

NTP Historical Controls Report

All Routes and Vehicles

RATS

March 2010

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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/20/2010

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Southern Research Institute	059902407	02/03/03	729	50(3)	21(661)	518.7	Androstenedione
Southern Research Institute	059903705	06/09/03	729	50(3)	27(662)	523.0	alpha/beta Thujone mixture
Battelle Columbus Laboratory	059902805	09/16/02	729	50(1)	21(676)	506.2	bis(2-Chloroethoxy)methane
Battelle Northwest	052001105	07/14/03	729	50(5)	23(678)	526.9	1-Bromopropane
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
Battelle Northwest	059901705	08/25/03	729	50(5)	28(686)	525.6	Diethylamine
Battelle Columbus Laboratory	058812305	03/21/01	727	50(3)	26(673)	509.7	Formamide
Battelle Columbus Laboratory	052000505	01/21/04	727	50(3)	30(679)	498.5	Ginseng
Southern Research Institute	059900705	04/21/03	729	50(3)	33(679)	460.9	Goldenseal root powder
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 Columbus Laboratory	052000705	08/18/04	727	49(3)	34(692)	515.2	Kava kava extract
Battelle Northwest	058800603	08/06/01	729	50(5)	27(680)	537.2	alpha-Methylstyrene
Southern Research Institute	052000803	03/04/03	729	50(3)	36(704)	452.1	Milk thistle extract
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
Battelle Columbus Laboratory	059902005	04/09/03	727	50(3)	39(685)	514.9	Pulegone
Battelle Columbus Laboratory	059903203	09/15/04	727	50(1)	23(651)	510.1	Pyrogallol
Southern Research Institute	052011407	10/02/02	730	50(3)	28(696)	532.4	Sodium dichromate dihydrate (VI)
Battelle Northwest	059302507	06/16/03	729	50(5)	20(668)	536.2	Tetralin
Southern Research Institute	058813307	01/18/05	729	50(1)	23(681)	516.1	Trimethylolpropane triacrylate
Southern Research Institute	059601905	09/26/01	729	50(3)	31(686)	526.0	Water disinfection byproducts (Bromochloroacetic acid)
Southern Research Institute	059601505	09/05/01	729	50(3)	31(692)	507.8	Water disinfection byproducts (Dibromoacetonitrile)

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 4

Report Date: 03/20/2010

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Female		
Southern Research Institute	059902407	02/03/03	729	50(5)	38(710)	356.5	Androstenedione
Southern Research Institute	059903705	06/09/03	730	50(5)	35(689)	335.4	alpha/beta Thujone mixture
Battelle Columbus Laboratory	059902805	09/17/02	730	50(1)	19(646)	341.0	bis(2-Chloroethoxy)methane
Battelle Northwest	052001105	07/14/03	730	50(5)	34(702)	386.5	1-Bromopropane
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
Battelle Northwest	059901705	08/25/03	730	50(5)	31(687)	378.3	Diethylamine
Battelle Columbus Laboratory	058812305	03/20/01	730	50(5)	38(703)	358.3	Formamide
Battelle Columbus Laboratory	052000505	01/22/04	728	50(5)	36(700)	355.0	Ginseng
Southern Research Institute	059900705	04/21/03	731	50(5)	30(699)	326.0	Goldenseal root powder
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 Columbus Laboratory	052000705	08/19/04	728	50(5)	34(683)	354.3	Kava kava extract
Battelle Northwest	058800603	08/06/01	730	50(5)	27(647)	351.9	alpha-Methylstyrene
Southern Research Institute	052000803	03/04/03	732	50(5)	38(693)	328.4	Milk thistle extract
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
Battelle Columbus Laboratory	059902005	04/10/03	728	50(5)	31(682)	341.2	Pulegone
Battelle Columbus Laboratory	059903203	09/16/04	728	50(1)	29(670)	351.0	Pyrogallol
Southern Research Institute	052011407	10/02/02	735	50(5)	33(700)	351.2	Sodium dichromate dihydrate (VI)
Battelle Northwest	059302507	06/16/03	730	50(5)	31(682)	370.8	Tetralin
Southern Research Institute	058813307	01/18/05	731	50(1)	27(688)	352.8	Trimethylolpropane triacrylate
Southern Research Institute	059601905	09/26/01	731	50(5)	34(688)	357.3	Water disinfection byproducts (Bromochloroacetic acid)
Southern Research Institute	059601505	09/05/01	734	50(5)	29(689)	337.6	Water disinfection byproducts (Dibromoacetonitrile)

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:								
Benign Tumors								
		47/50 (94%)	44/50 (88%)	49/50 (98%)		44/50 (88%)	46/50 (92%)	37/50 (74%)
		48/50 (96%)	49/50 (98%)	50/50 (100%)		45/50 (90%)	45/50 (90%)	42/50 (00%)
		48/50 (96%)	46/50 (92%)	44/50 (88%)		44/50 (88%)	46/50 (92%)	43/50 (86%)
		45/50 (90%)	49/50 (98%)	47/50 (94%)		43/50 (86%)	42/50 (84%)	46/50 (92%)
		50/50 (100%)	49/50 (98%)	49/49 (100%)		46/50 (92%)	41/50 (82%)	43/50 (86%)
		48/50 (96%)	50/50 (100%)	49/50 (98%)		43/50 (86%)	39/50 (78%)	40/50 (80%)
		48/49 (98%)	47/50 (94%)	47/50 (94%)		42/50 (84%)	42/50 (84%)	43/50 (86%)
		49/50 (98%)	48/50 (96%)	48/50 (96%)		47/50 (94%)	40/50 (80%)	43/50 (86%)
	-	50/50 (100%)	50/50 (100%)	00 0 570/	.	49/50 (98%)	44/50 (88%)	05 5 000/
Overall Incidence	Total	1248/1298 (96.15%)	Mean 96.15%	SD 3.57%	Total	1083/1250 (86.64%)	Mean 86.64%	SD 5.38%
#All Organs: Malignant Tumors								
_		34/50 (68%)	31/50 (62%)	26/50 (52%)		10/50 (20%)	20/50 (40%)	19/50 (38%)
		38/50 (76%)	27/50 (54%)	23/50 (46%)		26/50 (52%)	15/50 (30%)	
		36/50 (72%)	23/50 (46%)	31/50 (62%)		24/50 (48%)	15/50 (30%)	24/50 (48%)
		25/50 (50%)	26/50 (52%)	29/50 (58%)		15/50 (30%)	10/50 (20%)	19/50 (38%)
		35/50 (70%)	29/50 (58%)	17/49 (35%)		16/50 (32%)	18/50 (36%)	11/50 (22%)
		32/50 (64%)	26/50 (52%)	23/50 (46%)		25/50 (50%)	18/50 (36%)	11/50 (22%)
		32/49 (65%)	10/50 (20%)	22/50 (44%)		26/50 (52%)	8/50 (16%)	12/50 (24%)
		29/50 (58%)	33/50 (66%)	30/50 (60%)		20/50 (40%)	25/50 (50%)	21/50 (42%)
		27/50 (54%)	27/50 (54%)	, ,		18/50 (36%)	20/50 (40%)	,
Overall Incidence	Total	721/1298 (55.55%)	Mean 55.54%	SD 12.05%	Total	446/1250 (35.68%)	Mean 35.68%	SD 10.9%
#All Organs: Malignant and Benign								
		49/50 (98%)	48/50 (96%)	49/50 (98%)		46/50 (92%)	49/50 (98%)	44/50 (88%)
		50/50 (100%)	50/50 (100%)	50/50 (100%)		49/50 (98%)	47/50 (94%)	
		50/50 (100%)	50/50 (100%)	49/50 (98%)		50/50 (100%)	48/50 (96%)	48/50 (96%)
		48/50 (96%)	49/50 (98%)	50/50 (100%)		49/50 (98%)	45/50 (90%)	48/50 (96%)
		50/50 (100%)	50/50 (100%)	49/49 (100%)		48/50 (96%)	46/50 (92%)	46/50 (92%)
		50/50 (100%)	50/50 (100%)	50/50 (100%)		46/50 (92%)	46/50 (92%)	45/50 (90%)
		49/49 (100%)	47/50 (94%)	49/50 (98%)		47/50 (94%)	44/50 (88%)	45/50 (90%)
		50/50 (100%)	50/50 (100%)	50/50 (100%)		49/50 (98%)	46/50 (92%)	47/50 (94%)
		50/50 (100%)	50/50 (100%)			49/50 (98%)	48/50 (96%)	
Overall Incidence	Total	1286/1298 (99.08%)	Mean 99.08%	SD 1.62%	Total	1175/1250 (94%)	Mean 94%	SD 3.42%

^{*:} 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	
#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%)
		0/50 (0%)	0/50 (0%) 0/50 (0%	,	(0%)
		0/50 (0%)	0/50 (0%) 0/49 (0%	,	(0%)
		0/50 (0%)	1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50	(2%)
		0/49 (0%)	0/50 (0%) 1/50 (2%	,	(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	3/1298 (0.23%)	Mean 0.23% SD 0.65%	Total 2/1250 (0.16%) Mean 0.16% SD 0.5	
#All Organs: Hemangiosarcoma					
_		1/50 (2%)	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%) 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%) 0/49 (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%	2/50 (4%) 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%) 1/50 (2%)	
Overall Incidence	Total	7/1298 (0.54%)	Mean 0.54% SD 1.07%	Total 5/1250 (0.4%) Mean 0.4% SD 1.	
#All Organs: Hemangiosarcoma or H					
•	•	1/50 (2%)	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%)	0/50 (0%) 1/50 (2%)		(0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%	, , , , , , , , , , , , , , , , , , , ,	(0%)
		0/50 (0%)	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%)
		0/49 (0%)	0/50 (0%) 1/50 (2%		(0%)
		1/50 (2%)	1/50 (2%) 0/50 (0%	,	(0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%) 1/50 (2%)	. ,
Overall Incidence	Total	10/1298 (0.77%)	Mean 0.77% SD 1.14%	Total 7/1250 (0.56%) Mean 0.56% SD 1.2	23%

^{*:} 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
#All Organs: Histiocytic Sarcoma				
Histocytic Sarconia		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%) 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%) 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%)
		1/50 (2%)	3/50 (6%) 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%) 2/50 (4%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	10/1298 (0.77%)	Mean 0.77% SD 1.39%	Total 6/1250 (0.48%) Mean 0.48% SD 1.05%
#All Organs: Leukemia: Erythrocytic				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (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%)
		0/49 (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	0/1298 (0%)	Mean 0% SD 0%	Total 1/1250 (0.08%) Mean 0.08% SD 0.4%
#All Organs: Leukemia: Lymphocytic,		Mononuclear, or Undiffere	entiated	
		26/50 (52%)	22/50 (44%) 17/50 (34%)	5/50 (10%) 10/50 (20%) 12/50 (24%)
		29/50 (58%)	19/50 (38%) 15/50 (30%)	16/50 (32%) 9/50 (18%)
		26/50 (52%)	17/50 (34%) 25/50 (50%)	12/50 (24%) 10/50 (20%) 15/50 (30%)
		15/50 (30%)	18/50 (36%) 21/50 (42%)	10/50 (20%) 6/50 (12%) 9/50 (18%)
		28/50 (56%)	10/50 (20%) 7/49 (14%)	9/50 (18%) 8/50 (16%) 5/50 (10%)
		26/50 (52%)	17/50 (34%) 9/50 (18%)	18/50 (36%) 6/50 (12%) 5/50 (10%)
		21/49 (43%)	4/50 (8%) 11/50 (22%)	20/50 (40%) 4/50 (8%) 8/50 (16%)
		26/50 (52%)	25/50 (50%) 26/50 (52%)	8/50 (16%) 17/50 (34%) 12/50 (24%)
		21/50 (42%)	21/50 (42%)	15/50 (30%) 14/50 (28%)
Overall Incidence	Total	502/1298 (38.67%)	Mean 38.66% SD 13.73%	Total 263/1250 (21.04%) Mean 21.04% SD 8.93%

^{*:} 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
#All Organs:						
Malignant Lymphoma:	Histiocytic, Lym		or Undifferentiated Cell 1			
		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%)	0/50 (0%) 0/50 (0%)
		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%) 1/50 (2%)
		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%)	1/50 (2%)
Overall Incidence	Total	3/1298 (0.23%)	Mean 0.23%	SD 0.66%	Total 3/1250 (0.24%)	Mean 0.24% SD 0.66%
#All Organs: Mesothelioma: Benign						
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	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%)
		0/49 (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%)
Overall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total 1/1250 (0.08%)	Mean 0.08% SD 0.4%
#All Organs: Mesothelioma: Benign,						
		1/50 (2%)	2/50 (4%)	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%)
		3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		2/50 (4%)	2/50 (4%)	0/50 (0%)	2/50 (4%)	0/50 (0%) 0/50 (0%)
		2/50 (4%)	3/50 (6%)	3/49 (6%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%) 1/50 (2%)
		1/49 (2%)	2/50 (4%)	2/50 (4%)	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%)
		1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	32/1298 (2.47%)	Mean 2.47%	SD 2.15%	Total 5/1250 (0.4%)	Mean 0.4% SD 1%

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

Page: 8

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Strain: F 344/N Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs:		,						
Mesothelioma: Malignar	nt							
		1/50 (2%)	2/50 (4%)	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%)	
		3/50 (6%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	2/50 (4%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	3/50 (6%)	3/49 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/49 (2%)	2/50 (4%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	31/1298 (2.39%)	Mean 2.39%	SD 2.2%	Total	4/1250 (0.32%)	Mean 0.32%	SD 0.95%
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%)	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%)		0/50 (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%)	0/50 (0%)	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	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%
All Organs: Osteosarcoma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	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%)	2/50 (4%)	1/49 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	3/50 (6%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	. ,		1/50 (2%)	0/50 (0%)	
		• ,	. ,					

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

Page: 9

^{#:} 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: Osteosarcoma or Osteoma 1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%) 2/50 (4%)0/50 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%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)1/49 (2%)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%)1/49 (2%)0/50 (0%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)(2%)0/50 0/50 (0%)3/50 (6%)2/50 (4%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)SD 1.77% **Overall Incidence** Total 18/1298 (1.39%) Mean 1.39% Total 5/1250 (0.4%) Mean 0.4% SD 0.82% *Adrenal Cortex: Adenoma 3/50 (6%)1/50 (2%)0/50 (0%)0/50 (0%)1/47 (2%)0/50 (0%)(2%)0/50 (0%) 0/50 (0%) 3/50 (6%)2/50 (4%)1/50 0/50 (0%)3/50 (6%)1/50 (2%)0/50 (0%)0/50 (0%)4/50 (8%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)0/50 (0%)0/50 (0%)0/49 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (2%)(0%)2/50 (4%)1/50 2/50 (4%)0/48 (0%)0/50 (0%)0/49 (0%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 1/50 (2%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)8/50 (16%)0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 15/1298 (1.16%) Mean 1.15% SD 1.89% Total 24/1245 (1.93%) Mean 1.93% SD 3.63% *Adrenal Cortex: 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%)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%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (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%)Total 2/1298 (0.15%) Mean 0.16% SD 0.55% Total 0/1245 (0%) Mean 0% SD 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

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ALL VEHICLES

Page: 11

			Male				Female	
Adrenal Medulla:								
Ganglioneuroma		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%)	0/48 (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%)	0/30 (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%)		0/49 (0%)	0/48 (0%)	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%)		0/49 (0%)	0/50 (0%)	0/48 (0%)
		0/50 (0%)	0/50 (0%)	0/40 (070)		0/49 (0%)	0/49 (0%)	0/40 (070)
Overall Incidence	Total	1/1295 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1238 (0%)	Mean 0%	SD 0%
Adrenal Medulla:								
Hemangioma								
		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%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/48 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	1/50 (2%)
		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%)		0/49 (0%)	0/50 (0%)	0/48 (0%)
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	0/1295 (0%)	Mean 0%	SD 0%	Total	1/1238 (0.08%)	Mean 0.08%	SD 0.4%
Adrenal Medulla: Pheochromocytoma B								
		7/50 (14%)	6/50 (12%)	3/50 (6%)		3/50 (6%)	2/48 (4%)	1/50 (2%)
		10/50 (20%)	8/50 (16%)	8/50 (16%)		2/50 (4%)	1/50 (2%)	
		7/50 (14%)	5/50 (10%)	7/50 (14%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		9/50 (18%)	4/50 (8%)	5/49 (10%)		0/50 (0%)	1/50 (2%)	0/48 (0%)
		5/50 (10%)	5/50 (10%)	5/49 (10%)		0/50 (0%)	2/50 (4%)	3/50 (6%)
		8/50 (16%)	5/50 (10%)	11/50 (22%)		1/49 (2%)	1/48 (2%)	1/50 (2%)
		8/49 (16%)	8/50 (16%)	4/50 (8%)		1/50 (2%)	3/50 (6%)	1/50 (2%)
		6/49 (12%)	9/50 (18%)	11/49 (22%)		2/49 (4%)	2/50 (4%)	0/48 (0%)
		9/50 (18%)	10/50 (20%)			2/49 (4%)	1/49 (2%)	
Overall Incidence	Total	183/1295 (14.13%)	Mean 14.13%	SD 4.53%	Total	32/1238 (2.58%)	Mean 2.58%	SD 1.88%

^{*:} 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

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ALL VEHICLES

Page: 12

			Male				Female	
Adrenal Medulla:								
Pheochromocytoma Co	omplex							
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/48 (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%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/48 (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%)	1/48 (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%)		0/49 (0%)	0/50 (0%)	0/48 (0%)
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	
verall Incidence	Total	5/1295 (0.39%)	Mean 0.38%	SD 0.98%	Total	5/1238 (0.4%)	Mean 0.41%	SD 0.83%
Adrenal Medulla:								
Pheochromocytoma M	alignant	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/40 (00/)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%) 1/50 (2%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (00/)
		` '	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		()	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/48 (0%)
		0/50 (0%) 2/50 (4%)	3/50 (6%) 0/50 (0%)	0/49 (0%) 2/50 (4%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		` '	` ,	\ /		` '	0/48 (0%)	` '
		3/49 (6%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%) 1/50 (2%)	4/50 (8%) 0/50 (0%)	1/49 (2%)		1/49 (2%) 2/49 (4%)	1/50 (2%) 0/49 (0%)	0/48 (0%)
	T-1-1	` '	` ,	00 0 40/	T-1-1	` '	` ,	OD 4 040/
verall Incidence	Total	24/1295 (1.85%)	Mean 1.86%	SD 2.4%	Total	7/1238 (0.57%)	Mean 0.56%	SD 1.24%
Adrenal Medulla:								
Pheochromocytoma: B	senign, Compie	x, maiignant, NOS 8/50 (16%)	6/50 (12%)	3/50 (6%)		4/50 (8%)	3/48 (6%)	1/50 (2%)
		` ,	` ,	` '		` ,	` ,	1/50 (2%)
		` '	11/50 (22%)	8/50 (16%)		3/50 (6%)	3/50 (6%)	0/50 (00/)
		7/50 (14%)	5/50 (10%)	10/50 (20%)		3/50 (6%)	1/50 (2%)	0/50 (0%)
		9/50 (18%)	4/50 (8%)	6/49 (12%)		0/50 (0%)	1/50 (2%)	0/48 (0%)
		5/50 (10%)	7/50 (14%)	5/49 (10%)		0/50 (0%)	2/50 (4%)	3/50 (6%)
		10/50 (20%)	6/50 (12%)	13/50 (26%)		1/49 (2%)	2/48 (4%)	1/50 (2%)
		10/49 (20%)	8/50 (16%)	5/50 (10%)		1/50 (2%)	3/50 (6%)	1/50 (2%)
		7/49 (14%)	12/50 (24%)	12/49 (24%)		3/49 (6%)	3/50 (6%)	0/48 (0%)
		10/50 (20%)	10/50 (20%)			4/49 (8%)	1/49 (2%)	
Overall Incidence	Total	208/1295 (16.06%)	Mean 16.06%	SD 5.51%	Total	44/1238 (3.55%)	Mean 3.55%	SD 2.69%

^{*:} 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	
#Bone: Chondrosarcoma				,				
onona ocarooma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	(,
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
verall Incidence	Total	0/1298 (0%)	Mean 0%	SD 0%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%
Bone:								
Chondrosarcoma or Cl	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%)	0/49 (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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
verall Incidence	Total	0/1298 (0%)	Mean 0%	SD 0%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%
Bone: Chordoma								
onor doma		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%)	(0,00)
		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%)	0/49 (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%)
		1/49 (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%)	0/30 (0/0)		0/50 (0%)	0/50 (0%)	0/00 (0/0)
warall Incidence	Total	` '	, ,	SD 0.010/	Total	` '	, ,	SD 00/
verall Incidence	Total	7/1298 (0.54%)	Mean 0.54%	SD 0.91%	Total	0/1250 (0%)	Mean 0%	SD 0%

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

Page: 13

^{#:} 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	
Bone: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	,
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (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%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (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%)	
erall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%
one: Osteosarcoma								
00.0000.00		1/50 (2%)	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%)	0/00 (0/0)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	2/50 (4%)	1/49 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	3/50 (6%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	, ,		1/50 (2%)	0/50 (0%)	, ,
erall Incidence	Total	16/1298 (1.23%)	Mean 1.23%	SD 1.71%	Total	4/1250 (0.32%)	Mean 0.32%	SD 0.75%
one: Osteosarcoma or Osteo								•••••
		1/50 (2%)	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%)	(175)
		0/50 (0%)	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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	2/50 (4%)	1/49 (2%)		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%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	3/50 (6%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		` ,	` '	` '			. 1 1	` '
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	

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

Page: 14

^{#:} 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
*Brain:				
Astrocytoma Malignant				
		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%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (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%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 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	3/1297 (0.23%)	Mean 0.23% SD 0.65%	Total 1/1250 (0.08%) Mean 0.08% SD 0.4%
*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%)
		0/50 (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%) 0/49 (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%)
		0/49 (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	1/1297 (0.08%)	Mean 0.08% SD 0.39%	Total 0/1250 (0%) Mean 0% SD 0%
*Brain: Ependymoma Malignant				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (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%) 0/49 (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%) 0/50 (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	1/1297 (0.08%)	Mean 0.08% SD 0.4%	Total 0/1250 (0%) Mean 0% SD 0%

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

Page: 15

^{#:} 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
Brain:					
Glioma Malignant					
		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%) 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%) 0/49 (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%)
		0/49 (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	0/1297 (0%)	Mean 0% SD 0%	Total 4/1250 (0.32%)	Mean 0.32% SD 0.75%
Brain: Granular Cell Tumor Be	enign				
	J	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%) 0/49 (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%)	0/50 (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	2/1297 (0.15%)	Mean 0.15% SD 0.78%	Total 1/1250 (0.08%)	Mean 0.08% SD 0.4%
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%)
		0/50 (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%) 0/49 (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%)
		0/49 (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	1/1297 (0.08%)	Mean 0.08% SD 0.39%	Total 0/1250 (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	
Brain:								
Oligodendroglioma Ben	nign							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (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%)	0/49 (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%)
		0/49 (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	1/1297 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Mal								
ongodonarognoma mar	·g··a···	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%)	1700 (270)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/1297 (0.08%)	Mean 0.08%	SD 0.39%	Total	4/1250 (0.32%)	Mean 0.32%	SD 0.75%
Brain:								
Oligodendroglioma, Gli	oma, or Astroc	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%)		1/50 (2%)	0/50 (0%)	1/30 (2/0)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (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%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	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%)	0/50 (0%)	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	5/1297 (0.39%)	Mean 0.38%	SD 0.8%	Total	9/1250 (0.72%)	Mean 0.72%	SD 1.28%

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

Page: 17

^{#:} 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

Report Date: 03/20/2010

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			Male				Female	
Brain: Osteosarcoma								
		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%)	0/49 (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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	OD • • • • • • • • • • • • • • • • • • •		0/50 (0%)	0/50 (0%)	00.007
verall Incidence	Total	1/1297 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (0%)	Mean 0%	SD 0%
Brain: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (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%)	0/49 (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%)	0/50 (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	1/1297 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (0%)	Mean 0%	SD 0%
litoral/Preputial Gland: Adenoma								
		3/50 (6%)	2/49 (4%)	2/50 (4%)		12/50 (24%)	12/50 (24%)	2/50 (4%)
		4/50 (8%)	1/50 (2%)	5/50 (10%)		3/49 (6%)	10/50 (20%)	
		0/50 (0%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	6/50 (12%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	5/50 (10%)
		5/50 (10%)	2/50 (4%)	0/49 (0%)		3/50 (6%)	3/48 (6%)	2/50 (4%)
		0/50 (0%)	1/50 (2%)	5/50 (10%)		0/50 (0%)	11/50 (22%)	7/50 (14%)
		3/49 (6%)	3/50 (6%)	0/50 (0%)		4/50 (8%)	3/50 (6%)	3/50 (6%)
		4/50 (8%)	0/50 (0%)	3/50 (6%)		2/50 (4%)	0/50 (0%)	4/50 (8%)
		4/50 (8%)	1/48 (2%)			17/50 (34%)	5/50 (10%)	
verall Incidence	Total	51/1295 (3.94%)	Mean 3.93%	SD 3.56%	Total	119/1247 (9.54%)	Mean 9.53%	SD 8.77%

^{*:} 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	
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)	1/49 (2%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		1/49 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	4/50 (8%)
		1/50 (2%)	2/50 (4%)	1/49 (2%)		0/50 (0%)	2/48 (4%)	2/50 (4%)
		2/50 (4%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	3/50 (6%)	0/50 (0%)
		0/49 (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%)		8/50 (16%)	4/50 (8%)	7/50 (14%)
		2/50 (4%)	0/48 (0%)			0/50 (0%)	1/50 (2%)	
erall Incidence	Total	19/1295 (1.47%)	Mean 1.46%	SD 1.66%	Total	40/1247 (3.21%)	Mean 3.21%	SD 4.32%
litoral/Preputial Gland: Carcinoma or Adenoma		3/50 (6%)	3/49 (6%)	2/50 (4%)		13/50 (26%)	14/50 (28%)	2/50 (4%)
			()	` '		` ,	()	2/50 (4%)
		6/50 (12%)	1/50 (2%)	5/50 (10%)		4/49 (8%) 3/50 (6%)	10/50 (20%)	4/50 (20/)
		0/50 (0%) 2/50 (4%)	2/50 (4%) 0/50 (0%)	1/50 (2%) 2/50 (4%)		3/50 (6%) 2/50 (4%)	6/50 (12%) 2/50 (4%)	1/50 (2%) 9/50 (18%)
		6/50 (4%)	0/50 (0%) 4/50 (8%)	1/49 (2%)		3/50 (4%)	5/48 (10%)	9/50 (18%) 4/50 (8%)
		2/50 (4%)	3/50 (6%)	5/50 (10%)		1/50 (2%)	14/50 (28%)	7/50 (14%)
		3/49 (6%)	4/50 (8%)	0/50 (0%)		4/50 (8%)	3/50 (6%)	4/50 (8%)
		4/50 (8%)	0/50 (0%)	3/50 (6%)		10/50 (20%)	4/50 (8%)	10/50 (20%)
		5/50 (10%)	1/48 (2%)	0/00 (0/0)		17/50 (34%)	6/50 (12%)	10/00 (20/0)
rerall Incidence	Total	68/1295 (5.25%)	Mean 5.24%	SD 3.71%	Total	158/1247 (12.67%)	Mean 12.66%	SD 9.12%
litoral/Preputial Gland: Fibrosarcoma								
		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%)
		0/50 (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%)	0/50 (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%)
	T-1-1	0/50 (0%)	0/48 (0%)	CD 00/	T-1-1	0/50 (0%)	0/50 (0%)	CD 0 40/
verall Incidence	Total	0/1295 (0%)	Mean 0%	SD 0%	Total	1/1247 (0.08%)	Mean 0.08%	SD 0.4%

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

Page: 19

^{#:} 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: Sarcoma								
		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%)		0/49 (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%)		0/50 (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%)
		0/49 (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%)	0/48 (0%)			0/50 (0%)	0/50 (0%)	
rerall Incidence	Total	0/1295 (0%)	Mean 0%	SD 0%	Total	1/1247 (0.08%)	Mean 0.08%	SD 0.4%
ar: Neural Crest Tumor								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (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%)
		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%)	00 0 40/	-	0/50 (0%)	0/50 (0%)	OD 0 40/
erall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.4%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%
sophagus: 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 (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%)	0/49 (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%) 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%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/30 (070)		0/50 (0%)	0/50 (0%)	0/30 (0%)
vorall Incidence	Total	` ,	` '	SD 00/	Total	` ,	` ,	CD 0 40/
verall Incidence	Total	0/1298 (0%)	Mean 0%	SD 0%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%

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

Page: 20

^{#:} 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	
Esophagus: Lipoma								
•		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%)	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	0/1298 (0%)	Mean 0%	SD 0%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%
ye: Melanoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	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%)
		0/49 (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%)	
erall Incidence	Total	0/1298 (0%)	Mean 0%	SD 0%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%
iye: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	05		0/50 (0%)	0/50 (0%)	05.00/
verall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (0%)	Mean 0%	SD 0%

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

Page: 21

^{#:} 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** #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%)(2%)0/50 (0%)0/50 (0%)0/50 0/50 1/50 (0%)(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 0/50 (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%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/1298 (0.08%) Mean 0.08% SD 0.39% Total 0/1250 (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%)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 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (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 0/50 (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%)**Overall Incidence** Total 1/1298 (0.08%) Mean 0.08% SD 0.39% Total 0/1250 (0%) Mean 0% SD 0% *Heart: Schwannoma Benign 0/50 (0%)2/50 (4%)2/50 (4%)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

SD 1.14%

(0%)

(0%)

0/50

0/50

1/50

3/1250 (0.24%)

Total

(0%)

(0%)

(2%)

1/50

0/50

1/50

(2%)

(0%)

(2%)

Mean 0.24%

0/50

0/50

SD 0.66%

(0%)

(0%)

Total

1/49

0/50

0/50

5/1298 (0.39%)

(2%)

(0%)

(0%)

0/50

0/50

0/50

Mean 0.39%

(0%)

(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

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

1,50				Male				Female	
1/50	Heart:								
OSO	Schwannoma Maligna	nt							
10/50 (0%) 0/50 (0%)			` ,	` ,	` ,		` ,	` ,	0/50 (0%)
0.050			` ,	, ,	` ,		` '	` '	
0/50 (0%) 0/50 (0%) 0/40 (0%) 0/450 (0%) 0/50 (0%)			` ,	` '	` '		` '	` '	` '
			` ,	` '	` '		` ,	` '	` '
0/49 (0%) 0/50 (0%)			` ,	` ,	` '		` ,	` '	` '
0/50 (0%) 0/50			, ,	, ,	` ,		` ,	` ,	` '
verall Incidence Total 5/1298 (0.39%) Mean 0.38% SD 0.98% Total 3/1250 (0.24%) Mean 0.24% SD 0.66% ntestine Large: Colon/Rectum: Adenoma O/50 (0%) 0/50			()	` ,	` '		()	` ,	` ,
Verall Incidence Total 5/1298 (0.39%) Mean 0.38% SD 0.98% Total 3/1250 (0.24%) Mean 0.24% SD 0.66%			` ,	` ,	0/50 (0%)		` '	` ,	0/50 (0%)
Nestine Large: Colon/Rectum: Adenoma			` '	` '			` '	` '	
Adenoma Colon/Rectum: Adenoma Colon/Rectum: Colon/Re							` ,		SD 0.66%
0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50	ntestine Large: Colon/l								
0/50 (0%) 0/50			0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
0/50 (0%) 0/50			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%) 1/50 (2%) 0/50 (0%) 0/50			0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	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%)
O/49 (0%)			0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
O/50 (0%) 0/50			0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
O/50 (0%) O/50			0/49 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence Total 2/1298 (0.15%) Mean 0.15% SD 0.54% Total 4/1250 (0.32%) Mean 0.32% SD 0.75% Intestine Large: Colon/Rectum: Carcinoma 0/50 (0%) <th< td=""><td></td><td></td><td>0/50 (0%)</td><td>0/50 (0%)</td><td>0/50 (0%)</td><td></td><td>0/50 (0%)</td><td>0/50 (0%)</td><td>0/50 (0%)</td></th<>			0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
ntestine Large: Colon/Rectum: Carcinoma 0/50 (0%) 0/50			0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Carcinoma Colon/Rectum: Carcinoma Colon/Rectum: Carcinoma Colon/Rectum: Carcinoma Colon/Rectum: Colon/Re							` '		SD 0.75%
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	ntestine Large: Colon/l								
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
$\begin{array}{cccccccccccccccccccccccccccccccccccc$			` ,	` ,	` '		` ,	` ,	(-,-)
0/50 (0%) 0/50				` '	` ,		` ,	` '	0/50 (0%)
0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 0/50 0/50 0/50 0/50 0/50 0/50 0/50 0/50 0/50 0/50			` ,	` ,	` '		` '	` ,	` ,
0/50 (0%) 0/50 0/50 0/50 0/50 0/50 0/50 0/50 0/50 0/50 0/50 0/50 0/50 0/50			` ,	` ,	` '		` '	` ,	` '
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%) 1/50 (2%)			0/50 (0%)	1/50 (2%)	0,00 (0,0)		0/50 (0%)	1/50 (2%)	3,30 (0,70)
verall Incidence Total 1/1298 (0.08%) Mean 0.08% SD 0.39% Total 1/1250 (0.08%) Mean 0.08% SD 0.4%	verall Incidence	Total	` '	, ,	SD 0.30%	Total	` '	` '	SD 0.4%

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

Page: 23

^{#:} 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

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ALL VEHICLES

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			Male				Female	
#Intestine Large: Colon/Rectu Carcinoma or Adenoma	um:							
		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%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%)	0/50 (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%)	1/50 (2%)	00 0000		0/50 (0%)	1/50 (2%)	00.000
verall Incidence	Total	3/1298 (0.23%)	Mean 0.23%	SD 0.65%	Total	5/1250 (0.4%)	Mean 0.4%	SD 0.82%
Intestine Large: Colon/Recto Hemangioma	um:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (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%)	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%)	0/50 (0%)	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	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (0%)	Mean 0%	SD 0%
Intestine Small: Duodenum: 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%)	0/49 (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%)	0/50 (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	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (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	
ntestine Small: Duoden Leiomyoma	num:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	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%)	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%)
		0/49 (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%)	
verall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	2/1250 (0.16%)	Mean 0.16%	SD 0.55%
ntestine Small: lleum: 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%)	0/49 (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%)	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%)	00.00/	-	0/50 (0%)	0/50 (0%)	00 0 40/
rerall Incidence	Total	0/1298 (0%)	Mean 0%	SD 0%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%
ntestine Small: Jejunun 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%)	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%)
		0/49 (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%)	00 000/		0/50 (0%)	0/50 (0%)	00.007
verall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (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** #Intestine Small: Jejunum: **Granular Cell Tumor Malignant** 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%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)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%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/1298 (0.08%) Mean 0.08% SD 0.39% Total 0/1250 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)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%)(0%) 0/50 (0%)1/50 (2%)0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/1298 (0.08%) Mean 0.08% SD 0.39% Total 0/1250 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyosarcoma

0/50

0/50

0/50

0/50

0/49

0/50

0/50

0/50

SD 0%

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

0/50

0/50

0/50

0/50

0/50

0/50

0/50

0/50

1/50

1/1250 (0.08%)

Total

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(2%)

0/50

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%)

Mean 0.08%

0/50

0/50

0/50

0/50

0/50

0/50

0/50

SD 0.4%

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

Total

0/50

0/50

0/50

0/50

0/50

0/50

0/49

0/50

0/50

0/1298 (0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

0/50

0/50

0/50

0/50

0/50

0/50

0/50

0/50

0/50

Mean 0%

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(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

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 Un Adenoma	specified:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	, ,
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (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%)	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%)	
verall Incidence	Total	0/1298 (0%)	Mean 0%	SD 0%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%
ntestine Small: Site Un Carcinoma	ispecinea:	0/50 (0%)	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 (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%)	0/49 (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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	(070)		0/50 (0%)	0/50 (0%)	0,00 (0,0)
verall Incidence	Total	2/1298 (0.15%)	Mean 0.15%	SD 0.54%	Total	0/1250 (0%)	Mean 0%	SD 0%
						` ,		
Intestine Small: Site Un Carcinoma or Adenom								
		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%)	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%)
		0/49 (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%)	0/50 (0%)
	_	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/1298 (0.15%)	Mean 0.15%	SD 0.54%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%

^{*:} 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 Un										
	3	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%)		
		0/49 (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	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (0%)	Mean 0%	SD 0%		
ntestine Small: Site Un 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%)	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%)	0/49 (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%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
erall Incidence	Total	2/1298 (0.15%)	Mean 0.15%	SD 0.54%	Total	2/1250 (0.16%)	Mean 0.16%	SD 0.55%		
ntestine Small: Site Un										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (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%)	0/50 (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	0/1298 (0%)	Mean 0%	SD 0%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%		

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

Page: 28

^{#:} 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				
Islets, Pancreatic:										
		4/50 (8%)	1/50 (2%)	3/50 (6%)		1/50 (2%)	1/49 (2%)	0/50 (0%)		
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	2/49 (4%)			
		1/50 (2%)	6/50 (12%)	6/50 (12%)		1/50 (2%)	0/50 (0%)	2/50 (4%)		
		2/50 (4%)	0/50 (0%)	7/50 (14%)		1/50 (2%)	1/50 (2%)	0/49 (0%)		
		2/50 (4%)	4/50 (8%)	4/49 (8%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
		3/50 (6%)	3/50 (6%)	2/50 (4%)		3/50 (6%)	0/48 (0%)	1/50 (2%)		
		4/49 (8%)	2/50 (4%)	3/50 (6%)		1/50 (2%)	1/50 (2%)	2/50 (4%)		
		4/50 (8%)	3/50 (6%)	18/50 (36%)		2/50 (4%)	0/50 (0%)	3/50 (6%)		
		3/50 (6%)	5/49 (10%)			3/49 (6%)	1/50 (2%)			
verall Incidence	Total	92/1296 (7.1%)	Mean 7.1%	SD 6.91%	Total	27/1244 (2.17%)	Mean 2.17%	SD 2.01%		
slets, Pancreatic: Carcinoma		0/50 (00/)	0/50 (40/)	0/50 (00/)		4/50 /00/	0/40 (00/)	4/50 (00/)		
		0/50 (0%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	0/49 (0%)	1/50 (2%)		
		3/50 (6%)	1/50 (2%)	1/49 (2%)		1/50 (2%)	0/49 (0%)	0/50 (00/)		
		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%)	0/49 (0%)		
		2/50 (4%) 1/50 (2%)	0/50 (0%)	0/49 (0%) 1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		5/49 (10%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/48 (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%)	1/49 (2%)	0/30 (0 /8)		0/49 (0%)	0/50 (0%)	0/30 (0 /8)		
verall Incidence	Total	25/1296 (1.93%)	Mean 1.93%	SD 2.39%	Total	4/1244 (0.32%)	Mean 0.32%	SD 0.75%		
		25/1290 (1.95/6)		30 2.39/0		4/1244 (0.3276)	IVICALI 0.32 /0			
slets, Pancreatic: Carcinoma or Adenoma										
		4/50 (8%)	3/50 (6%)	3/50 (6%)		2/50 (4%)	1/49 (2%)	1/50 (2%)		
		3/50 (6%)	2/50 (4%)	2/49 (4%)		1/50 (2%)	2/49 (4%)	- / / / / / /		
		3/50 (6%)	6/50 (12%)	7/50 (14%)		2/50 (4%)	0/50 (0%)	2/50 (4%)		
		3/50 (6%)	0/50 (0%)	7/50 (14%)		1/50 (2%)	1/50 (2%)	0/49 (0%)		
		4/50 (8%)	4/50 (8%)	4/49 (8%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
		4/50 (8%)	4/50 (8%)	3/50 (6%)		3/50 (6%)	0/48 (0%)	1/50 (2%)		
		9/49 (18%)	2/50 (4%)	3/50 (6%)		1/50 (2%)	1/50 (2%)	2/50 (4%)		
		4/50 (8%)	4/50 (8%)	18/50 (36%)		2/50 (4%)	0/50 (0%)	3/50 (6%)		
	Tatal	5/50 (10%)	6/49 (12%)	CD C C70/	T-4-1	3/49 (6%)	1/50 (2%)	CD 4.050/		
verall Incidence	Total	117/1296 (9.03%)	Mean 9.03%	SD 6.67%	Total	31/1244 (2.49%)	Mean 2.49%	SD 1.95%		

^{*:} 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 Transitional Epithelium: Carcinoma											
		0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/44 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (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%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)			
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%)	0/48 (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%)				
verall Incidence	Total	2/1294 (0.15%)	Mean 0.15%	SD 0.54%	Total	0/1236 (0%)	Mean 0%	SD 0%			
(idney: Pelvis and Tran Carcinoma or Adenom			0/40 (00/)	0/50 (00/)		0/50 (00/)	0/44 /00/	0/50 (00/)			
		0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/44 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/47 (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%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)			
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%)	0/48 (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%)	0/50 (0%) 0/50 (0%)	0/50 (0%)			
	T-1-1	` '	` '	00 0540/	T-1-1	(,	` ,	OD 00/			
verall Incidence	Total	2/1294 (0.15%)	Mean 0.15%	SD 0.54%	Total	0/1236 (0%)	Mean 0%	SD 0%			
Kidney: Pelvis and Tran Papilloma	nsitional Epitheli	um:									
		0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/44 (0%)	0/50 (0%)			
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/49 (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%)	0/49 (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%)	0/48 (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%)				
Overall Incidence	Total	1/1294 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1236 (0%)	Mean 0%	SD 0%			

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

Page: 30

^{#:} 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: Renal Tubule: Adenoma									,					
		0/49	(0%)	0/48	(0%)	0/50	(0%)		0/50	(0%)	0/44	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/47	(0%)		
		1/50	(2%)	1/50	(2%)	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%)	0/49	(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%)	0/48	(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%)	0/49	(0%)				1/50	(2%)	0/50	(0%)		
Overall Incidence	Total	6/1294 (0.46		Mean 0		SD 0.869		Total	1/1236 (0	,		0.08%	SD 0	0.4%
Kidney: Renal Tubule: Carcinoma														
		0/49	(0%)	0/48	(0%)	0/50	(0%)		0/50	(0%)	0/44	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		1/49	(2%)	0/47	(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%)	0/49	(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%)	0/48	(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%)		()
Overall Incidence	Total	2/1294 (0.15	5%)	Mean 0	. ,	SD 0.549	6	Total	1/1236 (0	` ,		0.08%	SD 0.	41%
									,	,				
Kidney: Renal Tubule: Carcinoma or Adenoma														
		0/49	(0%)	0/48	(0%)	0/50	(0%)		0/50	(0%)	0/44	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)		1/49	(2%)	0/47	(0%)		
		2/50	(4%)	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%)	0/49	(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%)	0/48	(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%)	0/49	(0%)		. ,		1/50	(2%)	0/50	(0%)		. ,
Overall Incidence	Total	8/1294 (0.62	. ,	Mean 0	. ,	SD 1.249	/ _	Total	2/1236 (0		Mean	0.16%	SD 0.	56%

^{*:} 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: Renal Tubule: Hemangiosarcoma 0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/44 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49(0%)0/47 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/49 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(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%)0/48 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)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%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/1294 (0.08%) Mean 0.08% SD 0.39% Total 0/1236 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Lipoma 0/49 (0%)0/48 (0%)1/50 (2%)0/50 (0%)0/44 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%) 0/49 (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%)0/49 (0%)0/50 0/50 0/50 (0%)0/50 (0%)(0%)(0%) 0/50 (0%)0/50 (0%)0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(2%) 0/50 (0%)1/50 0/49 (0%)0/48 (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%)0/50 (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%)**Overall Incidence** Total 3/1294 (0.23%) Mean 0.23% SD 0.65% Total 1/1236 (0.08%) Mean 0.08% SD 0.4% *Kidney: Renal Tubule: Mesenchymal Tumor Benign 0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/44 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/47 (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%)0/50 (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%)0/48 (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%)Total 1/1294 (0.08%) Mean 0.08% SD 0.39% Total 0/1236 (0%) Mean 0% SD 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

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female					
Kidney: Renal Tubule:											
Mesenchymal Tumor N	lalignant	0/49 (0%)	0/49 (00/)	0/50 (00/)		0/50 (00/)	1/44 (20/)	0/50 (00/)			
		0/49 (0%) 0/50 (0%)	0/48 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/49 (0%)	1/44 (2%) 0/47 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/47 (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%)	0/48 (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%)	0/00 (0/0)		0/50 (0%)	0/50 (0%)	0/00 (0/0)			
erall Incidence	Total	0/1294 (0%)	Mean 0%	SD 0%	Total	1/1236 (0.08%)	Mean 0.09%	SD 0.45%			
dney: Renal Tubule:											
Nephroblastoma											
		0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/44 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (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%)	0/49 (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%)	0/48 (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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)				
erall Incidence	Total	0/1294 (0%)	Mean 0%	SD 0%	Total	1/1236 (0.08%)	Mean 0.08%	SD 0.4%			
idney: Renal Tubule: Sarcoma											
		0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/44 (0%)	1/50 (2%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (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%)	1/49 (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%)		0/49 (0%)	0/48 (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%)	0/49 (0%)			0/50 (0%)	0/50 (0%)				
	Total	0/1294 (0%)		SD 0%		3/1236 (0.24%)	Mean 0.24%	SD 0.67%			

^{*:} 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
*Liver:				
Cholangioma		0/50 (00/)	0/50 (00/) 0/50 (00/)	0/50 (001) 0/50 (001)
		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%) 0/49 (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%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/30 (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%)
Overall Incidence	Total	2/1298 (0.15%)	Mean 0.15% SD 0.54%	Total 0/1250 (0%) Mean 0% SD 0%
*Liver: Hemangiosarcoma				
•		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 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%) 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	1/1298 (0.08%)	Mean 0.08% SD 0.39%	Total 0/1250 (0%) Mean 0% SD 0%
*Liver: Hepatocellular Adenoma				
		2/50 (4%)	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%) 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%) 1/50 (2%)	2/50 (4%) 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%)	3/50 (6%) 0/50 (0%)	0/50 (0%) 2/50 (4%) 0/50 (0%)
		0/49 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 1/50 (2%) 2/50 (4%)
		0/50 (0%)	1/50 (2%) 1/50 (2%)	1/50 (2%) 0/50 (0%) 0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	15/1298 (1.16%)	Mean 1.16% SD 1.62%	Total 11/1250 (0.88%) Mean 0.88% SD 1.54%

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

Page: 34

^{#:} 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: **Hepatocellular Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 2/50 (4%)0/50 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%)(2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 1/50 (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%)1/49 (2%)(0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 6/1298 (0.46%) Mean 0.46% SD 1.03% Total 1/1250 (0.08%) Mean 0.08% SD 0.4% *Liver: Hepatocellular Carcinoma or Hepatoblastoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)(0%) 0/50 (0%) (2%)0/50 0/50 1/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (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 0/50 (0%)(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 6/1298 (0.46%) Mean 0.46% SD 1.03% Total 1/1250 (0.08%) Mean 0.08% SD 0.4% *Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)0/50 (0%)1/50 (2%)2/50 (4%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)2/50 (4%)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%)3/50 (6%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)1/49 (2%)1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)2/50 (4%)0/50 (0%)1/50 (2%)2/50 (4%)1/50 (2%)0/50 0/50 (0%)(0%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)Total 21/1298 (1.62%) Mean 1.62% SD 1.7% Total 12/1250 (0.96%) Mean 0.96% SD 1.54% 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					
Liver:											
Hepatocellular Carcinon	na, Hepatocell	ular Adenoma, or Hepa	toblastoma								
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		2/50 (4%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	2/50 (4%)				
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)			
		0/50 (0%)	1/50 (2%)	1/50 (2%)		2/50 (4%)	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%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)			
		1/49 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	2/50 (4%)			
		0/50 (0%)	1/50 (2%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	0/50 (0%)			
		2/50 (4%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
verall Incidence	Total	21/1298 (1.62%)	Mean 1.62%	SD 1.7%	Total	12/1250 (0.96%)	Mean 0.96%	SD 1.54%			
.iver: Ito Cell Tumor Benign				•••••							
_		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%)	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	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (0%)	Mean 0%	SD 0%			
₋ung: Alveolar/Bronchiolar Ad											
		0/50 (0%)	1/50 (2%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		2/50 (4%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)				
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	4/50 (8%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	1/50 (2%)			
		0/50 (0%)	3/50 (6%)	2/49 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)			
		0/50 (0%)	1/50 (2%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	4/50 (8%)			
		1/49 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	2/50 (4%)	0/50 (0%)			
		4/50 (8%)	0/50 (0%)	1/50 (2%)		4/50 (8%)	0/50 (0%)	0/50 (0%)			
		2/50 (4%)	3/50 (6%)			1/50 (2%)	1/50 (2%)				
verall Incidence	Total	31/1298 (2.39%)	Mean 2.39%	SD 2.6%	Total	22/1250 (1.76%)	Mean 1.76%	SD 2.6%			

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

Page: 36

^{#:} 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		
Lung: Alveolar/Bronchiolar C	`arainama													
Aiveolai/biolicillolai C	arcinoma	0/50 (0	(0%)	1/50	(2%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(00/)
			(0%) (2%)	0/50	(2%)	0/50	(2%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
			(2%)	1/50	(2%)	1/50	(2%)		1/50	(2%)	1/50	(2%)	0/50	(0%)
		`	(2%)	0/50	(0%)	1/50	(2%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
			(2%)	1/50	(2%)	1/49	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
			(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		,	(0%)	1/50	(2%)	3/50	(6%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		,	(0%)	1/50	(2%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		,	(2%)	1/50	(2%)	1700	(270)		0/50	(0%)	0/50	(0%)	0,00	(070)
verall Incidence	Total	19/1298 (1.46%	` '	Mean 1.4	, ,	SD 1.33%	%	Total	6/1250 (0	` '		0.48%	SD 0.8	87%
						•••••								
ung: Alveolar/Bronchiolar C	arcinoma or Alv	veolar/Bronchiolar	Adenoma											
		0/50 (0	(0%)	2/50	(4%)	5/50	(10%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		3/50 (6	(6%)	0/50	(0%)	1/50	(2%)		2/50	(4%)	1/50	(2%)		
		2/50 (4	(4%)	2/50	(4%)	1/50	(2%)		1/50	(2%)	4/50	(8%)	0/50	(0%)
		1/50 (2	(2%)	0/50	(0%)	1/50	(2%)		2/50	(4%)	1/50	(2%)	1/50	(2%)
		1/50 (2	(2%)	4/50	(8%)	2/49	(4%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50 (0	(0%)	1/50	(2%)	3/50	(6%)		0/50	(0%)	1/50	(2%)	4/50	(8%)
		1/49 (2	(2%)	1/50	(2%)	4/50	(8%)		1/50	(2%)	2/50	(4%)	0/50	(0%)
		4/50 (8	(8%)	1/50	(2%)	2/50	(4%)		4/50	(8%)	0/50	(0%)	0/50	(0%)
		3/50 (6	(6%)	4/50	(8%)				1/50	(2%)	1/50	(2%)		
	Total	49/1298 (3.78%	(6)	Mean 3.	77%	SD 2.9%		Total	27/1250 (2	2.16%)	Mean	(2%) 2.16%	SD 2.5	58%
		49/1298 (3.78%	(6)	Mean 3.	77%					2.16%)	Mean	` '	SD 2.	58%
ung:		49/1298 (3.78%	(6)	Mean 3.	77%				27/1250 (2	2.16%)	Mean	` '	SD 2.	58%
ung:		49/1298 (3.78%	(6)	Mean 3.	77%				27/1250 (2	2.16%)	Mean	` '	SD 2.9	(0%)
ung:		49/1298 (3.78% 0/50 (0	6)	Mean 3.	77%				27/1250 (2	2.16%)	Mean	2.16%		
ung:		49/1298 (3.78% 0/50 (0 0/50 (0	(0%)	Mean 3.	(0%)	0/50	(0%)		27/1250 (2	(0%)	Mean 0/50	(0%)		
ung:		49/1298 (3.78% 0/50 (0 0/50 (0 0/50 (0	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)		27/1250 (2 0/50 0/50	(0%)	Mean 0/50 0/50	(0%) (0%)	0/50	(0%)
ung:		49/1298 (3.78% 0/50 (0 0/50 (0 0/50 (0 0/50 (0	(0%) (0%) (0%)	0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 0/50	(0%) (0%) (0%)		27/1250 (2 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 0/50	(0%) (0%) (0%) (0%)	0/50	(0%)
ung:		49/1298 (3.78% 0/50 (0 0/50 (0 0/50 (0 0/50 (0 0/50 (0	(0%) (0%) (0%) (0%) (0%)	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%)		27/1250 (2 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%)	0/50 0/50 0/50	(0%) (0%) (0%)
ung:		49/1298 (3.78% 0/50 (0 0/50 (0 0/50 (0 0/50 (0 0/50 (0 0/50 (0	(0%) (0%) (0%) (0%) (0%) (0%)	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 0/49	(0%) (0%) (0%) (0%) (0%)		27/1250 (2 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%)	0/50 0/50 0/50 1/50	(0%) (0%) (0%) (0%) (2%)
ung:		49/1298 (3.78% 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%) (0%) (0%) (0%)	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 0/49 0/50	(0%) (0%) (0%) (0%) (0%) (0%)		27/1250 (2 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	2.16% (0%) (0%) (0%) (0%) (0%) (0%)	0/50 0/50 0/50 1/50 0/50	(0%) (0%) (0%) (0%) (2%) (0%)
verall Incidence ung: Fibrosarcoma		49/1298 (3.78% 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%) (0%) (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%) (0%) (0%)	0/50 0/50 0/50 0/50 0/50 0/49 0/50 0/50	(0%) (0%) (0%) (0%) (0%) (0%) (0%)		27/1250 (2 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	2.16% (0%) (0%) (0%) (0%) (0%) (0%) (0%)	0/50 0/50 0/50 1/50 0/50 0/50	(0%) (0%) (0%) (2%) (0%) (0%)

^{*:} 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

Page: 38

Report Date: 03/20/2010

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Lung:		,		,				,
Hemangiosarcoma								
		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%)	1/50 (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%)
		0/49 (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	2/1298 (0.15%)	Mean 0.15%	SD 0.54%	Total	0/1250 (0%)	Mean 0%	SD 0%
ung: Squamous Cell Carcinom								
.,		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%)	0/49 (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%)	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%)	0,00 (0,0)		0/50 (0%)	0/50 (0%)	0/00 (0/0)
verall Incidence	Total	2/1298 (0.15%)	Mean 0.15%	SD 0.54%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%
Lymph Node: Hemangiosarcoma					•••••			
		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%)	0/49 (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%)	0/50 (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	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (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	
Mammary Gland: Adenolipoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (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%)
		0/49 (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%)	
erall Incidence	Total	0/1298 (0%)	Mean 0%	SD 0%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%
lammary Gland: Adenoma		0/50 (0%)	0/50 (09/)	0/50 (00/)		1/50 (20/)	1/50 (20/)	0/50 (09/)
			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%)	1/50 (2%)	4/50 (00/)
		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%)	2/50 (4%)	2/50 (4%)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		2/50 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)
		2/49 (4%)	0/50 (0%)	0/50 (0%)		3/50 (6%)	2/50 (4%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	4/50 (8%)
		0/50 (0%)	0/50 (0%)	0/30 (0 /0)		0/50 (0%)	0/50 (0%)	4/30 (0/0)
verall Incidence	Total	4/1298 (0.31%)	Mean 0.31%	SD 0.94%	Total	26/1250 (2.08%)	Mean 2.08%	SD 2.27%
		4/1290 (0.3170)						
Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	2/50 (4%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		4/50 (8%)	0/50 (0%)	
		2/50 (4%)	0/50 (0%)	0/50 (0%)		10/50 (20%)	2/50 (4%)	9/50 (18%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	4/50 (8%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	4/50 (8%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		3/50 (6%)	4/50 (8%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	1/50 (2%)		7/50 (14%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	3/50 (6%)
		0/50 (0%)	1/50 (2%)	OD 0.0001		1/50 (2%)	2/50 (4%)	OD 5 (00)
verall Incidence	Total	5/1298 (0.39%)	Mean 0.38%	SD 0.98%	Total	65/1250 (5.2%)	Mean 5.2%	SD 5.42%

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

Page: 39

^{#:} 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%)	0/50 (0%)		3/50 (6%)	3/50 (6%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		4/50 (8%)	1/50 (2%)	
		2/50 (4%)	0/50 (0%)	0/50 (0%)		10/50 (20%)	3/50 (6%)	10/50 (20%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	2/50 (4%)	6/50 (12%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		2/50 (4%)	4/50 (8%)	3/50 (6%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		3/50 (6%)	4/50 (8%)	0/50 (0%)
		2/49 (4%)	0/50 (0%)	1/50 (2%)		10/50 (20%)	2/50 (4%)	3/50 (6%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	3/50 (6%)	6/50 (12%)
		0/50 (0%)	1/50 (2%)			1/50 (2%)	2/50 (4%)	
verall Incidence	Total	9/1298 (0.69%)	Mean 0.7%	SD 1.27%	Total	90/1250 (7.2%)	Mean 7.2%	SD 5.57%
//ammary Gland: Fibroadenoma								
		2/50 (4%)	3/50 (6%)	3/50 (6%)		35/50 (70%)	26/50 (52%)	16/50 (32%)
		2/50 (4%)	2/50 (4%)	0/50 (0%)		25/50 (50%)	29/50 (58%)	,
		0/50 (0%)	1/50 (2%)	2/50 (4%)		24/50 (48%)	14/50 (28%)	27/50 (54%)
		2/50 (4%)	2/50 (4%)	1/50 (2%)		33/50 (66%)	32/50 (64%)	30/50 (60%)
		1/50 (2%)	4/50 (8%)	0/49 (0%)		29/50 (58%)	26/50 (52%)	24/50 (48%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		22/50 (44%)	28/50 (56%)	17/50 (34%)
		1/49 (2%)	1/50 (2%)	0/50 (0%)		26/50 (52%)	21/50 (42%)	24/50 (48%)
		2/50 (4%)	1/50 (2%)	1/50 (2%)		37/50 (74%)	14/50 (28%)	22/50 (44%)
		3/50 (6%)	6/50 (12%)			43/50 (86%)	31/50 (62%)	
verall Incidence	Total	41/1298 (3.16%)	Mean 3.16%	SD 2.84%	Total	655/1250 (52.4%)	Mean 52.4%	SD 14.01%
Mammary Gland: Fibroma								
		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%)	
		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%)	0/49 (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%)	0/50 (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	2/1298 (0.15%)	Mean 0.15%	SD 0.54%	Total	2/1250 (0.16%)	Mean 0.16%	SD 0.55%

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

Page: 40

^{#:} 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:						
Fibroma, Fibroadenom	a or Adenoma					
		3/50 (6%)	3/50 (6%)	3/50 (6%)	36/50 (72%)	28/50 (56%) 16/50 (32%)
		2/50 (4%)	2/50 (4%)	1/50 (2%)	25/50 (50%)	30/50 (60%)
		0/50 (0%)	1/50 (2%)	2/50 (4%)	24/50 (48%)	15/50 (30%) 27/50 (54%)
		4/50 (8%)	2/50 (4%)	1/50 (2%)	33/50 (66%)	33/50 (66%) 30/50 (60%)
		1/50 (2%)	4/50 (8%)	0/49 (0%)	30/50 (60%)	26/50 (52%) 25/50 (50%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)	22/50 (44%)	28/50 (56%) 17/50 (34%)
		3/49 (6%)	1/50 (2%)	0/50 (0%)	28/50 (56%)	22/50 (44%) 25/50 (50%)
		2/50 (4%)	1/50 (2%)	1/50 (2%)	37/50 (74%)	14/50 (28%) 25/50 (50%)
		3/50 (6%)	6/50 (12%)		43/50 (86%)	31/50 (62%)
verall Incidence	Total	47/1298 (3.62%)	Mean 3.62%	SD 3%	Total 670/1250 (53.6%)	Mean 53.6% SD 13.93%
Mammary Gland: Fibroma, Fibroadenom	a, Carcinoma, c		3/50 (69/)	2/50 /69/\	27/50 /7/0/\	20/50 (609/) 47/50 (249/)
		3/50 (6%)	3/50 (6%)	3/50 (6%)	37/50 (74%)	30/50 (60%) 17/50 (34%)
		2/50 (4%)	2/50 (4%)	1/50 (2%)	27/50 (54%)	30/50 (60%)
		2/50 (4%) 4/50 (8%)	1/50 (2%) 2/50 (4%)	2/50 (4%)	31/50 (62%) 35/50 (70%)	17/50 (34%) 30/50 (60%) 33/50 (66%) 31/50 (62%)
		4/50 (8%) 1/50 (2%)	2/50 (4%) 4/50 (8%)	1/50 (2%) 0/49 (0%)	39/50 (70%)	33/50 (66%) 31/50 (62%) 28/50 (56%) 26/50 (52%)
		1/50 (2%)	0/50 (0%)	0/49 (0%)	24/50 (48%)	28/50 (56%) 26/50 (52%) 28/50 (56%) 17/50 (34%)
		3/49 (6%)	1/50 (0%)	1/50 (2%)	31/50 (62%)	22/50 (44%) 26/50 (52%)
		3/50 (6%)	1/50 (2%)	1/50 (2%)	37/50 (62%)	16/50 (32%) 25/50 (50%)
		3/50 (6%)	6/50 (12%)	1/30 (2 /6)	43/50 (86%)	31/50 (62%)
verall Incidence	Total	51/1298 (3.93%)	Mean 3.93%	SD 2.86%	Total 702/1250 (56.16%)	Mean 56.16% SD 13.48%
		, ,			,	Wedii 30.10% 3D 13.46%
Mesentery: Fibrous Histiocytoma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (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%)	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	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total 0/1250 (0%)	Mean 0% SD 0%

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

Page: 41

^{#:} 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	
#Mesentery: Hemangiosarcoma					
nemangiosarcoma		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%) 0/49 (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%) 0/50 (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	1/1298 (0.08%)	Mean 0.08% SD 0.39%	Total 0/1250 (0%) Mean 0% SD 0%	
#Mesentery: Lipoma					
•		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
		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%) 0/50 (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	1/1298 (0.08%)	Mean 0.08% SD 0.39%	Total 0/1250 (0%) Mean 0% SD 0%	
#Mesentery: Schwannoma Malignant					
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	
		0/50 (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%) 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%)	
Overall Incidence	Total	0/1298 (0%)	Mean 0% SD 0%	Total 2/1250 (0.16%) Mean 0.16% SD 0.8%	

^{*:} 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
*Nose:				
Adenoma		0/50 (00/)	0/50 (00/) 0/50 (00/)	0/50 (001) 0/50 (001) 0/40 (001)
		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%) 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%)	0/49 (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%)	0/49 (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%)
Overell Incidence	Total	` ,	, ,	
Overall Incidence	Total	0/1297 (0%)	Mean 0% SD 0%	Total 1/1247 (0.08%) Mean 0.08% SD 0.4%
*Nose: Chondroma				
		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%)	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%)	0/49 (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%)
		0/50 (0%)	0/50 (0%) 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	0/1297 (0%)	Mean 0% SD 0%	Total 1/1247 (0.08%) Mean 0.08% SD 0.4%
*Nose: Squamous Cell Carcinon				
		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%) 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%) 0/50 (0%) 0/50 (0%)
		0/49 (0%)	1/50 (2%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 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	1/1297 (0.08%)	Mean 0.08% SD 0.39%	Total 0/1247 (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: 03/20/2010

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Oral Cavity (Oral Mucos	. •	rynx, Tooth, Gingiva):						
	•	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%)		0/50 (0%)	0/50 (0%)	
		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%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	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%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	
verall Incidence	Total	7/1298 (0.54%)	Mean 0.54%	SD 0.91%	Total	6/1250 (0.48%)	Mean 0.48%	SD 0.87%
Oral Cavity (Oral Mucos Squamous Cell Carcin		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 (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%)	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%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
		0/30 (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%)
		0/49 (0%)	0/50 (0%)	0/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/30 (0 /8)		0/50 (0%)	0/50 (0%)	0/30 (0 /8)
verall Incidence	Total	4/1298 (0.31%)	Mean 0.31%	SD 0.74%	Total	3/1250 (0.24%)	Mean 0.24%	SD 0.66%
		` ,				3/1230 (0.2470)		
Oral Cavity (Oral Mucos Squamous Cell Carcin		rynx, Tooth, Gingiva): Squamous, or Papilloma						
		1/50 (2%)	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%)	
		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%)	1/50 (2%)
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	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%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	
verall Incidence	Total	11/1298 (0.85%)	Mean 0.85%	SD 1.16%	Total	9/1250 (0.72%)	Mean 0.72%	SD 1.14%

^{*:} 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	
#Oral Mucosa: Squamous Cell Carcinom	ıa							
		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%)	1/50 (2%)		1/50 (2%)	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%)
		0/49 (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	3/1298 (0.23%)	Mean 0.23%	SD 0.65%	Total	2/1250 (0.16%)	Mean 0.16%	SD 0.55%
#Oral Mucosa: Squamous Cell Papilloma	1							
		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%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		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	2/1298 (0.15%)	Mean 0.16%	SD 0.55%	Total	2/1250 (0.16%)	Mean 0.16%	SD 0.55%
*Ovary: Cystadenoma								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (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%)
						0/49 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	1/1248 (0.08%)	Mean 0.08%	SD 0.4%

^{*:} 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				Femal)	
*Ovary:						
Granulosa Cell Tumor Benign						
)%)	0/50 (0%		(0%)
		,)%)	0/50 (0%	•	
)%)	0/50 (0%		(0%)
)%)	0/50 (0%		(0%)
		•)%)	0/50 (0%	•	(0%)
		,)%) ()	0/50 (0%	,	(2%)
		,)%)	0/50 (0%	,	(2%)
)%)	0/50 (0%		(0%)
		`)%)	0/50 (0%	•	
Overall Incidence	Total	2/1248 (0.169		Mean 0.16	% SD	0.55%
*Ovary:						
Granulosa Cell Tumor Malignant						
		0/50 (0)%)	1/50 (2%) 1/50	(2%)
		0/50 (0)%)	0/50 (0%)	
		0/50 (0)%)	0/50 (0%	0/50	(0%)
		0/50 (0)%)	0/50 (0%) 0/50	(0%)
		0/49 (0)%)	0/50 (0%) 0/50	(0%)
		1/50 (2	2%)	2/50 (4%) 0/50	(0%)
		0/50 (0)%)	0/50 (0%) 0/50	(0%)
)%)	0/50 (0%		(2%)
		0/50 (0)%)	0/50 (0%)	
Overall Incidence	Total	6/1248 (0.489	,	Mean 0.48	-	1.05%
*Ovary:						
Granulosa Cell Tumor: Benign, Malignant, NOS						
		0/50 (0)%)	1/50 (2%) 1/50	(2%)
		,)%)	0/50 (0%	,	` '
)%)	0/50 (0%		(0%)
)%)	0/50 (0%		(0%)
		0/49 (0)%)	0/50 (0%	0/50	(0%)
		1/50 (2	2%)	2/50 (4%) 1/50	(2%)
)%)	0/50 (0%		(2%)
		0/49 (0)%)	0/50 (0%) 1/50	(2%)
		0/50 (0)%)	0/50 (0%)	
Overall Incidence	Total	8/1248 (0.649		Mean 0.64	· 0D	1.11%

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

Page: 46

^{#:} 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** *Ovary: **Granulosa-Theca Tumor Benign** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/50 0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)0/49 (0%)0/50 0/50 (0%)(0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 2/1248 (0.16%) Mean 0.16% SD 0.55% *Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/50 0/50 0/50 (0%)(0%)(0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)(0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/1248 (0.16%) Mean 0.16% SD 0.8% *Ovary: **Tubulostromal Adenoma** 1/50 (2%)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%)0/49 (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%)0/50 (0%)**Overall Incidence** Total 1/1248 (0.08%) Mean 0.08% SD 0.4%

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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	
Pancreas: Adenoma								
		3/50 (6%)	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%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		1/50 (2%)	7/50 (14%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/48 (0%)	0/50 (0%)
		0/49 (0%)	2/50 (4%)	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%)
		2/50 (4%)	1/49 (2%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	22/1294 (1.7%)	Mean 1.7%	SD 3.03%	Total	0/1245 (0%)	Mean 0%	SD 0%
ancreas: Carcinoma								
		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%)	0/50 (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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)
		0/49 (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%)	
rerall Incidence	Total	1/1294 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1245 (0%)	Mean 0%	SD 0%
ancreas: Carcinoma or Adenoma								
		3/50 (6%)	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%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		1/50 (2%)	8/50 (16%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/48 (0%)	0/50 (0%)
		0/49 (0%)	2/50 (4%)	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%)
		2/50 (4%)	1/49 (2%)	OD • • • • • • • • • • • • • • • • • • •		0/50 (0%)	0/50 (0%)	05 00/
verall Incidence	Total	23/1294 (1.78%)	Mean 1.77%	SD 3.36%	Total	0/1245 (0%)	Mean 0%	SD 0%

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

Page: 48

^{#:} 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	
Pancreas:								,
Mixed Tumor Benign								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	2/22 (22/)
		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%)	0/49 (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%)
		2/49 (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%)	0/49 (0%)	00 0040/	.	0/50 (0%)	0/50 (0%)	00.00/
verall Incidence	Total	4/1294 (0.31%)	Mean 0.31%	SD 0.94%	Total	0/1245 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Malignant								
_		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%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/48 (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%)	
verall Incidence	Total	1/1294 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1245 (0%)	Mean 0%	SD 0%
Parathyroid Gland: Adenoma								
		0/48 (0%)	0/48 (0%)	0/49 (0%)		0/49 (0%)	0/47 (0%)	0/43 (0%)
		0/46 (0%)	1/45 (2%)	1/46 (2%)		0/47 (0%)	0/48 (0%)	
		0/45 (0%)	0/49 (0%)	0/48 (0%)		0/49 (0%)	0/46 (0%)	1/43 (2%)
		0/48 (0%)	0/50 (0%)	0/49 (0%)		0/46 (0%)	0/48 (0%)	0/49 (0%)
		0/49 (0%)	0/47 (0%)	1/49 (2%)		0/48 (0%)	0/47 (0%)	0/44 (0%)
		0/47 (0%)	0/50 (0%)	1/45 (2%)		0/43 (0%)	0/49 (0%)	0/47 (0%)
		0/47 (0%)	1/49 (2%)	0/50 (0%)		0/49 (0%)	2/46 (4%)	0/49 (0%)
		0/46 (0%)	0/48 (0%)	0/45 (0%)		0/46 (0%)	0/49 (0%)	0/45 (0%)
		0/44 (0%)	1/46 (2%)			0/42 (0%)	0/42 (0%)	
verall Incidence	Total	6/1233 (0.49%)	Mean 0.5%	SD 0.92%	Total	3/1161 (0.26%)	Mean 0.27%	SD 0.97%

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

Page: 49

^{#:} 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	
*Pituitary Gland: Pars Dis Adenoma	stalis or Unspe	cified Site:					
7 taonoma		19/50 (38%)	24/50 (48%)	35/49 (71%)	19/50 (38%	%) 25/50 (50%)	22/50 (44%)
		37/50 (74%)	10/50 (20%)	20/50 (40%)	35/50 (70%	, , ,	
		36/50 (72%)	32/50 (64%)	31/50 (62%)	35/50 (70%	, , ,	29/50 (58%)
		11/50 (22%)	20/50 (40%)	8/50 (16%)	22/50 (44%	, , ,	25/50 (50%)
		15/50 (30%)	19/50 (38%)	21/49 (43%)	24/50 (48%	,	29/50 (58%)
		34/49 (69%)	13/50 (26%)	6/50 (12%)	35/50 (70%	6) 20/50 (40%)	25/50 (50%)
		36/49 (73%)	11/50 (22%)	33/50 (66%)	30/50 (60%	6) 27/50 (54%)	25/50 (50%)
		16/50 (32%)	36/50 (72%)	34/49 (69%)	28/50 (56%	6) 36/49 (73%)	36/50 (72%)
		23/48 (48%)	24/50 (48%)		28/50 (56%	6) 27/49 (55%)	
Overall Incidence	Total	604/1293 (46.71%)	Mean 46.79%	SD 20.55%	Total 682/1247 (54.69	, , , , , , , , , , , , , , , , , , ,	SD 11.31%
*Pituitary Gland: Pars Dis Carcinoma							
		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%	%) 1/49 (2%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%	,	2/50 (4%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%	,	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)	1/50 (2%	,	1/50 (2%)
		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%)	1/50 (2%)	0/49 (0%)	2/50 (4%	,	2/50 (4%)
		0/48 (0%)	0/50 (0%)		0/50 (0%	, , ,	
Overall Incidence	Total	1/1293 (0.08%)	Mean 0.08%	SD 0.39%	Total 14/1247 (1.12%	6) Mean 1.12%	SD 1.54%
*Pituitary Gland: Pars Dis Carcinoma or Adenoma	stalis or Unspe						
		19/50 (38%)	24/50 (48%)	35/49 (71%)	19/50 (38%	%) 26/50 (52%)	22/50 (44%)
		37/50 (74%)	10/50 (20%)	20/50 (40%)	35/50 (70%	%) 25/49 (51%)	
		36/50 (72%)	32/50 (64%)	31/50 (62%)	36/50 (72%	%) 35/50 (70%)	31/50 (62%)
		11/50 (22%)	20/50 (40%)	8/50 (16%)	24/50 (48%	%) 16/50 (32%)	25/50 (50%)
		15/50 (30%)	19/50 (38%)	21/49 (43%)	25/50 (50%	%) 25/50 (50%)	30/50 (60%)
		34/49 (69%)	13/50 (26%)	6/50 (12%)	35/50 (70%	, , ,	25/50 (50%)
		36/49 (73%)	11/50 (22%)	33/50 (66%)	30/50 (60%	%) 27/50 (54%)	25/50 (50%)
		16/50 (32%)	37/50 (74%)	34/49 (69%)	30/50 (60%	%) 36/49 (73%)	38/50 (76%)
		23/48 (48%)	24/50 (48%)		28/50 (56%	%) 27/49 (55%)	
Overall Incidence	Total	605/1293 (46.79%)	Mean 46.86%	SD 20.65%	Total 696/1247 (55.81)	%) Mean 55.82%	SD 11.48%

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

Page: 50

^{#:} 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	
Pituitary Gland: Pars Di	stalis or Unspec	cified Site:						
oungou		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%)	0/49 (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%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	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%)	0/49 (0%)	0/50 (0%)
		0/48 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
verall Incidence	Total	1/1293 (0.08%)	Mean 0.08%	SD 0.39%	Total	1/1247 (0.08%)	Mean 0.08%	SD 0.4%
ituitary Gland: Pars Int Adenoma	to modia.	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
			` ,	()		` ,	` '	1/50 (2%)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)		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%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/43 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
		0/48 (0%)	0/50 (0%)	(0,70)		0/50 (0%)	0/49 (0%)	(=70)
verall Incidence	Total	4/1293 (0.31%)	Mean 0.31%	SD 0.74%	Total	3/1247 (0.24%)	Mean 0.24%	SD 0.66%
						,		
ituitary Gland: Pars Int Carcinoma or Adenom								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
		0/48 (0%)	0/50 (0%)	05 0 - 10/		0/50 (0%)	0/49 (0%)	00 0000
verall Incidence	Total	4/1293 (0.31%)	Mean 0.31%	SD 0.74%	Total	3/1247 (0.24%)	Mean 0.24%	SD 0.66%

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

Page: 51

^{#:} 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

					Male				Female					
*Pituitary Gland: Pars Ner Craniopharyngioma	vosa:													
J		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%)	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%)	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%)	0/49	(0%)	1/50	(2%)
		0/48	(0%)	0/50	(0%)				0/50	(0%)	0/49	(0%)		
Overall Incidence	Total	0/1293 (0%	6)	Mean	0%	SD 0%		Total	1/1247 (0	.08%)	Mean	0.08%	SD (0.4%
*Prostate: Adenoma														
7 tuonoma		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%)	1/50	(2%)	1/50	(2%)							
		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%)							
		2/50	(4%)	0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/49	(0%)		,							
Overall Incidence	Total	6/1297 (0.46	6%)	Mean 0	, ,	SD 1.179	%							
*Prostate:														
Carcinoma or Adenoma														
		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%)	1/50	(2%)	1/50	(2%)							
		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%)							
		2/50	(4%)	0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/49	(0%)		•							
Overall Incidence	Total	6/1297 (0.46	3%)	Mean 0		SD 1.179	0/_							

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

Page: 52

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 53

Report Date: 03/20/2010

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female				
Salivary Glands: Carcinoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)		
		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/49 (0%)	0/50 (0%)	1/50 (2%)		0/50 (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	2/1295 (0.15%)	Mean 0.15%	SD 0.54%	Total	0/1249 (0%)	Mean 0%	SD 0%		
alivary Glands: Carcinoma or Adenoma		0/50 (00/)	0/50 (0%)	0/50 /00/		0/50 (00/)	0/50 (09/)	0/50 (09/)		
		0/50 (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 (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%) 0/48 (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%)	0/48 (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%)		0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)		
		0/50 (0%)	0/50 (0%)	1/30 (2%)		0/50 (0%)	0/50 (0%)	0/30 (0%)		
verall Incidence	Total	2/1295 (0.15%)	Mean 0.15%	SD 0.54%	Total	0/1249 (0%)	Mean 0%	SD 0%		
		2/1295 (0.15%)		ろD 0.54%		` ,	iviean 0%			
alivary Glands: Sarcoma										
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)		
		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
	.	0/50 (0%)	0/50 (0%)	OD 0.000′	+ · ·	0/50 (0%)	0/50 (0%)	OD 001		
verall Incidence	Total	1/1295 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1249 (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				
Salivary Glands: Schwannoma Malignant										
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)		
		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	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%)	0/30 (0 /8)		0/50 (0%)	0/50 (0%)	0/30 (0 /0)		
verall Incidence	Total	1/1295 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1249 (0%)	Mean 0%	SD 0%		
Seminal Vesicle: 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%)	1/50 (2%)	0/50 (0%)						
		0/50 (0%)	0/50 (0%)	0/49 (0%)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)						
		0/49 (0%)	0/50 (0%)	0/50 (0%)						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)						
verall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.39%						
verali incidence		,								
Skeletal Muscle: Fibrous Histiocytoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		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%)		
		0/49 (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%)	0/30 (0 /8)		0/50 (0%)	0/50 (0%)	0/50 (0%)		

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

Page: 54

^{#:} 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: Hemangiosarcoma								,		
3		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%)		
		0/49 (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	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (0%)	Mean 0%	SD 0%		
keletal Muscle: Rhabdomyosarcoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
		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%)	0/49 (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%)	0/50 (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	2/1298 (0.15%)	Mean 0.15%	SD 0.54%	Total	2/1250 (0.16%)	Mean 0.16%	SD 0.55%		
Skeletal Muscle: Rhabdomyosarcoma o		a								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	- ()		
		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%)	0/49 (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%)	0/50 (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%)		
	T-1-1	0/50 (0%)	0/50 (0%)	OD 0.540/	T-1-1	0/50 (0%)	0/50 (0%)	OD 0.550/		
verall Incidence	Total	2/1298 (0.15%)	Mean 0.15%	SD 0.54%	Total	2/1250 (0.16%)	Mean 0.16%	SD 0.55%		

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

Page: 55

^{#:} 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:								
Basal Cell Adenoma		0/50 (00/)	4/50 (00/)	0/50 (00/)		0/50 (00/)	4 (50 (001)	0/50 (00/)
		0/50 (0%)	1/50 (2%)	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 (00/)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	2/49 (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%)	1/50 (2%)
		1/49 (2%)	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%)	1/50 (2%)
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	15/1298 (1.16%)	Mean 1.16%	SD 1.41%	Total	5/1250 (0.4%)	Mean 0.4%	SD 0.82%
		0/50 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/49 (2%) 2/50 (4%) 0/50 (0%)	1/50 (2%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 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%) 0/50 (0%) 2/49 (4%) 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%) 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%) 1/50 (2%)
erall Incidence	Total	15/1298 (1.16%)	Mean 1.16%	SD 1.41%	Total	5/1250 (0.4%)	Mean 0.4%	SD 0.82%
Skin: Basal Cell Adenoma, B	asosquamous 1	Fumor Benign, or Trich 0/50 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/49 (2%) 2/50 (4%)	0epithelioma 3/50 (6%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 1/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%) 0/50 (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%) 2/50 (4%) 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%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%)
		3/50 (6%)	2/50 (4%)	` ,		0/50 (0%)	0/50 (0%)	, ,
		-, (0,0)				()		

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

Page: 56

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 57

Report Date: 03/20/2010

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: **Basal Cell Carcinoma** 1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%) (0%) 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/50 0/50 0/50 0/50 (0%)(0%)(0%)0/50 (0%)1/50 (2%)0/49 (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%)0/49 (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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 11/1298 (0.85%) Mean 0.85% SD 1.52% Total 2/1250 (0.16%) Mean 0.16% SD 0.55% #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%)(0%) (0%)0/50 (0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)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%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 1/50 (2%)0/49 (0%)0/50 (0%)3/50 (6%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 11/1298 (0.85%) Mean 0.85% SD 1.52% Total 2/1250 (0.16%) Mean 0.16% SD 0.55% #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma (2%)4/50 1/50 (2%)0/50 (0%)2/50 (4%)0/50 1/50 (8%)(0%)(0%)(0%) 0/50 1/50 (2%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)2/50 (4%)1/50 (2%)1/50 (2%)1/50 (2%)1/50 (2%)2/49 (4%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)1/49 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)2/50 (4%)4/50 (8%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)3/50 (6%)4/50 (8%) 0/50 (0%)0/50 (0%)**Overall Incidence** Total 32/1298 (2.47%) Mean 2.47% SD 2.49% Total 10/1250 (0.8%) Mean 0.8% SD 1.29%

^{*:} 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: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 2/50 0/50 5/50 (10%)9/50 (18%)(4%)0/50 (0%)2/50 (4%)(0%)(2%) (2%) 1/50 4/50 (8%)1/50 1/50 (2%)0/50 (0%)5/50 (10%)2/50 (4%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)10/50 (20%)2/50 (4%)2/50 (4%)4/50 (8%)3/50 1/50 (2%)(6%)4/50 (8%)8/50 (16%)2/49 (4%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)6/50 (12%)3/50 (6%)0/50 (0%)1/50 (2%)1/50 (2%)5/49 (10%)3/50 (6%) 3/50 (6%)1/50 (2%)1/50 (2%)1/50 (2%)5/50 (10%)5/50 (10%)5/50 (10%)1/50 (2%)1/50 (2%)1/50 (2%)6/50 (12%)11/50 (22%)0/50 (0%)0/50 (0%)Overall Incidence Total 112/1298 (8.63%) Mean 8.63% SD 5.54% Total 21/1250 (1.68%) Mean 1.68% SD 1.97% #Skin: **Fibroma** (4%)5/50 (10%)11/50 (22%)1/50 (2%)3/50 (6%)2/50 2/50 (4%)3/50 (6%)4/50 (8%) 1/50 (2%)2/50 (4%)0/50 (0%)3/50 (6%)7/50 (14%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)(12%)6/50 2/50 (4%)5/50 (10%)1/50 (2%)0/50 (0%)1/50 (2%)5/50 (10%)5/50 (10%)7/49 (14%)1/50 (2%)0/50 1/50 (2%)(0%)4/50 (8%)3/50 (6%)3/50 (6%) 1/50 (2%)2/50 (4%)1/50 (2%)3/49 (6%)3/50 (6%)1/50 (2%)1/50 (2%)3/50 1/50 (2%)(6%)8/50 (16%)3/50 (6%)4/50 (8%) 1/50 (2%)0/50 (0%)0/50 (0%)7/50 (14%)8/50 (16%)1/50 (2%)0/50 (0%)Overall Incidence Total 113/1298 (8.71%) Mean 8.71% SD 5.07% Total 25/1250 (2%) Mean 2% SD 1.83% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 6/50 (12%)(32%)3/50 (6%) 3/50 (6%)2/50 (4%)2/50 (4%)16/50 4/50 3/50 (6%)4/50 (8%) (8%) 2/50 (4%)0/50 (0%)3/50 (6%)8/50 (16%)2/50 (4%)1/50 (2%)0/50 (0%)1/50 (2%)7/50 (14%)3/50 (6%)5/50 (10%)1/50 (2%)0/50 (0%)3/50 (6%)6/50 (12%)7/50 (14%)7/49 (14%)1/50 (2%)0/50 (0%)1/50 (2%)5/50 (10%)4/50 (8%) 4/50 (8%) 1/50 (2%)1/50 (2%)3/50 (6%)(2%) 4/49 (8%)3/50 (6%)1/50 2/50 (4%)3/50 (6%)1/50 (2%)11/50 (22%)6/50 (12%)4/50 (8%) 1/50 (2%)0/50 (0%)0/50 (0%)8/50 (16%)9/50 (18%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 143/1298 (11.02%) Mean 11.02% SD 6.33% Total 31/1250 (2.48%) Mean 2.48% SD 2.02%

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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:									
Fibrosarcoma									
		1/50 (2%)	3/50 (6%)	2/50 (4%)	0/5	` ,	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	2/50 (4%)	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%)	0/50 (0%)	0/5	` '	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)	0/49 (0%)	0/5	` ,	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/5	` ,	1/50 (2%)	1/50 (2%)	
		1/49 (2%)	0/50 (0%)	0/50 (0%)	1/5	` '	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	3/50 (6%)	0/50 (0%)	0/5	` '	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)		0/5		1/50 (2%)		
Overall Incidence	Total	17/1298 (1.31%)	Mean 1.31%	SD 1.87%		(0.32%)	Mean 0.32%	SD 0.75%	
#Skin:									
Fibrosarcoma, Sarcoma,	Myxosarcom	a, or Fibrous Histiocyton	na						
		1/50 (2%)	6/50 (12%)	2/50 (4%)	0/5	0 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	3/50 (6%)	0/5		0/50 (0%)		
		0/50 (0%)	1/50 (2%)	1/50 (2%)	1/5	0 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)	0/50 (0%)	0/5	0 (0%)	0/50 (0%)	2/50 (4%)	
		1/50 (2%)	2/50 (4%)	0/49 (0%)	0/5	` ,	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)	1/50 (2%)	0/5	` '	1/50 (2%)	1/50 (2%)	
		1/49 (2%)	0/50 (0%)	0/50 (0%)	1/5	` ,	0/50 (0%)	0/50 (0%)	
		3/50 (6%)	3/50 (6%)	0/50 (0%)	0/5	` ,	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)		0/5	0 (0%)	1/50 (2%)		
Overall Incidence	Total	31/1298 (2.39%)	Mean 2.39%	SD 2.71%		(0.56%)	Mean 0.56%	SD 1.08%	
#Skin: Fibrous Histiocytoma									
		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%)	0/50 (0%)		
		0/50 (0%)	1/50 (2%)	1/50 (2%)	1/5	0 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)	0/50 (0%)	0/5	0 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/5	0 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/5	` '	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)	0/5	` ,	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/5	` ,	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)		0/5	0 (0%)	0/50 (0%)		
Overall Incidence	Total	5/1298 (0.39%)	Mean 0.38%	SD 0.8%	Total 1/1250	(0.08%)	Mean 0.08%	SD 0.4%	

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

Page: 59

^{#:} 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:								
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%)	2/22 (22/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (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%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 0.000/	T-1-1	0/50 (0%)	0/50 (0%)	00, 00/
Overall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (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%)	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%)	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	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma								
		3/50 (6%)	5/50 (10%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	3/50 (6%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	
		4/50 (8%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		8/50 (16%)	0/50 (0%)	2/50 (4%)		2/50 (4%)	2/50 (4%)	0/50 (0%)
		2/50 (4%)	7/50 (14%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	4/50 (8%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		4/49 (8%)	3/50 (6%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	4/50 (8%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	6/50 (12%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	67/1298 (5.16%)	Mean 5.16%	SD 4.39%	Total	7/1250 (0.56%)	Mean 0.56%	SD 1.23%

^{*:} 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: 03/20/2010

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Skin: Lipoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	(0.00)
		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%)	2/50 (4%)	1/49 (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%)
		2/49 (4%)	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%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	16/1298 (1.23%)	Mean 1.24%	SD 1.51%	Total	0/1250 (0%)	Mean 0%	SD 0%
			•••••	•••••				
Skin: Liposarcoma								
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%)	0/30 (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%)	0/50 (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%)
		0/49 (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%)	` ,
verall Incidence	Total	2/1298 (0.15%)	Mean 0.16%	SD 0.55%	Total	0/1250 (0%)	Mean 0%	SD 0%
Skin: Neural Crest Tumor								
riodiai oroot raino.		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%)	(170)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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%)
		0/49 (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%)	` '

^{*:} 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

Report Date: 03/20/2010

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Species: RATS Strain: F 344/N

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male			Female				
Skin:										
Neural Crest Tumor, M	lalignant	0/=0 (00/)	0/50 (00/)	0/50 (00/)		2/22 (22/)	0/50 (00/)	0/50 (004)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (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%)		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		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%)		
		0/49 (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%)		
		0/49 (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%)	0/30 (0/0)		
verall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (0%)	Mean 0%	SD 0%		
		` ,	IVIEAN 0.00%			` '	Mean 0%	3D 0%		
Skin: Neurofibroma or Schw	rannoma honian									
Neuronbronia or Schw	ailiioilia belligii	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/30 (0/8)		
		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%)		
		0/49 (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%)	(***)		0/50 (0%)	0/50 (0%)	(,		
verall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%		
Skin:										
Neurofibrosarcoma or	Schwannoma (n									
		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%)	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%)		
		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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/49 (2%)	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%)	0/50 (0%)	0/50 (0%)		
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 4.000/	T-1-!	0/50 (0%)	0/50 (0%)	00 0 550/		
Overall Incidence	Total	9/1298 (0.69%)	Mean 0.69%	SD 1.38%	Total	2/1250 (0.16%)	Mean 0.16%	SD 0.55%		

^{*:} 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, Neu	ırofibroma, or	Schwannoma (benign, n	nalignant or NOS)					
		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%)	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%)	0/50 (0%)
		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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	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%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	10/1298 (0.77%)	Mean 0.77%	SD 1.51%	Total	3/1250 (0.24%)	Mean 0.24%	SD 0.66%
Skin: Sarcoma		0/50 (0%)	3/50 (6%)	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%)	0/50 (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%)	2/50 (4%)
		0/50 (0%)	1/50 (2%)	0/49 (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%)
		0/49 (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%)	
erall Incidence	Total	9/1298 (0.69%)	Mean 0.69%	SD 1.49%	Total	2/1250 (0.16%)	Mean 0.16%	SD 0.8%
kin: 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%)	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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%

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

Page: 63

^{#:} 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: 03/20/2010

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

					Male				Female					
#Skin:														
Schwannoma Maligna	nt													
		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%)	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%)
		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%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/49	(2%)	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%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	9/1298 (0.6		Mean 0		SD 1.389		Total	2/1250 (0			0.16%	SD 0.	
#Skin:														
Squamous Cell Carcin	oma	0/-0	(00()	o /= o	(221)		(884)		0/-0	(00/)	0/=0	(221)	o /= o	(00/)
		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%)	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%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(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%)
		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%)		
Overall Incidence	Total	6/1298 (0.4		Mean 0		SD 0.869		Total	3/1250 (0			0.24%	SD 0.	
#Skin:														
Squamous Cell Carcin or Carcinoma	oma, Basal Cell	Carcinoma, Bas	sosquamo	ous Tumor (malignant	t or NOS),								
		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%)	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%)
		1/50	(2%)	1/50	(2%)	0/49	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	2/50	(4%)	1/50	(2%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	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%)	2/50	(4%)				0/50	(0%)	0/50	(0%)		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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:													
Squamous Cell Papillo	ma												
			2%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		,	0%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		,	0%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
			2%) 0/50	(0%)	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%) 1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		,	0%) 0/50	(0%)	1/50	(2%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		,	2%) 0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		,	6%) 1/50	(2%)				0/50	(0%)	0/50	(0%)		
verall Incidence	Total	10/1298 (0.77%)			SD 1.399		Total	2/1250 (0			0.16%	SD 0.	
Skin:													
Squamous Cell Papillo	ma or Papilloma												
		,	2%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		,	0%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		,	0%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		•	2%) 0/50	(0%)	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%) 1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		,	0%) 0/50	(0%)	1/50	(2%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		,	2%) 0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		3/50 (6	6%) 1/50	(2%)				0/50	(0%)	0/50	(0%)		
verall Incidence	Total	10/1298 (0.77%)	,		SD 1.399		Total	2/1250 (0	,		0.16%	SD 0.	
 Skin:													
Squamous Cell Papillo	ma, Papilloma,	Squamous Cell Car	rcinoma or Kerate	acanthon	na								
			3%) 5/50	(10%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50 (2	2%) 3/50	(6%)	1/50	(2%)		1/50	(2%)	0/50	(0%)		,
		4/50 (8	3%) 2/50	(4%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	1/50	(2%)
		9/50 (18	3%) 1/50	(2%)	2/50	(4%)		2/50	(4%)	3/50	(6%)	0/50	(0%)
		•	6%) 7/50	(14%)	0/49	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		,	2%) 6/50	(12%)	2/50	(4%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		•	3/50	(6%)	3/50	(6%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		4/50 (8	3%) 1/50	(2%)	5/50	(10%)		1/50	(2%)	1/50	(2%)	0/50	(0%)
		,	3%) 7/50	(14%)		. ,		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** #Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 4/50 (8%)5/50 (10%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)3/50 (6%)1/50 (2%)1/50 (2%)0/50 (0%)4/50 (8%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)9/50 (18%)0/50 (0%)2/50 (4%)2/50 (4%)3/50 0/50 (6%)(0%)2/50 (4%)7/50 (14%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)5/50 (10%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)4/49 (6%) 3/50 (0%)0/50 (8%)3/50 (6%)0/50 1/50 (2%)(0%)3/50 (6%)1/50 (2%)5/50 (10%)1/50 (2%)0/50 (0%)0/50 (0%)4/50 (8%)7/50 (14%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 77/1298 (5.93%) Mean 5.93% SD 4.82% Total 9/1250 (0.72%) Mean 0.72% SD 1.51% #Skin: Trichoepithelioma 0/50 (0%)2/50 (4%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%) (0%)0/50 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%)1/50 (2%)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%)0/49 (0%)0/50 (0%)0/50 (0%)(2%)0/50 0/50 (0%)1/50 (0%)0/50 (0%)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%)**Overall Incidence** Total 6/1298 (0.46%) Mean 0.46% SD 1.42% Total 3/1250 (0.24%) Mean 0.24% SD 0.66% **#Skin: Sebaceous Gland:** Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)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%) 0/50 (0%)0/50 (0%)0/50 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%)1/50 (2%)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%)2/50 (4%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Total 7/1298 (0.54%) Mean 0.54% SD 1.07% Total 1/1250 (0.08%) Mean 0.08% SD 0.4% 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

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ALL VEHICLES

					Male						F	emale		
#Skin: Sebaceous 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%)		
		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%)	1/50	(2%)	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%)
		1/49	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	2/50	(4%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)		
verall Incidence	Total	7/1298 (0.54	1%)	Mean 0	.54%	SD 1.079	%	Total	1/1250 (0	.08%)	Mean	0.08%	SD 0).4%
Spinal Cord: Astrocytoma Benign														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(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%)
		0/49	(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	0/1298 (0%		Mean		SD 0%		Total	1/1250 (0	,		0.08%	SD C	
Spinal Cord: Astrocytoma Malignant														
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(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%)	0/50	(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	1/1298 (0.08	3%)	Mean 0	.08%	SD 0.399	%	Total	0/1250	(0%)	Mea	n 0%	SD	0%

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

Page: 67

^{#:} 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
#Spinal Cord: Glioma Malignant				
33		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 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%) 1/49 (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%)
		0/49 (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	1/1298 (0.08%)	Mean 0.08% SD 0.4%	Total 1/1250 (0.08%) Mean 0.08% SD 0.4%
*Spleen: Fibrosarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/48 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/49 (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%) 0/49 (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%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%)
		0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (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%)
Overall Incidence	Total	1/1295 (0.08%)	Mean 0.08% SD 0.39%	Total 0/1246 (0%) Mean 0% SD 0%
*Spleen: Fibrous Histiocytoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/48 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/49 (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%) 1/49 (2%)	0/50 (0%) 0/50 (0%) 0/49 (0%)
		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%)
		0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (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%)
Overall Incidence	Total	1/1295 (0.08%)	Mean 0.08% SD 0.4%	Total 0/1246 (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	
Spleen: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/48 (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%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	1/50 (2%)	0/49 (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%)
		0/49 (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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	2/1295 (0.15%)	Mean 0.15%	SD 0.54%	Total	3/1246 (0.24%)	Mean 0.24%	SD 0.88%
oleen:								
Leiomyosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/40 (00/)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/49 (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%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
		0/49 (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%)
		0/50 (0%)	0/49 (0%)	0/30 (0 /0)		0/50 (0%)	0/50 (0%)	0/30 (0 /0)
verall Incidence	Total	3/1295 (0.23%)	Mean 0.23%	SD 0.65%	Total	0/1246 (0%)	Mean 0%	SD 0%
		3/1293 (0.23%)		3D 0.03%		` '	iviedii 070	
pleen: Sarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/48 (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%)	0/49 (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%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (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%)	
verall Incidence	Total	1/1295 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1246 (0%)	Mean 0%	SD 0%

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

Page: 69

^{#:} 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: 03/20/2010

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Stomach, Forestomach Leiomyosarcoma	:							
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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%)	0/50 (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%)	
erall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (0%)	Mean 0%	SD 0%
tomach, Forestomach Squamous Cell Carcin								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (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%)
		0/49 (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%)	
erall Incidence	Total	0/1298 (0%)	Mean 0%	SD 0%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%
Stomach, Forestomach Squamous Cell Carcin	:	na Squamous					(201)	2/22 (22/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (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%)	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%)	0/49 (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%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/30 (0/0)		0/50 (0%)	0/50 (0%)	0/30 (0/0)
vorall Incidence	Total	` '	, ,	SD 0.300/	Total	` '	` ,	SD 0.669/
verall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	3/1250 (0.24%)	Mean 0.24%	SD 0.66%

^{*:} 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	
#Stomach, Forestomach: Squamous Cell Papilloma								
equamous com rapinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	(0,0)
		0/50 (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%)	0/49 (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%)	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%)	
verall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	2/1250 (0.16%)	Mean 0.16%	SD 0.55%
Stomach, Glandular: 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%)	0/49 (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%)	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	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (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%)	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	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

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Report Date: 03/20/2010

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
Stomach, Glandular:				,				
_ 		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	,
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (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%)
		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%)	
verall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (0%)	Mean 0%	SD 0%
Stomach, Glandular: 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%)	0/50 (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%)
		0/49 (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	0/1298 (0%)	Mean 0%	SD 0%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%
estes: Adenoma	•••••		•••••					
		42/50 (84%)	35/50 (70%)	30/50 (60%)				
		34/50 (68%)	46/50 (92%)	49/50 (98%)				
		36/50 (72%)	37/50 (74%)	36/50 (72%)				
		44/50 (88%)	45/50 (90%)	42/50 (84%)				
		48/50 (96%)	46/50 (92%)	37/49 (76%)				
		33/50 (66%)	46/50 (92%)	47/50 (94%)				
		38/49 (78%)	46/50 (92%)	37/50 (74%)				
		48/50 (96%)	29/50 (58%)	27/50 (54%)				
		46/50 (92%)	49/50 (98%)					
verall Incidence	Total	1053/1298 (81.12%)	Mean 81.12%	SD 13.37%				

^{*:} 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	
*Testes: Hemangioma							
Hemangionia		0/50 (0%)	0/50 (0%) 0/50	(0%)			
		0/50 (0%)	0/50 (0%) 0/50	(0%)			
		0/50 (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%)			
		0/49 (0%)	0/50 (0%) 1/50	(2%)			
		0/50 (0%)	0/50 (0%) 0/50	(0%)			
		0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/1298 (0.08%)	Mean 0.08% SD 0.39%				
Thymus: Thymoma Benign							
		0/50 (0%)	0/44 (0%) 0/49	(0%)	0/50 (0%)	0/48 (0%) 0/49	(0%)
		0/43 (0%)	0/48 (0%) 0/47	(0%)	1/46 (2%)	0/46 (0%)	
		0/49 (0%)	0/49 (0%) 0/44	(0%)	0/48 (0%)	0/45 (0%) 0/48	(0%)
		0/49 (0%)	0/50 (0%) 1/48	(2%)	0/48 (0%)	0/48 (0%) 0/49	(0%)
		0/48 (0%)	0/47 (0%) 0/48	(0%)	` ,	0/47 (0%) 0/50	(0%)
		0/42 (0%)	0/41 (0%) 0/47	(0%)	` ,	0/50 (0%) 0/49	(0%)
		1/47 (2%)	0/50 (0%) 0/47	(0%)	` ,	0/50 (0%) 1/50	(2%)
		0/48 (0%)	0/47 (0%) 0/45	(0%)	` ,	0/44 (0%) 0/47	(0%)
		0/49 (0%)	0/43 (0%)		` '	0/48 (0%)	
Overall Incidence	Total	2/1219 (0.16%)	Mean 0.16% SD 0.57%		4/1204 (0.33%)		0.77%
*Thymus: Thymoma Malignant							
		0/50 (0%)	0/44 (0%) 0/49	(0%)	` ,	0/48 (0%) 0/49	(0%)
		0/43 (0%)	0/48 (0%) 0/47	(0%)	` ,	0/46 (0%)	
		0/49 (0%)	0/49 (0%) 0/44	(0%)	` ,	0/45 (0%) 0/48	(0%)
		0/49 (0%)	0/50 (0%) 0/48	(0%)	` ,	1/48 (2%) 0/49	(0%)
		0/48 (0%)	0/47 (0%) 0/48	(0%)	` ,	0/47 (0%) 0/50	(0%)
		0/42 (0%)	0/41 (0%) 0/47	(0%)	` ,	0/50 (0%) 0/49	(0%)
		0/47 (0%)	0/50 (0%) 0/47	(0%)	` '	0/50 (0%) 0/50	(0%)
		0/48 (0%) 0/49 (0%)	0/47 (0%) 0/45 0/43 (0%)	(0%)	` ,	0/44 (0%) 0/47 0/48 (0%)	(0%)
Overell In elden e e	Tatal	` '	` '	Tatel	` ,	` '	0.400/
Overall Incidence	Total	0/1219 (0%)	Mean 0% SD 0%	Total	1/1204 (0.08%)	Mean 0.08% SD	0.42%

^{*:} 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
*Thymus:				
Thymoma NOS				
		0/50 (0%)	0/44 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%) 0/49 (0%)
		0/43 (0%)	0/48 (0%) 0/47 (0%)	0/46 (0%) 0/46 (0%)
		0/49 (0%)	0/49 (0%) 0/44 (0%)	0/48 (0%) 0/45 (0%) 1/48 (2%)
		0/49 (0%)	0/50 (0%) 0/48 (0%)	0/48 (0%) 0/48 (0%) 0/49 (0%)
		0/48 (0%)	0/47 (0%) 0/48 (0%)	0/48 (0%) 0/47 (0%) 0/50 (0%)
		0/42 (0%)	0/41 (0%) 0/47 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)
		0/47 (0%) 0/48 (0%)	0/50 (0%) 0/47 (0%) 0/47 (0%) 0/45 (0%)	0/46 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/44 (0%) 0/47 (0%)
		0/48 (0%) 0/49 (0%)	0/47 (0%) 0/45 (0%) 0/43 (0%)	0/50 (0%) 0/44 (0%) 0/47 (0%) 0/50 (0%) 0/48 (0%)
Overell Insidence	Tatal	, ,	` '	· / /
Overall Incidence	Total	0/1219 (0%)	Mean 0% SD 0%	Total 1/1204 (0.08%) Mean 0.08% SD 0.42%
*Thymus: Thymoma: Benign, Mal	lianant NOS			
Triyinoma. Benign, Mai	ilgilalit, NOS	0/50 (0%)	0/44 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%) 0/49 (0%)
		0/43 (0%)	0/48 (0%) 0/47 (0%)	1/46 (2%) 0/46 (0%)
		0/49 (0%)	0/49 (0%) 0/44 (0%)	0/48 (0%) 0/45 (0%) 1/48 (2%)
		0/49 (0%)	0/50 (0%) 1/48 (2%)	0/48 (0%) 1/48 (2%) 0/49 (0%)
		0/48 (0%)	0/47 (0%) 0/48 (0%)	1/48 (2%) 0/47 (0%) 0/50 (0%)
		0/42 (0%)	0/41 (0%) 0/47 (0%)	1/50 (2%) 0/50 (0%) 0/49 (0%)
		1/47 (2%)	0/50 (0%) 0/47 (0%)	0/46 (0%) 0/50 (0%) 1/50 (2%)
		0/48 (0%)	0/47 (0%) 0/45 (0%)	0/50 (0%) 0/44 (0%) 0/47 (0%)
		0/49 (0%)	0/43 (0%)	0/50 (0%) 0/48 (0%)
Overall Incidence	Total	2/1219 (0.16%)	Mean 0.16% SD 0.57%	Total 6/1204 (0.5%) Mean 0.5% SD 0.9%
*Thyroid Gland: C-Cell: Adenoma				
		3/50 (6%)	6/46 (13%) 10/50 (20%)	4/50 (8%) 4/42 (10%) 6/50 (12%)
		5/50 (10%)	5/50 (10%) 6/50 (12%)	3/50 (6%) 3/49 (6%)
		3/50 (6%)	10/50 (20%) 7/50 (14%)	3/50 (6%) 8/50 (16%) 4/50 (8%)
		6/50 (12%)	11/50 (22%) 7/50 (14%)	5/50 (10%) 6/50 (12%) 4/50 (8%)
		1/50 (2%)	9/50 (18%) 8/49 (16%)	11/50 (22%) 7/50 (14%) 5/50 (10%)
		3/49 (6%)	5/48 (10%) 12/50 (24%)	2/50 (4%) 2/47 (4%) 5/50 (10%)
		4/49 (8%)	8/50 (16%) 9/50 (18%)	3/50 (6%) 8/50 (16%) 7/50 (14%)
		5/50 (10%)	5/50 (10%) 8/50 (16%)	8/50 (16%) 3/50 (6%) 3/50 (6%)
		3/50 (6%)	10/49 (20%)	6/49 (12%) 6/46 (13%)
Overall Incidence	Total	169/1290 (13.1%)	Mean 13.1% SD 5.72%	Total 126/1233 (10.22%) Mean 10.21% SD 4.48%

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

Page: 74

^{#:} 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	
Thyroid Gland: C-Cell: Carcinoma								
		1/50 (2%)	0/46 (0%)	1/50 (2%)		0/50 (0%)	3/42 (7%)	0/50 (0%)
		4/50 (8%)	4/50 (8%)	1/50 (2%)		1/50 (2%)	1/49 (2%)	
		1/50 (2%)	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%)	1/50 (2%)
		0/50 (0%)	6/50 (12%)	0/49 (0%)		1/50 (2%)	3/50 (6%)	0/50 (0%)
		0/49 (0%)	1/48 (2%)	0/50 (0%)		1/50 (2%)	0/47 (0%)	0/50 (0%)
		3/49 (6%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/49 (2%)			1/49 (2%)	0/46 (0%)	
verall Incidence	Total	32/1290 (2.48%)	Mean 2.47%	SD 3.01%	Total	16/1233 (1.3%)	Mean 1.33%	SD 2.03%
hyroid Gland: C-Cell: Carcinoma or Adenom	na	4/50 (8%)	6/46 (13%)	11/50 (22%)		4/50 (8%)	7/42 (17%)	6/50 (12%)
		9/50 (18%)	9/50 (18%)	7/50 (14%)		4/50 (8%)	4/49 (8%)	
		3/50 (6%)	12/50 (24%)	8/50 (16%)		3/50 (6%)	8/50 (16%)	4/50 (8%)
		6/50 (12%)	11/50 (22%)	8/50 (16%)		5/50 (10%)	6/50 (12%)	5/50 (10%)
		1/50 (2%)	15/50 (30%)	8/49 (16%)		12/50 (24%)	9/50 (18%)	5/50 (10%)
		3/49 (6%)	6/48 (13%)	12/50 (24%)		3/50 (6%)	2/47 (4%)	5/50 (10%)
		7/49 (14%) 6/50 (12%)	8/50 (16%) 6/50 (12%)	9/50 (18%) 8/50 (16%)		5/50 (10%) 10/50 (20%)	8/50 (16%) 3/50 (6%)	7/50 (14%) 3/50 (6%)
		4/50 (8%)	11/49 (22%)	0/30 (10%)		7/49 (14%)	6/46 (13%)	3/30 (6%)
verall Incidence	Total	198/1290 (15.35%)	Mean 15.34%	SD 6.44%	Total	141/1233 (11.44%)	Mean 11.46%	SD 4.95%
verali incidence		190/1290 (15.55%)				(11.44%)	Weall 11.40%	3D 4.95%
Γhyroid Gland: Follicula Adenoma	ar Cell:							
		3/50 (6%)	0/46 (0%)	0/50 (0%)		0/50 (0%)	0/42 (0%)	1/50 (2%)
		0/50 (0%)	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%)	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%)	1/49 (2%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/48 (0%)	1/50 (2%)		0/50 (0%)	0/47 (0%)	0/50 (0%)
		1/49 (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%)
wanali laakdanaa	Takel	2/50 (4%)	0/49 (0%)	CD 4 C20/	Tatal	0/49 (0%)	1/46 (2%)	CD 0.000/
verall Incidence	Total	12/1290 (0.93%)	Mean 0.93%	SD 1.63%	Total	5/1233 (0.41%)	Mean 0.41%	SD 0.83%

^{*:} 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

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Thyroid Gland: Follicula Carcinoma	ır Cell:							
		0/50 (0%)	0/46 (0%)	0/50 (0%)		0/50 (0%)	0/42 (0%)	1/50 (2%)
		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%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	0/49 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
		0/49 (0%)	0/48 (0%)	2/50 (4%)		0/50 (0%)	1/47 (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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)			0/49 (0%)	0/46 (0%)	
verall Incidence	Total	11/1290 (0.85%)	Mean 0.85%	SD 1.41%	Total	5/1233 (0.41%)	Mean 0.41%	SD 1.01%
Thyroid Gland: Follicula Carcinoma or Adenom	ır Cell:							
		3/50 (6%)	0/46 (0%)	0/50 (0%)		0/50 (0%)	0/42 (0%)	2/50 (4%)
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	
		2/50 (4%)	1/50 (2%)	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%)
		3/50 (6%)	2/50 (4%)	1/49 (2%)		2/50 (4%)	1/50 (2%)	1/50 (2%)
		0/49 (0%)	0/48 (0%)	3/50 (6%)		0/50 (0%)	1/47 (2%)	0/50 (0%)
		1/49 (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%)
		3/50 (6%)	0/49 (0%)			0/49 (0%)	1/46 (2%)	
verall Incidence	Total	23/1290 (1.78%)	Mean 1.77%	SD 2.29%	Total	9/1233 (0.73%)	Mean 0.73%	SD 1.29%
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%)	0/49 (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%)
		1/49 (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%)	05.00/
Overall Incidence	Total	1/1298 (0.08%)	Mean 0.08%	SD 0.4%	Total	0/1250 (0%)	Mean 0%	SD 0%

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

Page: 76

^{#:} 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					
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%)	0/49 (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%)
		0/49 (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	1/1298 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1250 (0%)	Mean 0%	SD 0%
ongue: Squamous Cell Carcino	oma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (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%)	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%)	
erall Incidence	Total	1/1298 (0.08%)		SD 0.39%	Total	1/1250 (0.08%)	Mean 0.08%	SD 0.4%
Fongue: Squamous Cell Carcino		a Saucmouc						
Squamous Cen Carcin	oma or r apmon	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%)	0/00 (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%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)	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%)
		0/50 (0%)	0/50 (0%)	` '		0/50 (0%)	1/50 (2%)	` '

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

Page: 77

^{#:} 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
#Tongue:				
Squamous Cell Papillom	na			
		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%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 1/50 (2%)
		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)
		0/49 (0%)	0/50 (0%) 0/50 (0%)	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%)
O	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	5/1298 (0.39%)	Mean 0.38% SD 0.8%	Total 4/1250 (0.32%) Mean 0.32% SD 0.75%
#Tooth: Adamantinoma Maligna	nt			
_		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (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%)	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	1/1298 (0.08%)	Mean 0.08% SD 0.39%	Total 0/1250 (0%) Mean 0% SD 0%
#Tooth: Odontoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		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%) 0/49 (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%) 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	0/1298 (0%)	Mean 0% SD 0%	Total 2/1250 (0.16%) Mean 0.16% SD 0.55%

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

Page: 78

^{#:} 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: Carcinoma or Papilloma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/49 (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%)	0/49 (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%)
		0/49 (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%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	4/1297 (0.31%)	Mean 0.31%	SD 0.74%	Total	0/1248 (0%)	Mean 0%	SD 0%
Irinary Bladder: 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%)	0/49 (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%)	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%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/1297 (0.08%)	Mean 0.08%	SD 0.39%	Total	0/1248 (0%)	Mean 0%	SD 0%
Jrinary Bladder: 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%)	0/49 (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%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (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%)	
verall Incidence	Total	0/1297 (0%)	Mean 0%	SD 0%	Total	1/1248 (0.08%)	Mean 0.08%	SD 0.4%

^{*:} 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						F	emale		
Urinary Bladder: Papilloma							,					
•		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%)	0/50 (0%)	1/49	(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%)	0/49	(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%)
		0/49 (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%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%)	0/50 (0%)				0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	4/1297 (0.31%)	Mean 0.31%	SD 0.749		Total	0/1248	` '		n 0%	SD	
#Uterus: Adenoma												
							0/50	(0%)	0/50	(0%)	0/50	(0%)
							0/50	(0%)	0/50	(0%)		, ,
							0/50	(0%)	0/50	(0%)	1/50	(2%)
							0/50	(0%)	0/50	(0%)	0/50	(0%)
							0/50	(0%)	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%)	1/50	(2%)	0/50	(0%)
							0/50	(0%)	0/50	(0%)		
Overall Incidence						Total	4/1250 (0	,		0.32%	SD 0.	
#Uterus: 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%)	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	2/1250 (0	.16%)	Mean	0.16%	SD 0.	55%

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

Page: 80

^{#:} 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		
#Uterus:							
Deciduoma Benign		0/50	(00/)	0/50	(00()	0/50	(00/)
		0/50 0/50	(0%) (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%)
		0/50	(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%)	0/00	(070)
Overall Incidence	Total	1/1250 (0			0.08%	SD ().4%
WH							
#Uterus: 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%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	1/1250 (0	,		0.08%	SD (
#Uterus:							
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%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)		• ,

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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Uterus: Leiomyosarcoma		0/50 0/50 0/50	(0%) (0%)	0/50 0/50	(0%)	0/50	(224)
Leiomyosarcoma		0/50 0/50				0/50	(001)
		0/50 0/50				0/50	
		0/50	(0%)	0/50			(0%)
					(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%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		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	1/1250 (0			0.08%	SD (
Uterus:							
Polyp Stromal		0/50	(4.00()	47/50	(0.40/)	E/E0	(400()
		9/50	(18%)	17/50	(34%)	5/50	(10%)
		8/50	(16%)	10/50	(20%)	0/50	(400/)
		13/50	(26%)	2/50	(4%)	8/50	(16%)
		7/50	(14%)	8/50	(16%)	14/50	(28%)
		8/50	(16%)	8/50	(16%)	7/50	(14%)
		6/50 12/50	(12%)	10/50	(20%)	8/50	(16%)
		10/50	(24%) (20%)	5/50 6/50	(10%) (12%)	7/50 9/50	(14%) (18%)
		9/50	(18%)	13/50	(26%)	9/50	(10%)
wasali hasidanaa	Tatal					CD C	4.407
verall Incidence	Total	219/1250 (1			17.52%	SD 6	
Jterus:							
Sarcoma		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0,00	(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%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	3,00	()
verall Incidence	Total	1/1250 (0			0.08%	SD (0.4%

^{*:} 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				ı	Female		
#Uterus:							
Sarcoma Stromal		0/50	(00()	0/50	(00()	4/50	(00/)
		0/50	(0%)	0/50	(0%)	1/50	(2%)
		2/50 1/50	(4%)	0/50	(0%)	0/50	(00/)
		0/50	(2%) (0%)	1/50 0/50	(2%) (0%)	0/50	(0%)
		0/50 0/50	(0%)	0/50	` ,	0/50 1/50	(0%) (2%)
		0/50	(0%)	0/50	(0%) (0%)	1/50 0/50	(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%)	0/30	(070)
Overall Incidence	Total	6/1250 (0.4	` ,		0.48%	SD 1	.05%
H Norman							
fUterus: Sarcoma Stromal or Polyp Stromal							
		9/50	(18%)	17/50	(34%)	6/50	(12%)
			(20%)	10/50	(20%)		
			(28%)	3/50	(6%)	8/50	(16%)
		7/50	(14%)	8/50	(16%)	14/50	(28%)
			(16%)	8/50	(16%)	7/50	(14%)
			(12%)	10/50	(20%)	8/50	(16%)
			(24%)	5/50	(10%)	7/50	(14%)
			(20%)	6/50	(12%)	9/50	(18%)
		9/50	(18%)	13/50	(26%)		
Overall Incidence	Total	224/1250 (1	7.92%)	Mean	17.92%	SD 6	.31%
Uterus:							
Schwannoma Malignant							
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	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	2/1250 (0.	16%)	Mean	0.16%	SD 0	.55%

^{*:} 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						ı	emale		
#Vagina:												
Polyp							0/50	(00/)	0/50	(00/)	0/50	(00/)
							0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
							2/50	(4%)	0/50	(0%)	0/50	(0%)
							0/50	(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%)	0/50	(0%)
							0/50	(0%)	0/50	(0%)	1/50	(2%)
							0/50	(0%)	0/50	(0%)	1/30	(270)
Overall Incidence						Total	4/1250 (0	` ,		0.32%	SD 0	.95%
	• • • • • • • • • • • • • • • • • • • •				• • • • • • • • • • • • • • • • • • • •							
#Vagina: Sarcoma												
							0/50	(0%)	0/50	(0%)	0/50	(0%)
							1/50	(2%)	0/50	(0%)	5.55	(=,=)
							0/50	(0%)	0/50	(0%)	0/50	(0%)
							0/50	(0%)	0/50	(0%)	0/50	(0%)
							0/50	(0%)	0/50	(0%)	0/50	(0%)
							0/50	(0%)	0/50	(0%)	0/50	(0%)
							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	1/1250 (0	,		0.08%	SD (
#Zymbal's Gland:												
Adenoma		0/50 (0%)	0/50 (0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/30	(070)
		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%)	0/49	(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%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%)	0/50 (0%)	1,00	(- /0)		0/50	(0%)	0/50	(0%)	3,30	(0,0)
Overall Incidence	Total	4/1298 (0.31%)	Mean 0.31%	SD 0.939	%	Total	0/1250	` ,		an 0%	SD	0%

^{*:} 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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Report Date: 03/20/2010

			Male			Female	
#Zymbal's 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%)	1/50 (2%)	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%)	0/50 (0%)
		0/50 (0%)	2/50 (4%)	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%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	6/1298 (0.46%)	Mean 0.46%	SD 1.03%	Total 6/1250 (0.48%)	Mean 0.48%	SD 0.87%
#Zymbal's Gland: Carcinoma or Adenoma							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	, ,
		1/50 (2%)	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%)	2/50 (4%)	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%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	10/1298 (0.77%)	Mean 0.77%	SD 1.27%	Total 6/1250 (0.48%)	Mean 0.48%	SD 0.87%

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

^{#:} Denominator is number of animals necropsied