NTP Historical Controls Report

By Route And Vehicle

RATS

November 2008

REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

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

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

Male	
	M1
	М2
	М3
	Μ4
	М5
Fema	ale
	F1
	F2
	F3
	F4
	F5

the data would be shown as:

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

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

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

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

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Report Date:11/17/2008

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical		
Male									
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058810503 059902303 059902005	04/22/02 03/25/02 04/09/03	729 729 727	50 (3) 50 (3) 50 (3)	35(702) 29(683) 39(685)	521.9 501.9 514.9	Isoeugenol beta-Myrcene Pulegone		
				Fen	nale				
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058810503 059902303 059902005	04/23/02 03/26/02 04/10/03	730 730 728	50 (5) 50 (5) 50 (5)	33(699) 31(668) 31(682)	339.3 323.8 341.2	Isoeugenol beta-Myrcene Pulegone		

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Contract/Lab: All Laboratories Species: RATS

Strain: F344 Length of Study: CHRONIC Route: GAVAGE Vehicle: CORN OIL

			Male			Female		
#All Organs: Benign Tumors		49/50 (98%)	49/50 (98%)	47/50 (94%)		41/50 (82%)	40/50 (80%)	42/50 (84%)
Overall Incidence	Total	145/150 (96.67%)	Mean 96.67%	SD 2.31%	Total	123/150 (82%)	Mean 82%	SD 2%
#All Organs: Malignant Tumors		20/50 (50%)	00/50 (400/)	40/50 (20%)		40/50 (20%)	44/50 (000()	0/50 /400/)
Overall Incidence	Total	29/50 (58%) 62/150 (41.33%)	23/50 (46%) Mean 41.33%	10/50 (20%) SD 19.43%	Total	18/50 (36%) 37/150 (24.67%)	11/50 (22%) Mean 24.67%	8/50 (16%) SD 10.26%
#All Organs: Malignant and Benign To	umors	F0/50 (400%)	50/50 (400%)	47/50 (04%)		40/50 (000/)	45/50 (00%)	44/50 (000)
Overall Incidence	Total	50/50 (100%) 147/150 (98%)	50/50 (100%) Mean 98%	47/50 (94%) SD 3.46%	Total	46/50 (92%) 135/150 (90%)	45/50 (90%) Mean 90%	44/50 (88%) SD 2%
#All Organs: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#All Organs: Hemangiosarcoma		1/50 (39/)	0/50 (0%)	0/50 (0%)		0/50 (09/)	0/50 (09/)	2/50 (49/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
#All Organs: Hemangiosarcoma or He	emangioma	4/50 (004)		0/50 (00/)		0/50 (00/)	4/50 (004)	0/50 (40/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 3/150 (2%)	1/50 (2%) Mean 2%	2/50 (4%) SD 2%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 6

Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Histiocytic Sarcoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Leukemia: Erythrocytic	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Leukemia: Lymphocytic, Undifferentiated	Monocytic, M	lononuclear, or						
verall Incidence	Total	10/50 (20%) 23/150 (15.33%)	9/50 (18%) Mean 15.33%	4/50 (8%) SD 6.43%	Total	8/50 (16%) 17/150 (11.33%)	5/50 (10%) Mean 11.33%	4/50 (8%) SD 4.16%
All Organs: Malignant Lymphoma: Hi or Undifferentiated Cell T	stiocytic, Lyn							
verall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Mesothelioma: Benign		0/50 (00)	0/50 (00)			0/50 (00/)	0/50 (004)	0/50 (00)
Mesothenoma. Beingn		0/50 (0%)	0/50 (0%)	0/50 (0%)	.	0/50 (0%)	0/50 (0%)	0/50 (0%)
•	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Overall Incidence						0/150 (0%)		

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

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 7

			Male				Female	
All Organs: Mesothelioma: Malignant								
	-	3/50 (6%)	2/50 (4%)	2/50 (4%)	-	0/50 (0%)	1/50 (2%)	1/50 (2%)
overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
All Organs: Osteoma		2/22	2(22)	0.50		2/22 (221)	2(-2)	2/22 (221)
verall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
veran incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Iolai	0/150 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma								
	-	2/50 (4%)	1/50 (2%)	0/50 (0%)	+	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma or Osteoma								
renell lesidense	Tatal	2/50 (4%)	1/50 (2%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
drenal Cortex: Adenoma								
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
Adrenal Cortex: Carcinoma		0/50 /00/	0/50 /00/	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:11/17/2008

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
*Adrenal Medulla: Ganglioneuroma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Adrenal Medulla: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Adrenal Medulla: Pheochromocytoma Benign		5/50 (10%)	11/50 (22%)	8/50 (16%)		2/50 (4%)	4/50 (20/)	2/50 (69/)
Overall Incidence	Total	5/50 (10%) 24/150 (16%)	Mean 16%	SD 6%	Total	2/50 (4%) 6/150 (4%)	1/50 (2%) Mean 4%	3/50 (6%) SD 2%
*Adrenal Medulla: Pheochromocytoma Complex	×	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Malignal	nt	(004)		(00)		(0)	(0.0)	(00)
Overall Incidence	Total	3/50 (6%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	0/50 (0%) SD 3.06%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Adrenal Medulla: Pheochromocytoma: Benign	, Complex	x, Malignant, NOS 7/50 (14%)	13/50 (26%)	8/50 (16%)		2/50 (4%)	1/50 (2%)	3/50 (6%)
Overall Incidence	Total	28/150 (18.67%)	Mean 18.67%	SD 6.43%	Total	6/150 (4%)	Mean 4%	SD 2%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Species: RATS Strain: F344 Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Bone: Chondrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Chondrosarcoma or Cho	ondroma		0/50 (00/)		•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Chordoma	•••••	0/50 (00/)			•••••			
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma	•••••	0/50 (40/)	4/50 (00)	0/50 (00/)	•••••	0/50 (00/)	0/50 (00()	0/50 (00/)
Overall Incidence	Total	2/50 (4%) 3/150 (2%)	1/50 (2%) Mean 2%	0/50 (0%) SD 2%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteosarcoma or Osteor	na		(204)		•••••			
Overall Incidence	Total	2/50 (4%) 3/150 (2%)	1/50 (2%) Mean 2%	0/50 (0%) SD 2%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 10

			Male	Female
Brain: Astrocytoma Malignant		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
Brain: Ependymoma Benign		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
Brain: Glioma Malignant	•••••	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
Brain: Granular Cell Tumor Benign		0/50 (00/)	0/50 (00)	0/50 (00) 0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
Brain: Medulloblastoma Mal		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0% SD 0%	Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 11

			Male				Female	
Brain:								
Meningioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Maligr	ant. NOS				•••••			
	,	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain:								
Oligodendroglioma Benign						- 4		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Maligna								
Oligodendi oglionia Malignai	ıı	1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Brain:								
Oligodendroglioma, Glioma,	or Astroc	vtoma						
g	-: /:5::00	1/50 (2%)	1/50 (2%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Brain: Osteosarcoma					•••••			(00)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male	Female
*Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Clitoral/Preputial Gland: Adenoma				
Overall Incidence	Total	2/50 (4%) 10/150 (6.67%)	5/50 (10%) 3/50 (6%) Mean 6.67% SD 3.06%	3/48 (6%) 7/50 (14%) 3/50 (6%) Total 13/148 (8.78%) Mean 8.75% SD 4.55%
*Clitoral/Preputial Gland: Carcinoma				
Overall Incidence	Total	2/50 (4%) 3/150 (2%)	0/50 (0%) 1/50 (2%) Mean 2% SD 2%	2/48 (4%) 0/50 (0%) 0/50 (0%) Total 2/148 (1.35%) Mean 1.39% SD 2.41%
*Clitoral/Preputial Gland: Carcinoma or Adenoma		4/50 (8%)	5/50 (10%) 4/50 (8%)	5/48 (10%) 7/50 (14%) 3/50 (6%)
Overall Incidence	Total	13/150 (8.67%)	Mean 8.67% SD 1.15%	Total 15/148 (10.14%) Mean 10.14% SD 4.01%
Clitoral/Preputial Gland: Fibrosarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/48 (0%) 0/50 (0%) 0/50 (0%) Total 0/148 (0%) Mean 0% SD 0%
*Clitoral/Preputial Gland: Sarcoma				0/40 (00/) 0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/48 (0%) 0/50 (0%) 0/50 (0%) Total 0/148 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Papilloma		0/50 (00/)	0/50 (0%)	0/50 (0%)		0/49 (00/)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/48 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Ear: Neural Crest Tumor		0/50 (00/)	0/50 (00/)	0/50 (00)		0/50 (00)	0/50 (00()	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Esophagus: Fibrosarcoma		0/50 /00()	0/50 (00/)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Esophagus: Lipoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Eye: Amelanotic Melanoma, Ber	nign	0/50 (00/)	0/50 /00/	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Eye: Melanoma Benign								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 14

			Male				Female	
#Eye: Melanoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Eye: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Heart: Schwannoma Malignant		0/50 (00)	0/50 (00)	0/50 (00/)		0/50 (00)		0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Large: Colon/Rectum Adenoma	1:	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectum Carcinoma	n:	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectum Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectum Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma		- ()		- / / / / / / / / / /				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Duodenum: Leiomyoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male	Female
Intestine Small: Jejunum: Carcinoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
Intestine Small: Jejunum: Granular Cell Tumor Malignan				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Jejunum: Leiomyoma				
		1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Jejunum: Leiomyosarcoma				0/50 (00/) 0/50 (00/) 0/50 (00/)
verell Incidence	Total	` ,	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/450 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Site Unspecified Carcinoma	:			
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Site Unspecified Carcinoma or Adenoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
#Intestine Small: Site Unspec Granular Cell Tumor Mali		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (09/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Site Unspec Leiomyoma	cified:	(20)	(00)	(201)	•••••	(201)	(004)	(00)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Site Unspec Leiomyosarcoma	cified:			(201)	•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Islets, Pancreatic: Adenoma		4/50 (8%)	2/50 (4%)	2/50 (4%)	•••••	0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	8/150 (5.33%)	Mean 5.33%	SD 2.31%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
*Islets, Pancreatic: Carcinoma		0/50 (00/)	4/50 (20()	0/50 (0%)		0/50 /00/	0/50 (0%)	0/50 (/0//)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma		4/50 (00())	0/50 (00/)	0/50 /40/)		0/50 (00/)	4/50 (00/)	4/50 (00)
Overall Incidence	Total	4/50 (8%) 9/150 (6%)	3/50 (6%) Mean 6%	2/50 (4%) SD 2%	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female					
*Kidney: Pelvis and Transitional Epithelium: Carcinoma												
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%				
(idney: Pelvis and Transition Carcinoma or Adenoma	al Epitheliur											
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%				
idney: Pelvis and Transition Papilloma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
idney: Renal Tubule: Adenoma						•••••						
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
rerall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%				
idney: Renal Tubule: Carcinoma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
rerall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
idney: Renal Tubule: Carcinoma or Adenoma		(00)	2/22 (22)	(00)		(00)	(0)	(20)				
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Toxicology Data

Species: RATS Strain: F344

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 19

			Male		Female
Kidney: Renal Tubule: Hemangiosarcoma					
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
Kidney: Renal Tubule: Lipoma		0/50 (00/)	4/50 (001)	0/50 (00)	0/50 (001)
verall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
verall illefaction	Total	1/130 (0.07/0)	Weat 0.07/6 3D 1.13/6	Total 0/130 (070)	Weati 076
Kidney: Renal Tubule: Liposarcoma		0/50 (00()	2/52 (221)	0/50 (00)	0/50 (001)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
verali ilicidence		, ,	Weatt 0% SD 0%	Total 0/150 (0%)	Medil 0% SD 0%
(idney: Renal Tubule: Mesenchymal Tumor Benign		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%)	Mean 0% SD 0%
				•••••	
Kidney: Renal Tubule: Nephroblastoma					
warali laaidanaa	Total	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 1/150 (0.67%)	Mean 0.67% SD 1.15%
Cidney: Renal Tubule: Sarcoma		0/50 (00()	0/50 (00/) 0/50 (00/)	0/50 (00)	0/50 (00/) 0/50 (00/)
Verall Incidence	Total	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%)	Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

31011.11012000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 20

			Male				Female	
Liver: Cholangioma		27-2 (22)		2(52 (22))		2/52 (221)	(201)	2/20 (201)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
.iver: Hemangiosarcoma		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/30 (0%)	Mean 0%	0/50 (0%) SD 0%
.iver: Hepatocellular Adenoma		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
iver: Hepatocellular Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
iver: Hepatocellular Carcinoma o	or Hepatob		0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
iver: Hepatocellular Carcinoma o	or Hepatoc	ellular Adenoma 1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Species: RATS Strain: F344 Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female					
*Liver: Hepatocellular Carcinon Hepatoblastoma	Hepatocellular Carcinoma, Hepatocellular Adenoma, or											
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%				
*Lung:		•••••	•••••									
Alveolar/Bronchiolar Ad	enoma	3/50 (6%)	3/50 (6%)	0/50 (0%)		1/50 (2%)	4/50 (8%)	2/50 (4%)				
Overall Incidence	Total	6/150 (4%)	Mean 4%	SD 3.46%	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%				
*Lung: Alveolar/Bronchiolar Ca	rcinoma											
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Lung: Alveolar/Bronchiolar Ca Adenoma	rcinoma or Al	veolar/Bronchiolar 4/50 (8%)	3/50 (6%)	1/50 (2%)		1/50 (2%)	4/50 (8%)	2/50 (4%)				
Overall Incidence	Total	8/150 (5.33%)	Mean 5.33%	SD 3.06%	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%				
*Lung: Hemangiosarcoma			•••••		•••••		•••••	••••••				
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Lung: Sarcoma												
Garconia		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: CORN OIL

Route: GAVAGE

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Report Date: 11/17/2008

Length of Study: CHRONIC

Male Female *Lung: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)(0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% **#Lymph Node:** Hemangiosarcoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%)Mean 0% **#Lymph Node, Mesenteric:** Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Mammary Gland: Adenoma (0%)(0%)0/50 (0%)(0%)(0%)2/50 (4%)0/50 0/50 0/50 0/50 2/150 (1.33%) **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total Mean 1.33% SD 2.31% #Mammary Gland: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)4/50 (8%)(0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 4/150 (2.67%) Mean 2.67% SD 4.62% #Mammary Gland: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)4/50 (8%)0/50 (0%)2/50 (4%)**Overall Incidence** 0/150 (0%) SD 0% SD 4% Total Mean 0% Total 6/150 (4%) Mean 4%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 23

			Male				Female	
Mammary Gland: Fibroadenoma								
		4/50 (8%)	0/50 (0%)	1/50 (2%)		26/50 (52%)	17/50 (34%)	21/50 (42%)
verall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 4.16%	Total	64/150 (42.67%)	Mean 42.67%	SD 9.02%
Mammary Gland: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenon								
		4/50 (8%)	0/50 (0%)	1/50 (2%)		26/50 (52%)	17/50 (34%)	22/50 (44%)
verall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 4.16%	Total	65/150 (43.33%)	Mean 43.33%	SD 9.02%
Mammary Gland: Fibroma, Fibroadenom		or Adenoma						
	T	4/50 (8%)	0/50 (0%)	1/50 (2%)	.	28/50 (56%)	17/50 (34%)	22/50 (44%)
verall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 4.16%	Total	67/150 (44.67%)	Mean 44.67%	SD 11.02%
Mesentery: Fibrosarcoma		0.50	0.750 (001)	(00)		2/52 (224)	2(22)	(201)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
lesentery: Hemangiosarcoma			0.70			(004)	(00)	(00)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
#Mesentery: Lipoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Mesentery: Rhabdomyosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Nose: Adenoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Nose: Chondroma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Nose: Squamous Cell Carcinoma	·····	0/50 (00/)	0/50 (00/)	(00)		0/50 (00)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Oral Cavity (Oral Mucosa, To Papilloma Squamous or P	ngue, Phary	nx, Tooth, Gingiva):						
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 25

Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

				Ma	ale					Female	
Oral Cavity (Oral Mucosa, Tong Squamous Cell Carcinoma	ue, Phary	nx, Tooth,	Gingiva):								
1		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
	•••••										
Oral Cavity (Oral Mucosa, Tong Squamous Cell Carcinoma, F Papilloma											
		1/50	(2%)		(2%)	0/50	(0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
verall Incidence	Total		(1.33%)		1.33%		1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
Oral Mucosa: Squamous Cell Carcinoma										4/50 (004)	
		1/50	(2%)		(0%)	0/50	(0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Oral Mucosa: Squamous Cell Papilloma		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50 (0%)	0/50 (09/)	0/50 (0%)
verall Incidence	Total		(0.67%)		0.67%		1.15%	Total	0/150 (0%)	0/50 (0%) Mean 0%	SD 0%
Ovary: Granulosa Cell Tumor Benig	n							Tatal	0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence								Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Ovary: Granulosa Cell Tumor Maligi	nant								0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence								Total	` ,	0/50 (0%) Mean 0%	` '
verali incidence								Total	0/150 (0%)	wean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 26

Report Date: 11/17/2008

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 1/50 (2%)(0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% **Granulosa-Theca Tumor Benign** 0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% Total 0/150 Mean 0% *Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% *Ovary: **Tubulostromal Adenoma** (0%)0/50 (0%)0/50 Mean 0% **Overall Incidence** Total 0/150 (0%) SD 0% *Pancreas: Adenoma 7/50 (14%)(2%)2/50 (4%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 10/150 (6.67%)Mean 6.67% SD 6.43% Total 0/150 Mean 0% SD 0% *Pancreas: Carcinoma (2%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 1.15% SD 0% Total 1/150 (0.67%) Mean 0.67% Total 0/150 (0%) Mean 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 27

			Male				Female	
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	8/50 (16%) 11/150 (7.33%)	1/50 (2%) Mean 7.33%	2/50 (4%) SD 7.57%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas: Mixed Tumor Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Pancreas: Mixed Tumor Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Parathyroid Gland: Adenoma		0/47 (00()	4/45 (00)	4/40 (00)		0/47 (00/)	0/47 (00/)	0(40 (40/)
Overall Incidence	Total	0/47 (0%) 2/141 (1.42%)	1/45 (2%) Mean 1.42%	1/49 (2%) SD 1.23%	Total	0/47 (0%) 2/140 (1.43%)	0/47 (0%) Mean 1.45%	2/46 (4%) SD 2.51%
#Peripheral Nerve: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Peripheral Nerve: Schwannoma: Benign, Mali	ignant, NOS							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for S

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 28

			Male				Female				
Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma											
		19/50 (38%)	6/50 (12%)	11/50 (22%)		25/50 (50%)	25/50 (50%)	27/50 (54%)			
verall Incidence	Total	36/150 (24%)	Mean 24%	SD 13.11%	Total	77/150 (51.33%)	Mean 51.33%	SD 2.31%			
Pituitary Gland: Pars Distalis o Carcinoma	or Unspecif										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
Pituitary Gland: Pars Distalis o Carcinoma or Adenoma											
		19/50 (38%)	6/50 (12%)	11/50 (22%)		25/50 (50%)	25/50 (50%)	27/50 (54%)			
verall Incidence	Total	36/150 (24%)	Mean 24%	SD 13.11%	Total	77/150 (51.33%)	Mean 51.33%	SD 2.31%			
Pituitary Gland: Pars Intermed Adenoma											
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%			
Pituitary Gland: Pars Intermed Carcinoma	ia:										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
Pituitary Gland: Pars Intermed Carcinoma or Adenoma	ia:	4/50 /00()	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 /00/			
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

SIUII. NUVZUUO

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 29

			Male		Female			
*Prostate: Adenoma		0/50 (00/)	0/50 (00/)	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Prostate: Carcinoma or Adenoma		0/50 (00()	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Salivary Glands: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Salivary Glands: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
#Skeletal Muscle: Hemangioma		0/50 (00()	0/50 (0%)	0/50 (0%)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

131011: 11012000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 30

			Male				Female	
#Skeletal Muscle: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skeletal Muscle: Lipoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skeletal Muscle: Rhabdomyosarcoma					•••••			
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skeletal Muscle: Rhabdomyosarcoma or R	habdomyom							
verall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
keletal Muscle: Sarcoma								
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Basal Cell Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 31

	Male				Female					
#Skin:										
Basal Cell Adenoma or	Basosquamou									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)		
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		
Skin:										
Basal Cell Adenoma, B	asosquamous '	Tumor Benign, or								
Trichoepithelioma		0/50 (0%)	0/50 (00/)	0/50 (00/)		0/50 (00/)	4/50 (20/)	0/50 (00/)		
	+	` ,	0/50 (0%)	0/50 (0%)	.	0/50 (0%)	1/50 (2%)	0/50 (0%)		
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		
Skin:										
Basal Cell Carcinoma		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
	T-1-1	` ,	` '	` '	T-1-1	` '	` '	` '		
		2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%		
	Total									
			or 1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Skin: Basal Cell Carcinoma o NOS)		ous Tumor (malignant c		0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Skin: Basal Cell Carcinoma c NOS) verall Incidence	or Basosquamo Total	ous Tumor (malignant o 1/50 (2%) 2/150 (1.33%)	1/50 (2%)	SD 1.15%		0/150 (0%)	Mean 0%	SD 0%		
Skin: Basal Cell Carcinoma o NOS) overall Incidence	or Basosquamo Total	ous Tumor (malignant o 1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	SD 1.15%		0/150 (0%)	Mean 0%	SD 0%		
Skin: Basal Cell Carcinoma o NOS) Everall Incidence Skin: Basal Cell Carcinoma,	or Basosquamo Total Basal Cell Ader	nus Tumor (malignant o 1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	SD 1.15%		0/150 (0%)	Mean 0%	SD 0%		
Skin: Basal Cell Carcinoma o NOS) verall Incidence Skin:	or Basosquamo Total Basal Cell Ader	1/50 (2%) 2/150 (1.33%) noma, Basosquamous	1/50 (2%) Mean 1.33%	SD 1.15%		0/150 (0%) ´	Mean 0%	SD 0%		
Skin: Basal Cell Carcinoma o NOS) verall Incidence Skin: Basal Cell Carcinoma, I Tumor (benign, maligna	Total Basal Cell Ader ant or NOS), or	nus Tumor (malignant of 1/50 (2%) 2/150 (1.33%) 2/150 moma, Basosquamous Trichoepithelioma 1/50 (2%)	1/50 (2%) Mean 1.33% 1/50 (2%)	SD 1.15% 		0/150 (0%)	Mean 0%	SD 0% 0/50 (0%)		
Skin: Basal Cell Carcinoma o NOS) verall Incidence Skin: Basal Cell Carcinoma, Tumor (benign, maligna	or Basosquamo Total Basal Cell Ader	1/50 (2%) 2/150 (1.33%) noma, Basosquamous	1/50 (2%) Mean 1.33%	SD 1.15%		0/150 (0%) ´	Mean 0%	SD 0%		
Skin: Basal Cell Carcinoma o NOS) verall Incidence Skin: Basal Cell Carcinoma, Tumor (benign, malign:	Total Basal Cell Aderant or NOS), or	noma, Basosquamous Trichoepithelioma 1/50 (2%) 2/150 (1.33%) noma, Basosquamous Trichoepithelioma 1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33% 1/50 (2%) Mean 1.33%	SD 1.15% 0/50 (0%) SD 1.15%	Total	0/150 (0%) 0/50 (0%) 1/150 (0.67%)	Mean 0% 1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%		
Skin: Basal Cell Carcinoma o NOS) Overall Incidence Skin: Basal Cell Carcinoma, Tumor (benign, maligna	Total Basal Cell Ader ant or NOS), or Total noma, Carcinon	nus Tumor (malignant of 1/50 (2%) 2/150 (1.33%) noma, Basosquamous Trichoepithelioma 1/50 (2%) 2/150 (1.33%) ma, Basosq. Tumor (M Papilloma, Sq	1/50 (2%) Mean 1.33% 1/50 (2%) Mean 1.33%	SD 1.15% 0/50 (0%) SD 1.15%	Total	0/150 (0%) 0/50 (0%) 1/150 (0.67%)	Mean 0% 1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%		
NOS) Overall Incidence Skin: Basal Cell Carcinoma, Tumor (benign, malignate) Overall Incidence Skin: Basal or Sq. Cell Carcinor B), Basal Cell Adence	Total Basal Cell Ader ant or NOS), or Total noma, Carcinon	nus Tumor (malignant of 1/50 (2%) 2/150 (1.33%) noma, Basosquamous Trichoepithelioma 1/50 (2%) 2/150 (1.33%) ma, Basosq. Tumor (M Papilloma, Sq	1/50 (2%) Mean 1.33% 1/50 (2%) Mean 1.33%	SD 1.15% 0/50 (0%) SD 1.15%	Total	0/150 (0%) 0/50 (0%) 1/150 (0.67%)	Mean 0% 1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

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

Route: GAVAGE Vehicle: CORN OIL Page: 32

Report Date:11/17/2008

Length of Study: CHRONIC

			Male			Female			
#Skin: Fibroma									
Overall Incidence	Total	5/50 (10%) 11/150 (7.33%)	3/50 (6%) Mean 7.33%	3/50 (6%) SD 2.31%	Total	0/50 (0%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	3/50 (6%) SD 3.06%	
	ı olul								
Skin: Fibroma, Fibrosarcoma, S Fibrous Histiocytoma	Sarcoma, My	xoma, Myxosarcoma, or							
·		7/50 (14%)	4/50 (8%)	3/50 (6%)		0/50 (0%)	3/50 (6%)	3/50 (6%)	
Overall Incidence	Total	14/150 (9.33%)	Mean 9.33%	SD 4.16%	Total	6/150 (4%)	Mean 4%	SD 3.46%	
Skin: Fibrosarcoma		4/50 (004)	0/50 (00/)	0/50 (00/)		0/50 (00)	4/50 (00/)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	
	rotai	17100 (0.0770)	Widaii 0.0170	05 1.1070		17100 (0.0770)	Wicaii 0.0770	05 1.1070	
Skin: Fibrosarcoma, Sarcoma, Histiocytoma	Myxosarcom	,							
Nucual Incidence	Total	2/50 (4%)	1/50 (2%)	0/50 (0%)	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)	
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
Skin: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Skin: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
	· Otal	37.33 (070)		G2 070	· Otal	0, 100 (070)		32 370	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 33

			Male				Female	
#Skin: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Keratoacanthoma		7/50 (440/)	2/50 /40/\	2/50 (69/)		0/50 (00/)	0/50 (/0//)	0/50 (00/)
Overall Incidence	Total	7/50 (14%) 12/150 (8%)	2/50 (4%) Mean 8%	3/50 (6%) SD 5.29%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Lipoma	•••••							
Overall Incidence	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Liposarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor		0/50 (/0//)	0/50 (00/.)	0/50 (00/)		0/50 (00/)	0/50 (/0//)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neural Crest Tumor, Mali	ignant							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 34

Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male			Female					
Skin: Neurofibroma or Schwannoma benign 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)											
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
Skin: Neurofibrosarcoma or So		malignant or NOS)			•••••	•••••					
verall Incidence	Total	0/50 (0%) 3/150 (2%)	0/50 (0%) Mean 2%	3/50 (6%) SD 3.46%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Skin: Neurofibrosarcoma, Neu malignant or NOS)	rofibroma, or	, ,		0/50 (00)		0/50 (00()	0/50 (0)()	0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 3/150 (2%)	0/50 (0%) Mean 2%	3/50 (6%) SD 3.46%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Skin: Osteosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
Skin: Sarcoma			(20)					0.50			
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Skin: Schwannoma Benign		0/50 (/0//)	0/50 (09/)	0/50 (09/)		0/50 (09/)	0/50 (09/)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 35

			Male				Female	
∜Skin: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 3.46%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Carcino		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
fSkin: Squamous Cell Carcino Basosquamous Tumor (1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papillon	na	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin:	na or Papillom		0/50 (00/)	0/50 /00/		0/50 (0%)	0/50 (0%)	1/50 (2%)
Squamous Cell Papillon	•	0/50 (00/)					0/30 (076)	1/30 (270)
•	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Overall Incidence	Total	0/150 (0%)	` '	SD 0%		1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 36

				Ma	ale					Female		
Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 7/50 (14%) 2/50 (4%) 2/50 (6%) 0/50 (0%) 0/50 (0%) 1/50 (2%)												
verall Incidence	Total	7/50 12/150	(14%) (8%)	2/50 Mean	(4%) 8%	3/50 SD	(6%) 5.29%	Total	0/50 (0% 1/150 (0.67%	, , ,	1/50 (2%) SD 1.15%	
verali ilicidence			,						•	,		
Skin: Trichoepithelioma												
verall Incidence	Total	0/50 0/150	(0%) (0%)	0/50 Mean	(0%)	0/50	(0%) 0%	Total	0/50 (0% 0/150 (0%)) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
			` ,						, ,			
Skin: Sebaceous Gland: Adenoma										· · · · · · · · · · · · · · · · · · ·		
	.	1/50	(2%)	1/50	(2%)	0/50	(0%)	.	0/50 (0%	, , ,	0/50 (0%)	
verall Incidence	Total	2/150	,		1.33%	_	1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
kin: Sebaceous Gland: Carcinoma	••••••											
verall Incidence	Total	0/50 0/150	(0%) (0%)	0/50 Mean	(0%) 0%	0/50 SD	(0%) 0%	Total	0/50 (0% 0/150 (0%)) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
rerail incluence	Total	0/130	(070)	Mean	070	OD	070	Total	0/130 (070)	Weatt 070	GD 070	
kin: Sebaceous Gland: Carcinoma or Adenoma												
		1/50	(2%)		(2%)	0/50	(0%)		0/50 (0%	, , ,	0/50 (0%)	
verall Incidence	Total	2/150	(1.33%)	Mean	1.33%	SD	1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
Spinal Cord: Astrocytoma Benign												
warall Incidence	Total	0/50	(0%)		(0%)	0/50	(0%)	Total	0/50 (0%	, , ,	0/50 (0%)	
verall Incidence	Total	0/150	(0%)	Mean	υ%	SD	0%	Total	1/150 (0.67%) Mean 0.67%	SD 1.15%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 37

			Male				Female	
#Spinal Cord: Astrocytoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Spinal Cord: Glioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
*Spleen: Fibrosarcoma		0/50 (00/)	0/50 (00/)			0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Spleen: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma		0/50 /00/	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Spleen: Hemangiosarcoma		4/50 (00)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (40/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 38
Report Date:11/17/2008

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
*Spleen: Leiomyosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Spleen: Sarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 /00()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Forestomach: Leiomyosarcoma	•••••	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 /00/	0/50 (00/)	0/50 /00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papillon		2/22 (22)	(00)	•••••	(0.1)	(004)	(00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Stomach, Forestomach: Squamous Cell Papilloma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 39

			Male				Female	
#Stomach, Glandular: Leiomyosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Lipoma		0/50 (00/)	0/50 (0%)	0/50 (00/)		0/50 (00)	0/50 (00()	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Testes: Adenoma		46/50 (020/)	47/50 (049/)	46/EQ (020/)				
Overall Incidence	Total	46/50 (92%) 139/150 (92.67%)	47/50 (94%) Mean 92.67%	46/50 (92%) SD 1.15%				
*Thymus: Sarcoma		0/47 (00/)	2/47 (22/)	0/50 (00/)	•••••	0/47 (00)	0/40 (00/)	0/50 (001)
Overall Incidence	Total	0/47 (0%) 0/144 (0%)	0/47 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/47 (0%) 0/146 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%
*Thymus: Thymoma Benign		0/47 (0%)	0/47 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/144 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/47 (00/)	0/47 (00/)	0/50 (00/)		0/47 (00/)	0/40 (00/)	0/50 /00/
Overall Incidence	Total	0/47 (0%) 0/144 (0%)	0/47 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/47 (0%) 0/146 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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

Page: 40 Report Date:11/17/2008

Species: RATS Strain: F344 Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

**Thymona: Benign, Malignant, NOS Overall Incidence Total O/144 (0%) Overall Incidence Total O/145 (0%) Overall Incidence Total O/146 (0%) Overall Incidence O/148 (0%) Overall Incidence O/150 (18%) Overall Incidence O/150 (18%) Overall Incidence Total O/150 (0%) Overall Incidence O/150 (12%) Overall Incidence O/150 (0%) Overall I				Male		Female				
Overall Incidence Total 0/144 (0%) Mean 0% SD 0% Total 0/146 (0%) Mean 0% SD 0% "Thyroid Gland: C-Cell: Adenoma 9/50 (18%) 12/50 (24%) 8/50 (16%) 7/50 (14%) 5/50 (10%) 8/50 (16%) Overall Incidence Total 29/50 (18.33%) Mean 19.33% SD 4.16% Total 20/150 (13.33%) Mean 13.33% SD 3.06% "Thyroid Gland: C-Cell: Carcinoma 6/50 (12%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) <t< th=""><th></th><th>nt, NOS</th><th>0/47 (0%)</th><th>0/47 (0%)</th><th>0/50 (0%)</th><th></th><th>0/47 (0%)</th><th>0/49 (0%)</th><th>0/50 (0%)</th></t<>		nt, NOS	0/47 (0%)	0/47 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)	0/50 (0%)	
Adenoma	Overall Incidence	Total	` ,	()	` ,	Total	` '	` '	` /	
Overall Incidence Total 29/150 (19.33%) Mean 19.33% SD 4.16% Total 20/150 (13.33%) Mean 13.33% SD 3.06% *Thyroid Gland: C-Cell: Carcinoma 6/50 (12%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) *Thyroid Gland: C-Cell: Carcinoma or Adenoma 15/50 (30%) 12/50 (24%) 8/50 (16%) 9/50 (18%) 5/50 (10%) 8/50 (10%) 8/50 (16%) Overall Incidence Total 35/150 (23.33%) Mean 23.33% SD 7.02% Total 22/150 (14.67%) Mean 14.67% SD 4.16% *Thyroid Gland: Follicular Cell: Adenoma 1/50 (2%) 1/50 (2%) 1/50 (2%) 0/50 (0%) Mean 1.33% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% *Thyroid Gland: Follicular Cell: Carcinoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 1/50 (0%) 1/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)			0/50 (400/)	40/50 (04%)	0/50 (400/)		7/50 (4.40())	5/50 (400)	0/50 (400/)	
Carcinoma Coroll Coroll Coroll Carcinoma	Overall Incidence	Total	` ,	` ,	, ,	Total	,	` ,	` '	
Overall Incidence Total 6/150 (4%) Mean 4% SD 6.93% Total 3/150 (2%) Mean 2% SD 3.46% *Thyroid Gland: C-Cell: Carcinoma or Adenoma 15/50 (30%) 12/50 (24%) 8/50 (16%) 9/50 (18%) 5/50 (10%) 8/50 (16%) Overall Incidence Total 35/150 (23.33%) Mean 23.33% SD 7.02% Total 22/150 (14.67%) Mean 14.67% SD 4.16% *Thyroid Gland: Follicular Cell: Adenoma 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0% *Thyroid Gland: Follicular Cell: Carcinoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50			0/50 (40%)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (00/)	
Carcinoma or Adenoma 15/50 (30%) 12/50 (24%) 8/50 (16%) Overall Incidence Total 35/150 (23.33%) Mean 23.33% SD 7.02% *Thyroid Gland: Follicular Cell: Adenoma 1/50 (2%) 1/50 (2%) 0/50 (0%) Overall Incidence Total 2/150 (1.33%) Mean 1.33% SD 7.02% Total 2/150 (14.67%) Mean 14.67% Mean 14.67% SD 4.16% *Thyroid Gland: Follicular Cell: Carcinoma 1/50 (2%) 1/50 (2%) 0/50 (0%) Mean 1.33% SD 1.15% Total 0/150 (0%) 0/50 (0%) Mean 0% SD 0% *Thyroid Gland: Follicular Cell: Carcinoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) O/50 (0%) Total 0/150 (0%) Mean 0% SD 0%	Overall Incidence	Total	` ,	` ,	` ,	Total	` '	` '	` /	
Overall Incidence Total 35/150 (23.33%) Mean 23.33% SD 7.02% Total 22/150 (14.67%) Mean 14.67% SD 4.16% *Thyroid Gland: Follicular Cell: Adenoma 1/50 (2%) 1/50 (2%) 0/50 (0%) </td <td></td> <td></td> <td>15/50 (30%)</td> <td>12/50 (24%)</td> <td>9/50 (169/)</td> <td></td> <td>0/50 /199/\</td> <td>5/50 (10%)</td> <td>9/50 (169/.)</td>			15/50 (30%)	12/50 (24%)	9/50 (169/)		0/50 /199/\	5/50 (10%)	9/50 (169/.)	
Adenoma 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 2/150 (1.33%) Mean 1.33% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% *Thyroid Gland: Follicular Cell: Carcinoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Overall Incidence	Total	` ,	` ,	, ,	Total	` ,	` ,	` '	
Overall Incidence Total 2/150 (1.33%) Mean 1.33% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% *Thyroid Gland: Follicular Cell: Carcinoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 1/50 (2%) 0/50 (0%) <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td>										
Carcinoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	Overall Incidence	Total	` '	` '	, ,	Total	` ,	` ,	` '	
	•		4/50 (00/)	0/50 (40/)	0/50 (00/)		4/50 (00/)	0/50 (0%)	0/50 (00/)	
	Overall Incidence	Total	, ,	` '	` ,	Total	(/	` '	` '	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 41 Report Date:11/17/2008

Species: RATS Strain: F344 Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male		Female
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma					
Overall Incidence	Total	2/50 (4%) 5/150 (3.33%)	3/50 (6%) 0/50 (0%) Mean 3.33% SD 3.06%	,	0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.15%
#Tissue NOS: Lipoma		0/50 (00/)	0/50 (00/) 0/50 (00	0/50 (00/)	0/50 /00/\ 0/50 /00/\
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	%) 0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
#Tissue NOS: Paraganglioma		0/50 (09/)	0/50 (00/) 0/50 (00	0/50 (00/)	0/50 /00/\ 0/50 /00/\
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	%) 0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%	%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	Total 0/150 (0%)	Mean 0% SD 0%
#Tongue: Squamous Cell Carcinoma		0/50 (00/)	0/50 (00) 0/50 (00)	N) 0/50 (00)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	%) 0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
#Tongue: Squamous Cell Carcinoma of	or Papillon		0/50 (00/) 0/50 (00	O/FQ (20%)	4/50 (00/) 0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	%) 0/50 (0%) Total 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%

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

^{#:} Denominator is number of animals necropsied

1072006

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 42

			Male				Female	
#Tongue: Squamous Cell Papilloma		2/20 (201)	2/52 (224)	2/22 (22)		2/22 (221)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Tooth: Adamantinoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma			0/50 (0%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
*Urinary Bladder: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma		0/50 (00/)	4/50 (00)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Urinary Bladder: Leiomyosarcoma		0/50 (00%)			•••••	0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
*Urinary Bladder: Papilloma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus:								
Adenoma								
O					T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
oaromoma						0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence					Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Uterus:								
Deciduoma Benign						1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Uterus:								
Hemangioma								
Overell Incidence					Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus: Hemangiosarcoma								
Overell Incidence					Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: CORN OIL

Length of Study: CHRONIC

	Male			Female	
#Uterus: Leiomyoma			2/22 (224)		2/20 (201)
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Leiomyosarcoma					
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Polyp Stromal		••••••			
Overall Incidence		Total	8/50 (16%) 21/150 (14%)	8/50 (16%) Mean 14%	5/50 (10%) SD 3.46%
#Uterus: Sarcoma Stromal					
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal		•••••			
Overall Incidence		Total	8/50 (16%) 21/150 (14%)	8/50 (16%) Mean 14%	5/50 (10%) SD 3.46%
#Uterus: Schwannoma Malignant					
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

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

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

d Control Animal Groups Report Date:11/17/2008

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			Male				Female	
#Vagina: Polyp						1/50 (2%)	0/50 (0%)	0/50 (09/)
Overall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
• • • • • • • • • • • • • • • • • • • •			•••••		• • • • • • • • • • • • • • • • • • • •		•••••	•••••
#Vagina: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Adenoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma		2/50 (4%)						
Overall Incidence	Total	2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Zymbal's Gland: Carcinoma or Adenoma	•••••							
Overall Incidence	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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Report Date:11/17/2008

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
				Ma	ale		
Southern Research Institute Southern Research Institute	059902407 059100507	02/03/03 06/26/00	729 730	50 (3) 50 (3)	21(661) 30(693)	518.7 520.6	Androstenedione Methylene blue trihydrate
				Fen	nale		
Southern Research Institute Southern Research Institute	059902407 059100507	02/03/03 06/26/00	729 733	50 (5) 50 (5)	38(710) 35(699)	356.5 335.9	Androstenedione Methylene blue trihydrate

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#All Organs: Benign Tumors								
Overall Incidence	Total	47/50 (94%) 94/100 (94%)	47/50 (94%) Mean 94%	SD 0%	Total	44/50 (88%) 91/100 (91%)	47/50 (94%) Mean 91%	SD 4.24%
#All Organs: Malignant Tumors		34/50 (68%)	30/50 (60%)		•••••	10/50 (20%)	19/50 (38%)	
Overall Incidence	Total	64/100 (64%)	Mean 64%	SD 5.66%	Total	29/100 (29%)	Mean 29%	SD 12.73%
#All Organs: Malignant and Benign T	umors	49/50 (98%)	49/50 (98%)			46/50 (92%)	50/50 (100%)	
Overall Incidence	Total	98/100 (98%)	Mean 98%	SD 0%	Total	96/100 (96%)	Mean 96%	SD 5.66%
#All Organs: Hemangioma		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma		(201)	(20)			0/50 (00)	(00)	
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#All Organs: Hemangiosarcoma or He								
Overall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#All Organs: Histiocytic Sarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
All Organs: Leukemia: Erythrocytic		0/50 (00/)	0/50 (00/)			0/50 (00()	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
All Organs: Leukemia: Lymphocytic, I Undifferentiated	Monocytic, M	ononuclear, or						
Overall Incidence	Total	26/50 (52%) 49/100 (49%)	23/50 (46%) Mean 49%	SD 4.24%	Total	5/50 (10%) 17/100 (17%)	12/50 (24%) Mean 17%	SD 9.9%
All Organs: Malignant Lymphoma: His or Undifferentiated Cell Ty	stiocytic, Lyn			,		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
All Organs: Mesothelioma: Benign, Ma			3/50 (6%)			0/50 (0%)	0/50 (0%)	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male			Female 0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0% SD 0%				
#All Organs: Mesothelioma: Malignant		1/50 (2%)	3/50 (6%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	` ,	` '	SD 0%		
#All Organs: Osteoma		0/50 (0%)	0/50 (09/)			0/50 (00/)	0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` ,	SD 0%		
#All Organs: Osteosarcoma		4/50 (00/)	0/50 (0%)			0/50 (00()	4/50 (00/)			
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%		
#All Organs: Osteosarcoma or Osteoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
*Adrenal Cortex: Adenoma		0/50 (00/)	4/50 (00()			0/50 (00/)	4/50 (00)			
Overall Incidence	Total	3/50 (6%) 4/100 (4%)	1/50 (2%) Mean 4%	SD 2.83%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%		
*Adrenal Cortex: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344 Route: GAVAGE

Vehicle: METHYLCELLULOSE

			Male				Female	
*Adrenal Medulla: Ganglioneuroma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Adrenal Medulla: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benigi	n	7/50 (14%)	9/50 (18%)			3/50 (6%)	2/50 (4%)	
Overall Incidence	Total	16/100 (16%)	Mean 16%	SD 2.83%	Total	5/100 (5%)	2/50 (4%) Mean 5%	SD 1.41%
*Adrenal Medulla: Pheochromocytoma Compl	ex	1/50 (2%)	1/50 (2%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Adrenal Medulla: Pheochromocytoma Malign	ant	(00)	(00)			(201)	(201)	•••••
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma: Benig	n, Comple		44/50 (000)			//F0 //00/C	0/50 (/0/)	
Overall Incidence	Total	8/50 (16%) 19/100 (19%)	11/50 (22%) Mean 19%	SD 4.24%	Total	4/50 (8%) 6/100 (6%)	2/50 (4%) Mean 6%	SD 2.83%

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

^{#:} Denominator is number of animals necropsied

II. NUVZUUO

Contract/Lab: All Laboratories Species: RATS

Strain: F344 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Bone: Chondrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Chondrosarcoma or Cho	ndroma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Chordoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Osteoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Bone: Osteosarcoma or Osteom	na	4/50 (20/)	0/50 (00/)			0/50 (00/)	1/50 (20()	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

31011: 1101/2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Brain: Meningioma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Malig	ınant, NOS	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Maligna	ant	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Glioma	a, or Astroc		0/50 (0%)			0/50 (00()	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Osteosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma								
Overall Incidence	Total	3/50 (6%) 4/100 (4%)	1/50 (2%) Mean 4%	SD 2.83%	Total	12/50 (24%) 19/100 (19%)	7/50 (14%) Mean 19%	SD 7.07%
Clitoral/Preputial Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
Clitoral/Preputial Gland: Carcinoma or Adenoma		3/50 (6%)	1/50 (2%)			13/50 (26%)	8/50 (16%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	21/100 (21%)	Mean 21%	SD 7.07%
Clitoral/Preputial Gland: Fibrosarcoma		0(50 (00))	0(50 (00))			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Clitoral/Preputial Gland: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Papillom	na Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall illicidence		` ,				,		
#Ear: Neural Crest Tumor					•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Esophagus: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Esophagus: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Eye: Amelanotic Melanoma, E	3enign				•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Eye: Melanoma Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

OII. 140V2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Intestine Large: Colon/Rectun Adenoma	n:	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectun Carcinoma	1:	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectun Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectun Hemangioma		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma							•••••	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: METHYLCELLULOSE

Report Date:11/17/2008

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			Male				Female	
#Intestine Small: Jejunum: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Granular Cell Tumor Maligna								
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma								
		0/50 (0%)	0/50 (0%)	00.00/		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspecifie Carcinoma	ed:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspecifie		•••••		•••••			•••••	
Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overell Incidence	Total	` ,	` '	CD 00/	Total	()	` ,	SD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Species: RATS Strain: F344 Route: GAVAGE

Vehicle: METHYLCELLULOSE

			Male				Female	
#Intestine Small: Site Unspec Granular Cell Tumor Mali								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		` ,				,	Wearr 070	
#Intestine Small: Site Unspec Leiomyoma								
		0/50 (0%)	0/50 (0%)	00.007		0/50 (0%)	0/50 (0%)	05 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec	cified:	2/20 (201)	0.70			0.50	(201)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	CD 00/	Total	0/50 (0%)	0/50 (0%) Mean 0%	CD 00/
Overall incidence	Total	0/100 (0%)	wean 0%	SD 0%	Total	0/100 (0%)	wean 0%	SD 0%
*Islets, Pancreatic: Adenoma		4/50 (8%)	4/50 (8%)			1/50 (2%)	2/49 (4%)	
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 0%	Total	3/99 (3.03%)	Mean 3.04%	SD 1.47%
*Islets, Pancreatic: Carcinoma		0/50 /00/	0/50 (00/)			4/50 (00)	0/40 //00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%)	0/49 (0%) Mean 1%	SD 1.41%
Overall illustrice	IUIAI	0/100 (0/0)	IVICALI U/0	30 0%	I Ulal	1/99 (1.01%)	IVICALI I /0	JD 1.41/0
*Islets, Pancreatic: Carcinoma or Adenoma		4/50 (00/)	4/50 (00/)			0/50 /40/	0/40 /40/)	
Overall Instidence	Tatal	4/50 (8%)	4/50 (8%)	CD 00/	Tata!	2/50 (4%)	2/49 (4%)	CD 0.000/
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 0%	Total	4/99 (4.04%)	Mean 4.04%	SD 0.06%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Kidney: Pelvis and Transition Carcinoma	nal Epitheliun		0/50 (00/)			0/50 (09/)	0/50 (00/)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Pelvis and Transitior Carcinoma or Adenoma	nal Epitheliur	n: 0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Pelvis and Transition Papilloma			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma		(20)	0.70			-(2/22 (221)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		•••••				•••••		
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Kidney: Renal Tubule: Hemangiosarcoma		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma	•••••	0/49 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Ben	ign	0/49 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma		0/40 /09/	0/50 (09/)			0/50 (09/.)	0/50 (/0//)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344 Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Liver: Cholangioma		0/50 (0%)	0/50 (0%)	OD 004	-	0/50 (0%)	0/50 (0%)	OD 004
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		0/50 (40/)	4/50 (00)			0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma	•••••	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma	or Hepatoc	ellular Adenoma 2/50 (4%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female					
*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma												
Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
Lung: Alveolar/Bronchiolar A	denoma	0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
Lung: Alveolar/Bronchiolar Ca	arcinoma	0/50 (00)	0/50 (00/)			0/50 (00/)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Lung: Alveolar/Bronchiolar Ca Adenoma	arcinoma or Alv	veolar/Bronchiolar										
Overall Incidence	Tatal	0/50 (0%)	1/50 (2%) Mean 1%	SD 1.41%	Tatal	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%				
Jverali incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	3D 0%				
*Lung: Hemangiosarcoma		4/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)					
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
Lung: Sarcoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Species: RATS Strain: F344 Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Lung: Squamous Cell Carcinoma	1	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
#Mammary Gland: Carcinoma		0/50 (00()	0/50 (00)			0/50 (40/)	4/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%
#Mammary Gland: Carcinoma or Adenoma		0/50 (00)	0/50 (00)			0/50 (00)	0/50 (40)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	3/50 (6%) 5/100 (5%)	2/50 (4%) Mean 5%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:11/17/2008

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Mammary Gland: Fibroadenoma		0/50 (40/)	0/50 (400)			05/50 (700()	00/50 (500/)	
Overall Incidence	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%	Total	35/50 (70%) 63/100 (63%)	28/50 (56%) Mean 63%	SD 9.9%
#Mammary Gland: Fibroma		4/50 (20/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma		3/50 (6%)	2/50 (4%)			36/50 (72%)	29/50 (58%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	65/100 (65%)	Mean 65%	SD 9.9%
#Mammary Gland: Fibroma, Fibroadenoma	ı, Carcinoma, c		0/50 (404)			07/50 (740()	00/50 (000/)	
Overall Incidence	Total	3/50 (6%) 5/100 (5%)	2/50 (4%) Mean 5%	SD 1.41%	Total	37/50 (74%) 67/100 (67%)	30/50 (60%) Mean 67%	SD 9.9%
#Mesentery: Fibrosarcoma	•••••							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma	•••••						0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344 Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Mesentery: Lipoma		0/50 (00/)	0/50 (00/)			0/50 /09/	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mesentery: Rhabdomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Adenoma		0/50 (0%)	0/50 (00/)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Nose: Chondroma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Squamous Cell Carcinoma	a				•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, To Papilloma Squamous or P	ngue, Phary	vnx, Tooth, Gingiva):						
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female				
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma											
•		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
	• • • • • • • • • • • • • • • • • • • •							•••••			
Oral Cavity (Oral Mucosa Squamous Cell Carcino Papilloma		Squamous, or									
Navall Incidence	Total	1/50 (2%)	1/50 (2%)	CD 00/	Total	0/50 (0%)	1/50 (2%)	CD 4 440/			
overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
Oral Mucosa: Squamous Cell Carcino	oma	0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
· · · · · · · · · · · · · · · · · · ·		1,100 (1,0)	Modil 170	05 1.1170	70101	1,700 (1,70)	Would 170				
Oral Mucosa: Squamous Cell Papillo	ma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
Ovary: Granulosa Cell Tumor	Benign					0/50 (0%)	0/50 (0%)				
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%			
 Ovary: Granulosa Cell Tumor	Malignant										
	J					0/50 (0%)	0/50 (0%)				
verall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Ovary: Granulosa Cell Tumor: E	Benign, Malign	nant, NOS				2/22 (22)	2/22 (221)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor	^r Malignant					0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma						1/50 (2%)	0/50 (0%)	
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%
*Pancreas: Adenoma					••••			
Overall Incidence	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	0/50 (0%) 1/99 (1.01%)	1/49 (2%) Mean 1.02%	SD 1.44%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	0/50 (0%) 1/99 (1.01%)	1/49 (2%) Mean 1.02%	SD 1.44%
Pancreas: Mixed Tumor Benign		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Malignant		0/50 (00/)	0/50 (00/)			0/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
Parathyroid Gland: Adenoma								
Overall Incidence	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/96 (0%)	0/47 (0%) Mean 0%	SD 0%
Peripheral Nerve: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Peripheral Nerve: Schwannoma: Benign, Mali)						
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Pituitary Gland: Pars Distalis Adenoma	or Unspecif	ied Site:						
		19/50 (38%)	25/50 (50%)			19/50 (38%)	36/50 (72%)	
Overall Incidence	Total	44/100 (44%)	Mean 44%	SD 8.49%	Total	55/100 (55%)	Mean 55%	SD 24.04%
*Pituitary Gland: Pars Distalis Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Distalis Carcinoma or Adenoma								
Carcinoma or Adenoma		19/50 (38%)	25/50 (50%)			19/50 (38%)	36/50 (72%)	
Overall Incidence	Total	44/100 (44%)	Mean 44%	SD 8.49%	Total	55/100 (55%)	Mean 55%	SD 24.04%
*Pituitary Gland: Pars Interme Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Interme Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Interme Carcinoma or Adenoma	edia:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344 Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Male Female *Prostate: Adenoma 0/50 (0%)(2%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% *Prostate: Carcinoma or Adenoma 0/50 (0%)1/50 (2%)**Overall Incidence** SD 1.41% Total 1/100 (1%) Mean 1% *Salivary Glands: Sarcoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/100 (1%) Total Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% *Salivary Glands: Schwannoma Malignant 0/50 (0%)(0%)(0%)0/50 0/50 Mean 0% **Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) SD 0% **#Seminal Vesicle:** Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Hemangioma 0/50 (0%)(2%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/100 (1%) 0/100 (0%) Mean 0% SD 0% Total Mean 1% SD 1.41% Total

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

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Skeletal Muscle: Hemangiosarcoma	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Lipoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (00/)	0/50 (00/)	•••••		0/50 (00/)	0/50 (00/)	•••••
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or R			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Basal Cell Adenoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

				Ma	ale				Female	
Skin:										
Basal Cell Adenoma or	Basosquamou									
		0/50	(0%)	0/50	(0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/100	(0%)	Mean	0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Nt	•••••	•••••	•••••	• • • • • • • • • • • • • • • • • • • •			•••••			
Skin: Basal Cell Adenoma, Ba	asosquamous ?	Tumor Ben	ign, or							
Trichoepithelioma		0/50	(0%)	0/50	(0%)			0/50 (0%)	1/50 (2%)	
verall Incidence	Total	0/100	` '	Mean	` '	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Skin:										
Basal Cell Carcinoma			4		,,					
		1/50	(2%)		(0%)			0/50 (0%)	1/50 (2%)	
verall Incidence	Total	1/100	` '	Mean		SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Skin: Basal Cell Carcinoma o NOS)	r Basosquamo	us Tumor (1/50	malignant o		(0%)			0/50 (0%)	1/50 (2%)	
			(40/)		40/	00 4 440/		1/100 /10/)	Mean 1%	CD 4 440/
verall Incidence	Total	1/100	(1%)	Mean	1%	SD 1.41%	Total	1/100 (1%)	IVICALI I /0	SD 1.41%
			` '					` '	ivicali 170	
Skin: Basal Cell Carcinoma, I	Basal Cell Aden	noma, Baso	squamous					` '		
Skin:	Basal Cell Aden	noma, Baso Trichoepith	osquamous helioma							
Skin: Basal Cell Carcinoma, I Tumor (benign, maligna	Basal Cell Aden	noma, Baso Trichoepith	esquamous helioma (2%)		(0%)			` '		
Skin: Basal Cell Carcinoma, I Tumor (benign, maligna verall Incidence	Basal Cell Aden ant or NOS), or Total	noma, Baso Trichoepith 1/50 1/100	osquamous helioma (2%) (1%)	0/50 Mean	(0%) 1%	SD 1.41%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%)	SD 2.83%
Skin: Basal Cell Carcinoma, I Tumor (benign, maligna verall Incidence	Basal Cell Adenant or NOS), or Total noma, Carcinoma, Adenoma,	noma, Baso Trichoepith 1/50 1/100 ma, Basosq Papilloma, pithelioma	osquamous helioma (2%) (1%) 	0/50 Mean	(0%) 1%	SD 1.41%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
Skin: Basal Cell Carcinoma, I Tumor (benign, maligna verall Incidence Skin: Basal or Sq. Cell Carcin or B), Basal Cell Adeno	Basal Cell Adenant or NOS), or Total noma, Carcinoma, Adenoma,	noma, Baso Trichoepith 1/50 1/100 ma, Basosq Papilloma,	psquamous helioma (2%) (1%)	0/50 Mean	(0%) 1%	SD 1.41%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
έSkin: Fibroma								
		5/50 (10%)	6/50 (12%)			3/50 (6%)	1/50 (2%)	
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 1.41%	Total	4/100 (4%)	Mean 4%	SD 2.83%
Skin: Fibroma, Fibrosarcoma, S Fibrous Histiocytoma	arcoma, Myz	koma, Myxosarcoma, o						
		6/50 (12%)	8/50 (16%)			3/50 (6%)	2/50 (4%)	
Overall Incidence	Total	14/100 (14%)	Mean 14%	SD 2.83%	Total	5/100 (5%)	Mean 5%	SD 1.41%
Skin:	•••••				•••••			
Fibrosarcoma								
		1/50 (2%)	3/50 (6%)			0/50 (0%)	1/50 (2%)	
verall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Skin: Fibrosarcoma, Sarcoma, I Histiocytoma			3/50 (6%)			0/50 (0%)	1/50 (2%)	
overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Skin: Fibrous Histiocytoma		0/50 (00()	0/50 (09/)			0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
	Total	0/100 (0%)			Total	0/100 (0%)		
Skin: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
veran moluence	TULAI	0/100 (0%)	IVIEALL 070	3D 0%	IUIAI	0/100 (0%)	IVIEATI U%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Skin: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Keratoacanthoma		3/50 (6%)	3/50 (6%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/50 (6%) 6/100 (6%)	3/50 (6%) Mean 6%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Lipoma		(22)	- ()			(201)	2/22 (221)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Liposarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Neural Crest Tumor, Malig	nant							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344 Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Skin: Neurofibroma or Schwan	noma benign							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or Sc							•••••	•••••
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Neu malignant or NOS)	rofibroma, or	Schwannoma (benign,	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Osteosarcoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
		2. 100 (0.0)		02 070	. 0.01			22 373

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Skin: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	_
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinom	na	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinom Basosquamous Tumor (n			0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Squamous Cell Papilloma	a	1/50 (2%)	4/50 (8%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Squamous Cell Papilloma	a or Papillom	a 1/50 (2%)	4/50 (8%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Squamous Cell Papilloma Carcinoma or Keratoacar			7/50 (4.49/)			0/50 (0%)	4/50 (29/)	
Overall Incidence	Total	4/50 (8%) 11/100 (11%)	7/50 (14%) Mean 11%	SD 4.24%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Skin: Squamous Cell Papilloma	, Papilloma,	or Keratoacanthoma 4/50 (8%)	7/50 (14%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Trichoepithelioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Sebaceous Gland: Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma		0/50 (09/)	0/50 (00/)			0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Spinal Cord: Astrocytoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Spinal Cord: Glioma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Spleen: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Spleen: Leiomyosarcoma		0(50 (00))	0/50 (00/)			0/50 (00/)	0/40 (004)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Spleen: Sarcoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyosarcoma	•••••				•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma c	or Papillon		(00)			(201)	(70)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Stomach, Forestomach: Squamous Cell Papilloma	•••••				•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS Strain: F344 Route: GAVAGE
Vehicle: METHYLCELLULOSE

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Length of Study: CHRONIC

			Male			Female 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%		
#Stomach, Glandular: Leiomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` '	` '	SD 0%
#Stomach, Glandular: Lipoma		0/50 (0%)	0/50 (00()			0/50 /00()	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` '	SD 0%
*Testes: Adenoma		42/50 (84%)	41/50 (82%)					
Overall Incidence	Total	83/100 (83%)	Mean 83%	SD 1.41%				
*Thymus: Sarcoma		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign		0/50 (0%)	0/49 (0%)		•••••	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Thymus: Thymoma Malignant					•••••			
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Species: RATS Strain: F344 Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Thymus: Thymoma: Benign, Maligna	nt, NOS	0/50 (00/)	0/40 (00/)			0/50 (00/)	4/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Thyroid Gland: C-Cell: Adenoma		2/50 (69/)	6/50 (439/)			4/50 (99/)	7/50 (4.49/)	
Overall Incidence	Total	3/50 (6%) 9/100 (9%)	6/50 (12%) Mean 9%	SD 4.24%	Total	4/50 (8%) 11/100 (11%)	7/50 (14%) Mean 11%	SD 4.24%
*Thyroid Gland: C-Cell: Carcinoma	••••	(00)	0.770			(201)		
Overall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		4/50 (8%)	8/50 (16%)			4/50 (8%)	7/50 (14%)	
Overall Incidence	Total	12/100 (12%)	Mean 12%	SD 5.66%	Total	11/100 (11%)	Mean 11%	SD 4.24%
*Thyroid Gland: Follicular Cell: Adenoma		0/50 (00/)	0/50 (00/)			0/50 (00)	0/50 (00)	
Overall Incidence	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma	••••	0/50 (00()	0/50 (00/)			0/50 /00/	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

			Male				Female	
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
Overall Incidence	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tissue NOS: Lipoma		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Paraganglioma		0/50 (00/)	0/50 /00/			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma of	or Papillom		0/50 /00/		••••	0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:11/17/2008

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Tongue: Squamous Cell Papilloma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tooth: Adamantinoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma		0/50 (00()	0/50 (00()			0/50 (00()	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Urinary Bladder: Papilloma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Adenoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#I Itam						•••••		
#Uterus: Carcinoma						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Deciduoma Benign								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Hemangioma						2/22 (221)	2/52 (221)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Hemangiosarcoma						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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M	lale			Fem	ale	
#Uterus: Leiomyoma						
·	Total	0/50	` '	0/50	(0%)	OD 00/
Overall Incidence	Total	0/100	` '		n 0%	SD 0%
#Uterus:						
Leiomyosarcoma		0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	0/100	` '		n 0%	SD 0%
#Uterus: Polyp Stromal						
Overall Incidence	Total	9/50 22/100	` ,	13/50 Mea	(26%) n 22%	SD 5.66%
#Uterus: Sarcoma Stromal						
Overall Incidence	Total	0/50 2/100	` '	2/50 Mea	(4%) n 2%	SD 2.83%
Overall molecules	Total	2/100	(270)	wica		OD 2.0070
#Uterus:						
Sarcoma Stromal or Polyp Stromal		9/50	(18%)	15/50	(30%)	
Overall Incidence	Total		(10%)		n 24%	SD 8.49%
#Uterus: Schwannoma Malignant						
	-	0/50	` ,	0/50	(0%)	05.00/
Overall Incidence	Total	0/100	(0%)	Mea	n 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

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Report Date:11/17/2008

			Male				Female	
#Vagina: Polyp						0/50 (09/)	0/50 (0%)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Adenoma		- 1	- 1		•••••	- / / / / / / / / / /		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma				•••••	••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

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Report Date:11/17/2008

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
				Ma	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058812305 052000505 059501107	03/21/01 01/21/04 03/06/02	727 727 727	50 (3) 50 (3) 50 (3)	26(673) 30(679) 22(673)	509.7 498.5 510.3	Formamide Ginseng 5-(Hydroxymethyl)-2-furfural
				Fen	nale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058812305 052000505 059501107	03/20/01 01/22/04 03/07/02	730 728 728	50 (5) 50 (5) 50 (5)	38(703) 36(700) 31(679)	358.3 355.0 332.2	Formamide Ginseng 5-(Hydroxymethyl)-2-furfural

Species: RATS

Strain: F344

Toxicology Data Management System

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Report Date:11/17/2008

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

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#All Organs: Benign Tumors								
Overall Incidence	Total	45/50 (90%) 144/150 (96%)	49/50 (98%) Mean 96%	50/50 (100%) SD 5.29%	Total	43/50 (86%) 131/150 (87.33%)	42/50 (84%) Mean 87.33%	46/50 (92%) SD 4.16%
#All Organs: Malignant Tumors		25/50 (50%)	26/50 (52%)	35/50 (70%)		15/50 (30%)	10/50 (20%)	16/50 (32%)
Overall Incidence	Total	86/150 (57.33%)	Mean 57.33%	SD 11.02%	Total	41/150 (27.33%)	Mean 27.33%	SD 6.43%
#All Organs: Malignant and Benign Tu	ımors	48/50 (96%)	49/50 (98%)	50/50 (100%)		49/50 (98%)	45/50 (90%)	48/50 (96%)
Overall Incidence	Total	147/150 (98%)	Mean 98%	SD 2%	Total	142/150 (94.67%)	Mean 94.67%	SD 4.16%
#All Organs: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#All Organs: Hemangiosarcoma or He	mangioma	0/50 (00/)	0/50 (0%)	0/50 /09/\		0/50 (00/)	0/50 /09/	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Species: RATS Strain: F344 Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
All Organs: Histiocytic Sarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	otal	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
\ll Organs: Leukemia: Erythrocytic					•••••			
verall Incidence To	otal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Leukemia: Lymphocytic, Monocy Undifferentiated	ytic, Moi		18/50 (36%)	29/50 (569/\		10/50 (20%)	6/50 /429/\	0/50 /499/
	otal	15/50 (30%) 61/150 (40.67%)	Mean 40.67%	28/50 (56%) SD 13.61%	Total	25/150 (16.67%)	6/50 (12%) Mean 16.67%	9/50 (18%) SD 4.16%
All Organs: Malignant Lymphoma: Histiocyti or Undifferentiated Cell Type		hocytic, Mixed, NOS,						
verall Incidence To	otal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Mesothelioma: Benign	•••••	0/50 (0%)	0/50 (0%)	0/50 (09/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence To	otal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Mesothelioma: Benign, Malignan					•••••			0/50 (00/)
	-1-1	2/50 (4%)	2/50 (4%)	2/50 (4%)	T-1-1	2/50 (4%)	0/50 (0%)	0/50 (0%)
verall Incidence To	otal	6/150 (4%)	Mean 4%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Contract/Lab: All Laboratories Species: RATS

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male				Female	
All Organs: Mesothelioma: Malignant		2/50 (4%)	2/50 (4%)	2/50 (4%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/150 (4%)	Mean 4%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
All Organs: Osteoma								
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Osteosarcoma	•••••	0/50 (00/)	4/50 (00)	0/50 (00/)		0/50 (00)	0/50 (00/)	4/50 (00/)
verall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
II Organs: Osteosarcoma or Osteoma			1/50 (2%)				0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/50 (0%) 1/150 (0.67%)	Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	Mean 0.67%	1/50 (2%) SD 1.15%
drenal Cortex: Adenoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (00/)	4/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
drenal Cortex: Carcinoma		4/50 (00()	0/50 (00/)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male				Female	
Adrenal Medulla: Ganglioneuroma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Medulla: Hemangioma	•••••	0/50 (004)	0(50 (00))	0/50 (00)	•••••	0/50 (00)	0/50 (00/)	0(50 (00))
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Medulla: Pheochromocytoma Benign	•••••							
verall Incidence	Total	9/50 (18%) 18/150 (12%)	4/50 (8%) Mean 12%	5/50 (10%) SD 5.29%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
drenal Medulla: Pheochromocytoma Comple	x	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
drenal Medulla: Pheochromocytoma Maligna	ınt							
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Medulla: Pheochromocytoma: Benign	, Complex		4/50 (00/)		•••••	0/50 (00)		0/50 (00)
Overall Incidence	Total	9/50 (18%) 18/150 (12%)	4/50 (8%) Mean 12%	5/50 (10%) SD 5.29%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE

Vehicle: WATER

Report Date:11/17/2008

Mean 0.67%

SD 1.15%

Page: 93

Species: RATS Strain: F344

Length of Study: CHRONIC

			Male	Female
#Bone: Chondrosarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Bone:				
Chondrosarcoma or Chondi	roma	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Bone: Chordoma		1/50 (2%)	0/50 (0%) 0/50 (0%)	.) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	,
#Bone: Osteoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Bone: Osteosarcoma	•••••	•••••		
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%	,
#Bone: Osteosarcoma or Osteoma		0/50 (0%)	1/50 (2%) 0/50 (0%)	.) 0/50 (0%) 0/50 (0%) 1/50 (2%)
		0,00 (0,0)	.,55 (2,75) 5,55 (0,75)	, 5,55 (5,5) 5,55 (5,5) 1,66 (2,5)

SD 1.15%

.....

Total

1/150 (0.67%)

Total

1/150 (0.67%)

Mean 0.67%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 94

			Male				Female	
Brain: Astrocytoma Malignant		2/22 (22)		2/72 (224)		2/72 (221)	2/72 (224)	7 (70 (70)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Ependymoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Ependymoma Malignant		0/50 (00/)	0/50 (09/)	0/50 (09/)		0/50 (00/)	0/50 (0%)	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Glioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Benign	••••	0/50 (00/)	0/50 (00/)	0/50 (00/)	•••••	4/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
Brain: Medulloblastoma Mal		0/50 (09()	0/50 (0%)	0/50 (0%)		0/50 (00/)	0/50 (0%)	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 95

			Male				Female	
Brain:								
Meningioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain:	NOS			•••••				
Meningioma: Benign, Maligi	iani, NOS	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain:			•••••					
Oligodendroglioma Benign		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Normall In all Inner	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Maligna	nt							
Ongodendrognoma mangna		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain:			•••••			• • • • • • • • • • • • • • • • • • • •		
Oligodendroglioma, Glioma	. or Astroc	vtoma						
	,	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Osteosarcoma			2/22 (224)					(201)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 96

			Male				Female	
Brain: Schwannoma Malignant								
Schwannoma Manghant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma		1/50 (2%)	0/50 (0%)	5/50 (10%)		2/50 (4%)	1/50 (2%)	3/50 (6%)
Overall Incidence	Total	6/150 (4%)	Mean 4%	SD 5.29%	Total	6/150 (4%)	Mean 4%	SD 2%
Clitoral/Preputial Gland:								
Carcinoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Clitoral/Preputial Gland: Carcinoma or Adenoma			(00)			- (101)	2/22 (101)	2/22 (221)
		2/50 (4%)	0/50 (0%)	6/50 (12%)		2/50 (4%)	2/50 (4%)	3/50 (6%)
verall Incidence	Total	8/150 (5.33%)	Mean 5.33%	SD 6.11%	Total	7/150 (4.67%)	Mean 4.67%	SD 1.15%
Clitoral/Preputial Gland: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Sarcoma		0/50 (00)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00/)
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

10V2UU8

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 97

			Male				Female	
Clitoral/Preputial Gland: Squamous Cell Papilloma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Ear: Neural Crest Tumor		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Esophagus: Fibrosarcoma		0/50 (00/)	0/50 (004)	0/50 (00/)		0/50 (00)	0/50 (00)	0/50 (004)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Esophagus: Lipoma	•••••	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Eye: Amelanotic Melanoma, Beni	ign							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Eye: Melanoma Benign		0/50 (00/)	0/50 (09/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

n: Nov2008 I oxicolog

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 98

			Male	Female
#Eye: Melanoma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 1/150 (0.67%) Mean 0.67% SD 1.15%
#Eye: Schwannoma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Harderian Gland: Carcinoma		0/50 (00()	A/F0 (00() 0/F0 (00()	0/50 (00) 0/50 (00) 0/50 (00)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Harderian Gland: Carcinoma or Adenoma		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
*Heart: Schwannoma Benign				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Heart: Schwannoma Malignant				0/50 (0%) 0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 99

Report Date:11/17/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Intestine Large: Colon/Rectum Adenoma	1:	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Large: Colon/Rectum Carcinoma	1:	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectum Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Large: Colon/Rectum Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma		0/50 (00)	0.750	0.70			0.750 (001)	2/72 (201)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Duodenum: Leiomyoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 100

				Ma	ale						Fem	ale		
Intestine Small: Jejunum: Carcinoma														
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
verall Incidence	Total	1/150 (0.	67%)	Mean	0.67%	SD	1.15%	Total	0/150	(0%)	Mea	n 0%	SD	0%
ntestine Small: Jejunum: Granular Cell Tumor Malignan														
	-		(0%)		(0%)	0/50	(0%)	-	0/50	(0%)	0/50	(0%)	0/50	(0%)
verall Incidence	Total	0/150 (09	,	Mean		SD		Total	0/150	` ,		n 0%	SD	
ntestine Small: Jejunum: Leiomyoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
	Total	0/150 (09	,	Mean		SD		Total	0/150	` '		n 0%	SD	
ntestine Small: Jejunum: Leiomyosarcoma			(0%)		(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
verall Incidence	Total		` '		` ,		` '	Total		, ,		` ,	0/50 SD	` ,
verall Incidence	Total	0/150 (09	%)	Mean	0%	SD	0%	Total	0/150	(0%)	iviea	n 0%	ู รบ	0%
ntestine Small: Site Unspecified Carcinoma	:													
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
	Total	1/150 (0.	,		0.67%		1.15%	Total	0/150	` '		n 0%	SD	
ntestine Small: Site Unspecified Carcinoma or Adenoma														
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
verall Incidence	Total	1/150 (0.	.67%)	Mean	0.67%	SD	1.15%	Total	0/150	(0%)	Mea	n 0%	SD	0%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 101

			Male				Female	
Intestine Small: Site Unspecif Granular Cell Tumor Maligi								
Cranalar Cen ramor Mang	· · · · · · · · · · · · · · · · · · ·	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ntestine Small: Site Unspecif Leiomyoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
ntestine Small: Site Unspecif Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
slets, Pancreatic: Adenoma								
		2/50 (4%)	0/50 (0%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
slets, Pancreatic: Carcinoma								
		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
slets, Pancreatic: Carcinoma or Adenoma								
		3/50 (6%)	0/50 (0%)	4/50 (8%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 4.16%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 102

Report Date:11/17/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

**Kidney: Pelvis and Transitional Epithelium: Carcinoma				Male				Female	
Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma 0/50 (0%) 0/		al Epitheliur	m:						
*Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/150 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: Papilloma 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/150 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Adenoma 1/50 (2%) 1/50 (2%) 0/50 (0%) Mean 1.33% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma 0/50 (0%) 1/50 (2%) Mean 0.67% SD 0.50 (0%) Mean 0.670 (0%) Mean 0.67% SD 0.50 (0%) Mean 0.670 (0%) Mean 0.67			0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Carcinoma or Adenoma O(50 O(%) O/50 O(%)	Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: Papilloma Overall Incidence Total 0/50 (0%) 0/50		nal Epitheliur		0/50 (00)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00()
*Kidney: Pelvis and Transitional Epithelium: Papilloma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)		.	` '	` '	` '	-	` ,	()	, ,
*Kidney: Pelvis and Transitional Epithelium: Papilloma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/150 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Adenoma 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 2/150 (1.33%) Mean 1.33% SD 1.15% Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma 0/50 (0%) 1/50 (2%) 0/50 (0%) Overall Incidence Total 1/150 (0%) 1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15% Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma 1/50 (2%) 2/50 (4%) 0/50 (0%) Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0%			, ,		SD 0%	I otal	0/150 (0%)	Mean 0%	SD 0%
Overall Incidence Total 0/150 (0%) 0/50 (0%)	*Kidney: Pelvis and Transition						•••••		
*Kidney: Renal Tubule: Adenoma 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 2/150 (1.33%) Mean 1.33% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma 0/50 (0%) 1/50 (2%) 0/50 (0%) Overall Incidence Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) 0/50 (0%) 0/50 (0%) *Kidney: Renal Tubule: Carcinoma or Adenoma 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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Adénoma 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 2/150 (1.33%) Mean 1.33% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma 0/50 (0%) 1/50 (2%) 0/50 (0%) Overall Incidence Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% *Kidney: Renal Tubule: Carcinoma or Adenoma 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%) Total 0/150 (0%) 0/50 (0%) Mean 0% SD 0%	Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Overall Incidence Total 2/150 (1.33%) Mean 1.33% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Nean 0% SD 0% *Kidney: Renal Tubule: Carcinoma or Adenoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 0/5			4/50 (00/)	4/50 (00)	0/50 (00()		0/50 (00/)	0/50 (0%)	0/50 (00/)
*Kidney: Renal Tubule:			` ,	` '	` '		` ,	` '	` '
*Kidney: Renal Tubule: Carcinoma 0/50 (0%) 1/50 (2%) 0/50 (0%) Overall Incidence Total 1/150 (0.67%) Mean 0.67% *Kidney: Renal Tubule: Carcinoma or Adenoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% Now Mean			2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Overall Incidence Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma or Adenoma 1/50 (2%) 2/50 (4%) 0/50 (0%)	*Kidney: Renal Tubule:								
*Kidney: Renal Tubule: Carcinoma or Adenoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)			0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Carcinoma or Adenoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 0/50<	Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
			4/50 (20/)	2/50 (40/)	0/50 (09/)		0/50 (00/)	0/50 (09/)	0/50 (00/)
Overall incidence Lotal 3/150 (2%) Mean 2% SD 2% Lotal 0/150 (0%) Mean 0% SD 0%	O	T-1-1	` ,	` '	` '	T-1-1	` ,	` ,	` '
	Overail incidence	I otal	3/150 (2%)	Mean 2%	SD 2%	I otal	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male		Female	
Kidney: Renal Tubule: Hemangiosarcoma						
	-	0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0	0% Total	0/150 (0%) Mean 0%	SD 0%
Kidney: Renal Tubule: Lipoma						
	-	0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0	0% Total	0/150 (0%) Mean 0%	SD 0%
Kidney: Renal Tubule: Liposarcoma		- (a)		(00)		0.000
	-	0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0		0/150 (0%) Mean 0%	SD 0%
Kidney: Renal Tubule: Mesenchymal Tumor Benign		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0	` '	0/30 (0%) 0/30 (0%) 0/150 (0%) Mean 0%	SD 0%
				····	(67.00 (67.0) mount 67.0	
Kidney: Renal Tubule: Nephroblastoma						
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0	0% Total	0/150 (0%) Mean 0%	SD 0%
Kidney: Renal Tubule: Sarcoma						
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0	0% Total	0/150 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 104

				Ma	ale						Fema	ale		
Liver: Cholangioma														
		0/50	` ,		(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Meai	ո 0%	SD	0%
_iver:														
Hemangiosarcoma		0/50	(00()	0/50	(00/)	0/50	(00/)		0/50	(00/)	0/50	(00/)	0/50	(00/)
warell lucidence	Tatal	0/50	` ,		(0%)	0/50	(0%)	Tatal	0/50	(0%)	0/50	(0%)	0/50	(0%)
verall Incidence	Total	0/150	(0%)	Mean	1 0%	SD	0%	Total	0/150	(0%)	ivieai	ո 0%	20	0%
_iver:														
Hepatocellular Adenoma														
		0/50	` ,		(0%)	0/50	(0%)		2/50	(4%)	0/50	(0%)	0/50	(0%)
verall Incidence	Total	0/150	` ,	Mean		SD		Total		(1.33%)		n 1.33%		2.31%
_iver:							• • • • • • • • • • • • • • • • • • • •							• • • • • • • • • • • • • • • • • • • •
Hepatocellular Carcinoma														
		0/50	` ,		(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
verall Incidence	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%	Total	0/150	(0%)	Mea	n 0%	SD	0%
.iver:			•••••	•••••				•••••						
Hepatocellular Carcinoma	or Hepatob	lastoma												
•		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
verall Incidence	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%	Total	0/150	(0%)	Mear	า 0%	SD	0%
iver: Hepatocellular Carcinoma	or Hepatoc	ellular Ade	enoma											
. Topatoochalar oaromonia	o. Hopatoo	0/50		1/50	(2%)	0/50	(0%)		2/50	(4%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total		(0.67%)		0.67%		1.15%	Total		(1.33%)		1.33%		2.31%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 105

			Male				Female	
Liver: Hepatocellular Carcino Hepatoblastoma	oma, Hepatocell	ular Adenoma, or						
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
Lung:	donomo		•••••	•••••		•••••		
Alveolar/Bronchiolar A	denoma	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
Lung:		, 	•••••	•••••		•••••		
Alveolar/Bronchiolar C	Carcinoma	4/50 (00/)	0/50 (00/)	4/50 (00/)		4/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
		2/130 (1.33%)				, ,		
Lung: Alveolar/Bronchiolar C Adenoma	Carcinoma or Al	veolar/Bronchiolar						
Adenoma		1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 2%
Lung: Hemangiosarcoma		,	•••••	•••••				
ricinangiosarooma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
overall initiating								
Lung:								
'Lung: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 106 Report Date:11/17/2008

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male				Female	
*Lung: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma		0/50 (00()	0/50 /00/\	0/50 (0%)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node, Mesenteric: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mammary Gland: Adenoma		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	2/50 (4%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%
#Mammary Gland: Carcinoma		0/50 (0%)	0/50 /09/\	0/50 (0%)		2/50 (49/)	0/50 (09/)	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
#Mammary Gland: Carcinoma or Adenoma		4/50 (00)	0/50 (00/)	0/50 (00/)		0/50 (40/)	0/50 (40/)	0/50 (404)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	2/50 (4%) 6/150 (4%)	2/50 (4%) Mean 4%	2/50 (4%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 107 Report Date:11/17/2008

Species: RATS Strain: F344 Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male	Female
#Mammary Gland: Fibroadenoma				
		2/50 (4%)	2/50 (4%) 1/50 (29	9%) 33/50 (66%) 32/50 (64%) 29/50 (58%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33% SD 1.15	5% Total 94/150 (62.67%) Mean 62.67% SD 4.16%
#Mammary Gland: Fibroma				
		1/50 (2%)	0/50 (0%) 0/50 (09	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15	,
#Mammary Gland: Fibroma, Fibroadenoma				
		4/50 (8%)	2/50 (4%) 1/50 (29	9%) 33/50 (66%) 33/50 (66%) 30/50 (60%)
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67% SD 3.06	·
#Mammary Gland: Fibroma, Fibroadenoma,			2/50 (4%) 1/50 (29	
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67% SD 3.06	,
#Mesentery: Fibrosarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (09	
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	` '
Mesentery: Hemangiosarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (09	,
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories Species: RATS

Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 108

			Male				Female	
fMesentery: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Mesentery: Rhabdomyosarcoma		0/50 (00/)	0/50 (00()	0/50 /00/		0/50 (00/)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Nose: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Nose: Chondroma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Nose: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): **Squamous Cell Carcinoma** 0/50 (0%)(0%)0/50 (0%)(2%)0/50 (0%)(0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or **Papilloma** 0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% **#Oral Mucosa: Squamous Cell Carcinoma** 0/50 (0%)(0%)0/50 (0%)1/50 (2%)(0%)0/50 (0%)SD 0% SD 1.15% Overall Incidence Total 0/150 (0%) Mean 0% Total 1/150 (0.67%)Mean 0.67% **#Oral Mucosa: Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)0/49 (0%)SD 0% Overall Incidence Total 0/149 (0%) Mean 0% *Ovary: **Granulosa Cell Tumor Malignant** 0/50 (0%)0/49 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/17/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)(0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% **Granulosa-Theca Tumor Benign** 0/50 0/50 0/49 (0%)**Overall Incidence** SD 0% Total 0/149 Mean 0% *Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% *Ovary: **Tubulostromal Adenoma** (0%)0/49 (0%)0/50 Mean 0% **Overall Incidence** Total 0/149 (0%) SD 0% *Pancreas: Adenoma 0/50 (0%)(0%)1/50 (2%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 Mean 0% SD 0% *Pancreas: Carcinoma (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/150 (0%) SD 0% SD 0% Total Mean 0% Total 0/150 (0%) Mean 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 111

			Male				Female	
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Pancreas: Mixed Tumor Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
*Pancreas: Mixed Tumor Malignant					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Parathyroid Gland: Adenoma		0/40 (00/)	0/50 (00/)	0/40 (00)		0/40 (00)	0/40 (00)	0/40 (00/)
Overall Incidence	Total	0/48 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/46 (0%) 0/142 (0%)	0/48 (0%) Mean 0%	0/48 (0%) SD 0%
Peripheral Nerve: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Peripheral Nerve: Schwannoma: Benign, Mali	ignant, NOS							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		Male	Female
r Unspecif	ied Site:		
Total	11/50 (22%) 46/150 (30.67%)	20/50 (40%) 15/50 (30%) Mean 30.67% SD 9.02%	22/50 (44%) 16/50 (32%) 24/50 (48%) Total 62/150 (41.33%) Mean 41.33% SD 8.33%
	ied Site:		
Total	0/150 (0%)	Mean 0% SD 0%	2/50 (4%) 0/50 (0%) 1/50 (2%) Total 3/150 (2%) Mean 2% SD 2%
	ied Site:		
Total	46/150 (30.67%)	Mean 30.67% SD 9.02%	24/50 (48%) 16/50 (32%) 25/50 (50%) Total 65/150 (43.33%) Mean 43.33% SD 9.87%
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
a:			
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
a:			
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
	Total Total Total Total Total Total Total Total	Total 46/150 (30.67%) or Unspecified Site: 0/50 (0%) Total 0/150 (0%) or Unspecified Site: 11/50 (22%) Total 46/150 (30.67%) ia: 0/50 (0%) Total 0/150 (0%) Total 0/150 (0%)	Total 11/50 (22%) 20/50 (40%) 15/50 (30%) Total 46/150 (30.67%) Mean 30.67% SD 9.02% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 11/50 (22%) 20/50 (40%) 15/50 (30%) Total 46/150 (30.67%) Mean 30.67% SD 9.02% Total 46/150 (30.67%) Mean 30.67% SD 9.02% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Species: RATS Strain: F344 Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Prostate: Adenoma		0/50 (0%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
*Prostate: Carcinoma or Adenoma		0/50 (0%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
*Salivary Glands: Sarcoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma	•••••				•••••			
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%				
#Skeletal Muscle: Hemangioma		0/50 (00/.)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (09/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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

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Report Date:11/17/2008

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male			Female			
#Skeletal Muscle: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Skeletal Muscle: Lipoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (00/)	0/50 (00()	0/50 (00()	•••••	0/50 (0%)	0/50 (00()	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Skeletal Muscle: Rhabdomyosarcoma or R	habdomyom		0/50 (00/)	0/50 (00/)	•••••	0/50 (0%)	0/50 (00()	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Skeletal Muscle: Sarcoma					•••••				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
:Skin: Basal Cell Adenoma					•••••				
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Basal Cell Adenoma or Basosquamous Tumor Benign 1/50 (2%)(2%)(2%)(2%)1/50 (2%)(0%)**Overall Incidence** Total 3/150 (2%) Mean 2% SD 0% Total 2/150 (1.33%) Mean 1.33% SD 1.15% #Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma 1/50 1/50 (2%)2/50 1/50 0/50 (0%)**Overall Incidence** Total 3/150 (2%) Mean 2% SD 0% 3/150 (2%) Mean 2% SD 2% Total #Skin: **Basal Cell Carcinoma** 0/50 (0%)0/50 (0%)(0%)0/50 (0%)SD 0% SD 0% **Overall Incidence** Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 0% #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/150 (0%)Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 1/50 (2%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 3/150 (2%) Mean 2% SD 0% Total 3/150 (2%) Mean 2% SD 2% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq. Papilloma, Keratoacanthoma, Trichoepithelioma (20%)2/50 (4%)(8%) 3/50 0/50 (0%)10/50 4/50 4/50 (6%)16/150 (10.67%) **Overall Incidence** Total Mean 10.67% SD 8.33% Total 7/150 (4.67%) Mean 4.67% SD 4.16%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female				
#Skin: Fibroma		6/50 (12%)	2/50 (4%)	5/50 (10%)		1/50 (2%)	0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	13/150 (8.67%)	Mean 8.67%	SD 4.16%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%		
#Skin: Fibroma, Fibrosarcoma, Fibrous Histiocytoma	, Sarcoma, My	xoma, Myxosarcoma, or								
Overall Incidence	Total	7/50 (14%) 16/150 (10.67%)	3/50 (6%) Mean 10.67%	6/50 (12%) SD 4.16%	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%		
#Skin: Fibrosarcoma		0/50 (00()	0/50 (00/)	4/50 (00()		0/50 (00)	0/50 (00/)	0/50 /00/)		
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
#Skin: Fibrosarcoma, Sarcoma Histiocytoma	ı, M yxosarcom	,								
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
#Skin: Fibrous Histiocytoma		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%		
#Skin: Hemangioma										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 117

			Male				Female	
#Skin: Hemangiosarcoma Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/5 Mean 0%	50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
overall illiciaerice		` '	Mean 070			,		
∜Skin: Keratoacanthoma		8/50 (16%)	0/50 (0%) 2/5			2/50 (4%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	10/150 (6.67%)	` ,	SD 8.33%	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%
Skin: Lipoma		0/50 (0%)	0/50 (00)	(00/)		0/50 (00/)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/5 Mean 0%	50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Liposarcoma		0/50 (0%)	0/50 (0%) 0/5			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	` ,	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Neural Crest Tumor								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/5 Mean 0%	50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Neural Crest Tumor, Mali		0/50 (0%)	0/50 (0%) 0/5			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	` '	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

				M	ale						Fem	ale		
#Skin:	h a miana													
Neurofibroma or Schwannoma	benign	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Γotal	0/30	` '	Mean	` '		0%	Total	0/30	` ,		n 0%	SD	` '
:Skin:		•••••											•••••	
Neurofibrosarcoma or Schwani	noma (m	•												
		1/50	(2%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Γotal	2/150	(1.33%)	Mear	1.33%	SD	1.15%	Total	1/150	(0.67%)	Mea	n 0.67%	SD	1.15%
Skin: Neurofibrosarcoma, Neurofibro malignant or NOS)	oma, or S	Schwanno	oma (benign,											
,		1/50	(2%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Γotal	2/150	(1.33%)	Mean	1.33%	SD	1.15%	Total	1/150	(0.67%)	Mea	n 0.67%	SD	1.15%
έSkin: Osteosarcoma	•••••	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Γotal	0/150	` '	Mean	` '		0%	Total	0/150	` '		n 0%	SD	` '
#Skin: Sarcoma		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Γotal	0/30	` '	Mean	` '		0%	Total	0/30	` ,		n 0%	SD	` '
#Skin:														
Schwannoma Benign		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Γotal		(0%)	Mean	` '		0%	Total		(0%)		n 0%	0/30 SD	` '
veran incluence	otai	0/130	(0 /0)	ivieal	0 /0	30	0 /0	i Ulai	0/130	(0/0)	IVIE	III U/0	30	0 70

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Species: RATS Strain: F344 Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Skin: Schwannoma Malignant	t	4/50 (004)	0/50 (004)			0(50 (004)	0/50 (004)	4/50 (00)
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Skin: Squamous Cell Carcino	ma							
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Squamous Cell Carcino Basosquamous Tumor (1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papillon							4/50 (00/)	
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Skin: Squamous Cell Papillon	na or Papillom		0/50 (0%)	0/50 (0%)		0/50 (00/)	1/50 (20()	0/50 (09/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
			•••••					
Skin: Squamous Cell Papillon Carcinoma or Keratoaca		oquamous ocn						

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Skin: Squamous Cell Papilloma,	Papilloma,	or Keratoacanthoma						
Overall Incidence	Total	9/50 (18%) 11/150 (7.33%)	0/50 (0%) Mean 7.33%	2/50 (4%) SD 9.45%	Total	2/50 (4%) 5/150 (3.33%)	3/50 (6%) Mean 3.33%	0/50 (0%) SD 3.06%
#Skin: Trichoepithelioma	•••••	0/50 (00)	0/50 (001)	0/50 (00)		4/50 (00)	0/50 (004)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
#Skin: Sebaceous Gland: Adenoma		0/50 (00/)	0/50 (001)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Sebaceous Gland: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (/0//)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Spinal Cord: Astrocytoma Benign		(201)			••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: WATER

Page: 121

Report Date:11/17/2008

Length of Study: CHRONIC

			Male				Female	
#Spinal Cord: Astrocytoma Malignant Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	ı Olai		ivican 070		ı Olai		ivican 070	
#Spinal Cord: Glioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Spleen: Fibrosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	0/50 (0%) SD 0%
*Spleen: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Species: RATS Strain: F344

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 122

			Male				Female	
Spleen:								
Leiomyosarcoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Spleen: Sarcoma		0/50 (00/)	0/50 (00/)	0/50 (00)		0/50 (00)	0/50 (0%)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Stomach, Forestomach:		•••••						
Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma								
Squamous Cen Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Stomach, Forestomach:								
Squamous Cell Carcinoma o	r Papillon	na Squamous						
	upo	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Species: RATS Strain: F344 Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male			Female			
#Stomach, Glandular: Leiomyosarcoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Stomach, Glandular: Lipoma	•••••	0/50 (00/)	0/50 /00/)	0/50 (00/)	•••••	0/50 (00)	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Testes: Adenoma		44/50 (000/)	45/50 (00%)	40/50 (000)					
Overall Incidence	Total	44/50 (88%) 137/150 (91.33%)	45/50 (90%) Mean 91.33%	48/50 (96%) SD 4.16%					
Thymus: Sarcoma	•••••	0/49 (0%)	0/50 (0%)	0/48 (0%)	•••••	0/48 (0%)	0/48 (0%)	0/48 (0%)	
Overall Incidence	Total	0/147 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%	
Thymus: Thymoma Benign		0/40 (00/)	0/50 (0%)	0/40 (00/)		0/40 (00/)	0/40 (00/)	4/40 (00/)	
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/48 (0%) 1/144 (0.69%)	0/48 (0%) Mean 0.69%	1/48 (2%) SD 1.2%	
Thymus: Thymoma Malignant	•••••	0/40 (00/)	0/50 (00/)	0/40 (00/)	•••••	0/40 (00)	4/40 (00/)	0(40 (00))	
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/48 (0%) 1/144 (0.69%)	1/48 (2%) Mean 0.69%	0/48 (0%) SD 1.2%	

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

^{#:} Denominator is number of animals necropsied

I. NUV2006

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 124

			Male		Female	
Thymus: Thymoma: Benign, Malignar	nt, NOS	0/10 /00/	0/50 (00)	(994)	0149 (001) 4/49 (751)	1/10 (00/)
verall Incidence	Total	0/49 (0%) 0/147 (0%)	0/50 (0%) 0/48 Mean 0% SD	(0%) 0% Total	0/48 (0%) 1/48 (2%) 2/144 (1.39%) Mean 1.39%	1/48 (2%) SD 1.2%
Thyroid Gland: C-Cell: Adenoma						
verall Incidence	Total	6/50 (12%) 18/150 (12%)	11/50 (22%) 1/50 Mean 12% SD	(2%) 10% Total	5/50 (10%) 6/50 (12%) 22/150 (14.67%) Mean 14.67%	11/50 (22%) SD 6.43%
Thyroid Gland: C-Cell: Carcinoma						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SD	(0%) 0% Total	0/50 (0%) 0/50 (0%) 1/150 (0.67%) Mean 0.67%	1/50 (2%) SD 1.15%
hyroid Gland: C-Cell: Carcinoma or Adenoma		6/50 (12%)	11/50 (22%) 1/50	(2%)	5/50 (10%) 6/50 (12%)	12/50 (24%)
Overall Incidence	Total	18/150 (12%)	Mean 12% SD	` '	23/150 (15.33%) Mean 15.33%	SD 7.57%
hyroid Gland: Follicular Cell: Adenoma						
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) 1/50 Mean 0.67% SD	(2%) 1.15% Total	0/50 (0%) 0/50 (0%) 1/150 (0.67%) Mean 0.67%	1/50 (2%) SD 1.15%
Thyroid Gland: Follicular Cell: Carcinoma					0/50 (00)	
Overall Incidence	Total	1/50 (2%) 4/150 (2.67%)	1/50 (2%) 2/50 Mean 2.67% SD	(4%) 1.15% Total	0/50 (0%) 0/50 (0%) 2/150 (1.33%) Mean 1.33%	2/50 (4%) SD 2.31%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

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Report Date:11/17/2008

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female	
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		1/50 (2%)	1/50 (2%) 3/50	(6%)	0/50 (0%) 0/50 (0%)	2/50 (4%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33% SD	2.31% Total	2/150 (1.33%) Mean 1.33%	SD 2.31%
#Tissue NOS: Lipoma		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	` '	0% Total	0/150 (0%) 0/30 (0%) 0/150 (0%) Mean 0%	SD 0%
#Tissue NOS: Paraganglioma		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	` '	0% Total	0/150 (0%) 0/30 (0%) 0/150 (0%) Mean 0%	0/50 (0%) SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	` '	0% Total	0/150 (0%) Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma		0/50 (00/)	0/50 (00/) 0/50	(00/)	0/50 (0%) 0/50 (0%)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SD	(0%) 0% Total	0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%	0/50 (0%) SD 0%
#Tongue: Squamous Cell Carcinoma o	or Papillon		0/50 (00/) 0/50	(00()	0/50 (00/) 0/50 (00/)	0/50 /00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SD	(0%) 0% Total	0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 126

			Male				Female	
#Tongue: Squamous Cell Papilloma		0/50 (00/)	0/50 (00/)	0/50 (09/)		0/50 (00/)	0/50 (09/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tooth: Adamantinoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (09/)	0/50 (/0//)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Urinary Bladder: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma	•••••	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 /00/	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Urinary Bladder: Leiomyosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/17/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Urinary Bladder: Papilloma 0/50 (0%)(0%)(0%)(0%)0/50 (0%)(0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Uterus: Adenoma 0/50 (0%)0/50 0/50 **Overall Incidence** SD 0% Total 0/150 Mean 0% #Uterus: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% #Uterus: Deciduoma Benign 0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/150 (0%) SD 0% Hemangioma 0/50 0/50 0/50 (0%)**Overall Incidence** Total 0/150 Mean 0% SD 0% **#Uterus:** Hemangiosarcoma (0%)(0%)0/50 0/50 (0%)0/50 SD 0% **Overall Incidence** 0/150 (0%) Total Mean 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/17/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Uterus: Leiomyoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% #Uterus: Leiomyosarcoma 0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% Total 0/150 Mean 0% #Uterus: **Polyp Stromal** 7/50 (14%)8/50 (16%)8/50 (16%) **Overall Incidence** Total 23/150 (15.33%) Mean 15.33% SD 1.15% #Uterus: Sarcoma Stromal (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/150 (0%) SD 0% Sarcoma Stromal or Polyp Stromal 7/50 (14%)(16%)8/50 (16%)**Overall Incidence** Total 23/150 (15.33%) Mean 15.33% SD 1.15% **#Uterus:** Schwannoma Malignant 1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/150 (0.67%) SD 1.15% Total Mean 0.67%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female			
#Vagina: Polyp						0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%	
#Vagina: Sarcoma						0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%	
#Zymbal's Gland: Adenoma	•••••								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Zymbal's Gland: Carcinoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma or Adenoma	•••••								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Report Date:11/17/2008

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
				M	ale		
Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest	052001105 059601105 058800405 059700601 058800603 059700805 059302507	07/14/03 06/04/01 09/13/99 05/25/00 08/06/01 10/01/01 06/16/03	729 729 729 726 729 729 729	50 (5) 50 (5) 50 (5) 50 (5) 50 (5) 49 (5) 50 (5)	23(678) 26(676) 31(686) 32(693) 27(680) 27(683) 20(668)	526.9 540.9 519.5 529.7 537.2 525.0 536.2	1-Bromopropane Cumene Divinylbenzene Methyl isobutyl ketone alpha-Methylstyrene Propargyl alcohol Tetralin
				Fer	male		
Battelle Northwest	052001105 059601105 058800405 059700601 058800603 059700805 059302507	07/14/03 06/04/01 09/13/99 05/25/00 08/06/01 10/01/01 06/16/03	730 731 731 727 730 730 730	50 (5) 50 (5) 50 (5) 50 (5) 50 (5) 50 (5) 50 (5)	34(702) 21(674) 33(679) 35(694) 27(647) 29(678) 31(682)	386.5 356.9 355.3 365.6 351.9 353.3 370.8	1-Bromopropane Cumene Divinylbenzene Methyl isobutyl ketone alpha-Methylstyrene Propargyl alcohol Tetralin

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male	Female
#All Organs: Benign Tumors				
		48/50 (96%) 50/50 (100%) 48/50 (96%)	48/50 (96%) 49/50 (98%) 48/50 (96%) 48/49 (98%)	45/50 (90%) 44/50 (88%) 43/50 (86%) 44/50 (88%) 43/50 (86%) 42/50 (84%) 40/50 (80%)
Overall Incidence	Total	339/349 (97.13%)	Mean 97.14% SD 1.57%	Total 301/350 (86%) Mean 86% SD 3.27%
#All Organs: Malignant Tumors	•••••			
ū		38/50 (76%) 31/50 (62%) 33/50 (66%)	36/50 (72%) 29/50 (58%) 32/50 (64%) 32/49 (65%)	26/50 (52%) 24/50 (48%) 17/50 (34%) 22/50 (44%) 25/50 (50%) 26/50 (52%) 25/50 (50%)
Overall Incidence	Total	231/349 (66.19%)	Mean 66.19% SD 6.06%	Total 165/350 (47.14%) Mean 47.14% SD 6.41%
#All Organs: Malignant and Benign Tu				
		50/50 (100%) 50/50 (100%) 50/50 (100%)	50/50 (100%) 50/50 (100%) 50/50 (100%) 49/49 (100%)	49/50 (98%) 50/50 (100%) 46/50 (92%) 46/50 (92%) 46/50 (92%) 47/50 (94%) 46/50 (92%)
Overall Incidence	Total	349/349 (100%)	Mean 100% SD 0%	Total 330/350 (94.29%) Mean 94.29% SD 3.35%
#All Organs: Hemangioma	•••••			
-		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%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29% SD 0.76%	Total 1/350 (0.29%) Mean 0.29% SD 0.76%

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

II. NUVZUUO

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Hemangiosarcoma								
		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%) 2/50 (4%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	2/350 (0.57%)	Mean 0.57%	SD 1.51%
#All Organs: Hemangiosarcoma or He					•••••			
•	·	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%) 2/50 (4%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	3/350 (0.86%)	Mean 0.86%	SD 1.57%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%) 0/49 (0%)		0/50 (0%) 2/50 (4%) 2/50 (4%)	0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	6/350 (1.71%)	Mean 1.71%	SD 2.14%
All Organs: Leukemia: Erythrocytic	•••••				••••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

Report Date:11/17/2008

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Species: RATS Strain: F344

Length of Study: CHRONIC

Vehicle: AIR

			Male		Fem	ale					
#All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated											
Ondinerentiated		29/50 (58%) 25/50 (50%) 25/50 (50%)		(43%)	16/50 (32%) 12/50 14/50 (28%) 18/50 17/50 (34%)	(24%) 10/50 (20%) (36%) 20/50 (40%)					
Overall Incidence	Total	174/349 (49.86%)	Mean 49.84% SD 5.	15% Total 10	07/350 (30.57%) Mea	ın 30.57% SD 7%					
#All Organs: Malignant Lymphoma: or Undifferentiated Cell		nphocytic, Mixed, NOS,									
		0/50 (0%) 0/50 (0%) 0/50 (0%)		(0%)	0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 (0%)	(0%) 0/50 (0%) (0%) 0/50 (0%)					
Overall Incidence	Total	0/349 (0%)	Mean 0% SD 0%	6 Total 0/	/350 (0%) Mea	n 0% SD 0%					
#All Organs: Mesothelioma: Benign				······							
•		0/50 (0%) 0/50 (0%) 0/50 (0%)		(0%)	0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 (0%)	(0%) 0/50 (0%) (0%) 1/50 (2%)					
Overall Incidence	Total	0/349 (0%)	Mean 0% SD 0%		` '	n 0.29% SD 0.76%					
#All Organs: Mesothelioma: Benign,	Malignant, NOS	 S		······							
,	3 , -	0/50 (0%) 1/50 (2%) 0/50 (0%)		(2%)	0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 (0%)	(0%) 0/50 (0%) (0%) 1/50 (2%)					

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Mesothelioma: Malignant								
-		0/50 (0%) 1/50 (2%) 0/50 (0%)	3/50 (6%) 0/50 (0%)	2/50 (4%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	7/349 (2.01%)	Mean 2.01%	SD 2.31%	Total	0/350 (0%)	Mean 0%	SD 0%
All Organs: Osteoma	••••••				•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma			•••••					•••••
		2/50 (4%) 0/50 (0%) 3/50 (6%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	7/349 (2.01%)	Mean 2.01%	SD 2.31%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
All Organs: Osteosarcoma or Osteoma	••••••				•••••			
		2/50 (4%) 0/50 (0%) 3/50 (6%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	7/349 (2.01%)	Mean 2.01%	SD 2.31%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Adrenal Cortex:								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		3/50 (6%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	8/50 (16%) 13/350 (3.71%)	Mean 3.71%	SD 5.94%
Adrenal Cortex:								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Ganglioneuroma								
-		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (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	0/349 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Hemangioma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Adrenal Medulla: Pheochromocytoma Ben	nign							
·		10/50 (20%) 8/50 (16%) 9/50 (18%)	7/50 (14%) 8/50 (16%)	12/50 (24%) 8/49 (16%)		2/50 (4%) 3/50 (6%) 2/50 (4%)	1/50 (2%) 1/49 (2%)	2/50 (4%) 1/50 (2%)
Overall Incidence	Total	62/349 (17.77%)	Mean 17.76%	SD 3.33%	Total	12/349 (3.44%)	Mean 3.43%	SD 1.51%
Adrenal Medulla: Pheochromocytoma Con	nplex				•••••			
·	-	1/50 (2%) 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%)	1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%
Adrenal Medulla: Pheochromocytoma Mal	ignant							
·		0/50 (0%) 0/50 (0%) 4/50 (8%)	1/50 (2%) 2/50 (4%)	1/50 (2%) 3/49 (6%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	11/349 (3.15%)	Mean 3.16%	SD 3.04%	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%
Adrenal Medulla: Pheochromocytoma: Be	nign, Complex	ς, Malignant, NOS			••••••			
·	•	11/50 (22%) 8/50 (16%) 12/50 (24%)	7/50 (14%) 10/50 (20%)	13/50 (26%) 10/49 (20%)		3/50 (6%) 3/50 (6%) 3/50 (6%)	3/50 (6%) 1/49 (2%)	2/50 (4%) 1/50 (2%)
Overall Incidence	Total	71/349 (20.34%)	Mean 20.34%	SD 4.23%	Total	16/349 (4.58%)	Mean 4.58%	SD 1.89%

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

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Bone: Chondrosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Bone: Chondrosarcoma or Cho	ondroma							
ononarosarosma or one	, mar o ma	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Bone: Chordoma			•••••					
		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.58%	SD 0.99%	Total	0/350 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male			Female			
#Bone: Osteosarcoma									
		1/50 (2%) 0/50 (0%) 3/50 (6%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	6/349 (1.72%)	Mean 1.72%	SD 2.14%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	
#Bone: Osteosarcoma or Osteoma									
		1/50 (2%) 0/50 (0%) 3/50 (6%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	6/349 (1.72%)	Mean 1.72%	SD 2.14%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	
Brain: Astrocytoma Malignant									
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	
*Brain: Ependymoma Benign									
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%	

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Brain: Ependymoma Malignant								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Brain: Glioma Malignant								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)		1/50 (2%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	3/350 (0.86%)	Mean 0.86%	SD 1.07%
*Brain: Granular Cell Tumor Benig								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Brain: Medulloblastoma Mal								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/49 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/348 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female				
*Brain: Meningioma Malignant											
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%			
Brain:							•••••				
Meningioma: Benign, Mali	gnant, NOS										
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
verall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%			
Brain: Oligodendroglioma Benig	n										
gg.		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%)	0/50 (0%)	0/50 (0%)			
verall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%			
Brain:							•••••				
Oligodendroglioma Maligr	iant	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%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%			

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Brain:								
Oligodendroglioma, Glion	na, or Astroc		0.750 (00.4)	2/12 (22/)		. (== (==()	0/50 (404)	0 (=0 (00))
		0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%)	2/50 (4%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	2/50 (4%)	0/50 (0%)
Normall Institutes	Tatal	` ,	Mana 00/	CD 00/	Tatal	` '	Mana 4 400/	CD 4.00/
verall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	5/350 (1.43%)	Mean 1.43%	SD 1.9%
Brain: Osteosarcoma								
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	1/348 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
Brain: Schwannoma Malignant					•••••			
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	, ,	, ,		0/50 (0%)	, ,	, ,
verall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma			•••••	•••••				
		4/50 (8%)	0/50 (0%)	0/48 (0%)		3/49 (6%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	3/49 (6%)		0/50 (0%)	0/50 (0%)	4/50 (8%)
		0/50 (0%)	(/	- (/		0/50 (0%)	(/	(/
		` '/				` ,		

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Clitoral/Preputial Gland: Carcinoma								
		2/50 (4%)	0/50 (0%)	0/48 (0%)		1/49 (2%)	2/50 (4%)	0/50 (0%)
		1/50 (2%) 0/50 (0%)	2/50 (4%)	0/49 (0%)		1/50 (2%) 4/50 (8%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	5/347 (1.44%)	Mean 1.43%	SD 1.9%	Total	9/349 (2.58%)	Mean 2.58%	SD 2.76%
Clitoral/Preputial Gland: Carcinoma or Adenoma								•••••
		6/50 (12%)	0/50 (0%)	0/48 (0%)		4/49 (8%)	3/50 (6%)	0/50 (0%)
		1/50 (2%) 0/50 (0%)	2/50 (4%)	3/49 (6%)		1/50 (2%) 4/50 (8%)	1/50 (2%)	4/50 (8%)
verall Incidence	Total	12/347 (3.46%)	Mean 3.45%	SD 4.44%	Total	17/349 (4.87%)	Mean 4.88%	SD 3.46%
Clitoral/Preputial Gland: Fibrosarcoma								•••••
		0/50 (0%)	0/50 (0%)	0/48 (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%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/347 (0%)	Mean 0%	SD 0%	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%
Clitoral/Preputial Gland: Sarcoma								•••••
		0/50 (0%)	0/50 (0%)	0/48 (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%)
verall Incidence	Total	0/347 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/48 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/347 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
#Ear: Neural Crest Tumor	•••••			•••••				
Neural Crest Fullion		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%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.77%	Total	0/350 (0%)	Mean 0%	SD 0%
#Esophagus: Fibrosarcoma	•••••							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Esophagus: Lipoma	• • • • • • • • • • • • • • • • • • • •							
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

49 1 49 1

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Eye: Amelanotic Melanoma, B	enign							
,	J	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Eye: Melanoma Benign								
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Eye: Melanoma Malignant								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Eye: Schwannoma Malignant				•••••				
, and the second		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#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%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (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%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Benign			•••••					•••••
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.77%	Total	0/350 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Malignant					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%

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

SIOII. NOV2006

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male	Female	
#Intestine Large: Colon/Re	ectum:				
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 0/50 (0%) 0/50 (0%) 0/50 0/50 (0%)	(0%) (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0% SD 0%	Total 0/350 (0%) Mean 0% SD 0	1%
fintestine Large: Colon/Re	ectum:				
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 0/50 (0%) 0/50 (0%) 0/50 0/50 (0%)	(0%) (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0% SD 0%	Total 0/350 (0%) Mean 0% SD 0	
Intestine Large: Colon/Re Carcinoma or Adenom	ectum:				
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 0/50 (0%) 0/50 (0%) 0/50 0/50 (0%)	(0%) (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0% SD 0%	Total 0/350 (0%) Mean 0% SD 0	1%
fintestine Large: Colon/Re Hemangioma					
-		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 0/50 (0%) 0/50 (0%) 0/50 0/50 (0%)	(0%) (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0% SD 0%	Total 0/350 (0%) Mean 0% SD 0	1%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Granular Cell Tumor Malign								
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Intestine Small: Jejunum: Leiomyoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma	•••••				• • • • • • • • • • • • • • • • • • • •			
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspeci Carcinoma					• • • • • • • • • • • • • • • • • • • •			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspeci Carcinoma or Adenoma	fied:				•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Species: RATS Strain: F344

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Site Unspe Granular Cell Tumor Mal								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Leiomyoma	cified:							
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Leiomyosarcoma								
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic:								
		0/50 (0%) 3/50 (6%) 3/50 (6%)	1/50 (2%) 3/50 (6%)	5/50 (10%) 4/49 (8%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 3/50 (6%)	1/50 (2%) 1/50 (2%)
Overall Incidence	Total	19/349 (5.44%)	Mean 5.45%	SD 3.43%	Total	6/350 (1.71%)	Mean 1.71%	SD 2.14%

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

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: INHALATION Vehicle: AIR

			Male		Fema	ale
Islets, Pancreatic:						
		3/50 (6%) 4/50 (8%) 1/50 (2%)	2/50 (4%) 1/50 1/50 (2%) 5/49		1/50 (2%) 1/50 0/50 (0%) 0/50 0/50 (0%)	(2%) 0/50 (0%) (0%) 0/50 (0%)
Overall Incidence	Total	17/349 (4.87%)	Mean 4.89% SE	O 3.29% Total	2/350 (0.57%) Mean	n 0.57% SD 0.98%
Islets, Pancreatic: Carcinoma or Adenoma	•••••					
		3/50 (6%) 7/50 (14%) 4/50 (8%)	3/50 (6%) 6/50 4/50 (8%) 9/49	` ,	1/50 (2%) 2/50 0/50 (0%) 3/50 0/50 (0%)	(4%) 1/50 (2%) (6%) 1/50 (2%)
Overall Incidence	Total	36/349 (10.32%)	Mean 10.34% SE	O 4.64% Total	8/350 (2.29%) Mean	n 2.29% SD 2.14%
Kidney: Pelvis and Transition Carcinoma						
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 0/50 (0%) 0/49		0/49 (0%) 0/50 0/50 (0%) 0/49 0/50 (0%)	(0%) 0/50 (0%) (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29% SE	0 0.76% Total	0/348 (0%) Mean	n 0% SD 0%
Kidney: Pelvis and Transition Carcinoma or Adenoma						
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 0/50 (0%) 0/49	` ,	0/49 (0%) 0/50 0/50 (0%) 0/49 0/50 (0%)	(0%) 0/50 (0%) (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29% SE	0 0.76% Total	0/348 (0%) Mea	n 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female					
*Kidney: Pelvis and Transitional Epithelium: Papilloma												
		1/50 (2%) 0/50 (0%) 0/50 (0%)	` ,	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/348 (0%)	Mean 0%	SD 0%				
*Kidney: Renal Tubule: Adenoma					•••••							
		1/50 (2%) 0/50 (0%) 0/50 (0%)	(/	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	0/348 (0%)	Mean 0%	SD 0%				
*Kidney: Renal Tubule: Carcinoma												
		0/50 (0%) 0/50 (0%) 0/50 (0%)	` ,	0/50 (0%) 0/49 (0%)		1/49 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	1/348 (0.29%)	Mean 0.29%	SD 0.77%				
*Kidney: Renal Tubule: Carcinoma or Adenoma					•••••							
		1/50 (2%) 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/49 (0%)		1/49 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	3/349 (0.86%)	Mean 0.86%	SD 1.57%	Total	1/348 (0.29%)	Mean 0.29%	SD 0.77%				

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma	•••••				•••••			
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/348 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma	•••••							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/348 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Beni	gn				•••••			
-	-	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories Species: RATS

Strain: F344 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Kidney: Renal Tubule: Nephroblastoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma	•••••				•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%
*Liver: Cholangioma				•••••				
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (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%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories Species: RATS

Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 154

			Male				Female	
Liver:								
Hepatocellular Adenoma	a	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%)
		1/50 (2%)	0/30 (0/0)	0/43 (070)		0/50 (0%)	0/30 (0/0)	0/30 (0/0)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	0/350 (0%)	Mean 0%	SD 0%
		` ,				,		
Liver: Hepatocellular Carcinon	ma							
riepatocendiai Garcinon	iiu	2/50 (4%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	(-,-,	(=/		0/50 (0%)	(-,-,	(-,-)
Overall Incidence	Total	3/349 (0.86%)	Mean 0.86%	SD 1.58%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Liver: Hepatocellular Carcinon								
•	•	2/50 (4%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	3/349 (0.86%)	Mean 0.86%	SD 1.58%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Liver:								••••
Hepatocellular Carcinon	na or Hepatoce							
		2/50 (4%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	+	1/50 (2%)	NA 4 400'	05 4 540/	.	0/50 (0%)	NA 0.0001	OD 0 700/
Overall Incidence	Total	5/349 (1.43%)	Mean 1.43%	SD 1.51%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%

^{*:} 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: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR Page: 155

			Male				Female				
*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma											
Hepatoblastoma		0/50 (40/)	0/50 (00/)	0/50 (00/)		4/50 (00/)	0/50 (00/)	0/50 (00/)			
		2/50 (4%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			
		1/50 (2%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	5/349 (1.43%)	Mean 1.43%	SD 1.51%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%			
Lung: Alveolar/Bronchiolar A	denoma										
		2/50 (4%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	1/49 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	4/349 (1.15%)	Mean 1.15%	SD 1.58%	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%			
Lung: Alveolar/Bronchiolar C											
Aiveolai/Bronchiolai Ca	arcinoma	1/50 (2%)	1/50 (2%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)			
		1/50 (2%)	0/00 (0/0)	0/40 (070)		0/50 (0%)	0/00 (0/0)	1700 (270)			
Overall Incidence	Total	4/349 (1.15%)	Mean 1.14%	SD 1.07%	Total	3/350 (0.86%)	Mean 0.86%	SD 1.07%			
	• • • • • • • • • • • • • • • • • • • •		•••••		•••••						
Lung: Alveolar/Bronchiolar Ca Adenoma	arcinoma or Al	veolar/Bronchiolar									
, (401101114		3/50 (6%)	2/50 (4%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	1/49 (2%)		1/50 (2%)	0/50 (0%)	1/50 (2%)			
		1/50 (2%)	3,00 (0,0)	(=/5)		0/50 (0%)	2,00 (0,0)	(=,3)			
		1/30 (270)									

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

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Lung: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Lung: Squamous Cell Carcinoma					•••••			
		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%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma					•••••			
-		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Lymph Node, Mesenteric: Sarcoma								
		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%)	, ,	, ,
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenoma							•••••	•••••
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/49 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.58%	SD 1.54%	Total	3/350 (0.86%)	Mean 0.86%	SD 2.27%
Mammary Gland: Carcinoma								
		0/50 (0%)	2/50 (4%)	1/50 (2%)		4/50 (8%)	10/50 (20%)	3/50 (6%)
		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		5/50 (10%) 3/50 (6%)	3/50 (6%)	7/50 (14%)
overall Incidence	Total	5/349 (1.43%)	Mean 1.43%	SD 1.9%	Total	35/350 (10%)	Mean 10%	SD 5.29%
Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	2/50 (4%)	1/50 (2%)		4/50 (8%)	10/50 (20%)	3/50 (6%)
		2/50 (4%) 0/50 (0%)	0/50 (0%)	2/49 (4%)		5/50 (10%) 3/50 (6%)	3/50 (6%)	10/50 (20%)
Overall Incidence	Total	7/349 (2.01%)	Mean 2.01%	SD 2.01%	Total	38/350 (10.86%)	Mean 10.86%	SD 6.41%

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Mammary Gland: Fibroadenoma								
		2/50 (4%) 2/50 (4%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	1/50 (2%) 1/49 (2%)		25/50 (50%) 22/50 (44%) 14/50 (28%)	24/50 (48%) 22/50 (44%)	20/50 (40%) 26/50 (52%)
Overall Incidence	Total	8/349 (2.29%)	Mean 2.29%	SD 1.38%	Total	153/350 (43.71%)	Mean 43.71%	SD 8.04%
#Mammary Gland: Fibroma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenor								
		2/50 (4%) 2/50 (4%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	1/50 (2%) 3/49 (6%)		25/50 (50%) 22/50 (44%) 14/50 (28%)	24/50 (48%) 22/50 (44%)	20/50 (40%) 28/50 (56%)
Overall Incidence	Total	10/349 (2.87%)	Mean 2.87%	SD 1.98%	Total	155/350 (44.29%)	Mean 44.29%	SD 8.83%
Mammary Gland: Fibroma, Fibroadenor	na, Carcinoma, c	or Adenoma						
·	,	2/50 (4%) 4/50 (8%) 1/50 (2%)	2/50 (4%) 1/50 (2%)	1/50 (2%) 3/49 (6%)		27/50 (54%) 26/50 (52%) 16/50 (32%)	31/50 (62%) 24/50 (48%)	22/50 (44%) 31/50 (62%)
Overall Incidence	Total	14/349 (4.01%)	Mean 4.02%	SD 2.33%	Total	177/350 (50.57%)	Mean 50.57%	SD 10.56%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Mesentery: Fibrosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma								
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (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%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Mesentery: Rhabdomyosarcoma				•••••				
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories Species: RATS

Strain: F344 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Nose: Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%
Nose: Chondroma	•••••							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/348 (0.29%)	Mean 0.29%	SD 0.76%
Nose: Squamous Cell Carcino					•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	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%) 0/49 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Papilloma Squamous o	Tongue, Phary		•••••					
,	,	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%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%

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

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
FOral Cavity (Oral Mucosa Squamous Cell Carcin		nx, Tooth, Gingiva):						
·		1/50 (2%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Oral Cavity (Oral Mucosa Squamous Cell Carcin Papilloma	, Tongue, Phary	nx, Tooth, Gingiva):						
·		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%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/349 (0.86%)	Mean 0.86%	SD 1.07%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Oral Mucosa: Squamous Cell Carcin	oma		•••••			•••••	•••••	
		1/50 (2%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	0/350 (0%)	Mean 0%	SD 0%
Oral Mucosa: Squamous Cell Papillo								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	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%)
		0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 162 Report Date:11/17/2008

Species: RATS Strain: F344 Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male			Female	
*Ovary: Granulosa Cell Tumor Benign				
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%
*Ovary:				
Granulosa Cell Tumor Malignant		0/50 (0%)	0/50 (09/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	, ,	
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
Grandosa sen ramor. Berngn, mangnant, 1100		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/350 (0.29%)	Mean 0.29%	SD 0.76%
Overall molecules	10141	17000 (0.2070)	WCGIT 0.2570	05 0.70%
*Ovary:				
Granulosa-Theca Tumor Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%
Overall illefuence	IUlai	0/350 (0%)	IVICALI U70	3D 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

Report Date:11/17/2008

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Species: RATS Strain: F344

Length of Study: CHRONIC

Vehicle: AIR

			Male				Female	
Ovary: Granulosa-Theca Tum	or Malignant							
						2/50 (4%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	2/350 (0.57%)	Mean 0.57%	SD 1.51%
*Ovary: Tubulostromal Adenor	ma							
rusuissii siiiai ytusiisi						0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	0/350 (0%)	Mean 0%	SD 0%
Pancreas: Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

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Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Pancreas: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	` ,	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Benign					•••••			
		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%)
overall Incidence	Total	2/349 (0.57%)	Mean 0.58%	SD 1.54%	Total	0/350 (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%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Parathyroid Gland: Adenoma					•••••			
		0/46 (0%) 0/49 (0%) 0/48 (0%)	()	0/46 (0%) 0/47 (0%)		0/47 (0%) 0/46 (0%) 0/49 (0%)	0/49 (0%) 0/43 (0%)	0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/328 (0%)	Mean 0%	SD 0%	Total	0/332 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344 Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Peripheral Nerve: Schwannoma Malignant	;							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Peripheral Nerve:	Malianant NOS							
Schwannoma: Benign, N	Manghant, NOS	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distal Adenoma								
		37/50 (74%) 35/50 (70%) 36/50 (72%)	36/50 (72%) 34/49 (69%)	36/50 (72%) 36/49 (73%)		35/50 (70%) 24/49 (49%) 36/49 (73%)	35/50 (70%) 35/50 (70%)	37/50 (74%) 30/50 (60%)
Overall Incidence	Total	250/348 (71.84%)	Mean 71.84%	SD 1.67%	Total	232/348 (66.67%)	Mean 66.64%	SD 9.04%
Pituitary Gland: Pars Distal Carcinoma								
		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/49 (0%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/348 (0.29%)	Mean 0.29%	SD 0.76%	Total	1/348 (0.29%)	Mean 0.29%	SD 0.76%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Pituitary Gland: Pars Distal Carcinoma or Adenoma	is or Unspecif	ied Site:						
		37/50 (74%) 35/50 (70%) 37/50 (74%)	36/50 (72%) 34/49 (69%)	36/50 (72%) 36/49 (73%)		35/50 (70%) 24/49 (49%) 36/49 (73%)	36/50 (72%) 35/50 (70%)	37/50 (74%) 30/50 (60%)
verall Incidence	Total	251/348 (72.13%)	Mean 72.12%	SD 1.87%	Total	233/348 (66.95%)	Mean 66.92%	SD 9.2%
Pituitary Gland: Pars Intern Adenoma	nedia:							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/348 (0.29%)	Mean 0.29%	SD 0.77%	Total	0/348 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Intern Carcinoma					•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Intern Carcinoma or Adenoma	nedia:							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/348 (0.29%)	Mean 0.29%	SD 0.77%	Total	0/348 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Prostate: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)				
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)				
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant						•••••		
3		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories Species: RATS

Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male			Female				
#Seminal Vesicle: Adenoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)						
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%						
#Skeletal Muscle: Hemangioma										
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%		
#Skeletal Muscle: Hemangiosarcoma										
5		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%		
#Skeletal Muscle: Lipoma										
F		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/30 (0/8)				0/30 (0/0)				

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 169

			Male				Female	
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	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%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Skeletal Muscle: Rhabdomyosarcoma or I	Rhabdomyom	a						
·	Í	0/50 (0%) 0/50 (0%) 0/50 (0%)	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%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Skeletal Muscle: Sarcoma			•••••				•••••	
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
		0/50 (0%) 0/50 (0%) 1/50 (2%)	1/50 (2%) 1/50 (2%)	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%)
Overall Incidence	Total	4/349 (1.15%)	Mean 1.15%	SD 1.07%	Total	0/350 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

OII. 140V2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin:								
Basal Cell Adenoma or E	Basosquamou		(0/50 (00/)		2/22 (22/)	2/22 (22()	2/52 (22/)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)		00 / 000/		0/50 (0%)	• • • • • • • • • • • • • • • • • • • •	00.00/
Overall Incidence	Total	4/349 (1.15%)	Mean 1.15%	SD 1.07%	Total	0/350 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Adenoma, Bas Trichoepithelioma	sosquamous ⁻	Tumor Benign, or						•••••
•		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	5/349 (1.43%)	Mean 1.43%	SD 0.98%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
∜Skin: Basal Cell Carcinoma		0/50 (0%) 0/50 (0%)	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%)
		3/50 (6%)	0/30 (0 /8)	0/49 (070)		0/50 (0%)	0/30 (0/0)	0/30 (0/6)
Overall Incidence	Total	3/349 (0.86%)	Mean 0.86%	SD 2.27%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma or NOS)	Basosquamo	us Tumor (malignant o	r					
,		0/50 (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%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
	Total	3/349 (0.86%)	Mean 0.86%	SD 2.27%	Total	0/350 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR Page: 171

Report Date: 11/17/2008

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%)1/50 1/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/49 (2%)0/50 (0%)0/50 (0%)1/50 (2%)4/50 (8%)0/50 (0%)**Overall Incidence** Total 8/349 (2.29%) Mean 2.29% SD 2.69% Total 1/350 (0.29%) Mean 0.29% SD 0.76% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq. Papilloma, Keratoacanthoma, Trichoepithelioma (2%)(10%)2/50 (4%)1/50 0/50 (0%)0/50 (0%)5/50 0/50 (0%)2/50 (4%)(10%)0/50 (0%)0/50 (0%)1/50 (2%)5/50 (10%)1/50 (2%)**Overall Incidence** Total 20/349 (5.73%)Mean 5.74% SD 4.27% Total 3/350 (0.86%)Mean 0.86% SD 1.07% #Skin: Fibroma 3/50 (6%)3/50 (6%)5/50 (10%)2/50 (4%)0/50 (0%)0/50 (0%)(8%) 4/50 (8%)3/49 0/50 (0%)(2%)(2%)4/50 (6%)1/50 1/50 3/50 (6%)0/50 (0%)SD 1.57% **Overall Incidence** Total 25/349 (7.16%) Mean 7.16% SD 1.56% Total 4/350 (1.14%) Mean 1.14% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma (6%)3/50 (6%)6/50 (12%)2/50 (4%)1/50 (2%)0/50 (0%)5/50 (10%)5/50 (10%)(8%)0/50 (0%)(2%)2/50 (4%)4/49 1/50 6/50 (12%)0/50 (0%)**Overall Incidence** Total 32/349 (9.17%) Mean 9.17% SD 2.53% Total 6/350 (1.71%) Mean 1.71% SD 1.8%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

Report Date:11/17/2008

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Species: RATS Strain: F344

Vehicle: AIR

Length of Study: CHRONIC

			Male						Femal	е		
#Skin: Fibrosarcoma												
	0/5 1/5 3/5	0 (2%)	0/50 (0% 1/50 (2%	,	(0%) (2%)		0/50 0/50 0/50	` '		` '	0/50 1/50	(0%) (2%)
Overall Incidence		(1.72%)	Mean 1.7	72% SD	2.14%	Total	1/350 (` '	Mean	0.29%	SD (0.76%
#Skin:							• • • • • • • • • • • • • • • • • • • •					
Fibrosarcoma, Sarcoma, Myxos Histiocytoma	sarcoma, or Fib	rous										
	0/5 1/5 3/5	0 (2%)	0/50 (0% 1/50 (2%	,	(2%) (2%)		0/50 0/50 0/50				0/50 1/50	(0%) (2%)
Overall Incidence	Total 7/349	(2.01%)	Mean 2.0	01% SD	2%	Total	2/350 (0.57%)	Mean	0.57%	SD ().98%
#Skin: Fibrous Histiocytoma												
•	0/5 0/5 0/5	0 (0%)	0/50 (0% 0/50 (0%	,	(2%) (0%)		0/50 0/50 0/50	` '		` '	0/50 0/50	(0%) (0%)
Overall Incidence	Γotal 1/349	0.29%)	Mean 0.2	29% SD	0.76%	Total	1/350 (0.29%)	Mean	0.29%	SD (0.76%
#Skin: Hemangioma								•••••				
	0/5 0/5 0/5	0 (0%)	0/50 (0% 0/50 (0%	,	(0%) (0%)		0/50 0/50 0/50				0/50 0/50	(0%) (0%)
Overall Incidence	Total 0/349	` '	Mean 0%	% SD	0%	Total		0%)	Mean	0%	SD ()%

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

^{#:} Denominator is number of animals necropsied

131011. 11072000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Hemangiosarcoma								
		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%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma					•••••			
		0/50 (0%) 0/50 (0%) 1/50 (2%)	4/50 (8%) 1/50 (2%)	0/50 (0%) 4/49 (8%)		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	10/349 (2.87%)	Mean 2.88%	SD 3.66%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Skin: Lipoma					•••••			
		2/50 (4%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%) 2/49 (4%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	6/349 (1.72%)	Mean 1.73%	SD 1.82%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma					•••••			
-		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Neural Crest Tumor								
		1/50 (2%) 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%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Skin: Neural Crest Tumor, Ma	llignant							
,	3	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin: Neurofibroma or Schwa					•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or S					•••••			
	()	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%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.58%	SD 0.99%	Total	0/350 (0%)	Mean 0%	SD 0%

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

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344 Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male		Female								
¢Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)													
manghant of 1100)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 0/50 (0%) 1/49	(0%) (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)							
Overall Incidence	Total	2/349 (0.57%)	Mean 0.58% SD	0.99% Total	0/350 (0%) Mean 0%	SD 0%							
#Skin: Osteosarcoma													
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%) 0/49	(0%) (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	0/349 (0%)	Mean 0% SD		0/350 (0%) Mean 0%	SD 0%							
Skin: Sarcoma													
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%) 0/49	(0%) (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	0/349 (0%)	Mean 0% SD		0/350 (0%) Mean 0%	SD 0%							
Skin: Schwannoma Benign													
· ·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%) 0/49	(0%) (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	0/349 (0%)	Mean 0% SD	0% Total	0/350 (0%) Mean 0%	SD 0%							

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

^{#:} Denominator is number of animals necropsied

2131011: 11012000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 11/17/2008

(0%)

Mean 0%

0/50

(0%)

0/50

SD 0%

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Male Female #Skin: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/50 (0%)1/49 0/50 (0%)0/50 0/50 (0%)(2%)1/50 0/50 (0%)SD 0.99% SD 0% Overall Incidence Total 2/349 (0.57%)Mean 0.58% Total 0/350 Mean 0% #Skin: **Squamous Cell Carcinoma** 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)(0%)0/50 0/50 0/50 0/49 (0%)0/50 (0%)0/50 (0%)(2%)0/50 1/50 SD 0.76% **Overall Incidence** Total 1/349 (0.29%) Mean 0.29% SD 0.76% Total 1/350 (0.29%) Mean 0.29% #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 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%)0/50 (0%)0/50 (0%)0/50 (0%)3/50 (6%)1/50 (2%)**Overall Incidence** 4/349 (1.15%) Mean 1.14% SD 2.27% Total 1/350 (0.29%) Mean 0.29% SD 0.76% Total #Skin: **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)

(0%)

SD 0.76%

0/50

0/50

0/350 (0%)

Total

(0%)

(0%)

Total

(0%)

(0%)

(0.29%)

0/50

0/50

1/349

(0%)

Mean 0.29%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin:								
Squamous Cell Papillon	na or Papilloma							
		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%)		00 0 700/	-	0/50 (0%)		00.00/
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
Skin:	••••••							
Squamous Cell Papillon Carcinoma or Keratoaca		Squamous Cell						
ouromonia or neratouol	antinoma	1/50 (2%)	4/50 (8%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	4/49 (8%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	(11,	()		1/50 (2%)	(,	(111)
Overall Incidence	Total	12/349 (3.44%)	Mean 3.45%	SD 3.25%	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%
#Skin:	.	16						
Squamous Cell Papillon	na, Papilloma,		4/50 (00/)	4/50 (00/)		4/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	4/50 (8%)	1/50 (2%)		1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
		0/50 (0%) 1/50 (2%)	1/50 (2%)	4/49 (8%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
O	Tatal	` ,	Mana 0 470/	CD 2 400/	Tatal	` ,	Mann 0.000/	CD 0.700/
Overall Incidence	Total	11/349 (3.15%)	Mean 3.17%	SD 3.48%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Skin:								
Trichoepithelioma								
		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%)	1/50 (2%)
		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: INHALATION

Report Date:11/17/2008

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Species: RATS Strain: F344

Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%) 1/50 (2%) 2/50 (4%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	5/349 (1.43%)	Mean 1.43%	SD 1.51%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 1/50 (2%) 2/50 (4%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	5/349 (1.43%)	Mean 1.43%	SD 1.51%	Total	0/350 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Benign								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Spinal Cord: Astrocytoma Malignant								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Spinal Cord: Glioma Malignant								
Ü		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Spleen: Fibrosarcoma	•••••							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Spleen: Fibrous Histiocytoma				•••••				
-		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Spleen: Hemangioma								
		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%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma								
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Spleen: Leiomyosarcoma								
		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%)
overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
Spleen: Sarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Species: RATS Strain: F344

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma					• • • • • • • • • • • • • • • • • • • •			
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma					•••••			
oquamous con curomoma	or r upmon	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma					•••••		•••••	•••••
,		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
Stomach, Glandular: Leiomyosarcoma								
		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%)
verall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Lipoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
estes: Adenoma								
		34/50 (68%) 42/50 (84%) 29/50 (58%)	36/50 (72%) 33/50 (66%)	38/50 (76%) 38/49 (78%)				
verall Incidence	Total	250/349 (71.63%)	Mean 71.65%	SD 8.54%				
Гhymus: Sarcoma								
		0/43 (0%) 0/49 (0%) 0/47 (0%)	0/49 (0%) 0/42 (0%)	0/48 (0%) 0/47 (0%)		0/46 (0%) 0/47 (0%) 0/44 (0%)	0/48 (0%) 0/50 (0%)	0/45 (0%) 0/46 (0%)
Overall Incidence	Total	0/325 (0%)	Mean 0%	SD 0%	Total	0/326 (0%)	Mean 0%	SD 0%

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

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^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Thymus: Thymoma Benign								
		0/43 (0%) 0/49 (0%) 0/47 (0%)	0/49 (0%) 0/42 (0%)	0/48 (0%) 1/47 (2%)		1/46 (2%) 0/47 (0%) 0/44 (0%)	0/48 (0%) 1/50 (2%)	0/45 (0%) 0/46 (0%)
Overall Incidence	Total	1/325 (0.31%)	Mean 0.3%	SD 0.8%	Total	2/326 (0.61%)	Mean 0.6%	SD 1.02%
Thymus: Thymoma Malignant					•••••			
		0/43 (0%) 0/49 (0%) 0/47 (0%)	0/49 (0%) 0/42 (0%)	0/48 (0%) 0/47 (0%)		0/46 (0%) 0/47 (0%) 0/44 (0%)	0/48 (0%) 0/50 (0%)	0/45 (0%) 0/46 (0%)
Overall Incidence	Total	0/325 (0%)	Mean 0%	SD 0%	Total	0/326 (0%)	Mean 0%	SD 0%
Thymus: Thymoma: Benign, Malig					•••••			
		0/43 (0%) 0/49 (0%) 0/47 (0%)	0/49 (0%) 0/42 (0%)	0/48 (0%) 1/47 (2%)		1/46 (2%) 0/47 (0%) 0/44 (0%)	0/48 (0%) 1/50 (2%)	0/45 (0%) 0/46 (0%)
Overall Incidence	Total	1/325 (0.31%)	Mean 0.3%	SD 0.8%	Total	2/326 (0.61%)	Mean 0.6%	SD 1.02%
Thyroid Gland: C-Cell: Adenoma					•••••			
		5/50 (10%) 1/50 (2%) 5/50 (10%)	3/50 (6%) 3/49 (6%)	2/50 (4%) 4/49 (8%)		3/50 (6%) 3/50 (6%) 3/50 (6%)	3/50 (6%) 2/50 (4%)	0/50 (0%) 3/50 (6%)
Overall Incidence	Total	23/348 (6.61%)	Mean 6.61%	SD 3%	Total	17/350 (4.86%)	Mean 4.86%	SD 2.27%

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male			F	emale	
Thyroid Gland: C-Cell: Carcinoma								
		4/50 (8%)		/50 (2%)	1/50			/50 (2%)
		2/50 (4%) 2/50 (4%)	0/49 (0%) 3/	/49 (6%)	1/50 0/50		0 (2%) 2	2/50 (4%)
Overall Incidence	Total	13/348 (3.74%)	Mean 3.73%	SD 2.71%	Total 6/350	(1.71%) N	lean 1.71%	SD 1.38%
Thyroid Gland: C-Cell: Carcinoma or Adenoma	•••••							
		9/50 (18%)		/50 (6%)	4/50	()	- ()	/50 (2%)
		3/50 (6%) 6/50 (12%)	3/49 (6%) 7/	/49 (14%)	4/50 3/50	` ,	0 (6%) 5	5/50 (10%)
overall Incidence	Total	34/348 (9.77%)	Mean 9.77%		Total 23/350	,	Mean 6.57%	SD 2.51%
Гhyroid Gland: Follicular Cell: Adenoma								
		0/50 (0%)	` ,	/50 (2%)	0/50)/50 (0%)
		0/50 (0%) 0/50 (0%)	0/49 (0%) 1/	/49 (2%)	1/50 0/50	` ,	0 (0%) 0)/50 (0%)
overall Incidence	Total	2/348 (0.57%)	Mean 0.58%	SD 0.99%	Total 1/350	(0.29%) N	lean 0.29%	SD 0.76%
Thyroid Gland: Follicular Cell: Carcinoma								
		0/50 (0%)	2/50 (4%) 0/	/50 (0%)	0/50	0/50	0 (0%) 0)/50 (0%)
		1/50 (2%) 0/50 (0%)	0/49 (0%) 0/	/49 (0%)	0/50 0/50	` ,	0 (0%) 0	0/50 (0%)
Overall Incidence	Total	3/348 (0.86%)	Mean 0.86%	SD 1.57%	Total 0/350	(0%) N	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		0/50 (0%) 1/50 (2%) 0/50 (0%)	2/50 (4%) 0/49 (0%)	1/50 (2%) 1/49 (2%)		0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	5/348 (1.44%)	Mean 1.43%	SD 1.51%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Tissue NOS: Lipoma			•••••					
•		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%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.77%	Total	0/350 (0%)	Mean 0%	SD 0%
Tissue NOS: Paraganglioma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
FTissue NOS: Schwannoma Malignant								
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Tongue: Squamous Cell Carcinoma	a							
		0/50 (0%) 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%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Tongue:	or Donillon	Caucamaua	•••••	•••••				•••••
Squamous Cell Carcinoma	a or Papillon	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%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Tongue: Squamous Cell Papilloma	•••••				•••••			
		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%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
#Tooth: Adamantinoma Malignant	•••••				•••••			
Ç		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%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%

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

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Tooth: Odontoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma								
·		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%) 0/49 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/349 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma								
•		0/50 (0%) 0/50 (0%) 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%) 0/49 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%

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

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Urinary Bladder: Papilloma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/349 (0%)	Mean 0%	SD 0%
Uterus: Adenoma								
						0/50 (0%)	0/50 (0%)	1/50 (2%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/50 (2%)	Mean 0.57%	SD 0.98%
						2/350 (0.57%)		
Uterus: Carcinoma								
Garomoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						1/50 (2%)		
verall Incidence					Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Uterus: Deciduoma Benign								
· · · · · · · · · · · · · · · · · · ·						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)		00.007
verall Incidence					Total	0/350 (0%)	Mean 0%	SD 0%

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

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: INHALATION Vehicle: AIR

Male			Female	
Uterus: Hemangioma				
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Uterus: Hemangiosarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
		0/50 (0%)	(***)	(11,
verall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Jterus:				•••••
Leiomyoma		- ()		
		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)	0/30 (0 /8)
verall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%
Uterus:	• • • • • • • • • • • • • • • • • • • •	•••••		
Leiomyosarcoma				
·		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence		` ,		SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Species: RATS Strain: F344 Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

	Male			Female	
#Uterus:					
Polyp Stromal			0/50 /460/	() 42/50 (260/)	0/50 (400/)
			8/50 (16% 12/50 (24%		9/50 (18%) 12/50 (24%)
			6/50 (12%		12/30 (24/0)
Overall Incidence		Total	66/350 (18.86	,	SD 5.87%
			,	,	
Uterus:					
Sarcoma Stromal			2/50 (4%)	1/50 (2%)	0/50 (0%)
			1/50 (2%)		0/50 (0%)
			0/50 (0%)	0,00 (0,0)	0/00 (0/0)
Overall Incidence		Total	4/350 (1.14%)	Mean 1.14%	SD 1.57%
			,		
fUterus: Sarcoma Stromal or Polyp Stromal					
oarcoma ou omar or r oryp ou omar			10/50 (20%	6) 14/50 (28%)	9/50 (18%)
			13/50 (26%		12/50 (24%)
			6/50 (12%		(),
Overall Incidence		Total	70/350 (20%)	Mean 20%	SD 6.43%
tUterus:					
Schwannoma Malignant					
oonwannoma mangnant			0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	` ,	,
Overall Incidence		Total	0/350 (0%)	Mean 0%	SD 0%
			. ,		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Vagina: Polyp								
						0/50 (0%) 0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	2/350 (0.57%)	Mean 0.57%	SD 1.51%
#Vagina: Sarcoma								
						1/50 (2%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%
#Zymbal's Gland: Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
		0/50 (0%) 1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		1/50 (2%) 0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	4/350 (1.14%)	Mean 1.14%	SD 1.07%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 192

			Male			Female
#Zymbal's Gland: Carcinoma or Adenoma		0/50 (0%) 1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	1/50 (2%) 0/50 (0%) 1/50 (2%)	1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98% T	otal 4/350 (1.14%)	Mean 1.14% SD 1.07%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

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Report Date:11/17/2008

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
				Ma	ale		
Battelle Columbus Laboratory Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute Southern Research Institute	058813803 059902703 050517405 059900705 059201305 052000803	08/16/99 08/12/02 08/05/02 04/21/03 01/20/00 03/04/03	729 729 729 729 730 729	50 (3) 50 (3) 50 (3) 50 (3) 50 (3) 50 (3)	22(681) 37(705) 33(703) 33(679) 31(702) 36(704)	501.7 452.8 510.0 460.9 448.0 452.1	Benzophenone Chromium picolinate monohydrate Cresols Goldenseal root powder 4-Methylimidazole Milk thistle extract
				Fen	nale		
Battelle Columbus Laboratory Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute Southern Research Institute	058813803 059902703 050517405 059900705 059201305 052000803	08/17/99 08/12/02 N/A 04/21/03 01/20/00 03/04/03	729 733 N/A 731 735 732	50 (5) 50 (5) 0 (0) 50 (5) 50 (5) 50 (5)	32(688) 36(702) 0(0) 30(699) 40(702) 38(693)	348.7 314.7 N/A 326.0 311.3 328.4	Benzophenone Chromium picolinate monohydrate Cresols Goldenseal root powder 4-Methylimidazole Milk thistle extract

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 194

			Male				Female	
All Organs: Benign Tumors								
_ · · · · · · · · · · · · · · · · · · ·		49/50 (98%)	49/50 (98%)	50/50 (100%)		42/50 (84%)	45/50 (90%)	
		47/50 (94%)	50/50 (100%)	50/50 (100%)		46/50 (92%)	48/50 (96%)	39/50 (78%)
verall Incidence	Total	295/300 (98.33%)	Mean 98.33%	SD 2.34%	Total	220/250 (88%)	Mean 88%	SD 7.07%
All Organs: Malignant Tumors								
_		33/50 (66%)	27/50 (54%)	23/50 (46%)		20/50 (40%)	15/50 (30%)	
		29/50 (58%)	22/50 (44%)	26/50 (52%)		19/50 (38%)	19/50 (38%)	18/50 (36%)
verall Incidence	Total	160/300 (53.33%)	Mean 53.33%	SD 8.07%	Total	91/250 (36.4%)	Mean 36.4%	SD 3.85%
All Organs: Malignant and Benign T	umors						•••••	•••••
		50/50 (100%)	50/50 (100%)	50/50 (100%)		46/50 (92%)	47/50 (94%)	
		50/50 (100%)	50/50 (100%)	50/50 (100%)		48/50 (96%)	48/50 (96%)	46/50 (92%)
verall Incidence	Total	300/300 (100%)	Mean 100%	SD 0%	Total	235/250 (94%)	Mean 94%	SD 2%
All Organs: Hemangioma								
· ·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
All Organs: Hemangiosarcoma	••••••							
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0.000
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%	Total	0/250 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 195

Report Date:11/17/2008

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
All Organs: Hemangiosarcoma or He	emangioma							
nomangrood on a cr	, mangioma	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	3/300 (1%)	Mean 1%	SD 1.67%	Total	0/250 (0%)	Mean 0%	SD 0%
All Organs: Histiocytic Sarcoma						•••••	•••••	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/20 (00/)
	T-1-1	0/50 (0%)	0/50 (0%)	3/50 (6%)	T-1-1	1/50 (2%)	2/50 (4%)	0/50 (0%)
verall Incidence	Total	3/300 (1%)	Mean 1%	SD 2.45%	Total	4/250 (1.6%)	Mean 1.6%	SD 1.67%
All Organs: Leukemia: Erythrocytic								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	4/50 (00/)
verall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0.4%	1/50 (2%) SD 0.89%
veran incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	wean 0.4%	SD 0.69%
All Organs: Leukemia: Lymphocytic Undifferentiated	, Monocytic, N	lononuclear, or						
		27/50 (54%)	19/50 (38%)	15/50 (30%)		19/50 (38%)	9/50 (18%)	- / / / / / / / / / / / / / / / / / /
		21/50 (42%)	15/50 (30%)	17/50 (34%)		9/50 (18%)	9/50 (18%)	6/50 (12%)
verall Incidence	Total	114/300 (38%)	Mean 38%	SD 9.12%	Total	52/250 (20.8%)	Mean 20.8%	SD 9.96%
All Organs: Malignant Lymphoma: H or Undifferentiated Cell		nphocytic, Mixed, NOS,	,					
or oriumerentiated cen	i ype	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%)		0/30 (0/0)	0/30 (0/0)	0/30 (0/0)

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 196

			Male		Female	
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%)
verall Incidence	Total	0/300 (0%)	Mean 0% SD (0/250 (0%) Mean 0%	SD 0%
All Organs:						
Mesothelioma: Benign, Ma	ilighant, NO	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%)
Overall Incidence	Total	3/300 (1%)	Mean 1% SD	.67% Total	0/250 (0%) Mean 0%	SD 0%
All Organs: Mesothelioma: Malignant		0/50 (40/)	4/50 (00() 0/50	(0)()	0/50 /00/\ 0/50 /00/\	
		2/50 (4%) 0/50 (0%)	1/50 (2%) 0/50 0/50 (0%) 0/50	(0%) (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	3/300 (1%)	` ,	1.67% Total	0/30 (0%) 0/30 (0%) 0/250 (0%) Mean 0%	SD 0%
All Organs:						
Osteoma		0/50 (00/)	0/50 (00/) 0/50	(00/)	0/50 (00/) 0/50 (00/)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%) 1/50	(0%) (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	(/).82% Total	0/250 (0%) Mean 0%	SD 0%
All Organs: Osteosarcoma						•••••
		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%)
Overall Incidence	Total	3/300 (1%)	Mean 1% SD	.67% Total	1/250 (0.4%) Mean 0.4%	SD 0.89%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 197

			Male		Female	
All Organs: Osteosarcoma or Osteoma						
		1/50 (2%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		2/50 (4%)	0/50 (0%) 1/50	(2%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
verall Incidence	Total	4/300 (1.33%)		.63% Total	1/250 (0.4%) Mean 0.4%	SD 0.89%
Adrenal Cortex: Adenoma						
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 2/50 (4%)	2/12 /22/
		0/50 (0%)	1/50 (2%) 2/50	(4%)	1/50 (2%) 1/49 (2%)	0/48 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1% SD 1	.67% Total	4/247 (1.62%) Mean 1.61%	SD 1.68%
Adrenal Cortex: Carcinoma						
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/49 (0%)	0/48 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0% SD 0		0/247 (0%) Mean 0%	SD 0%
Adrenal Medulla: Ganglioneuroma						
_		0/50 (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%) 0/48 (0%)	0/48 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0% SD 0		0/244 (0%) Mean 0%	SD 0%
Adrenal Medulla: Hemangioma						
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/40 (00/)
Normall Implidance	Tatal	0/49 (0%)	0/50 (0%) 0/50	(0%)	0/48 (0%) 0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD 0	% Total	0/244 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 198

			Male				Female	
Adrenal Medulla:	nian							
Pheochromocytoma Be	nign	8/50 (16%)	8/50 (16%)	8/50 (16%)		0/50 (0%)	1/50 (2%)	
		5/49 (10%)	8/50 (16%)	5/50 (10%)		0/48 (0%)	2/48 (4%)	1/48 (2%)
verall Incidence	Total	42/299 (14.05%)	Mean 14.03%	SD 3.05%	Total	4/244 (1.64%)	Mean 1.65%	SD 1.74%
drenal Medulla: Pheochromocytoma Co					•••••			
,, ,		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	2/50 (4%)	1/50 (2%)		0/48 (0%)	0/48 (0%)	1/48 (2%)
verall Incidence	Total	3/299 (1%)	Mean 1%	SD 1.67%	Total	1/244 (0.41%)	Mean 0.42%	SD 0.93%
Adrenal Medulla: Pheochromocytoma Ma	lignant	0/50 (00/)	2/50 (69/)	0/50 (09/)		0/50 (00/)	2/50 (40/)	
		0/50 (0%) 1/49 (2%)	3/50 (6%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/48 (0%)	2/50 (4%) 1/48 (2%)	0/48 (0%)
verall Incidence	Total	4/299 (1.34%)	Mean 1.34%	SD 2.42%	Total	3/244 (1.23%)	Mean 1.22%	SD 1.8%
Adrenal Medulla:	mian Cample	Malianant NOS		•••••		•••••		
Pheochromocytoma: Be	enign, Complex	8/50 (16%)	11/50 (22%)	8/50 (16%)		0/50 (0%)	3/50 (6%)	
		6/49 (12%)	10/50 (20%)	6/50 (12%)		0/48 (0%)	3/48 (6%)	2/48 (4%)
verall Incidence	Total	49/299 (16.39%)	Mean 16.37%	SD 4.03%	Total	8/244 (3.28%)	Mean 3.28%	SD 3.1%
Bone: Chondrosarcoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 199

			Male		Female
Bone: Chondrosarcoma or Chondr	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%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%)	Mean 0% SD 0%
Bone: Chordoma					
		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%)
Overall Incidence	Total	3/300 (1%)	Mean 1% SD 1.1%	Total 0/250 (0%)	Mean 0% SD 0%
#Bone: Osteoma					
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	,	Mean 0% SD 0%
#Bone: Osteosarcoma					
		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	2/300 (0.67%)	Mean 0.67% SD 1.63%	Total 1/250 (0.4%)	Mean 0.4% SD 0.89%
#Bone: Osteosarcoma or Osteoma					
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
S	T-1-1	2/50 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1% SD 1.67%	Total 1/250 (0.4%)	Mean 0.4% SD 0.89%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Page: 200 Report Date:11/17/2008

Species: RATS Strain: F344

Vehicle: FEED

Length of Study: CHRONIC

			Male	Female
*Brain: Astrocytoma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/299 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% SD 0%
*Brain: Ependymoma Benign		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/299 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% SD 0%
*Brain: Ependymoma Malignant	Total	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%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34% SD 0.83%	Total 0/250 (0%) Mean 0% SD 0%
*Brain: Glioma Malignant		0/50 (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	0/299 (0%)	Mean 0% SD 0%	Total 0/250 (0%) Mean 0% SD 0%
*Brain: Granular Cell Tumor Benign		0/50 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/49 (0%) 2/299 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.63%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

on: NOV2008

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 201

			Male				Female	
Brain: Medulloblastoma Mal		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
overall Incidence	Total	0/49 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Meningioma Malignant								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		2.200 (0,0)						
Brain: Meningioma: Benign, Mal	ignant, NOS							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2 (22 (22 (22 (22 (22 (22 (22 (22 (22 (
Overall Incidence	Total	0/49 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		0,200 (0,0)	Modif 070			0,200 (0,0)	Moun 070	02 070
Brain: Oligodendroglioma Benig	ın							
3 3 4 4 5	•	0/50 (0%)	0/50 (0%)	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%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Malig		0/50 (0%)	0/50 (0%)	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%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 202

			Male				Female	
Brain:								
Oligodendroglioma, Gli	oma, or Astroc	ytoma 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%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
					• • • • • • • • • • • • • • • • • • • •			•••••
Brain: Osteosarcoma								
Osteosarcoma		0/50 (0%)	0/50 (0%)	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%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Brain: Schwannoma Malignan	t							
3		0/50 (0%)	0/50 (0%)	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%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland:						•••••		
Adenoma		0/50 (00/)	1/50 (20/)	E/EO (400/)		2/50 (60/)	40/50 (200/)	
		0/50 (0%) 0/50 (0%)	1/50 (2%) 2/50 (4%)	5/50 (10%) 1/50 (2%)		3/50 (6%) 5/50 (10%)	10/50 (20%) 8/50 (16%)	11/50 (22%)
Overall Incidence	Total	9/300 (3%)	Mean 3%	SD 3.74%	Total	37/250 (14.8%)	Mean 14.8%	SD 6.72%
		` ,				` ,		
Clitoral/Preputial Gland: Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	
		2/50 (4%)	0/50 (0%)	2/50 (4%)		4/50 (8%)	2/50 (4%)	3/50 (6%)
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 1.97%	Total	10/250 (4%)	Mean 4%	SD 3.16%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 203

			Male				Female	
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		1/50 (2%)	1/50 (2%)	5/50 (10%)		4/50 (8%)	10/50 (20%)	
		2/50 (4%)	2/50 (4%)	3/50 (6%)		9/50 (18%)	10/50 (20%)	14/50 (28%)
verall Incidence	Total	14/300 (4.67%)	Mean 4.67%	SD 3.01%	Total	47/250 (18.8%)	Mean 18.8%	SD 7.16%
Clitoral/Preputial Gland: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/52 (22/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: 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%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Papilloma								
- -		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	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Ear: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Werall illustrate	i olai	0/300 (0%)	IVICALI U70	3D 0%	ı Olai	0/230 (0%)	IVICALI U%	3D 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 204

			Male				Female	
Esophagus: Fibrosarcoma								
		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%)
overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Esophagus: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Eye: Amelanotic Melanoma, I	Benign							
•	Ü	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Eye: Melanoma Benign			•••••			•••••		
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Eye: Melanoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 205

			Male				Female	
Eye:								
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%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
Harderian Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	- / / / / / / / / / /
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Harderian Gland: Carcinoma or Adenoma			•••••			•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Benign			•••••			•••••		
John Marine Domign		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Heart: Schwannoma Malignant								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (00/)
Normall Institutes	Tatal	0/50 (0%)	0/50 (0%)	1/50 (2%)	Tatal	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

Page: 206

Species: RATS Strain: F344 Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male	Female
Intestine Large: Colon/Red Adenoma	ctum:			
		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	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 0/250 (0%) Mean 0% SD 0%
Intestine Large: Colon/Red 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%)
verall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%) Mean 0% SD 0%
Intestine Large: Colon/Red Carcinoma or Adenoma				
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 0/250 (0%) Mean 0% SD 0%
Intestine Large: Colon/Red Hemangioma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 0/250 (0%) Mean 0% SD 0%
Intestine Small: Duodenur Carcinoma				
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
	-	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 0/250 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

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

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Duodenum: Leiomyoma								
,		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
	•••••	•••••						
#Intestine Small: Jejunum: Carcinoma							- / / / / / / / / / /	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/250 (0%)	0/30 (0%) Mean 0%	SD 0%
Overall incidence	TOtal	0/300 (0%)	Mean 0%	3D 0%	Total	0/250 (0%)	Mean 0%	3D 0%
#Intestine Small: Jejunum: Granular Cell Tumor Malig	ınant		•••••					
	,	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total		0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall incluence	Total	0/300 (0%)	iviean 0%	30 0%	I Ulai	0/250 (0%)	Weari 0%	30 0%
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall illelucites	i otai	0/300 (0/0)	IVICALI U/0	3D 0/0	iolai	0/200 (0/0)	IVICALI U/0	30 0/0

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

Page: 207

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 208

			Male				Female						
#Intestine Small: Site Unspecified: Carcinoma													
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%					
Intestine Small: Site Uns Carcinoma or Adenom					•••••		•••••						
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (004)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%					
fintestine Small: Site Uns Granular Cell Tumor N													
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)					
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%					
fIntestine Small: Site Uns Leiomyoma	pecified:												
,		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%					
Intestine Small: Site Uns Leiomyosarcoma													
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (001)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%					

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

^{#:} Denominator is number of animals necropsied

......

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 209

			Male				Female	
Islets, Pancreatic: Adenoma								
		1/50 (2%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	2/49 (4%)	0/40 (00/)
Second Head days	T-1-1	7/50 (14%)	3/50 (6%)	3/50 (6%)	T-1-1	0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	16/299 (5.35%)	Mean 5.34%	SD 4.67%	Total	2/245 (0.82%)	Mean 0.82%	SD 1.83%
Islets, Pancreatic: Carcinoma								
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/49 (0%)	2/12 (22/)
	-	0/50 (0%)	0/50 (0%)	1/50 (2%)	-	0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1.01%	SD 1.1%	Total	0/245 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Carcinoma or Adenoma						•••••		
		1/50 (2%)	2/50 (4%)	2/49 (4%)		0/50 (0%)	2/49 (4%)	
		7/50 (14%)	3/50 (6%)	4/50 (8%)		0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	19/299 (6.35%)	Mean 6.35%	SD 4.27%	Total	2/245 (0.82%)	Mean 0.82%	SD 1.83%
Kidney: Pelvis and Transition Carcinoma						•••••	•••••	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		1/50 (2%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/48 (0%)
verall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/242 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transition Carcinoma or Adenoma		m:						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	2442 (221)
		1/50 (2%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/242 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 210

			Male				Female	
Kidney: Pelvis and Transition Papilloma	al Epitheliui	m:						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	1/48 (2%)	0/48 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	1/242 (0.41%)	Mean 0.42%	SD 0.93%
Kidney: Renal Tubule: Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	2/12 (22/)
		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/242 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/48 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/242 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma			•••••		•••••			
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/48 (0%)
verall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/242 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	0/40 (00/)
Novell Incidence	Total	0/50 (0%)	0/48 (0%)	0/50 (0%)	Total	0/49 (0%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/242 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 211

			Male	Female
*Kidney: Renal Tubule: Lipoma		0/50 (00/)	0/50 (00/)	0/50 (00) 0/47 (00)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/48 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%) 0/49 (0%) 0/48 (0%) 0/48 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0% SD 0%	Total 0/242 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Liposarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/48 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	0/48 (0%) 0/50 (0%) Mean 0% SD 0%	Total 0/242 (0%)
Overall includince	Total	0/200 (0/0)	Wedit 070	10tal 0/242 (0/0) Wican 0/0 GD 0/0
*Kidney: Renal Tubule: Mesenchymal Tumor Benign				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%)
Overall Incidence	Total	0/50 (0%) 0/298 (0%)	0/48 (0%) 0/50 (0%) Mean 0% SD 0%	0/49 (0%) 0/48 (0%) 0/48 (0%) Total 0/242 (0%) Mean 0% SD 0%
		,		· ·
*Kidney: Renal Tubule: Nephroblastoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/48 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%) 0/49 (0%) 0/48 (0%) 0/48 (0%)
Overall Incidence	Total	0/50 (0%)	0/48 (0%) 0/50 (0%) Mean 0% SD 0%	0/49 (0%) 0/48 (0%) 0/48 (0%) Total 0/242 (0%) Mean 0% SD 0%
		,	Wedit 070	10tal 0/242 (0/0) Wican 0/0 05 0/0
*Kidney: Renal Tubule: Sarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%)
Overall Incidence	Total	0/50 (0%)	1/48 (2%) 0/50 (0%) Mean 0.35% SD 0.85%	1/49 (2%) 0/48 (0%) 0/48 (0%) Total 1/242 (0.41%) Mean 0.41% SD 0.91%
Overall incluence	Total	1/298 (0.34%)	Weatt 0.33% 3D 0.03%	Total 1/242 (0.41%) Mean 0.41% SD 0.91%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 212

			Male		Female
Liver:					
Cholangioma		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%)
overall Incidence	Total	2/300 (0.67%)	Mean 0.67% SD 1.03%	Total 0/250 (0%)	Mean 0% SD 0%
Liver:					
Hemangiosarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%)	Mean 0% SD 0%
Liver: Hepatocellular Adenoma					
		2/50 (4%)	1/50 (2%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
		1/50 (2%)	0/50 (0%) 3/50 (6%)	0/50 (0%)	0/50 (0%) 2/50 (4%)
Overall Incidence	Total	7/300 (2.33%)	Mean 2.33% SD 2.34%	Total 4/250 (1.6%)	Mean 1.6% SD 2.19%
Liver:					
Hepatocellular Carcinoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%)	Mean 0% SD 0%
Liver: Hepatocellular Carcinoma c					
riepatocenulai Carcillollia C	n nepatob	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%)	Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 213

			Male				Female	
Liver:								
Hepatocellular Carcinon	na or Hepatoce		(00)	0/=0 (00/)		0/=0 (00/)	0.700 (404)	
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (40/)
	-	1/50 (2%)	0/50 (0%)	3/50 (6%)	-	0/50 (0%)	0/50 (0%)	2/50 (4%)
verall Incidence	Total	7/300 (2.33%)	Mean 2.33%	SD 2.34%	Total	4/250 (1.6%)	Mean 1.6%	SD 2.19%
_iver:			•••••	•••••		•••••		
Hepatocellular Carcinon Hepatoblastoma	na, Hepatocell	ular Adenoma, or						
Пераговіазгоніа		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	
		1/50 (2%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	7/300 (2.33%)	Mean 2.33%	SD 2.34%	Total	4/250 (1.6%)	Mean 1.6%	SD 2.19%
Lung: Alveolar/Bronchiolar Ad	enoma							
7.1.100.101.7 E.		4/50 (8%)	0/50 (0%)	1/50 (2%)		4/50 (8%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	6/300 (2%)	Mean 2%	SD 3.1%	Total	6/250 (2.4%)	Mean 2.4%	SD 3.29%
Lung:	•••••					•••••		
Alveolar/Bronchiolar Ca	rcinoma							
		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%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Lung:	•••••						•••••	
Alveolar/Bronchiolar Ca	rcinoma or Alv	veolar/Bronchiolar						
Adenoma		4/50 (8%)	0/50 (0%)	1/50 (2%)		4/50 (8%)	1/50 (2%)	
		4/50 (8%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		4/50 (8%) 1/50 (2%)	0/50 (2%)	1/50 (2%)
Overall Incidence	Total	7/300 (2.33%)	Mean 2.33%	SD 2.94%		7/250 (2.8%)	Mean 2.8%	SD 3.03%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F344 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 214

			Male	Female
*Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% SD 0%
*Lung: Sarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%) Mean 0% SD 0%
*Lung: Squamous Cell Carcinoma				
·		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 0/250 (0%) Mean 0% SD 0%
#Lymph Node: 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%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%) Mean 0% SD 0%
#Lymph Node, Mesenteric: Sarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F344

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 215

			Male				Female	
Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	0/50 (00/)
	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	2/50 (4%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	5/250 (2%)	Mean 2%	SD 2%
Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	4/50 (00/)
	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	4/50 (8%)	2/50 (4%)	4/50 (8%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	10/250 (4%)	Mean 4%	SD 4%
Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		6/50 (12%)	2/50 (4%)	4/50 (8%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	15/250 (6%)	Mean 6%	SD 4%
Mammary Gland: Fibroadenoma								
1 101 0 0 0 0 1 1 1 1 1 1 1 1 1 1 1 1 1		2/50 (4%)	2/50 (4%)	0/50 (0%)		27/50 (54%)	29/50 (58%)	
		1/50 (2%)	3/50 (6%)	0/50 (0%)		30/50 (60%)	24/50 (48%)	28/50 (56%)
verall Incidence	Total	8/300 (2.67%)	Mean 2.67%	SD 2.42%	Total	138/250 (55.2%)	Mean 55.2%	SD 4.6%
Mammary Gland: Fibroma	•••••				•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Normall In all Invan	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 216

			Male				Female	
Mammary Gland:								
Fibroma, Fibroadenom	na or Adenoma	0/50 (404)	0/50 (40/)	4/50 (00/)		00/50 (500/)	00/50 (000/)	
		2/50 (4%)	2/50 (4%)	1/50 (2%)		28/50 (56%)	30/50 (60%)	00/50 /500/\
	-	1/50 (2%)	3/50 (6%)	0/50 (0%)	.	30/50 (60%)	24/50 (48%)	28/50 (56%)
verall Incidence	Total	9/300 (3%)	Mean 3%	SD 2.1%	Total	140/250 (56%)	Mean 56%	SD 4.9%
Mammary Gland:								
Fibroma, Fibroadenom	na, Carcinoma, o	or Adenoma						
		2/50 (4%)	2/50 (4%)	1/50 (2%)		28/50 (56%)	30/50 (60%)	00/00 /05::
		1/50 (2%)	3/50 (6%)	0/50 (0%)		31/50 (62%)	25/50 (50%)	28/50 (56%)
verall Incidence	Total	9/300 (3%)	Mean 3%	SD 2.1%	Total	142/250 (56.8%)	Mean 56.8%	SD 4.6%
Mesentery: Fibrosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Hemangiosarcoma								
		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	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
Mesentery: 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%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 217

			Male				Female	
Mesentery: Rhabdomyosarcoma		2/52 (224)	2(72)			2/22 (22)	2/22 (224)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50) (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	` ,	D 0%
Nose: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	(00/)
Overall Incidence	Total	0/50 (0%)	0/49 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%)	0/49 (0%) 0/50	` '
verali incidence	Total	0/299 (0%)	Mean 0%	3D 0%	Total	0/249 (0%)	Mean 0% S	D 0%
Nose: Chondroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	(00/)
No. 11 10 12 12 10 10 10	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/49 (0%) 0/50	()
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)		D 0%
Nose: Squamous Cell Carcinoma								
.,		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%) 0/50	()
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0% S	D 0%
			•••••					
Oral Cavity (Oral Mucosa, Tong Papilloma Squamous or Pag		nx, Tooth, Gingiva):						
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%) 0/50	` '
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.03%	Total	1/250 (0.4%)	Mean 0.4% S	D 0.89%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: FEED

Animal Groups Report Date:11/17/2008

Page: 218

Species: RATS Strain: F344

Length of Study: CHRONIC

			Male				Female	
#Oral Cavity (Oral Mucosa, Squamous Cell Carcino		nx, Tooth, Gingiva):						
·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
		•••••	•••••		• • • • • • • • • • • • • • • • • • • •		•••••	•••••
#Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		2/50 (4%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 1.51%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Oral Mucosa: Squamous Cell Carcino	ma	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Papillom	na							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
O	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor B	Renian			•••••				
C. analosa con Tullior B	y.,					0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence					Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 219

Report Date: 11/17/2008

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: **Granulosa Cell Tumor Malignant** 0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/50 2/50 (4%)**Overall Incidence** Total 2/250 (0.8%) Mean 0.8% SD 1.79% *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 2/50 (4%)**Overall Incidence** Total 2/250 (0.8%) Mean 0.8% SD 1.79% *Ovary: **Granulosa-Theca Tumor Benign** 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0.89% Total (0.4%)Mean 0.4% *Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Mean 0% SD 0% Total 0/250 **Tubulostromal Adenoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%)Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 220

			Male				Female	
Pancreas: Adenoma								
		0/50 (0%)	())/49 (0%)		0/50 (0%)	0/49 (0%)	
		0/50 (0%)	1/50 (2%) 2	2/50 (4%)		0/49 (0%)	0/49 (0%)	0/48 (0%)
verall Incidence	Total	3/298 (1.01%)	Mean 1%	SD 1.67%	Total	0/245 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma								
		0/50 (0%)	()	/49 (0%)		0/50 (0%)	0/49 (0%)	2/12 (22/)
		0/50 (0%)	` ')/50 (0%)		0/49 (0%)	0/49 (0%)	0/48 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma								•••••
		0/50 (0%)	()	/49 (0%)		0/50 (0%)	0/49 (0%)	
		0/50 (0%)	1/50 (2%) 2	2/50 (4%)		0/49 (0%)	0/49 (0%)	0/48 (0%)
verall Incidence	Total	3/298 (1.01%)	Mean 1%	SD 1.67%	Total	0/245 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Benign								
•		1/50 (2%)	0/49 (0%)	/49 (0%)		0/50 (0%)	0/49 (0%)	
		0/50 (0%)	0/50 (0%))/50 (0%)		0/49 (0%)	0/49 (0%)	0/48 (0%)
verall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/245 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Malignant								
		0/50 (0%)	()	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/40 (00/)
Second Head days	T-1-1	1/50 (2%)	` '	0/50 (0%)	T-1-1	0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/245 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 221 Report Date:11/17/2008

			Male				Female	
Parathyroid Gland: Adenoma								
		0/49 (0%)	1/45 (2%)	1/46 (2%)		0/47 (0%)	0/48 (0%)	
		0/49 (0%)	` ,	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	3/287 (1.05%)	Mean 1.08%	SD 1.18%	Total	0/243 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma Malignant								
_		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	` ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma: Benign, Mal	ignant, NOS	3						
		0/50 (0%)	` ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	` ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis Adenoma								
		10/50 (20%)	10/50 (20%)	20/50 (40%)		17/50 (34%)	24/49 (49%)	
		8/50 (16%)	16/49 (33%)	13/50 (26%)		25/50 (50%)	29/48 (60%)	20/50 (40%)
verall Incidence	Total	77/299 (25.75%)	Mean 25.78%	SD 9.08%	Total	115/247 (46.56%)	Mean 46.68%	SD 10.13%
Pituitary Gland: Pars Distalis Carcinoma								
		0/50 (0%)		0/50 (0%)		0/50 (0%)	1/49 (2%)	
		0/50 (0%)	` '	0/50 (0%)		0/50 (0%)	0/48 (0%)	1/50 (2%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/247 (0.81%)	Mean 0.81%	SD 1.11%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: FEED

Route: ORAL

Length of Study: CHRONIC

Male Female *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 10/50 (20%)10/50 (20%)20/50 (40%)(34%)(51%)8/50 (16%)16/49 (33%)13/50 (26%)25/50 (50%)29/48 (60%)21/50 (42%) 77/299 (25.75%) **Overall Incidence** Total Mean 25.78% SD 9.08% 117/247 (47.37%) Mean 47.49% SD 9.97% Total *Pituitary Gland: Pars Intermedia: Adenoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Mean 0.33% SD 0.82% 0/247 (0%) SD 0% Total 1/299 (0.33%) Total Mean 0% *Pituitary Gland: Pars Intermedia: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)(0%)0/50 (0%) 0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/299 (0%) Mean 0% Total 0/247 (0%) Mean 0% *Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)1/50 (2%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** 1/299 (0.33%) SD 0.82% SD 0% Total Mean 0.33% Total 0/247 (0%) Mean 0% *Prostate: Adenoma

0/50

0/50

.....

(0%)

(0%)

SD 0.82%

Total

0/49

1/50

1/299

(0%)

(2%)

(0.33%)

0/50

0/50

(0%)

(0%)

Mean 0.33%

Overall Incidence

Page: 222

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

			Male				Female	
*Prostate: Carcinoma or Adenoma		0/49 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%				
*Salivary Glands: Sarcoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/296 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall illeliderice	Total	0/290 (076)	Weatt 070	3D 0/0	Total	0/230 (0/8)	Weatt 076	3D 0%
*Salivary Glands: Schwannoma Malignant		1/49 (2%)	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%)	0/50 (0%)
Overall Incidence	Total	1/296 (0.34%)	Mean 0.34%	SD 0.83%	Total	0/250 (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%)				
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangioma		0/50 (00/)	0/50 (00)	0/50 (004)		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%)
Overall Incidence	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall includince	i otai	0/300 (0/0)	WICAIT 070	OD 070	i Otai	0/200 (0/0)	Wicall 070	3D 070

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 224

			Male				Female	
Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0 (70 (00))
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma					•••••	•••••		
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma or	Rhahdomyom	a	•••••		•••••	•••••		
Kilabaoliiyosarcollia or	itiiabaoiiiyoiii	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Sarcoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00)
Normall In airlands	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 225

			Male				Female	
Skin: Basal Cell Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.03%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	TOLAI	2/300 (0.67%)	ivieaii 0.07 /6	3D 1.0376	ı Olai	0/230 (0/8)	iviean 076	
≮Skin: Basal Cell Adenoma or I	Pacacauamau	s Tumor Ponian						
Dasai Celi Adelionia or i	basosquamou	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%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Adenoma, Ba Trichoepithelioma Overall Incidence	sosquamous [·] Total	Tumor Benign, or 0/50 (0%) 0/50 (0%) 2/300 (0.67%)	1/50 (2%) 1/50 (2%) Mean 0.67%	0/50 (0%) 0/50 (0%) SD 1.03%	Total	0/50 (0%) 1/50 (2%) 2/250 (0.8%)	0/50 (0%) 1/50 (2%) Mean 0.8%	0/50 (0%) SD 1.1%
	·····	2/300 (0.07/0)	ivicali 0.0770	1.0370		2/230 (0.076)	Mean 0.070	JD 1.176
tSkin: Basal Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma or NOS)	· Basosquamo	us Tumor (malignant o	r					
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	- / / / / / / / / / /
Overall Incidence	-	0/50 (0%)	0/50 (0%) Mean 0.33%	1/50 (2%) SD 0.82%	+	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	Total	1/300 (0.33%)	Maan (1990/		Total			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344 Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Skin: Basal Cell Carcinoma, Tumor (benign, maligna		Trichoepithelioma 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/22 (22)
verall Incidence	Total	0/50 (0%) 3/300 (1%)	1/50 (2%) Mean 1%	1/50 (2%) SD 1.1%	Total	1/50 (2%) 2/250 (0.8%)	1/50 (2%) Mean 0.8%	0/50 (0%) SD 1.1%
Skin: Basal or Sq. Cell Carcii or B), Basal Cell Adeno Papilloma, Keratoacant	ma, Adenoma,	Papilloma, Sq pithelioma 11/50 (22%)	4/50 (8%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	
Overall Incidence	Total	2/50 (4%) 27/300 (9%)	3/50 (6%) Mean 9%	6/50 (12%) SD 7.24%	Total	1/50 (2%) 7/250 (2.8%)	2/50 (4%) Mean 2.8%	1/50 (2%) SD 2.28%
		277000 (070)	Widaii 570	OD 1.2470		17200 (2.070)	Wicari 2.070	OD 2.2070
Skin: Fibroma		F/F0 (400())	4/50 (00/)	4/50 (00)		0/50 (00/)	0/50 (00)	
		5/50 (10%) 5/50 (10%)	4/50 (8%) 8/50 (16%)	1/50 (2%) 3/50 (6%)		3/50 (6%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	1/50 (2%)
verall Incidence	Total	26/300 (8.67%)	Mean 8.67%	SD 4.68%	Total	6/250 (2.4%)	Mean 2.4%	SD 2.19%
Skin: Fibroma, Fibrosarcoma Fibrous Histiocytoma	ı, Sarcoma, My	xoma, Myxosarcoma, or	4/50 (8%)	4/50 (8%)		4/50 (8%)	0/50 (0%)	
		5/50 (12%)	8/50 (16%)	4/50 (8%)		3/50 (6%)	1/50 (2%)	1/50 (2%)
verall Incidence	Total	31/300 (10.33%)	Mean 10.33%	SD 3.2%	Total	9/250 (3.6%)	Mean 3.6%	SD 3.29%
Skin: Fibrosarcoma								
		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%)	1/50 (2%)
		U/5U (U%)	U/3U (U%)	U/5U (U%)		U/5U (U%)	U/5U (U%)	1/50 (2%)

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Male Female #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma (2%)(6%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)0/50 (0%)1/50 (2%)SD 2.34% Mean 1.6% SD 1.67% Overall Incidence Total 5/300 (1.67%) Mean 1.67% Total 4/250 (1.6%) #Skin: **Fibrous Histiocytoma** 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)SD 0.82% SD 0% **Overall Incidence** Total 1/300 (0.33%) Mean 0.33% Total 0/250 (0%) Mean 0% #Skin: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% 0/250 (0%) Mean 0% SD 0% Total #Skin: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)(0%)0/50 0/50 (0%)0/50 0/50 (0%)SD 0% SD 0% **Overall Incidence** Total 0/300 (0%) Mean 0% Total 0/250 (0%) Mean 0% #Skin: Keratoacanthoma 10/50 (20%)3/50 1/50 (2%)(6%)0/50 (0%)(0%)2/50 (4%)1/50 (2%)4/50 (8%) 0/50 (0%)0/50 0/50 (0%) **Overall Incidence** Total 21/300 (7%) Mean 7% SD 6.78% Total 3/250 (1.2%) Mean 1.2% SD 2.68%

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Page: 227

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 228

			Male		Female
Skin:					
Lipoma		0/50 (0%)	0/50 (0%) 1/50 (2	2%) 0/50 (0%	%) 0/50 (0%)
		1/50 (2%)		2%) 0/50 (0%	
verall Incidence	Total	3/300 (1%)	Mean 1% SD 1.1	% Total 0/250 (0%)	Mean 0% SD 0%
Skin:					
Liposarcoma		0/50 (0%)	0/50 (0%) 0/50 (0	0%) 0/50 (0%	%) 0/50 (0%)
		0/50 (0%)		0%) 0/50 (0%)	, , ,
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%)	Mean 0% SD 0%
#Skin: Neural Crest Tumor					
		0/50 (0%)	` ,	0%) 0/50 (0%	, , ,
		0/50 (0%)	` ,	0%) 1/50 (2%	, , , , , , , , , , , , , , , , , , , ,
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.8	2% Total 1/250 (0.4%)) Mean 0.4% SD 0.89%
Skin: Neural Crest Tumor, M	alianant				
Neural Orest Tullion, III	angnant	0/50 (0%)	0/50 (0%) 0/50 (0	0%) 0/50 (0%	%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 1/50 (2	2%) 0/50 (0%	%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.8	(111)	Mean 0% SD 0%
Skin: Neurofibroma or Schw					
		0/50 (0%)		0%) 0/50 (0%)	, , ,
Normall In addange	Tatal	0/50 (0%)	` ,	0%) 0/50 (0%) 7-4-1 0/250 (0%)	, , , , , , , , , , , , , , , , , , , ,
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%)	Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 229
Report Date:11/17/2008

Species: RATS Strain: F344 Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Skin:								
Neurofibrosarcoma or So	chwannoma (i	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Neu malignant or NOS)	rofibroma, or	Schwannoma (benign,						
manghant of Noo,		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Osteosarcoma		4/50 (004)	0/50 (00/)	0(50 (00))		0(50 (004)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin:								
Sarcoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.03%	Total	2/50 (4%) 2/250 (0.8%)	0/50 (0%) Mean 0.8%	0/50 (0%) SD 1.79%
#Skin: Schwannoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

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Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 230

			Male				Female	
#Skin: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Carcinom	 ıa							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	4/50 (00/)
verall Incidence	Total	0/50 (0%) 2/300 (0.67%)	1/50 (2%) Mean 0.67%	1/50 (2%) SD 1.03%	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	1/50 (2%) SD 0.89%
verall incluence	Total	2/300 (0.67%)	Weatt 0.07%	3D 1.03%	TOtal	1/230 (0.4%)	Wealt 0.4%	3D 0.09%
Squamous Cell Carcinom Basosquamous Tumor (m verall Incidence			0/50 (0%) 1/50 (2%) Mean 1%	0/50 (0%) 2/50 (4%) SD 1.67%	Tatal	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
		3/300 (1%)	Wican 170		Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
		······			i otal			SD 0.69%
Skin: Squamous Cell Papilloma	a	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Skin: Squamous Cell Papilloma		1/50 (2%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	
Skin: Squamous Cell Papilloma overall Incidence	a Total	1/50 (2%) 0/50 (0%) 2/300 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67%	0/50 (0%) 1/50 (2%) SD 1.03%		0/50 (0%) 0/50 (0%) 1/250 (0.4%)	0/50 (0%) 1/50 (2%) Mean 0.4%	0/50 (0%)
Skin: Squamous Cell Papilloma Overall Incidence Skin:	a Total	1/50 (2%) 0/50 (0%) 2/300 (0.67%)	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%)

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

ed Control Animal Groups

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Report Date:11/17/2008

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Squamous Cell Papillo Carcinoma or Keratoac		Squamous Cell						
		11/50 (22%)	3/50 (6%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	4/50 (00/)
Overall Incidence	Total	2/50 (4%) 25/300 (8.33%)	2/50 (4%) Mean 8.33%	6/50 (12%) SD 7.53%	Total	0/50 (0%) 5/250 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 2.45%
#Skin:								
Squamous Cell Papillo	ma, Papilloma,	or Keratoacanthoma 11/50 (22%) 2/50 (4%)	3/50 (6%) 1/50 (2%)	1/50 (2%) 5/50 (10%)		3/50 (6%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	23/300 (7.67%)	Mean 7.67%	SD 7.63%	Total	4/250 (1.6%)	Mean 1.6%	SD 2.61%
#Skin: Trichoepithelioma	•••••							
•		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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
#Skin: Sebaceous Gland: Adenoma	•••••	(201)	(00)	0.50			(201)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0.50
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Our well by all laws a	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Malignant								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Spinal Cord: Glioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Spleen: Fibrosarcoma		0/50 (00/)	0/50 (00/)	0/40 (00/)		0/40 (00/)	0/50 (00/)	
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
TVEI all illuluellue	TULAI	0/290 (0%)	IVICALI U70	SD 0%	i Ulai	0/24/ (0%)	IVICALI U70	3D 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 233

			Male		Female	
Spleen: Fibrous Histiocytoma						
r izrodo monocytoma		0/50 (0%)	0/50 (0%) 0/49	(0%)	0/49 (0%) 0/50 (0%)	
		1/49 (2%)	0/50 (0%) 0/50	(0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/298 (0.34%)		0.83% Total	0/247 (0%) Mean 0%	SD 0%
Spleen: Hemangioma						
_		0/50 (0%)	0/50 (0%) 0/49	(0%)	0/49 (0%) 0/50 (0%)	0/40 /00/
		0/49 (0%)	0/50 (0%) 0/50	(0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0% SD	0% Total	0/247 (0%) Mean 0%	SD 0%
Spleen: Hemangiosarcoma						
•		0/50 (0%)	1/50 (2%) 0/49	(0%)	0/49 (0%) 0/50 (0%)	
		0/49 (0%)	0/50 (0%) 0/50	(0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/298 (0.34%)		0.82% Total	0/247 (0%) Mean 0%	SD 0%
Spleen: Leiomyosarcoma						
•		0/50 (0%)	1/50 (2%) 0/49	(0%)	0/49 (0%) 0/50 (0%)	
		0/49 (0%)	0/50 (0%) 0/50	(0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/298 (0.34%)	Mean 0.33% SD	0.82% Total	0/247 (0%) Mean 0%	SD 0%
Spleen: Sarcoma						
		0/50 (0%)	0/50 (0%) 0/49	(0%)	0/49 (0%) 0/50 (0%)	0/40 (00%)
Normall In all Inner	T-1-1	0/49 (0%)	0/50 (0%) 0/50	(0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0% SD	0% Total	0/247 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 234

			Male		Female	
Stomach, Forestomach: Leiomyosarcoma						
•		0/50 (0%)	0/50 (0%) 1/5	- ()	0/50 (0%) 0/50 (0%)	
Normall In all Invan	T-1-1	0/50 (0%)	0/50 (0%) 0/5	` '	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82% Total	l 0/250 (0%) Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma						
-		0/50 (0%)	0/50 (0%) 0/5		0/50 (0%) 0/50 (0%)	2 (22 (22 (22 (22 (22 (22 (22 (22 (22 (
		0/50 (0%)	0/50 (0%) 0/5	` '	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0% Total	I 0/250 (0%) Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma c	or Papillon	na Squamous 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5 0/50 (0%) 0/5	` ,	0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	` /	SD 0% Total	, , , , , , , , , , , , , , , , , , , ,	SD 0.89%
Stomach, Forestomach: Squamous Cell Papilloma						
		0/50 (0%)	0/50 (0%) 0/5	` ,	0/50 (0%) 0/50 (0%)	0/50 (00/)
	-	0/50 (0%)	0/50 (0%) 0/5	` '	1/50 (2%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)		SD 0% Total		SD 0.89%
Stomach, Glandular: Leiomyosarcoma						
		0/50 (0%)	0/50 (0%) 0/5	- ()	0/50 (0%) 0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) 0/5	` '	0/50 (0%) 0/50 (0%) I 0/250 (0%) Mean 0%	0/50 (0%)
	LOtal	0/300 (0%)	Mean 0%	SD 0% Total	1 1/250 //10/1 N/1000 /10/	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344 Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Stomach, Glandular: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		` ,				` ,		
*Testes: Adenoma								
		45/50 (90%)	46/50 (92%)	49/50 (98%)				
Overall Incidence	Total	42/50 (84%) 274/300 (91.33%)	46/50 (92%) Mean 91.33%	46/50 (92%) SD 4.5%				
Overall molacines		,						
*Thymus: Sarcoma								
		0/48 (0%)	0/48 (0%)	0/47 (0%)		0/50 (0%)	0/46 (0%)	
O	T-1-1	0/48 (0%)	0/48 (0%)	0/41 (0%)	T-1-1	0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence	Total	0/280 (0%)	Mean 0%	SD 0%	Total	0/242 (0%)	Mean 0%	SD 0%
*Thymus:		•••••						•••••
Thymoma Benign		0/48 (0%)	0/48 (0%)	0/47 (0%)		0/50 (0%)	0/46 (0%)	
		1/48 (2%)	0/48 (0%)	0/41 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence	Total	1/280 (0.36%)	Mean 0.35%	SD 0.85%	Total	0/242 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
		0/48 (0%) 0/48 (0%)	0/48 (0%) 0/48 (0%)	0/47 (0%) 0/41 (0%)		0/50 (0%) 0/49 (0%)	0/46 (0%) 0/47 (0%)	0/50 (0%)
Overall Incidence	Total	()	` '	` '	Total	` ,	` '	` ,
Overall Incidence	Total	0/280 (0%)	Mean 0%	SD 0%	Total	0/242 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 236

			Male				Female	
Thymus:								
Thymoma: Benign, Malignan	it, NOS	0/40 (00/)	0/40 /00/)	0/47 (00/)		0/50 (00/)	0/46 (00/)	
		0/48 (0%) 1/48 (2%)	0/48 (0%) 0/48 (0%)	0/47 (0%) 0/41 (0%)		0/50 (0%) 0/49 (0%)	0/46 (0%) 0/47 (0%)	0/50 (0%)
Overall Incidence	Total	1/280 (0.36%)	Mean 0.35%	SD 0.85%	Total	0/49 (0%)	Mean 0%	SD 0%
verali ilicidence		,				,		
Thyroid Gland: C-Cell: Adenoma								
		10/50 (20%)	5/50 (10%)	6/50 (12%)		4/50 (8%)	3/49 (6%)	
		7/50 (14%)	11/47 (23%)	5/48 (10%)		4/50 (8%)	10/47 (21%)	2/47 (4%)
Overall Incidence	Total	44/295 (14.92%)	Mean 14.97%	SD 5.51%	Total	23/243 (9.47%)	Mean 9.53%	SD 6.75%
Thyroid Gland: C-Cell: Carcinoma		1/50 (2%) 1/50 (2%)	4/50 (8%) 0/47 (0%)	1/50 (2%) 1/48 (2%)	T . /	0/50 (0%) 1/50 (2%)	1/49 (2%) 1/47 (2%)	0/47 (0%)
Overall Incidence	Total	8/295 (2.71%)	Mean 2.68%	SD 2.73%	Total	3/243 (1.23%)	Mean 1.23%	SD 1.13%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		11/50 (22%)	9/50 (18%)	7/50 (14%)		4/50 (8%)	4/49 (8%)	
		8/50 (16%)	11/47 (23%)	6/48 (13%)		5/50 (10%)	11/47 (23%)	2/47 (4%)
Overall Incidence	Total	52/295 (17.63%)	Mean 17.65%	SD 4.35%	Total	26/243 (10.7%)	Mean 10.76%	SD 7.37%
Thyroid Gland: Follicular Cell: Adenoma								
		2/50 (4%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	
		0/50 (0%)	0/47 (0%)	0/48 (0%)		0/50 (0%)	2/47 (4%)	0/47 (0%)
Overall Incidence	Total	4/295 (1.36%)	Mean 1.33%	SD 2.07%	Total	2/243 (0.82%)	Mean 0.85%	SD 1.9%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Page: 237

Report Date:11/17/2008

Strain: F344
Length of Study: CHRONIC

Male

			Male			Female
*Thyroid Gland: Follicular Cell: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/50 (0%) 0/295 (0%)	0/47 (0%) Mean 0%	0/48 (0%) SD 0%	0/50 (0%) Total 1/243 (0.41%)	0/47 (0%) 1/47 (2%) Mean 0.43% SD 0.95%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma						
		2/50 (4%) 0/50 (0%)	2/50 (4%) 0/47 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 2/47 (4%) 1/47 (2%)
Overall Incidence	Total	4/295 (1.36%)	Mean 1.33%	SD 2.07%	Total 3/243 (1.23%)	Mean 1.28% SD 1.9%
#Tissue NOS: Lipoma						
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total 0/250 (0%)	Mean 0% SD 0%
#Tissue NOS:	•••••					
Paraganglioma		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	1/50 (2%) SD 0.82%	0/50 (0%) Total 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total 1/250 (0.4%)	Mean 0.4% SD 0.89%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 238

			Male				Female	
Tongue: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
	.	0/50 (0%)	0/50 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Tongue:								
Squamous Cell Carcinoma	or Papillon		4/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	
		1/50 (2%) 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%)
Overall Incidence	Total	4/300 (1.33%)	0/50 (0%) Mean 1.33%	SD 1.03%	Total	1/250 (0.4%)	0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%
verali ilicidence	ı olal	4/300 (1.3376)	IVICALI 1.3376		ı Olai	1/250 (0.476)	ivicaii 0.476	3D 0.8976
Tongue: Squamous Cell Papilloma								
- 4		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.03%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Tooth:	•••••							
Adamantinoma Malignant		0/=0 (00/)	2/22 (22/)	2 (22 (22 (22 (22 (22 (22 (22 (22 (22 (0.770 (00.1)	2/52 (22/)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
brandl looklanes	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Tooth: Odontoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 239

			Male		Fema	le
*Urinary Bladder: Carcinoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 0/49 (0%) 0/50	(0%) (0%)	0/50 (0%) 0/50 0/50 (0%) 0/49	(0%) (0%) 0/50 (0%)
Overall Incidence	Total	0/298 (0%)	,	0% Total	0/249 (0%) Mean	` '
*Urinary Bladder: Carcinoma or Papilloma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 0/49 (0%) 0/50	(2%) (0%)	0/50 (0%) 0/50 0/50 (0%) 0/49	(0%) (0%) 0/50 (0%)
Overall Incidence	Total	1/298 (0.34%)	` ,	0.83% Total	0/249 (0%) Mean	` '
*Urinary Bladder: Leiomyosarcoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 0/49 (0%) 0/50	(0%) (0%)	0/50 (0%) 0/50 0/50 (0%) 0/49	(0%) (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	, ,	0% Total	0/249 (0%) Mean	` '
*Urinary Bladder: Papilloma						
		0/50 (0%)	0/50 (0%) 1/49	(2%)		(0%)
Overall Incidence	Total	0/50 (0%) 1/298 (0.34%)	0/49 (0%) 0/50 Mean 0.34% SD	(0%) 0.83% Total	0/50 (0%) 0/49 0/249 (0%) Mean	(0%) 0/50 (0%) 0% SD 0%
#Uterus: Adenoma						
, asilolila					0/50 (0%) 0/50 0/50 (0%) 0/50	(0%) (0%) 1/50 (2%)
Overall Incidence				Total	` ,	(0%) 1/50 (2%) 0.4% SD 0.89%

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

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 240

0/50

0/50

0/50

0/250

Total

(0%)

(0%)

(0%)

(0%)

Mean 0%

0/50

SD 0%

(0%)

Report Date: 11/17/2008

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Carcinoma 0/50 (0%)0/50 (0%)(0%) (0%) (0%) 0/50 0/50 0/50 **Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% #Uterus: Deciduoma Benign 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% #Uterus: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/250 Mean 0% **#Uterus:** Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/250 (0%) Mean 0% SD 0% Total **#Uterus:** Leiomyoma

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 241

	ale		Female	
Jterus:				
Leiomyosarcoma		0/50 (0%)	0/50 (0%)	
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Jterus:				
Polyp Stromal		6/50 (12%)	10/50 (20%)	
		14/50 (28%)	16/50 (32%)	10/50 (20%)
verall Incidence	Total	56/250 (22.4%)	Mean 22.4%	SD 7.8%
Jterus:				
Sarcoma Stromal		0/50 (00/)	0/50 (00/)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Jterus: Sarcoma Stromal or Polyp Stromal				
Sarsonia Sasinar of Folyp Sasinar		6/50 (12%)	10/50 (20%)	
		14/50 (28%)	17/50 (34%)	10/50 (20%)
verall Incidence	Total	57/250 (22.8%)	Mean 22.8%	SD 8.44%
Manua.				
Jterus: Schwannoma Malignant				
amanananan		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

ontrol Animal Groups Report Date:11/17/2008

Page: 242

			Male				Female	
#Vagina: Polyp						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Vagina: Sarcoma	•••••					0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Carcinoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%) 4/300 (1.33%)	3/50 (6%) Mean 1.33%	0/50 (0%) SD 2.42%	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%
#Zymbal's Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%) 4/300 (1.33%)	3/50 (6%) Mean 1.33%	0/50 (0%) SD 2.42%	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 243

Report Date:11/17/2008

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
				Ma	ale		
Southern Research Institute Southern Research Institute Southern Research Institute Southern Research Institute	052011407 059601905 059601705 059601505	10/02/02 09/26/01 03/08/00 09/05/01	730 729 729 729	50 (3) 50 (3) 50 (3) 50 (3)	28(696) 31(686) 34(683) 31(692)	532.4 526.0 522.9 507.8	Sodium dichromate dihydrate (VI) Water disinfection byproducts (Bromochloroacetic acid) Water disinfection byproducts (Dibromoacetic acid) Water disinfection byproducts (Dibromoacetonitrile)
				Fen	nale		
Southern Research Institute Southern Research Institute Southern Research Institute Southern Research Institute	052011407 059601905 059601705 059601505	10/02/02 09/26/01 03/08/00 09/05/01	735 731 734 734	50 (5) 50 (5) 50 (5) 50 (5)	33(700) 34(688) 35(693) 29(689)	351.2 357.3 350.5 337.6	Sodium dichromate dihydrate (VI) Water disinfection byproducts (Bromochloroacetic acid) Water disinfection byproducts (Dibromoacetic acid) Water disinfection byproducts (Dibromoacetonitrile)

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#All Organs: Benign Tumors								
ŭ		49/50 (98%) 50/50 (100%)	50/50 (100%)	47/50 (94%)		47/50 (94%) 44/50 (88%)	49/50 (98%)	42/50 (84%)
Overall Incidence	Total	196/200 (98%)	Mean 98%	SD 2.83%	Total	182/200 (91%)	Mean 91%	SD 6.22%
#All Organs: Malignant Tumors							•••••	
-		29/50 (58%) 27/50 (54%)	27/50 (54%)	29/50 (58%)		20/50 (40%) 20/50 (40%)	18/50 (36%)	16/50 (32%)
Overall Incidence	Total	112/200 (56%)	Mean 56%	SD 2.31%	Total	74/200 (37%)	Mean 37%	SD 3.83%
#All Organs: Malignant and Benign To								
		50/50 (100%) 50/50 (100%)	50/50 (100%)	50/50 (100%)		49/50 (98%) 48/50 (96%)	49/50 (98%)	45/50 (90%)
Overall Incidence	Total	200/200 (100%)	Mean 100%	SD 0%	Total	191/200 (95.5%)	Mean 95.5%	SD 3.79%
#All Organs: Hemangioma							•••••	•••••
•		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

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Report Date:11/17/2008

Strain: F344 Vehicle: WATER Length of Study: CHRONIC

		Male				Female	
mangioma	4/50 (004)	0/50 (00/)	4/50 (00/)		0/50 (00/)	2/52 (224)	0/50 (00/)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)
Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
				•••••			
	0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Total	2/200 (1%)	Mean 1%	SD 2%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
			•••••	•••••			
	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Monocytic, N	lononuclear, or			•••••			
	26/50 (52%) 21/50 (42%)	21/50 (42%)	17/50 (34%)		8/50 (16%) 14/50 (28%)	15/50 (30%)	11/50 (22%)
Total	85/200 (42.5%)	Mean 42.5%	SD 7.37%	Total	48/200 (24%)	Mean 24%	SD 6.32%
	mphocytic, Mixed, NOS,			•••••			
, r -	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
	Total Total Monocytic, N Total stiocytic, Lyrype	1/50 (2%) 0/50 (0%) Total 2/200 (1%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 2/200 (1%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/200 (0%) Monocytic, Mononuclear, or 26/50 (52%) 21/50 (42%) Total 85/200 (42.5%) stiocytic, Lymphocytic, Mixed, NOS, ype 0/50 (0%) 0/50 (0%)	Total 2/200 (1%) Mean 1% 0/50 (0%) Total 2/200 (1%) Mean 1% 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 1% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 1% 0/50 (0%) 0/50 (0%) Mean 0% Monocytic, Mononuclear, or 26/50 (52%) 21/50 (42%) Total 85/200 (42.5%) Mean 42.5% stiocytic, Lymphocytic, Mixed, NOS, ype 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Total 2/200 (1%) Mean 1% SD 1.15% 0/50 (0%)	Total 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) Total 2/200 (1%) Mean 1% SD 1.15% Total 1.15% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 2/200 (1%) Mean 1% SD 2% Total 1.15% Total 0/50 (0%) 0/50 (0%) Mean 1% SD 2% Total 0/50 (0%) Mean 0% SD 0% Total 1.15% Total 0/200 (0%) Mean 0% SD 0% Total 1.15% Total 1.15% SD 7.37% Total 1.15% SD 7.37% Total 1.15% Stiocytic, Lymphocytic, Mixed, NOS, type 0/50 (0%) 0/50	Managioma	Total 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 1/50

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F344 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 246

			Male				Female	
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%)	0/30 (0 /0)	0/30 (0/8)		0/50 (0%)	0/30 (0 /8)	0/30 (0/8)
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Benign, Mal								
moodmonan zamgn, mar	.g.iaiit, itot	2/50 (4%) 0/50 (0%)	1/50 (2%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2.58%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Malignant	•••••							
		2/50 (4%) 0/50 (0%)	1/50 (2%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2.58%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteoma		•••••	•••••			•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: 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%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 247

			Male				Female	
#All Organs: Osteosarcoma or Osteo	ma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Adrenal Cortex: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%
*Adrenal Cortex: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Ganglioneuroma								
3		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Hemangioma	•••••							
. J		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344 Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Adrenal Medulla: Pheochromocytoma Ben	ian							
i necomonicoytema Ben	.9	6/49 (12%) 10/50 (20%)	9/50 (18%)	7/49 (14%)		2/49 (4%) 1/49 (2%)	2/49 (4%)	1/49 (2%)
verall Incidence	Total	32/198 (16.16%)	Mean 16.13%	SD 3.51%	Total	6/196 (3.06%)	Mean 3.06%	SD 1.18%
drenal Medulla: Pheochromocytoma Con			•••••			•••••	•••••	
·		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Mali	ignant				•••••			
•		1/49 (2%) 0/50 (0%)	1/50 (2%)	0/49 (0%)		1/49 (2%) 0/49 (0%)	2/49 (4%)	0/49 (0%)
verall Incidence	Total	2/198 (1.01%)	Mean 1.01%	SD 1.17%	Total	3/196 (1.53%)	Mean 1.53%	SD 1.95%
drenal Medulla: Pheochromocytoma: Ber		x, Malignant, NOS	•••••				•••••	
		7/49 (14%) 10/50 (20%)	10/50 (20%)	7/49 (14%)		3/49 (6%) 1/49 (2%)	4/49 (8%)	1/49 (2%)
verall Incidence	Total	34/198 (17.17%)	Mean 17.14%	SD 3.3%	Total	9/196 (4.59%)	Mean 4.59%	SD 3.06%
Bone: Chondrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

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

^{#:} Denominator is number of animals necropsied

47 1 411 1

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 249

			Male				Female	
Bone: Chondrosarcoma or Chondr	oma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Bone: Chordoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma	• • • • • • • • • • • • • • • • • • • •			•••••		•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Bone: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

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

^{#:} Denominator is number of animals necropsied

4. 4. 1. 4.1.1.1.

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 250

			Male				Female	
Brain: Astrocytoma Malignant		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Ependymoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/00 (0/0)	0/00 (0/0)		0/50 (0%)	0/00 (0/0)	0/00 (0/0)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Glioma Malignant								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Benig								
		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	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 251

			Male				Female	
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%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/30 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Brain: Meningioma: Benign, Mali	gnant, NOS	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Brain: Oligodendroglioma Benig	n	0/50 (00)	0/50 (004)	0/50 (00/)		0/50 (00/)	0/50 (004)	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%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Maligr		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	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 252

			Male				Female	
*Brain: Oligodendroglioma, Glion	na. or Astroc	evtoma						
	,	0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: 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%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma		•••••	•••••					•••••
		4/50 (8%) 1/48 (2%)	4/50 (8%)	3/50 (6%)		2/50 (4%) 5/50 (10%)	17/50 (34%)	8/50 (16%)
Overall Incidence	Total	12/198 (6.06%)	Mean 6.02%	SD 2.79%	Total	32/200 (16%)	Mean 16%	SD 12.96%
*Clitoral/Preputial Gland: Carcinoma				•••••				•••••
		1/50 (2%) 0/48 (0%)	2/50 (4%)	0/50 (0%)		8/50 (16%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/198 (1.52%)	Mean 1.5%	SD 1.91%	Total	10/200 (5%)	Mean 5%	SD 7.39%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F344 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 253

			Male				Female	
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		4/50 (8%) 1/48 (2%)	5/50 (10%)	3/50 (6%)		10/50 (20%) 6/50 (12%)	17/50 (34%)	9/50 (18%)
Overall Incidence	Total	13/198 (6.57%)	Mean 6.52%	SD 3.38%	Total	42/200 (21%)	Mean 21%	SD 9.31%
Clitoral/Preputial Gland: Fibrosarcoma			•••••	•••••				
		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Sarcoma					•••••			
		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Papilloma					•••••			
		0/50 (0%) 0/48 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Ear: Neural Crest Tumor	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 254

			Male				Female	
#Esophagus: Fibrosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Esophagus: Lipoma		2/22 (22)	(20)	(201)		0.000	(00)	0/20 (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%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Eye: Amelanotic Melanoma	Benign							
	.	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Eye: Melanoma Benign								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories Species: RATS

Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 255

			Male				Female	
#Eye: Schwannoma Malignant								
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Harderian Gland: Carcinoma							•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Harderian Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Benign							•••••	
_		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Heart: Schwannoma 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%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 256

			Male				Female	
fIntestine Large: Colon/Rectun Adenoma	n:							
		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	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Large: Colon/Rectun Carcinoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
fIntestine Large: Colon/Rectun Carcinoma or Adenoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Intestine Large: Colon/Rectun 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%)
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female	
fIntestine Small: Duodenum: Leiomyoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Intestine Small: Jejunum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Granular Cell Tumor Maligr								•••••
J		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

31011.11012000

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 258

			Male				Female	
Intestine Small: Site Uns Carcinoma	pecified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Site Uns Carcinoma or Adenom	pecified:		•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Granular Cell Tumor N		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Site Uns								
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Intestine Small: Site Uns Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 259

			Male				Female	
Islets, Pancreatic: Adenoma								
		4/50 (8%) 5/49 (10%)	3/50 (6%)	5/48 (10%)		2/50 (4%) 1/50 (2%)	3/49 (6%)	0/47 (0%)
Overall Incidence	Total	17/197 (8.63%)	Mean 8.66%	SD 2.08%	Total	6/196 (3.06%)	Mean 3.03%	SD 2.63%
Islets, Pancreatic: Carcinoma					•••••			
		0/50 (0%) 1/49 (2%)	2/50 (4%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/47 (0%)
Overall Incidence	Total	3/197 (1.52%)	Mean 1.51%	SD 1.92%	Total	0/196 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Carcinoma or Adenoma	•••••				•••••			
		4/50 (8%) 6/49 (12%)	5/50 (10%)	5/48 (10%)		2/50 (4%) 1/50 (2%)	3/49 (6%)	0/47 (0%)
Overall Incidence	Total	20/197 (10.15%)	Mean 10.17%	SD 1.74%	Total	6/196 (3.06%)	Mean 3.03%	SD 2.63%
Kidney: Pelvis and Transition Carcinoma					•••••			
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transition Carcinoma or Adenoma					•••••			
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Kidney: Pelvis and Transition	al Epitheliur	m:						
•		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Adenoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Kidney: Renal Tubule: Hemangiosarcoma					• • • • • • • • • • • • • • • • • • • •			
3		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

Page: 260

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Kidney: Renal Tubule: Lipoma								
•		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Liposarcoma				•••••				
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Mesenchymal Tumor Benign					•••••			
, a a a a		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
(idney: Renal Tubule: Nephroblastoma								
•		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Sarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

Page: 261

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 262

			Male				Female	
Liver: Cholangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenoma	• • • • • • • • • • • • • • • • • • • •							
•		0/50 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
Liver: Hepatocellular Carcinoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinoma o		lastoma						
		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	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

31011: 11012000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 263

			Male				Female	
Liver:								
Hepatocellular Carcino	oma or Hepatoce	0/50 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
Liver: Hepatocellular Carcino Hepatoblastoma	oma, Hepatocell	ular Adenoma, or						
		0/50 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
₋ung: Alveolar/Bronchiolar A	Adenoma							
		4/50 (8%) 3/50 (6%)	2/50 (4%)	2/50 (4%)		4/50 (8%) 1/50 (2%)	1/50 (2%)	1/50 (2%)
verall Incidence	Total	11/200 (5.5%)	Mean 5.5%	SD 1.91%	Total	7/200 (3.5%)	Mean 3.5%	SD 3%
Lung: Alveolar/Bronchiolar C	Carcinoma							
		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Lung: Alveolar/Bronchiolar C Adenoma								
		4/50 (8%) 4/50 (8%)	3/50 (6%)	2/50 (4%)		4/50 (8%) 1/50 (2%)	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	13/200 (6.5%)	Mean 6.5%	SD 1.91%	Total	8/200 (4%)	Mean 4%	SD 2.83%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 264

			Male				Female	
*Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/30 (0 /8)	0/30 (0 /8)		0/50 (0%)	0/30 (0 /8)	0/30 (0 /8)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Lung: Squamous Cell Carcinoma					•••••			
.,,		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma					•••••			
3		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Sarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

5131011. NOV2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 265

			Male				Female	
Mammary Gland: Adenoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (/0/)	0/50 (00/)	0/50 /00/
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%
Mammary Gland: Carcinoma	•••••				• • • • • • • • • • • • • • • • • • • •			
		1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 2/50 (4%)	1/50 (2%)	3/50 (6%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	6/200 (3%)	Mean 3%	SD 2.58%
Mammary Gland: Carcinoma or Adenoma					• • • • • • • • • • • • • • • • • • • •			
		1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%) 2/50 (4%)	1/50 (2%)	3/50 (6%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	8/200 (4%)	Mean 4%	SD 1.63%
Mammary Gland: Fibroadenoma	•••••				•••••			
		2/50 (4%) 6/50 (12%)	3/50 (6%)	4/50 (8%)		37/50 (74%) 31/50 (62%)	43/50 (86%)	32/50 (64%)
Overall Incidence	Total	15/200 (7.5%)	Mean 7.5%	SD 3.42%	Total	143/200 (71.5%)	Mean 71.5%	SD 11%
Mammary Gland: Fibroma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 266

			Male				Female	
Mammary Gland:								
Fibroma, Fibroadenoma	or Adenoma	2/50 (40/)	2/50 (60/)	4/EO (00/)		27/50 /740/)	42/50 (060/)	20/50 (640/)
		2/50 (4%) 6/50 (12%)	3/50 (6%)	4/50 (8%)		37/50 (74%) 31/50 (62%)	43/50 (86%)	32/50 (64%)
Overall Incidence	Total	15/200 (7.5%)	Mean 7.5%	SD 3.42%	Total	143/200 (71.5%)	Mean 71.5%	SD 11%
Mammary Gland: Fibroma, Fibroadenoma	Carcinoma o	or Adenoma						
i ibioina, i ibioadenome	i, Garcinoma, c	3/50 (6%)	3/50 (6%)	5/50 (10%)		37/50 (74%)	43/50 (86%)	32/50 (64%)
		6/50 (12%)		()		31/50 (62%)		(- /-)
Overall Incidence	Total	17/200 (8.5%)	Mean 8.5%	SD 3%	Total	143/200 (71.5%)	Mean 71.5%	SD 11%
••								•••••
Mesentery: Fibrosarcoma								
Tibrosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	(,	(111)		0/50 (0%)	()	(,
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mesentery:							• • • • • • • • • • • • • • • • • • • •	•••••
Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	••	05.00/		0/50 (0%)		05.00/
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mesentery: Lipoma							•••••	
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 267
Report Date:11/17/2008

Species: RATS Strain: F344 Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Mesentery: Rhabdomyosarcoma								
·		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	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Nose: Adenoma			•••••	•••••		•••••	•••••	•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Nose: Chondroma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Nose: Squamous Cell Carcino								
equamous sen surome	u	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Papilloma Squamous or	Tongue, Phary							
	p	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 268

Report Date: 11/17/2008

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)Mean 0% 0/200 (0%) **Overall Incidence** Total 0/200 (0%) SD 0% Total Mean 0% SD 0% #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or **Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)(2%) 1/50 0/200 (0%) SD 0% SD 1% Overall Incidence Total Mean 0% Total 3/200 (1.5%) Mean 1.5% **#Oral Mucosa: Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%) 0/50 0/50 **Overall Incidence** Total 0/200 (0%) SD 0% Total 0/200 (0%) SD 0% Mean 0% Mean 0% **#Oral Mucosa: Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/200 (0.5%) SD 1% **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total Mean 0.5% *Ovary: **Granulosa Cell Tumor Benign** 0/49(0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 269

Report Date:11/17/2008

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male			Female	
*Ovary: Granulosa Cell Tumor Malignant		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%
*Ovary:				
Granulosa-Theca Tumor Benign		0/49 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
*Ovary: Granulosa-Theca Tumor Malignant				
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 270

			Male				Female	
Pancreas: Adenoma								
		1/50 (2%) 1/49 (2%)	2/50 (4%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
verall Incidence	Total	4/197 (2.03%)	Mean 2.01%	SD 1.63%	Total	0/197 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma							•••••	
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma								
		1/50 (2%) 1/49 (2%)	2/50 (4%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	4/197 (2.03%)	Mean 2.01%	SD 1.63%	Total	0/197 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Benign								
-		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Malignant	•••••							
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 271

			Male				Female	
Parathyroid Gland: Adenoma								
		0/46 (0%) 1/46 (2%)	0/44 (0%)	0/50 (0%)		0/46 (0%) 0/42 (0%)	0/42 (0%)	0/50 (0%)
Overall Incidence	Total	1/186 (0.54%)	Mean 0.54%	SD 1.09%	Total	0/180 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma Malignant		•••••	•••••		•••••			
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma: Benign, Mal		i		0/50 (0%)		0/50 (0%)		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis Adenoma								
		16/50 (32%) 24/50 (48%)	23/48 (48%)	23/50 (46%)		28/50 (56%) 27/49 (55%)	28/50 (56%)	26/50 (52%)
Overall Incidence	Total	86/198 (43.43%)	Mean 43.48%	SD 7.71%	Total	109/199 (54.77%)	Mean 54.78%	SD 1.9%
Pituitary Gland: Pars Distalis Carcinoma								
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		2/50 (4%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	2/199 (1.01%)	Mean 1%	SD 2%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

Page: 272

Species: RATS Strain: F344 Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Pituitary Gland: Pars Dist Carcinoma or Adenom		ied Site:						
		16/50 (32%) 24/50 (48%)	23/48 (48%)	23/50 (46%)		30/50 (60%) 27/49 (55%)	28/50 (56%)	26/50 (52%)
verall Incidence	Total	86/198 (43.43%)	Mean 43.48%	SD 7.71%	Total	111/199 (55.78%)	Mean 55.78%	SD 3.3%
Pituitary Gland: Pars Inte Adenoma								
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Pituitary Gland: Pars Inte								
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Inte Carcinoma or Adenom	rmedia:							
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Prostate: Adenoma								
		2/50 (4%) 0/49 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%				

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 273
Report Date:11/17/2008

Species: RATS Strain: F344 Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Prostate: Carcinoma or Adenoma								
Carcinoma of Adenoma		2/50 (4%) 0/49 (0%)	0/50 (0%)	0/50 (0%)				
overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%				
Salivary Glands: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Salivary Glands: Schwannoma Malignant								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Seminal Vesicle: Adenoma						•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				
Skeletal Muscle: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 274

			Male				Female	
Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Lipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma	••••••							
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma or		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%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Sarcoma	••••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 275

			Male				Female	
#Skin: Basal Cell Adenoma								
		2/50 (4%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.31%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma o			•••••					
Basar sen Adenoma s	Busosquamou	2/50 (4%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.31%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, E Trichoepithelioma	Basosquamous '	•	0/50 (00/)	4/50 (00()		0/50 /00/	0/50 (0%)	0/50 (0%)
		2/50 (4%) 2/50 (4%)	3/50 (6%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	8/200 (4%)	Mean 4%	SD 1.63%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma		•••••						
		0/50 (0%) 2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%
	or Basosquamo	ous Tumor (malignant o	r					
NOSI		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
NOS)		2/50 (4%)	` ,			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: ORAL

Report Date:11/17/2008

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Species: RATS Strain: F344

Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Skin: Basal Cell Carcinoma, Tumor (benign, malign		Trichoepithelioma 2/50 (4%)	3/50 (6%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/50 (8%) 11/200 (5.5%)	Mean 5.5%	SD 1.91%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan	oma, Adenoma,	Papilloma, Sq pithelioma	0/50 (40%)	7/50 (440)		4/50 (00)	0/50 (00)	4/50 (00)
		5/50 (10%) 11/50 (22%)	6/50 (12%)	7/50 (14%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
overall Incidence	Total	29/200 (14.5%)	Mean 14.5%	SD 5.26%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Skin: Fibroma		0/50 (460/)	7/50 (4.40()	E/E0 (400()		4/50 (20/)	1/50 (20/)	4/50 (20/)
		8/50 (16%) 8/50 (16%)	7/50 (14%)	5/50 (10%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	28/200 (14%)	Mean 14%	SD 2.83%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
\$Skin:		xoma, Myxosarcoma, or		6/50 (12%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
		9/50 (18%)	,	,		1/50 (2%)	(11,	,
Overall Incidence	Total	34/200 (17%)	Mean 17%	SD 4.16%	Total	4/200 (2%)	Mean 2%	SD 0%
Skin: Fibrosarcoma								
		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 277

			Male				Female					
#Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma												
· iioliooytoilia		3/50 (6%) 1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				
#Skin: Fibrous Histiocytoma	•••••											
·		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%				
#Skin: Hemangioma												
		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%				
#Skin: Hemangiosarcoma	•••••											
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%				
#Skin: Keratoacanthoma	•••••											
		2/50 (4%) 6/50 (12%)	1/50 (2%)	3/50 (6%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	12/200 (6%)	Mean 6%	SD 4.32%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 278

			Male				Female	
Skin: Lipoma								
P • • •		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Liposarcoma			•••••		•••••	•••••	•••••	
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Neural Crest Tumor, M						•••••		
,	.	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	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Neurofibroma or Schw								
		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	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Page: 279

Report	Date:1	1/17/20	800

			Male				Female	
#Skin: Neurofibrosarcoma or Scl	hwannoma (ı	malignant or NOS) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/30 (0%)	0/30 (0%)		0/50 (0%)	0/30 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Neur malignant or NOS)								
mangham of Noo,		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	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
		2/50 (4%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Schwannoma Benign								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 280

			Male				Female	
Skin: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Carcinoma	a							
		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
SKIN: Squamous Cell Carcinoma Basosquamous Tumor (m		IOS), or Carcinoma	0/50 (00/)	4/50 (20/)		0/50 /00/	0/50 (00/)	0/50 (00/)
Squamous Cell Carcinoma Basosquamous Tumor (m.			0/50 (0%) Mean 2%	1/50 (2%) SD 1.63%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Squamous Cell Carcinoma Basosquamous Tumor (ma Overall Incidence	Total	IOS), or Carcinoma 1/50 (2%) 2/50 (4%) 4/200 (2%)	Mean 2%	SD 1.63%		0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
Squamous Cell Carcinoma Basosquamous Tumor (ma Overall Incidence	Total	IOS), or Carcinoma 1/50 (2%) 2/50 (4%) 4/200 (2%)	Mean 2%	SD 1.63%		0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
Squamous Cell Carcinoma Basosquamous Tumor (ma Overall Incidence Skin:	Total	IOS), or Carcinoma 1/50 (2%) 2/50 (4%) 4/200 (2%)	Mean 2%	SD 1.63%		0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
Squamous Cell Carcinoma Basosquamous Tumor (ma Overall Incidence Skin: Squamous Cell Papilloma	Total	IOS), or Carcinoma 1/50 (2%) 2/50 (4%) 4/200 (2%) 1/50 (2%)	Mean 2%	SD 1.63%		0/50 (0%) 0/200 (0%) 	Mean 0%	SD 0%
Squamous Cell Carcinoma Basosquamous Tumor (m. Overall Incidence Skin: Squamous Cell Papilloma Overall Incidence	Total Total	1/50 (2%) 2/50 (4%) 4/200 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 7/200 (3.5%)	Mean 2%	SD 1.63% 2/50 (4%)		0/50 (0%) 0/200 (0%) 	Mean 0%	SD 0%
Basosquamous Tumor (ma Overall Incidence 	Total Total	1/50 (2%) 2/50 (4%) 4/200 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 7/200 (3.5%)	Mean 2%	SD 1.63% 2/50 (4%)		0/50 (0%) 0/200 (0%) 	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 281

			Male				Female	
#Skin: Squamous Cell Papillo Carcinoma or Keratoac		Squamous Cell						
	annoma .	4/50 (8%) 7/50 (14%)	4/50 (8%)	6/50 (12%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	21/200 (10.5%)	Mean 10.5%	SD 3%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Skin:	• • • • • • • • • • • • • • • • • • • •				• • • • • • • • • • • • • • • • • • • •			
Squamous Cell Papillo	ma, Papilloma,	or Keratoacanthoma 3/50 (6%) 7/50 (14%)	4/50 (8%)	5/50 (10%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	19/200 (9.5%)	Mean 9.5%	SD 3.42%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Skin: Trichoepithelioma								
		0/50 (0%) 0/50 (0%)	3/50 (6%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.83%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Sebaceous Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Skin: Sebaceous Gland: Carcinoma	•••••				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 282

			Male				Female	
Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
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%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spinal Cord: Astrocytoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spinal Cord: Glioma 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%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Fibrosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 283

			Male				Female	
Spleen: Fibrous Histiocytoma								
•		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Spleen: Hemangioma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma								
· ·		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Spleen: Leiomyosarcoma								
·		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Spleen: Sarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 284

			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%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma c Overall Incidence	or Papillon Total	na Squamous 0/50 (0%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	1/50 (2%) SD 1%	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	1/50 (2%) SD 1%
Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	(****)	,		0/50 (0%)	(111)	,
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Stomach, Glandular: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 285

			Male				Female	
#Stomach, Glandular: Lipoma		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	(0,0)	0,00 (0,0)		0/50 (0%)	(070)	(6,0)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Testes: Adenoma				•••••				
		48/50 (96%) 49/50 (98%)	46/50 (92%)	41/50 (82%)				
Overall Incidence	Total	184/200 (92%)	Mean 92%	SD 7.12%				
*Thymus: Sarcoma					•••••			
		0/48 (0%) 0/43 (0%)	0/49 (0%)	1/49 (2%)		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/189 (0.53%)	Mean 0.51%	SD 1.02%	Total	0/197 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign				•••••				
,		0/48 (0%) 0/43 (0%)	0/49 (0%)	1/49 (2%)		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/189 (0.53%)	Mean 0.51%	SD 1.02%	Total	0/197 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant	•••••			•••••	•••••			
,		0/48 (0%) 0/43 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/189 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 286

			Male				Female	
Thymus: Thymoma: Benign, Malig	nant, NOS							
		0/48 (0%) 0/43 (0%)	0/49 (0%)	1/49 (2%)		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/189 (0.53%)	Mean 0.51%	SD 1.02%	Total	0/197 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Adenoma								
		5/50 (10%) 10/49 (20%)	3/50 (6%)	6/50 (12%)		8/50 (16%) 6/46 (13%)	6/49 (12%)	6/50 (12%)
Overall Incidence	Total	24/199 (12.06%)	Mean 12.1%	SD 6.07%	Total	26/195 (13.33%)	Mean 13.32%	SD 1.84%
Thyroid Gland: C-Cell: Carcinoma								
		1/50 (2%) 1/49 (2%)	1/50 (2%)	1/50 (2%)		2/50 (4%) 0/46 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 0.02%	Total	3/195 (1.54%)	Mean 1.51%	SD 1.92%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		6/50 (12%) 11/49 (22%)	4/50 (8%)	7/50 (14%)		10/50 (20%) 6/46 (13%)	7/49 (14%)	6/50 (12%)
Overall Incidence	Total	28/199 (14.07%)	Mean 14.11%	SD 6.09%	Total	29/195 (14.87%)	Mean 14.83%	SD 3.57%
Thyroid Gland: Follicular Ce Adenoma	:::							
		0/50 (0%) 0/49 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%) 1/46 (2%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	1/195 (0.51%)	Mean 0.54%	SD 1.09%

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

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 287

			Male				Female	
Thyroid Gland: Follicular Cell: Carcinoma								
		0/50 (0%) 0/49 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/46 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/195 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma					•••••			
		0/50 (0%) 0/49 (0%)	3/50 (6%)	1/50 (2%)		0/50 (0%) 1/46 (2%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2%	SD 2.83%	Total	1/195 (0.51%)	Mean 0.54%	SD 1.09%
#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%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Tissue NOS: Paraganglioma	• • • • • • • • • • • • • • • • • • • •							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Tissue NOS: Schwannoma Malignant					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 288

			Male				Female	
#Tongue: Squamous Cell Carcinoma	1							
.,		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Tongue:						•••••		
Squamous Cell Carcinoma	or Papillon	na Squamous 0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Tongue: Squamous Cell Papilloma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Tooth: Adamantinoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Tooth: Odontoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 289

			Male				Female	
Urinary Bladder: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/199 (0%)	Mean 0%	SD 0%
Jrinary Bladder: Carcinoma or Papilloma								•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/199 (0%)	Mean 0%	SD 0%
Urinary Bladder: Leiomyosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Urinary Bladder: Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Uterus: Adenoma								
						1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/200 (0.5%)	Mean 0.5%	SD 1%

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

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Carcinoma 0/50 0/50 (0%)(0%)(0%)0/50 **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Uterus: Deciduoma Benign 0/50 (0%)(0%)(0%)0/50 (0%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Uterus: Hemangioma 0/50 (0%)0/50 (0%)(0%)0/50 (0%) **Overall Incidence** Mean 0% SD 0% Total 0/200 (0%) **#Uterus:** Hemangiosarcoma 0/50 (0%) 0/50 (0%)0/50 1/50 (2%)**Overall Incidence** (0.5%)Mean 0.5% SD 1% Total 1/200 **#Uterus:** Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%)Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/17/2008

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Leiomyosarcoma (0%)(0%)(0%)0/50 **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Uterus: **Polyp Stromal** 10/50 (20%)(18%)(8%) (26%) 13/50 **Overall Incidence** Total 36/200 (18%) Mean 18% SD 7.48% #Uterus: Sarcoma Stromal 0/50 (0%)0/50 (0%)(0%)0/50 (0%) **Overall Incidence** SD 0% Total 0/200 (0%) Mean 0% **#Uterus:** Sarcoma Stromal or Polyp Stromal (20%)(18%)(8%) 13/50 (26%)**Overall Incidence** Mean 18% SD 7.48% Total 36/200 (18%) **#Uterus:** Schwannoma Malignant (0%)0/50 0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/200 (0.5%)Mean 0.5% SD 1%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Route: ORAL Species: RATS Vehicle: WATER

Strain: F344 Length of Study: CHRONIC Page: 292

			Male				Female	
#Vagina: Polyp								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
					•••••			
#Vagina: Sarcoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
#Zymbal's Gland:								•••••
Carcinoma		0/50 (00/)	4 (50 (004)	0/50 (00/)		4/50 (00/)	0/50 (00/)	4/50 (00/)
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 1.15%
≠Zymbal's Gland:	•••••							
Carcinoma or Adenoma		0/50 (0%)	1/50 (2%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/30 (2/0)	1/30 (2/0)		0/50 (2%)	0/30 (0 /0)	1/30 (2/0)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	2/200 (1%)	Mean 1%	SD 1.15%

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

SIOII. INUVZUUO

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date:11/17/2008

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				M	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Southern Research Institute	059902805 059700307 059302007	09/16/02 07/10/02 04/24/00	729 728 729	50 (1) 50 (1) 50 (1)	21(676) 25(680) 20(670)	506.2 510.4 484.2	bis(2-Chloroethoxy)methane 1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide
				Fer	nale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Southern Research Institute	059902805 059700307 059302007	09/17/02 07/11/02 04/24/00	730 729 731	50 (1) 50 (1) 50 (1)	19(646) 29(695) 30(672)	341.0 337.8 319.5	bis(2-Chloroethoxy)methane 1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide

Species: RATS

Strain: F344

Toxicology Data Management System

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Report Date:11/17/2008

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male			Female 37/50 (74%) 46/50 (92%) 44/50 (88%) 127/150 (84.67%) Mean 84.67% SD 9.45% 19/50 (38%) 15/50 (30%) 22/50 (44%) 56/150 (37.33%) Mean 37.33% SD 7.02%				
#All Organs: Benign Tumors		40/50 /000/	40/50 (000/)	47/50 (040()		27/50 /740/	40/50 (00%)	44/50 (000/)		
Overall Incidence	Total	49/50 (98%) 142/150 (94.67%)	46/50 (92%) Mean 94.67%	47/50 (94%) SD 3.06%	Total	, ,	` ,	` ,		
#All Organs: Malignant Tumors		20/50 /500/	00/50 /400/	24/50 (000)		40/50 (200/)	45/50 /200/	20/50 (449())		
Overall Incidence	Total	26/50 (52%) 83/150 (55.33%)	23/50 (46%) Mean 55.33%	34/50 (68%) SD 11.37%	Total	, ,	` ,	, ,		
#All Organs: Malignant and Benign Tu	ımors	49/50 (98%)	50/50 (100%)	50/50 (100%)		44/50 (88%)	48/50 (96%)	48/50 (96%)		
Overall Incidence	Total	149/150 (99.33%)	Mean 99.33%	SD 1.15%	Total	140/150 (93.33%)	Mean 93.33%	SD 4.62%		
#All Organs: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
#All Organs: Hemangiosarcoma		(00)	0.50	(00)	•••••	(00)	0.50	2/22 (201)		
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
#All Organs: Hemangiosarcoma or He	emangioma	(00)	(00)	(201)	•••••	(201)	(00)			
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:11/17/2008

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#All Organs: Histiocytic Sarcoma		4/50 /00/	4/50 (00()	0/50 (0%)		4/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
All Organs: Leukemia: Erythrocytic					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Leukemia: Lymphocytic Undifferentiated	, Monocytic, N			(000)				
Overall Incidence	Total	17/50 (34%) 47/150 (31.33%)	17/50 (34%) Mean 31.33%	13/50 (26%) SD 4.62%	Total	12/50 (24%) 31/150 (20.67%)	10/50 (20%) Mean 20.67%	9/50 (18%) SD 3.06%
All Organs: Malignant Lymphoma: H or Undifferentiated Cell	listiocytic, Lyr			2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Benign		(a) (a) (a)	(20)	(20)		(201)	(004)	(00)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs:				•••••			•••••	
Mesothelioma: Benign, I	wangnant, NO	2/50 (4%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date:11/17/2008

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			Male				Female	
All Organs: Mesothelioma: Malignant								
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Osteoma			0/50 (00()					
	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma		0(50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	2/52 (224)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma or Osteoma								
ranall lockdones	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
drenal Cortex: Adenoma								
		0/50 (0%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 3.46%	Total	3/150 (2%)	Mean 2%	SD 3.46%
drenal Cortex: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
*Adrenal Medulla: Ganglioneuroma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Adrenal Medulla: Hemangioma		0/50 /00/	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (0%)	0/40 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Adrenal Medulla: Pheochromocytoma Benig	n							
Overall Incidence	Total	3/50 (6%) 11/150 (7.33%)	5/50 (10%) Mean 7.33%	3/50 (6%) SD 2.31%	Total	1/50 (2%) 2/149 (1.34%)	1/50 (2%) Mean 1.33%	0/49 (0%) SD 1.15%
*Adrenal Medulla: Pheochromocytoma Comp	lex	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Maligr	nant	0/50 (00/)	0/50 (00/)	4/50 (00)		0/50 (00/)	0/50 (004)	0/40 (00/)
Overall Incidence	Total	0/50 (0%) 4/150 (2.67%)	0/50 (0%) Mean 2.67%	4/50 (8%) SD 4.62%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Adrenal Medulla: Pheochromocytoma: Benig	ın, Comple			•••••				
Overall Incidence	Total	3/50 (6%) 14/150 (9.33%)	5/50 (10%) Mean 9.33%	6/50 (12%) SD 3.06%	Total	1/50 (2%) 2/149 (1.34%)	1/50 (2%) Mean 1.33%	0/49 (0%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male			Female 0/50 (0%) 0/150 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) 0/50 (0%) 0/50 (0%)		Female			
#Bone: Chondrosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
#Bone: Chondrosarcoma or Cho	ndroma	0/50 (09/)	0/50 /00/	0/50 /00/		0/50 (0%)	0/50 (00/)	0/50 /00/)			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` ,	` ,	` '			
#Bone: Chordoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	` ,	()	` '			
#Bone: Osteoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	` ,	()	` ,			
#Bone: Osteosarcoma	••••••	0/50 (00/)	0(50 (00))	0/50 (00/)		0(50 (00))	0/50 (00/)	0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` ,	()	,			
#Bone: Osteosarcoma or Osteom	 na	0/50 (0%)	0/50 /00/	0/50 (00/)		0/50 (00()	0/50 (0%)	0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 299

			Male			0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%			Female			
Brain: Astrocytoma Malignant		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	` '	` ,					
Brain: Ependymoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (00/)	0/50 (09/)	0/50 (09/)				
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	` '	` '	` '				
Brain: Ependymoma Malignant		0/50 (00()	0/50 /0%	0/50 (0%)		0/50 (00/)	0/50 (00/)	0/50 (00()				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` ,	` ,	` '				
Brain: Glioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	` '	(/	` '				
Brain: Granular Cell Tumor Benign												
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
Brain: Medulloblastoma Mal		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Species: RATSRoute: SKINStrain: F344Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 300

			Male			Total 0/150 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/50 (0 Total 0/150 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/50 (0 Total 0/150 (0%) Mean 0% SD 0%			
Brain: Meningioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	` ,	` ,	SD 0%	
Brain: Meningioma: Benign, Ma	lignant, NOS	0/50 (09/)	0/50 (0%)	0/50 (0%)		0/50 (00/)	0/50 /09/	0/50 /09/\	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` ,	` ,	0/50 (0%) SD 0%	
Brain: Oligodendroglioma Beni								0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` '	` ,	0/50 (0%) SD 0%	
Brain: Oligodendroglioma Maliç									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	
Brain: Oligodendroglioma, Glio	ma, or Astroc		4/50 (00)	4/50 (00)		4/50 (00)	0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	
Brain: Osteosarcoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 301

			Male				Female	
Brain: Schwannoma Malignant								
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Clitoral/Preputial Gland: Adenoma						0.50	(100)	
overall Incidence	Total	2/50 (4%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	1/50 (2%) SD 1.15%	Total	2/50 (4%) 10/150 (6.67%)	6/50 (12%) Mean 6.67%	2/50 (4%) SD 4.62%
Clitoral/Preputial Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
Clitoral/Preputial Gland: Carcinoma or Adenoma		2/50 (4%)	2/50 (4%)	2/50 (4%)		2/50 (4%)	6/50 (12%)	4/50 (8%)
overall Incidence	Total	6/150 (4%)	Mean 4%	SD 0%	Total	12/150 (8%)	Mean 8%	SD 4%
Clitoral/Preputial Gland: Fibrosarcoma			0/50 (00/)	0/50 (00)		0/50 (004)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Clitoral/Preputial Gland: Sarcoma		0/50 (00/)	0/50 /0%	0/50 (00/)		0/50 (00()	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

imal Groups Report Date:11/17/2008

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			Male				Female					
*Clitoral/Preputial Gland: Squamous Cell Papilloma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Insidence Total 0/450 (0%)												
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
#Ear: Neural Crest Tumor		0/50 (00)						0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
#Esophagus: Fibrosarcoma		0/50 (00/)	0/50 (00()	0/50 /00/		0/50 (00)	0/50 /0%	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
#Esophagus: Lipoma												
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%				
Eye: Amelanotic Melanoma, E	Benign						•••••					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%				
#Eye: Melanoma Benign												
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date:11/17/2008

Page: 303

			Male				Female	
#Eye: Melanoma Malignant		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Eye: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Harderian Gland: Carcinoma		0/50 (00()	0/50 (00()	0/50 (00/)		0/50 (0%)	0/50 (00()	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Benign			0.70 (00)	(201)		(00)		(201)
Overall Incidence	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Heart: Schwannoma Malignant		0/50 (00/)	0/50 (00()	4/50 (20()		0/50 (00/)	0/50 (09/)	4/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 304

			Male	Female
#Intestine Large: Colon/Rectum	:			
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) 1/50 (2%) Mean 0.67% SD 1.15%	,
#Intestine Large: Colon/Rectum Carcinoma	:	0/50 (00()	0/50 (00) 0/50 (00))
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Intestine Large: Colon/Rectum Carcinoma or Adenoma				
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) 1/50 (2%) Mean 0.67% SD 1.15%	,
#Intestine Large: Colon/Rectum Hemangioma	:	0/50 (0%)	0/50 (0%) 0/50 (0%)	o) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Duodenum: Carcinoma		(201)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Duodenum: Leiomyoma	•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#Intestine Small: Jejunum: Carcinoma								
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)	T	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Granular Cell Tumor Maligna	nt	4/50 (00/)	0/50 (00/)	0/50 (00/)		0(50 (004)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall illicidence		` ,				` ,		JD 070
#Intestine Small: Jejunum: Leiomyoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall incidence	Total	0/150 (0%)	wean 0%	SD 0%	TOtal	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspecified Carcinoma	d:							
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
Overall incidence	Total	0/150 (0%)	Mean 0%	3D 0%	Total	0/150 (0%)	Mean 0%	3D U%
#Intestine Small: Site Unspecified	d:						•••••	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 306

			Male				Female	
#Intestine Small: Site Unspe Granular Cell Tumor Mal								
	3	1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspe Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspe Leiomyosarcoma								0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Adenoma								
		3/50 (6%)	6/50 (12%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	14/150 (9.33%)	Mean 9.33%	SD 3.06%	Total	0/150 (0%)	Mean 0%	SD 0%
slets, Pancreatic: Carcinoma		0/50 (09/)	0/50 (09/)	2/50 (49/)		4/50 (20/)	0/50 (00/)	0/50 (00/)
N 11 In 1 I	T-1-1	0/50 (0%)	0/50 (0%)	2/50 (4%)	T-1-1	1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
slets, Pancreatic: Carcinoma or Adenoma								
		3/50 (6%)	6/50 (12%)	7/50 (14%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	16/150 (10.67%)	Mean 10.67%	SD 4.16%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 307

				Ma	ale						Fen	nale		
*Kidney: Pelvis and Transition Carcinoma	al Epithelium	1:												
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150 (0%)	Mea	an 0%	SD	0%
					• • • • • • • • • • • • • • • • • • • •				• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •		• • • • • • • • • • • • • • • • • • • •		
*Kidney: Pelvis and Transition Carcinoma or Adenoma	al Epithelium		()	- 1		- /							- 4	455.1
		0/50	` '		(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150 (0%)	Mea	an 0%	SD	0%
*Kidney: Pelvis and Transition Papilloma	al Epithelium	1:												
•		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150 (0%)	Mea	an 0%	SD	0%
*Kidney: Renal Tubule: Adenoma														
		0/50	` ,		(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%	Total	0/150 (0%)	Mea	an 0%	SD	0%
*Kidney: Renal Tubule:														•••••
Carcinoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150 (0%)	Mea	an 0%	SD	0%
*Kidney: Renal Tubule: Carcinoma or Adenoma														
Caronionia or Adonoma		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total		(0.67%)		0.67%		1.15%	Total	0/150 (` ,		an 0%	SD	` '

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incide

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 308

			Male	Female
*Kidney: Renal Tubule: Hemangiosarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Lipoma				
		1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Liposarcoma		(00)		
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Benign		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
	ı olal		iviean 0.07% 3D 1.13%	10tal 0/130 (0%) Wealt 0% 3D 0%
*Kidney: Renal Tubule: Nephroblastoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Sarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 1/150 (0.67%) Mean 0.67% SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

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			Male	Female
*Liver: Cholangioma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Liver: Hepatocellular Adenoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 6/50 (12%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 6/150 (4%) Mean 4% SD 6.93%
*Liver: Hepatocellular Carcinoma		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
*Liver: Hepatocellular Carcinoma	or Hepatobl			
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Liver: Hepatocellular Carcinoma	or Hepatoce			
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 6/50 (12%) Total 6/150 (4%) Mean 4% SD 6.93%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male				Female	
*Liver: Hepatocellular Carcino Hepatoblastoma	oma, Hepatocell	ular Adenoma, or						
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 6/150 (4%)	0/50 (0%) Mean 4%	6/50 (12%) SD 6.93%
*Lung:					•••••			
Alveolar/Bronchiolar A	denoma							
		4/50 (8%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	4/50 (8%)	0/50 (0%)
Overall Incidence	Total	6/150 (4%)	Mean 4%	SD 3.46%	Total	4/150 (2.67%)	Mean 2.67%	SD 4.62%
*Lung: Alveolar/Bronchiolar C	arcinoma							
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Lung: Alveolar/Bronchiolar C Adenoma	arcinoma or Al							
		5/50 (10%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	4/50 (8%)	0/50 (0%)
Overall Incidence	Total	8/150 (5.33%)	Mean 5.33%	SD 4.16%	Total	4/150 (2.67%)	Mean 2.67%	SD 4.62%
*Lung: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma				•••••				•••••
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 311

			Male				Female	
Lung: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
_ymph Node: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
ymph Node, Mesenteric: Sarcoma					•••••			
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
lammary Gland: Adenoma					•••••			
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
lammary Gland: Carcinoma			•••••					
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 7/150 (4.67%)	2/50 (4%) Mean 4.67%	4/50 (8%) SD 3.06%
//ammary Gland: Carcinoma or Adenoma					•••••			
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 8/150 (5.33%)	3/50 (6%) Mean 5.33%	4/50 (8%) SD 3.06%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:11/17/2008

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#Mammary Gland: Fibroadenoma		2/52 (224)		2/22 (224)		10/50 (000)		
Overall Incidence	Total	3/50 (6%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	0/50 (0%) SD 3.06%	Total	16/50 (32%) 42/150 (28%)	14/50 (28%) Mean 28%	12/50 (24%) SD 4%
#Mammary Gland: Fibroma			- 4				- 4	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mammary Gland: Fibroma, Fibroadenoma o	or Adenoma	•••••						
Overall Incidence	Total	3/50 (6%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	0/50 (0%) SD 3.06%	Total	16/50 (32%) 43/150 (28.67%)	15/50 (30%) Mean 28.67%	12/50 (24%) SD 4.16%
#Mammary Gland: Fibroma, Fibroadenoma,	Carcinoma, o	r Adenoma						
Overall Incidence	Total	3/50 (6%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	0/50 (0%) SD 3.06%	Total	17/50 (34%) 48/150 (32%)	17/50 (34%) Mean 32%	14/50 (28%) SD 3.46%
#Mesentery: Fibrosarcoma	•••••							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mesentery: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Mean 2%

SD 2%

Report Date:11/17/2008

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#Mesentery: Lipoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mesentery: Rhabdomyosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Nose: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Nose: Chondroma		0/50 (00/)				0/40 (00/)		0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Nose: Squamous Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Oral Cavity (Oral Mucosa, Ton Papilloma Squamous or Pa		vnx, Tooth, Gingiva):						
rapilionia squamous or ra	pilionia	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	2/50 (4%)

SD 0%

.....

Total

3/150 (2%)

Total

0/150 (0%)

Mean 0%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male				Female	
#Oral Cavity (Oral Mucosa, Squamous Cell Carcino		nx, Tooth, Gingiva):						
Squamous Cen Carcino	ilia .	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma	Tongue, Phary	Squamous, or						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 4/150 (2.67%)	0/50 (0%) Mean 2.67%	3/50 (6%) SD 3.06%
#Oral Mucosa: Squamous Cell Carcino	oma							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Oral Mucosa: Squamous Cell Papillo	ma	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Ovary: Granulosa Cell Tumor I	3enign							
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Ovary: Granulosa Cell Tumor I	Walignant							
Overall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 315 Report Date:11/17/2008

			Male				Female	
*Ovary: Granulosa Cell Tumor:	Benign, Malign	ant, NOS				4/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
*Ovary: Granulosa-Theca Tumo	or Benign							
Overall Incidence	-				Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Ovary: Granulosa-Theca Tumo	or Malignant							
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Ovary: Tubulostromal Adenon	na					•••••		
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas: Adenoma	•••••							
Overall Incidence	Total	0/50 (0%) 3/150 (2%)	0/50 (0%) Mean 2%	3/50 (6%) SD 3.46%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas: Carcinoma			•••••		•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: ETHANOL

Route: SKIN

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0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Report Date: 11/17/2008

Length of Study: CHRONIC

Male Female *Pancreas: Carcinoma or Adenoma 0/50 (0%)(0%)(6%)(0%)0/50 (0%)0/50 (0%)0/150 (0%) **Overall Incidence** Total 3/150 (2%) Mean 2% SD 3.46% Total Mean 0% SD 0% *Pancreas: **Mixed Tumor Benign** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 Mean 0% *Pancreas: **Mixed Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Parathyroid Gland: Adenoma 0/49 (0%)(0%)0/49 (0%)(0%)0/45 (0%)0/49 0/46 **Overall Incidence** Total 0/147 (0%) Mean 0% SD 0% Total 0/134 (0%) Mean 0% SD 0% **#Peripheral Nerve:** Schwannoma Malignant 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 Mean 0% SD 0%

0/50

SD 0%

(0%)

Total

0/150 (0%)

Total

0/50

0/150 (0%)

(0%)

(0%)

Mean 0%

Schwannoma: Benign, Malignant, NOS

#Peripheral Nerve:

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

d Control Animal Groups Report Date:11/17/2008
SKIN

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			Male				Female				
*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma											
		35/49 (71%)	32/50 (64%)	29/50 (58%)		22/50 (44%)	35/50 (70%)	33/50 (66%)			
Overall Incidence	Total	96/149 (64.43%)	Mean 64.48%	SD 6.73%	Total	90/150 (60%)	Mean 60%	SD 14%			
Pituitary Gland: Pars Distali Carcinoma		ied Site:			•••••						
		0/49 (0%)	0/50 (0%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	3/50 (6%)			
Overall Incidence	Total	5/149 (3.36%)	Mean 3.33%	SD 5.77%	Total	3/150 (2%)	Mean 2%	SD 3.46%			
Pituitary Gland: Pars Distali Carcinoma or Adenoma		ied Site:			•••••						
		35/49 (71%)	32/50 (64%)	34/50 (68%)		22/50 (44%)	35/50 (70%)	36/50 (72%)			
verall Incidence	Total	101/149 (67.79%)	Mean 67.81%	SD 3.72%	Total	93/150 (62%)	Mean 62%	SD 15.62%			
Pituitary Gland: Pars Interm Adenoma											
		0/49 (0%)	0/50 (0%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	0/50 (0%)			
verall Incidence	Total	2/149 (1.34%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%			
Pituitary Gland: Pars Interm					•••••						
		0/49 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%			
Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:	0/40 (00/)	0/50 (0%)	0/50 (00/)	•••••	4/50 (00()	0/50 (00/)	0/50 (00/)			
		0/49 (0%)	0/50 (0%)	3/50 (6%)		1/50 (2%)	0/50 (0%)	0/50 (0%)			
verall Incidence	Total	3/149 (2.01%)	Mean 2%	SD 3.46%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%			

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

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 318

			Male	Female
*Prostate: Adenoma				
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) 1/50 (3 Mean 0.67% SD 1.1	2%) 15%
*Prostate: Carcinoma or Adenoma		0/50 (0%)		2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.1	
*Salivary Glands: Sarcoma				
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	0/50 (0%) 1/49 (3 Mean 0.68% SD 1.1	2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 18% Total 0/150 (0%) Mean 0% SD 0%
*Salivary Glands: Schwannoma Malignant		0/50 (0%)		0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0% SD 0%	
#Seminal Vesicle: Adenoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0 Mean 0% SD 0%	0%) 6
#Skeletal Muscle: Hemangioma				00() 0/50 (00() 0/50 (00()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0 Mean 0% SD 0%	0%)

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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	Male						Female	
#Skeletal Muscle: Hemangiosarcoma								
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skeletal Muscle: Lipoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skeletal Muscle: Rhabdomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Skeletal Muscle: Rhabdomyosarcoma or F	Rhabdomyom	n a 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skeletal Muscle: Sarcoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Basal Cell Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female				
#Skin: Basal Cell Adenoma or Basosquamous Tumor Benign 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)											
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
#Skin: Basal Cell Adenoma, B Trichoepithelioma	asosquamous [·]	•									
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
#Skin: Basal Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%			
#Skin: Basal Cell Carcinoma o NOS)	or Basosquamo	us Tumor (malignant or									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
#Skin: Basal Cell Carcinoma, I Tumor (benign, maligna			0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%			
#Skin: Basal or Sq. Cell Carcir or B), Basal Cell Adeno Papilloma, Keratoacant	ma, Adenoma,	Papilloma, Sq pithelioma									
Overall Incidence	Total	2/50 (4%) 8/150 (5.33%)	2/50 (4%) Mean 5.33%	4/50 (8%) SD 2.31%	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%			

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:11/17/2008

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#Skin: Fibroma		1/50 (2%)	7/50 (14%)	5/50 (10%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	13/150 (8.67%)	Mean 8.67%	SD 6.11%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
#Skin: Fibroma, Fibrosarcoma, Fibrous Histiocytoma	Sarcoma, My	xoma, Myxosarcoma, or						
Overall Incidence	Total	3/50 (6%) 16/150 (10.67%)	8/50 (16%) Mean 10.67%	5/50 (10%) SD 5.03%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
Overall incluence	TOlai	16/150 (10.67%)	Weatt 10.67%	3D 3.03%	ı Olai	2/130 (1.33%)	Weall 1.33%	30 2.31%
#Skin: Fibrosarcoma		2/50 (4%)	0/50 (00/)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/30 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Fibrosarcoma, Sarcoma, Histiocytoma	Myxosarcom	a, or Fibrous 2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin:					•••••			
Fibrous Histiocytoma		0/50 (00/)	4/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Fibrous Histiocytoma	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
_	Total	` ,	` '	` ,	Total	` ,	` '	` '

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

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 322

			Male	Female
#Skin: Hemangiosarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
Skin: Keratoacanthoma				0/50 (00/) 0/50 (00/) 4/50 (00/)
Overall Incidence	Total	0/50 (0%) 5/150 (3.33%)	2/50 (4%) 3/50 (6%) Mean 3.33% SD 3.06%	0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15%
Skin: Lipoma				
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
Skin: Liposarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	Total 0/150 (0%) 0/30 (0%) 0/30 (0%) Mean 0% SD 0%
Skin: Neural Crest Tumor				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
Skin: Neural Crest Tumor, Mal		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%)

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

	Male						Female	
#Skin: Neurofibroma or Schwa	nnoma benign	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/30 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or S	Schwannoma (r		4/50 (20/)	2/50 (49/)		0/50 (00/)	0/50 (0%)	2/50 (40/)
Overall Incidence	Total	1/50 (2%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	2/50 (4%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
#Skin: Neurofibrosarcoma, Net malignant or NOS)	urofibroma, or		2/50 (40/)	2/50 /40/\		0/50 (0%)	0/50 (00/)	2/50 (40/)
Overall Incidence	Total	1/50 (2%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	2/50 (4%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
#Skin: Osteosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Benign		0/50 (0%)	1/50 (2%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Species: RATS Strain: F344 Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
#Skin: Schwannoma Malignant		1/50 (2%)	1/50 (29/)	2/50 (40/)		0/50 (0%)	0/50 (0%)	2/50 (40/)
Overall Incidence	Total	1/50 (2%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	2/50 (4%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
#Skin: Squamous Cell Carcinon	na							
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
∜Skin: Squamous Cell Carcinon Basosquamous Tumor (r			0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin: Squamous Cell Papillom		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papillom	a or Papilloma		0/50 (0%)	1/50 (29/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Squamous Cell Papillom Carcinoma or Keratoaca		Squamous Cell						
Overall Incidence	Total	1/50 (2%) 7/150 (4.67%)	2/50 (4%) Mean 4.67%	4/50 (8%) SD 3.06%	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date:11/17/2008

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			Male				Female				
#Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma											
Overall Incidence	Total	0/50 (0%) 6/150 (4%)	2/50 (4%) Mean 4%	4/50 (8%) SD 4%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%			
#Skin: Trichoepithelioma		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%			
#Skin: Sebaceous Gland: Adenoma											
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
#Skin: Sebaceous Gland: Carcinoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%			
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (00/)	0/50 (00)	4/50 (00)		0/50 (00/)	0/50 (00/)	0/50 (00)			
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
#Spinal Cord: Astrocytoma Benign											
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 326

Report Date:11/17/2008

Length of Study: CHRONIC

			Male	Female
#Spinal Cord: Astrocytoma Malignant		1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
#Spinal Cord: Glioma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Spleen: Fibrosarcoma		0/50 (0%)	4/50 (201) 0/50 (001)	0/50 (00/) 0/50 (00/) 0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Spleen: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Spleen: Hemangioma		0/50 (00/)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Spleen: Hemangiosarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date:11/17/2008 Vehicle: ETHANOL

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			Male				Female	
*Spleen: Leiomyosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Spleen: Sarcoma	•••••	4/50 (00()	0/50 (00/)	0/50 (00/)		0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Forestomach:								
Leiomyosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	0/50 (0%) SD 0%
#Stomach, Forestomach:								
Squamous Cell Carcinoma	or Papillor	na Squamous						
•	-	0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma		•••••		•••••		•••••		
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Species: RATS Strain: F344 Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male		Female			
#Stomach, Glandular: Leiomyosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Glandular: Lipoma		0/50 (00/)	0/50 (00/)	0/50 (00()	•••••	0/50 (00)	0/50 (00/)	0/50 /00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Testes: Adenoma		20/50 (600/)	27/50 (749/)	26/50 (720/)	•••••			
Overall Incidence	Total	30/50 (60%) 103/150 (68.67%)	37/50 (74%) Mean 68.67%	36/50 (72%) SD 7.57%				
*Thymus: Sarcoma		0/40 (00/)	0/40 (00/)	0/40 (00%)		0/40 (00)	0/45 (00/)	0/50 (00()
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/49 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/49 (0%) 0/144 (0%)	0/45 (0%) Mean 0%	0/50 (0%) SD 0%
*Thymus: Thymoma Benign		0/40 (00/)	0/40 (00/)	0/40 (00/)	•••••	0/40 (00)	0/45 (00/)	0/50 (00()
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/49 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/49 (0%) 0/144 (0%)	0/45 (0%) Mean 0%	0/50 (0%) SD 0%
*Thymus: Thymoma Malignant		0/40 (00/)	0/40 (00/)	0/40 (00%)	•••••	0/40 /000	0/45 (00%)	0/50 /00/)
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/49 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/49 (0%) 0/144 (0%)	0/45 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:11/17/2008

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
*Thymus: Thymoma: Benign, Maligna	nt, NOS	0/49 (0%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	0/45 (0%)	0/50 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma		40/50 (00%)	40/50 (00%)	F/F0 /400/\		C/F0 (400())	0/50 /400/)	2/50 /09/
Overall Incidence	Total	10/50 (20%) 25/150 (16.67%)	10/50 (20%) Mean 16.67%	5/50 (10%) SD 5.77%	Total	6/50 (12%) 17/150 (11.33%)	8/50 (16%) Mean 11.33%	3/50 (6%) SD 5.03%
*Thyroid Gland: C-Cell: Carcinoma								
Overall Incidence	Total	1/50 (2%) 8/150 (5.33%)	2/50 (4%) Mean 5.33%	5/50 (10%) SD 4.16%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		11/50 (22%)	12/50 (24%)	10/50 (20%)		6/50 (12%)	8/50 (16%)	5/50 (10%)
Overall Incidence	Total	11/50 (22%) 33/150 (22%)	12/50 (24%) Mean 22%	SD 2%	Total	6/50 (12%) 19/150 (12.67%)	Mean 12.67%	5/50 (10%) SD 3.06%
*Thyroid Gland: Follicular Cell: Adenoma	•••••							
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
*Thyroid Gland: Follicular Cell: Carcinoma	•••••				•••••			
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		0/50 (0%)	1/50 (2%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 2%
#Tissue NOS: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tissue NOS: Paraganglioma		0/50 (00)	0/50 (00)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma	or Papillon		0/50 (00)	0/50 (00)		0/50 /00/	0/50 (00/)	0/50 (404)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

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			Male				Female	
#Tongue: Squamous Cell Papilloma			(00)			2/20 /20/	2(72 (224)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
Tooth: Adamantinoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Tooth: Odontoma		0/50 /00/	0/50 (00%)	0/50 (00/)		0/50 (00)	4/50 (004)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Jrinary Bladder: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Jrinary Bladder: Carcinoma or Papilloma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Urinary Bladder: Leiomyosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

d Control Animal Groups Report Date:11/17/2008 SKIN

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			Male			Female			
*Urinary Bladder: Papilloma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Uterus: Adenoma					•••••				
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Uterus: Carcinoma		•••••	•••••						
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Uterus: Deciduoma Benign					•••••				
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Uterus: Hemangioma									
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Uterus: Hemangiosarcoma			•••••						
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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	Male		Female	
#Uterus: Leiomyoma		0/50 (0%)	0/50 (0%)	4/50 (20/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Uterus: Leiomyosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	0/50 (0%) SD 0%
#Uterus: Polyp Stromal		5/50 (10%)	2/50 (4%)	10/50 (20%)
Overall Incidence	Total	17/150 (11.33%)	Mean 11.33%	SD 8.08%
#Uterus: Sarcoma Stromal		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
#Uterus: Sarcoma Stromal or Polyp Stromal		6/50 (12%)	3/50 (6%)	10/50 (20%)
Overall Incidence	Total	19/150 (12.67%)	Mean 12.67%	SD 7.02%
#Uterus: Schwannoma Malignant		0/50 /00/	0/50 (00/)	0/50 /00/\
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

d Control Animal Groups Report Date:11/17/2008 SKIN

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			Male				Female	
#Vagina: Polyp						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
	• • • • • • • • • • • • • • • • • • • •		•••••		• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •	
#Vagina: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Zymbal's Gland:								
Carcinoma or Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied