (6%) Mean 6% 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	
#Skin: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#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: Hemangiosarcoma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Keratoacanthoma 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: 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 (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				
#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%			
#Skin: Neurofibroma or Schwa											
nour on bronna or conne	annoma bomgn	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 S	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						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 (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	
#Skin: 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%
#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 Overall Incidence	Basal Cell C	Carcinoma, Basosquam 0/50 (0%) 0/50 (0%)	ous Tumor (malignar Mean 0%	nt or NOS), SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Squamous Cell 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 o	r 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%

^{*:} 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: 05/27/2022

Route: GAVAGE

Vehicle: METHYLCELLULOSE

			Male				Female				
#Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma 7/50 (14%) 1/50 (2%)											
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
#Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 7/50 (14%) 1/50 (2%)											
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
#Skin: Trichoepithelioma		0/50 (0%)				1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
#Skin: 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		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 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	
#Spinal Cord: Astrocytoma 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%
*Spleen: Fibrosarcoma				•••••				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma		1/50 (2%)				0/49 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Spleen: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (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%

^{*:} 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	
#Stomach, Forestomach: Schwannoma Malignant									
			(0%)		05 00/		0/50 (0%)		05.00
Overall Incidence	Total	0/50 (0%)	Me	an 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma	1								
			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Me	an 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papilloma	-	(0%)				1/50 (2%)		
			` '				` '		
Overall Incidence	Total	0/50 (0%)	Me	an 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
Overall Incidence #Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)	Me	an 0%	SD 0%	Total	` '	Mean 2%	SD 0%
#Stomach, Forestomach:		0/50 (0%)	Me (0%)	an 0% an 0%	SD 0%	Total Total	1/50 (2%)	Mean 2% Mean 2%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%) 0/50	Me (0%)				1/50 (2%) 1/50 (2%)		
#Stomach, Forestomach: Squamous Cell Papilloma Overall Incidence #Stomach, Glandular: Leiomyosarcoma	Total	0/50 (0%) 0/50 0/50 (0%)	(0%) Me	an 0%	SD 0%	Total	1/50 (2%) 1/50 (2%) 1/50 (2%) 0/50 (0%)	Mean 2%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma Overall Incidence #Stomach, Glandular:		0/50 (0%) 0/50 (0/50 (0%)	(0%) Me				1/50 (2%) 1/50 (2%) 1/50 (2%)		
#Stomach, Forestomach: Squamous Cell Papilloma Overall Incidence #Stomach, Glandular: Leiomyosarcoma	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	(0%) Me	an 0%	SD 0%	Total	1/50 (2%) 1/50 (2%) 1/50 (2%) 0/50 (0%)	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: METHYLCELLULOSE

Route: GAVAGE

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			Male				Female	
*Testes: Adenoma Overall Incidence	Total	41/50 (82%) 41/50 (82%)	Mean 82%	SD 0%				
·····		` '						
*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		0/49 (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, Malign								
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Thyroid Gland: C-Cell: Adenoma								
Overall Incidence	Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%	Total	7/50 (14%) 7/50 (14%)	Mean 14%	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: 05/27/2022

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Thyroid Gland: C-Cell: 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% *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 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Thyroid Gland: Follicular Cell: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (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 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total SD 0% 0/50 (0%) Mean 0%

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

^{#:} Denominator is number of animals necropsied

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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: METHYLCELLULOSE

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			Male				Female	
#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%
#Tissue NOS: 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%
#Tissue NOS: Paraganglioma		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%
		` '						
#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								
		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	
#Tongue: Squamous Cell Carcinoma	or Papilloma								
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) Mear	0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma									
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) Mear	0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		0/50 (0)%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mear	0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma	Total	0/50 (0 0/50 (0%)	0%) Mear	0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma)%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mear	0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma		0/50 (0	D%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mear	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

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Report Date: 05/27/2022

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female		
*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%	
#Uterus: Adenoma									
						0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Carcinoma									
						0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Deciduoma Benign									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Hemangioma									
ū						0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Hemangiosarcoma				•••••					•••••
-						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

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

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

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	Male		Female	
#Uterus: Leiomyoma		0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal				
Overall Incidence	Total	13/50 (26%) 13/50 (26%)	Mean 26%	SD 0%
#Uterus: Sarcoma Stromal		2/50 (4%)		
Overall Incidence	Total	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		0/50 /00/		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Polyp				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/27/2022

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#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

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 84

Report Date: 05/27/2022

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 Battelle Columbus Laboratory	058812305 059501107	03/21/01 03/06/02	727 727	50(3) 50(3)	26(673) 22(673)	509.7 510.3	Formamide 5-(Hydroxymethyl)-2-furfural
					Female		
Battelle Columbus Laboratory Battelle Columbus Laboratory	058812305 059501107	03/20/01 03/07/02	730 728	50(5) 50(5)	38(703) 31(679)	358.3 332.2	Formamide 5-(Hydroxymethyl)-2-furfural

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 85

			Male			Female			
#All Organs: Benign Tumors									
		45/50 (90%)	50/50 (100%)			43/50 (86%)	46/50 (92%)		
Overall Incidence	Total	95/100 (95%)	Mean 95%	SD 7.07%	Total	89/100 (89%)	Mean 89%	SD 4.24%	
#All Organs: Malignant Tumors									
		25/50 (50%)	35/50 (70%)			15/50 (30%)	16/50 (32%)		
Overall Incidence	Total	60/100 (60%)	Mean 60%	SD 14.14%	Total	31/100 (31%)	Mean 31%	SD 1.41%	
#All Organs: Malignant and Benign Tu	ımors	48/50 (96%)	50/50 (100%)			49/50 (98%)	48/50 (96%)		
Overall Incidence	Total	98/100 (98%)	Mean 98%	SD 2.83%	Total	97/100 (97%)	Mean 97%	SD 1.41%	
#All Organs: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma or He	emangioma	0/50 (00)	0/50 (00/)			0/50 /00/	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
		0/100 (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: 86

			Male				Female	
#All Organs: Histiocytic Sarcoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic, N	Monocytic. Mo	ononuclear. or Undifferen	tiated					
	,	15/50 (30%)	28/50 (56%)			10/50 (20%)	9/50 (18%)	
Overall Incidence	Total	43/100 (43%)	Mean 43%	SD 18.38%	Total	19/100 (19%)	Mean 19%	SD 1.41%
Malignant Lymphoma: His	stiocytic, Lym	phocytic, Mixed, NOS, or 0/50 (0%)	Undifferentiated Cel 0/50 (0%)	I Туре		0/50 (0%)	0/50 (0%)	
Overall Incidence #All Organs:	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	Total		Mean 0%	SD 0%	Total		Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
#All Organs: Mesothelioma: Benign Overall Incidence	Total		0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)		SD 0% SD 0%
#All Organs: Mesothelioma: Benign Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%)	
#All Organs: Mesothelioma: Benign Overall Incidence #All Organs:	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%)	
#All Organs: Mesothelioma: Benign Overall Incidence #All Organs: Mesothelioma: Benign, Ma	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	
#All Organs: Mesothelioma: Benign Overall Incidence #All Organs:	Total	0/50 (0%) 0/100 (0%) 2/50 (4%) 4/100 (4%)	0/50 (0%) Mean 0% 2/50 (4%)	SD 0%	Total	0/50 (0%) 0/100 (0%) 2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%
#All Organs: Mesothelioma: Benign Overall Incidence #All Organs: Mesothelioma: Benign, Ma Overall Incidence #All Organs:	Total	0/50 (0%) 0/100 (0%) 3 2/50 (4%)	0/50 (0%) Mean 0% 2/50 (4%)	SD 0%	Total	0/50 (0%) 0/100 (0%) 2/50 (4%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 87

			Male				Female	
#All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma		0/50 (00)	(201)			27-2 (221)	477	
Overall Institutes	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	1/50 (2%)	CD 4 440/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#All Organs: Osteosarcoma or Osteoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Adrenal Cortex: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Adrenal Cortex: Carcinoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Ganglioneuroma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 88

			Male				Female	
*Adrenal Medulla: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Be	enign							
		9/50 (18%)	5/50 (10%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	14/100 (14%)	Mean 14%	SD 5.66%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Co	omplex							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Ma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	10tai	0/100 (0%)		3D 0%	10tai	0/100 (0%)	iviean 0%	3D 0%
*Adrenal Medulla: Pheochromocytoma: B	enign, Complex	, Malignant, NOS 9/50 (18%)	5/50 (10%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	14/100 (14%)	Mean 14%	SD 5.66%	Total	0/100 (0%)	Mean 0%	SD 0%
#Blood Vessel: Osteosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 05/27/2022

Page: 89

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

Length of Study: CHRONIC

			Male				Female	
#Bone: Chondrosarcoma								
Overell Incidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Chondrosarcoma or Chond	roma							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Chordoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Osteoma		0/50 (001)	0/50 (00/)			0/50 (001)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Bone: Osteosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Bone: Osteosarcoma or Osteoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

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: 90

			Male				Female		
*Brain: Astrocytoma Malignant									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Brain: Ependymoma Benign									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Brain: Glioma Malignant									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Brain: Granular Cell Tumor Benig									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	
*Brain: Medulloblastoma Mal		•••••				•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Brain: Meningioma Malignant		0/50 /00/	0/50 (00/)			0/50 (0%)	0/50 (00()		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

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:** 91

			Male				Female	
*Brain: Meningioma: Benign, Mali	gnant, NOS							
		0/50 (0%)	0/50 (0%)	25 22/		0/50 (0%)	0/50 (0%)	05 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Benigr	n							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Malign	ant							
		0/50 (0%)	0/50 (0%)	05 00/		0/50 (0%)	0/50 (0%)	00.007
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Gliom	a, or Astrocy	rtoma						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma								
		1/50 (2%)	5/50 (10%)			2/50 (4%)	3/50 (6%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 5.66%	Total	5/100 (5%)	Mean 5%	SD 1.41%
*Clitoral/Preputial Gland: Carcinoma								
One will be add on a co	Taral	1/50 (2%)	1/50 (2%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 92

			Male				Female	
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		2/50 (4%)	6/50 (12%)			2/50 (4%)	3/50 (6%)	
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 5.66%	Total	5/100 (5%)	Mean 5%	SD 1.41%
*Clitoral/Preputial Gland: Fibrosarcoma								
Overall Insidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Papilloma		0/50 (00%)	0/50 (00/)			0/50 (00/)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	10tai							
#Ear: Neural Crest Tumor		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Esophagus: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Eye: Amelanotic Melanoma, Ben	ign	- (ac)	(00)					
Overall Institutes	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

#Eye:

#Eye:

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Melanoma Benign

Overall Incidence

Overall Incidence

#Harderian Gland: Adenoma

Overall Incidence

#Harderian Gland: Carcinoma

Overall Incidence

#Harderian Gland:

Overall Incidence

Overall Incidence

*Heart:

Carcinoma or Adenoma

Schwannoma Benign

Length of Study: CHRONIC

......

Schwannoma Malignant

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

SD 0%

SD 0%

SD 0%

SD 0%

SD 0%

SD 0%

Total

Total

Total

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Page: 93

Report Date: 05/27/2022

	Female									
0/50	(00()	0./50	(00()							
	(0%) (0%)	0/50 Mean	, ,	SD	0%					
							•			
0/50	(0%)	0/50	(0%)							
0/100	(0%)	Mean	0%	SD	0%					
0/50	(0%)	0/50	(0%)							
0/100	(0%)	Mean	0%	SD	0%					
							•			
0/50	(0%)	0/50	(0%)							

Mean 0%

Mean 0%

Mean 0%

(0%)

(0%)

0/50

0/50

SD 0%

SD 0%

SD 0%

			microscopically

Total

Total

Total

Total

Total

Total

......

^{#:} 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	
*Heart: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Large: Colon/Rectu Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Large: Colon/Rectu Carcinoma	m:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Carcinoma or Adenoma	m:	2/22 (221)	2/52 (221)			2/52 (224)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Intestine Large: Colon/Rectu Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma								
Occupation of the second	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 95

			Male				Female	
#Intestine Small: Duodenum: Leiomyoma	:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma								
Overell Insidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%) Mean 0%	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
	.	0/50 (0%)	0/50 (0%)	OD 00/	-	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma	cified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma or Adenoma	cified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Leiomyoma								
	T	0/50 (0%)	0/50 (0%)	OD 00/	-	0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
#Intestine Small: Site Unspec	cified:							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
Overall Incidence	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Islets, Pancreatic: Carcinoma								
Overall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma						4/50 (00/)	0/50 (00/)	
Overall Incidence	Total	3/50 (6%) 7/100 (7%)	4/50 (8%) Mean 7%	SD 1.41%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Kidney: Pelvis and Transitic								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Pelvis and Transition Carcinoma or Adenoma	onal Epitheliu							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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					
*Kidney: Pelvis and Transitional Epithelium: Papilloma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Kidney: Renal Tubule: Adenoma												
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Kidney: Renal Tubule: Carcinoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Kidney: Renal Tubule: Carcinoma or Adenoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Kidney: Renal Tubule: Hemangiosarcoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Kidney: Renal Tubule: Lipoma		2/22 (22)	(00)			0/50 (00)	0/20 (00)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

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:** 98

			Male				Female	
*Kidney: Renal Tubule: Liposarcoma								
		0/50 (0%)	0/50 (0%)	OD .00/		0/50 (0%)	0/50 (0%)	00.00
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Benig	jn	0/50 (00/)	0/50 (00/)			0/50 (001)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
		0/100 (0%)				0/100 (0%)	wiean 0%	טע עא טיי
*Kidney: Renal Tubule: Sarcoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Liver: Cholangiocarcinoma								
• " ' '		0/50 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Cholangioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
*Liver: Hemangiosarcoma								
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenoma								
		0/50 (0%)	0/50 (0%)			2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%
Liver: Hepatocellular Carcinoma	1	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinoma		stoma				0/20 (00)	(201)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Liver: Hepatocellular Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%
Liver: Hepatocellular Carcinoma	ı, Hepatocellu	lar Adenoma, or Hepatob	lastoma 0/50 (0%)			2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%

^{*:} 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					
*Lung: Alveolar/Bronchiolar 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%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Lung: Alveolar/Bronchiolar Ca	ırcinoma											
		1/50 (2%)	1/50 (2%)			1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
Overall Incidence	Total	eolar/Bronchiolar Adenor 1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%				
*Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
Lung: Sarcoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
Lung: Squamous Cell Carcino	ma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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

Page: 101

Report Date: 05/27/2022

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Lymph Node, Mesenteric: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mammary Gland: Adenoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
#Mammary Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%
#Mammary Gland: Carcinoma or Adenoma		4/50 (00)	0/50 (00)			0/50 (404)	0/50 /40/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%
#Mammary Gland: Fibroadenoma		•••••						
Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	33/50 (66%) 62/100 (62%)	29/50 (58%) Mean 62%	SD 5.66%
#Mammary Gland: Fibroma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

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					
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma 4/50 (8%) 1/50 (2%) 30/50 (66%) 30/50 (60%)												
		4/50 (8%)	1/50 (2%)			33/50 (66%)	30/50 (60%)					
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 4.24%	Total	63/100 (63%)	Mean 63%	SD 4.24%				
#Mammary Gland: Fibroma, Fibroadenoma,	Carcinoma, or	Adenoma										
	,	4/50 (8%)	1/50 (2%)			35/50 (70%)	30/50 (60%)					
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 4.24%	Total	65/100 (65%)	Mean 65%	SD 7.07%				
#Mesentery: Fibrosarcoma			- /									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Mesentery: Hemangiosarcoma		0/50 (00)	2(22)			2/22 (221)	272 (221)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
		` /				` '						
#Mesentery: Osteosarcoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Mesentery: Rhabdomyosarcoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Species: RATS Route: GAVAGE

Strain: F 344/N Length of Study: CHRONIC Vehicle: WATER

Page: 103

			Male				Female	
*Nose: Adenoma								
	-	0/50 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Chondroma								
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Sarcoma								
		0/50 (0%)	0/50 (0%)	05.00/		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Squamous Cell Carcino	oma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o	sa, Tongue, Phary							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcino	sa, Tongue, Phary	ynx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

^{*:} 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: WATER Page: 104

Report Date: 05/27/2022

Length of Study: CHRONIC

			Male				Female	
#Oral Cavity (Oral Mucosa, Squamous Cell Carcinon		Squamous, or Papilloma						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Oral Mucosa: Squamous Cell Carcinon	na	0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Oral Mucosa: Squamous Cell Papillom						(00)	(201)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Be	enign					0/50 (0%)	0/49 (0%)	
Overall Incidence					Total	0/99 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Ma	alignant							
Overall Incidence					Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: B	enign, Maligna	ant, NOS				0/50 (00/)	0/40 (000)	
Overall Incidence					Total	0/50 (0%) 0/99 (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: GAVAGE Vehicle: WATER Page: 105

			Male				Female	
*Ovary: Granulosa-Theca Tumor B	Benign							
Overall Incidence					Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pancreas: Adenoma		0/50 (00/)	4/50 (00)					
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pancreas: Mixed Tumor Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
Overall Incidence	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/46 (0%) 0/94 (0%)	0/48 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 106

report	Date.	03/21/2022	

			Male				Female	
#Peripheral Nerve: Schwannoma Malignan	t							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma: Benign,								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Dis Adenoma	talis or Unspec	ified Site:						
		11/50 (22%)	15/50 (30%)			22/50 (44%)	24/50 (48%)	
Overall Incidence	Total	26/100 (26%)	Mean 26%	SD 5.66%	Total	46/100 (46%)	Mean 46%	SD 2.83%
Pituitary Gland: Pars Dis Carcinoma								
		0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%
Pituitary Gland: Pars Dis Carcinoma or Adenoma	talis or Unspec							
		11/50 (22%)	15/50 (30%)			24/50 (48%)	25/50 (50%)	
Overall Incidence	Total	26/100 (26%)	Mean 26%	SD 5.66%	Total	49/100 (49%)	Mean 49%	SD 1.41%
Pituitary Gland: Pars Into Adenoma	ermedia:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 107

			Male				Female					
*Pituitary Gland: Pars Intermedia: Carcinoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Interm Carcinoma or Adenoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Prostate: Adenoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%								
*Prostate: Carcinoma or Adenoma		0(50 (00())	0/50 (00/)									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%								
		` ,										
*Salivary Glands: Sarcoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Schwannoma Malignant												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 108

Report Date: 05/27/2022

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

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Skeletal Muscle: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangioma		-4						
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
• " ' '	-	0/50 (0%)	0/50 (0%)	OD 00/	-	0/50 (0%)	0/50 (0%)	OD 20/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Lipoma		0/50 (00/)	0/50 (00/)			0/50 (00()	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or F								
•	-	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 109

0%)	0/100 (0%) Mean 0% SD 0%	Total 0	1/50 (2%) 0/4	/50 (0%)	SD 0%
0%)	0/100 (0%) Mean 0% SD 0% 1/50 (2%) 1/50 (2%)	Total 0	1/50 (2%)	Mean 0% 5	SD 0%
) (2%) (2%) !	1/50 (2%) 1/50 (2%)		1/50 (2%) 0/9	/50 (0%)	SD 0%
2%)	()		` '	` '	
2%)	()		` '	` '	
	2/100 (2%) Mean 2% SD 0%	Total 1	/100 (1%)	Mean 1% SI	
ian					D 1.41%
-	Fumor Benign 1/50 (2%) 1/50 (2%)		1/50 (2%) 0/9	/50 (0%)	
,	2/100 (2%) Mean 2% SD 0%	Total 1	/100 (1%)	Mean 1% SI	D 1.41%
n, or Trichoepitheli	mor Benign, or Trichoepithelioma 1/50 (2%) 1/50 (2%)		2/50 (4%) 0/9	/50 (0%)	
2%)	2/100 (2%) Mean 2% SD 0%		` '	` '	D 2.83%
` '	()		` '	` '	
(0%) N	0/100 (0%) Mean 0% SD 0%	Total 0)/100 (0%)	Mean 0%	SD 0%
alignant or NOS)	Tumor (malignant or NOS)		0/50 (00/)	(50)	
•	()		` '	` '	SD 0%
	0/100 (0%) Mean 0% SD 0% alignant or NOS) 0 (0%) 0/50 (0%)	0%) Mean 0% SD 0% Total 0 alignant or NOS) 0 (0%) 0/50 (0%) 0%) Mean 0% SD 0% Total 0	0%) Mean 0% SD 0% Total 0/100 (0%) alignant or NOS) 0 (0%) 0/50 (0%) 0/50 (0%)	0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% S alignant or NOS) 0 (0%) 0/50 (0%) 0 Mean 0% SD 0% Total 0/100 (0%) Mean 0% S

^{*:} 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: 110

Report Date: 05/27/2022

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

	Male						Female					
#Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma												
Overall Incidence	Total	1/50 (2%)	1/50 (2%)	SD 0%	Total	2/50 (4%)	0/50 (0%) Mean 2%	SD 2.83%				
Overall incidence	Total	2/100 (2%)	Mean 2%	 	Total	2/100 (2%)	2%	SD 2.83%				
		a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 10/50 (20%)		na,		4/50 (8%)	0/50 (0%)					
Overall Incidence	Total	14/100 (14%)	Mean 14%	SD 8.49%	Total	4/100 (4%)	Mean 4%	SD 5.66%				
#Skin: Fibroma												
		6/50 (12%)	5/50 (10%)			1/50 (2%)	1/50 (2%)					
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 0%				
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myxo	oma, Myxosarcoma, or Fi 7/50 (14%)	ibrous Histiocytoma 6/50 (12%)			1/50 (2%)	1/50 (2%)					
Overall Incidence	Total	13/100 (13%)	Mean 13%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 0%				
#Skin: Fibrosarcoma												
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Fibrosarcoma, Sarcom	na, Myxosarcoma	, or Fibrous Histiocytom					0/50					
Occupation of decree	T-1-1	1/50 (2%)	1/50 (2%)	OD 00/	T-1-!	0/50 (0%)	0/50 (0%)	00,007				
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 111

			Male				Female	
#Skin: Fibrous Histiocytoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Hemangiosarcoma		0/50 (00/)	0/50 /02/			0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Keratoacanthoma		8/50 (16%)	2/50 (4%)			2/50 (4%)	0/50 (09/)	
Overall Incidence	Total	10/100 (10%)	Mean 10%	SD 8.49%	Total	2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%
#Skin: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Liposarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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						
#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%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Neurofibroma or Schwi	annoma benian											
	g	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Neurofibrosarcoma or Overall Incidence	Schwannoma (m	alignant or NOS) 1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
#Skin:		Schwannoma (benign, ma 1/50 (2%) 2/100 (2%)		SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
		2/100 (2%)				(,						
#Skin: Osteosarcoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Sarcoma												
		0/50 (0%)	0/50 (0%)		_	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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

Page: 113

Report Date: 05/27/2022

Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Skin: Schwannoma Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Skin: Schwannoma Malignant		4/50 (00)	4/50 (001)			0/50 (00/)	4/50 (00)	
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
Skin: Squamous Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell (•	, -	or NOS),				
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Skin: Squamous Cell Papilloma	•••••							
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Skin: Squamous Cell Papilloma o	r Papilloma							
		1/50 (2%)	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: GAVAGE Vehicle: WATER Page: 114

			Male			Female						
#Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma												
Overall Incidence	Total	9/50 (18%) 12/100 (12%)	3/50 (6%) Mean 12%	SD 8.49%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%				
#Skin:												
Squamous Cell Papilloma,	, Papilloma, o	or Keratoacanthoma										
	-	9/50 (18%)	2/50 (4%)			2/50 (4%)	0/50 (0%)					
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 9.9%	Total	2/100 (2%)	Mean 2%	SD 2.83%				
#Skin: Trichoepithelioma												
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
#Skin: Sebaceous Gland: Adenoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Sebaceous Gland: Carcinoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (00)	0/50 (000)			0/50 (00)	0/50 /00/					
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	SD 0%				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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: WATER **Page:** 115

			Male		Female					
#Spinal Cord: Astrocytoma Benign										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Spleen: Fibrosarcoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Spleen: Hemangioma		-/								
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Spleen: Hemangiosarcoma										
Overall Incidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	SD 0%		
Overall incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Spleen: Leiomyosarcoma										
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Stomach, Forestomach: Leiomyosarcoma		0/50 (00/)	0/50 /00()			0/50 (00/)	0/50 (00/)			
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/		
Overali incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 116

			Male				Female	
#Stomach, Forestomach: Schwannoma Malignant								
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
	10tai	0/100 (0%)	iviean 0%	3D 0%		1/100 (1%)	wiean 1%	งบ 1.41%
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papillom	a Squamous 0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Lipoma		0/50 (00)	0/50 (00)			0/50 (00/)	0/50 /00/	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incluence	TOLAI	0/100 (0%)	IVIEATI 0%	3D 0%	TOlai	0/100 (0%)	Mean 0%	30 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

			Male		Female				
*Testes: Adenoma Overall Incidence	Total	44/50 (88%) 92/100 (92%)	48/50 (96%) Mean 92%	SD 5.66%					
*Thymus: Sarcoma		0/40 (00/)	0/40 (00/)			0/40 (00/)	0/40 (00)		
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/96 (0%)	0/48 (0%) Mean 0%	SD 0%	
*Thymus: Thymoma Benign						(20)			
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 1/96 (1.04%)	1/48 (2%) Mean 1.04%	SD 1.47%	
*Thymus: Thymoma Malignant		0/49 (0%)	0/48 (0%)			0/48 (0%)	0/48 (0%)		
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/96 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma: Benign, Malig									
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 1/96 (1.04%)	1/48 (2%) Mean 1.04%	SD 1.47%	
*Thyroid Gland: C-Cell: Adenoma			4/50 (000)			F/F0 (400)	44/50 (000)		
Overall Incidence	Total	6/50 (12%) 7/100 (7%)	1/50 (2%) Mean 7%	SD 7.07%	Total	5/50 (10%) 16/100 (16%)	11/50 (22%) Mean 16%	SD 8.49%	

^{*:} 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: 118

			Male				Female					
Thyroid Gland: C-Cell: Carcinoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Thyroid Gland: C-Cell: Carcinoma or Adenoma												
		6/50 (12%)	1/50 (2%)			5/50 (10%)	12/50 (24%)					
Overall Incidence	Total	7/100 (7%)	Mean 7%	SD 7.07%	Total	17/100 (17%)	Mean 17%	SD 9.9%				
*Thyroid Gland: Follicular Cell: Adenoma												
		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Thyroid Gland: Follicular Cell: Carcinoma												
Overall Insidence	Tatal	1/50 (2%)	2/50 (4%)	CD 4 440/	Tatal	0/50 (0%)	2/50 (4%) Mean 2%	CD 0.000/				
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	2/100 (2%)	wean 2%	SD 2.83%				
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma												
		1/50 (2%)	3/50 (6%)			0/50 (0%)	2/50 (4%)					
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	2/100 (2%)	Mean 2%	SD 2.83%				
#Tissue NOS: Fibrosarcoma		0/50 (00/)	0/50 (00)			0/50 (00/)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 119

Male						
	0/50 (0%) 0/50 (0%)					
Total	l 0/100 (0%) Mean 0% SD 0%					
	0/50 (0%) 0/50 (0%)					
Total	l 0/100 (0%) Mean 0% SD 0%					
	0/50 (0%) 0/50 (0%)					
Total	l 0/100 (0%) Mean 0% SD 0%					
	0/50 (0%) 0/50 (0%)					
Total	l 0/100 (0%) Mean 0% SD 0%					
	0/50 (0%) 0/50 (0%)					
Total	l 0/100 (0%) Mean 0% SD 0%					
	0/50 (0%) 0/50 (0%)					
Total						
	Tota					

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 120

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Report Date: (05/2	27/	202
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			Male				Female	
#Tongue: Squamous Cell Carcinoma	or Papillom	a Squamous						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Urinary Bladder: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Urinary Bladder: Carcinoma or Papilloma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Urinary Bladder: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

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			Male			Female			
*Urinary Bladder: Papilloma									
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Uterus: Adenoma									
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Uterus: Carcinoma									
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Uterus: Deciduoma Benign									
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Uterus: Hemangioma									
.						0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%	
#Uterus: Hemangiosarcoma									
						0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (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: 05/27/2022

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus:** Leiomyoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Uterus: **Polyp Stromal** 7/50 (14%) 8/50 (16%) **Overall Incidence** Total 15/100 (15%) Mean 15% SD 1.41% **#Uterus:** Sarcoma Stromal 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Uterus: Sarcoma Stromal or Polyp Stromal 7/50 (14%) 8/50 (16%) **Overall Incidence** Total 15/100 (15%) Mean 15% SD 1.41% #Uterus: Schwannoma Malignant 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% #Vagina: Polyp 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 123

			Male				Female	
#Vagina: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/27/2022

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

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 Northwest	059601105	06/04/01	729	50(5)	26(676)	540.9	Cumene
Battelle Northwest	058800405	09/13/99	729	50(5)	31(686)	519.5	Divinylbenzene
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	059700805	10/01/01	729	49(5)	27(683)	525.0	Propargyl alcohol
Battelle Northwest	059600105	01/18/99	729	50(5)	29(701)	534.2	Stoddard solvent (type IIC)
					Female		
Battelle Northwest	059601105	06/04/01	731	50(5)	21(674)	356.9	Cumene
Battelle Northwest	058800405	09/13/99	731	50(5)	33(679)	355.3	Divinylbenzene
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	059700805	10/01/01	730	50(5)	29(678)	353.3	Propargyl alcohol
Battelle Northwest	059600105	01/18/99	730	50(5)	36(696)	363.6	Stoddard solvent (type IIC)

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	
#All Organs: Benign Tumors								
		48/50 (96%)	49/50 (98%)	50/50 (100%)		44/50 (88%)	43/50 (86%)	44/50 (88%)
		48/50 (96%)	48/49 (98%)	50/50 (100%)		43/50 (86%)	42/50 (84%)	37/50 (74%)
verall Incidence	Total	293/299 (97.99%)	Mean 97.99%	SD 1.79%	Total	253/300 (84.33%)	Mean 84.33%	SD 5.28%
#All Organs: Malignant Tumors								
		36/50 (72%)	29/50 (58%)	31/50 (62%)		24/50 (48%)	17/50 (34%)	22/50 (44%)
		32/50 (64%)	32/49 (65%)	33/50 (66%)		25/50 (50%)	26/50 (52%)	30/50 (60%)
Overall Incidence	Total	193/299 (64.55%)	Mean 64.55%	SD 4.65%	Total	144/300 (48%)	Mean 48%	SD 8.67%
#All Organs: Malignant and Benign T	umors							
		50/50 (100%)	50/50 (100%)	50/50 (100%)		50/50 (100%)	46/50 (92%)	46/50 (92%)
		50/50 (100%)	49/49 (100%)	50/50 (100%)		46/50 (92%)	47/50 (94%)	44/50 (88%)
Overall Incidence	Total	299/299 (100%)	Mean 100%	SD 0%	Total	279/300 (93%)	Mean 93%	SD 3.95%
All Organs: Hemangioma								
		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%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
All Organs: Hemangiosarcoma								
		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%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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					Male			Female						
All Organs: Hemangiosarcoma or H	emangioma													
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/50 1/299 (0.33%	(0%) %)	0/49 Mean 0	(0%) .33%	0/50 SD 0.82%	(0%) %	Total	1/50 3/300 ((2%) 1%)	2/50 Mea	(4%) in 1%	0/50 SD 1	(0%) .67%
										• • • • • • • • • • • • • • • • • • • •				
#All Organs: Histiocytic Sarcoma														
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	2/50	(4%)	2/50	(4%)
O	T-1-1	1/50	(2%)	0/49	(0%)	0/50	(0%)	T-1-1	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/299 (0.679	,	Mean 0		SD 1.03%		Total	4/300 (1.	,		1.33%	SD 2	.07%
#All Organs: Leukemia: Lymphocytic		Mononuclear, or U 26/50	Jndiffere	ntiated 22/50	(44%)	25/50	(50%)		12/50	(24%)	10/50	(20%)	14/50	(28%)
#All Organs:		Mononuclear, or U 26/50	Jndiffere (52%) (52%)	ntiated	(44%) (43%)	25/50	(50%) (50%)	Total		(24%) (36%)	10/50 20/50	(20%) (40%) 33.33%	14/50 26/50 SD 1	(52%)
#All Organs: Leukemia: Lymphocytic Overall Incidence#All Organs:	Total	Mononuclear, or U 26/50 26/50 145/299 (48.4	Jndiffere (52%) (52%) (52%)	ntiated 22/50 21/49 Mean 48	(44%) (43%) 3.48%	25/50 25/50 SD 4.039	(50%) (50%)		12/50 18/50	(24%) (36%)	10/50 20/50	(40%)	26/50	(52%)
#All Organs: Leukemia: Lymphocytic Overall Incidence	Total	Mononuclear, or U 26/50 26/50 145/299 (48.4	Jndiffere (52%) (52%) (52%)	ntiated 22/50 21/49 Mean 48	(44%) (43%) 3.48%	25/50 25/50 SD 4.039	(50%) (50%)		12/50 18/50	(24%) (36%)	10/50 20/50	(40%)	26/50	(52%)
#All Organs: Leukemia: Lymphocytic Overall Incidence #All Organs:	Total	Mononuclear, or U 26/50 26/50 145/299 (48.4	Jndifferen (52%) (52%) (9%)	ntiated 22/50 21/49 Mean 48	(44%) (43%) 3.48% tiated Cel	25/50 25/50 SD 4.039	(50%) (50%) %		12/50 18/50 100/300 (3	(24%) (36%) 3.33%)	10/50 20/50 Mean	(40%) 33.33%	26/50 SD 1	(52%) 1.78%
#All Organs: Leukemia: Lymphocytic Overall Incidence#All Organs:	Total	Mononuclear, or U 26/50 26/50 145/299 (48.4 	Jndifferer (52%) (52%) (9%) 	ntiated 22/50 21/49 Mean 48 r Undifferent 0/50	(44%) (43%) 3.48% tiated Cell (0%) (0%)	25/50 25/50 SD 4.039	(50%) (50%) % (0%) (0%)		12/50 18/50 100/300 (3	(24%) (36%) 3.33%) 	10/50 20/50 Mean 0/50 0/50	(40%) 33.33% (0%)	26/50 SD 1	(52%) 1.78% (0%) (0%)
#All Organs: Leukemia: Lymphocytic Overall Incidence #All Organs: Malignant Lymphoma: F	Total	Mononuclear, or U 26/50 26/50 145/299 (48.4 	Jndifferer (52%) (52%) (9%) 	22/50 21/49 Mean 48 T Undifferent 0/50 0/49	(44%) (43%) 3.48% tiated Cell (0%) (0%)	25/50 25/50 SD 4.039 I Type 0/50 0/50	(50%) (50%) % (0%) (0%)	Total	12/50 18/50 100/300 (3 0/50 0/50	(24%) (36%) 3.33%) 	10/50 20/50 Mean 0/50 0/50	(40%) 33.33% (0%) (0%)	26/50 SD 1: 0/50 0/50	(52%) 1.78% (0%) (0%)
#All Organs: Leukemia: Lymphocytic Overall Incidence #All Organs: Malignant Lymphoma: F Overall Incidence #All Organs:	Total	Mononuclear, or U 26/50 26/50 145/299 (48.4 mphocytic, Mixed 0/50 0/50 0/299 (0%)	Jndifferer (52%) (52%) (9%) 	ntiated 22/50 21/49 Mean 48 r Undifferen 0/50 0/49 Mean	(44%) (43%) 3.48% tiated Cell (0%) (0%) 0%	25/50 25/50 SD 4.039 I Type 0/50 0/50 SD 0%	(50%) (50%) % (0%) (0%)	Total	12/50 18/50 100/300 (3 0/50 0/50 0/300 ((24%) (36%) 3.33%) 	10/50 20/50 Mean 0/50 0/50	(40%) 33.33% 	26/50 SD 11 0/50 0/50 SD	(52%) 1.78% (0%) (0%) 0% (0%)
#All Organs: Leukemia: Lymphocytic Overall Incidence #All Organs: Malignant Lymphoma: F Overall Incidence #All Organs:	Total	Mononuclear, or U 26/50 26/50 145/299 (48.4 mphocytic, Mixed 0/50 0/50 0/299 (0%)	Jndifferer (52%) (52%) (9%)	ntiated 22/50 21/49 Mean 48 r Undifferent 0/50 0/49 Mean	(44%) (43%) 3.48% tiated Cell (0%) (0%) 0%	25/50 25/50 SD 4.039 I Type 0/50 0/50 SD 0%	(50%) (50%) % (0%) (0%) (0%) (0%)	Total	12/50 18/50 100/300 (3 0/50 0/50 0/300 ((24%) (36%) 3.33%) 	10/50 20/50 Mean 0/50 0/50 Mea	(40%) 33.33% (0%) (0%) in 0%	26/50 SD 11 0/50 0/50 SD	(52%) 1.78% (0%) (0%) 0% (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				Female	
#All Organs: Mesothelioma: Benign, N	//alignant, NOS	· · · · · · · · · · · · · · · · · · ·						
_		3/50 (6%) 0/50 (0%)	2/50 (4%) 1/49 (2%)	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	7/299 (2.34%)	Mean 2.34%	SD 2.34%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#All Organs: Mesothelioma: Malignant	t							
		3/50 (6%) 0/50 (0%)	2/50 (4%) 1/49 (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%)
Overall Incidence	Total	7/299 (2.34%)	Mean 2.34%	SD 2.34%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 4/299 (1.34%)	1/49 (2%) Mean 1.34%	2/50 (4%) SD 1.64%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
#All Organs: Osteosarcoma or Osteon	 na							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 4/299 (1.34%)	1/49 (2%) Mean 1.34%	2/50 (4%) SD 1.64%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%

^{*:} 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

Vehicle: AIR

Report Date: 05/27/2022

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

Length of Study: CHRONIC

			Male			Female			
*Adrenal Cortex: Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%	
Adrenal Cortex: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	
Adrenal Medulla: Ganglioneuroma									
		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%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%	
Adrenal Medulla: Hemangioma									
		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%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%	
Adrenal Medulla: Pheochromocytoma Benign									
		7/50 (14%)	12/50 (24%)	8/50 (16%)		1/50 (2%)	2/50 (4%)	3/50 (6%)	
		8/50 (16%)	8/49 (16%)	5/50 (10%)		1/49 (2%)	1/50 (2%)	2/50 (4%)	
Overall Incidence	Total	48/299 (16.05%)	Mean 16.05%	SD 4.56%	Total	10/299 (3.34%)	Mean 3.34%	SD 1.63%	

^{*:} 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: INHALATION Vehicle: AIR

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		Male				Female	
mplex							
	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Tatal	` '	` '	` '	Tatal	` '	` ,	0/50 (0%)
	` ,				,		SD 0.82%
lignant							
	1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		, ,	` '		` '	` '	1/50 (2%)
	, ,			Total	,		SD 1.03%
nign, Complex	c, Malignant, NOS 7/50 (14%) 10/50 (20%) 54/299 (18.06%)	13/50 (26%) 10/49 (20%) Mean 18.07%	8/50 (16%) 6/50 (12%) SD 5.09%	Total	3/50 (6%) 1/49 (2%) 13/299 (4.35%)	2/50 (4%) 1/50 (2%) Mean 4.34%	3/50 (6%) 3/50 (6%) SD 1.96%
	()	` ,	` ,		` '	` ,	0/50 (0%)
Total	, ,	` ,	` '	Total	` '	, ,	0/50 (0%) SD 0%
·····	0/299 (0/0)						
	0/50 (09/)	0/50 (0%)	0/50 (09/)		0/50 (09/)	0/50 (09/)	0/50 (0%)
		, ,	` '		(/	` ,	0/50 (0%) 0/50 (0%)
Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
li	Total ignant Total nign, Complex Total Total	O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/299 (0%) O/299 (0%) O/250 (4%) O/50 (2%) O/50 (0%) O	O/50 (0%)	O/50 (0%)	O/50 (0%)	1/50 (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%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	O/50 (0%) O/50

^{*:} 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

Report Date: 05/27/2022 Female

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			Male				Female	
#Bone: Chondrosarcoma or Chond	Iroma							
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma		•••••				•••••		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.34%	SD 1.64%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Bone: Osteosarcoma or Osteoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.34%	SD 1.64%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

^{*:} 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	
*Brain: Astrocytoma Malignant								
		0/50 (0%)	0/49 (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%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
*Brain: Ependymoma Benign								
		0/50 (0%)	0/49 (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%)	0/49 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Brain: Glioma Malignant								
_		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
*Brain: Granular Cell Tumor Benigr	1					•••••		
G		0/50 (0%)	0/49 (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%)	0/49 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Brain: Medulloblastoma Mal								
		0/50 (0%)	0/49 (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%)	0/49 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/299 (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	
Brain: Meningioma Malignant								
		0/50 (0%)	0/49 (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%)	0/49 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, M	alignant. NOS							
	g , c	0/50 (0%)	0/49 (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%)	0/49 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Ben	ign							
		0/50 (0%)	0/49 (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%)	0/49 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Mali	gnant							
	•	0/50 (0%)	0/49 (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%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Brain: Oligodendroglioma, Glid	oma, or Astrocy	ytoma						
- ·	•	0/50 (0%)	0/49 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	4/299 (1.34%)	Mean 1.33%	SD 2.07%

^{*:} 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	
Clitoral/Preputial Gland: Adenoma								
		0/50 (0%)	0/48 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	3/49 (6%)	0/50 (0%)		0/50 (0%)	4/50 (8%)	0/49 (0%)
verall Incidence	Total	3/297 (1.01%)	Mean 1.02%	SD 2.5%	Total	5/299 (1.67%)	Mean 1.67%	SD 3.2%
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)	0/48 (0%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	1/50 (2%)
		2/50 (4%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	3/297 (1.01%)	Mean 1%	SD 1.67%	Total	5/299 (1.67%)	Mean 1.67%	SD 1.51%
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/48 (0%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	1/50 (2%)
		2/50 (4%)	3/49 (6%)	0/50 (0%)		1/50 (2%)	4/50 (8%)	1/49 (2%)
Overall Incidence	Total	6/297 (2.02%)	Mean 2.02%	SD 2.57%	Total	10/299 (3.34%)	Mean 3.34%	SD 3.01%
Clitoral/Preputial Gland: Fibrosarcoma								
		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/50 (0%)	0/48 (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%)	0/49 (0%)
overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (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	
#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%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (0%)	Mean 0%	SD 0%
#Esophagus: Fibrosarcoma								
		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%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Eye: Amelanotic Melanoma, Be Overall Incidence	enign Total	0/50 (0%) 0/50 (0%) 0/299 (0%)	0/50 (0%) 0/49 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (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%)	0/49 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Eye: Schwannoma Malignant								
_		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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: INHALATION Vehicle: AIR

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			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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/299 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Malignant								
		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%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

2007 Toxicology Data Man

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	
#Intestine Large: Colon/Re	ectum:							
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Re Carcinoma								
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Re Carcinoma or Adenoma		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%)
O	Taral	0/50 (0%)	0/49 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Re Leiomyosarcoma	ectum:							
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenu Carcinoma								
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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	
#Intestine Small: Duodenum: Leiomyoma								
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma	ified:							
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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: INHALATION Vehicle: AIR

Page: 138

			Male				Female	
#Intestine Small: Site Unspe Leiomyoma	ecified:							
		0/50 (0%) 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%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Leiomyosarcoma								
		0/50 (0%) 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%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma						•••••		
		1/50 (2%)	5/50 (10%)	3/50 (6%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/50 (6%) 19/299 (6.35%)	4/49 (8%) Mean 6.36%	3/50 (6%) SD 2.68%	Total	3/50 (6%) 7/299 (2.34%)	1/50 (2%) Mean 2.34%	1/49 (2%) SD 1.97%
*Islets, Pancreatic: Carcinoma								
		2/50 (4%) 1/50 (2%)	1/50 (2%)	4/50 (8%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 14/299 (4.68%)	5/49 (10%) Mean 4.7%	1/50 (2%) SD 3.56%	Total	0/50 (0%) 1/299 (0.33%)	0/50 (0%) Mean 0.33%	0/49 (0%) SD 0.82%
'Islets, Pancreatic: Carcinoma or Adenoma								
		3/50 (6%)	6/50 (12%)	7/50 (14%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	4/50 (8%) 33/299 (11.04%)	9/49 (18%) Mean 11.06%	4/50 (8%) SD 4.63%	Total	3/50 (6%) 8/299 (2.68%)	1/50 (2%) Mean 2.67%	1/49 (2%) SD 2.06%

^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
*Kidney: Pelvis and Trans Carcinoma	sitional Epitheli	um:						
		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%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/298 (0%)	Mean 0%	SD 0%
*Kidney: Pelvis and Trans Carcinoma or Adenoma	-	um:						
		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%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/298 (0%)	Mean 0%	SD 0%
*Kidney: Pelvis and Trans Papilloma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/299 (0%)	0/50 (0%) 0/49 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/49 (0%) 0/298 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/49 (0%) SD 0%
*Kidney: Renal Tubule: Adenoma								
		1/50 (2%)	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%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/298 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma		1/50 (29/)	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%) 1/50 (2%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/49 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Overall illelidelide	ı olai	2/233 (0.01 /0)	IVICALI U.U1 /0	1.03/0	ı olal	0/200 (0/0)	IVICALI U70	3D 070

^{*:} 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	
Kidney: Renal Tubule: Carcinoma or Adenoma								
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1%	SD 1.67%	Total	0/298 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
		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%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma								
		1/50 (2%)	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%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/298 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Liposarcoma								
		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%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/298 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Mesenchymal Tumor Benig								
		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%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/298 (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: INHALATION Vehicle: AIR

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			Male				Female	
Kidney: Renal Tubule: Nephroblastoma								
		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%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/298 (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%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
Liver: Cholangiocarcinoma								
		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%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Liver: Cholangioma								
		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%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (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: INHALATION Vehicle: AIR

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			Male				Female	
Liver: Hepatocellular Adenoma	a							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/299 (0.33%)	0/49 (0%) Mean 0.33%	0/50 (0%) SD 0.82%	Total	0/50 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Liver: Hepatocellular Carcinon	na							
		0/50 (0%)	0/50 (0%) 1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/50 (0%) 1/299 (0.33%)	1/49 (2%) Mean 0.34%	0/50 (0%) SD 0.83%	Total	0/50 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
		` ,				, ,		
Liver: Hepatocellular Carcinon	na or Hepatobl	astoma						
		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%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/299 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinon	na or Hepatoce	ellular Adenoma						
•	•	0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.04%	Total	0/299 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinon	na. Hepatocelli	ılar Adenoma, or Hepato	blastoma					
	, ,	0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (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: INHALATION Vehicle: AIR

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			Male				Female	
Lung: Alveolar/Bronchiolar A	denoma							
		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%) 3/299 (1%)	1/49 (2%) Mean 1.01%	1/50 (2%) SD 1.1%	Total	0/50 (0%) 1/299 (0.33%)	Mean 0.33%	0/49 (0%) SD 0.82%
Lung: Alveolar/Bronchiolar C	arcinoma	•••••	•••••					
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
	.	0/50 (0%)	0/49 (0%)	1/50 (2%)	+	0/50 (0%)	1/50 (2%)	0/49 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1%	SD 1.1%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
Overall Incidence	Total	2/50 (4%) 0/50 (0%) 6/299 (2.01%)	1/50 (2%) 1/49 (2%) Mean 2.01%	0/50 (0%) 2/50 (4%) SD 1.79%	Total	1/50 (2%) 0/50 (0%) 3/299 (1%)	0/50 (0%) 1/50 (2%) Mean 1%	1/50 (2%) 0/49 (0%) SD 1.1%
Lung: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
	างเลา	0/299 (0%)	ivieari u%	0% U%	ıoıal	0/299 (0%)	Wean 0%	OD 0%
*Lung: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 /00/						
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/49 (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: 05/27/2022

			Male				Female	
Lung: Squamous Cell Carcinoma	ı							
		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%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Sarcoma								
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		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%)	3/50 (6%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.68%	SD 1.67%	Total	3/300 (1%)	Mean 1%	SD 2.45%
#Mammary Gland: Carcinoma								
		2/50 (4%)	1/50 (2%)	2/50 (4%)		10/50 (20%)	3/50 (6%)	5/50 (10%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		3/50 (6%)	7/50 (14%)	4/50 (8%)
Overall Incidence	Total	5/299 (1.67%)	Mean 1.67%	SD 1.97%	Total	32/300 (10.67%)	Mean 10.67%	SD 5.47%
#Mammary Gland: Carcinoma or Adenoma								
		2/50 (4%)	1/50 (2%)	2/50 (4%)		10/50 (20%)	3/50 (6%)	5/50 (10%)
		0/50 (0%)	2/49 (4%)	0/50 (0%)		3/50 (6%)	10/50 (20%)	4/50 (8%)
Overall Incidence	Total	7/299 (2.34%)	Mean 2.35%	SD 1.98%	Total	35/300 (11.67%)	Mean 11.67%	SD 6.62%

^{*:} 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: 05/27/2022

Length of Study: CHRONIC

Vehicle: AIR

			Male				Female	
#Mammary Gland: Fibroadenoma								
		0/50 (0%)	1/50 (2%)	2/50 (4%)		24/50 (48%)	20/50 (40%)	22/50 (44%)
	-	1/50 (2%)	1/49 (2%)	3/50 (6%)	.	22/50 (44%)	26/50 (52%)	19/50 (38%)
Overall Incidence	Total	8/299 (2.68%)	Mean 2.67%	SD 2.06%	Total	133/300 (44.33%)	Mean 44.33%	SD 5.13%
Mammary Gland: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenom	na or Adenoma	0/50 (0%) 1/50 (2%)	1/50 (2%) 3/49 (6%)	2/50 (4%) 3/50 (6%)		24/50 (48%) 22/50 (44%)	20/50 (40%) 28/50 (56%)	22/50 (44%) 19/50 (38%)
Overall Incidence	Total	10/299 (3.34%)	Mean 3.35%	SD 2.45%	Total	135/300 (45%)	Mean 45%	SD 6.42%
#Mammary Gland: Fibroma, Fibroadenom		or Adenoma 2/50 (4%) 1/50 (2%)	1/50 (2%) 3/49 (6%)	4/50 (8%) 3/50 (6%)		31/50 (62%) 24/50 (48%)	22/50 (44%) 31/50 (62%)	26/50 (52%) 23/50 (46%)
Overall Incidence	Total	14/299 (4.68%)	Mean 4.69%	SD 2.44%	Total	157/300 (52.33%)	Mean 52.33%	SD 7.94%
Mesentery: Fibrosarcoma								
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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	
#Mesentery: Hemangiosarcoma								
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	0/49 (0%)	1/50 (2%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/297 (0%)	Mean 0%	SD 0%
*Nose: Chondroma								
		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%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/297 (0.34%)	Mean 0.33%	SD 0.82%

^{*:} 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	
*Nose: Sarcoma								
		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%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/297 (0%)	Mean 0%	SD 0%
*Nose: Squamous Cell Carcino	oma							
		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%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/297 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous c		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Papilloma Squamous o			1/50 (2%) 0/49 (0%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
Papilloma Squamous o Overall Incidence #Oral Cavity (Oral Mucos	Total sa, Tongue, Phai	0/50 (0%) 0/50 (0%) 1/299 (0.33%)	0/49 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Papilloma Squamous o	Total sa, Tongue, Phai	0/50 (0%) 0/50 (0%) 1/299 (0.33%)	0/49 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Papilloma Squamous o Overall Incidence #Oral Cavity (Oral Mucos	Total sa, Tongue, Phai	0/50 (0%) 0/50 (0%) 1/299 (0.33%) Tynx, Tooth, Gingiva):	0/49 (0%) Mean 0.33%	0/50 (0%) SD 0.82%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Papilloma Squamous of Overall Incidence #Oral Cavity (Oral Mucos Squamous Cell Carcine Overall Incidence	or Papilloma Total sa, Tongue, Pharoma Total	0/50 (0%) 0/50 (0%) 1/299 (0.33%) Tynx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%) 1/299 (0.33%)	0/49 (0%) Mean 0.33% 0/50 (0%) 0/49 (0%) Mean 0.33%	0/50 (0%) SD 0.82% 1/50 (2%)	Total Total	0/50 (0%) 0/300 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)
Papilloma Squamous of Overall Incidence #Oral Cavity (Oral Mucos Squamous Cell Carcing Overall Incidence	Total Sa, Tongue, Pharoma Total Total Total	0/50 (0%) 0/50 (0%) 1/299 (0.33%) Tynx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%) 1/299 (0.33%)	0/49 (0%) Mean 0.33% 0/50 (0%) 0/49 (0%) Mean 0.33%	0/50 (0%) SD 0.82% 1/50 (2%) 0/50 (0%)		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)
Papilloma Squamous of Overall Incidence #Oral Cavity (Oral Mucos Squamous Cell Carcine Overall Incidence	Total Sa, Tongue, Pharoma Total Total Total	0/50 (0%) 0/50 (0%) 1/299 (0.33%) Tynx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%) 1/299 (0.33%)	0/49 (0%) Mean 0.33% 0/50 (0%) 0/49 (0%) Mean 0.33%	0/50 (0%) SD 0.82% 1/50 (2%) 0/50 (0%)		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)
Papilloma Squamous of Overall Incidence #Oral Cavity (Oral Mucos Squamous Cell Carcine Overall Incidence	Total Sa, Tongue, Pharoma Total Total Total	0/50 (0%) 0/50 (0%) 1/299 (0.33%) Tynx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%) 1/299 (0.33%) Tynx, Tooth, Gingiva): Squamous, or Papillon	0/49 (0%) Mean 0.33% 0/50 (0%) 0/49 (0%) Mean 0.33%	0/50 (0%) SD 0.82% 1/50 (2%) 0/50 (0%) SD 0.82%		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Version: Oct2007 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

					Male						Fe	emale		
#Oral Mucosa: Squamous Cell Carcinoma														
		0/50	(0%)	0/50	(0%)	1/50	(2%)		,	0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/50	(0%)	0/49 Mean 0	(0%)	0/50 SD 0.829	(0%)	Total	,	0%)	0/50	(0%)	0/50 SD ((0%)
	Total	1/299 (0.33	%) 	wean u		SD 0.827	⁄o 	Total	0/300 (0%) 	Mear	1 0%	י עפ	J%
#Oral Mucosa: Squamous Cell Papilloma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		,	0%)	0/50	(0%)	0/50	(0%)
Occupation and desired	T-1-1	0/50	(0%)	0/49	(0%)	0/50	(0%)	T-1-1	,	0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/299 (0%	o) 	Mean	0%	SD 0%		Total	0/300 (0%)	Mear	1 0%	SD (J%
*Ovary: Granulosa Cell Tumor Beni	gn								2/52	(204)	2/52	(00)	0/5	(224)
									,	0%)	0/50	(0%)	0/50	(0%)
Overall Incidence								Total	0/50 (0/300 (0%	0%)	0/50 Mear	(0%)	0/50 SD ((0%)
									0/300 (0 %	<i>)</i> 			، تاری	J /0
*Ovary: Granulosa Cell Tumor Maliç	gnant													
										0%)	0/50	(0%)	0/50	(0%)
										2%)	0/50	(0%)	0/50	(0%)
Overall Incidence								Total	1/300 (0.339	%)	Mean	0.33%	SD 0.	82%
*Ovary: Granulosa Cell Tumor: Ben	ian Malian	ant. NOS												
	g,ug	,							0/50 (0%)	0/50	(0%)	0/50	(0%)
									1/50 (2%)	0/50	(0%)	0/50	(0%)
Overall Incidence								Total	1/300 (0.339	%)	Mean	0.33%	SD 0.	82%

^{*:} 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	
Ovary: Granulosa-Theca Tumor B	Benign							
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
						0/300 (0%)	wiean 0%	 บบ บ%
*Pancreas: Adenoma								
		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%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma								
		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%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (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%)	2/49 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.68%	SD 1.67%	Total	0/299 (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:

Overall Incidence

#Peripheral Nerve:

Overall Incidence

Adenoma

Schwannoma Malignant

Schwannoma: Benign, Malignant, NOS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Male **Female** 0/45 (0%)0/46 (0%)0/49 (0%)0/49 (0%)0/49 (0%)0/46 (0%)0/47 (0%)0/47 (0%)0/50 (0%)0/43 (0%)0/49 (0%)0/49 (0%)0/284 (0%) Mean 0% SD 0% Total 0/285 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/49 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 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%)0/50 (0%)0/50 (0%)0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% *Pituitary Gland: Pars Distalis or Unspecified Site:

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		30
		34

Overall Incidence	Total	215/298 (72.15%)	Mean 72.14%	SD 2.4%	Total 188/298 (63.09%)	Mean 63.01%	SD 9.87%
		34/49 (69%)	36/49 (73%)	38/50 (76%)	35/50 (70%)	30/50 (60%)	27/49 (55%)
		36/50 (72%)	36/50 (72%)	35/50 (70%)	35/50 (70%)	37/50 (74%)	24/49 (49%)

*Pituitary Gland: Pars Distalis or Unspecified Site:

		0/50 0/49	(0%) (0%)	0/50 0/49	(0%) (0%)	0/50 1/50	(0%) (2%)		1/50 0/50	(2%) (0%)	0/50 0/50	(0%) (0%)	0/49 0/49	(0%) (0%)
Overall Incidence	Total	1/298 (0.349	%)	Mean 0.3	33%	SD 0.82%	,	Total	1/298 (0.3	4%)	Mean	0.33%	SD 0.8	82% ´

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

Total

Total

Total

^{#:} 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	
Pituitary Gland: Pars Dis Carcinoma or Adenoma	•	cified Site:						
		36/50 (72%)	36/50 (72%)	35/50 (70%)		36/50 (72%)	37/50 (74%)	24/49 (49%)
Overall Incidence	Total	34/49 (69%) 216/298 (72.48%)	36/49 (73%) Mean 72.48%	39/50 (78%) SD 3.09%	Total	35/50 (70%) 189/298 (63.42%)	30/50 (60%) Mean 63.35%	27/49 (55%) SD 10.18%
*Pituitary Gland: Pars Inte Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
O	T-1-1	0/49 (0%)	1/49 (2%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.34%	SD 0.83%	Total	0/298 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Inte Carcinoma	ermedia:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Inte Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overell Incidence	Tata!	0/49 (0%)	1/49 (2%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.34%	SD 0.83%	Total	0/298 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
O	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/299 (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: INHALATION Vehicle: AIR

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			Male				Female	
Prostate: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/299 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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	
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skeletal Muscle: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/49 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	
#Skeletal Muscle: Rhabdomyosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skeletal Muscle: Rhabdomyosarcoma or	Rhabdomvoma							
,	,	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%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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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Species: RATS Strain: F 344/N Route: INHALATION Vehicle: AIR

			Male				Female	
≮Skin: Basal Cell Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1.01%	SD 1.1%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Adenoma or I	Basosquamous	s Tumor Benian						
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1.01%	SD 1.1%	Total	0/300 (0%)	Mean 0%	SD 0%
Basal Cell Adenoma, Ba	sosquamous 1	Tumor Benign, or Trichoe		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Basal Cell Adenoma, Ba	sosquamous 1	1/50 (2%)	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)
Overall Incidence	Total	<u> </u>		0/50 (0%) 0/50 (0%) SD 1.04%	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 1/50 (2%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%
Overall Incidence	·	1/50 (2%) 1/50 (2%) 4/299 (1.34%)	1/50 (2%) 1/49 (2%) Mean 1.34%	0/50 (0%) SD 1.04%	Total	0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
Overall Incidence Skin:	·	1/50 (2%) 1/50 (2%) 4/299 (1.34%) 0/50 (0%)	1/50 (2%) 1/49 (2%) Mean 1.34% 0/50 (0%)	0/50 (0%) SD 1.04%	Total	0/50 (0%) 1/300 (0.33%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%)
Overall Incidence Skin: Basal Cell Carcinoma	Total	1/50 (2%) 1/50 (2%) 4/299 (1.34%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 1/49 (2%) Mean 1.34% 0/50 (0%) 0/49 (0%)	0/50 (0%) SD 1.04% 0/50 (0%) 0/50 (0%)		0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%)
Overall Incidence #Skin: Basal Cell Carcinoma	·	1/50 (2%) 1/50 (2%) 4/299 (1.34%) 0/50 (0%)	1/50 (2%) 1/49 (2%) Mean 1.34% 0/50 (0%)	0/50 (0%) SD 1.04%	Total Total	0/50 (0%) 1/300 (0.33%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%)
Overall Incidence #Skin: Basal Cell Carcinoma Overall Incidence	Total Total	1/50 (2%) 1/50 (2%) 4/299 (1.34%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 1/49 (2%) Mean 1.34% 0/50 (0%) 0/49 (0%) Mean 0%	0/50 (0%) SD 1.04% 0/50 (0%) 0/50 (0%)		0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%)
Overall Incidence #Skin: Basal Cell Carcinoma Overall Incidence	Total Total	1/50 (2%) 1/50 (2%) 4/299 (1.34%) 0/50 (0%) 0/50 (0%) 0/299 (0%) us Tumor (malignant or N 0/50 (0%)	1/50 (2%) 1/49 (2%) Mean 1.34% 0/50 (0%) 0/49 (0%) Mean 0% OS) 0/50 (0%)	0/50 (0%) SD 1.04% 0/50 (0%) 0/50 (0%) SD 0% 0/50 (0%)		0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%) SD 0%
Overall Incidence #Skin: Basal Cell Carcinoma Overall Incidence	Total Total	1/50 (2%) 1/50 (2%) 4/299 (1.34%) 0/50 (0%) 0/50 (0%) 0/299 (0%)	1/50 (2%) 1/49 (2%) Mean 1.34% 0/50 (0%) 0/49 (0%) Mean 0%	0/50 (0%) SD 1.04% 0/50 (0%) 0/50 (0%) SD 0%		0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (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: 05/27/2022

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 0/50 (0%)0/50 0/50 (0%)1/50 (2%)1/50 (2%)(0%)(0%)1/50 (2%)1/49 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)SD 0.82% **Overall Incidence** Total 4/299 (1.34%) Mean 1.34% SD 1.04% Total 1/300 (0.33%) Mean 0.33% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq, Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 5/50 (10%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)(0%)(2%)(2%)5/49 (10%)1/50 (2%)0/50 1/50 1/50 **Overall Incidence** Total 15/299 (5.02%) Mean 5.03% SD 4.2% 2/300 (0.67%) Mean 0.67% SD 1.03% Total #Skin: **Fibroma** 3/50 4/50 0/50 (6%)5/50 (10%)(8%)(0%)0/50 (0%)0/50 (0%)4/50 (8%) 3/49 (6%)2/50 (4%)1/50 (2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 21/299 (7.02%) Mean 7.02% SD 2.09% 2/300 (0.67%) Mean 0.67% SD 1.03% Total #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 3/50 (6%)6/50 (12%)5/50 (10%)1/50 (2%)0/50 (0%)(0%)5/50 (10%)(8%) 3/50 (6%)(2%)2/50 (4%)0/50 (0%)4/49 1/50 **Overall Incidence** Total 26/299 (8.7%) Mean 8.69% SD 2.41% Total 4/300 (1.33%) Mean 1.33% SD 1.63% #Skin: **Fibrosarcoma** 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)1/49 (2%) 1/50 (2%) (0%)(2%)0/50 (0%)1/50 0/50 1/50 **Overall Incidence** SD 1.04% Mean 0.33% SD 0.82% Total 4/299 (1.34%) Mean 1.34% Total 1/300 (0.33%)

^{*:} 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: 05/27/2022

Length of Study: CHRONIC

Male **Female** #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)1/49 (2%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)2/300 (0.67%) **Overall Incidence** Total 5/299 (1.67%) Mean 1.67% SD 0.82% Total Mean 0.67% SD 1.03% #Skin: Fibrous Histiocytoma (0%)0/50 1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)(0%) 0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Skin: Hemangioma 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%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% 0/300 (0%) Mean 0% SD 0% Total #Skin: Hemangiosarcoma 0/50 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%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Skin: Keratoacanthoma 4/50 (8%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)4/49 (8%) 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 9/299 (3.01%) Mean 3.03% SD 3.99% Total 1/300 (0.33%) Mean 0.33% SD 0.82%

^{*:} 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	
#Skin: Lipoma								
		0/50 (0%) 1/50 (2%)	1/50 (2%) 2/49 (4%)	0/50 (0%) 2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	6/299 (2.01%)	Mean 2.01%	SD 1.81%	Total	0/300 (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%)
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neural Crest Tumor		0/50 (0%) 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%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Neurofibroma or Schw	annoma benign							
		0/50 (0%) 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%) 1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Neurofibrosarcoma or	Schwannoma (m	nalignant or NOS)						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (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	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (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: 05/27/2022

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Species: RATS Strain: F 344/N

Vehicle: AIR

			Male				Female	
#Skin: Neurofibrosarcoma, Neuro	ofibroma, or	Schwannoma (benign, m	alignant or NOS)					
,	ŕ	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)	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	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
‡Skin: Osteosarcoma								
		0/50 (0%) 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%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
·····		0/299 (0/0)			10tai			
Skin: Schwannoma Benign								
		0/50 (0%) 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%) 1/50 (2%)
Overall Incidence	Total	0/30 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/300 (0.33%)	0/50 (0%) Mean 0.33%	1/50 (2%) SD 0.82%
Skin: Schwannoma Malignant								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/299 (0.33%)	1/49 (2%) Mean 0.34%	0/50 (0%) SD 0.83%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		1/299 (0.33%)				` '		

^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Squamous Cell Carcino	oma							
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcino or Carcinoma	oma, Basal Cell	Carcinoma, Basosquamo	ous Tumor (malignant o	or NOS),				
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 2/299 (0.67%)	0/49 (0%) Mean 0.67%	1/50 (2%) SD 1.03%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Squamous Cell Papillo	ma or Papilloma	a 0/50 (0%) 0/50 (0%)	1/50 (2%) 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%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma, Papilloma, S	Squamous Cell Carcinom	na or Keratoacanthoma					
-		4/50 (8%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	4/49 (8%)	1/50 (2%)	T	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	11/299 (3.68%)	Mean 3.69%	SD 3.49%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
#Skin:								
Squamous Cell Papilloma,	, Papilloma, d							
		4/50 (8%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	4/49 (8%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	11/299 (3.68%)	Mean 3.69%	SD 3.49%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Trichoepithelioma								
		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%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Sebaceous Gland: Adenoma								
		1/50 (2%)	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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/299 (2.01%)	Mean 2.01%	SD 2.19%	Total	0/300 (0%)	Mean 0%	SD 0%
#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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		1/50 (2%)	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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/299 (2.01%)	Mean 2.01%	SD 2.19%	Total	0/300 (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	
#Spinal Cord: Astrocytoma Benign								
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Spleen: Fibrosarcoma								
		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%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma								
_		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%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/299 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Spleen: Leiomyosarcoma								
-		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%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/299 (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: 05/27/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

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

Vehicle: AIR

			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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinom	ıa							
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinom	na 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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma	1							
·		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Stomach, Glandular: Leiomyosarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Testes: Adenoma								
		36/50 (72%)	38/50 (76%)	42/50 (84%)				
		33/50 (66%)	38/49 (78%)	41/50 (82%)				
Overall Incidence	Total	228/299 (76.25%)	Mean 76.26%	SD 6.6%				
Thymus: Sarcoma								
		0/49 (0%)	0/48 (0%)	0/49 (0%)		0/48 (0%)	0/45 (0%)	0/47 (0%)
		0/42 (0%)	0/47 (0%)	0/49 (0%)		0/50 (0%)	0/46 (0%)	0/47 (0%)
verall Incidence	Total	0/284 (0%)	Mean 0%	SD 0%	Total	0/283 (0%)	Mean 0%	SD 0%
Thymus: Thymoma Benign								
		0/49 (0%)	0/48 (0%)	0/49 (0%)		0/48 (0%)	0/45 (0%)	0/47 (0%)
		0/42 (0%)	1/47 (2%)	0/49 (0%)		1/50 (2%)	0/46 (0%)	0/47 (0%)
Overall Incidence	Total	1/284 (0.35%)	Mean 0.35%	SD 0.87%	Total	1/283 (0.35%)	Mean 0.33%	SD 0.82%

^{*:} 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	
Thymus: Thymoma Malignant								
		0/49 (0%) 0/42 (0%)	0/48 (0%) 0/47 (0%)	0/49 (0%) 1/49 (2%)		0/48 (0%) 0/50 (0%)	0/45 (0%) 0/46 (0%)	0/47 (0%)
Overall Incidence	Total	0/42 (0%) 1/284 (0.35%)	0/47 (0%) Mean 0.34%	1/49 (2%) SD 0.83%	Total	0/50 (0%) 0/283 (0%)	0/46 (0%) Mean 0%	0/47 (0%) SD 0%
Thymus: Thymoma: Benign, Malign	ant, NOS							
		0/49 (0%)	0/48 (0%)	0/49 (0%)		0/48 (0%)	0/45 (0%)	0/47 (0%)
Overall Incidence	Total	0/42 (0%) 2/284 (0.7%)	1/47 (2%) Mean 0.69%	1/49 (2%) SD 1.08%	Total	1/50 (2%) 1/283 (0.35%)	0/46 (0%) Mean 0.33%	0/47 (0%) SD 0.82%
		` '				` ,		SD 0.02%
*Thyroid Gland: C-Cell: Adenoma								
		3/50 (6%)	2/50 (4%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	3/50 (6%)
Overell Incidence	Tatal	3/49 (6%)	4/49 (8%)	7/50 (14%)	Tatal	2/50 (4%)	3/50 (6%)	3/49 (6%)
Overall Incidence	Total	20/298 (6.71%)	Mean 6.71%	SD 4.14%	Total	14/299 (4.68%)	Mean 4.69%	SD 2.44%
*Thyroid Gland: C-Cell: Carcinoma								
		1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Tatal	0/49 (0%)	3/49 (6%)	2/50 (4%)	Tatal	1/50 (2%)	2/50 (4%)	1/49 (2%)
	Total	9/298 (3.02%)	Mean 3.02%	SD 2.13%	Total	6/299 (2.01%)	Mean 2.01%	SD 1.27%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		3/50 (6%)	3/50 (6%)	3/50 (6%)		3/50 (6%)	1/50 (2%)	4/50 (8%)
Overall Incidence	Total	3/49 (6%)	7/49 (14%)	9/50 (18%)	Total	3/50 (6%)	5/50 (10%)	4/49 (8%)
Jveran incluence	Total	28/298 (9.4%)	Mean 9.4%	SD 5.35%	Total	20/299 (6.69%)	Mean 6.69%	SD 2.75%

^{*:} 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	
Thyroid Gland: Follicular Cel Adenoma	II:							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	2/298 (0.67%)	Mean 0.67%	SD 1.04%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
*Thyroid Gland: Follicular Cel Carcinoma								
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	4/298 (1.34%)	Mean 1.33%	SD 1.63%	Total	0/299 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cel Carcinoma or Adenoma								
		2/50 (4%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	1/49 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	6/298 (2.01%)	Mean 2.01%	SD 1.27%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
#Tissue NOS: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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: INHALATION Vehicle: AIR

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			Male				Female	
#Tissue NOS: Lipoma								
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Tongue: Liposarcoma								
-		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (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: 05/27/2022

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Species: RATS Strain: F 344/N

Vehicle: AIR

		Male				Female	
a or Papillom	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%)
Total	1/299 (0.33%)	` '	` '	Total	0/300 (0%)	Mean 0%	SD 0%
i							
	` ,	` ,	` ,		` '	` '	0/50 (0%) 0/50 (0%)
Total	1/299 (0.33%)	` '	` '	Total	0/300 (0%)	Mean 0%	SD 0%
	0/50 (0%)	` ,	` '		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	` ,	` '	` '	Total	` '	` ,	0/50 (0%) SD 0%
10lal	0/299 (0%)			10tai	0/300 (0%)		3D 0%
	0/50 (0%)	` ,	` ,		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	` '	` '	` '	Total	` '	` ,	0/49 (0%) SD 0%
					0/290 (0/0)		
	0/50 (0%)	` '	` '		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	` ,	` '	` '	Total	, ,	` ,	1/49 (2%) SD 0.83%
3	Total a Total	0/50 (0%) Total 1/299 (0.33%) a 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/299 (0%) Total 0/299 (0%) Total 0/299 (0%)	O/50 (0%)	As or Papilloma Squamous 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) Total 1/299 (0.33%) Mean 0.33% SD 0.82% 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) Total 1/299 (0.33%) Mean 0.33% SD 0.82% 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) Total 0/299 (0%) Mean 0% SD 0% 0/50 (0%) 0/49 (0%) 0/50 (0%) Total 0/299 (0%) Mean 0% SD 0% 0/50 (0%) 0/49 (0%) 0/50 (0%) Total 0/299 (0%) Mean 0% SD 0%	Ala or Papilloma Squamous 0/50 (0%) 1/50 (2%) 0/50 (0%) Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 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%) Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/299 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/299 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/299 (0%) Mean 0% SD 0% Total	As or Papilloma Squamous 0/50 (0%)	As or Papilloma Squamous 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

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Report Date: 05/27/2022

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

Route: INHALATION Vehicle: AIR

			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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/49 (2%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/298 (0.67%)	Mean 0.67%	SD 1.04%
Urinary Bladder: Papilloma								
		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%)	1/49 (2%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/298 (0.34%)	Mean 0.34%	SD 0.83%
Uterus: Adenoma								
						0/50 (0%)	1/50 (2%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Jterus: Carcinoma								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	0/300 (0%)	Mean 0%	SD 0%
Jterus: Deciduoma Benign								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Version: Oct2007 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: 05/27/2022

Route: INHALATION Vehicle: AIR

Male			Female	
Uterus:				
Hemangioma				
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
	• • • • • • • • • • • • • • • • • • • •			
Uterus:				
Hemangiosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall In Alders	+	0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
eUterus:				
Leiomyoma				
Leioniyonia		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%
······································				
Uterus:				
Polyp Stromal				
<i></i>		13/50 (26%)	9/50 (18%)	12/50 (24%)
		6/50 (12%)	12/50 (24%)	10/50 (20%)
Overall Incidence	Total	62/300 (20.67%)	Mean 20.67%	SD 5.16%
Uterus:				
Sarcoma Stromal				
		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%

^{*:} 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: 05/27/2022

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus:** Sarcoma Stromal or Polyp Stromal 14/50 (28%)9/50 (18%)13/50 (26%)(12%)12/50 (24%)11/50 (22%)**Overall Incidence** Total 65/300 (21.67%) Mean 21.67% SD 5.85% #Uterus: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% #Vagina: Polyp 2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/300 (0.67%) Mean 0.67% SD 1.63% #Vagina: Sarcoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% #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%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (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: INHALATION Vehicle: AIR

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Report Date: 05/27/2022

		Male 1/50 (2%) 0/50 (0%) 1/50 (2%)					Female			
#Zymbal's Gland: Carcinoma										
		1/50 (2%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	3/300 (1%)	Mean 1%	SD 1.1%		
#Zymbal's Gland: Carcinoma or Adenoma										
		1/50 (2%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	3/300 (1%)	Mean 1%	SD 1.1%		

^{*:} 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: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

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
Southern Research Institute	059902703	08/12/02	729	50(3)	37(705)	452.8	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517405	08/05/02	729	50(3)	33(703)	510.0	Cresols
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
					Female		
Battelle Columbus Laboratory	058813803	08/17/99	729	50(5)	32(688)	348.7	Benzophenone
Southern Research Institute	059902703	08/12/02	733	50(5)	36(702)	314.7	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517405	N/A	N/A	0(0)	0(0)	N/A	Cresols
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

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date: 05/27/2022

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Species: RATS Strain: F 344/N

Vehicle: FEED

			Male				Female	
#All Organs: Benign Tumors								
		49/50 (98%) 49/50 (98%)	49/50 (98%) 50/50 (100%)	50/50 (100%)		42/50 (84%) 43/50 (86%)	45/50 (90%) 48/50 (96%)	
Overall Incidence	Total	247/250 (98.8%)	Mean 98.8%	SD 1.1%	Total	178/200 (89%)	Mean 89%	SD 5.29%
All Organs: Malignant Tumors								
		33/50 (66%)	27/50 (54%)	23/50 (46%)		20/50 (40%)	15/50 (30%)	
Overall Incidence	Total	22/50 (44%) 127/250 (50.8%)	22/50 (44%) Mean 50.8%	SD 9.44%	Total	19/50 (38%) 73/200 (36.5%)	19/50 (38%) Mean 36.5%	SD 4.43%
#All Organs: Malignant and Benign T	umors							
3		50/50 (100%)	50/50 (100%)	50/50 (100%)		46/50 (92%)	47/50 (94%)	
		50/50 (100%)	50/50 (100%)			45/50 (90%)	48/50 (96%)	
Overall Incidence	Total	250/250 (100%)	Mean 100%	SD 0%	Total	186/200 (93%)	Mean 93%	SD 2.58%
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	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
All Organs: Hemangiosarcoma								
•		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overell Incidence	Tatal	1/50 (2%)	0/50 (0%)	CD 4.700/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	0/200 (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: ORAL Vehicle: FEED Page: 174

			Male				Female	
#All Organs: Hemangiosarcoma or H	emangioma							
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%) 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%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 2/50 (4%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
		27/50 (54%)	19/50 (38%)	15/50 (30%)		19/50 (38%)	9/50 (18%)	
Overall Incidence	Total	15/50 (30%) 91/250 (36.4%)	15/50 (30%) Mean 36.4%	SD 10.43%	Total	6/50 (12%) 43/200 (21.5%)	9/50 (18%) Mean 21.5%	SD 11.36%
#All Organs:		91/250 (36.4%)	Mean 36.4%		Total	` '	, ,	SD 11.36%
#All Organs:		` ,	Mean 36.4%		Total	` '	, ,	SD 11.36%
#All Organs: Malignant Lymphoma: I		91/250 (36.4%) nphocytic, Mixed, NOS, or 0/50 (0%)	Mean 36.4% Undifferentiated Cel 0/50 (0%)	I Туре	Total Total	43/200 (21.5%) 0/50 (0%)	Mean 21.5% 0/50 (0%)	SD 11.36% SD 0%
#All Organs:	Histiocytic, Lyn	91/250 (36.4%) nphocytic, Mixed, NOS, or 0/50 (0%) 0/50 (0%)	Mean 36.4% r Undifferentiated Cel 0/50 (0%) 0/50 (0%)	I Type 1/50 (2%)		43/200 (21.5%) 0/50 (0%) 0/50 (0%)	Mean 21.5% 0/50 (0%) 0/50 (0%)	
#All Organs: Malignant Lymphoma: H Overall Incidence #All Organs:	Histiocytic, Lyn	91/250 (36.4%) nphocytic, Mixed, NOS, or 0/50 (0%) 0/50 (0%)	Mean 36.4% r Undifferentiated Cel 0/50 (0%) 0/50 (0%)	I Type 1/50 (2%)		43/200 (21.5%) 0/50 (0%) 0/50 (0%)	Mean 21.5% 0/50 (0%) 0/50 (0%)	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

Route: ORAL Vehicle: FEED Page: 175

Report Date: 05/27/2022

			Male				Female	
#All Organs: Mesothelioma: Benign, Mal	ignant, NOS	8						
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/50 (4%) 5/250 (2%)	0/50 (0%) Mean 2%	SD 2%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
		` '						
All Organs: Mesothelioma: Malignant								
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
	.	2/50 (4%)	0/50 (0%)	00.00/	T	0/50 (0%)	0/50 (0%)	OD 00/
verall Incidence	Total	5/250 (2%)	Mean 2%	SD 2%	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%)	
		2/50 (4%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
All Organs: Osteosarcoma or Osteoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		2/50 (4%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	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: ORAL Vehicle: FEED **Page:** 176

			Male				Female	
*Adrenal Cortex: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 5/50 (10%)	2/50 (4%) 1/49 (2%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	8/199 (4.02%)	Mean 4.01%	SD 4.31%
*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%) 0/49 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Ganglioneuroma								
-		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	0/49 (0%) 0/197 (0%)	0/48 (0%) Mean 0%	SD 0%
*Adrenal Medulla: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Bei	nign							
•	-	8/50 (16%)	8/50 (16%)	8/50 (16%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	8/50 (16%) 40/250 (16%)	8/50 (16%) Mean 16%	SD 0%	Total	0/49 (0%) 3/197 (1.52%)	2/48 (4%) Mean 1.54%	SD 1.99%

^{*:} 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: 05/27/2022

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

			Male				Female	
*Adrenal Medulla: Pheochromocytoma C	omplex							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 2/250 (0.8%)	2/50 (4%) Mean 0.8%	SD 1.79%	Total	0/49 (0%) 0/197 (0%)	0/48 (0%) Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma M	lalignant					•••••		
		0/50 (0%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	0/50 (0%) 3/250 (1.2%)	0/50 (0%) Mean 1.2%	SD 2.68%	Total	0/49 (0%) 3/197 (1.52%)	1/48 (2%) Mean 1.52%	SD 1.92%
*Adrenal Medulla: Pheochromocytoma: E			11/50 (22%) 10/50 (20%)	8/50 (16%)		0/50 (0%) 0/49 (0%)	3/50 (6%) 3/48 (6%)	
Overall Incidence	Total	45/250 (18%)	Mean 18%	SD 2.83%	Total	6/197 (3.05%)	Mean 3.06%	SD 3.54%
#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%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Chondrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
		0/250 (0%)	0/50 (0%)	SD 0%		0/200 (0%)	0/50 (0%)	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED **Page:** 178

			Male				Female	
#Bone: Chondrosarcoma or Cho	ondroma							
		0/50 (0%) 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: Chordoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		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%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: 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%) 1/50 (2%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Bone: Osteosarcoma or Osteo	ma							
		0/50 (0%) 2/50 (4%)	0/50 (0%) 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 1.79%	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: ORAL Vehicle: FEED **Page:** 179

			Male				Female	
*Brain: Astrocytoma Malignant								
		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	0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Ependymoma 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%
*Brain: Glioma 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%
*Brain: Granular Cell Tumor Ben	nign							
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 2/250 (0.8%)	0/50 (0%) Mean 0.8%	SD 1.79%	Total	0/50 (0%) 0/200 (0%)	0/50 (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%)	
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

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 05/27/2022

Page: 180

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

			Male				Female	
*Brain: Meningioma 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%
Overall incluence	10tai	0/250 (0%)	iviean 0%	3D 0%			Weatt 0%	JD 0%
*Brain: Meningioma: Benign, N	Malignant, NOS							
	g ,	0/50 (0%) 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%
*Brain: Oligodendroglioma Ber		•••••						
		0/50 (0%)	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%
*Brain: Oligodendroglioma Mal	lignant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overell Insidence	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%
*Brain: Oligodendroglioma, Gli	ioma, or Astrocy	toma						
, , , , , , , , , , , , , , , , , , ,		0/50 (0%) 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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED Page: 181

			Male				Female	
Clitoral/Preputial Gland:								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 2/50 (4%)	5/50 (10%)		3/50 (6%) 5/50 (10%)	10/50 (20%) 8/50 (16%)	
Overall Incidence	Total	8/250 (3.2%)	Mean 3.2%	SD 4.15%	Total	26/200 (13%)	Mean 13%	SD 6.22%
*Clitoral/Preputial Gland: Carcinoma	•							
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 3/50 (6%)	0/50 (0%) 2/50 (4%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	6/200 (3%)	Mean 3%	SD 2.58%
Clitoral/Preputial Gland: Carcinoma or Adenoma	•••••							
		1/50 (2%) 0/50 (0%)	1/50 (2%) 2/50 (4%)	5/50 (10%)		4/50 (8%) 8/50 (16%)	10/50 (20%) 10/50 (20%)	
Overall Incidence	Total	9/250 (3.6%)	Mean 3.6%	SD 3.85%	Total	32/200 (16%)	Mean 16%	SD 5.66%
Clitoral/Preputial Gland: 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%
Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%

^{*:} 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: FEED Page: 182

			Male			0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%) Mean 0% SD 0% 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/200 (0.5%) Mean 0.5% SD 1%		
#Ear: Neural Crest Tumor								
		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%	
#Esophagus: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		` '	` '	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 00/
	Total	0/250 (0%)				` ,		
#Eye: Amelanotic Melanoma, Be	nign							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		` '	` ,	
		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%
#Eye: Melanoma Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		` ,	` '	
Normall Implications	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	` ,	` ,	CD 40/
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	` '		SD 1%
‡Eye: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		` '	` ,	
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%
Overall incluence		,				(,		

^{*:} 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: 05/27/2022

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

			Male				Female	
#Harderian Gland: Adenoma								
		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%
#Harderian Gland: Carcinoma								
Garomoma		0/50 (0%)	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%
#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%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	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%)			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%
*Heart: Schwannoma Malignant								
J		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	
Occupation of the con-	T-1-1	0/50 (0%)	0/50 (0%)	00 440/	T. (- 1	0/50 (0%)	0/50 (0%)	OD 40/
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

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: FEED Page: 184 Report Date: 05/27/2022

			Male				Female	
#Intestine Large: Colon/R Adenoma	ectum:							
		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%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Large: Colon/R 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 Large: Colon/R Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%)	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%
Intestine Large: Colon/R Leiomyosarcoma	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%)	
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Duoden 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	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	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: 05/27/2022

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

Route: ORAL Vehicle: FEED

			Male				Female	
#Intestine Small: Duodenum 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: 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: 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%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe	cified:							
		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%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 0.000/	Total	0/50 (0%)	0/50 (0%)	CD 00/
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

Report Date: 05/27/2022

Page: 186

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

			Male				Female	
#Intestine Small: Site Unspec 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 Unspec 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%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Islets, Pancreatic:								
		1/50 (2%) 0/50 (0%)	1/50 (2%) 3/50 (6%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	2/49 (4%) 0/49 (0%)	
Overall Incidence	Total	6/249 (2.41%)	Mean 2.41%	SD 2.19%	Total	2/198 (1.01%)	Mean 1.02%	SD 2.04%
Islets, Pancreatic: Carcinoma							•••••	
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/49 (2%)		0/50 (0%) 2/50 (4%)	0/49 (0%) 0/49 (0%)	
Overall Incidence	Total	2/249 (0.8%)	Mean 0.81%	SD 1.11%	Total	2/198 (1.01%)	Mean 1%	SD 2%
Islets, Pancreatic: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	2/50 (4%) 3/50 (6%)	2/49 (4%)		0/50 (0%) 2/50 (4%)	2/49 (4%) 0/49 (0%)	
Overall Incidence	Total	8/249 (3.21%)	Mean 3.22%	SD 2.29%	Total	4/198 (2.02%)	Mean 2.02%	SD 2.33%

^{*:} 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: 05/27/2022

Page: 187

Species: RATS Strain: F 344/N

Vehicle: FEED

			Male				Female	
*Kidney: Pelvis and Trans Carcinoma	sitional Epitheliu	ım:						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
Overall Incidence	Total	0/49 (0%) 0/247 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/195 (0%)	0/48 (0%) Mean 0%	SD 0%
		0/247 (0 /0)			ı olal			
*Kidney: Pelvis and Trans Carcinoma or Adenoma		ım:						
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)	
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	0/48 (0 %) Mean 0%	SD 0%
						, ,		
*Kidney: Pelvis and Trans Papilloma	sitional Epitheliu	ım:						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
Overell Incidence	Tatal	0/49 (0%)	0/48 (0%)	CD 00/	Tatal	0/50 (0%)	1/48 (2%)	CD 4 040/
Overall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	1/195 (0.51%)	Mean 0.52%	SD 1.04%
*Kidney: Renal Tubule: Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
	.	0/49 (0%)	0/48 (0%)	OD 0.000/	-	0/50 (0%)	0/48 (0%)	OD 00/
Overall Incidence	Total	1/247 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/195 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
Overall Incidence	Total	0/49 (0%) 0/247 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/195 (0%)	0/48 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED Page: 188 Report Date: 05/27/2022

			Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		1/50 (2%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)	
Overall Incidence	Total	1/247 (0.4%)	Mean 0.4% SD	0.89%	Total	0/195 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)	
Overall Incidence	Total	0/247 (0%)		SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)	
Overall Incidence	Total	0/247 (0%)	` '	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)	
Overall Incidence	Total	0/247 (0%)	` '	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Beni	ign							
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)	
Overall Incidence	Total	0/247 (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

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: FEED

d Control Animal Groups

Report Date: 05/27/2022

DRAL

FEED

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			Male				Female	
*Kidney: Renal Tubule: Nephroblastoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		0/49 (0%)	0/48 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		0/49 (0%)	1/48 (2%)	00.000/		0/50 (0%)	0/48 (0%)	00.00
Overall Incidence	Total	1/247 (0.4%)	Mean 0.42%	SD 0.93%	Total	0/195 (0%)	Mean 0%	SD 0%
*Liver: Cholangiocarcinoma								
_		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	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Liver: Cholangioma								
_		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%
*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%)	
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

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Report Date: 05/27/2022

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** *Liver: Hepatocellular Adenoma 2/50 (4%)1/50 (2%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 3/250 (1.2%) Mean 1.2% SD 1.79% Total 3/200 (1.5%) Mean 1.5% SD 1.91% *Liver: **Hepatocellular Carcinoma** (0%)(0%) 0/50 0/50 (0%)0/50 (0%)0/50 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% *Liver: Hepatocellular Carcinoma or Hepatoblastoma 0/50 (0%)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% *Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 2/50 1/50 (2%)0/50 0/50 (0%)2/50 (4%)(4%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 3/250 (1.2%) Mean 1.2% SD 1.79% Total 3/200 (1.5%) Mean 1.5% SD 1.91% *Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma (4%)1/50 (2%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)

SD 1.79%

Total

3/200 (1.5%)

Mean 1.5%

SD 1.91%

Total

3/250 (1.2%)

.....

Mean 1.2%

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

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Report Date: 05/27/2022

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

Route: ORAL Vehicle: FEED

			Male				Female	
*Lung: Alveolar/Bronchiolar A	Adenoma							
		4/50 (8%) 2/50 (4%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		4/50 (8%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	
Overall Incidence	Total	7/250 (2.8%)	Mean 2.8%	SD 3.35%	Total	5/200 (2.5%)	Mean 2.5%	SD 3.79%
*Lung: Alveolar/Bronchiolar C								
		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%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/200 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar C Overall Incidence	Carcinoma or Alv	reolar/Bronchiolar Adeno 4/50 (8%) 4/50 (8%) 9/250 (3.6%)	ma 0/50 (0%) 0/50 (0%) Mean 3.6%	1/50 (2%) SD 4.1%	Total	4/50 (8%) 0/50 (0%) 5/200 (2.5%)	1/50 (2%) 0/50 (0%) Mean 2.5%	SD 3.79%
*Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/30 (0 /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%
*Lung: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/30 (0 /6)		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

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Report Date: 05/27/2022

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		Male				Female	
	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Total	` ,	, ,	SD 0%	Total	` '	` '	SD 0%
	` '						
	` '	` '	1/50 (2%)		` ,	` ,	
Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 4/50 (8%)	0/50 (0%) 2/50 (4%)	
Total	0/250 (0%)	Mean 0%	SD 0%	Total	6/200 (3%)	Mean 3%	SD 3.83%
	0/50 (0%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	
Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	4/50 (8%) 9/200 (4.5%)	` '	SD 2.52%
	Total Total	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 1/250 (0.4%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Total 1/250 (0.4%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Total 0/250 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) Total 1/250 (0.4%) Mean 0.4% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 1/250 (0.4%) Mean 0.4% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0.4% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0%	0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 1/250 (0.4%) Mean 0.4% SD 0.89% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 1/250 (0.4%) Mean 0% SD 0.89% Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total Total Total 1/50 (2%) 0/50 (2%) 0/50 (0%) Total Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 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 (2%) 0/50 (0	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 0/200 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 2/50 (4%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 2/50 (4%) 0/50 (0%) Total 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (4%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (4%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	O/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

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Report Date: 05/27/2022

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

Route: ORAL Vehicle: FEED

			Male				Female	
Mammary Gland: Fibroadenoma								
		2/50 (4%)	2/50 (4%)	0/50 (0%)		27/50 (54%)	29/50 (58%)	
	T-1-1	0/50 (0%)	3/50 (6%)	OD 0.000/	T-1-1	26/50 (52%)	24/50 (48%)	00 4400/
verall Incidence	Total	7/250 (2.8%)	Mean 2.8%	SD 2.68%	Total	106/200 (53%)	Mean 53%	SD 4.16%
Mammary Gland: Fibroma								
		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%)	OD 00/
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenom	na or Adenoma							
		2/50 (4%)	2/50 (4%)	1/50 (2%)		28/50 (56%)	30/50 (60%)	
		0/50 (0%)	3/50 (6%)	05 0 000/		26/50 (52%)	24/50 (48%)	00 - 400/
verall Incidence	Total	8/250 (3.2%)	Mean 3.2%	SD 2.28%	Total	108/200 (54%)	Mean 54%	SD 5.16%
Mammary Gland: Fibroma, Fibroadenom	na, Carcinoma, o	· Adenoma						
		2/50 (4%)	2/50 (4%)	1/50 (2%)		28/50 (56%)	30/50 (60%)	
		0/50 (0%)	3/50 (6%)			28/50 (56%)	25/50 (50%)	
verall Incidence	Total	8/250 (3.2%)	Mean 3.2%	SD 2.28%	Total	111/200 (55.5%)	Mean 55.5%	SD 4.12%
Mesentery: Fibrosarcoma								
		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%)	1/50 (2%)	05.40/
Overall Incidence	Total	0/250 (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

Toxicology Data Management System

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Report Date: 05/27/2022

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

Route: ORAL

Strain: F 344/N Vehicle: FEED Length of Study: CHRONIC

			Male				Female	
#Mesentery: Hemangiosarcoma								
-		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%)	
verall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/200 (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%)	
Overall Incidence	Total	0/250 (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%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	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%)	
		1/50 (2%)	0/49 (0%)			0/50 (0%)	0/49 (0%)	
verall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/199 (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%)	0/49 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/249 (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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/27/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Nose: 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%)0/49 (0%)0/199 (0%) **Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% Total Mean 0% SD 0% *Nose: **Squamous Cell Carcinoma** (0%)(0%) 0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% Total 0/199 (0%) Mean 0% SD 0% **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):** Papilloma Squamous or Papilloma 1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)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% **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma** (0%)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% **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):** Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma 1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 1.1%

0/50

0/200 (0%)

Total

(0%)

0/50

(0%)

SD 0%

Mean 0%

Total

0/50

2/250 (0.8%)

......

(0%)

0/50

Mean 0.8%

(0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Version: Oct2007 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: 05/27/2022

Route: ORAL Vehicle: FEED

	Male					Female		
#Oral Mucosa: Squamous Cell Carcinor	ma							
·		0/50 (0%) 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%
#Oral Mucosa: Squamous Cell Papillom	ıa				•••••			
		0/50 (0%) 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%
*Ovary: Granulosa Cell Tumor B	enign					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 M	alignant		•••••					
						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: E					•••••			
						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

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED **Page:** 197

			Male				Female	
Ovary: Granulosa-Theca Tumor B	enign							
						0/50 (0%)	1/50 (2%)	
						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Pancreas: Adenoma								
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	
		1/49 (2%)	1/50 (2%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	2/247 (0.81%)	Mean 0.81%	SD 1.11%	Total	0/198 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma								
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma								
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	
		1/49 (2%)	1/50 (2%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	2/247 (0.81%)	Mean 0.81%	SD 1.11%	Total	0/198 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Benign								
-		1/50 (2%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/247 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/198 (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: FEED

Route: ORAL

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Report Date: 05/27/2022

Length of Study: CHRONIC

Male **Female** *Parathyroid Gland: Adenoma 0/49 (0%)1/45 (2%)1/46 (2%)0/47 (0%)0/48 (0%)0/47 (0%)1/48 (2%)0/49 (0%)0/50 (0%)0/194 (0%) **Overall Incidence** Total 3/235 (1.28%) Mean 1.3% SD 1.18% Total Mean 0% SD 0% **#Peripheral Nerve:** Schwannoma Malignant (0%)(0%) (0%) 0/50 0/50 0/50 (0%)0/50 (0%)0/50 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% **#Peripheral Nerve:** Schwannoma: Benign, Malignant, 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% *Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma (34%)(49%)10/50 (20%)10/50 (20%)20/50 (40%)17/50 24/49 9/50 (18%)16/49 (33%)23/50 (46%)29/48 (60%)Overall Incidence Total 65/249 (26.1%) Mean 26.13% SD 9.7% Total 93/197 (47.21%) Mean 47.35% SD 10.85% *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/49 (0%)2/50 (4%)0/48 (0%)**Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% Total 3/197 (1.52%) Mean 1.51% SD 1.92%

^{*:} 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: 05/27/2022

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

			Male				Female	
*Pituitary Gland: Pars Dis Carcinoma or Adenoma		cified Site:						
		10/50 (20%) 9/50 (18%)	10/50 (20%) 16/49 (33%)	20/50 (40%)		17/50 (34%) 25/50 (50%)	25/49 (51%) 29/48 (60%)	
Overall Incidence	Total	65/249 (26.1%)	Mean 26.13%	SD 9.7%	Total	96/197 (48.73%)	Mean 48.86%	SD 10.96%
*Pituitary Gland: Pars Inte								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)	
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/197 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Inte				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Inte								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)	
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/197 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

*Prostate:

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Carcinoma or Adenoma

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

(0%)

(0%)

0/49

0/50

Male Female

0/50 (0%) 0/50 (0%)
0/50 (0%)
Mean 0% SD 0%

0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%)
0/50 (0%) 0/50 (0%) 0/50 (0%)

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Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Sarcoma								
		0/49 (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%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant								
		1/49 (2%) 0/50 (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	1/248 (0.4%)	Mean 0.41%	SD 0.91%	Total	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%)	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: Hemangioma								•••••
ŭ		0/50 (0%) 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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Mean 0%

SD 0%

Report Date: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female #Skeletal Muscle:** Hemangiosarcoma 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 1/250 (0.4%) Mean 0.4% SD 0.89% Total 0/200 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Lipoma (0%) (0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 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 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 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 Rhabdomyoma 0/50 (0%)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%)0/50 (0%)0/50 (0%)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%)

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: ORAL Vehicle: FEED

d Control Animal Groups Report Date: 05/27/2022

RAL

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			Male				Female	
#Skin: Basal Cell Adenoma								
24041 001171401101114		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	, ,		1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin:								
Basal Cell Adenoma or	Basosquamous	s Tumor Benign						
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Overall Incidence	Total	Fumor Benign, or Trichoe 0/50 (0%) 1/50 (2%) 3/250 (1.2%)	1/50 (2%) 1/50 (2%) 1/50 (2%) Mean 1.2%	0/50 (0%) SD 1.1%	Total	0/50 (0%) 1/50 (2%) 2/200 (1%)	0/50 (0%) 1/50 (2%) Mean 1%	SD 1.15%
#Skin: Basal 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%
#Skin:		us Tumor (malignant or N	OS)					
		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	1/50 (2%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%
		0/250 (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

Length of Study: CHRONIC

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			Male				Female	
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tur	nor (benign, maligna	nt or				
, .		0/50 (0%) 1/50 (2%)	1/50 (2%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	0/50 (0%) 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: Basal or Sq. Cell Carci	noma, Carcinon	na, Basosq. Tumor (M or E eratoacanthoma, Trichoep 11/50 (22%)	B), Basal Cell Adenon oithelioma 4/50 (8%)			3/50 (6%)	0/50 (0%)	
O	T-1-1	2/50 (4%)	3/50 (6%)	00.7.000/	T-1-1	2/50 (4%)	2/50 (4%)	00.0.500/
Overall Incidence	Total	21/250 (8.4%)	Mean 8.4%	SD 7.92%	Total	7/200 (3.5%)	Mean 3.5%	SD 2.52%
#Skin: Fibroma		5/50 (10%)	4/50 (8%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	
Overall Incidence	Total	2/50 (4%) 20/250 (8%)	8/50 (16%) Mean 8%	SD 5.48%	Total	1/50 (2%) 5/200 (2.5%)	1/50 (2%) Mean 2.5%	SD 2.52%
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myx	koma, Myxosarcoma, or Fi 6/50 (12%) 2/50 (4%)	ibrous Histiocytoma 4/50 (8%) 8/50 (16%)	4/50 (8%)		4/50 (8%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	24/250 (9.6%)	Mean 9.6%	SD 4.56%	Total	6/200 (3%)	Mean 3%	SD 3.46%
#Skin: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	2/50 (4%)		1/50 (2%) 0/50 (0%)	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%

^{*:} 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: 05/27/2022

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

			Male				Female	
#Skin:								
Fibrosarcoma, Sarcoma	, Myxosarcom	a, or Fibrous Histiocytoma						
		1/50 (2%)	0/50 (0%)	3/50 (6%)		1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 2.61%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Fibrous Histiocytoma								
		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%
#Skin: 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%
#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								
		10/50 (20%)	3/50 (6%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	16/250 (6.4%)	Mean 6.4%	SD 7.8%	Total	3/200 (1.5%)	Mean 1.5%	SD 3%

^{*:} 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: ORAL Vehicle: FEED Page: 205

			Male				Female	
#Skin: Lipoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	00 0000		0/50 (0%)	0/50 (0%)	00.007
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (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%)	
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%)		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: 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%)			0/50 (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	nalignant or NOS)						
	•	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	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: FEED

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			Male				Female	
#Skin:								
Neurofibrosarcoma, Neur	rofibroma, or	, -	•	0 (=0 (00))		(224)	0.50	
		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	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Osteosarcoma								
		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%
#Skin: 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%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#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								
3		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	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: 05/27/2022

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Species: RATS Strain: F 344/N

Vehicle: FEED

			Male				Female	
#Skin: Squamous Cell Carcinoma								
		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%
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell	Carcinoma, Basosquamo		or NOS),				
o. Garomonia		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%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Squamous Cell Papilloma								
		1/50 (2%) 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	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Squamous Cell Papilloma c		1						
		1/50 (2%) 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	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Squamous Cell Papilloma, l	Papilloma, S	Squamous Cell Carcinom	a or Keratoacanthoma	ı				
		11/50 (22%) 1/50 (2%)	3/50 (6%) 2/50 (4%)	1/50 (2%)		3/50 (6%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	18/250 (7.2%)	Mean 7.2%	SD 8.44%	Total	4/200 (2%)	Mean 2%	SD 2.83%

^{*:} 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: ORAL Vehicle: FEED

Report Date: 05/27/2022

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			Male				Female	
#Skin:								
Squamous Cell Papilloma,	, Papilloma,	or Keratoacanthoma						
		11/50 (22%) 1/50 (2%)	3/50 (6%) 1/50 (2%)	1/50 (2%)		3/50 (6%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	17/250 (6.8%)	Mean 6.8%	SD 8.67%	Total	4/200 (2%)	Mean 2%	SD 2.83%
#Skin: Trichoepithelioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	00 0000		0/50 (0%)	1/50 (2%)	05 404
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Sebaceous 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%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#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%)	05 00/		0/50 (0%)	0/50 (0%)	22.00/
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Occupation of desires	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
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

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Mean 0%

SD 0%

Report Date: 05/27/2022

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female #Spinal Cord:** Astrocytoma 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% *Spleen: **Fibrosarcoma** (0%) (0%) 0/50 (0%)0/50 0/49 (0%)0/49(0%)0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% Total 0/199 (0%) Mean 0% SD 0% *Spleen: Hemangioma 0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)(0%)0/49 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% Total 0/199 (0%) Mean 0% SD 0% *Spleen: Hemangiosarcoma 0/50 (0%)1/50 (2%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/248 (0.4%) Mean 0.4% SD 0.89% Total 0/199 (0%) Mean 0% SD 0% *Spleen: Leiomyosarcoma 0/50 (0%)1/50 (2%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0.89%

Total

0/199 (0%)

Total

1/248 (0.4%)

Mean 0.4%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

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Mean 0%

SD 0%

Report Date: 05/27/2022

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female #Stomach**, Forestomach: Leiomyosarcoma 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%)**Overall Incidence** Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 0/200 (0%) Mean 0% SD 0% #Stomach, Forestomach: Schwannoma Malignant (0%) (0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/250 (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%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma 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%)**Overall Incidence** Total 0/250 (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%)0/50 (0%)0/50 (0%)

SD 0%

Total

0/200 (0%)

Total

0/250 (0%)

Mean 0%

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: FEED

ontrol Animal Groups Report Date: 05/27/2022

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	Male				Female			
Stomach, Glandular: Leiomyosarcoma								
		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%)	OD 00/
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	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%)	
Overell Includence	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%
Testes: Adenoma								
		45/50 (90%)	46/50 (92%)	49/50 (98%)				
	-	48/50 (96%)	46/50 (92%)	00.0004				
Overall Incidence	Total	234/250 (93.6%)	Mean 93.6%	SD 3.29%				
Thymus: Sarcoma								
		0/48 (0%)	0/48 (0%)	0/47 (0%)		0/50 (0%)	0/46 (0%)	
N	T-1-1	0/48 (0%)	0/48 (0%)	OD 00/	T-1-1	0/48 (0%)	0/47 (0%)	OD 00/
verall Incidence	Total	0/239 (0%)	Mean 0%	SD 0%	Total	0/191 (0%)	Mean 0%	SD 0%
Thymus: Thymoma Benign								
		0/48 (0%)	0/48 (0%)	0/47 (0%)		0/50 (0%)	0/46 (0%)	
Duranell Inclidence	Tatal	0/48 (0%)	0/48 (0%)	CD 00/	Tatal	0/48 (0%)	0/47 (0%)	CD 00/
Overall Incidence	Total	0/239 (0%)	Mean 0%	SD 0%	Total	0/191 (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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Report Date: 05/27/2022

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%)0/48 (0%)0/47 (0%)0/50 (0%)0/46 (0%)0/48 (0%)0/48 (0%)0/48 (0%)0/47 (0%)0/191 (0%) Overall Incidence Total 0/239 (0%) Mean 0% SD 0% Total Mean 0% SD 0% *Thymus: Thymoma: Benign, Malignant, NOS (0%)(0%) 0/48(0%)0/48 (0%)0/47 (0%)0/50 0/46 0/48 (0%)0/48 (0%)0/48 (0%)0/47 (0%)Overall Incidence Total 0/239 (0%) Mean 0% SD 0% Total 0/191 (0%) Mean 0% SD 0% *Thyroid Gland: C-Cell: Adenoma 10/50 (20%)5/50 (10%)6/50 (12%)4/50 3/49 (6%)9/48 (19%)11/47 (23%)9/49 (18%)10/47 (21%)**Overall Incidence** Total 41/245 (16.73%) Mean 16.83% SD 5.63% Total 26/195 (13.33%) Mean 13.44% SD 7.5% *Thyroid Gland: C-Cell: Carcinoma 1/50 (2%)4/50 (8%)1/50 (2%)0/50 (0%)1/49 (2%)1/48 (2%)0/47 (0%)0/49 (0%)1/47 (2%)**Overall Incidence** Total 7/245 (2.86%) Mean 2.82% SD 3.03% Total 2/195 (1.03%) Mean 1.04% SD 1.2% *Thyroid Gland: C-Cell: Carcinoma or Adenoma 11/50 (22%)9/50 (18%)7/50 (14%)4/50 4/49 (8%)

SD 3.73%

9/49

28/195 (14.36%)

Total

(18%)

11/47

(23%)

SD 7.67%

Mean 14.48%

Total

10/48

48/245 (19.59%)

(21%)

.....

11/47

Mean 19.65%

(23%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

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Report Date: 05/27/2022

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** *Thyroid Gland: Follicular Cell: Adenoma 2/50 (4%)2/50 (4%)0/50 (0%)0/50 (0%)0/49 (0%)1/48 (2%)0/47 (0%)0/49(0%)2/47 (4%)Mean 2.02% 2/195 (1.03%) **Overall Incidence** Total 5/245 (2.04%) SD 2% Total Mean 1.06% SD 2.13% *Thyroid Gland: Follicular Cell: Carcinoma (0%) (0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/49 0/48 (0%)0/47 (0%)1/49 (2%)0/47 (0%)**Overall Incidence** Total 0/245 (0%) Mean 0% SD 0% Total 1/195 (0.51%) Mean 0.51% SD 1.02% *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma 2/50 (4%)2/50 (4%)0/50 (0%)0/50 (0%)0/49 (0%)1/48 (2%)0/47 (0%)1/49 (2%)2/47 (4%)**Overall Incidence** Total 5/245 (2.04%) Mean 2.02% SD 2% Total 3/195 (1.54%) Mean 1.57% SD 2.03% **#Tissue NOS: Fibrosarcoma** 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% **#Tissue NOS:** Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

0/50

0/200 (0%)

Total

(0%)

0/50

(0%)

SD 0%

Mean 0%

Total

0/50

0/250 (0%)

(0%)

0/50

Mean 0%

(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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Vehicle: FEED

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		Male				Female			
#Tissue NOS: 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%	
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%)		
Overall Incidence	Total	0/250 (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%)		
		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%	
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%)	1/50 (2%)		
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
Tongue: Liposarcoma									
		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%	

^{*:} 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: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** #Tongue: Squamous Cell Carcinoma or Papilloma Squamous 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%)**Overall Incidence** Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total 0/200 (0%) Mean 0% SD 0% #Tongue: **Squamous Cell Papilloma** 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%)SD 1.1% **Overall Incidence** Total 2/250 (0.8%) Mean 0.8% Total 0/200 (0%) Mean 0% SD 0% #Tooth: Odontoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% *Urinary Bladder: Carcinoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% Total 0/199 (0%) Mean 0% SD 0% *Urinary Bladder: Carcinoma or Papilloma 0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)1/50 (2%)0/49 (0%)**Overall Incidence** Total 1/248 (0.4%) Mean 0.41% SD 0.91% Total 1/199 (0.5%) Mean 0.5% SD 1%

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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: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% Total 0/199 (0%) Mean 0% SD 0% *Urinary Bladder: **Papilloma** (0%) 0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%) 0/50 (0%)0/49 (0%)1/50 (2%)0/49 Mean 0.41% **Overall Incidence** Total 1/248 (0.4%) SD 0.91% Total 1/199 (0.5%) Mean 0.5% SD 1% #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%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Uterus: **Deciduoma Benign** 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: Oct2007 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: 05/27/2022

Route: ORAL Vehicle: FEED

	Male			Female	
#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: Hemangiosarcoma					
_			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: Polyp Stromal					
•			6/50 (12%)	10/50 (20%)	
			8/50 (16%)	16/50 (32%)	
Overall Incidence		Total	40/200 (20%)	Mean 20%	SD 8.64%
#Uterus: Sarcoma Stromal					
			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

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Mean 0%

Mean 0%

(0%)

(0%)

0/50

0/50

SD 0%

SD 0%

Report Date: 05/27/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus:** Sarcoma Stromal or Polyp Stromal 6/50 (12%)10/50 (20%)(16%)17/50 (34%)**Overall Incidence** Total 41/200 (20.5%) Mean 20.5% SD 9.57% #Uterus: **Schwannoma Malignant** (0%) 0/50 (0%)0/50 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%)

0/50

SD 0%

(0%)

Total

Total

0/200 (0%)

0/50

0/50

0/200 (0%)

(0%)

(0%)

Total

0/50

0/50

0/250 (0%)

(0%)

(0%)

0/50

0/50

Mean 0%

(0%)

(0%)

Overall Incidence

#Zymbal's Gland: Adenoma

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

Vehicle: FEED

Route: ORAL

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Report Date: 05/27/2022

		Male				Female			
#Zymbal's Gland: Carcinoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%) 3/50 (6%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)		
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 2.61%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
#Zymbal's Gland: Carcinoma or Adenoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%) 3/50 (6%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)		
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 2.61%	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: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

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	052011407	10/02/02	730	50(3)	28(696)	532.4	Sodium dichromate dihydrate (VI)
Southern Research Institute	059601905	09/26/01	729	50(3)	31(686)	526.0	Water disinfection byproducts (Bromochloroacetic acid)
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	059601505	09/05/01	729	50(3)	31(692)	507.8	Water disinfection byproducts (Dibromoacetonitrile)
Southern Research Institute	059601003	09/16/98	729	50(3)	36(687)	514.1	Water disinfection byproducts (Sodium chlorate)
					Female		
Southern Research Institute	052011407	10/02/02	735	50(5)	33(700)	351.2	Sodium dichromate dihydrate (VI)
Southern Research Institute	059601905	09/26/01	731	50(5)	34(688)	357.3	Water disinfection byproducts (Bromochloroacetic acid)
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	059601505	09/05/01	734	50(5)	29(689)	337.6	Water disinfection byproducts (Dibromoacetonitrile)
Southern Research Institute	059601003	09/16/98	734	50(5)	37(699)	341.7	Water disinfection byproducts (Sodium chlorate)

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
All Organs: Benign Tumors								
		49/50 (98%)	50/50 (100%)	49/50 (98%)		47/50 (94%)	49/50 (98%)	
		47/50 (94%)	50/50 (100%)	48/50 (96%)		42/50 (84%)	44/50 (88%)	46/50 (92%)
verall Incidence	Total	293/300 (97.67%)	Mean 97.67%	SD 2.34%	Total	228/250 (91.2%)	Mean 91.2%	SD 5.4%
All Organs: Malignant Tumors								
		29/50 (58%)	27/50 (54%)	28/50 (56%)		20/50 (40%)	18/50 (36%)	
		29/50 (58%)	27/50 (54%)	27/50 (54%)		16/50 (32%)	20/50 (40%)	21/50 (42%)
verall Incidence	Total	167/300 (55.67%)	Mean 55.67%	SD 1.97%	Total	95/250 (38%)	Mean 38%	SD 4%
#All Organs: Malignant and Benign T	umors							
		50/50 (100%)	50/50 (100%)	50/50 (100%)		49/50 (98%)	49/50 (98%)	
		50/50 (100%)	50/50 (100%)	49/50 (98%)		45/50 (90%)	48/50 (96%)	49/50 (98%)
verall Incidence	Total	299/300 (99.67%)	Mean 99.67%	SD 0.82%	Total	240/250 (96%)	Mean 96%	SD 3.46%
All Organs: Hemangioma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/250 (0%)	Mean 0%	SD 0%
All Organs: Hemangiosarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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: 05/27/2022

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: Hemangiosarcoma or Hemangioma 1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)(0%) 1/50 (2%)0/50 (0%)0/50 0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 3/300 (1%) Mean 1% SD 1.1% Total 1/250 (0.4%) Mean 0.4% SD 0.89% #All Organs: **Histiocytic Sarcoma** (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 1/50 (2%)2/50 (4%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 3/300 (1%) Mean 1% SD 1.67% Total 1/250 (0.4%) Mean 0.4% SD 0.89% #All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated 26/50 (52%)21/50 (42%)16/50 (32%)8/50 (16%)15/50 (30%)17/50 (34%)21/50 (42%)13/50 (26%)11/50 (22%)14/50 (28%)11/50 (22%)**Overall Incidence** Total 114/300 (38%) Mean 38% SD 9.21% 59/250 (23.6%) Mean 23.6% SD 5.55% Total **#All Organs:** Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type (0%)0/50 (0%)0/50 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 1/300 (0.33%) Mean 0.33% SD 0.82% Total 1/250 (0.4%) Mean 0.4% SD 0.89% **#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%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/250 (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: 05/27/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male			Female	
#All Organs: Mesothelioma: Benign,	, Malignant, NOS						
		2/50 (4%)	` ,	6%)	0/50 (0%)	0/50 (0%)	
		3/50 (6%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	9/300 (3%)	Mean 3% SD 2.76%	Total	0/250 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Maligna	ant						
		2/50 (4%)	` ,	6%)	0/50 (0%)	0/50 (0%)	
		3/50 (6%)	` ,	0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	9/300 (3%)	Mean 3% SD 2.76%	Total	0/250 (0%)	Mean 0%	SD 0%
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%)
verall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma							
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%) 3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	3/300 (1%)	Mean 1% SD 2.45%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
All Organs: Osteosarcoma or Oste	oma						
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%) 3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1% SD 2.45%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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: ORAL Vehicle: WATER Page: 224

			Male				Female	
Adrenal Cortex: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/49 (0%)		1/49 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	2/249 (0.8%)	Mean 0.81%	SD 1.11%
Adrenal Cortex: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Ganglioneuroma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Hemangioma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Benigr	1							
-		6/49 (12%)	9/50 (18%)	8/50 (16%)		2/49 (4%)	2/49 (4%)	
		7/49 (14%)	10/50 (20%)	6/49 (12%)		1/49 (2%)	1/49 (2%)	2/50 (4%)
Overall Incidence	Total	46/297 (15.49%)	Mean 15.46%	SD 3.14%	Total	8/246 (3.25%)	Mean 3.25%	SD 1.1%

^{*:} 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: ORAL Vehicle: WATER Page: 225

			Male				Female	
Adrenal Medulla: Pheochromocytoma C	omplex							
		0/49 (0%)	0/50 (0%)	2/50 (4%)		0/49 (0%)	0/49 (0%)	
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	2/297 (0.67%)	Mean 0.67%	SD 1.63%	Total	0/246 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma M	lalignant							
		1/49 (2%)	1/50 (2%)	1/50 (2%)		1/49 (2%)	2/49 (4%)	
		0/49 (0%)	0/50 (0%)	3/49 (6%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	6/297 (2.02%)	Mean 2.03%	SD 2.24%	Total	3/246 (1.22%)	Mean 1.22%	SD 1.83%
Pheochromocytoma: E	Benign, Complex	· ·	40/50 (000()	44/50 (000()		0/40 (00/)	4/40 (00/)	
•	Senign, Comple : Total	7/49 (14%) 7/49 (14%) 7/49 (14%) 54/297 (18.18%)	10/50 (20%) 10/50 (20%) Mean 18.16%	11/50 (22%) 9/49 (18%) SD 3.21%	Total	3/49 (6%) 1/49 (2%) 11/246 (4.47%)	4/49 (8%) 1/49 (2%) Mean 4.47%	2/50 (4%) SD 2.66%
Overall Incidence #Blood Vessel:		7/49 (14%) 7/49 (14%)	10/50 (20%)	9/49 (18%)	Total	1/49 (2%)	1/49 (2%)	` '
Overall Incidence		7/49 (14%) 7/49 (14%) 54/297 (18.18%)	10/50 (20%) Mean 18.16%	9/49 (18%) SD 3.21%	Total	1/49 (2%) 11/246 (4.47%)	1/49 (2%) Mean 4.47%	` '
Overall Incidence #Blood Vessel:		7/49 (14%) 7/49 (14%)	10/50 (20%)	9/49 (18%)	Total	1/49 (2%)	1/49 (2%)	` '
Overall Incidence #Blood Vessel: Osteosarcoma		7/49 (14%) 7/49 (14%) 54/297 (18.18%) 	10/50 (20%) Mean 18.16% 0/50 (0%)	9/49 (18%) SD 3.21% 0/50 (0%)	Total Total	1/49 (2%) 11/246 (4.47%) 0/50 (0%)	1/49 (2%) Mean 4.47% 0/50 (0%)	SD 2.66%
Overall Incidence #Blood Vessel: Osteosarcoma Overall Incidence	Total	7/49 (14%) 7/49 (14%) 54/297 (18.18%) 0/50 (0%) 0/50 (0%)	10/50 (20%) Mean 18.16% 0/50 (0%) 0/50 (0%)	9/49 (18%) SD 3.21% 0/50 (0%) 1/50 (2%)		1/49 (2%) 11/246 (4.47%) 0/50 (0%) 0/50 (0%)	1/49 (2%) Mean 4.47% 0/50 (0%) 0/50 (0%)	SD 2.66% O/50 (0%)
Overall Incidence #Blood Vessel: Osteosarcoma Overall Incidence #Bone:	Total	7/49 (14%) 7/49 (14%) 54/297 (18.18%) 0/50 (0%) 0/50 (0%) 1/300 (0.33%)	10/50 (20%) Mean 18.16% 0/50 (0%) 0/50 (0%) Mean 0.33%	9/49 (18%) SD 3.21% 0/50 (0%) 1/50 (2%) SD 0.82%		1/49 (2%) 11/246 (4.47%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	1/49 (2%) Mean 4.47% 0/50 (0%) 0/50 (0%)	SD 2.66% O/50 (0%)
Overall Incidence #Blood Vessel: Osteosarcoma Overall Incidence #Bone:	Total	7/49 (14%) 7/49 (14%) 54/297 (18.18%) 0/50 (0%) 0/50 (0%) 1/300 (0.33%)	10/50 (20%) Mean 18.16% 0/50 (0%) 0/50 (0%) Mean 0.33%	9/49 (18%) SD 3.21% 0/50 (0%) 1/50 (2%) SD 0.82%		1/49 (2%) 11/246 (4.47%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	1/49 (2%) Mean 4.47% 0/50 (0%) 0/50 (0%) Mean 0%	SD 2.66% O/50 (0%)

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date: 05/27/2022

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Species: RATS Strain: F 344/N

Vehicle: WATER

			Male				Female	
#Bone: Chondrosarcoma or Ch	hondroma							
		0/50 (0%)	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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma								
		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%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Bone: Osteosarcoma or Oste								
		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%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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: 05/27/2022

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

			Male				Female	
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%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/249 (0%)	Mean 0%	SD 0%
Brain: Ependymoma 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%)	0/49 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
Brain: Glioma Malignant								
_		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%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/249 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Benigr	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%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/249 (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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/249 (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: 05/27/2022

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC Male **Female** *Brain: Meningioma 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%)1/50 (2%)0/50 (0%)0/49 (0%)1/249 (0.4%) **Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total Mean 0.4% SD 0.89% *Brain: Meningioma: Benign, Malignant, 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%)1/50 (2%)0/50 (0%)0/49 (0%)Mean 0% **Overall Incidence** Total 0/300 (0%) SD 0% Total 1/249 (0.4%) Mean 0.4% SD 0.89% *Brain: Oligodendroglioma Benign 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%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 0/249 (0%) Mean 0% SD 0% *Brain: Oligodendroglioma Malignant 0/50 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%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/249 (0%) Mean 0% SD 0% *Brain: Oligodendroglioma, Glioma, or Astrocytoma 0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)

0/50

SD 1.67%

(0%)

0/50

0/249 (0%)

Total

(0%)

0/50

(0%)

Mean 0%

0/49

SD 0%

(0%)

Total

1/50

3/300 (1%)

(2%)

0/50

Mean 1%

(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: ORAL Vehicle: WATER Page: 229

			Male				Female	
Clitoral/Preputial Gland:								
		4/50 (8%)	4/50 (8%)	2/50 (4%)		2/50 (4%)	17/50 (34%)	
		3/50 (6%)	1/48 (2%)	1/48 (2%)		8/50 (16%)	5/50 (10%)	11/49 (22%)
Overall Incidence	Total	15/296 (5.07%)	Mean 5.03%	SD 2.72%	Total	43/249 (17.27%)	Mean 17.29%	SD 11.59%
Clitoral/Preputial Gland: Carcinoma								
		1/50 (2%)	2/50 (4%)	1/50 (2%)		8/50 (16%)	0/50 (0%)	
		0/50 (0%)	0/48 (0%)	3/48 (6%)		1/50 (2%)	1/50 (2%)	3/49 (6%)
Overall Incidence	Total	7/296 (2.36%)	Mean 2.38%	SD 2.42%	Total	13/249 (5.22%)	Mean 5.22%	SD 6.42%
Clitoral/Preputial Gland:								
		4/50 (8%)	5/50 (10%)	3/50 (6%)		10/50 (20%)	17/50 (34%)	
		3/50 (6%)	1/48 (2%)	4/48 (8%)		9/50 (18%)	6/50 (12%)	14/49 (29%)
Overall Incidence	Total	20/296 (6.76%)	Mean 6.74%	SD 2.74%	Total	56/249 (22.49%)	Mean 22.51%	SD 8.74%
Clitoral/Preputial Gland: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/48 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Papilloma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/48 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/296 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/249 (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: 05/27/2022

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

			Male	Female	Female			
#Ear: Neural Crest Tumor								
		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)				
	T	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 0/250 (0%) Mean 0%	SD 0%			
Esophagus: 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%)			
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%) Mean 0%	SD 0%			
#Eye: Amelanotic Melanoma, B								
		0/50 (0%)	0/50 (0%) 0/50 (0%)	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	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (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%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%) Mean 0%	SD 0%			
Eye: Schwannoma Malignant								
ū		0/50 (0%)	0/50 (0%) 0/50 (0%)	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	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (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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Report Date: 05/27/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: ORAL Vehicle: WATER

			Male				Female	
#Harderian Gland: Adenoma								
		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%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (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%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma								
		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%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/250 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign								
		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%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
*Heart: Schwannoma Malignant								
,		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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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: 05/27/2022

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female					
#Intestine Large: Colon/Ro	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%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%		
#Intestine Large: Colon/Re	ectum:									
		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%)		
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%		
#Intestine Large: Colon/Ro Carcinoma or Adenoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/22 (221)		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%		
#Intestine Large: Colon/Ro 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%)	1/50 (2%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%		
#Intestine Small: Duodenu Carcinoma	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%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (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: 233

			Male				Female	
#Intestine Small: Duodenu Leiomyoma	ım:							
		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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Small: Site Unsp 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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Carcinoma or Adenoma	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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (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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Report Date: 05/27/2022

Contract/Lab: All Laboratories

Species: RATS

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC Male **Female** #Intestine Small: Site Unspecified: 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%)0/50 (0%)0/50 (0%)1/250 (0.4%) **Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total Mean 0.4% SD 0.89% #Intestine Small: Site Unspecified: Leiomyosarcoma (0%)0/50 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%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/250 (0.4%) Mean 0.4% SD 0.89% *Islets, Pancreatic: Adenoma 4/50 (8%)3/50 (6%)3/49 (6%)2/50 (4%)3/49 (6%)5/48 (10%)5/49 (10%)3/50 (6%)0/47 (0%)1/50 (2%)2/50 (4%)**Overall Incidence** Total 23/296 (7.77%) Mean 7.79% SD 2.1% 8/246 (3.25%) Mean 3.22% SD 2.32% Total *Islets, Pancreatic: Carcinoma 0/49 0/50 (0%)2/50 (4%)(0%)0/50 (0%)0/49 (0%)0/48 (0%)1/49 (2%)2/50 (4%)0/47 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 5/296 (1.69%) Mean 1.67% SD 1.97% Total 1/246 (0.41%) Mean 0.4% SD 0.89% *Islets, Pancreatic:

3/49

5/50

SD 2.12%

(6%)

(10%)

2/50

0/47

9/246 (3.66%)

Total

(4%)

(0%)

3/49

1/50

(6%)

(2%)

Mean 3.62%

3/50

SD 2.64%

(6%)

Total

4/50

5/48

28/296 (9.46%)

(8%)

(10%)

5/50

6/49

Mean 9.46%

(10%)

(12%)

Carcinoma or Adenoma

Overall Incidence

^{*:} 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

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Report Date: 05/27/2022

Strain: F 344/N Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male			Female				
*Kidney: Pelvis and Trans	sitional Epitheliu	um:								
		0/50 (0%)	` ,	(49 (0%)		0/50 (0%)	0/50 (0%)			
		0/49 (0%)	` '	(47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/294 (0%)	Mean 0% SD	0%	Total	0/250 (0%)	Mean 0%	SD 0%		
*Kidney: Pelvis and Trans Carcinoma or Adenoma		um:								
		0/50 (0%)	` ,	(49 (0%)		0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/49 (0%) 0/	(47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/294 (0%)	Mean 0% SD	0%	Total	0/250 (0%)	Mean 0%	SD 0%		
*Kidney: Pelvis and Trans Papilloma	sitional Epitheliu	um: 0/50 (0%)	0/50 (0%) 0/	/49 (0% <u>)</u>		0/50 (0%)	0/50 (0%)			
		0/49 (0%)	` ,	(47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/294 (0%)	` '	0%	Total	0/250 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Adenoma										
		0/50 (0%)	` ,	(49 (0%)		0/50 (0%)	1/50 (2%)			
		1/49 (2%)	` '	(47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/294 (0.34%)	Mean 0.34% SD	0.83%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%		
*Kidney: Renal Tubule: Carcinoma										
		0/50 (0%)	0/50 (0%) 0/	(49 (0%)		0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/49 (0%) 0/	(47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/294 (0%)	Mean 0% SD	0%	Total	0/250 (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: 05/27/2022

Route: ORAL Vehicle: WATER

			Male			Female				
'Kidney: Renal Tubule: Carcinoma or Adenoma										
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)			
		1/49 (2%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/294 (0.34%)	Mean 0.34%	SD 0.83%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%		
Kidney: Renal Tubule: Hemangiosarcoma										
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Lipoma										
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%		
Kidney: Renal Tubule: Liposarcoma										
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%		
Kidney: Renal Tubule: Mesenchymal Tumor Benig	gn									
-	-	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%	Total	0/250 (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: ORAL Vehicle: WATER Page: 237

			Male				Female	
Kidney: Renal Tubule: Nephroblastoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Liver: Cholangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (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

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male		Female				
Liver: Hepatocellular Adenom	na								
		0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%)	0/50 (0%)		
		1/50 (2%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	
iver: Hepatocellular Carcino	ma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%	
Liver: Hepatocellular Carcino	ma or Hepatobl								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2(52 (524)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%	
iver: Hepatocellular Carcino	ma or Hepatoce	ellular Adenoma							
		0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%)	0/50 (0%)		
		1/50 (2%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	
-iver: -iver: Hepatocellular Carcino	ma, Hepatocelli	ılar Adenoma, or Hepato							
,	, ,	0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%)	0/50 (0%)		
		1/50 (2%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	

^{*:} 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: 05/27/2022

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Species: RATS Strain: F 344/N

Vehicle: WATER

			Male		Female							
*Lung: Alveolar/Bronchiolar Adenoma 4/50 (8%) 2/50 (4%) 0/50 (0%) 4/50 (8%) 1/50 (2%)												
		4/50 (8%)	2/50 (4%)	0/50 (0%)		4/50 (8%)	1/50 (2%)					
		2/50 (4%)	3/50 (6%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	1/50 (2%)				
Overall Incidence	Total	12/300 (4%)	Mean 4%	SD 2.83%	Total	8/250 (3.2%)	Mean 3.2%	SD 2.68%				
_ung: _Alveolar/Bronchiolar C	Carcinoma											
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)					
		0/50 (0%)	1/50 (2%)	3/50 (6%)		1/50 (2%)	0/50 (0%)	1/50 (2%)				
verall Incidence	Total	6/300 (2%)	Mean 2%	SD 2.19%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%				
Lung: Alveolar/Bronchiolar C Overall Incidence	Carcinoma or Alv	reolar/Bronchiolar Adence 4/50 (8%) 2/50 (4%) 18/300 (6%)	3/50 (6%) 4/50 (8%) Mean 6%	1/50 (2%) 4/50 (8%) SD 2.53%	Total	4/50 (8%) 2/50 (4%) 10/250 (4%)	1/50 (2%) 1/50 (2%) Mean 4%	2/50 (4%) SD 2.45%				
₋ung: Hemangiosarcoma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%				
ung: Sarcoma												
		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%)				
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (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: 240

			Male				Female	
*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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	5/250 (2%)	Mean 2%	SD 2.83%
#Mammary Gland: Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	
		1/50 (2%)	1/50 (2%)	0/50 (0%)		3/50 (6%)	2/50 (4%)	3/50 (6%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%	Total	9/250 (3.6%)	Mean 3.6%	SD 2.61%
#Mammary Gland: Carcinoma or Adenoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	
		1/50 (2%)	1/50 (2%)	0/50 (0%)		3/50 (6%)	2/50 (4%)	6/50 (12%)
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.03%	Total	14/250 (5.6%)	Mean 5.6%	SD 3.85%

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

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

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SD 0%

Mean 0%

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male			Female		
#Mammary Gland: Fibroadenoma								
		2/50 (4%)	3/50 (6%)	1/50 (2%)		37/50 (74%)	43/50 (86%)	22/50 (669/)
Overall Incidence	Total	4/50 (8%) 18/300 (6%)	6/50 (12%) Mean 6%	2/50 (4%) SD 3.58%	Total	32/50 (64%) 176/250 (70.4%)	31/50 (62%) Mean 70.4%	33/50 (66%) SD 9.84%
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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenom	na or Adenoma							
		2/50 (4%)	3/50 (6%)	2/50 (4%)		37/50 (74%)	43/50 (86%)	
		4/50 (8%)	6/50 (12%)	2/50 (4%)		32/50 (64%)	31/50 (62%)	35/50 (70%)
Overall Incidence	Total	19/300 (6.33%)	Mean 6.33%	SD 3.2%	Total	178/250 (71.2%)	Mean 71.2%	SD 9.55%
Mammary Gland: Fibroma, Fibroadenom	na, Carcinoma, o	or Adenoma						
		3/50 (6%)	3/50 (6%)	2/50 (4%)		37/50 (74%)	43/50 (86%)	
		5/50 (10%)	6/50 (12%)	2/50 (4%)		32/50 (64%)	31/50 (62%)	37/50 (74%)
Overall Incidence	Total	21/300 (7%)	Mean 7%	SD 3.29%	Total	180/250 (72%)	Mean 72%	SD 9.59%
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%)	0/50 (0%)	0/50 (0%)

SD 0%

Total

0/250 (0%)

Total

0/300 (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: ORAL Vehicle: WATER Page: 242

			Male				Female	
#Mesentery: 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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (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%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
#Mesentery: Rhabdomyosarcoma								
		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%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
Nose: Adenoma								
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Nose: Chondroma								
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/250 (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: 243
Report Date: 05/27/2022

			Male				Female	
*Nose: Sarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
Nose: Squamous Cell Carcinom	na							
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Papilloma Squamous or F Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 0/50 (0%) Mean 0.33%	1/50 (2%) 0/50 (0%) SD 0.82%	Total	1/50 (2%) 0/50 (0%) 3/250 (1.2%)	1/50 (2%) 1/50 (2%) Mean 1.2%	0/50 (0%) SD 1.1%
Oral Cavity (Oral Mucosa, Squamous Cell Carcinom		rynx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Squamous Cell Carcinom	•							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%

^{*:} 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

Page: 244

Report Date: 05/27/2022

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

					Male						Fe	emale		
#Oral Mucosa: Squamous Cell Carcinom	ıa													
•		0/50	(0%)	0/50	(0%)	0/50	(0%)		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	0/300 (0%)	Mean		SD 0%		Total	0/250 (0%) 	Mear	า 0%	SD	0%
#Oral Mucosa: Squamous Cell Papilloma	a													
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(00()
	+	0/50	(0%)	0/50	(0%)	0/50	(0%)	.	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300 (0%)	Mean	0%	SD 0%		Total	1/250 (0	.4%)	Mean	0.4%	SD 0	.89%
*Ovary: Granulosa Cell Tumor Be	nign								0/49 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	1/50	(2%)
Overall Incidence								Total	1/249 (0	,	Mean	0.4%	SD 0	.89%
*Ovary: Granulosa Cell Tumor Ma	ılignant								0/49 0/50	(0%) (0%)	0/50 0/50	(0%)	0/50	(09/)
Overall Incidence								Total	0/30	` ,	0/50 Mear	(0%) n 0%	SD	(0%) 0%
*Ovary: Granulosa Cell Tumor: Bo	enign, Maligna	ant, NOS												
	J . U	•							0/49 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	1/50	(2%)
Overall Incidence								Total	1/249 (0	` '	Mean	` '	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: ORAL Vehicle: WATER Page: 245

			Male				Female						
*Ovary: Granulosa-Theca Tumor B	Granulosa-Theca Tumor Benign												
						0/49 (0%)	0/50 (0%)	0/50 (00/)					
Overall Incidence					Total	0/50 (0%) 1/249 (0.4%)	1/50 (2%) Mean 0.4%	0/50 (0%) SD 0.89%					
*Pancreas:								•••••					
		1/50 (2%)	2/50 (4%)	3/49 (6%)		0/50 (0%)	0/50 (0%)						
		0/48 (0%)	1/49 (2%)	0/49 (0%)		0/47 (0%)	0/50 (0%)	2/50 (4%)					
Overall Incidence	Total	7/295 (2.37%)	Mean 2.36%	SD 2.38%	Total	2/247 (0.81%)	Mean 0.8%	SD 1.79%					
*Pancreas: Carcinoma													
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)						
		0/48 (0%)	0/49 (0%)	0/49 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%					
Pancreas: Carcinoma or Adenoma													
		1/50 (2%)	2/50 (4%)	3/49 (6%)		0/50 (0%)	0/50 (0%)						
		0/48 (0%)	1/49 (2%)	0/49 (0%)		0/47 (0%)	0/50 (0%)	2/50 (4%)					
Overall Incidence	Total	7/295 (2.37%)	Mean 2.36%	SD 2.38%	Total	2/247 (0.81%)	Mean 0.8%	SD 1.79%					
Pancreas: Mixed Tumor Benign													
ŭ		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)						
		0/48 (0%)	0/49 (0%)	0/49 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	0/247 (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: ORAL Vehicle: WATER Page: 246

			Male				Female			
*Parathyroid Gland: Adenoma										
		0/46 (0%)	0/44 (0%)	0/48 (0%)		0/46 (0%)	0/42 (0%)			
		0/50 (0%)	1/46 (2%)	0/49 (0%)		0/50 (0%)	0/42 (0%)	0/47 (0%)		
Overall Incidence	Total	1/283 (0.35%)	Mean 0.36%	SD 0.89%	Total	0/227 (0%)	Mean 0%	SD 0%		
Peripheral Nerve: 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%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%		
Schwannoma: Benign, N	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Pituitary Gland: Pars Dist Adenoma	alis or Unspec	cified Site:								
		16/50 (32%)	23/48 (48%)	22/49 (45%)		28/50 (56%)	28/50 (56%)			
		23/50 (46%)	24/50 (48%)	16/48 (33%)		26/50 (52%)	27/49 (55%)	23/49 (47%)		
Overall Incidence	Total	124/295 (42.03%)	Mean 42.02%	SD 7.36%	Total	132/248 (53.23%)	Mean 53.21%	SD 3.87%		
Pituitary Gland: Pars Dist										
		0/50 (0%)	0/48 (0%)	0/49 (0%)		2/50 (4%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/49 (0%)	1/49 (2%)		
		((, , ,)	((() ()	()		` '	(() ()	` ,		

^{*:} 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

Tumor Incidence for Selected Control Animal Groups

Page: 247

Report Date: 05/27/2022

Species: RATS

Route: ORAL Vehicle: WATER

			Male				Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma												
		16/50 (32%)	23/48 (48%)	22/49 (45%)		30/50 (60%)	28/50 (56%)					
		23/50 (46%)	24/50 (48%)	16/48 (33%)		26/50 (52%)	27/49 (55%)	24/49 (49%)				
verall Incidence	Total	124/295 (42.03%)	Mean 42.02%	SD 7.36%	Total	135/248 (54.44%)	Mean 54.42%	SD 4.17%				
Pituitary Gland: Pars Int Adenoma	ermedia:											
		0/50 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)					
		0/50 (0%)	0/50 (0%)	0/48 (0%)		1/50 (2%)	0/49 (0%)	1/49 (2%)				
verall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	2/248 (0.81%)	Mean 0.81%	SD 1.11%				
Pituitary Gland: Pars Int Carcinoma	ermedia:											
		0/50 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	2/12 /22/				
	-	0/50 (0%)	0/50 (0%)	0/48 (0%)	-	0/50 (0%)	0/49 (0%)	0/49 (0%)				
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%				
Pituitary Gland: Pars Int Carcinoma or Adenom												
		0/50 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)					
		0/50 (0%)	0/50 (0%)	0/48 (0%)		1/50 (2%)	0/49 (0%)	1/49 (2%)				
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	2/248 (0.81%)	Mean 0.81%	SD 1.11%				
Prostate: Adenoma												
		2/50 (4%)	0/50 (0%)	0/50 (0%)								
		0/50 (0%)	0/49 (0%)	0/50 (0%)								
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.63%								

^{*:} 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: 248

			Male				Female	
*Prostate: Carcinoma or Adenoma								
		2/50 (4%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.63%				
*Salivary Glands: Sarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/250 (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%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Fibrosarcoma								
		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%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangioma								
		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%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (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: 249

Report Date: 05/27/2022

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

			Male				Female	
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%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (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%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
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%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma or	Rhabdomyoma	a						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Sarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/250 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

n: Oct2007

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: 250

			Male				Female					
#Skin: Basal Cell Adenoma												
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)					
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 1.97%	Total	0/250 (0%)	Mean 0%	SD 0%				
#Skin:												
Basal Cell Adenoma or E	Basosquamou:	s Tumor Benign										
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)					
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 1.97%	Total	0/250 (0%)	Mean 0%	SD 0%				
Overall Incidence	Total	2/50 (4%) 1/50 (2%) 10/300 (3.33%)	3/50 (6%) 2/50 (4%) Mean 3.33%	1/50 (2%) 1/50 (2%) SD 1.63%	Total	0/50 (0%) 0/50 (0%) 2/250 (0.8%)	0/50 (0%) 0/50 (0%) Mean 0.8%	2/50 (4%) SD 1.79%				
Overall Incidence #Skin: Basal Cell Carcinoma	Total	1/50 (2%)	2/50 (4%)	1/50 (2%)	Total	0/50 (0%)	0/50 (0%)	` ,				
#Skin:	Total	1/50 (2%)	2/50 (4%)	1/50 (2%)	Total	0/50 (0%)	0/50 (0%)	` ,				
#Skin:	Total	1/50 (2%) 10/300 (3.33%)	2/50 (4%) Mean 3.33%	1/50 (2%) SD 1.63%	Total	0/50 (0%) 2/250 (0.8%)	0/50 (0%) Mean 0.8%	` ,				
#Skin:	Total Total	1/50 (2%) 10/300 (3.33%) 0/50 (0%)	2/50 (4%) Mean 3.33% 0/50 (0%)	1/50 (2%) SD 1.63% 1/50 (2%)	Total Total	0/50 (0%) 2/250 (0.8%) 0/50 (0%)	0/50 (0%) Mean 0.8% 0/50 (0%)	SD 1.79 [°] %				
#Skin: Basal Cell Carcinoma Overall Incidence #Skin:	Total	1/50 (2%) 10/300 (3.33%) 0/50 (0%) 1/50 (2%)	2/50 (4%) Mean 3.33% 0/50 (0%) 2/50 (4%) Mean 1.33%	1/50 (2%) SD 1.63% 1/50 (2%) 0/50 (0%)		0/50 (0%) 2/250 (0.8%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0.8% 0/50 (0%) 0/50 (0%)	SD 1.79%				
#Skin: Basal Cell Carcinoma Overall Incidence #Skin:	Total	1/50 (2%) 10/300 (3.33%) 0/50 (0%) 1/50 (2%) 4/300 (1.33%)	2/50 (4%) Mean 3.33% 0/50 (0%) 2/50 (4%) Mean 1.33%	1/50 (2%) SD 1.63% 1/50 (2%) 0/50 (0%)		0/50 (0%) 2/250 (0.8%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0.8% 0/50 (0%) 0/50 (0%)	SD 1.79%				
#Skin: Basal Cell Carcinoma Overall Incidence #Skin:	Total	1/50 (2%) 10/300 (3.33%) 0/50 (0%) 1/50 (2%) 4/300 (1.33%)	2/50 (4%) Mean 3.33% 0/50 (0%) 2/50 (4%) Mean 1.33%	1/50 (2%) SD 1.63% 1/50 (2%) 0/50 (0%) SD 1.63%		0/50 (0%) 2/250 (0.8%) 0/50 (0%) 0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.8% 0/50 (0%) 0/50 (0%) Mean 0.4%	SD 1.79%				

^{*:} 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: WATER

Length of Study: CHRONIC

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			Male				Female					
Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma												
,,		2/50 (4%)	3/50 (6%)	2/50 (4%)		0/50 (0%)	0/50 (0%)					
		2/50 (4%)	4/50 (8%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	3/50 (6%)				
verall Incidence	Total	14/300 (4.67%)	Mean 4.67%	SD 2.07%	Total	3/250 (1.2%)	Mean 1.2%	SD 2.68%				
		ma, Basosq. Tumor (M or eratoacanthoma, Trichoe	pithelioma	·								
		5/50 (10%)	6/50 (12%)	4/50 (8%)		1/50 (2%)	0/50 (0%)	2/50 (60/)				
Overall Incidence	Total	7/50 (14%) 38/300 (12.67%)	11/50 (22%) Mean 12.67%	5/50 (10%) SD 5.01%	Total	1/50 (2%) 5/250 (2%)	0/50 (0%) Mean 2%	3/50 (6%) SD 2.45%				
		30/300 (12.07%)	Weall 12.07%	3.01%	10tai	5/250 (276)	IVIEdII 270					
Skin: Fibroma		8/50 (16%) 5/50 (10%)	7/50 (14%) 8/50 (16%)	6/50 (12%) 9/50 (18%)		1/50 (2%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	4/50 (8%)				
Overall Incidence	Total	43/300 (14.33%)	Mean 14.33%	SD 2.94%	Total	7/250 (2.8%)	Mean 2.8%	SD 3.03%				
		xoma, Myxosarcoma, or F 11/50 (22%) 6/50 (12%)	8/50 (16%) 9/50 (18%)	7/50 (14%) 10/50 (20%)		1/50 (2%) 1/50 (2%)	1/50 (2%) 1/50 (2%)	4/50 (8%)				
Overall Incidence	Total	51/300 (17%)	Mean 17%	SD 3.74%	Total	8/250 (3.2%)	Mean 3.2%	SD 2.68%				
Skin: Fibrosarcoma												
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)				
Normall Implication	Tata!	0/50 (0%)	0/50 (0%)	1/50 (2%)	Tatal	0/50 (0%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%				

^{*:} 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: 05/27/2022

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

Vehicle: WATER

			Male				Female					
#Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma												
	•	3/50 (6%) 1/50 (2%)	1/50 (2%) 1/50 (2%)	1/50 (2%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	8/300 (2.67%)	Mean 2.67%	SD 1.63%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%				
#Skin: Fibrous Histiocytoma												
		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%)				
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%				
#Skin: Hemangioma			•••••									
-		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/50 (2%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.03%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
#Skin: Hemangiosarcoma			•••••									
.		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)					
Overell Incidence	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%				
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	3D 0%				
#Skin: Keratoacanthoma												
		2/50 (4%) 3/50 (6%)	1/50 (2%) 6/50 (12%)	3/50 (6%) 4/50 (8%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	19/300 (6.33%)	Mean 6.33%	4/50 (8%) SD 3.44%	Total	1/250 (0.4%)	0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%				

^{*:} 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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Report Date: 05/27/2022

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Male **Female** #Skin: Lipoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)1/50 (2%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 1/250 (0.4%) Mean 0.4% SD 0.89% #Skin: Liposarcoma (0%) (0%)0/50 1/50 (2%)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%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 0/250 (0%) Mean 0% SD 0% #Skin: **Neural Crest Tumor** 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(2%) 1/50 (2%)0/50 (0%)1/50 0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 3/300 (1%) Mean 1% SD 1.1% 1/250 (0.4%) Mean 0.4% SD 0.89% Total #Skin: Neurofibroma or 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%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS) (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

0/50

SD 0%

(0%)

Total

0/50

0/250 (0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

......

0/50

0/300 (0%)

(0%)

0/50

Mean 0%

(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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

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Report Date: 05/27/2022

Species: RATS Strain: F 344/N

Vehicle: WATER

Length of Study: CHRONIC

			Male		Female			
#Skin:			II (NOO)					
Neurofibrosarcoma, Neur	ofibroma, or			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 (09/)
Overell Institutes	Tatal	` '	0/50 (0%)	0/50 (0%)	Tatal	, ,	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: 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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma		2/50 (4%)	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%)	0/50 (0%)
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/22 (224)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: 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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (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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Report Date: 05/27/2022

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Male **Female** #Skin: **Squamous Cell Carcinoma** 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)**Overall Incidence** Total 2/300 (0.67%) Mean 0.67% SD 1.03% Total 0/250 (0%) Mean 0% SD 0% #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 0/50 (4%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** 5/300 (1.67%) Mean 1.67% SD 1.51% 1/250 (0.4%) SD 0.89% Total Total Mean 0.4% #Skin: **Squamous Cell Papilloma** 0/50 1/50 (2%)3/50 (6%)(0%)0/50 (0%)0/50 (0%)(2%)2/50 (4%)1/50 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 7/300 (2.33%) Mean 2.33% SD 2.34% Total 1/250 (0.4%) Mean 0.4% SD 0.89% #Skin: Squamous Cell Papilloma or Papilloma 0/50 1/50 (2%)3/50 (6%)(0%)0/50 (0%)0/50 (0%)(4%)(2%)2/50 1/50 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 7/300 (2.33%) Mean 2.33% SD 2.34% Total 1/250 (0.4%) Mean 0.4% SD 0.89% #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma 4/50 (8%)4/50 (8%)3/50 (6%)1/50 (2%)0/50 (0%)6/50 (12%)7/50 (14%)4/50 (8%) 1/50 (2%)0/50 (0%)0/50 (0%)

SD 3.01%

Total

2/250 (0.8%)

Mean 0.8%

SD 1.1%

Total

28/300 (9.33%)

Mean 9.33%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Adenoma

Trichoepithelioma

...... **#Skin: Sebaceous Gland:**

#Skin:

#Skin:

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

Male

(8%)

(6%)

(0%)

(0%)

(0%)

(14%)

4/50

7/50

3/50

0/50

0/50

0/50

Mean 0%

Mean 0%

Mean 1.67%

Mean 8.67%

Female 3/50 (6%)1/50 (2%)0/50 (0%)4/50 (8%)1/50 (2%)0/50 (0%)0/50 (0%)SD 3.01% Total 2/250 (0.8%) Mean 0.8% SD 1.1% (0%)0/50 (0%)0/50 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)2/50 (4%)SD 2.34% Total 2/250 (0.8%) Mean 0.8% SD 1.79%

1/50

0/50

1/250 (0.4%)

0/250 (0%)

(2%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0.4%

Mean 0%

0/50

SD 0.89%

SD 0%

(0%)

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Report Date: 05/27/2022

	• • • • • • • • • • • • • • • • • • • •											
#Skin: Sebaceous Gland: Carcinoma												
	0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50 0/50	` ,	0/50 0/50	(0%) (0%)	0/50	(0%)

0/50

0/50

SD 0%

SD 0%

(0%)

(0%)

Total

Total

#Skin: Sebaceous Gland: Carcinoma or Adenoma

Overall Incidence	Total	0/300 (0%)	Mean (0%	SD 0%		Total	1/250 (0.4	4%)	Mean	0.4%	SD 0.8	39%
		0/50	(0%)	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%)		
our official of Auctionia														

Squamous Cell Papilloma, Papilloma, or Keratoacanthoma

Total

Total

Total

Total

3/50

5/50

26/300 (8.67%)

0/50

1/50

5/300 (1.67%)

0/50

0/50

0/300 (0%)

0/300 (0%)

(6%)

(0%)

(2%)

(0%)

(0%)

(10%)

^{*:} 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: 257

			Male				Female	
#Spinal Cord: Astrocytoma 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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Spleen: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	1/48 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/295 (0.34%)	Mean 0.35%	SD 0.85%	Total	0/247 (0%)	Mean 0%	SD 0%
*Spleen: Leiomyosarcoma								
-		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	0/247 (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: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/250 (0%) **Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Stomach, Forestomach: Schwannoma Malignant (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 0/250 (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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% 0/250 (0%) Mean 0% SD 0% Total #Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous 0/50 0/50 (0%)0/50 (0%)(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%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 1/250 (0.4%) Mean 0.4% SD 0.89% #Stomach, Forestomach: Squamous Cell Papilloma 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%)

SD 0.82%

Total

1/250 (0.4%)

Mean 0.4%

SD 0.89%

Total

1/300 (0.33%)

Mean 0.33%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 259 Report Date: 05/27/2022

			Male		Female				
#Stomach, Glandular: 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%)	
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%	
#Stomach, Glandular: Lipoma									
		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%)	
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%	
Testes: Adenoma									
		48/50 (96%)	46/50 (92%)	45/50 (90%)					
		41/50 (82%)	49/50 (98%)	45/50 (90%)					
Overall Incidence	Total	274/300 (91.33%)	Mean 91.33%	SD 5.61%					
*Thymus: Sarcoma									
		0/48 (0%)	0/49 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)		
		1/49 (2%)	0/43 (0%)	0/48 (0%)		0/49 (0%)	0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	1/285 (0.35%)	Mean 0.34%	SD 0.83%	Total	0/246 (0%)	Mean 0%	SD 0%	
Thymus: Thymoma Benign									
. .		0/48 (0%)	0/49 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)		
		1/49 (2%)	0/43 (0%)	0/48 (0%)		0/49 (0%)	0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	1/285 (0.35%)	Mean 0.34%	SD 0.83%	Total	0/246 (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: ORAL Vehicle: WATER Page: 260

			Male		Female				
Thymus: Thymoma Malignant									
		0/48 (0%)	0/49 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)		
		0/49 (0%)	0/43 (0%)	0/48 (0%)		0/49 (0%)	0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	0/285 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%	
Thymus: Thymoma: Benign, Maligna	ant, NOS								
		0/48 (0%)	0/49 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)		
		1/49 (2%)	0/43 (0%)	0/48 (0%)		0/49 (0%)	0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	1/285 (0.35%)	Mean 0.34%	SD 0.83%	Total	0/246 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Adenoma									
		5/50 (10%)	3/50 (6%)	8/46 (17%)		8/50 (16%)	6/49 (12%)		
		6/50 (12%)	10/49 (20%)	9/47 (19%)		6/50 (12%)	6/46 (13%)	12/47 (26%)	
Overall Incidence	Total	41/292 (14.04%)	Mean 14.16%	SD 5.71%	Total	38/242 (15.7%)	Mean 15.76%	SD 5.69%	
*Thyroid Gland: C-Cell: Carcinoma									
		1/50 (2%)	1/50 (2%)	1/46 (2%)		2/50 (4%)	1/49 (2%)		
		1/50 (2%)	1/49 (2%)	2/47 (4%)		0/50 (0%)	0/46 (0%)	1/47 (2%)	
Overall Incidence	Total	7/292 (2.4%)	Mean 2.41%	SD 0.91%	Total	4/242 (1.65%)	Mean 1.63%	SD 1.68%	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
		6/50 (12%)	4/50 (8%)	9/46 (20%)		10/50 (20%)	7/49 (14%)		
		7/50 (14%)	11/49 (22%)	11/47 (23%)		6/50 (12%)	6/46 (13%)	13/47 (28%)	
Overall Incidence	Total	48/292 (16.44%)	Mean 16.57%	SD 6.18%	Total	42/242 (17.36%)	Mean 17.4%	SD 6.52%	

^{*:} 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: 261

			Male	Female				
Thyroid Gland: Follicular Cell Adenoma	l:							
		0/50 (0%)	2/50 (4%)	0/46 (0%)		0/50 (0%)	0/49 (0%)	
		1/50 (2%)	0/49 (0%)	1/47 (2%)		0/50 (0%)	1/46 (2%)	0/47 (0%)
Overall Incidence	Total	4/292 (1.37%)	Mean 1.35%	SD 1.64%	Total	1/242 (0.41%)	Mean 0.43%	SD 0.97%
Thyroid Gland: Follicular Cell Carcinoma	l:							
		0/50 (0%)	1/50 (2%)	0/46 (0%)		0/50 (0%)	0/49 (0%)	
		0/50 (0%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/46 (0%)	1/47 (2%)
Overall Incidence	Total	1/292 (0.34%)	Mean 0.33%	SD 0.82%	Total	1/242 (0.41%)	Mean 0.43%	SD 0.95%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	l:	0/50 (0%) 1/50 (2%)	3/50 (6%) 0/49 (0%)	0/46 (0%) 1/47 (2%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 1/46 (2%)	1/47 (2%)
Overall Incidence	Total	5/292 (1.71%)	Mean 1.69%	SD 2.34%	Total	2/242 (0.83%)	Mean 0.86%	SD 1.18%
#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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (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%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (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: WATER

Route: ORAL

Page: 262

Report Date: 05/27/2022

Length of Study: CHRONIC

			Male			Female				
#Tissue NOS: 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%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (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%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (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%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%		
#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%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (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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Mean 0%

SD 0%

Report Date: 05/27/2022

Contract/Lab: All Laboratories

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

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC Male **Female** #Tongue: Squamous Cell Carcinoma or Papilloma Squamous 0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 2/250 (0.8%) Mean 0.8% SD 1.1% #Tongue: **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)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%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 2/250 (0.8%) Mean 0.8% SD 1.1% #Tooth: Odontoma 0/50 (0%)0/50 (0%)0/50 (0%)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 0/300 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% *Urinary Bladder: Carcinoma 0/49 0/50 (0%)0/50 (0%)(0%)0/49 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/297 (0.34%) Mean 0.33% SD 0.82% Total 0/249 (0%) Mean 0% SD 0% *Urinary Bladder: Carcinoma or Papilloma 0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0.82%

Total

0/249 (0%)

Total

1/297 (0.34%)

.....

Mean 0.33%

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: 05/27/2022

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/297 (0%) Mean 0% SD 0% Total 0/249 (0%) Mean 0% SD 0% *Urinary Bladder: **Papilloma** 0/50 (0%) 0/50 (0%)0/50 (0%)0/49 (0%)0/49(0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/297 (0%) Mean 0% SD 0% Total 0/249 (0%) Mean 0% SD 0% #Uterus: Adenoma 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% #Uterus: Carcinoma 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% #Uterus: **Deciduoma Benign** 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%

^{*:} 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: 05/27/2022

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male			Female	
#Uterus:			,		
Hemangioma			0/50 (00/)	0/50 (09/)	
			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%
Uterus: Hemangiosarcoma					
			0/50 (0%)	0/50 (0%)	
			0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence		Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Uterus: Leiomyoma					
			0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence		Total	0/250 (0%)	Mean 0%	SD 0%
Uterus: Polyp Stromal					
, .			10/50 (20%)	9/50 (18%)	
			4/50 (8%)	13/50 (26%)	9/50 (18%)
verall Incidence		Total	45/250 (18%)	Mean 18%	SD 6.48%
Jterus: Sarcoma Stromal					
			0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence		Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

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

^{#:} Denominator is number of animals necropsied

Version: Oct2007 Contract/Lab: All Laboratories

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

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			Male				Female		
#Uterus: Sarcoma Stromal or Po	olyp Stromal								
						10/50 (20%)	9/50 (18%)	10/50 (200/)	
Overall Incidence					Total	4/50 (8%) 46/250 (18.4%)	13/50 (26%) Mean 18.4%	10/50 (20%) SD 6.54%	
Uterus: Schwannoma Malignar							•••••		
ū						0/50 (0%)	0/50 (0%)		
						0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence					Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	
#Vagina: Polyp						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%	
Vagina: Sarcoma									
						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%	
₹Zymbal's Gland: Adenoma									
		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%)	
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (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: WATER Page: 267

Report Date: 05/27/2022

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Zymbal's Gland: Carcinoma 0/50 (0%)1/50 (2%)1/50 (2%)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** SD 1.03% Total 2/300 (0.67%) Mean 0.67% Total 2/250 (0.8%) Mean 0.8% SD 1.1% #Zymbal's Gland: Carcinoma or Adenoma 0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)(0%) 1/50 (2%)0/50 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 3/300 (1%) Mean 1% SD 1.1% Total 2/250 (0.8%) Mean 0.8% SD 1.1%

^{*:} 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: 05/27/2022

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		
Battelle Columbus Laboratory Southern Research Institute	059700307 059302007	07/10/02 04/24/00	728 729	50(1) 50(1)	25(680) 20(670)	510.4 484.2	1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide
					Female		
Battelle Columbus Laboratory Southern Research Institute	059700307 059302007	07/11/02 04/24/00	729 731	50(1) 50(1)	29(695) 30(672)	337.8 319.5	1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide

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

ute: SKIN

Page: 269

			Male				Female	
#All Organs: Benign Tumors								
		46/50 (92%)	47/50 (94%)			46/50 (92%)	44/50 (88%)	
Overall Incidence	Total	93/100 (93%)	Mean 93%	SD 1.41%	Total	90/100 (90%)	Mean 90%	SD 2.83%
#All Organs: Malignant Tumors								
		23/50 (46%)	34/50 (68%)			15/50 (30%)	22/50 (44%)	
Overall Incidence	Total	57/100 (57%)	Mean 57%	SD 15.56%	Total	37/100 (37%)	Mean 37%	SD 9.9%
#All Organs: Malignant and Benign T	umors							
		50/50 (100%)	50/50 (100%)			48/50 (96%)	48/50 (96%)	
Overall Incidence	Total	100/100 (100%)	Mean 100%	SD 0%	Total	96/100 (96%)	Mean 96%	SD 0%
#All Organs: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma or He	emangioma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
						,		/-

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date: 05/27/2022

Page: 270

			Male				Female	
#All Organs: Histiocytic Sarcoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
¢All Organs: Leukemia: Lymphocytic, M	onocytic, M	ononuclear, or Undifferen	tiated					
	•	17/50 (34%)	13/50 (26%)			10/50 (20%)	9/50 (18%)	
Overall Incidence	Total	30/100 (30%)	Mean 30%	SD 5.66%	Total	19/100 (19%)	Mean 19%	SD 1.41%
#All Organs: Malignant Lymphoma: Hist Overall Incidence	iocytic, Lym	nphocytic, Mixed, NOS, or 0/50 (0%) 2/100 (2%)	Undifferentiated Cel 2/50 (4%) Mean 2%	I Type SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
All Organs: Mesothelioma: Benign		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
‡All Organs: Mesothelioma: Benign, Ma	lignant, NOS	3						
Mesothelioma: Benign, Ma	lignant, NOS	1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Mesothelioma: Benign, Ma	lignant, NOS		1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Mesothelioma: Benign, Ma		1/50 (2%) 2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%) ´	Mean 0%	SD 0%
Overall Incidence #All Organs:		1/50 (2%)	` ,	SD 0% SD 1.41%	Total	` '	` ,	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: 271

			Male				Female		
#All Organs: Osteoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#All Organs: Osteosarcoma									
	.	0/50 (0%)	0/50 (0%)	OD 00/	-	0/50 (0%)	0/50 (0%)	05.00/	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#All Organs: Osteosarcoma or Osteoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
·····									
*Adrenal Cortex: Adenoma							- ()		
Overall Incidence	Tatal	3/50 (6%)	0/50 (0%) Mean 3%	CD 4.040/	Tatal	0/50 (0%)	3/50 (6%) Mean 3%	CD 4.040/	
Overali incidence	Total	3/100 (3%)		SD 4.24%	Total	3/100 (3%)		SD 4.24%	
*Adrenal Cortex: Carcinoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Ganglioneuroma		0(50 (00))	0/50 (05.)			0(50 (00))	0.40 (00.1)		
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/49 (0%)	CD 00/	
Overall incluence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (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: SKIN Vehicle: ETHANOL Page: 272

			Male				Female					
*Adrenal Medulla: Hemangioma												
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%				
Adrenal Medulla: Pheochromocytoma Ben	ign											
-		5/50 (10%)	3/50 (6%)			1/50 (2%)	0/49 (0%)					
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 2.83%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%				
Adrenal Medulla: Pheochromocytoma Con	nplex	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)					
Overall Incidence	Total	0/100 (0%)	0/30 (0%) Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%				
Adrenal Medulla: Pheochromocytoma Mali		0/50 (0%)	4/50 (8%)			0/50 (0%)	0/49 (0%)					
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 5.66%	Total	0/99 (0%)	Mean 0%	SD 0%				
Adrenal Medulla: Pheochromocytoma: Ber		, Malignant, NOS 5/50 (10%)	6/50 (12%)			1/50 (2%)	0/49 (0%)					
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 1.41%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%				
Blood Vessel: Osteosarcoma			- (OS 1)				(20)					
		0/50 (0%)	0/50 (0%)	05.00/		0/50 (0%)	0/50 (0%)	05.00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 273

			Male		0/50 (0%) 0/50 (0%)				
#Bone: Chondrosarcoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	()	SD 0%	
#Bone: Chondrosarcoma or Chond	Iroma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` '	SD 0%	
#Bone: Chordoma		2/22	(00)				(00)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Bone: Osteoma		0/50 (00/)	0(50 (00))			0/50 (00/)	0/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Bone: Osteosarcoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Bone: Osteosarcoma or Osteoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

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: 274

			Male					
*Brain: Astrocytoma Malignant								
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Ependymoma Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Glioma Malignant		0/50 (001)	0/50 (00/)			0/50 /00/	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Granular Cell Tumor Benig		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Medulloblastoma Mal								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Meningioma Malignant		0/50 (0%)	0/50 /09/\			0/50 /09/\	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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: 275

			Male				Female	
*Brain: Meningioma: Benign, M	lalignant, NOS							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Oligodendroglioma Ber	nign							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Oligodendroglioma Mal	lignant	0/50 (0%)	0/50 (00)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Oligodendroglioma, Gli						0/20 (00)	(20)	
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma								
Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	6/50 (12%) 8/100 (8%)	2/50 (4%) Mean 8%	SD 5.66%
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%)	4/50 (00)			0/50 (00/)	0/50 (40/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%

^{*:} 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: 276

			Male				Female	
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		2/50 (4%)	2/50 (4%)			6/50 (12%)	4/50 (8%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	10/100 (10%)	Mean 10%	SD 2.83%
*Clitoral/Preputial Gland: Fibrosarcoma							- /	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland:								
Squamous Cell Papilloma		2/52 (221)	2/22 (22/)			2/22 (22/)	2/22 (22/)	
		0/50 (0%)	0/50 (0%)	00.00/		0/50 (0%)	0/50 (0%)	05 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Ear: Neural Crest Tumor								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Esophagus: Fibrosarcoma		•••••				•••••		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Eye: Amelanotic Melanoma, Ben								
,	-	0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

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: 277

		Male				Female	
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
T-1-1		` '	00.00/	T-1-1	` '	` '	00.00/
	` '			ı otal	0/100 (0%)	Mean 0%	SD 0%
	2/22 (221)	0.750 (001)			2/22 (221)	(00)	
Total		` '	SD 00/	Total	, ,	` '	SD 0%
	` ,				` '		
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	` '	` ,	SD 0%	Total	` '	` '	SD 0%
	Total	Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Total 0/50 (0%) Total 0/100 (0%) Total 0/50 (0%) Total 0/50 (0%) 0/50 (0%)	O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% Total O/100 (0%) O/50 (0%) Total O/100 (0%) Mean 0%	O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) SD 0% Total O/50 (0%) O/50 (0%) O/50 (0%) SD 0% Total O/50 (0%) O/50 (0%) O/50 (0%) SD 0% Total O/50 (0%) O/50 (0%) O/50 (0%) SD 0% Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Mean 0% SD 0%	Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total	O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Total O/50 (0%) O/50 (0%) D/50 (0%) O/50 (0%) O/50 (0%) Total O/50 (0%) O/50 (0%) D/50 (0%) O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%)	O/50 (0%) Mean 0% SD 0% Total O/100 (0%) O/50 (0%) O/50 (0%) Mean 0% Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Mean 0% Mean 0% Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Mean 0% Mean 0% Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Mean 0% Mean 0% Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Mean 0% Mean 0% Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Mean 0% Mean 0% Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Mean 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: SKIN Vehicle: ETHANOL Page: 278

			Male				Female	
*Heart: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Intestine Large: Colon/Rectu Adenoma	m:							
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Intestine Large: Colon/Rectu Carcinoma	m:							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Intestine Large: Colon/Rectu Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL **Page**: 279

			Male				Female	
#Intestine Small: Duodenum: Leiomyoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma	ified:							
	-	0/50 (0%)	0/50 (0%)	OD 00/	-	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma or Adenoma	ified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Leiomyoma								
Occupil be of the con-	Taral	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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: 280

Mean 0%

SD 0%

Report Date: 05/27/2022

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Male **Female** #Intestine Small: Site Unspecified: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Islets, Pancreatic: Adenoma 0/50 6/50 (12%)5/50 (10%)0/50 (0%)(0%)**Overall Incidence** Total 11/100 (11%) Mean 11% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% *Islets, Pancreatic: Carcinoma 0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/100 (2%) Mean 2% SD 2.83% Total 0/100 (0%) Mean 0% SD 0% *Islets, Pancreatic: Carcinoma or Adenoma 6/50 (12%) 7/50 (14%) 0/50 (0%)0/50 (0%)**Overall Incidence** Total 13/100 (13%) Mean 13% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

0/100 (0%)

Total

Total

0/100 (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

Page: 281

Report Date: 05/27/2022

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Kidney: Pelvis and Transition	onal Epitheliu	ım:						
• "		0/50 (0%)	0/50 (0%)	05.00/	+	0/50 (0%)	0/50 (0%)	OD 004
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma								
		1/50 (2%)	0/50 (0%)	05		0/50 (0%)	0/50 (0%)	25
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma	•••••							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 282

			Male				Female	
*Kidney: Renal Tubule: Liposarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Beni	gn							
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Cholangiocarcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Cholangioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 283

			Male				Female				
*Liver: Hemangiosarcoma											
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Adenoma	1										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	6/50 (12%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	6/100 (6%)	Mean 6%	SD 8.49%			
*Liver: Hepatocellular Carcinom	na	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Carcinom Overall Incidence	na or Hepatobla Total	s stoma 1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Liver: Hepatocellular Carcinom			0/50 (0%)			0/50 (0%)	6/50 (12%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	6/100 (6%)	Mean 6%	SD 8.49%			
*Liver: Hepatocellular Carcinom	na, Hepatocellu	lar Adenoma, or Hepatobl	lastoma 0/50 (0%)			0/50 (0%)	6/50 (12%)				
Overall Incidence	Total	1/100 (1%)	0/30 (0%) Mean 1%	SD 1.41%	Total	6/100 (6%)	Mean 6%	SD 8.49%			

^{*:} 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: 284

			Male				Female			
*Lung: Alveolar/Bronchiolar Adenoma										
		1/50 (2%)	1/50 (2%)			4/50 (8%)	0/50 (0%)			
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	4/100 (4%)	Mean 4%	SD 5.66%		
*Lung: Alveolar/Bronchiolar C										
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%		
*Lung: Alveolar/Bronchiolar C Overall Incidence	Carcinoma or Alve	eolar/Bronchiolar Adenon 2/50 (4%) 3/100 (3%)	na 1/50 (2%) Mean 3%	SD 1.41%	Total	4/50 (8%) 4/100 (4%)	0/50 (0%) Mean 4%	SD 5.66%		
*Lung:										
Hemangiosarcoma	Taral	0/50 (0%)	0/50 (0%)	05 , 00/	Tatal	0/50 (0%)	0/50 (0%)	OD 00/		
_	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
Hemangiosarcoma	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
Hemangiosarcoma Overall Incidence *Lung:	Total Total	` '	, ,	SD 0% SD 0%	Total Total	` '	` '	SD 0% SD 0%		
Hemangiosarcoma Overall Incidence *Lung: Sarcoma	Total	0/100 (0%)	Mean 0%			0/100 (0%) 0/50 (0%)	Mean 0% 00 00 00 00 00 00 00 00 00 00 00 00			

^{*:} 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: 285

			Male				Female	
#Lymph Node, Mesenteric: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mammary Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Mammary Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 6/100 (6%)	4/50 (8%) Mean 6%	SD 2.83%
#Mammary Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	3/50 (6%) 7/100 (7%)	4/50 (8%) Mean 7%	SD 1.41%
#Mammary Gland: Fibroadenoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	14/50 (28%) 26/100 (26%)	12/50 (24%) Mean 26%	SD 2.83%
#Mammary Gland: Fibroma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 286

			Male				Female				
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma											
		1/50 (2%)	0/50 (0%)			15/50 (30%)	12/50 (24%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	27/100 (27%)	Mean 27%	SD 4.24%			
#Mammary Gland: Fibroma, Fibroadenoma,	Carcinoma, or	Adenoma									
,	,	1/50 (2%)	0/50 (0%)			17/50 (34%)	14/50 (28%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	31/100 (31%)	Mean 31%	SD 4.24%			
#Mesentery: Fibrosarcoma			- /								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Mesentery: Hemangiosarcoma		0/50 (00)	2(20)			0.470 (004)	272 (221)				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
		` /				` '					
#Mesentery: Osteosarcoma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Mesentery: Rhabdomyosarcoma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 287

			Male				Female	
*Nose: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Chondroma								
	T	0/50 (0%)	0/50 (0%)	OD 00/	-	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Squamous Cell Carcinom	na							
		0/50 (0%)	1/50 (2%)	05		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, Papilloma Squamous or I		ynx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Oral Cavity (Oral Mucosa, Squamous Cell Carcinom	Tongue, Phary							
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

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

Page: 288

			Male				Female		
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma 0/50 (0%) 0/50 (0%) 0/50 (0%) 3/50 (6%)									
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%	
#Oral Mucosa: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
#Oral Mucosa: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor Ben	ign					0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor Mali	gnant					2(22)	2/52 (224)		
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor: Ber	nign, Maligna	nnt, NOS				0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 289

			Male				Female	
*Ovary: Granulosa-Theca Tumor B	Benign							
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Adenoma		0.170 (001)	- ()					
Overall Incidence	Total	0/50 (0%) 3/100 (3%)	3/50 (6%) Mean 3%	SD 4.24%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma						0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	3/50 (6%) Mean 3%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pancreas: Mixed Tumor Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
Overall Incidence	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/46 (0%) 0/91 (0%)	0/45 (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: 290

	Male Female				0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 09 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 09 35/50 (70%) 33/50 (66%) Total 68/100 (68%) Mean 68% SD 2.83 0/50 (0%) 3/50 (6%) Total 3/100 (3%) Mean 3% SD 4.24			
#Peripheral Nerve: Schwannoma Malignan	t							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		, ,	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign,	Malignant, NOS							
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Adenoma	talis or Unspec							
		32/50 (64%)	29/50 (58%)			` '	` '	
Overall Incidence	Total	61/100 (61%)	Mean 61%	SD 4.24%		68/100 (68%)	Mean 68%	SD 2.83%
Pituitary Gland: Pars Dis Carcinoma								
		0/50 (0%)	5/50 (10%)			0/50 (0%)	3/50 (6%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 7.07%		` ,		SD 4.24%
Pituitary Gland: Pars Dis Carcinoma or Adenoma	talis or Unspeci							
		32/50 (64%)	34/50 (68%)			35/50 (70%)	36/50 (72%)	
Overall Incidence	Total	66/100 (66%)	Mean 66%	SD 2.83%	Total	71/100 (71%)	Mean 71%	SD 1.41%
Pituitary Gland: Pars Inte Adenoma	ermedia:							
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence		2/100 (2%)	Mean 2%	SD 2.83%		0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ETHANOL

			Male				Female	
*Pituitary Gland: Pars Interm Carcinoma	edia:							
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
				30 1.4176	10tai			
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:							
		0/50 (0%)	3/50 (6%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma		-1						
Overall Incidence	Total	0/50 (0%)	1/50 (2%)	SD 1.41%				
Overali incidence	Total	1/100 (1%)	Mean 1%					
*Prostate: Carcinoma or Adenoma		0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Salivary Glands: Sarcoma								
		0/50 (0%)	1/49 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant								
Occupation of James	Tatal	0/50 (0%)	0/49 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (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

Report Date: 05/27/2022

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			Male				Female	
#Skeletal Muscle: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Lipoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Skeletal Muscle: Rhabdomyosarcoma or F	Rhabdomyoma		0/50 /00//			4/50 (00)	0/50 (000)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%

^{*:} 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 Report Date: 05/27/2022

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		Male Female				0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 09 Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 09		
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%		` '	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		` '		SD 0%
#Skin: Basal Cell Adenoma or B	·	0/50 (0%)	0/50 (0%)	SD 00/	Total	` '	` '	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	ı otaı	0/100 (0%)	Wean 0%	SD 0%
#Skin: Basal Cell Adenoma, Bas	osquamous T	umor Benign, or Trichoep 0/50 (0%)	oithelioma 0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
		0/50 (0%)	0/50 (0%)			` ,	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		` ,		SD 0%
#Skin: Basal Cell Carcinoma or								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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: 05/27/2022

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female				
#Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma											
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
		na, Basosq. Tumor (M or E eratoacanthoma, Trichoep	ithelioma	na,		4/50 (0%)	4/50 (00()				
Overall Incidence	Total	2/50 (4%) 6/100 (6%)	4/50 (8%) Mean 6%	SD 2.83%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%			
			······								
#Skin: Fibroma											
		7/50 (14%)	5/50 (10%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	12/100 (12%)	Mean 12%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Fibroma, Fibrosarcom	a, Sarcoma, Myx	oma, Myxosarcoma, or Fi 8/50 (16%)	brous Histiocytoma 5/50 (10%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	13/100 (13%)	Mean 13%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Fibrosarcoma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Fibrosarcoma, Sarcom	na, Myxosarcoma	a, or Fibrous Histiocytoma	1								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%			

^{*:} 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: 295

			Male			Female		
#Skin: Fibrous Histiocytoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma		- (OO)				2(72)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Keratoacanthoma		2/50 (49/)	2/50 (69/)			0/50 (0%)	4/50 (20/)	
Overall Incidence	Total	2/50 (4%) 5/100 (5%)	3/50 (6%) Mean 5%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Skin: Lipoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Liposarcoma		0.50	0/50 (00.1)			0/50 (001)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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: 296

		Male				Female				
#Skin: Neural Crest Tumor										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Neurofibroma or Schw										
	g	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Neurofibrosarcoma or Overall Incidence	Schwannoma (m Total	alignant or NOS) 1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%		
#Skin:		chwannoma (benign, ma 2/50 (4%)				0/50 (0%)	2/50 (4%)			
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%		
#Skin: Osteosarcoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Sarcoma										
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	SD 0%		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	2D 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 roups Report Date: 05/27/2022

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			Male			Female 0/50 (0%) 0/50 (0%) SD 0% 0/50 (0%) 2/50 (4%) SD 2.83% 1/50 (2%) Mean 2% SD 2.83% 1/50 (2%) 0/50 (0%) 1/100 (1%) Mean 1% SD 1.41% 1/50 (2%) 0/50 (0%) 1/100 (1%) Mean 1% SD 1.41% 0/50 (0%) 0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%) SD 0%		
#Skin: Schwannoma Benign								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/100 (0%)	` ,	SD 0%
Skin: Schwannoma Malignant								
Overall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	` ,	, ,	SD 2.83%
Skin: Squamous Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` '	SD 1.41%
Skin: Squamous Cell Carcinoma, E or Carcinoma	Basal Cell (Carcinoma, Basosquamoı		or NOS),				
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Skin: Squamous Cell Papilloma								
		0/50 (0%)	1/50 (2%)			` '	, ,	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papilloma or	Papilloma							
	.	0/50 (0%)	1/50 (2%)	05 4 4407	-	` ,	` ,	OD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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: 298

			Male				Female				
#Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma											
Overall Incidence	Total	2/50 (4%) 6/100 (6%)	4/50 (8%) Mean 6%	SD 2.83%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%			
#Skin: Squamous Cell Papilloma	a, Papilloma, o	r Keratoacanthoma									
Overall Incidence	Total	2/50 (4%) 6/100 (6%)	4/50 (8%) Mean 6%	SD 2.83%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%			
#Skin: Trichoepithelioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Sebaceous Gland: Adenoma		0/50 (00()	0/50 (0%)			0/50 /00/	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Skin: Sebaceous Gland: Carcinoma											
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Skin: Sebaceous Gland: Carcinoma or Adenoma			(05.2)				(20)				
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 299

			Male				Female	
#Spinal Cord: Astrocytoma Benign								
Overall Institutes	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Fibrosarcoma								
Overall Incidence	Tatal	1/50 (2%)	0/50 (0%)	CD 4 440/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incidence	ıotai	0/100 (0%)	iviean 0%	טט ט%	ı olal	0/100 (0%)	iviean 0%	
*Spleen: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyosarcoma		- (ac)	(05.1)				(00)	
• " "	-	0/50 (0%)	0/50 (0%)	OD 00/	-	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 300

			Male				Female	
#Stomach, Forestomach: Schwannoma Malignant			-1					
O	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma o	-	1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Lipoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 301

			Male				Female	
*Testes: Adenoma								
Overall Incidence	Total	37/50 (74%) 73/100 (73%)	36/50 (72%) Mean 73%	SD 1.41%				
*Thymus: Sarcoma		0/49 (0%)	0/49 (0%)			0/45 (0%)	0/50 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign		0/49 (0%)	0/49 (0%)			0/45 (0%)	0/50 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/49 (0%)	0/49 (0%)			0/45 (0%)	0/50 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malign	ant, NOS	0(10 (00))	0/40 (00/)			0/45 (00)	0/50 (00/)	
Overall Incidence	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma			E/EQ			0/50 (469/)	2/50 (69/)	
Overall Incidence	Total	10/50 (20%) 15/100 (15%)	5/50 (10%) Mean 15%	SD 7.07%	Total	8/50 (16%) 11/100 (11%)	3/50 (6%) Mean 11%	SD 7.07%

^{*:} 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: 302

Report Date: 05/27/2022

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Thyroid Gland: C-Cell: Carcinoma								
		2/50 (4%)	5/50 (10%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	7/100 (7%)	Mean 7%	SD 4.24%	Total	2/100 (2%)	Mean 2%	SD 2.83%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		12/50 (24%)	10/50 (20%)			8/50 (16%)	5/50 (10%)	
Overall Incidence	Total	22/100 (22%)	Mean 22%	SD 2.83%	Total	13/100 (13%)	Mean 13%	SD 4.24%
*Thyroid Gland: Follicular Cell: Adenoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Tissue NOS: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 303

			Male				Female	
#Tissue NOS: Leiomyoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tissue NOS: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tissue NOS: Paraganglioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tissue NOS: Sarcoma		0.50 (00)	0/50 (004)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tongue: Liposarcoma		0.50 (001)	0/50 (00)			0/50 (00.0)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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

Page: 304

			Male				Female			
#Tongue: Squamous Cell Carcinoma or Papilloma Squamous										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	2/50 (4%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%		
fTongue: Squamous Cell Papilloma										
		0/50 (0%)	0/50 (0%)	05.00/		0/50 (0%)	2/50 (4%)	05 0 000/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%		
#Tooth: Odontoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%		
						, ,				
Urinary Bladder: Carcinoma										
2	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
Urinary Bladder: Carcinoma or Papilloma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
Urinary Bladder: Leiomyosarcoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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	
*Urinary Bladder: Papilloma		2/52 (224)	0/50 (00/)			0/50 (00/)	0(50 (00))	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Adenoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Deciduoma Benign						0/50 (0%)	0/50 (00/)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Hemangioma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Hemangiosarcoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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

Page: 306

	Male			Female	
#Uterus: Leiomyoma			0/20 (00)	(100 ii	
Overall Incidence		Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Uterus: Polyp Stromal					
Overall Incidence		Total	2/50 (4%) 12/100 (12%)	10/50 (20%) Mean 12%	SD 11.31%
#Uterus: Sarcoma Stromal			4/50 (001)	0/50 (00/)	
Overall Incidence		Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Uterus: Sarcoma Stromal or Polyp Stromal					
Overall Incidence		Total	3/50 (6%) 13/100 (13%)	10/50 (20%) Mean 13%	SD 9.9%
#Uterus: Schwannoma Malignant					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Polyp					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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: 307

,								
			Male				Female	
#Vagina: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied