

NTP Historical Controls Report

All Routes and Vehicles

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.

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

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

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

the data would be shown as:

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

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

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

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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	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
Battelle Northwest	059601105	06/04/01	729	50(5)	26(676)	540.9	Cumene
Battelle Columbus Laboratory	059700307	07/10/02	728	50(1)	25(680)	510.4	1,2-Dibromo-2,4-dicyanobutane
Southern Research Institute	059302007	04/24/00	729	50(1)	20(670)	484.2	Diisopropylcarbodiimide
Battelle Northwest	058800405	09/13/99	729	50(5)	31(686)	519.5	Divinylbenzene
Battelle Columbus Laboratory	058812305	03/21/01	727	50(3)	26(673)	509.7	Formamide
Battelle Columbus Laboratory	059501107	03/06/02	727	50(3)	22(673)	510.3	5-(Hydroxymethyl)-2-furfural
Battelle Columbus Laboratory	058810503	04/22/02	729	50(3)	35(702)	521.9	Isoeugenol
Battelle Northwest	059700601	05/25/00	726	50(5)	32(693)	529.7	Methyl isobutyl ketone
Southern Research Institute	059100507	06/26/00	730	50(3)	30(693)	520.6	Methylene blue trihydrate
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
Battelle Northwest	058800603	08/06/01	729	50(5)	27(680)	537.2	alpha-Methylstyrene
Battelle Columbus Laboratory	059902303	03/25/02	729	50(3)	29(683)	501.9	beta-Myrcene
Battelle Northwest	059700805	10/01/01	729	49(5)	27(683)	525.0	Propargyl alcohol
Southern Research Institute	052011407	10/02/02	730	50(3)	28(696)	532.4	Sodium dichromate dihydrate (VI)
Battelle Northwest	059600105	01/18/99	729	50(5)	29(701)	534.2	Stoddard solvent (type IIC)
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)

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: ALL ROUTES
Vehicle: ALL VEHICLES

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
					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
Battelle Northwest	059601105	06/04/01	731	50(5)	21(674)	356.9	Cumene
Battelle Columbus Laboratory	059700307	07/11/02	729	50(1)	29(695)	337.8	1,2-Dibromo-2,4-dicyanobutane
Southern Research Institute	059302007	04/24/00	731	50(1)	30(672)	319.5	Diisopropylcarbodiimide
Battelle Northwest	058800405	09/13/99	731	50(5)	33(679)	355.3	Divinylbenzene
Battelle Columbus Laboratory	058812305	03/20/01	730	50(5)	38(703)	358.3	Formamide
Battelle Columbus Laboratory	059501107	03/07/02	728	50(5)	31(679)	332.2	5-(Hydroxymethyl)-2-furfural
Battelle Columbus Laboratory	058810503	04/23/02	730	50(5)	33(699)	339.3	Isoeugenol
Battelle Northwest	059700601	05/25/00	727	50(5)	35(694)	365.6	Methyl isobutyl ketone
Southern Research Institute	059100507	06/26/00	733	50(5)	35(699)	335.9	Methylene blue trihydrate
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
Battelle Northwest	058800603	08/06/01	730	50(5)	27(647)	351.9	alpha-Methylstyrene
Battelle Columbus Laboratory	059902303	03/26/02	730	50(5)	31(668)	323.8	beta-Myrcene
Battelle Northwest	059700805	10/01/01	730	50(5)	29(678)	353.3	Propargyl alcohol
Southern Research Institute	052011407	10/02/02	735	50(5)	33(700)	351.2	Sodium dichromate dihydrate (VI)
Battelle Northwest	059600105	01/18/99	730	50(5)	36(696)	363.6	Stoddard solvent (type IIC)
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
Route: ALL ROUTES

Species: RATS Strain: F 344/N

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#All Organs:								
Benign Tumors								
		49/50 (98%)	49/50 (98%)	50/50 (100%)		42/50 (84%)	45/50 (90%)	
		48/50 (96%)	46/50 (92%)	47/50 (94%)		44/50 (88%)	46/50 (92%)	44/50 (88%)
		49/50 (98%)	45/50 (90%)	50/50 (100%)		43/50 (86%)	43/50 (86%)	46/50 (92%)
		49/50 (98%)	50/50 (100%)	47/50 (94%)		41/50 (82%)	44/50 (88%)	47/50 (94%)
		49/50 (98%)	50/50 (100%)	48/50 (96%)		43/50 (86%)	48/50 (96%)	43/50 (86%)
		49/50 (98%)	48/49 (98%)	49/50 (98%)		40/50 (80%)	42/50 (84%)	47/50 (94%)
		50/50 (100%)	50/50 (100%)	49/50 (98%)		37/50 (74%)	49/50 (98%)	
		47/50 (94%)	50/50 (100%)	48/50 (96%)		42/50 (84%)	44/50 (88%)	46/50 (92%)
Overall Incidence	Total	1166/1199 (97.25%)	Mean 97.25%	SD 2.75%	Total	966/1100 (87.82%)	Mean 87.82%	SD 5.55%
#All Organs: Malignant Tumors								
J		33/50 (66%)	27/50 (54%)	23/50 (46%)		20/50 (40%)	15/50 (30%)	
		36/50 (72%)	23/50 (46%)	34/50 (68%)		24/50 (48%)	15/50 (30%)	22/50 (44%)
		29/50 (58%)	25/50 (50%)	35/50 (70%)		17/50 (34%)	15/50 (30%)	16/50 (32%)
		29/50 (58%)	31/50 (62%)	30/50 (60%)		18/50 (36%)	22/50 (44%)	19/50 (38%)
		22/50 (44%)	22/50 (44%)	32/50 (64%)		19/50 (38%)	19/50 (38%)	25/50 (50%)
		23/50 (46%)	32/49 (65%)	29/50 (58%)		11/50 (22%)	26/50 (52%)	20/50 (40%)
		33/50 (66%)	27/50 (54%)	28/50 (56%)		30/50 (60%)	18/50 (36%)	,
		29/50 (58%)	27/50 (54%)	27/50 (54%)		16/50 (32%)	20/50 (40%)	21/50 (42%)
Overall Incidence	Total	686/1199 (57.21%)	Mean 57.22%	SD 8.39%	Total	428/1100 (38.91%)	Mean 38.91%	SD 8.59%
#All Organs:	• • • • • • • • • • • • • • • • • • • •			•••••				
Malignant and Benign T	Tumors							
•		50/50 (100%)	50/50 (100%)	50/50 (100%)		46/50 (92%)	47/50 (94%)	
		50/50 (100%)	50/50 (100%)	50/50 (100%)		50/50 (100%)	48/50 (96%)	48/50 (96%)
		50/50 (100%)	48/50 (96%)	50/50 (100%)		46/50 (92%)	49/50 (98%)	48/50 (96%)
		50/50 (100%)	50/50 (100%)	49/50 (98%)		46/50 (92%)	46/50 (92%)	50/50 (100%)
		50/50 (100%)	50/50 (100%)	50/50 (100%)		45/50 (90%)	48/50 (96%)	46/50 (92%)
		50/50 (100%)	49/49 (100%)	50/50 (100%)		45/50 (90%)	47/50 (94%)	49/50 (98%)
		50/50 (100%)	50/50 (100%)	50/50 (100%)		44/50 (88%)	49/50 (98%)	(/
		50/50 (100%)	50/50 (100%)	49/50 (98%)		45/50 (90%)	48/50 (96%)	49/50 (98%)
Overall Incidence	Total	1195/1199 (99.67%)	Mean 99.67%	SD 0.96%	Total	1039/1100 (94.45%)	Mean 94.45%	SD 3.49%

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

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^{#:} 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: ALL ROUTES

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

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			Male				Female	Female					
#All Organs: Hemangioma													
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	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%)	1/50 (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%)						
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	4/1199 (0.33%)	Mean 0.33%	SD 0.76%	Total	2/1100 (0.18%)	Mean 0.18%	SD 0.59%					
#All Organs: Hemangiosarcoma													
•		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (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%)	1/50 (2%)		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%)					
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)					
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	6/1199 (0.5%)	Mean 0.5%	SD 1.06%	Total	4/1100 (0.36%)	Mean 0.36%	SD 1%					
#All Organs: Hemangiosarcoma or H													
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (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%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)					
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)					
		0/50 (0%)	0/49 (0%)	1/50 (2%)		1/50 (2%)	2/50 (4%)	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%)	1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	10/1199 (0.83%)	Mean 0.83%	SD 1.31%	Total	6/1100 (0.55%)	Mean 0.55%	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**

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: ALL VEHICLES

Route: ALL ROUTES

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Report Date: 05/27/2022

Length of Study: CHRONIC

				Male				Female					
All Organs:													
Histiocytic Sarcoma													
			0%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)		
		`	0%) 1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		,	2%) 1/50	(2%)	0/50	(0%)		2/50	(4%)	0/50	(0%)	0/50	(0%)
		,	0%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	2/50	(4%)	1/50	(2%)
		,	0%) 0/50	(0%)	1/50	(2%)		0/50	(0%)	2/50	(4%)	0/50	(0%)
		,	2%) 0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
			0%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	- /	(00()
		,	4%) 0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	8/1199 (0.67%)			SD 1.13		Total	9/1100 (0			0.82%	SD 1	
All Organs:													
Leukemia: Lymphocyt	ic, Monocytic. N	Mononuclear, or Und	differentiated										
, , , , .	,	•	4%) 19/50	(38%)	15/50	(30%)		19/50	(38%)	9/50	(18%)		
		,	2%) 17/50	(34%)	13/50	(26%)		12/50	(24%)	10/50	(20%)	9/50	(18%)
		22/50 (44	4%) 15/50	(30%)	28/50	(56%)		10/50	(20%)	10/50	(20%)	9/50	(18%)
		10/50 (20	0%) 25/50	(50%)	23/50	(46%)		8/50	(16%)	14/50	(28%)	12/50	(24%)
		•	0%) 15/50	(30%)	26/50	(52%)		6/50	(12%)	9/50	(18%)	18/50	(36%)
		9/50 (18	8%) 21/49	(43%)	26/50	(52%)		5/50	(10%)	20/50	(40%)	8/50	(16%)
		25/50 (50	0%) 21/50	(42%)	16/50	(32%)		26/50	(52%)	15/50	(30%)		,
		17/50 (3 ₄	4%) 21/50	(42%)	13/50	(26%)		11/50	(22%)	14/50	(28%)	11/50	(22%)
Overall Incidence	Total	465/1199 (38.789	%) Mean 3	8.79%	SD 11.29	1%	Total	265/1100 (24.09%)	Mean	24.09%	SD 10	0.04%
#All Organs: Malignant Lymphoma:	Histocytic Ly	mnhocytic Miyed N	NOS or Undifferer	ntiated Ce	II Type								
manghant Lymphoma.	, <u>_</u>		0%) 0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)		
		,	0%) 0/50	(0%)	2/50	(4%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
			0%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		`	0%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		`	0%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		,	2%) 0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		•	0%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0,00	(070)
		,	0%) 0/50	(0%)	1/50	(2%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	5/1199 (0.42%)	,	` ,	SD 1.029	` '	Total	1/1100 (0	` '		0.09%	SD 0	` ,
Jyciail Illuluelle	i Ulai	3/1199 (0.4270)	, ivi c an (J.≒∠ /0	30 1.02	/0	i Ulai	1/1100 (0	.03 /0)	ivicali	0.05/0	3D 0	·· · ···········/0

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES

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

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					Male				Female					
#All Organs:														
Mesothelioma: Benign		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	(00/)
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 0/50	(0%)	0/50 0/50	(0%) (0%)	0/50 0/50	(0%)		0/50 0/50	(0%)	0/50 0/50	(0%)	0/50 0/50	(0%)
		0/50	(0%) (0%)	0/50	(0%)	0/50	(0%) (0%)		0/50	(0%) (0%)	0/50	(0%) (0%)	0/50	(0%) (0%)
		0/50	(0%)	0/30	(0%)	0/50	(0%)		0/50	(0%)	1/50	(0%)	0/50	(0%)
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/30	(0 /0)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/1199 (0.0	. ,	Mean 0	` '	SD 0.419	, ,	Total	1/1100 (0	, ,		0.09%	SD 0	, ,
										,				
#All Organs:														
Mesothelioma: Benign,	Malignant, NOS	3												
		2/50	(4%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		3/50	(6%)	1/50	(2%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)	2/50	(4%)	2/50	(4%)		0/50	(0%)	2/50	(4%)	0/50	(0%)
		3/50	(6%)	1/50	(2%)	3/50	(6%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)	1/49	(2%)	2/50	(4%)		1/50	(2%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	3/50	(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	35/1199 (2.9	92%)	Mean 2	.92%	SD 2.29	6	Total	4/1100 (0	.36%)	Mean	0.36%	SD	1%
All Organs: Mesothelioma: Malignar														
		2/50	(4%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		3/50	(6%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)	2/50	(4%)	2/50	(4%)		0/50	(0%)	2/50	(4%)	0/50	(0%)
		3/50	(6%)	1/50	(2%)	3/50	(6%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)	1/49	(2%)	2/50	(4%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	3/50	(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	34/1199 (2.8	34%)	Mean 2	.84%	SD 2.289	%	Total	3/1100 (0	.27%)	Mean	0.27%	SD 0	.94%

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female					
#All Organs:						,				
Osteoma										
		0/50 (0%)	` ,	0/50 (0%)	0/50 (0%) 0/50 (0%)					
		0/50 (0%)	` '	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
		0/50 (0%)	` '	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
		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%)	0/50 (0%)				
		0/50 (0%)	` '	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
		0/50 (0%)	` ,	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	2/1199 (0.17%)			otal 0/1100 (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%) 0/50 (0%)	0/50 (0%)				
		1/50 (2%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)				
		1/50 (2%)	1/49 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
		2/50 (4%)	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	11/1199 (0.92%)			otal 5/1100 (0.45%) Mean 0.45%					
#All Organs:		• • • • • • • • • • • • • • • • • • • •		• • • • • • • • • • • • • • • • • • • •		•••••				
Osteosarcoma or Osteo	ma									
		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%) 0/50 (0%)	0/50 (0%)				
		1/50 (2%)	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%)				
		2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)				
		1/50 (2%)	1/49 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
		2/50 (4%)	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	13/1199 (1.08%)	Mean 1.09% SD	O 1.77%	otal 5/1100 (0.45%) Mean 0.45%	SD 0.86%				

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

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^{#:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female	
*Adrenal Cortex:						
		0/50 (0%)	0/50 (0%) 0/50	(0%) 0/5	0 (0%) 2/50 (4%)	
		0/50 (0%)	3/50 (6%) 0/50	(0%) 0/5	0 (0%) 0/50 (0%)	3/50 (6%)
		0/50 (0%)	0/50 (0%) 0/50	(0%) 0/5	0 (0%) 0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%) 1/50	(2%) 0/5	0 (0%) 0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/50 (2%) 0/50	(0%) 5/5	0 (10%) 1/49 (2%)	2/50 (4%)
		1/50 (2%)	0/49 (0%) 0/50	(0%) 0/5	0 (0%) 0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%) 0/50	(0%) 0/5	0 (0%) 0/50 (0%)	
		0/49 (0%)	0/50 (0%) 0/49	(0%) 1/4	9 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/1197 (0.5%)	Mean 0.5% SD 1.35%		3 (1.55%) Mean 1.55%	SD 2.54%
*Adrenal Cortex: Carcinoma						
		0/50 (0%)	0/50 (0%) 0/50	(0%) 0/5	0 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%) 0/50	(0%) 0/5	0 (0%) 0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%) 0/50	(0%) 0/5	` ,	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50	(0%) 0/5	0 (0%) 0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50	(0%) 0/5	0 (0%) 0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%) 0/50	(0%) 0/5	0 (0%) 0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50	(0%) 1/5	()	
		0/49 (0%)	0/50 (0%) 0/49	(0%) 0/4	9 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/1197 (0.08%)	Mean 0.08% SD 0.41%		(0.09%) Mean 0.09%	
*Adrenal Medulla: Ganglioneuroma						
		0/50 (0%)	0/50 (0%) 0/50	(0%) 0/5	` ,	
		0/50 (0%)	0/50 (0%) 0/50	(0%) 0/5	` ,	0/49 (0%)
		0/50 (0%)	0/50 (0%) 0/50	(0%) 0/5	()	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50	(0%) 0/5	()	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50	(0%) 0/4	` ,	0/49 (0%)
		1/50 (2%)	` ,	(0%) 0/5	()	0/49 (0%)
		0/50 (0%)	` ,	(0%) 0/5	` ,	
		0/49 (0%)	0/50 (0%) 0/49	(0%) 0/4	9 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/1196 (0.08%)	Mean 0.08% SD 0.41%	Total 0/109	91 (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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female					
Adrenal Medulla: Hemangioma											
J		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/49 (0%)			
		0/50 (0%)	0/49 (0%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/49 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)				
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)			
verall Incidence	Total	0/1196 (0%)	Mean 0%	SD 0%	Total	1/1091 (0.09%)	Mean 0.09%	SD 0.43%			
drenal Medulla:											
Pheochromocytoma B	enign		- / /								
		8/50 (16%)	8/50 (16%)	8/50 (16%)		0/50 (0%)	1/50 (2%)				
		7/50 (14%)	5/50 (10%)	3/50 (6%)		1/50 (2%)	1/50 (2%)	0/49 (0%)			
		12/50 (24%)	9/50 (18%)	5/50 (10%)		2/50 (4%)	0/50 (0%)	0/50 (0%)			
		5/50 (10%)	8/50 (16%)	9/50 (18%)		2/50 (4%)	3/50 (6%)	2/50 (4%)			
		8/50 (16%)	8/50 (16%)	8/50 (16%)		0/49 (0%)	2/48 (4%)	1/49 (2%)			
		11/50 (22%)	8/49 (16%)	6/49 (12%)		1/50 (2%)	1/50 (2%)	2/49 (4%)			
		5/50 (10%)	9/50 (18%)	8/50 (16%)		2/50 (4%)	2/49 (4%)	2/22 //2/			
		7/49 (14%)	10/50 (20%)	6/49 (12%)		1/49 (2%)	1/49 (2%)	2/50 (4%)			
erall Incidence	Total	181/1196 (15.13%)	Mean 15.13%	SD 4.11%	Total	27/1091 (2.47%)	Mean 2.48%	SD 1.75%			
drenal Medulla: Pheochromocytoma C				•••••							
		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%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/49 (0%)			
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)			
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/49 (0%)				
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)			
verall Incidence	Total	5/1196 (0.42%)	Mean 0.42%	SD 1.18%	Total	1/1091 (0.09%)	Mean 0.09%	SD 0.43%			

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

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^{#:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

					Male				Female					
Adrenal Medulla:					,									
Pheochromocytoma Ma	alignant													
		0/50	(0%)	3/50	(6%)	0/50	(0%)		0/50	(0%)	2/50	(4%)		
		1/50	(2%)	0/50	(0%)	4/50	(8%)		1/50	(2%)	0/50	(0%)	0/49	(0%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		3/50	(6%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	2/50	(4%)		0/49	(0%)	1/48	(2%)	0/49	(0%)
		2/50	(4%)	3/49	(6%)	1/49	(2%)		0/50	(0%)	0/50	(0%)	1/49	(2%)
		1/50	(2%)	1/50	(2%)	1/50	(2%)		1/50	(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	27/1196 (2.	,	Mean 2.		SD 2.54%		Total	8/1091 (0	.73%)	Mean	0.74%	SD 1.	33%
Adrenal Medulla: Pheochromocytoma: B	Benign, Comple	x, Malignant, No 8/50	OS (16%)	11/50	(22%)	8/50	(16%)		0/50	(0%)	3/50	(6%)		
		7/50	(14%)	5/50	(10%)	6/50	(12%)		3/50	(6%)	1/50	(2%)	0/49	(0%)
		13/50	(26%)	9/50	(10%)	5/50	(12%)		2/50	(4%)	0/50	(0%)	0/49	(0%)
		7/50	(14%)	8/50	(16%)	11/50	(22%)		2/50	(4%)	3/50	(6%)	2/50	(4%)
		8/50	(16%)	10/50	(20%)	10/50	(20%)		0/49	(0%)	3/48	(6%)	1/49	(2%)
		13/50	(26%)	10/30	(20%)	7/49	(14%)		1/50	(2%)	1/50	(2%)	3/49	(6%)
		6/50	(12%)	10/49	(20%)	11/50	(22%)		3/50	(6%)	4/49	(8%)	3/43	(070)
			(14%)	10/50	(20%)		(18%)		1/49	(2%)	1/49	(2%)	2/50	(4%)
					(20/0)		(10/0)			(2/0)		(2/0)		(4/0)
Word! Incidence	Total	7/49	` ,		170/		y` ´	Total		, ,		2 20/		E 10/
Overall Incidence	Total	209/1196 (17	` ,	Mean 17	.47%	SD 4.51%	% 	Total	36/1091 (, ,		3.3%	SD 2.	54%
	Total		` ,				%	Total		, ,		3.3%		.54%
Blood Vessel:	Total		` ,		(0%)		(0%)	Total		, ,		(0%)		
Blood Vessel:	Total	209/1196 (17	7.47%)	Mean 17		SD 4.51%		Total	36/1091 (3.3%)	Mean			(0%)
Blood Vessel:	Total	209/1196 (17	(0%)	Mean 17	(0%)	SD 4.51%	(0%)	Total	36/1091 ((0%)	Mean 0/50	(0%)	SD 2.	
Blood Vessel:	Total	209/1196 (17 0/50 0/50	(0%) (0%)	Mean 17 0/50 0/50	(0%) (0%)	SD 4.51% 0/50 0/50	(0%) (0%)	Total	36/1091 ((0%)	Mean 0/50 0/50	(0%) (0%)	SD 2.	(0%)
Blood Vessel:	Total	209/1196 (17 0/50 0/50 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 0/50 0/50	(0%) (0%) (0%)	0/50 0/50 0/50 0/50	(0%) (0%) (0%)	Total	36/1091 (0/50 0/50 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 0/50	(0%) (0%) (0%)	SD 2. 0/50 0/50	(0%) (0%)
Blood Vessel:	Total	0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%) (0%)	0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%)	Total	36/1091 (0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%) (0%)	0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%)	SD 2. 0/50 0/50 0/50	(0%) (0%) (0%)
Blood Vessel:	Total	0/50 0/50 0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%) (0%) (0%)	0/50 0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%) (0%)	0/50 0/50 0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%) (0%)	Total	36/1091 (0/50 0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%) (0%) (0%)	0/50 0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%) (0%)	SD 2. 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%)
Dverall Incidence #Blood Vessel: Osteosarcoma	Total	0/50 0/50 0/50 0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%) (0%) (0%) (0%) (0%)	0/50 0/50 0/50 0/50 0/50 0/50 0/50 0/49	(0%) (0%) (0%) (0%) (0%) (0%)	0/50 0/50 0/50 0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%) (0%) (0%)	Total	36/1091 (0/50 0/50 0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%) (0%) (0%) (0%)	0/50 0/50 0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%) (0%) (0%)	SD 2. 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%)

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

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^{#:} 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

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Report Date: 05/27/2022

Species: RATS

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		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%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/1199 (0%)	Mean 0%	SD 0%	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%
#Bone:								
Chondrosarcoma or C	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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	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	0/1199 (0%)	Mean 0%	SD 0%	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%
Bone:		•••••						
Chordoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	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%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	5/1199 (0.42%)	Mean 0.42%	SD 0.83%	Total	0/1100 (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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male			Female
#Bone: Osteoma						
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/	/50 (0%)
		0/50 (0%)	` ,	. ,	` '	/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/	/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/	/50 (0%) 0/50 (0%)
		2/50 (4%)	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%)
		0/50 (0%)	0/50 (0%) 0/50	(0%)	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	2/1199 (0.17%)	Mean 0.17% SD 0.82%	Total 0/	/1100 (0%)	Mean 0% SD 0%
			•••••	•••••		•••••
#Bone:						
Osteosarcoma		0/50 (0%)	0/50 (0%) 0/50	(00/)	0/50 (0%) 0/	/FO (09/)
		0/50 (0%)	` ,	(0%) (0%)	` '	/50 (0%) /50 (0%) 0/50 (0%)
		1/50 (2%)	` ,	,	, ,	/50 (0%) 0/50 (0%) /50 (0%) 1/50 (2%)
		2/50 (4%)	` ,	. ,	` '	/50 (0%) 1/50 (2%)
		0/50 (0%)	` ,	. ,	` ,	/50 (2%) 1/50 (2%) /50 (2%) 0/50 (0%)
		1/50 (2%)	` ,	,	` '	/50 (0%) 0/50 (0%)
		2/50 (4%)	` ,	,	` '	/50 (2%)
		0/50 (0%)	` ,	,	` '	/50 (0%) 0/50 (0%)
Overall Incidence	Total	` '	Mean 0.67% SD 1.28%	,	, ,	Mean 0.45% SD 0.86%
		8/1199 (0.67%)		10tai 5/1	100 (0.45%) N	
#Bone:						
Osteosarcoma or Oste	eoma	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%)	` ,	. ,	` '	/50 (0%) 0/50 (0%) /50 (0%) 1/50 (2%)
		2/50 (4%)	` ,	· ,	` ,	/50 (0%) 1/50 (2%)
		2/50 (4%)	` ,	,	` '	/50 (2%) 1/50 (2%) /50 (2%) 0/50 (0%)
		1/50 (4%)	` ,	. ,	` '	/50 (2%)
		2/50 (4%)	` ,	· ,	` ,	/50 (2%)
		0/50 (4%)	` ,	,	` ,	/50 (2%) /50 (0%) 0/50 (0%)
Overell Incidence	Tatal	` '	, ,	,	, ,	` ,
Overall Incidence	Total	10/1199 (0.83%)	Mean 0.84% SD 1.44%	Total 5/1	100 (0.45%) N	Mean 0.45% SD 0.86%

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

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^{#:} Denominator is number of animals necropsied

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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES **Page:** 15 Report Date: 05/27/2022

			Male				Female	
Brain:								
Astrocytoma Malignant				- / / /				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/49 (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	4/1198 (0.33%)	Mean 0.33%	SD 0.76%	Total	1/1098 (0.09%)	Mean 0.09%	SD 0.43%
*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%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		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%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/1198 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1098 (0%)	Mean 0%	SD 0%
		, ,				` '		
*Brain: Glioma Malignant								
Onoma mangnam		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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%)	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%)	3/30 (0/0)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overell Incidence	Total	` '	, ,	, ,	Total	` '	` '	` '
Overall Incidence	Total	1/1198 (0.08%)	Mean 0.08%	SD 0.41%	Total	2/1098 (0.18%)	Mean 0.18%	SD 0.59%

^{*:} 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 Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Brain: **Granular Cell Tumor Benign** 0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/49 (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 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)2/1198 (0.17%) Mean 0.17% SD 0.82% Mean 0.09% SD 0.43% Overall Incidence Total Total 1/1098 (0.09%) *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%)0/50 (0%)0/49 (0%)(0%) (0%) (0%)0/50 0/50 0/50 0/50 0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)(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%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/49 **Overall Incidence** 1/1198 (0.08%) Mean 0.08% SD 0.41% 0/1098 (0%) Mean 0% SD 0% Total Total *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%)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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (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%)1/50 (2%)0/50 (0%)0/49 (0%)

SD 0%

1/1098 (0.09%)

Total

Mean 0.09%

SD 0.43%

Total

0/1198 (0%)

Mean 0%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

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

Length of Study: CHRONIC

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					Male						F	emale		
*Brain:														
Meningioma: Benign, M	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%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/40	(00()
	-	0/50	(0%)	0/50	(0%)	0/50	(0%)	.	1/50	(2%)	0/50	(0%)	0/49	(0%)
Overall Incidence	Total	0/1198 (0	,	Mean		SD 0%		Total	1/1098 (0	,		0.09%	SD 0	
Brain:														
Oligodendroglioma Be	enign													
	_	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/49	(0%)	0/50	(0%)		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%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/49	(0%)
Overall Incidence	Total	2/1198 (0.1		Mean 0		SD 0.569		Total	0/1098			n 0%	SD	
Brain:														
Oligodendroglioma Ma	alignant													
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(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%)
		0/50	(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%)	0/49	(0%)
Overall Incidence	Total	1/1198 (0.0	8%)	Mean 0	.08%	SD 0.419	%	Total	2/1098 (0).18%)	Mean	0.18%	SD 0	.59%

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
Brain:								
Oligodendroglioma, Glid	oma, or Astroc	ytoma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/49 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	8/1198 (0.67%)	Mean 0.67%	SD 1.13%	Total	5/1098 (0.46%)	Mean 0.45%	SD 1.22%
Clitoral/Preputial Gland:								
Adenoma		0/50 (00/)	4/50 (00/)	E/EO (400/)		0/50 (00/)	40/50 (000/)	
		0/50 (0%)	1/50 (2%)	5/50 (10%)		3/50 (6%)	10/50 (20%)	0/50 (40/)
		0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%)	6/50 (12%)	2/50 (4%)
		0/48 (0%)	1/50 (2%)	5/50 (10%)		0/50 (0%)	2/50 (4%)	3/50 (6%)
		2/50 (4%)	0/50 (0%)	1/50 (2%)		3/48 (6%)	0/50 (0%)	7/50 (14%)
		0/50 (0%)	2/50 (4%)	0/50 (0%)		5/50 (10%)	8/50 (16%)	0/50 (0%)
		5/50 (10%)	3/49 (6%)	4/50 (8%)		7/50 (14%)	4/50 (8%)	2/50 (4%)
		0/50 (0%)	4/50 (8%)	2/50 (4%)		0/49 (0%)	17/50 (34%)	44/40 (000/)
	.	3/50 (6%)	1/48 (2%)	1/48 (2%)	-	8/50 (16%)	5/50 (10%)	11/49 (22%)
Overall Incidence	Total	43/1193 (3.6%)	Mean 3.6%	SD 3.49%	Total	104/1096 (9.49%)	Mean 9.49%	SD 8.61%
Clitoral/Preputial Gland: Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	2/50 (4%)
		0/48 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	0/50 (0%)		2/48 (4%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		3/50 (6%)	2/50 (4%)	1/50 (2%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	8/50 (16%)
		0/50 (0%)	2/50 (4%)	1/50 (2%)		1/49 (2%)	0/50 (0%)	
		0/50 (0%)	0/48 (0%)	3/48 (6%)		1/50 (2%)	1/50 (2%)	3/49 (6%)
Overall Incidence	Total	16/1193 (1.34%)	Mean 1.34%	SD 1.77%	Total	29/1096 (2.65%)	Mean 2.65%	SD 3.57%

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

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^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		1/50 (2%)	1/50 (2%)	5/50 (10%)		4/50 (8%)	10/50 (20%)	
		0/50 (0%)	2/50 (4%)	2/50 (4%)		3/50 (6%)	6/50 (12%)	4/50 (8%)
		0/48 (0%)	2/50 (4%)	6/50 (12%)		0/50 (0%)	2/50 (4%)	3/50 (6%)
		4/50 (8%)	1/50 (2%)	1/50 (2%)		5/48 (10%)	1/50 (2%)	8/50 (16%)
		0/50 (0%)	2/50 (4%)	2/50 (4%)		8/50 (16%)	10/50 (20%)	1/50 (2%)
		5/50 (10%)	3/49 (6%)	4/50 (8%)		7/50 (14%)	4/50 (8%)	10/50 (20%)
		0/50 (0%)	5/50 (10%)	3/50 (6%)		1/49 (2%)	17/50 (34%)	
		3/50 (6%)	1/48 (2%)	4/48 (8%)		9/50 (18%)	6/50 (12%)	14/49 (29%)
verall Incidence	Total	57/1193 (4.78%)	Mean 4.77%	SD 3.64%	Total	133/1096 (12.14%)	Mean 12.14%	SD 8.87%
Fibrosarcoma		0/50 (0%) 0/50 (0%) 0/48 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/48 (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%)	1/50 (2%) 0/50 (0%) 0/49 (0%)
verall Incidence	Total	0/1193 (0%)	Mean 0%	SD 0%	Total	1/1096 (0.09%)	Mean 0.09%	SD 0.43%
Clitoral/Preputial Gland: Squamous Cell Papillon		0/50 (0%) 0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)		0/48 (0%) 1/50 (2%) 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%)	0/48 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/1193 (0.08%)	Mean 0.08%	SD 0.41%	Total	2/1096 (0.18%)	Mean 0.18%	SD 0.59%

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

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Toxicology Data Management System

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Report Date: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** #Ear: **Neural Crest Tumor** 0/50 (0%)0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/49 (2%)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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/1100 (0%) 2/1199 (0.17%) Mean 0.17% SD 0.57% SD 0% Overall Incidence Total Total Mean 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%)0/50 (0%)(0%) (0%) (0%)0/50 0/50 0/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)**Overall Incidence** Total 0/1199 (0%) Mean 0% SD 0% 1/1100 (0.09%) Mean 0.09% SD 0.43% Total #Eye: Amelanotic 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%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

0/50

0/50

SD 0%

(0%)

(0%)

Total

0/50

0/50

1/1100 (0.09%)

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0.09%

0/50

SD 0.43%

(0%)

Total

0/50

0/50

0/1199 (0%)

(0%)

(0%)

0/50

0/50

Mean 0%

(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: ALL ROUTES

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Report Date: 05/27/2022

Species: RATS Strain: F 344/N

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
⊭Eye:								
Melanoma 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%	, , ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	, , ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	, , ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	, , ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	, , ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%	6) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/1199 (0%)	Mean 0%	SD 0%	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%
‡Eye:								
Schwannoma Malignant								
		0/50 (0%	6) 0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%	6) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	6) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	6) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	5) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	6) 0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	6) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%	5) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (0%)	Mean 0%	SD 0%
Harderian Gland:			•••••			•••••		
Adenoma								
		0/50 (0%	6) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%	6) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	6) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	6) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	6) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	6) 0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	6) 0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%	6) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male	Female
#Harderian Gland: Carcinoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/1199 (0.08%)	Mean 0.08% SD 0.41%	Total 0/1100 (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%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/1199 (0.17%)	Mean 0.17% SD 0.56%	Total 0/1100 (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%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/49 (0%) 1/50 (2%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	2/1199 (0.17%)	Mean 0.17% SD 0.57%	Total 3/1099 (0.27%) Mean 0.27% SD 0.7%

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

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^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Heart:								
Schwannoma Malignar	nt							
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	. (=== (==:)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (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%)
Overall Incidence	Total	4/1199 (0.33%)	Mean 0.33%	SD 0.76%	Total	4/1099 (0.36%)	Mean 0.36%	SD 0.79%
fintestine Large: Colon/F Adenoma	Rectum:							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		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%)
Overall Incidence	Total	2/1199 (0.17%)	Mean 0.17%	SD 0.56%	Total	2/1100 (0.18%)	Mean 0.18%	SD 0.59%
fintestine Large: Colon/f Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
O	T-1-!	0/50 (0%)	1/50 (2%)	0/50 (0%)	T-1-1	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%

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

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^{#:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Large: Colon/Red Carcinoma or Adenoma	ctum:							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/1199 (0.25%)	Mean 0.25%	SD 0.68%	Total	3/1100 (0.27%)	Mean 0.27%	SD 0.7%
fIntestine Large: Colon/Red Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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	0/1199 (0%)	Mean 0%	SD 0%	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%
#Intestine Small: Duodenur Carcinoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
fIntestine Small: Duodenum Leiomyoma	n:							
Loiomyoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	(,
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/1199 (0%)	Mean 0%	SD 0%	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%
fintestine Small: Jejunum:								
Leiomyoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (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%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/30 (0/0)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/1199 (0%)	Mean 0%	SD 0%	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%

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

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^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Small: Site Unspecified: Carcinoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/1199 (0.08%) Mean 0.08% SD 0.41% 0/1100 (0%) SD 0% Total Total Mean 0% #Intestine Small: Site Unspecified: Carcinoma or Adenoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) (0%) (0%)0/50 0/50 0/50 0/50 0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)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** 1/1199 (0.08%) Mean 0.08% SD 0.41% 0/1100 (0%) Mean 0% SD 0% Total Total #Intestine Small: Site Unspecified: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (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%)0/50 (0%)0/50 (0%)0/50 (0%)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 0.41%

Total

1/1100 (0.09%)

Mean 0.09%

SD 0.43%

Total

1/1199 (0.08%)

Mean 0.08%

Overall Incidence

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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

Toxicology Data Management System

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(0%)

Mean 0.36%

1/50

SD 1%

(2%)

0/50

Report Date: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** #Intestine Small: Site Unspecified: Leiomyosarcoma 0/50 (0%)0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/1199 (0%) Mean 0% SD 0% 1/1100 (0.09%) Mean 0.09% SD 0.43% Total Total *Islets. Pancreatic: Adenoma 1/49 1/50 (2%)1/50 (2%)(2%)0/50 (0%)2/49 (4%)1/50 (2%)6/50 (12%)5/50 (10%)1/50 (2%)0/50 (0%)0/50 (0%)5/50 (4%)0/50 (10%)2/50 (4%)2/50 1/50 (2%)1/50 (2%)(0%)4/50 (8%)3/50 (6%)4/50 (8%) 0/50 (0%)0/50 (0%)2/49 (4%)3/50 0/50 (0%)3/50 (6%)3/50 (6%)0/50 (0%)0/49 (0%)(6%)2/50 (4%)4/49 (8%)4/50 (8%) 1/50 (2%)1/50 (2%)2/50 (4%)3/50 3/50 (6%)(6%)3/49 (6%)1/49 (2%)3/49 (6%)5/48 (10%)3/50 (6%)0/47 (0%)1/50 (2%)2/50 (4%)5/49 (10%)**Overall Incidence** 73/1194 (6.11%) Mean 6.12% SD 3.18% 21/1092 (1.92%) Mean 1.92% SD 2.02% Total Total *Islets, Pancreatic: Carcinoma 0/50 (0%)1/50 (2%)1/49 (2%)0/50 (0%)0/49 (0%)2/50 (4%)0/50 (0%)2/50 (4%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)4/50 (8%) 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)0/49 (0%)(0%)1/50 (2%)5/49 (10%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)0/49 (0%)0/49 (0%)0/49 (0%)

2/50

SD 2.62%

(4%)

0/47

4/1092 (0.37%)

Total

(0%)

Total

0/48

27/1194 (2.26%)

(0%)

1/49

Mean 2.26%

(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

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
slets, Pancreatic:	_							
Carcinoma or Adenom	ıa	1/50 (20/)	2/50 (4%)	2/49 (4%)		0/50 (00/)	2/40 (40/)	
		1/50 (2%) 3/50 (6%)	2/50 (4%) 6/50 (12%)	2/49 (4%) 7/50 (14%)		0/50 (0%) 2/50 (4%)	2/49 (4%) 0/50 (0%)	0/50 (0%)
		6/50 (12%)	3/50 (6%)	4/50 (8%)		1/50 (4%)	1/50 (2%)	0/50 (0%)
		4/50 (8%)	7/50 (14%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	2/49 (4%)
		0/50 (0%)	3/50 (14%)	4/50 (8%)		2/50 (4%)	0/49 (0%)	3/50 (6%)
		3/50 (6%)	9/49 (18%)	4/50 (8%)		1/50 (2%)	1/50 (2%)	2/50 (4%)
		4/50 (8%)	5/50 (10%)	3/49 (6%)		1/49 (2%)	3/49 (6%)	2/30 (4/0)
		5/48 (10%)	6/49 (12%)	5/50 (10%)		0/47 (0%)	1/50 (2%)	3/50 (6%)
verall Incidence	Total	100/1194 (8.38%)	Mean 8.38%	SD 4.12%	Total	25/1092 (2.29%)	Mean 2.29%	SD 2.18%
idney: Pelvis and Tran		ium:						
Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/49 (0%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	
		0/49 (0%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
erall Incidence	Total	2/1190 (0.17%)	Mean 0.17%	SD 0.56%	Total	0/1093 (0%)	Mean 0%	SD 0%
(idney: Pelvis and Tran		ium:						
Carcinoma or Adenom	ıa							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/49 (0%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/50 (00/)
		0/49 (0%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/1190 (0.17%)	Mean 0.17%	SD 0.56%	Total	0/1093 (0%)	Mean 0%	SD 0%

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

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^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Kidney: Pelvis and Trans Papilloma	itional Epitheli	ium:						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	1/48 (2%)	0/49 (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%)	0/49 (0%)		0/49 (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	0/1190 (0%)	Mean 0%	SD 0%	Total	1/1093 (0.09%)	Mean 0.09%	SD 0.44%
Kidney: Renal Tubule: Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/49 (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%)	0/49 (0%)		0/49 (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	5/1190 (0.42%)	Mean 0.42%	SD 0.83%	Total	1/1093 (0.09%)	Mean 0.09%	SD 0.43%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/49 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/49 (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	2/1190 (0.17%)	Mean 0.17%	SD 0.56%	Total	0/1093 (0%)	Mean 0%	SD 0%

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

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^{#:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Kidney: Renal Tubule:								
Carcinollia of Aueriollia		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/49 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	1/50 (2%)	(****)
		1/49 (2%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	7/1190 (0.59%)	Mean 0.59%	SD 1.1%	Total	1/1093 (0.09%)	Mean 0.09%	SD 0.43%
Kidney: Renal Tubule: Hemangiosarcoma						•••••		
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/49 (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%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	
		0/49 (0%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/1190 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1093 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/49 (0%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	
		0/49 (0%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/1190 (0.17%)	Mean 0.17%	SD 0.56%	Total	0/1093 (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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Kidney: Renal Tubule: Liposarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/47 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/49 (0%)0/49 0/50 (0%)0/49 (0%)0/49 (0%)0/47 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/1190 (0.08%) Mean 0.08% SD 0.41% 0/1093 (0%) SD 0% Total Total Mean 0% *Kidney: Renal Tubule: **Mesenchymal Tumor Benign** 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/47 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%) (0%)0/50 0/50 (0%)0/50 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 0/47 **Overall Incidence** 1/1190 (0.08%) Mean 0.08% SD 0.41% Total 0/1093 (0%) Mean 0% SD 0% Total *Kidney: Renal Tubule: Nephroblastoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/47 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/47 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

1/1093 (0.09%)

Mean 0.09%

SD 0.43%

Total

0/1190 (0%)

Mean 0%

Overall Incidence

^{*:} 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: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Kidney: Renal Tubule: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/47 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)0/49 (0%)1/48 (2%)0/50 (0%)0/50 (0%)0/48 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/49 (0%)0/49 0/50 (0%)0/49 (0%)0/49 (0%)0/47 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/1190 (0.08%) Mean 0.09% SD 0.43% 0/1093 (0%) SD 0% Total Total Mean 0% *Liver: Cholangiocarcinoma 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%)0/50 (0%)0/50 (0%)(0%) (0%) (0%)0/50 0/50 0/50 0/50 0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(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%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/1199 (0.08%) Mean 0.08% SD 0.41% 1/1099 (0.09%) Mean 0.09% SD 0.43% Total Total *Liver: Cholangioma 0/50 (0%)1/50 (2%)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%)0/49 (0%)0/50 (0%)

Total

0/50

1/1199 (0.08%)

(0%)

0/50

Mean 0.08%

(0%)

0/50

SD 0.41%

(0%)

0/50

0/1099 (0%)

Total

(0%)

0/50

(0%)

Mean 0%

0/50

SD 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
Liver:				,				
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%)
		0/50 (0%)	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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/1199 (0.17%)	Mean 0.17%	SD 0.56%	Total	0/1099 (0%)	Mean 0%	SD 0%
Liver:								
Hepatocellular Adenoma								
·		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	6/50 (12%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/49 (0%)	0/50 (0%)	,
		1/50 (2%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	10/1199 (0.83%)	Mean 0.83%	SD 1.31%	Total	14/1099 (1.27%)	Mean 1.27%	SD 2.8%
Liver:		•••••	•••••	•••••	• • • • • • • • • • • • • • • • • • • •			• • • • • • • • • • • • • • • • • • • •
Hepatocellular Carcinoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/1199 (0.17%)	Mean 0.17%	SD 0.57%	Total	0/1099 (0%)	Mean 0%	SD 0%
		2/1100 (0.1770)				` '		

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

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^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Liver: Hepatocellular Carcinoma or Hepatoblastoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0.17% SD 0.57% 0/1099 (0%) SD 0% Overall Incidence Total 2/1199 (0.17%) Total Mean 0% *Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 2/50 (4%)1/50 (2%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)6/50 (12%)0/50 (0%)(0%) (0%) 0/50 0/50 0/50 0/50 (0%)2/50 (4%)(0%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)2/50 (4%)1/50 (2%)0/49 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)12/1199 (1%) **Overall Incidence** Mean 1% SD 1.32% 14/1099 (1.27%) Mean 1.27% SD 2.8% Total Total *Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 1/50 (2%)0/50 (0%)0/50 (0%)2/50 (4%)2/50 (4%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)6/50 (12%)(4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)2/50 (4%)1/50 (2%)0/49 (0%)0/50 (0%)(0%) 1/50 (2%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 0/50 (0%)**Overall Incidence** Total 12/1199 (1%) Mean 1% SD 1.32% 14/1099 (1.27%) Mean 1.27% SD 2.8% Total

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/27/2022

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
Lung:								
Alveolar/Bronchiolar A	Adenoma					., ,,		
		4/50 (8%)	0/50 (0%)	1/50 (2%)		4/50 (8%)	1/50 (2%)	2/22 (22/)
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	4/50 (8%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		3/50 (6%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	1/49 (2%)	4/50 (8%)		4/50 (8%)	0/50 (0%)	4/50 (8%)
		1/50 (2%)	2/50 (4%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	. (=== (==:)
		2/50 (4%)	3/50 (6%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	31/1199 (2.59%)	Mean 2.59%	SD 2.6%	Total	24/1099 (2.18%)	Mean 2.18%	SD 2.95%
Lung:								
Alveolar/Bronchiolar (Carcinoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	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%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/49 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	3/50 (6%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	15/1199 (1.25%)	Mean 1.25%	SD 1.54%	Total	6/1099 (0.55%)	Mean 0.55%	SD 0.91%
Lung:								
Alveolar/Bronchiolar (Carcinoma or Al	veolar/Bronchiolar Aden 4/50 (8%)		1/50 (2%)		4/50 (8%)	1/50 (2%)	
		` ,	, ,	` '		` '	` ,	0/50 (0%)
		2/50 (4%) 1/50 (2%)	2/50 (4%) 1/50 (2%)	1/50 (2%) 1/50 (2%)		1/50 (2%) 0/50 (0%)	4/50 (8%) 2/50 (4%)	0/50 (0%) 0/50 (0%)
		4/50 (8%)	0/50 (2%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		(- · - /	` ,	` '		0/50 (2%)	0/50 (2%)	` '
		4/50 (8%) 3/50 (6%)	0/50 (0%) 1/49 (2%)	0/50 (0%) 4/50 (8%)		4/50 (8%)	1/50 (2%)	0/50 (0%) 4/50 (8%)
		(,	` ,	` '		(,	` ,	4/30 (070)
		(/	3/50 (6%) 4/50 (8%)	` '		()	1/50 (2%)	2/50 (49/)
0	T-1-1	(/	` '	` '	T-1-1	()	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	46/1199 (3.84%)	Mean 3.84%	SD 2.94%	Total	29/1099 (2.64%)	Mean 2.64%	SD 2.92%

^{*:} 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: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Lung: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/1199 (0.08%) Mean 0.08% SD 0.41% 0/1099 (0%) SD 0% Overall Incidence Total Total Mean 0% *Lung: Sarcoma 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%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%) (0%)0/50 0/50 (0%)0/50 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)0/49 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/1199 (0.08%) Mean 0.08% SD 0.41% 0/1099 (0%) Mean 0% SD 0% Total Total *Lung: **Squamous Cell Carcinoma** 0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)

0/50

0/50

SD 0.56%

(0%)

(0%)

Total

0/49

0/50

1/1099 (0.09%)

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0.09%

0/50

SD 0.43%

(0%)

Total

0/50

0/50

2/1199 (0.17%)

(0%)

(0%)

0/50

0/50

Mean 0.17%

(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 SystemTumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
#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%)
		1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	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	1/1199 (0.08%)	Mean 0.08% SD 0.41%	Total 0/1100 (0%) Mean 0% SD 0%
#Mammary Gland: Adenoma				
		0/50 (0%)	0/50 (0%) 1/50 (2%)	2/50 (4%) 1/50 (2%)
		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%) 2/50 (4%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	2/49 (4%) 0/50 (0%)	0/50 (0%) 3/50 (6%) 2/50 (4%)
		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 3/50 (6%)
Overall Incidence	Total	5/1199 (0.42%)	Mean 0.42% SD 1.03%	Total 15/1100 (1.36%) Mean 1.36% SD 2.08%
#Mammary Gland: Carcinoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		2/50 (4%)	0/50 (0%) 0/50 (0%)	10/50 (20%) 2/50 (4%) 4/50 (8%)
		1/50 (2%)	0/50 (0%) 0/50 (0%)	3/50 (6%) 2/50 (4%) 0/50 (0%)
		0/50 (0%)	2/50 (4%) 0/50 (0%)	4/50 (8%) 5/50 (10%) 1/50 (2%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	4/50 (8%) 2/50 (4%) 3/50 (6%)
		0/50 (0%)	0/49 (0%) 1/50 (2%)	0/50 (0%) 7/50 (14%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	4/50 (8%) 1/50 (2%)
		1/50 (2%)	1/50 (2%) 0/50 (0%)	3/50 (6%) 2/50 (4%) 3/50 (6%)
Overall Incidence	Total	8/1199 (0.67%)	Mean 0.67% SD 1.27%	Total 60/1100 (5.45%) Mean 5.45% SD 4.94%

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

Page: 37

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female	
#Mammary Gland: Carcinoma or Adenoma							
		0/50 (0%)	0/50 (0%) 1	/50 (2%)	2/50 (4%)	1/50 (2%)	
		2/50 (4%)	0/50 (0%) 0)/50 (0%)	10/50 (20%)	3/50 (6%)	4/50 (8%)
		1/50 (2%)	1/50 (2%) 0)/50 (0%)	3/50 (6%)	2/50 (4%)	2/50 (4%)
		0/50 (0%)	2/50 (4%) 0)/50 (0%)	4/50 (8%)	5/50 (10%)	2/50 (4%)
		0/50 (0%)	0/50 (0%) 0)/50 (0%)	4/50 (8%)	2/50 (4%)	3/50 (6%)
		0/50 (0%)	2/49 (4%) 1	/50 (2%)	0/50 (0%)	10/50 (20%)	2/50 (4%)
		0/50 (0%)	` ,	/50 (2%)	4/50 (8%)	1/50 (2%)	
		1/50 (2%)	1/50 (2%) 0)/50 (0%)	3/50 (6%)	2/50 (4%)	6/50 (12%)
verall Incidence	Total	13/1199 (1.08%)	Mean 1.09% SD	1.45%	5/1100 (6.82%)	Mean 6.82%	SD 5.08%
Mammary Gland: Fibroadenoma							
		2/50 (4%)	2/50 (4%) 0)/50 (0%)	27/50 (54%)	29/50 (58%)	
		0/50 (0%)	1/50 (2%) 0)/50 (0%)	24/50 (48%)	14/50 (28%)	12/50 (24%)
		1/50 (2%)	2/50 (4%) 1	/50 (2%)	20/50 (40%)	33/50 (66%)	29/50 (58%)
		4/50 (8%)	2/50 (4%) 2	2/50 (4%)	26/50 (52%)	22/50 (44%)	28/50 (56%)
		0/50 (0%)	3/50 (6%) 1	/50 (2%)	26/50 (52%)	24/50 (48%)	22/50 (44%)
		0/50 (0%)	1/49 (2%) 2	2/50 (4%)	17/50 (34%)	26/50 (52%)	37/50 (74%)
		3/50 (6%)	3/50 (6%) 1	/50 (2%)	19/50 (38%)	43/50 (86%)	
		4/50 (8%)	6/50 (12%) 2	2/50 (4%)	32/50 (64%)	31/50 (62%)	33/50 (66%)
verall Incidence	Total	43/1199 (3.59%)	Mean 3.59% SD	3.01%	4/1100 (52.18%)	Mean 52.18%	SD 14.72%
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%)
		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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0)/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%) 0)/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0)/50 (0%)	0/50 (0%)	0/50 (0%)	, ,
		0/50 (0%)	` ,)/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)

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

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^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N **Toxicology Data Management System**

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

		Male					Female	
#Mammary Gland:								
Fibroma, Fibroadenom	a or Adenoma							
		2/50 (4%)	2/50 (4%)	1/50 (2%)		28/50 (56%)	30/50 (60%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		24/50 (48%)	15/50 (30%)	12/50 (24%)
		1/50 (2%)	4/50 (8%)	1/50 (2%)		20/50 (40%)	33/50 (66%)	30/50 (60%)
		4/50 (8%)	2/50 (4%)	2/50 (4%)		26/50 (52%)	22/50 (44%)	29/50 (58%)
		0/50 (0%)	3/50 (6%)	1/50 (2%)		26/50 (52%)	24/50 (48%)	22/50 (44%)
		0/50 (0%)	3/49 (6%)	2/50 (4%)		17/50 (34%)	28/50 (56%)	37/50 (74%)
		3/50 (6%)	3/50 (6%)	2/50 (4%)		19/50 (38%)	43/50 (86%)	
		4/50 (8%)	6/50 (12%)	2/50 (4%)		32/50 (64%)	31/50 (62%)	35/50 (70%)
Overall Incidence	Total	49/1199 (4.09%)	Mean 4.09%	SD 3.04%	Total	583/1100 (53%)	Mean 53%	SD 14.91%
#Mammary Gland:								
Fibroma, Fibroadenom	a, Carcinoma, c	or Adenoma						
		2/50 (4%)	2/50 (4%)	1/50 (2%)		28/50 (56%)	30/50 (60%)	
		2/50 (4%)	1/50 (2%)	0/50 (0%)		31/50 (62%)	17/50 (34%)	14/50 (28%)
		1/50 (2%)	4/50 (8%)	1/50 (2%)		22/50 (44%)	35/50 (70%)	30/50 (60%)
		4/50 (8%)	4/50 (8%)	2/50 (4%)		28/50 (56%)	26/50 (52%)	30/50 (60%)
		0/50 (0%)	3/50 (6%)	1/50 (2%)		28/50 (56%)	25/50 (50%)	24/50 (48%)
		0/50 (0%)	3/49 (6%)	3/50 (6%)		17/50 (34%)	31/50 (62%)	37/50 (74%)
		3/50 (6%)	3/50 (6%)	2/50 (4%)		23/50 (46%)	43/50 (86%)	
		5/50 (10%)	6/50 (12%)	2/50 (4%)		32/50 (64%)	31/50 (62%)	37/50 (74%)
Overall Incidence	Total	55/1199 (4.59%)	Mean 4.59%	SD 3.15%	Total	619/1100 (56.27%)	Mean 56.27%	SD 13.93%
#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%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	0/1199 (0%)	Mean 0%	SD 0%	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%

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

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^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

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

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** #Mesentery: Hemangiosarcoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)0/50 (0%)0/50 0/50 (0%)1/50 (0%)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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/1100 (0%) 3/1199 (0.25%) Mean 0.25% SD 0.68% SD 0% Overall Incidence Total Total Mean 0% #Mesentery: Osteosarcoma 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%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%) (0%)0/50 0/50 (0%)0/50 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/1199 (0.08%) Mean 0.08% SD 0.41% Total 0/1100 (0%) Mean 0% SD 0% Total #Mesentery: Rhabdomyosarcoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

Total

1/50

1/1199 (0.08%)

(2%)

0/50

Mean 0.08%

(0%)

0/50

SD 0.41%

(0%)

0/50

0/1100 (0%)

Total

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Overall Incidence

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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

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
Nose:								,
Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/49 (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	2/1196 (0.17%)	Mean 0.17%	SD 0.56%	Total	0/1096 (0%)	Mean 0%	SD 0%
Nose: Chondroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	(0,70)
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/1196 (0%)	Mean 0%	SD 0%	Total	1/1096 (0.09%)	Mean 0.09%	SD 0.43%
Nose:	• • • • • • • • • • • • • • • • • • • •							
Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (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	1/1196 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1096 (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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Nose:								
Squamous Cell Carcin	ioma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	2 (= 2 (22 ()
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/1196 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1096 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous	sa, Tongue, Phai							
	·	1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		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	5/1199 (0.42%)	Mean 0.42%	SD 0.83%	Total	6/1100 (0.55%)	Mean 0.55%	SD 1.1%
#Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Pha	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%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/1199 (0.25%)	Mean 0.25%	SD 0.68%	Total	4/1100 (0.36%)	Mean 0.36%	SD 0.79%

^{*:} 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

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

Route: ALL ROUTES

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

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			Male			Female
#Oral Cavity (Oral Mucosa						
Squamous Cell Carcino	ma, Papilloma	Squamous, or Papilloma				
		1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 3/50 (6%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%) 1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%) 1/50 (2%)
		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	8/1199 (0.67%)	Mean 0.67%	SD 0.96%	Total 10/1100 (0.91%)	Mean 0.91% SD 1.6%
#Oral Mucosa: Squamous Cell Carcino						
Squamous Cen Carcino	illa	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%) 1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
			()	1/50 (2%)	0/50 (0%)	0/50 (0%) 1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (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%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	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	3/1199 (0.25%)	Mean 0.25%	SD 0.68%	Total 4/1100 (0.36%)	Mean 0.36% SD 0.79%
#Oral Mucosa: Squamous Cell Papillon	na					
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total 1/1100 (0.09%)	Mean 0.09% SD 0.43%

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

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Report Date: 05/27/2022

Male				
Ovary: Granulosa Cell Tumor 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%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)
overall Incidence	Total	2/1098 (0.18%)	Mean 0.18%	SD 0.59%
	•••••			
Ovary:				
Granulosa Cell Tumor Malignant		0/50 (00/)	0/50 (00/)	
		0/50 (0%)	0/50 (0%)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
		()	` ,	0/50 (00/)
hisaali laaddanaa	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/1098 (0.09%)	Mean 0.09%	SD 0.43%
Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)
overall Incidence	Total	3/1098 (0.27%)	Mean 0.27%	SD 0.7%

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female		
Ovary: Granulosa-Theca Tum	nor Benign							
	J					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%)	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%)	0/50 (0%)
verall Incidence					Total	2/1098 (0.18%)	Mean 0.18%	SD 0.59%
Pancreas:								
Adenoma								
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	
		0/50 (0%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		7/50 (14%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/49 (2%)
		1/49 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	2/50 (4%)	3/49 (6%)		0/49 (0%)	0/50 (0%)	, ,
		0/48 (0%)	1/49 (2%)	0/49 (0%)		0/47 (0%)	0/50 (0%)	2/50 (4%)
verall Incidence	Total	21/1191 (1.76%)	Mean 1.76%	SD 3.2%	Total	3/1093 (0.27%)	Mean 0.27%	SD 0.94%
Pancreas: Carcinoma								
Carcinoma		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	
		0/50 (0%)	0/49 (0%)	0/49 (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%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	3/00 (0/0)
		0/48 (0%)	0/49 (0%)	0/49 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/1191 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1093 (0%)	Mean 0%	SD 0%
veran incluence	i Ulai	1/1191 (0.00/0)	WEATT 0.0070	3D 0.41/0	TULA	0/1093 (0/0)	IVICALI U/0	30 0/0

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Pancreas: Carcinoma or Adenoma 0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)3/50 (6%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)8/50 (16%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 1/49 (2%)(0%)1/49 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)1/50 (2%)0/49 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)3/49 (6%)0/49 (0%)0/50 (0%)0/48 (0%)1/49 (2%)0/49 (0%)0/47 (0%)0/50 (0%)2/50 (4%)**Overall Incidence** 22/1191 (1.85%) Mean 1.84% SD 3.54% 3/1093 (0.27%) Mean 0.27% SD 0.94% Total Total *Pancreas: **Mixed Tumor Benign** 0/49 1/50 (2%)0/49 (0%)(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%) (0%) (0%)0/50 0/50 0/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)(0%)0/50 (0%)2/49 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)(0%)(0%)(0%)0/47 (0%)0/50 0/50 (0%)0/48 0/49 0/49 (0%)**Overall Incidence** 4/1191 (0.34%) Mean 0.34% SD 0.98% 0/1093 (0%) Mean 0% SD 0% Total Total *Parathyroid Gland: Adenoma 0/49 (0%)1/45 (2%)1/46 (2%)0/47 (0%)0/48 (0%)0/45 (0%)0/49 (0%)0/49 (0%)0/49 (0%)0/46 (0%)0/45 (0%)0/46 (0%)0/48 (0%)0/49 (0%)0/49 (0%)0/46 (0%)0/48 (0%)0/47 (0%)0/49 (0%)0/50 (0%)0/47 (0%)0/46 (0%)0/47 (0%)0/47 (0%)1/48 (2%)0/47 (0%)0/49 (0%)0/50 (0%)0/43 (0%)1/45 (2%)0/47 (0%)0/46 (0%)0/47 (0%)0/49 (0%)0/46 (0%)0/50 (0%)0/44 (0%)0/48 (0%)0/49 (0%)0/42 (0%)0/50 (0%)1/46 (2%)0/49 (0%)0/50 (0%)0/42 (0%)0/47 (0%)

SD 0.9%

Total

0/1032 (0%)

Mean 0%

SD 0%

Total

5/1139 (0.44%)

Mean 0.45%

Overall Incidence

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^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

			Male			Female				
Peripheral Nerve:										
Schwannoma Malignant		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/=0 /00/)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
erall Incidence	Total	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (0%)	Mean 0%	SD 0%		
eripheral Nerve:										
Schwannoma: Benign, M	alignant, NOS	5								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (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%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (0%)	Mean 0%	SD 0%		
						······				
Pituitary Gland: Pars Dista Adenoma	ilis or Unspec	cified Site:								
		10/50 (20%)	10/50 (20%)	20/50 (40%)		17/50 (34%)	24/49 (49%)			
		36/50 (72%)	32/50 (64%)	29/50 (58%)		35/50 (70%)	35/50 (70%)	33/50 (66%)		
		36/50 (72%)	11/50 (22%)	15/50 (30%)		37/50 (74%)	22/50 (44%)	24/50 (48%)		
		19/50 (38%)	35/50 (70%)	25/50 (50%)		25/50 (50%)	24/49 (49%)	36/50 (72%)		
		9/50 (18%)	16/49 (33%)	34/49 (69%)		23/50 (46%)	29/48 (60%)	35/50 (70%)		
		6/50 (12%)	36/49 (73%)	16/50 (32%)		25/50 (50%)	30/50 (60%)	28/50 (56%)		
		38/50 (76%)	23/48 (48%)	22/49 (45%)		27/49 (55%)	28/50 (56%)	` '		
		23/50 (46%)	24/50 (48%)	16/48 (33%)		26/50 (52%)	27/49 (55%)	23/49 (47%)		

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male						ļ	Female		
Pituitary Gland: Pars Dis Carcinoma	stalis or Unspe	cified Site:										,
Carcinoma		0/50	(0%) 0/50	(0%)	0/50 (0%)	0/50	(0%)	1/49	(2%)		
		· ·	(0%) 0/50	(0%)	,)%))%)		(2%)	0/50	(2 %)	3/50	(6%)
			(0%) 0/50	(0%)	,)%)		(0%)	2/50	(4%)	1/50	(2%)
		· ·	(0%) 0/50	(0%)	,)%)		(0%)	0/49	(0%)	0/50	(0%)
		· ·	(0%) 0/49	(0%)	,)%)		(4%)	0/48	(0%)	0/50	(0%)
		· ·	(0%) 0/49	(0%)	,)%)		(0%)	0/50	(0%)	2/50	(4%)
			(2%) 0/48	(0%)	,)%)		(0%)	0/50	(0%)	2,00	(170)
			(0%) 0/50	(0%)	,)%)		(0%)	0/49	(0%)	1/49	(2%)
Overall Incidence	Total	6/1192 (0.5%)	` '	` '	SD 2.06%	Total	13/1093 (1.1	,		1.19%	SD 1	` '
Pituitary Gland: Pars Dis	stalis or Unspe											
Carcinoma or Adenom	a	40/50 /0	2007) 40/50	(000()	00/50 /4/	2077	47/50 /6	1407)	05/40	(540/)		
		`	20%) 10/50	(20%))%)	`	34%)	25/49	(51%)	20/50	(700/)
		,	72%) 32/50	(64%)	,	3%)	,	'2%) '40()	35/50	(70%)	36/50	(72%)
		`	72%) 11/50 38%) 35/50	(22%) (70%)	`)%))%)	`	'4%) 60%)	24/50 24/49	(48%) (49%)	25/50 36/50	(50%) (72%)
		`	18%) 35/30 16/49	(33%)	,	9%)	`	50%)	29/48	(49%)	35/50	(72%)
		`	16%) 16/49 12%) 36/49	(33%)	(-	2%)	`	50%)	30/50	(60%)	30/50	(60%)
		`	78%) 23/48	(48%)	,	5%)	,	55%)	28/50	(56%)	30/30	(60%)
		`	16%) 24/50	(48%)	,	3%)	`	52%)	27/49	(55%)	24/49	(49%)
Overall Incidence	Total	547/1192 (45.89	,	, ,	SD 20.69%	Total	626/1093 (57.	,		57.25%	SD 10	` ,
Pituitary Gland: Pars Int Adenoma									•••••			
		0/50	(0%) 0/50	(0%)	1/50 (2	2%)	0/50	(0%)	0/49	(0%)		
		0/50	(0%) 0/50	(0%)	2/50 (4	1%)	0/50	(0%)	0/50	(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 ()%)	0/50	(0%)	0/49	(0%)	0/50	(0%)
		· ·	(2%) 0/49	(0%)	`)%)		(0%)	0/48	(0%)	0/50	(0%)
			(0%) 1/49	(2%)		0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
			(0%) 0/48	(0%)		0%)		(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	6/1192 (0.5%)) Mean	0.5%	SD 1.07%	Total	2/1093 (0.18	3%)	Mear	0.18%	SD 0	.59%

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

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^{#:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Pituitary Gland: Pars Int	ermedia:							
		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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/48 (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%)	0/48 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	1/1192 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1093 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Int Carcinoma or Adenom	ermedia:							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	
		0/50 (0%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/48 (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%)	0/48 (0%)	0/49 (0%)		0/49 (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	7/1192 (0.59%)	Mean 0.59%	SD 1.38%	Total	2/1093 (0.18%)	Mean 0.18%	SD 0.59%
Prostate: Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	1/50 (2%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	1/50 (2%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/49 (0%)	2/50 (4%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/49 (0%)	0/50 (0%)				
verall Incidence	Total	4/1197 (0.33%)	Mean 0.33%	SD 0.96%				

^{*:} 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: ALL ROUTES

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

Page: 50

			Male		Female
*Prostate: Carcinoma or Adenoma					
Carcinoma or Adenoma		0/49 (0%)	0/50 (0%) 0/50 (0%)		
		0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%)		
		0/50 (0%)	0/50 (0%) 1/50 (2%)		
		0/50 (0%)	0/50 (0%) 0/50 (0%)		
		0/50 (0%)	0/50 (0%) 1/50 (2%)		
		0/50 (0%)	0/49 (0%) 2/50 (4%)		
		0/50 (0%)	0/50 (0%) 0/50 (0%)		
		0/50 (0%)	0/49 (0%) 0/50 (0%)		
Overall Incidence	Total	4/1197 (0.33%)	Mean 0.33% SD 0.96%		
*Salivary Glands:					
Sarcoma					
Sarcoma		0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 1/49 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (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%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/1195 (0.08%)	Mean 0.09% SD 0.42%	Total 0/1098 (0%)	Mean 0% SD 0%
		, ,		` ,	
*Salivary Glands: Schwannoma Malignant					
3		1/49 (2%)	0/50 (0%) 0/49 (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%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (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%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/1195 (0.08%)	Mean 0.09% SD 0.42%	Total 0/1098 (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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)		
Skeletal Muscle: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	` ,		
#Skeletal Muscle: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (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%)
		0/50 (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	2/1199 (0.17%)	Mean 0.17%	SD 0.56%	Total	` '	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (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%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skeletal Muscle:								
Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (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%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (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%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	2/1100 (0.18%)	Mean 0.18%	SD 0.59%
#Skeletal Muscle: Rhabdomyosarcoma or								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	2/1100 (0.18%)	Mean 0.18%	SD 0.59%

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

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^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			O/50 (0%)		
#Skeletal Muscle:								
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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/1199 (0.25%)	Mean 0.25%	SD 0.68%	Total	` '	Mean 0%	SD 0%
#Skin:								
Basal Cell Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	2/50 (4%)		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%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	12/1199 (1%)	Mean 1%	SD 1.32%	Total			
#Skin:	• • • • • • • • • • • • • • • • • • • •		•••••					
Basal Cell Adenoma or	Basosquamou	s Tumor Benign						
	-	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	2/50 (4%)		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%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	12/1199 (1%)	Mean 1%	SD 1.32%	Total	3/1100 (0.27%)	Mean 0.27%	SD 0.7%

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

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^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

					Male						F	emale		
#Skin:														
Basal Cell Adenoma, B	Basosquamous 1	Γumor Benign, α	or Trichoe	pithelioma										
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	1/50	(2%)	1/50	(2%)		0/50	(0%)	2/50	(4%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		1/50	(2%)	1/50	(2%)	1/50	(2%)		1/50	(2%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	1/49	(2%)	2/50	(4%)		1/50	(2%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	3/50	(6%)	1/50	(2%)		0/50	(0%)	0/50	(0%)		
		1/50	(2%)	2/50	(4%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	2/50	(4%)
Overall Incidence	Total	19/1199 (1.5		Mean 1.		SD 1.569		Total	9/1100 (0			0.82%	SD 1	33%
#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%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/49	(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%)		
		1/50	(2%)	2/50	(4%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	6/1199 (0.5	,	Mean 0		SD 1.069		Total	3/1100 (0	,		0.27%	SD 0	.7%
#Skin:		•••••							• • • • • • • • • • • • • • • • • • • •		• • • • • • • • • • • • • • • • • • • •			
Basal Cell Carcinoma	or Basosquamo	us Tumor (maliç	gnant or N	OS)										
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/49	(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%)		
		1/50	(2%)	2/50	(4%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	6/1199 (0.5	5%)	Mean 0	.5%	SD 1.069	%	Total	3/1100 (0	.27%)	Mean	0.27%	SD 0	.7%

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

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^{#:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin:						,		
Basal Cell Carcinoma, NOS), or Trichoepithel		noma, Basosquamous T	umor (benign, malignar	nt or				
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	1/49 (2%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	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%)
Overall Incidence	Total	25/1199 (2.09%)	Mean 2.09%	SD 2%	Total	12/1100 (1.09%)	Mean 1.09%	SD 1.82%
\$Skin:								
Basal or Sq. Cell Carci Adenoma, Papilloma,	inoma, Carcinoı Sq Papilloma, K	ma, Basosq. Tumor (M o Keratoacanthoma, Tricho	r B), Basal Cell Adenom epithelioma	na,				
		11/50 (22%)	4/50 (8%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	
		5/50 (10%)	2/50 (4%)	4/50 (8%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		2/50 (4%)	10/50 (20%)	4/50 (8%)		0/50 (0%)	4/50 (8%)	0/50 (0%)
		8/50 (16%)	0/50 (0%)	7/50 (14%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
		2/50 (4%)	3/50 (6%)	2/50 (4%)		2/50 (4%)	2/50 (4%)	0/50 (0%)
		3/50 (6%)	5/49 (10%)	5/50 (10%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)	6/50 (12%)	4/50 (8%)		1/50 (2%)	0/50 (0%)	
		7/50 (14%)	11/50 (22%)	5/50 (10%)		1/50 (2%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	112/1199 (9.34%)	Mean 9.34%	SD 6.15%	Total	24/1100 (2.18%)	Mean 2.18%	SD 2.46%
tSkin: Fibroma								
FIDIUIIIa		5/50 (10%)	4/50 (8%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	
		3/50 (10%)	7/50 (8%) 7/50 (14%)	5/50 (2%) 5/50 (10%)		0/50 (6%)	0/50 (0%)	0/50 (0%)
		5/50 (10%)	6/50 (12%)	5/50 (10%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		5/50 (10%)	4/50 (12%)	6/50 (10%)		0/50 (0%)	0/50 (2%)	1/50 (2%)
		2/50 (10%)	8/50 (8%) 8/50 (16%)	4/50 (8%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
		3/50 (4%)	3/49 (6%)	8/50 (16%)		2/50 (4%)	1/50 (2%)	1/50 (2%)
		2/50 (4%)	7/50 (14%)	6/50 (10%)		0/50 (4%)	1/50 (2%)	1/30 (2/0)
		5/50 (4%) 5/50 (10%)	8/50 (14%) 8/50 (16%)	9/50 (12%)		1/50 (0%)	0/50 (2%)	4/50 (8%)
Dunnell In airlange	Tatal	` '	` '	,	Tatal	` '	` ,	` ,
Overall Incidence	Total	121/1199 (10.09%)	Mean 10.09%	SD 4.23%	Total	19/1100 (1.73%)	Mean 1.73%	SD 2.07%

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

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#Skin:								
Fibroma, Fibrosarcom	ia, Sarcoma, My	xoma, Myxosarcoma, or	•					
		6/50 (12%)	4/50 (8%)	4/50 (8%)		4/50 (8%)	0/50 (0%)	
		3/50 (6%)	8/50 (16%)	5/50 (10%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		6/50 (12%)	7/50 (14%)	6/50 (12%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		7/50 (14%)	5/50 (10%)	8/50 (16%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		2/50 (4%)	8/50 (16%)	5/50 (10%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
		4/50 (8%)	4/49 (8%)	11/50 (22%)		3/50 (6%)	2/50 (4%)	1/50 (2%)
		3/50 (6%)	8/50 (16%)	7/50 (14%)		0/50 (0%)	1/50 (2%)	
		6/50 (12%)	9/50 (18%)	10/50 (20%)		1/50 (2%)	1/50 (2%)	4/50 (8%)
Overall Incidence	Total	146/1199 (12.18%)	Mean 12.17%	SD 4.6%	Total	25/1100 (2.27%)	Mean 2.27%	SD 2.41%
#Skin:								
Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	3/50 (6%)		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%)	1/49 (2%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0,00 (0,0)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	14/1199 (1.17%)	Mean 1.17%	SD 1.55%	Total	5/1100 (0.45%)	Mean 0.45%	SD 0.86%
		14/1199 (1.17/0)		3D 1.3370	ı Olai	3/1100 (0.43 %)	IVICALI 0.4570	3D 0.80%
Skin:								
Fibrosarcoma, Sarcom	na, Myxosarcom	a, or Fibrous Histiocyto	ma					
	. •	1/50 (2%)	0/50 (0%)	3/50 (6%)		1/50 (2%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	3/50 (6%)		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%)
		1/50 (2%)	1/49 (2%)	3/50 (6%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	3,30 (0,70)
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	` ,	` '	SD 1.76%	Total	` '	Mean 0.55%	` '
overan incluence	rotal	26/1199 (2.17%)	Mean 2.17%	JU 1./0%	างเลเ	6/1100 (0.55%)	เงเษสก บ.55%	SD 0.91%

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

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^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
#Skin:				
Fibrous Histiocytoma				
		1/50 (2%)	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%) 0/50 (0%)
		1/50 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	` '	Mean 0.42% SD 0.83%	Total 1/1100 (0.09%) Mean 0.09% SD 0.43%
	10tai	5/1199 (0.42%)	Wiedii 0.42% SD 0.65%	10tal 1/1100 (0.09%) Weat 0.09% 3D 0.43%
#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%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/49 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/1199 (0.17%)	Mean 0.17% SD 0.56%	Total 0/1100 (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%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (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%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	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	0/1199 (0%)	Mean 0% SD 0%	Total 1/1100 (0.09%) Mean 0.09% SD 0.43%

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

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^{#:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#Skin: Keratoacanthoma								
		10/50 (20%)	3/50 (6%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	
		4/50 (8%)	2/50 (4%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	8/50 (16%)	2/50 (4%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
		7/50 (14%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	4/49 (8%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/50 (2%)	3/50 (6%)		1/50 (2%)	0/50 (0%)	
		3/50 (6%)	6/50 (12%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	71/1199 (5.92%)	Mean 5.92%	SD 5.16%	Total	8/1100 (0.73%)	Mean 0.73%	SD 1.58%
#Skin: Lipoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		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%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	2/49 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	11/1199 (0.92%)	Mean 0.92%	SD 1.45%	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%
#Skin: Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Neural Crest Tumor				,				
Neural Orest Tamor		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (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%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	, ,
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	5/1199 (0.42%)	Mean 0.42%	SD 0.83%	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%
#Skin:								
Neurofibroma or Schw	annoma benign							
	_	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%
#Skin:								
Neurofibrosarcoma or	Schwannoma (r	nalignant or NOS)						
		0/50 (0%)	0/50 (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%)	2/50 (4%)
		0/50 (0%)	1/50 (2%)	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%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (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%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	7/1199 (0.58%)	Mean 0.59%	SD 1.1%	Total	3/1100 (0.27%)	Mean 0.27%	SD 0.94%

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Skin:								
Neurofibrosarcoma, Ne	eurofibroma, or	Schwannoma (benign,	malignant or NOS)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	2/50 (4%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	1/50 (2%)	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%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (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%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	8/1199 (0.67%)	Mean 0.67%	SD 1.28%	Total	4/1100 (0.36%)	Mean 0.36%	SD 1%
#Skin:								
Osteosarcoma		4/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (0%)	Mean 0%	SD 0%
≇Skin: Sarcoma								
Gui Goilla		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	3/00 (0/0)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	7/1199 (0.58%)	Mean 0.58%	SD 1.1%	Total	0/1100 (0%)	Mean 0%	SD 0%
		7/1199 (0.56%)						

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

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^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male		Female
#Skin: Schwannoma Benign					
		0/50 (0%)	0/50 (0%) 0/50 (0	%)) 0/50 (0%)
		0/50 (0%)	1/50 (2%) 0/50 (0	,	,
		0/50 (0%)	0/50 (0%) 0/50 (0	%) 0/50 (0%	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0	%) 0/50 (0%	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0	6) 0/50 (0%	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/49 (0%) 0/50 (0	6) 0/50 (0%	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0	6) 1/50 (2%	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0	6) 0/50 (0%	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/1199 (0.08%)	Mean 0.08% SD 0.41%	Total 1/1100 (0.09%)	Mean 0.09% SD 0.43%
#Skin:					
Schwannoma Malignant					
		0/50 (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%) 2/50 (4%)
		0/50 (0%)	1/50 (2%) 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%) 0/50 (0%)
		1/50 (2%)	0/50 (0%) 0/50 (0	%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	1/49 (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%)	0/50 (0%) 0/50 (0	%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	7/1199 (0.58%)	Mean 0.59% SD 1.1%	Total 3/1100 (0.27%)	Mean 0.27% SD 0.94%
#Skin: Squamous Cell Carcinor					
•		0/50 (0%)	0/50 (0%) 0/50 (0	%)) 0/50 (0%)
		0/50 (0%)	` ,	%) 0/50 (0%	, ,
		0/50 (0%)	0/50 (0%) 1/50 (2	,	, , , , , , , , , , , , , , , , , , , ,
		0/50 (0%)	0/50 (0%) 0/50 (0	,	, , , , , , , , , , , , , , , , , , , ,
		0/50 (0%)	1/50 (2%) 0/50 (0	ó) 0/50 (0%	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/49 (0%) 1/50 (2	ó) 0/50 (0%	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0	6) 0/50 (0%	0/50 (0%)
		1/50 (2%)	0/50 (0%) 0/50 (0	6) 0/50 (0%	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	4/1199 (0.33%)	Mean 0.33% SD 0.76%	Total 1/1100 (0.09%)	Mean 0.09% SD 0.43%

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/49 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)9/1199 (0.75%) 4/1100 (0.36%) Mean 0.36% SD 0.79% **Overall Incidence** Total Mean 0.75% SD 1.15% Total #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%)1/50 (2%)0/50 (0%)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%)0/50 (0%)4/50 (8%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/49 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)3/50 (6%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)Overall Incidence 16/1199 (1.33%) Mean 1.33% SD 2.1% 3/1100 (0.27%) Mean 0.27% SD 0.7% Total Total #Skin: Squamous Cell Papilloma or Papilloma 0/50 1/50 (2%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)4/50 (8%) 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/49 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)3/50 (6%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)

SD 2.1%

.....

Total

3/1100 (0.27%)

Mean 0.27%

SD 0.7%

Total

16/1199 (1.33%)

Mean 1.33%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Skin:								
Squamous Cell Papillo	ma, Papilloma,	Squamous Cell Carcino	oma or Keratoacanthom	na				
		11/50 (22%)	3/50 (6%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	
		4/50 (8%)	2/50 (4%)	4/50 (8%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)	9/50 (18%)	3/50 (6%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
		7/50 (14%)	0/50 (0%)	7/50 (14%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)	4/49 (8%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	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%)
Overall Incidence	Total	91/1199 (7.59%)	Mean 7.59%	SD 5.6%	Total	12/1100 (1.09%)	Mean 1.09%	SD 1.6%
#Skin:								
Squamous Cell Papillo	ma. Papilloma.	or Keratoacanthoma						
oquamous som i upmo	a, . ap	11/50 (22%)	3/50 (6%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	
		4/50 (8%)	2/50 (4%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	9/50 (18%)	2/50 (4%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
		7/50 (14%)	0/50 (0%)	7/50 (14%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)	4/49 (8%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	4/50 (8%)	3/50 (6%)		1/50 (2%)	0/50 (0%)	(=70)
		5/50 (10%)	7/50 (14%)	4/50 (8%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	87/1199 (7.26%)	Mean 7.26%	SD 5.65%	Total	11/1100 (1%)	Mean 1%	SD 1.6%
		······						
#Skin:								
Trichoepithelioma		0/=0 (00/)	2/=2 (22/)	0.770 (00.1)		2/22 (22/)	0/50 (00/)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/22 (22/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
				SD 1.38%			Mean 0.55%	SD 1.1%

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

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^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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					Male						F	emale		
#Skin: Sebaceous 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%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	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%)	1/49	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		3/50	(6%)	0/50	(0%)	0/50	(0%)		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	8/1199 (0.67		Mean 0		SD 1.419		Total	1/1100 (0	,		0.09%	SD 0	.43%
#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%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		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	1/1199 (0.08	,	Mean 0		SD 0.41		Total	0/1100	` '		ın 0%	SD	
#Skin: Sebaceous Gland: Carcinoma or Adenoma														
		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%)	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%)	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%)
		1/50	(2%)	1/49	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		3/50	(6%)	0/50	(0%)	0/50	(0%)		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	9/1199 (0.75		Mean 0	75%	SD 1.429	%	Total	1/1100 (0		Mean	0.09%	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: ALL ROUTES

Species: RATS Strain: F 344/N

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#Spinal Cord: Astrocytoma Benign								
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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/1199 (0%)	Mean 0%	SD 0%	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%
Spleen: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (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%)
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	0/50 (0%)	,
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/1192 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1094 (0%)	Mean 0%	SD 0%
Spleen: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (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%)
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/1192 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1094 (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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
Spleen: Hemangiosarcoma								
•		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (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%)
		0/50 (0%)	0/50 (0%)	1/48 (2%)		0/49 (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	4/1192 (0.34%)	Mean 0.34%	SD 0.77%	Total	1/1094 (0.09%)	Mean 0.09%	SD 0.43%
*Spleen: Leiomyosarcoma								
•		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/49 (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	3/1192 (0.25%)	Mean 0.25%	SD 0.68%	Total	0/1094 (0%)	Mean 0%	SD 0%
#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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

					Male						F	emale		
Stomach, Forestomach:														
Schwannoma Malignan	t	0/-0	(22()	2/=2	(00()	0/-0	(00()		0.700	(00/)	0.450	(224)		
		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%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50 1/50	(0%) (2%)		0/50 0/50	(0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
S	T-1-1		` ,		` ,		` ,	T-1-1		` '		. ,		` '
Overall Incidence	Total	1/1199 (0.0		Mean 0.		SD 0.419		Total	0/1100			n 0%	SD	
Stomach, Forestomach:														
oquamous con caronis	,,,,,	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		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	0/1199 (09	%)	Mean	0%	SD 0%	` '	Total	1/1100 (0	.09%)	Mean	0.09%	SD 0.	.43%
::::::::::::::::::::::::::::::::::::::												•••••		
Squamous Cell Carcino	ma or Papillom	a Squamous												
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)	1/50	(2%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(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%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	3/1199 (0.2	5%)	Mean 0.	25%	SD 0.689	6	Total	3/1100 (0	.27%)	Mean	0.27%	SD 0).7%

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

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^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Stomach, Forestomach:	ma			,				
oquamous ocn i upmoi	iiu	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (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%)
		0/50 (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%)
verall Incidence	Total	3/1199 (0.25%)	Mean 0.25%	SD 0.68%	Total	2/1100 (0.18%)	Mean 0.18%	SD 0.59%
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%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Lipoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (0%)	Mean 0%	SD 0%

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

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^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 05/27/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

			Male			Female	
*Testes:							
Adenoma							
		45/50 (90%)	46/50 (92%)	49/50 (98%)			
		36/50 (72%)	37/50 (74%)	36/50 (72%)			
		38/50 (76%)	44/50 (88%)	48/50 (96%)			
		46/50 (92%)	42/50 (84%)	41/50 (82%)			
		48/50 (96%)	46/50 (92%)	33/50 (66%)			
		47/50 (94%)	38/49 (78%)	48/50 (96%)			
		41/50 (82%)	46/50 (92%)	45/50 (90%)			
		41/50 (82%)	49/50 (98%)	45/50 (90%)			
Overall Incidence	Total	1035/1199 (86.32%)	Mean 86.31%	SD 9.34%			
*Thymus:							
Sarcoma							
		0/48 (0%)	0/48 (0%)	0/47 (0%)	0/50 (0%	6) 0/46 (0%)	
		0/49 (0%)	0/49 (0%)	0/49 (0%)	0/48 (0%	6) 0/45 (0%)	0/50 (0%)
		0/48 (0%)	0/49 (0%)	0/48 (0%)	0/45 (0%	6) 0/48 (0%)	0/48 (0%)
		0/47 (0%)	0/49 (0%)	0/49 (0%)	0/47 (0%	6) 0/47 (0%)	0/50 (0%)
		0/48 (0%)	0/48 (0%)	0/42 (0%)	0/48 (0%	6) 0/47 (0%)	0/50 (0%)
		0/47 (0%)	0/47 (0%)	0/48 (0%)	0/49 (0%	6) 0/46 (0%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)	0/48 (0%)	0/47 (0%	6) 0/50 (0%)	
		1/49 (2%)	0/43 (0%)	0/48 (0%)	0/49 (0%	6) 0/48 (0%)	0/49 (0%)
Overall Incidence	Total	1/1146 (0.09%)	Mean 0.09%	SD 0.42%	Total 0/1057 (0%)	Mean 0%	SD 0%
*Thymus:	•••••					•••••	•••••
Thymoma Benign							
,		0/48 (0%)	0/48 (0%)	0/47 (0%)	0/50 (0%	%) 0/46 (0%)	
		0/49 (0%)	0/49 (0%)	0/49 (0%)	0/48 (0%	,	0/50 (0%)
		0/48 (0%)	0/49 (0%)	0/48 (0%)	0/45 (0%	, , ,	1/48 (2%)
		0/47 (0%)	0/49 (0%)	0/49 (0%)	0/47 (0%	,	1/50 (2%)
		0/48 (0%)	0/48 (0%)	0/42 (0%)	0/48 (0%	, , ,	1/50 (2%)
		0/47 (0%)	1/47 (2%)	0/48 (0%)	0/49 (0%	, , ,	0/50 (0%)
		0/49 (0%)	0/49 (0%)	0/48 (0%)	0/47 (0%	,	` '
		1/49 (2%)	0/43 (0%)	0/48 (0%)	0/49 (0%	, , ,	0/49 (0%)
Overall Incidence	Total	2/1146 (0.17%)	Mean 0.17%	SD 0.59%	Total 3/1057 (0.28%)	, , ,	SD 0.71%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES

Page: 70

Report Date: 05/27/2022

Species: RATS Strain: F 344/N

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
Thymus:								
Thymoma Malignant		-4				- / / /		
		0/48 (0%)	0/48 (0%)	0/47 (0%)		0/50 (0%)	0/46 (0%)	
		0/49 (0%)	0/49 (0%)	0/49 (0%)		0/48 (0%)	0/45 (0%)	0/50 (0%)
		0/48 (0%)	0/49 (0%)	0/48 (0%)		0/45 (0%)	0/48 (0%)	0/48 (0%)
		0/47 (0%)	0/49 (0%)	0/49 (0%)		0/47 (0%)	0/47 (0%)	0/50 (0%)
		0/48 (0%)	0/48 (0%)	0/42 (0%)		0/48 (0%)	0/47 (0%)	0/50 (0%)
		0/47 (0%)	0/47 (0%)	0/48 (0%)		0/49 (0%)	0/46 (0%)	0/50 (0%)
		1/49 (2%)	0/49 (0%)	0/48 (0%)		0/47 (0%)	0/50 (0%)	
		0/49 (0%)	0/43 (0%)	0/48 (0%)		0/49 (0%)	0/48 (0%)	0/49 (0%)
verall Incidence	Total	1/1146 (0.09%)	Mean 0.09%	SD 0.42%	Total	0/1057 (0%)	Mean 0%	SD 0%
Thymus: Thymoma: Benign, Mali	anant NOS							
mymoma. Benign, Man	gnant, NOS	0/48 (0%)	0/48 (0%)	0/47 (0%)		0/50 (0%)	0/46 (0%)	
		0/49 (0%)	0/49 (0%)	0/49 (0%)		0/48 (0%)	0/45 (0%)	0/50 (0%)
		0/48 (0%)	0/49 (0%)	0/48 (0%)		0/45 (0%)	0/48 (0%)	1/48 (2%)
		0/47 (0%)	0/49 (0%)	0/49 (0%)		0/47 (0%)	0/47 (0%)	1/50 (2%)
		0/48 (0%)	0/48 (0%)	0/42 (0%)		0/48 (0%)	0/47 (0%)	1/50 (2%)
		0/47 (0%)	1/47 (2%)	0/48 (0%)		0/49 (0%)	0/46 (0%)	0/50 (0%)
		1/49 (2%)	0/49 (0%)	0/48 (0%)		0/47 (0%)	0/50 (0%)	0/00 (0/0)
		1/49 (2%)	0/43 (0%)	0/48 (0%)		0/49 (0%)	0/48 (0%)	0/49 (0%)
Overall Incidence	Total	3/1146 (0.26%)	Mean 0.26%	SD 0.7%	Total	3/1057 (0.28%)	Mean 0.28%	SD 0.71%
Thyroid Gland: C-Cell: Adenoma								
		10/50 (20%)	5/50 (10%)	6/50 (12%)		4/50 (8%)	3/49 (6%)	
		3/50 (6%)	10/50 (20%)	5/50 (10%)		3/50 (6%)	8/50 (16%)	3/50 (6%)
		2/50 (4%)	6/50 (12%)	1/50 (2%)		0/50 (0%)	5/50 (10%)	11/50 (22%)
		9/50 (18%)	1/50 (2%)	6/50 (12%)		7/50 (14%)	3/50 (6%)	7/50 (14%)
		9/48 (19%)	11/47 (23%)	3/49 (6%)		9/49 (18%)	10/47 (21%)	2/50 (4%)
		12/50 (24%)	4/49 (8%)	5/50 (10%)		5/50 (10%)	3/50 (6%)	8/50 (16%)
		7/50 (14%)	3/50 (6%)	8/46 (17%)		3/49 (6%)	6/49 (12%)	
		6/50 (12%)	10/49 (20%)	9/47 (19%)		6/50 (12%)	6/46 (13%)	12/47 (26%)
Overall Incidence	Total	151/1185 (12.74%)	Mean 12.81%	SD 6.66%	Total	124/1086 (11.42%)	Mean 11.49%	SD 6.51%

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
Thyroid Gland: C-Cell: Carcinoma								
		1/50 (2%)	4/50 (8%)	1/50 (2%)		0/50 (0%)	1/49 (2%)	
		1/50 (2%)	2/50 (4%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		6/50 (12%)	2/50 (4%)	2/50 (4%)		3/50 (6%)	1/50 (2%)	0/50 (0%)
		1/48 (2%)	0/47 (0%)	0/49 (0%)		0/49 (0%)	1/47 (2%)	1/50 (2%)
		0/50 (0%)	3/49 (6%)	1/50 (2%)		0/50 (0%)	2/50 (4%)	2/50 (4%)
		2/50 (4%)	1/50 (2%)	1/46 (2%)		1/49 (2%)	1/49 (2%)	
		1/50 (2%)	1/49 (2%)	2/47 (4%)		0/50 (0%)	0/46 (0%)	1/47 (2%)
Overall Incidence	Total	38/1185 (3.21%)	Mean 3.19%	SD 3.12%	Total	18/1086 (1.66%)	Mean 1.65%	SD 1.71%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		11/50 (22%)	9/50 (18%)	7/50 (14%)		4/50 (8%)	4/49 (8%)	
		3/50 (6%)	12/50 (24%)	10/50 (20%)		3/50 (6%)	8/50 (16%)	5/50 (10%)
		3/50 (6%)	6/50 (12%)	1/50 (2%)		1/50 (2%)	5/50 (10%)	12/50 (24%)
		15/50 (30%)	3/50 (6%)	8/50 (16%)		9/50 (18%)	4/50 (8%)	7/50 (14%)
		10/48 (21%)	11/47 (23%)	3/49 (6%)		9/49 (18%)	11/47 (23%)	3/50 (6%)
		12/50 (24%)	7/49 (14%)	6/50 (12%)		5/50 (10%)	5/50 (10%)	10/50 (20%)
		9/50 (18%)	4/50 (8%)	9/46 (20%)		4/49 (8%)	7/49 (14%)	, ,
		7/50 (14%)	11/49 (22%)	11/47 (23%)		6/50 (12%)	6/46 (13%)	13/47 (28%)
Overall Incidence	Total	188/1185 (15.86%)	Mean 15.92%	SD 7.44%	Total	141/1086 (12.98%)	Mean 13.05%	SD 6.59%
*Thyroid Gland: Follicular Adenoma								
		2/50 (4%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		1/48 (2%)	0/47 (0%)	0/49 (0%)		0/49 (0%)	2/47 (4%)	0/50 (0%)
		1/50 (2%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	2/50 (4%)	0/46 (0%)		0/49 (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	15/1185 (1.27%)	Mean 1.26%	SD 1.43%	Total	5/1086 (0.46%)	Mean 0.47%	SD 1.11%

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

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^{#:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
Thyroid Gland: Follicula	ar Cell:							,
our on roma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/48 (0%)	0/47 (0%)	0/49 (0%)		1/49 (2%)	0/47 (0%)	0/50 (0%)
		2/50 (4%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/46 (0%)		0/49 (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	12/1185 (1.01%)	Mean 1%	SD 1.44%	Total	6/1086 (0.55%)	Mean 0.55%	SD 1.11%
Thyroid Gland: Follicula Carcinoma or Adenom	ar Cell:							
		2/50 (4%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	
		2/50 (4%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	1/50 (2%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		2/50 (4%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		1/48 (2%)	0/47 (0%)	0/49 (0%)		1/49 (2%)	2/47 (4%)	0/50 (0%)
		3/50 (6%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	3/50 (6%)	0/46 (0%)		0/49 (0%)	0/49 (0%)	
		1/50 (2%)	0/49 (0%)	1/47 (2%)		0/50 (0%)	1/46 (2%)	1/47 (2%)
Overall Incidence	Total	27/1185 (2.28%)	Mean 2.26%	SD 1.98%	Total	10/1086 (0.92%)	Mean 0.94%	SD 1.38%
#Tissue NOS: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	0/1199 (0%)	Mean 0%	SD 0%	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%

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

Page: 72

^{#:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#Tissue NOS: Leiomyoma								
Loiomyoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	(175)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (0%)	Mean 0%	SD 0%
#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%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	1/1199 (0.08%)	Mean 0.09%	SD 0.42%	Total	0/1100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Paraganglioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (0%)	Mean 0%	SD 0%

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

Page: 73

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%)	` ,	0/50 (09/)
0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%)	` ,	0/50 (0%)
0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)		` ,	0/50 (0%)	0/50 (00/)
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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
0/50 (0%)	` ,			0/50 (0%)	0/50 (0%)	0/50 (0%)
` ,		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	` ,
0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
0/1199 (0%)	Mean 0%	SD 0%	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%
			•••••			
0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
` '	` '	, ,		` ,	` ,	0/50 (0%)
` ,	` ,	` ,		` ,	` ,	0/50 (0%)
` ,	` '	, ,		, ,	` '	
` ,	` '	, ,		` '	` ,	0/50 (0%)
U/OU (U%)	, ,		Total	` '	` '	SD 0.43%
	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/1199 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/1199 (0%) Mean 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%) 0/1199 (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%) 0/50 (0%) 0/50 (0%) 0/1199 (0%) Mean 0% SD 0% Total	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/1199 (0%) Mean 0% SD 0% Total 1/1100 (0.09%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)

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

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^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
fTongue:								
Squamous Cell Carcino	oma or Papillon	na 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%)	0/50 (0%)	2/50 (4%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	4/1199 (0.33%)	Mean 0.33%	SD 0.76%	Total	5/1100 (0.45%)	Mean 0.45%	SD 1.06%
ongue:								
Squamous Cell Papillo	ma							
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	4/1199 (0.33%)	Mean 0.33%	SD 0.76%	Total	5/1100 (0.45%)	Mean 0.45%	SD 1.06%
Footh:	•••••		•••••	• • • • • • • • • • • • • • • • • • • •			•••••	
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%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	0/1199 (0%)	Mean 0%	SD 0%	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%

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

Page: 75

^{#:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male			Female					
Urinary Bladder: Carcinoma											
our on roma		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)			
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)			
		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%)			
Overall Incidence	Total	1/1194 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1096 (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%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/49 (0%)	0/50 (0%)			
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)			
		0/50 (0%)	0/50 (0%)	0/49 (0%)		1/49 (2%)	0/50 (0%)				
		1/50 (2%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	4/1194 (0.34%)	Mean 0.34%	SD 0.77%	Total	2/1096 (0.18%)	Mean 0.18%	SD 0.59%			
Urinary Bladder: Leiomyosarcoma											
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)			
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)			
		0/50 (0%)	0/50 (0%)	0/49 (0%)		1/49 (2%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/1194 (0%)	Mean 0%	SD 0%	Total	2/1096 (0.18%)	Mean 0.18%	SD 0.59%			

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

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^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Urinary Bladder: Papilloma				,				,
•		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%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/49 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		1/49 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	3/1194 (0.25%)	Mean 0.25%	SD 0.68%	Total	2/1096 (0.18%)	Mean 0.18%	SD 0.59%
Jterus: 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%)
						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%)
erall Incidence					Total	2/1100 (0.18%)	Mean 0.18%	SD 0.59%
Jterus: Carcinoma								
						0/50 (0%)	0/50 (0%)	
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (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%)
verall Incidence					Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%

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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: ALL ROUTES
Vehicle: ALL VEHICLES

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	Male		Female	
#Uterus:				
Deciduoma 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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		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	1/1100 (0.09%)	Mean 0.09%	SD 0.43%
#Uterus:				
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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	` ,
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%
				•••••
#Uterus:				
Hemangiosarcoma		0/50 (00/)	0/50 (00/)	
		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%) 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%)
				0/30 (070)
		` '	` ,	0/50 (0%)
Overell Insidence	T-1-1		` ,	` ,
Overall Incidence	Total	2/1100 (0.18%)	Mean 0.18%	SD 0.59%

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

	Male		Female	
#Uterus:				
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%)	` ,	0/50 (0%)
		0/50 (0%)	0/50 (0%)	O/FO (00/)
Normall In address of	-	0/50 (0%)	' '	0/50 (0%)
Overall Incidence	Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%
Uterus:				
Polyp Stromal				
. o.yp oo.na.		6/50 (12%)	10/50 (20%)	
		13/50 (26%)	` ,	0/50 (20%)
		9/50 (18%)	` '	3/50 (16%)
		8/50 (16%)	, ,	3/50 (26%)
		8/50 (16%)	, ,	6/50 (12%)
		8/50 (16%)	12/50 (24%) 10	0/50 (20%)
		10/50 (20%)	9/50 (18%)	, ,
		4/50 (8%)	13/50 (26%)	9/50 (18%)
Overall Incidence	Total	203/1100 (18.45%)	Mean 18.45%	SD 6.44%
tUterus: Sarcoma Stromal				
Sarcoma Stromai		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	` ,	0/50 (0%)
		0/50 (0%)	` ,	0/50 (0%)
		0/50 (0%)	, ,	2/50 (4%)
		0/50 (0%)	` ,	0/50 (0%)
		0/50 (0%)		0/50 (0%)
		1/50 (2%)	0/50 (0%)	(070)
		0/50 (0%)	` ,	1/50 (2%)
Overall Incidence	Total	8/1100 (0.73%)		SD 1.16%
	Total	, ,		05 1.10/0

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

Page: 79

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female	
fUterus: Sarcoma Stromal or Polyp Stromal				
, , , , , , , , , , , , , , , , , , ,		6/50 (12%)	10/50 (20%)	
		14/50 (28%)	3/50 (6%)	10/50 (20%)
		9/50 (18%)	7/50 (14%)	8/50 (16%)
		8/50 (16%)	13/50 (26%)	15/50 (30%)
		8/50 (16%)	17/50 (34%)	6/50 (12%)
		8/50 (16%)	12/50 (24%)	10/50 (20%)
		11/50 (22%)	9/50 (18%)	
		4/50 (8%)	13/50 (26%)	10/50 (20%)
overall Incidence	Tota	,	Mean 19.18%	SD 6.95%
Uterus:				
Schwannoma Malignant				
		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	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	Tota	()	Mean 0.18%	SD 0.59%
₹Vagina:				
Polyp		0/50 (00/)	0/50 (00/)	
		0/50 (0%)	0/50 (0%)	0/50 (00/)
		2/50 (4%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (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%)
Overall Incidence	Tota	l 3/1100 (0.27%)	Mean 0.27%	SD 0.94%

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

Page: 80

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female				
Vagina: 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%)	1/50 (2%)	0/50 (0%)		
						0/50 (0%)	0/50 (0%)	0/50 (0%)		
						0/50 (0%)	0/50 (0%)	0/50 (0%)		
						0/50 (0%)	0/50 (0%)			
						0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence					Total	1/1100 (0.09%)	Mean 0.09%	SD 0.43%		
Zymbal's Gland: Adenoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	1/1199 (0.08%)	Mean 0.08%	SD 0.41%	Total	0/1100 (0%)	Mean 0%	SD 0%		
Zymbal's Gland: Carcinoma										
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)			
		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%)		1/50 (2%)	0/50 (0%)	0/50 (0%)		
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	3/50 (6%)	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%)		
		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%)		
verall Incidence	Total	10/1199 (0.83%)	Mean 0.83%	SD 1.55%	Total	6/1100 (0.55%)	Mean 0.55%	SD 0.91%		

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

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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					Male						Female			
#Zymbal's Gland:														
Carcinoma or Adenoma														
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	1/50	(2%)		
		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%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	3/50	(6%)	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%)
		0/50	(0%)	1/50	(2%)	1/50	(2%)		1/50	(2%)	0/50	(0%)		` ,
		1/50	(2%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	11/1199 (0.9	92%)	Mean 0	.92%	SD 1.56	%	Total	6/1100 (0	.55%)	Mean	0.55%	SD 0.	, ,

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

^{#:} Denominator is number of animals necropsied