

NTP Historical Controls Report

By Route and Vehicle

F 344/N RATS

May 2011

REPORT DESCRIPTION

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

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

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

Male									
M1									
M2									
M3									
M4									
M5									
Female									
Female F1									
F1									
F1 F2									

the data would be shown as:

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

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

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

Table of Contents

Route	Vehicle	Page Number		
GAVAGE	CORN OIL	4		
GAVAGE	METHYLCELLULOSE	54		
GAVAGE	WATER	96		
INHALATION	AIR	138		
ORAL	FEED	180		
ORAL	WATER	230		
PERINATAL AND POSTNATAL	FEED	272		
SKIN	ACETONE	314		
SKIN	ETHANOL	356		

Species: RATS

Toxicology Data Management System

Page: 4

Report Date: 05/18/2011

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

Route: GAVAGE Vehicle: CORN OIL

Strain: F 344/N Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	059903103	03/23/05	727	50(3)	38(706)	512.7	Ginkgo biloba extract
Battelle Columbus Laboratory	058810503	04/22/02	729	50(3)	35(702)	521.9	Isoeugenol
Battelle Columbus Laboratory	052000705	08/18/04	727	49(3)	34(692)	515.2	Kava kava extract
Battelle Columbus Laboratory	059902303	03/25/02	729	50(3)	29(683)	501.9	beta-Myrcene
Battelle Columbus Laboratory	052010703	10/20/04	727	50(3)	37(702)	503.5	N,N-Dimethyl-p-toluidine
Battelle Columbus Laboratory	059902005	04/09/03	727	50(3)	39(685)	514.9	Pulegone
					Female		
Battelle Columbus Laboratory	059903103	03/24/05	728	50(5)	37(700)	350.7	Ginkgo biloba extract
Battelle Columbus Laboratory	058810503	04/23/02	730	50(5)	33(699)	339.3	Isoeugenol
Battelle Columbus Laboratory	052000705	08/19/04	728	50(5)	34(683)	354.3	Kava kava extract
Battelle Columbus Laboratory	059902303	03/26/02	730	50(5)	31(668)	323.8	beta-Myrcene
Battelle Columbus Laboratory	052010703	10/21/04	728	50(5)	33(704)	354.1	N,N-Dimethyl-p-toluidine
Battelle Columbus Laboratory	059902005	04/10/03	728	50(5)	31(682)	341.2	Pulegone

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 5

			Male				Female	
#All Organs: Benign Tumors								
-		50/50 (100%)	49/50 (98%)	49/49 (100%)		47/50 (94%)	41/50 (82%)	43/50 (86%)
		49/50 (98%)	48/50 (96%)	47/50 (94%)		40/50 (80%)	46/50 (92%)	42/50 (84%)
Overall Incidence	Total	292/299 (97.66%)	Mean 97.67%	SD 2.34%	Total	259/300 (86.33%)	Mean 86.33%	SD 5.57%
#All Organs: Malignant Tumors								
		13/50 (26%)	29/50 (58%)	17/49 (35%)		12/50 (24%)	18/50 (36%)	11/50 (22%)
	T	23/50 (46%)	20/50 (40%)	10/50 (20%)	-	11/50 (22%)	23/50 (46%)	8/50 (16%)
Overall Incidence	Total	112/299 (37.46%)	Mean 37.45%	SD 13.75%	Total	83/300 (27.67%)	Mean 27.67%	SD 11.13%
#All Organs: Malignant and Benign T	umors							
		50/50 (100%)	50/50 (100%)	49/49 (100%)		49/50 (98%)	46/50 (92%)	46/50 (92%)
		50/50 (100%)	49/50 (98%)	47/50 (94%)		45/50 (90%)	49/50 (98%)	44/50 (88%)
Overall Incidence	Total	295/299 (98.66%)	Mean 98.67%	SD 2.42%	Total	279/300 (93%)	Mean 93%	SD 4.15%
#All Organs: Hemangioma								
		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%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#All Organs: Hemangiosarcoma								
-		0/50 (0%)	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%)	2/50 (4%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 6

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Strain: F 344/N
Length of Study: CHRONIC

Male

			Male				Female	
#All Organs: Hemangiosarcoma or He	emangioma							
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	3/300 (1%)	Mean 1%	SD 1.67%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Erythrocytic								
		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic,	, Monocytic, M	lononuclear, or Undiffere						
		9/50 (18%)	10/50 (20%)	7/49 (14%)		8/50 (16%)	8/50 (16%)	5/50 (10%)
		9/50 (18%)	14/50 (28%)	4/50 (8%)		5/50 (10%)	15/50 (30%)	4/50 (8%)
Overall Incidence	Total	53/299 (17.73%)	Mean 17.71%	SD 6.59%	Total	45/300 (15%)	Mean 15%	SD 8.07%
#All Organs: Malignant Lymphoma: H	istiocytic, Lyn	nphocytic, Mixed, NOS, o	r Undifferentiated Cel	I Туре				
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1,00 (2,70)	0/00 (0/0)	(-,-,			` ,	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 7

			Male				Female	
All Organs: Mesothelioma: Benign								
		0/50 (0%)	0/50 (0%)	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%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Benign, M	lalignant, NOS	3						
		3/50 (6%)	3/50 (6%)	3/49 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	14/299 (4.68%)	Mean 4.69%	SD 1.65%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
All Organs: Mesothelioma: Malignant		3/50 (6%)	3/50 (6%)	3/49 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	14/299 (4.68%)	Mean 4.69%	SD 1.65%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)	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%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma								
		0/50 (0%)	2/50 (4%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	5/299 (1.67%)	Mean 1.67%	SD 1.51%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Page: 8 Report Date: 05/18/2011

			Male				Female	
#All Organs: Osteosarcoma or Osteoma	a							
		0/50 (0%)	2/50 (4%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/299 (1.67%)	Mean 1.67%	SD 1.51%	Total	0/300 (0%)	Mean 0%	SD 0%
Adrenal Cortex: Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	3/50 (6%)	0/50 (0%)
verall Incidence	Total	4/299 (1.34%)	Mean 1.33%	SD 1.63%	Total	3/300 (1%)	Mean 1%	SD 2.45%
Adrenal Cortex: Carcinoma								
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Ganglioneuroma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

GAVAGE

Page: 9

			Male				Female	
Adrenal Medulla: Pheochromocytoma Be	enign							
		11/50 (22%)	5/50 (10%)	5/49 (10%)		2/50 (4%)	2/50 (4%)	3/50 (6%)
Overall Incidence	Total	11/50 (22%) 46/299 (15.38%)	6/50 (12%) Mean 15.37%	8/50 (16%) SD 5.57%	Total	1/50 (2%) 13/300 (4.33%)	2/50 (4%) Mean 4.33%	3/50 (6%) SD 1.51%
		40/299 (13.3676)				13/300 (4.33 /6)		
*Adrenal Medulla: Pheochromocytoma Co	omplex							
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma M	alignant							
		2/50 (4%)	3/50 (6%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
O	T-1-1	2/50 (4%)	1/50 (2%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	8/299 (2.68%)	Mean 2.67%	SD 2.42%	Total	0/300 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma: B	senign, Comple	x, Malignant, NOS						
-		12/50 (24%)	7/50 (14%)	5/49 (10%)		2/50 (4%)	2/50 (4%)	3/50 (6%)
		13/50 (26%)	8/50 (16%)	8/50 (16%)		1/50 (2%)	2/50 (4%)	3/50 (6%)
Overall Incidence	Total	53/299 (17.73%)	Mean 17.7%	SD 6.07%	Total	13/300 (4.33%)	Mean 4.33%	SD 1.51%
#Bone: Chordoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Page: 10

Mean 0%

SD 0%

Report Date: 05/18/2011

Contract/Lab: All Laboratories

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

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** #Bone: Osteoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Bone: Osteosarcoma (0%)(0%)0/50 2/50 (4%)1/49 (2%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 1.67% Mean 0% **Overall Incidence** Total 5/299 (1.67%) SD 1.51% Total 0/300 (0%) SD 0% #Bone: Osteosarcoma or Osteoma 0/50 (0%)2/50 (4%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 5/299 (1.67%) Mean 1.67% SD 1.51% 0/300 (0%) Mean 0% SD 0% Total *Brain: **Astrocytoma Malignant** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 0/300 (0%) Mean 0% SD 0% *Brain: **Ependymoma Benign** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0.82%

Total

0/300 (0%)

Total

1/299 (0.33%)

.....

Mean 0.33%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

rted Control Animal Groups

Report Date: 05/18/2011

GAVAGE

CORN OIL

Page: 11

			Male				Female	
Brain: Ependymoma Malignant								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Brain: Glioma								
		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%
*Brain: Glioma Benign								
_		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%
Brain: Glioma Malignant								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Benign								
_		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 12

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Contract/Lab: All Laboratories

Strain: F 344/N Length of Study: CHRONIC

			Male				Female	
Brain: Oligodendroglioma Benign	ı							
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Maligna								
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Oligodendroglioma, Glioma	Total	0/50 (0%) 1/50 (2%) 3/299 (1%)	1/50 (2%) 0/50 (0%) Mean 1%	0/49 (0%) 1/50 (2%) SD 1.1%	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	1/50 (2%) 0/50 (0%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%
*Brain: Osteosarcoma		0/50 (0%)	0/50 (0%)	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	0/300 (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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Clitoral/Preputial Gland: Adenoma 4/50 (8%)2/50 (4%)0/49 (0%)5/50 (10%)3/48 (6%)2/50 (4%)(10%)5/50 (10%)0/50 (0%)3/50 (6%)(14%)5/50 3/50 (6%)14/299 (4.68%) 25/298 (8.39%) **Overall Incidence** Total Mean 4.67% SD 4.13% Total Mean 8.38% SD 3.64% *Clitoral/Preputial Gland: Carcinoma (0%) (0%) 0/50 2/50 (4%)1/49 (2%)0/50 2/48 (4%)2/50 (4%)(0%) 0/50 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 1.34% **Overall Incidence** Total 4/299 (1.34%) SD 1.64% Total 4/298 (1.34%) Mean 1.36% SD 2.11% *Clitoral/Preputial Gland: Carcinoma or Adenoma 4/50 (8%)4/50 (8%)1/49 (2%)5/50 (10%)5/48 (10%)4/50 (8%)5/50 (10%)0/50 (0%)4/50 (8%)7/50 (14%)5/50 (10%)3/50 (6%)**Overall Incidence** Total 18/299 (6.02%) Mean 6.01% SD 3.99% 29/298 (9.73%) Mean 9.74% SD 2.67% Total *Clitoral/Preputial Gland: Sarcoma 0/50 0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/298 (0%) Mean 0% SD 0% #Ear: **Neural Crest Tumor** 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%)1/50 (2%)0/50 (0%)

SD 0%

Total

2/300 (0.67%)

Total

0/299 (0%)

Mean 0%

Overall Incidence

Page: 13

Mean 0.67%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 14

Report Date: 05/18/2011

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

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male	Female
#Esophagus: Lipoma				
		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overell lesidenes	Tatal	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Tatal 0/300 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD 0%	Total 0/300 (0%) Mean 0% SD 0%
#Eye: Melanoma Benign				
		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
	.	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD 0%	Total 1/300 (0.33%) Mean 0.33% SD 0.82%
#Eye: Melanoma Malignant				
		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD 0%	Total 0/300 (0%) Mean 0% SD 0%
#Eye: Schwannoma Malignant				
		0/50 (0%)	0/50 (0%) 0/49 (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 0/300 (0%) Mean 0% SD 0%
#Harderian Gland: Adenoma				
		0/50 (0%)	0/50 (0%) 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 0/300 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 15

			Male				Female	
#Harderian Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (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	0/300 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Heart: 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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rect Adenoma								
		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 16

			Male				Female	
#Intestine Large: Colon/Red Carcinoma or Adenoma	ctum:							
		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Red Hemangioma								
		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenun Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenun Leiomyoma	n:							
		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenun Schwannoma Malignant	n:							
•		0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

Route: GAVAGE Vehicle: CORN OIL Page: 17

Report Date: 05/18/2011

Length of Study: CHRONIC

Male **Female** #Intestine Small: Ileum: Adenoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Intestine Small: Jejunum: Carcinoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: **Granular Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyoma 0/49 1/50 (2%)1/50 (2%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/299 (0.67%) Mean 0.67% SD 1.03% Total 0/300 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Page: 18

Report Date: 05/18/2011

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
#Intestine Small: Site Un Adenoma	specified:							
		0/50 (0%)	0/50 (0%)	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%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Site Un Carcinoma	specified:							
		0/50 (0%)	0/50 (0%)	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%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Site Un Carcinoma or Adenom								
		0/50 (0%)	0/50 (0%)	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%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Site Un Granular Cell Tumor N	•							
		0/50 (0%)	0/50 (0%)	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%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Site Un Leiomyoma	specified:							
		1/50 (2%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Page: 19

Report Date: 05/18/2011

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** #Intestine Small: Site Unspecified: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/300 (0.33%) **Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total Mean 0.33% SD 0.82% #Intestine Small: Site Unspecified: Schwannoma Malignant (0%)(2%)0/50 0/50 (0%)0/49 (0%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% *Islets, Pancreatic: Adenoma 4/50 (8%)4/50 (8%)4/49 (8%)1/50 (2%)0/50 (0%)1/50 (2%)2/50 (4%)2/50 (4%)2/50 (4%)1/50 (2%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 18/299 (6.02%) Mean 6.03% SD 2.22% 4/300 (1.33%) Mean 1.33% SD 1.03% Total *Islets, Pancreatic: Carcinoma 0/49 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/299 (0.67%) Mean 0.67% SD 1.03% Total 0/300 (0%) Mean 0% SD 0% *Islets, Pancreatic: Carcinoma or Adenoma 4/50 (8%)4/50 (8%)4/49 (8%)1/50 0/50 (0%)1/50 (2%)

2/50

SD 1.66%

(4%)

1/50

4/300 (1.33%)

Total

(2%)

0/50

(0%)

Mean 1.33%

1/50

(2%)

Total

3/50

20/299 (6.69%)

(6%)

3/50

Mean 6.69%

(6%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 05/18/2011

Page: 20

			Male				Female	
Kidney: Pelvis and Tran Carcinoma	sitional Epitheli	um:						
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Tran Carcinoma or Adenom		um:						
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Tran Papilloma	sitional Epitheli	um:						
		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 21

			Male				Female	
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma								
•		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Mesenchymal Tumor Beni	gn							
•	_	0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Mesenchymal Tumor Malig	gnant							
,	-	0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 22

			Male				Female	
*Kidney: Renal Tubule: Nephroblastoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
*Kidney: Renal Tubule: Sarcoma								
		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%
*Liver: Cholangioma								
		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma								
-		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenoma								
-		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/299 (1%)	Mean 1.01%	SD 1.1%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 23

Report Date: 05/18/2011

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

			Male				Female	
Liver: Hepatocellular Carcinor	na							
		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinor								
·	•	0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) Mean 1.01%	1/49 (2%) 1/50 (2%) SD 1.1%	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 1/50 (2%) SD 0.82%
Overall Incidence	Total	3/299 (1%)						
						(
Liver:		lar Adenoma, or Hepatol	plastoma 1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Liver:		lar Adenoma, or Hepatol	olastoma	1/49 (2%) 1/50 (2%)			0/50 (0%) 0/50 (0%)	
Liver: Hepatocellular Carcinor		lar Adenoma, or Hepatol	plastoma 1/50 (2%)	` ,	Total	0/50 (0%)	` ,	0/50 (0%)
Liver:	na, Hepatocellu	lar Adenoma, or Hepatol 0/50 (0%) 0/50 (0%)	Dlastoma 1/50 (2%) 0/50 (0%)	1/50 (2%)	Total	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/50 (2%)
Liver: Hepatocellular Carcinor Overall Incidence Liver:	na, Hepatocellu	lar Adenoma, or Hepatol 0/50 (0%) 0/50 (0%) 3/299 (1%) 0/50 (0%)	olastoma 1/50 (2%) 0/50 (0%) Mean 1.01% 0/50 (0%)	1/50 (2%) SD 1.1% 0/49 (0%)	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%) 0/50 (0%)	0/50 (0%) Mean 0.33% 	0/50 (0%) 1/50 (2%) SD 0.82% 0/50 (0%)
'Liver: Hepatocellular Carcinor Overall Incidence 'Liver:	na, Hepatocellu	lar Adenoma, or Hepatol 0/50 (0%) 0/50 (0%) 3/299 (1%)	olastoma 1/50 (2%) 0/50 (0%) Mean 1.01%	1/50 (2%) SD 1.1%	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) 1/50 (2%) SD 0.82%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 24

			Male				Female	
Lung: Alveolar/Bronchiolar A	denoma							
		1/50 (2%)	3/50 (6%)	2/49 (4%)		4/50 (8%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/50 (6%) 9/299 (3.01%)	0/50 (0%) Mean 3.01%	0/50 (0%) SD 2.76%	Total	4/50 (8%) 12/300 (4%)	1/50 (2%) Mean 4%	2/50 (4%) SD 3.35%
Lung: Alveolar/Bronchiolar C								
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1.01%	SD 1.1%	Total	0/300 (0%)	Mean 0%	SD 0%
Alveolar/Bronchiolar C	arcinoma or Alv	veolar/Bronchiolar Aden		2/40 (40/)		A/FO (90/)	4/50 (20/)	0/50 (00/)
	arcinoma or Alv Total	veolar/Bronchiolar Aden 1/50 (2%) 3/50 (6%) 11/299 (3.68%)	4/50 (8%) 0/50 (0%) Mean 3.68%	2/49 (4%) 1/50 (2%) SD 2.95%	Total	4/50 (8%) 4/50 (8%) 12/300 (4%)	1/50 (2%) 1/50 (2%) Mean 4%	0/50 (0%) 2/50 (4%) SD 3.35%
Overall Incidence 		1/50 (2%) 3/50 (6%)	4/50 (8%) 0/50 (0%) Mean 3.68%	1/50 (2%)		4/50 (8%) 12/300 (4%)	1/50 (2%)	2/50 (4%)
Overall Incidence		1/50 (2%) 3/50 (6%)	4/50 (8%) 0/50 (0%) Mean 3.68%	1/50 (2%) SD 2.95%		4/50 (8%) 12/300 (4%)	1/50 (2%)	2/50 (4%)
Overall Incidence Lung:		1/50 (2%) 3/50 (6%) 11/299 (3.68%)	4/50 (8%) 0/50 (0%) Mean 3.68%	1/50 (2%) SD 2.95%		4/50 (8%) 12/300 (4%)	1/50 (2%) Mean 4%	2/50 (4%) SD 3.35%
Overall Incidence 'Lung: Fibrosarcoma		1/50 (2%) 3/50 (6%) 11/299 (3.68%) 0/50 (0%)	4/50 (8%) 0/50 (0%) Mean 3.68%	1/50 (2%) SD 2.95% 0/49 (0%)		4/50 (8%) 12/300 (4%) 0/50 (0%)	1/50 (2%) Mean 4% 0/50 (0%)	2/50 (4%) SD 3.35% 1/50 (2%)
Overall Incidence *Lung: Fibrosarcoma Overall Incidence	Total	1/50 (2%) 3/50 (6%) 11/299 (3.68%) 0/50 (0%) 0/50 (0%)	4/50 (8%) 0/50 (0%) Mean 3.68% 0/50 (0%) 0/50 (0%)	1/50 (2%) SD 2.95% 0/49 (0%) 0/50 (0%)		4/50 (8%) 12/300 (4%) 0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 4% 0/50 (0%) 0/50 (0%)	2/50 (4%) SD 3.35% 1/50 (2%) 0/50 (0%)
Overall Incidence *Lung: Fibrosarcoma Overall Incidence *Lung:	Total	1/50 (2%) 3/50 (6%) 11/299 (3.68%) 0/50 (0%) 0/50 (0%) 0/299 (0%)	4/50 (8%) 0/50 (0%) Mean 3.68% 0/50 (0%) 0/50 (0%) Mean 0%	1/50 (2%) SD 2.95% 0/49 (0%) 0/50 (0%) SD 0%		4/50 (8%) 12/300 (4%) 0/50 (0%) 0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 4% 0/50 (0%) 0/50 (0%) Mean 0.33% 0/50 (0%)	2/50 (4%) SD 3.35% 1/50 (2%) 0/50 (0%) SD 0.82%
Overall Incidence Lung: Fibrosarcoma Overall Incidence	Total	1/50 (2%) 3/50 (6%) 11/299 (3.68%) 0/50 (0%) 0/50 (0%) 0/299 (0%)	4/50 (8%) 0/50 (0%) Mean 3.68% 0/50 (0%) 0/50 (0%) Mean 0%	1/50 (2%) SD 2.95% 0/49 (0%) 0/50 (0%) SD 0%		4/50 (8%) 12/300 (4%) 0/50 (0%) 0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 4% 0/50 (0%) 0/50 (0%) Mean 0.33%	2/50 (4%) SD 3.35% 1/50 (2%) 0/50 (0%) SD 0.82%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Page: 25

Report Date: 05/18/2011

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Lung: Squamous Cell Carcinoma			-1					
		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%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/300 (2%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
		, ,				` ,		
Lymph Node: Hemangiosarcoma								
nemangiosai coma		0/50 (0%)	0/50 (0%)	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%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenolipoma								
•		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	4/300 (1.33%)	Mean 1.33%	SD 2.07%
lammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	4/50 (8%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	6/300 (2%)	Mean 2%	SD 3.1%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 26

			Male				Female	
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	4/50 (8%)	3/50 (6%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	10/300 (3.33%)	Mean 3.33%	SD 3.27%
#Mammary Gland: Fibroadenoma								
		2/50 (4%)	4/50 (8%)	0/49 (0%)		23/50 (46%)	26/50 (52%)	24/50 (48%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		17/50 (34%)	29/50 (58%)	21/50 (42%)
Overall Incidence	Total	7/299 (2.34%)	Mean 2.33%	SD 3.2%	Total	140/300 (46.67%)	Mean 46.67%	SD 8.26%
#Mammary Gland: Fibroma								
		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma	or Adenoma							
		2/50 (4%)	4/50 (8%)	0/49 (0%)		23/50 (46%)	26/50 (52%)	25/50 (50%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		17/50 (34%)	29/50 (58%)	22/50 (44%)
Overall Incidence	Total	7/299 (2.34%)	Mean 2.33%	SD 3.2%	Total	142/300 (47.33%)	Mean 47.33%	SD 8.16%
#Mammary Gland: Fibroma, Fibroadenoma,								
•	ŕ	2/50 (4%)	4/50 (8%)	0/49 (0%)		23/50 (46%)	28/50 (56%)	26/50 (52%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		17/50 (34%)	30/50 (60%)	22/50 (44%)
Overall Incidence	Total	7/299 (2.34%)	Mean 2.33%	SD 3.2%	Total	146/300 (48.67%)	Mean 48.67%	SD 9.35%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 27

Report Date: 05/18/2011

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

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Male **Female** #Mesentery: **Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Mesentery: Hemangiosarcoma (0%) 0/50 (0%)0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Mesentery: Lipoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Mesentery: Schwannoma Malignant 0/49 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% *Nose: Adenoma 0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/299 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Page: 28

			Male				Female	
*Nose: Squamous Cell Carcin	oma							
		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%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o	. •	ynx, Tooth, Gingiva):						
	•	0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.04%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/299 (0.33%)	1/50 (2%) 0/50 (0%) Mean 0.33%	0/49 (0%) 0/50 (0%) SD 0.82%	Total	0/50 (0%) 1/50 (2%) 1/300 (0.33%)	0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%
#Oral Cavity (Oral Mucos Squamous Cell Carcine	. •	ynx, Tooth, Gingiva): Squamous, or Papilloma						
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
O	Taral	1/50 (2%)	0/50 (0%)	0/50 (0%)	T-1-1	2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1.01%	SD 1.1%	Total	3/300 (1%)	Mean 1%	SD 1.67%
#Oral Mucosa: Squamous Cell Carcin	oma							
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/299 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%	Total	1/50 (2%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
	Total	1/299 (0.33%)	iviean 0.33%	SU U.07%	Total	1/300 (0.33%)	iviean 0.33%	SU U.0/%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Page: 29

			Male				Female	
Oral Mucosa: Squamous Cell Papillom	a							
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	1/49 (2%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.04%	Total	0/300 (0%)	Mean 0%	SD 0%
Ovary: Cystadenoma								
•						0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence					Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
Ovary: Fibrosarcoma								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
Ovary: Granulosa Cell Tumor Be	enign	•••••						
	J					0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Tatal	1/50 (2%)	0/50 (0%)	0/50 (0%)
					Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Ovary: Granulosa Cell Tumor M	alignant							
						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%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 30

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% *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 0/300 (0%) Mean 0% SD 0% *Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% *Ovary: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% *Ovary: **Tubulostromal Adenoma** 1/50 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%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Report Date: 05/18/2011

Page: 31

			Male				Female	
Pancreas: Adenoma								
		0/50 (0%) 1/50 (2%)	7/50 (14%)	1/49 (2%) 2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 11/299 (3.68%)	0/50 (0%) Mean 3.67%	2/50 (4%) SD 5.28%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas: Carcinoma								
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/299 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas: Carcinoma or Adenoma								
		0/50 (0%)	8/50 (16%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 12/299 (4.01%)	0/50 (0%) Mean 4.01%	2/50 (4%) SD 6.06%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Pancreas: Mixed Tumor Benign								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
O	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	T -1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Pancreas: Mixed Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 32

Report Date: 05/18/2011

Route: GAVAGE

Contract/Lab: All Laboratories

Strain: F 344/N Vehicle: CORN OIL Length of Study: CHRONIC

			Male				Female	
*Parathyroid Gland: Adenoma								
		0/47 (0%)	0/47 (0%)	1/49 (2%)		1/38 (3%)	0/47 (0%)	0/44 (0%)
		1/45 (2%)	0/49 (0%)	1/49 (2%)		0/47 (0%)	0/50 (0%)	2/46 (4%)
Overall Incidence	Total	3/286 (1.05%)	Mean 1.05%	SD 1.15%	Total	3/272 (1.1%)	Mean 1.16%	SD 1.88%
Pituitary Gland: Pars Dis								
		38/50 (76%)	19/50 (38%)	21/49 (43%)		34/50 (68%)	25/50 (50%)	29/50 (58%)
		6/50 (12%)	23/50 (46%)	11/50 (22%)		25/50 (50%)	31/50 (62%)	27/50 (54%)
Overall Incidence	Total	118/299 (39.46%)	Mean 39.48%	SD 22.14%	Total	171/300 (57%)	Mean 57%	SD 7.13%
*Pituitary Gland: Pars Dis Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/299 (0.33%)	0/50 (0%) 1/50 (2%) Mean 0.33%	0/49 (0%) 0/50 (0%) SD 0.82%	Total	2/50 (4%) 0/50 (0%) 3/300 (1%)	0/50 (0%) 0/50 (0%) Mean 1%	1/50 (2%) 0/50 (0%) SD 1.67%
Pituitary Gland: Pars Dis Carcinoma or Adenoma	•	cified Site:						
		38/50 (76%)	19/50 (38%)	21/49 (43%)		36/50 (72%)	25/50 (50%)	30/50 (60%)
		6/50 (12%)	24/50 (48%)	11/50 (22%)		25/50 (50%)	31/50 (62%)	27/50 (54%)
Overall Incidence	Total	119/299 (39.8%)	Mean 39.81%	SD 22.27%	Total	174/300 (58%)	Mean 58%	SD 8.49%
*Pituitary Gland: Pars Dis Ganglioneuroma								
-		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Contract/Lab: All Laboratories

Toxicology Data Management System

Page: 33

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Strain: F 344/N Vehicle: CORN OIL

Length of Study: CHRONIC

Male

			Male				Female	
Pituitary Gland: Pars Interme Adenoma	edia:							
		1/50 (2%)	1/50 (2%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Pituitary Gland: Pars Interme Carcinoma or Adenoma	edia:							
		1/50 (2%)	1/50 (2%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
*Pituitary Gland: Pars Nervos Craniopharyngioma Overall Incidence		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/49 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
	Total	0/299 (0%)			Total	0/300 (0%)		
Prostate: Adenoma		0/50 (0%)	0/50 (0%)	0/49 (0%)				
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
		` '						
Prostate: Carcinoma or Adenoma		0/50 (09/)	0/50 (0%)	0/40 (09/)				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
		0/299 (0%)						

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Salivary Glands: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Salivary Glands: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (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%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%
Salivary Glands: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Seminal Vesicle: Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%				

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

Page: 34

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 35

(0%)

(0%)

Mean 0%

0/50

0/50

SD 0%

(0%)

(0%)

0/50

0/50

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Skeletal Muscle: Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.34% SD 0.83% Total 0/300 (0%) Mean 0% SD 0%

#Skeletal	Muscle:
· ·	

Overall Incidence

#Skeletal Muscle: Hemangiosarcoma

#Skeletal Muscle: Rhabdomyosarcoma								
,,		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skeletal Muscle:	Dhahdamuam	_						

0/49

0/50

SD 0%

(0%)

(0%)

Total

0/50

0/50

0/300 (0%)

(0%)

(0%)

Rhabdomyosarcoma or Rhabdomyoma

		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

#Skin:

Basal Cell Adenoma

Overall Incidence	Total	4/299 (1.34	l%)	Mean 1.	35%	SD 1.66%	6	Total	1/300 (0.3	33%)	Mean	0.33%	SD 0.	82%
		0/50	(0%)	1/50	(2%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
Basar Gen Adenoma		1/50	(2%)	0/50	(0%)	2/49	(4%)		0/50	(0%)	0/50	(0%)	0/50	(0%)

Total

0/50

0/50

0/299 (0%)

(0%)

(0%)

0/50

0/50

Mean 0%

(0%)

(0%)

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 36

			Male				Female					
#Skin: Basal Cell Adenoma or Basosquamous Tumor Benign												
Basal Cell Adenoma or	Basosquamou	s Tumor Benign										
		1/50 (2%)	0/50 (0%)	2/49 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	4/299 (1.34%)	Mean 1.35%	SD 1.66%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
#Skin:												
Basal Cell Adenoma, B	asosquamous 1	Tumor Benign, or Trichoe	pithelioma									
	•	1/50 (2%)	0/50 (0%)	2/49 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	4/299 (1.34%)	Mean 1.35%	SD 1.66%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
#Skin: Basal Cell Carcinoma				•••••		•••••						
		0/50 (0%)	1/50 (2%)	0/49 (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%)				
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
#Skin:												
Basal Cell Carcinoma o	or Basosquamo	us Tumor (malignant or N	,									
		0/50 (0%)	1/50 (2%)	0/49 (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%)				
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
#Skin: Basal Cell Carcinoma, I NOS), or Trichoepitheli		oma, Basosquamous Tu	mor (benign, malignaı	nt or								
•		1/50 (2%)	1/50 (2%)	2/49 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	6/299 (2.01%)	Mean 2.01%	SD 1.29%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%				

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 37

			Male				Female	
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	inoma, Carcinon Sq Papilloma, Ko	na, Basosq. Tumor (M or E eratoacanthoma, Trichoep	3), Basal Cell Adenon ithelioma	na,				
		2/50 (4%) 3/50 (6%)	8/50 (16%) 4/50 (8%)	2/49 (4%) 3/50 (6%)		1/50 (2%) 1/50 (2%)	0/50 (0%) 2/50 (4%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	22/299 (7.36%)	Mean 7.35%	SD 4.49%	Total	5/300 (1.67%)	Mean 1.67%	SD 1.51%
#Skin: Fibroma								
		1/50 (2%) 3/50 (6%)	5/50 (10%) 6/50 (12%)	7/49 (14%) 3/50 (6%)		1/50 (2%) 2/50 (4%)	0/50 (0%) 1/50 (2%)	1/50 (2%) 3/50 (6%)
Overall Incidence	Total	25/299 (8.36%)	Mean 8.38%	SD 4.53%	Total	8/300 (2.67%)	Mean 2.67%	SD 2.07%
#Skin: Fibroma, Fibrosarcom:	a, Sarcoma, Myx	xoma, Myxosarcoma, or Fi 2/50 (4%) 4/50 (8%)	ibrous Histiocytoma 7/50 (14%) 6/50 (12%)	7/49 (14%) 3/50 (6%)		1/50 (2%) 3/50 (6%)	0/50 (0%) 4/50 (8%)	1/50 (2%) 3/50 (6%)
Overall Incidence	Total	29/299 (9.7%)	Mean 9.71%	SD 4.33%	Total	12/300 (4%)	Mean 4%	SD 3.1%
#Skin: Fibrosarcoma		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 3/50 (6%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	4/300 (1.33%)	Mean 1.33%	SD 2.42%
#Skin:		a, or Fibrous Histiocytom						
·	. •	1/50 (2%) 1/50 (2%)	2/50 (4%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 3/50 (6%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.33%	SD 1.63%	Total	4/300 (1.33%)	Mean 1.33%	SD 2.42%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 38

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: **Fibrous Histiocytoma** 1/50 (2%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total Mean 0% SD 0% #Skin: Hemangioma 0/50 (0%)0/50 (0%)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 0/300 (0%) Mean 0% SD 0% #Skin: Hemangiosarcoma 0/50 (0%)0/50 (0%)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% 0/300 (0%) Mean 0% SD 0% Total #Skin:

0/49

3/50

SD 4.63%

1/49

0/50

SD 1.68%

(0%)

(6%)

(2%)

(0%)

Total

Total

0/50

0/50

0/50

0/50

0/300 (0%)

1/300 (0.33%)

(0%)

(0%)

(0%)

(0%)

0/50

1/50

0/50

0/50

(0%)

(2%)

(0%)

(0%)

Mean 0.33%

Mean 0%

0/50

0/50

0/50

0/50

SD 0.82%

SD 0%

(0%)

(0%)

(0%)

(0%)

Total

Total

2/50

2/50

17/299 (5.69%)

0/50

0/50

3/299 (1%)

(4%)

(4%)

(0%)

(0%)

.....

7/50

3/50

2/50

0/50

Mean 1.01%

Mean 5.67%

(14%)

(6%)

(4%)

(0%)

Keratoacanthoma

Overall Incidence

Overall Incidence

#Skin: Lipoma

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 39

(0%)

(0%)

(0%)

(0%)

Mean 0%

Mean 0%

0/50

0/50

0/50

0/50

SD 0%

SD 0%

(0%)

(0%)

(0%)

(0%)

0/50

0/50

0/50

0/50

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Liposarcoma 0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 0/50 (0%)1/50 (2%)0/50 (0%)1/300 (0.33%) **Overall Incidence** Total 1/299 (0.33%) Mean 0.34% SD 0.83% Total Mean 0.33% SD 0.82% #Skin: **Neural Crest Tumor** (0%)(0%)0/50 0/50 (0%)0/49 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Skin: **Neural Crest Tumor, Malignant** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% 0/300 (0%) Mean 0% SD 0% Total #Skin:

0/49

0/50

SD 0%

0/49

3/50

SD 2.42%

(0%)

(0%)

(0%)

(6%)

Total

Total

0/50

0/50

0/50

0/50

0/300 (0%)

0/300 (0%)

(0%)

(0%)

(0%)

(0%)

Neurofibrosarcoma or Schwannoma (malignant or NOS)

Total

Total

0/50

0/50

0/299 (0%)

0/50

4/299 (1.34%)

(0%)

(0%)

(2%)

(0%)

0/50

0/50

0/50

0/50

Mean 1.33%

Mean 0%

(0%)

(0%)

(0%)

(0%)

Neurofibroma or Schwannoma benign

Overall Incidence

Overall Incidence

#Skin:

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Page: 40

			Male				Female	
#Skin: Neurofibrosarcoma, Neuro	fibroma, or	Schwannoma (benign, m	alignant or NOS)					
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.33%	SD 2.42%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 2/299 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.03%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	• • • • • • • • • • • • • • • • • • • •		•••••					
#Skin: Schwannoma Benign								
•		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignant								
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 4/299 (1.34%)	0/50 (0%) Mean 1.33%	3/50 (6%) SD 2.42%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Squamous Cell Carcinoma		2(72 (224)	2/22 (22()	0 (10 (100))		(20)	0(70 (00))	2/22 (221)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 41

Mean 0.67%

SD 1.03%

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)(2%)0/49 (0%)1/50 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 2/299 (0.67%) Mean 0.67% SD 1.03% Total 2/300 (0.67%) Mean 0.67% SD 1.03% #Skin: **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)1/50 (2%)0/299 (0%) Mean 0% SD 0% 1/300 (0.33%) Mean 0.33% SD 0.82% **Overall Incidence** Total Total #Skin: Squamous Cell Papilloma or Papilloma 0/50 0/50 (0%)0/50 0/50 0/50 (0%)0/49 (0%)(0%)(0%)(0%)(0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma 2/50 (4%)7/50 (14%)0/49 (0%)1/50 (2%)0/50 (0%)0/50 (0%)(4%)2/50 3/50 (6%)3/50 (6%)0/50 (0%)1/50 (2%)1/50 (2%)Mean 5.67% **Overall Incidence** Total 17/299 (5.69%) SD 4.63% Total 3/300 (1%) Mean 1% SD 1.1% #Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma (4%)7/50 (14%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)3/50 (6%)3/50 (6%)0/50 (0%)1/50 (2%)1/50 (2%)

SD 4.63%

Total

2/300 (0.67%)

Total

17/299 (5.69%)

Mean 5.67%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Page: 42

Mean 0%

SD 0%

Report Date: 05/18/2011

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Male **Female** #Skin: Trichoepithelioma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Skin: Sebaceous Gland: Adenoma (0%)0/50 (0%)1/50 (2%)0/49 (0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 3/299 (1%) Mean 1% SD 1.1% Total 0/300 (0%) SD 0% **#Skin: Sebaceous Gland:** Carcinoma or Adenoma 0/50 (0%)1/50 (2%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 3/299 (1%) Mean 1% SD 1.1% Total 0/300 (0%) Mean 0% SD 0% **#Spinal Cord:** Astrocytoma Benign 0/49 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% **#Spinal Cord: Astrocytoma Malignant** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

0/300 (0%)

Total

0/299 (0%)

Mean 0%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 43

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Spinal Cord: Glioma Malignant** 0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 1/299 (0.33%) Mean 0.34% SD 0.83% Total Mean 0% SD 0% *Spleen: **Fibrosarcoma** (0%) 0/50 (0%)0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/299 (0%) SD 0% Total 0/300 (0%) Mean 0% SD 0% *Spleen: Fibrous Histiocytoma 0/50 (0%)0/50 (0%)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 0/300 (0%) Mean 0% SD 0% *Spleen: Hemangiosarcoma 0/49 0/50 (0%)1/50 (2%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 2/300 (0.67%) Mean 0.67% SD 1.63% *Spleen: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 44

Report Date: 05/18/2011

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

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male		Female 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/300 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 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 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 1/300 (0.33%) Mean 0.33% SD 0.82%			
Spleen: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		` ,	` ,	(,
		0/50 (0%)	0/50 (0%)	0/50 (0%)		` '	` '	` '
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		` '	` ,	` ,
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinom	a							
		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	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinom	a or Papilloma	a Squamous						
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Stomach, Forestomach: Squamous Cell Papilloma	ı							
-		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Stomach, Glandular: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	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%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
≠Stomach, Glandular: Lipoma								
		0/50 (0%)	0/50 (0%)	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%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Testes: Adenoma								
		37/50 (74%)	46/50 (92%)	37/49 (76%)				
		47/50 (94%)	40/50 (80%)	46/50 (92%)				
Overall Incidence	Total	253/299 (84.62%)	Mean 84.59%	SD 9.1%				

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

Page: 45

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Page: 46

Mean 0.33%

SD 0.82%

Report Date: 05/18/2011

Contract/Lab: All Laboratories

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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Testes: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/49 (0%) 0/50 (0%)				
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%				
Thymus: Thymoma Benign								
, ,		1/47 (2%)	0/47 (0%)	0/48 (0%)		1/50 (2%)	0/47 (0%)	0/50 (0%)
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence	Total	1/289 (0.35%)	Mean 0.35%	SD 0.87%	Total	1/293 (0.34%)	Mean 0.33%	SD 0.82%
Thymus: Thymoma Malignant								
		0/47 (0%)	0/47 (0%)	0/48 (0%)		0/50 (0%)	0/47 (0%)	0/50 (0%)
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence	Total	0/289 (0%)	Mean 0%	SD 0%	Total	0/293 (0%)	Mean 0%	SD 0%
Thymus: Thymoma NOS								
		0/47 (0%)	0/47 (0%)	0/48 (0%)		0/50 (0%)	0/47 (0%)	0/50 (0%)
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence	Total	0/289 (0%)	Mean 0%	SD 0%	Total	0/293 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malig	nant, NOS							
	·	1/47 (2%)	0/47 (0%)	0/48 (0%)		1/50 (2%)	0/47 (0%)	0/50 (0%)
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)

SD 0.87%

Total

1/293 (0.34%)

Mean 0.35%

Total

1/289 (0.35%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 05/18/2011

Page: 47

Mean 0.33%

SD 0.82%

			ľ	Male						F	emale		
Гhyroid Gland: C-Cell: Adenoma													
		10/50 (20%)		(18%)	8/49	(16%)		11/49	(22%)	7/50	(14%)	5/50	(10%)
wanali luaidanaa	Tatal	12/50 (24%)		(22%)	8/50	(16%)	Tatal	5/50	(10%)	9/49	(18%)	8/50	(16%)
verall Incidence	Total	58/299 (19.4%)	Mean 19.		SD 3.2%		Total	45/298 (1	,		15.14%	SD 4	
Thyroid Gland: C-Cell: Carcinoma													
		1/50 (2%)		(12%)	0/49	(0%)		0/49	(0%)	3/50	(6%)	0/50	(0%)
	-	0/50 (0%)		(0%)	0/50	(0%)	.	0/50	(0%)	0/49	(0%)	0/50	(0%)
verall Incidence	Total	7/299 (2.34%)	Mean 2.3		SD 4.8%		Total	3/298 (1.	,		ın 1%	SD 2	
Гhyroid Gland: C-Cell: Carcinoma or Adenoma													
		11/50 (22%)		(30%)	8/49	(16%)		11/49	(22%)	9/50	(18%)	5/50	(10%)
		12/50 (24%)		(22%)		(16%)		5/50	(10%)	9/49	(18%)	8/50	(16%)
verall Incidence	Total	65/299 (21.74%)	Mean 21.		SD 5.219		Total	47/298 (1	5.77%)	Mean	15.8%	SD 4	.96%
Γhyroid Gland: Follicular (Adenoma													
		2/50 (4%)		(2%)	1/49	(2%)		1/49	(2%)	0/50	(0%)	1/50	(2%)
		1/50 (2%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	1/49	(2%)	0/50	(0%)
verall Incidence	Total	6/299 (2.01%)	Mean 2.0	01%	SD 1.279	%	Total	3/298 (1.	01%)	Mean	1.01%	SD 1	.11%
Γhyroid Gland: Follicular 0 Carcinoma													
		0/50 (0%)	1/50	(2%)	0/49	(0%)		0/49	(0%)	1/50	(2%)	0/50	(0%)
		2/50 (4%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)

SD 1.67%

Total

1/298 (0.34%)

Total

3/299 (1%)

Mean 1%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 48

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

		Male				Female			
*Thyroid Gland: Follicular Cel Carcinoma or Adenoma	l:								
		2/50 (4%)	2/50 (4%)	1/49 (2%)		1/49 (2%)	1/50 (2%)	1/50 (2%)	
		3/50 (6%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/49 (2%)	0/50 (0%)	
Overall Incidence	Total	9/299 (3.01%)	Mean 3.01%	SD 2.09%	Total	4/298 (1.34%)	Mean 1.35%	SD 1.04%	
†Tissue NOS: Paraganglioma									
		0/50 (0%)	0/50 (0%)	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%)	
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%	
Tongue: Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%	
Tongue: Squamous Cell Carcinoma	or Papillom	na Squamous							
1		0/50 (0%)	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%)	1/50 (2%)	0/50 (0%)	
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	
Tongue: Squamous Cell Papilloma									
-		0/50 (0%)	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%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 49

		Male				0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) otal 1/300 (0.33%) Mean 0.33% SD 0.82% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)			Female			
#Tooth: Adamantinoma Malignant												
		0/50 (0%)	0/50 (0%)	0/49 (0%)		` ,	` ,					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		` '	, ,					
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%				
Tooth: Odontoma												
		0/50 (0%)	0/50 (0%)	0/49 (0%)		` '	` '	` '				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		` '	` ,					
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	` ,		SD 0.82%				
Urinary Bladder: Carcinoma												
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%				
Urinary Bladder: Carcinoma or Papilloma												
		0/50 (0%)	0/50 (0%)	0/49 (0%)		` ,	` ,	` ,				
		1/50 (2%)	0/50 (0%)	0/50 (0%)		` ,	, ,	` '				
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
Urinary Bladder: Hemangiosarcoma												
-		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 50

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: **Papilloma** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Uterus: 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% #Uterus: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Uterus: Deciduoma Benign 0/50 (0%)1/50 (2%)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% **#Uterus:** Leiomyosarcoma 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%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 51

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

	Male			Female	
#Uterus: Polyp Stromal					
Polyp Stromai			3/50 (6%)	8/50 (16%)	7/50 (14%)
			8/50 (16%)	3/50 (6%)	5/50 (10%)
Overall Incidence		Total	34/300 (11.33%)	Mean 11.33%	SD 4.68%
#Uterus: Sarcoma					
			0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/300 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal					
			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%
#Uterus: Sarcoma Stromal or Polyp Stromal					
			3/50 (6%)	8/50 (16%)	7/50 (14%)
			8/50 (16%)	3/50 (6%)	5/50 (10%)
Overall Incidence		Total	34/300 (11.33%)	Mean 11.33%	SD 4.68%
#Uterus: Schwannoma Malignant					
-			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%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 52

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Vagina: Polyp 0/50 (0%)1/50 (2%)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% #Vagina: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% #Vagina: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Zymbal's Gland: Adenoma 0/49 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Zymbal's Gland: Carcinoma 1/50 (2%)2/50 (4%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 3/299 (1%) Mean 1% SD 1.67% Total 1/300 (0.33%) Mean 0.33% SD 0.82%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Female

Page: 53

	Male				Female	
#Zymbal's Gland: Carcinoma or Adenoma						
		1/50 (2%)	2/50 (4%) 0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/299 (1%)	Mean 1% SD 1.67%	Total 1/300 (0.33%)	Mean 0.33%	SD 0.82%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Page: 54

Report Date: 05/18/2011

Species: RATS Strain: F 344/N

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Southern Research Institute Southern Research Institute	059902407 059903705	02/03/03 06/09/03	729 729	50(3) 50(3)	21(661) 27(662)	518.7 523.0	Androstenedione alpha/beta Thujone mixture
					Female		
Southern Research Institute Southern Research Institute	059902407 059903705	02/03/03 06/09/03	729 730	50(5) 50(5)	38(710) 35(689)	356.5 335.4	Androstenedione alpha/beta Thujone mixture

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 55

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male			10/50 (20%) 20/50 (40%) 30/100 (30%) Mean 30% SD 14.14% 46/50 (92%) 49/50 (98%)				
#All Organs: Benign Tumors										
		47/50 (94%)	44/50 (88%)			44/50 (88%)	46/50 (92%)			
Overall Incidence	Total	91/100 (91%)	Mean 91%	SD 4.24%	Total	, ,				
#All Organs: Malignant Tumors										
	T	34/50 (68%)	31/50 (62%)	00 40404	.	` ,	,	00 44 440/		
Overall Incidence	Total	65/100 (65%)	Mean 65%	SD 4.24%	Total	, ,				
#All Organs: Malignant and Benign To										
		49/50 (98%)	48/50 (96%)			` ,	49/50 (98%)			
Overall Incidence	Total	97/100 (97%)	Mean 97%	SD 1.41%	Total	95/100 (95%)	Mean 95%	SD 4.24%		
All Organs: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
All Organs: Hemangiosarcoma										
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		
All Organs: Hemangiosarcoma or He	emangioma	(0)				0.50				
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 56

			Male				Female	
#All Organs: Histiocytic Sarcoma								
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	10tai	2/100 (2/0)		30 0%	101a1	0/100 (0 /6)		
#All Organs: Leukemia: Erythrocytic	:	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%
Leakeima. Lymphocym	c, monocync, wi	ononuclear, or Undifferen				E/EO (400/)	10/50 (200/)	
Overall Incidence	Total	26/50 (52%) 48/100 (48%)	22/50 (44%) Mean 48%	SD 5.66%	Total	5/50 (10%) 15/100 (15%)	10/50 (20%) Mean 15%	SD 7.07%
#All Organs:		48/100 (48%) phocytic, Mixed, NOS, or	Mean 48% Undifferentiated Cel		Total	15/100 (15%)	Mean 15%	SD 7.07%
#All Organs: Malignant Lymphoma:		48/100 (48%)	Mean 48%		Total Total	` ,	, ,	SD 7.07% SD 1.41%
#All Organs:	Histiocytic, Lym	48/100 (48%) phocytic, Mixed, NOS, or	Mean 48% Undifferentiated Cel 0/50 (0%) Mean 0%	I Туре		15/100 (15%) 0/50 (0%) 1/100 (1%)	Mean 15% 1/50 (2%) Mean 1%	
#All Organs: Malignant Lymphoma: Overall Incidence	Histiocytic, Lym	48/100 (48%) phocytic, Mixed, NOS, or 0/50 (0%)	Mean 48% Undifferentiated Cel 0/50 (0%)	I Туре		15/100 (15%)	Mean 15% 1/50 (2%)	
#All Organs: Malignant Lymphoma: Overall Incidence #All Organs:	Histiocytic, Lym Total Total	48/100 (48%) phocytic, Mixed, NOS, or 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/100 (0%)	Mean 48% Undifferentiated Cel	I Type SD 0%	Total	15/100 (15%) 0/50 (0%) 1/100 (1%) 0/50 (0%)	Mean 15% 1/50 (2%) Mean 1% 0/50 (0%)	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 57

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#All Organs: Mesothelioma: Malignant								
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%
#All Organs: Osteoma		0/20 (001)	2(72 (224)			2/52 (221)	2/52 (221)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Osteosarcoma		•••••				•••••		
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: Osteosarcoma or Osteom		1/50 (2%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Adrenal Cortex: Adenoma								
Overall Incidence	Total	3/50 (6%) 4/100 (4%)	1/50 (2%) Mean 4%	SD 2.83%	Total	0/50 (0%) 1/97 (1.03%)	1/47 (2%) Mean 1.06%	SD 1.5%
*Adrenal Cortex: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/97 (0%)	0/47 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 58

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Strain: F 344/N Length of Study: CHRONIC

			Male		Total 0/50 (0%) 0/48 (0%) Total 0/98 (0%) Mean 0% SD 0% 0/50 (0%) 0/48 (0%) Total 0/98 (0%) Mean 0% SD 0%			
*Adrenal Medulla: Ganglioneuroma								
		0/50 (0%)	0/50 (0%)			` ,	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		` '		
Adrenal Medulla: Hemangioma								
		0/50 (0%)	0/50 (0%)			` ,	` ,	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		, ,		
Adrenal Medulla: Pheochromocytoma Benign								
		7/50 (14%)	6/50 (12%)			3/50 (6%)	2/48 (4%)	
Overall Incidence	Total	13/100 (13%)	Mean 13%	SD 1.41%	Total	5/98 (5.1%)	Mean 5.08%	SD 1.3%
Adrenal Medulla: Pheochromocytoma Comple		1/50 (2%)	0/50 (0%)			1/50 (2%)	1/48 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/98 (2.04%)	Mean 2.04%	SD 0.06%
		` '				` ,		
Adrenal Medulla: Pheochromocytoma Maligna	ant							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma: Benigr			6/50 (12%)			4/50 (8%)	3/48 (6%)	
Overall Incidence	Total	14/100 (14%)	Mean 14%	SD 2.83%	Total	7/98 (7.14%)	Mean 7.13%	SD 1.24%
		` ,				,		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 59

			Male				Female	
#Bone: Chordoma								
Our well be add as a s	T -1-1	1/50 (2%)	0/50 (0%)	00 4 440/	Taral	0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#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%)	1/50 (2%)	05.00/		0/50 (0%)	1/50 (2%)	05
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Bone: Osteosarcoma or Osteoma								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Brain: Astrocytoma Malignant								
		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%
*Brain: Ependymoma Benign		0/50 (00/)	0/50 (00)			0/50 /00/	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		0/100 (0%)				` '		

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 60

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*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		(20)	(201)			2/52 (221)	0.770 (001)	
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 Benign			•••••			•••••		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Glioma Malignant		0/50 (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%
*Brain: Granular Cell Tumor Benig								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Oligodendroglioma Benign	1	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	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 61

			Male				Female	
*Brain: Oligodendroglioma Maligr	nant							
		0/50 (0%)	0/50 (0%)	OD 00/	-	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Gliom	ıa, or Astrocy	ytoma						
	•	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%
*Brain: Osteosarcoma		2/22 (22)					0.50	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	CD 00/	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
		0/100 (0%)		SD 0%		0/100 (0%)		טע עס
*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								
		3/50 (6%)	2/49 (4%)			12/50 (24%)	12/50 (24%)	
Overall Incidence	Total	5/99 (5.05%)	Mean 5.04%	SD 1.36%	Total	24/100 (24%)	Mean 24%	SD 0%
*Clitoral/Preputial Gland: Carcinoma								
Occupation and the second	T-1-1	0/50 (0%)	1/49 (2%)	OD 4 440/	T-1-1	1/50 (2%)	2/50 (4%)	00 4 440/
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	3/100 (3%)	Mean 3%	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: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 62

		Male				Female	
	3/50 (6%)	3/49 (6%)			13/50 (26%)	14/50 (28%)	
Total	6/99 (6.06%)			Total	, ,	Mean 27%	SD 1.41%
	, ,	` '	05 00/		, ,	0/50 (0%)	
Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
T-1-1	` '	` '	OD 00/	T-1-1	, ,	` ,	00, 00/
ı otai	0/100 (0%)	wean u%	SD 0%	ı otal	0/100 (0%)	Mean 0%	SD 0%
	2(72 (224)	2(72 (22))			(201)	0(50 (00))	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (00/)	0/50 (0%)			0/50 (09/)	0/50 (09/)	
Total	` '	` ,	SD 0%	Total	` '	` ,	SD 0%
	Total Total	Total 6/99 (6.06%) O/50 (0%) Total 0/99 (0%) Total 0/50 (0%) Total 0/100 (0%) Total 0/100 (0%) Total 0/100 (0%) Total 0/50 (0%) Total 0/100 (0%)	Total 6/99 (6.06%) Mean 6.06% 0/50 (0%) 0/49 (0%) Total 0/99 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% Total 0/100 (0%) Mean 0% Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%	Total 6/99 (6.06%) Mean 6.06% SD 0.09% O/50 (0%)	Total 6/99 (6.06%) Mean 6.06% SD 0.09% Total 0/50 (0%) 0/49 (0%) SD 0% Total Total 0/99 (0%) 0/50 (0%) SD 0% Total Total 0/100 (0%) 0/50 (0%) SD 0% Total	Total 6/99 (6.06%) Mean 6.06% SD 0.09% Total 27/100 (27%) 0/50 (0%) 0/49 (0%) SD 0% Total 1/50 (2%) Total 0/99 (0%) Mean 0% SD 0% Total 1/100 (1%) Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) Total 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Total 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)	Total 6/99 (6.06%) Mean 6.06% SD 0.09% Total 27/100 (27%) Mean 27% 0/50 (0%) 0/49 (0%)

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 63

			Male				Female		
#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	0/100 (0%)	Mean 0%	SD 0%	
#Harderian 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%	
#Harderian Gland: Carcinoma									
		0/50 (0%)	0/50 (0%)	05 00/		0/50 (0%)	0/50 (0%)	00.00	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Harderian Gland: Carcinoma or Adenoma									
Overall Incidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	SD 0%	
Overall incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%		
*Heart: Schwannoma Benign									
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Heart: Schwannoma Malignant		2 (2 2)	(00)				(201)		
Overell Incidence	Total	0/50 (0%)	1/50 (2%)	CD 4 440/	Total	0/50 (0%)	0/50 (0%)	CD 00/	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 64

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male			Female 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41% 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41% 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%) Mean 0% SD 0%			
#Intestine Large: Colon/Rectu Adenoma	ım:								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		` '			
#Intestine Large: Colon/Rectu Carcinoma or Adenoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` '	SD 1.41%	
		` '				` '			
#Intestine Large: Colon/Rectu Hemangioma	ım:								
		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						2(22)	-((
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									
•		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: 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

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Page: 65

			Male				Female	
#Intestine Small: Ileum: 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%
#Intestine Small: Jejunum: 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: Jejunum: Granular Cell Tumor Malig	nant	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma						0(50 (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%
#Intestine Small: Jejunum: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unspec	cified:							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 66

Report Date: 05/18/2011

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% 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) 0/50 (0%) SD 0%		
#Intestine Small: Site Uns Carcinoma	pecified:							
		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 Uns Carcinoma or Adenoma	•							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Intestine Small: Site Uns Granular Cell Tumor Ma		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%
#Intestine Small: Site Uns Leiomyoma Overall Incidence	specified: 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: Site Uns 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 Uns Schwannoma Malignan	•	0/50 (05.)	0/50 (00.1)			0(50 (00%)	0/50 (00/)	
	.	0/50 (0%)	0/50 (0%)	00.00/	T	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 67

Report Date: 05/18/2011

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

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
'Islets, Pancreatic: Adenoma								
		4/50 (8%)	1/50 (2%)			1/50 (2%)	1/49 (2%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 4.24%	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%
Islets, Pancreatic: Carcinoma								
		0/50 (0%)	2/50 (4%)			1/50 (2%)	0/49 (0%)	
verall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
Islets, Pancreatic: Carcinoma or Adenoma								
		4/50 (8%)	3/50 (6%)			2/50 (4%)	1/49 (2%)	
Overall Incidence	Total	7/100 (7%)	Mean 7%	SD 1.41%	Total	3/99 (3.03%)	Mean 3.02%	SD 1.39%
Kidney: Pelvis and Transi Carcinoma								
		0/49 (0%)	0/48 (0%)			0/50 (0%)	0/44 (0%)	
verall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/94 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transi Carcinoma or Adenoma								
		0/49 (0%)	0/48 (0%)			0/50 (0%)	0/44 (0%)	
verall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/94 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transi Papilloma	tional Epitheliu							
		0/49 (0%)	0/48 (0%)			0/50 (0%)	0/44 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/94 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 68

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Parity CAVAC

Length of Study: CHRONIC

			Male			Female			
*Kidney: Renal Tubule: Adenoma									
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/94 (0%)	0/44 (0%) Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma									
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/94 (0%)	0/44 (0%) Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma or Adenoma									
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/94 (0%)	0/44 (0%) Mean 0%	SD 0%	
*Kidney: Renal Tubule: Hemangiosarcoma						0/50 (00/)	0/44 (00/)		
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/94 (0%)	0/44 (0%) Mean 0%	SD 0%	
*Kidney: Renal Tubule: Lipoma									
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/94 (0%)	0/44 (0%) Mean 0%	SD 0%	
*Kidney: Renal Tubule: Mesenchymal Tumor Benign									
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/94 (0%)	0/44 (0%) Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 69

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Mesenchymal Tumor Malignant				Male				Female	
Overall Incidence Total 0/97 (0%) Mean 0% SD 0% Total 1/94 (1.06%) Mean 1.14% SD 1.61% *Kidiney: Renal Tubule: Nephroblastoma 0/49 (0%) 0/48 (0%) OVerall Incidence Total 0/97 (0%) Mean 0% SD 0% Total 0/94 (0%) 0/44 (0%) Mean 0% SD 0% **Kidiney: Renal Tubule: Sarcoma 0/49 (0%) 0/48 (0%) O/48 (0%) O/50 (0%) 0/50 (0%) O/50 (0%) 0/44 (0%) Mean 0% SD 0% **Cholangioma O/50 (0%) 0/50 (0%) O/50 (0%) 0/50 (0%) O/50 (0%) 0/50 (0%) SD 0% **Cholangioma O/50 (0%) 0/50 (0%) O/50 (0%) 0/50 (0%) O/50 (0%) 0/50 (0%) SD 0% **Cholangioma O/50 (0%) 0/50 (0%) O/50 (0%) 0/50 (0%) SD 0% **Cholangioma O/50 (0%) 0/50 (0%) 0/50 (0%) SD 0% **Cholangioma O/50 (0%) 0/50 (0%) 0/50 (0%) SD 0% SD 0% <th< th=""><th>*Kidney: Renal Tubule: Mesenchymal Tumor Mali</th><th>ignant</th><th></th><th></th><th></th><th></th><th></th><th></th><th></th></th<>	*Kidney: Renal Tubule: Mesenchymal Tumor Mali	ignant							
*Kidney: Renal Tubule: Nephroblastoma 0/49 (0%) 0/48 (0%) Overall Incidence Total 0/97 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/44 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Sarcoma 0/49 (0%) 0/48 (0%) Overall Incidence Total 0/50 (0%) 0/44 (0%) 0/50 (0%) 0/44 (0%) Overall Incidence Total 0/97 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/44 (0%) Overall Incidence Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% *Liver: Hemangiosarcoma 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% *Liver: Hemangiosarcoma 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0%	•		0/49 (0%)	0/48 (0%)			0/50 (0%)	1/44 (2%)	
*Kidney: Renal Tubule: Nephroblastoma 0/49 (0%) 0/48 (0%) 5D 0% Total 0/94 (0%) 0/44 (0%) Overall Incidence Total 0/97 (0%) Mean 0% SD 0% Total 0/94 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Sarcoma 0/49 (0%) 0/48 (0%) Overall Incidence Total 0/97 (0%) Mean 0% SD 0% *Liver: Cholangioma 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% *Liver: Hemangiosarcoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Liver: Hemangiosarcoma 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% *Liver: Hematocellular Adenoma 2/50 (4%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Overall Incidence		` '				` ,		SD 1.61%
Overall Incidence Total 0/97 (0%) Mean 0% SD 0% Total 0/94 (0%) Mean 0% SD 0% **Kidney: Renal Tubule: Sarcoma 0/49 (0%) 0/48 (0%) 0/88 (0%) 0/50 (0%) 0/50 (0%) 0/44 (0%) Coverall Incidence Total 0/97 (0%) Mean 0% SD 0% Total 0/94 (0%) Mean 0% SD 0% **Liver: Cholangioma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% **Liver: Hemangiosarcoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%) Mean 0% SD 0% **Colspan="8">**Colspan="8	*Kidney: Renal Tubule:								
*Kidney: Renal Tubule: Sarcoma O/49 (0%) 0/48 (0%) Overall Incidence Total 0/97 (0%) Mean 0% SD 0% *Liver: Cholangioma O/50 (0%) 0/50 (0%) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Mean 0% SD 0% Total 0/94 (0%) Mean 0% SD 0% *Liver: Cholangioma O/50 (0%) 0/50 (0%) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Liver: Hemangiosarcoma O/50 (0%) 0/50 (0%) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Liver: Hemangiosarcoma O/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Liver: Hepatocellular Adenoma 2/50 (4%) 0/50 (0%) O/50 (0%) 0/50 (0%) 0/50 (0%) O/50 (0%) 0/50 (0%) O/50 (0%) 0/50 (0%)			, ,	` ,			` '	` ,	
Sarcoma O/49 (0%) O/48 (0%) Overall Incidence Total O/97 (0%) Mean 0% SD 0% Total O/94 (0%) Mean 0% SD 0% *Liver: Cholangioma O/50 (0%) O/50 (0%) Overall Incidence Total O/100 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Mean 0% SD 0% Total O/100 (0%) O/50 (0%) Overall Incidence Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Mean 0% SD 0% *Liver: Hemangiosarcoma O/50 (0%) O/50 (0%) Overall Incidence Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Mean 0% SD 0% *Liver: Hemangiosarcoma O/50 (0%) O/50 (0%) Mean 0% SD 0% Total O/100 (0%) Mean 0% SD 0% *Liver: Hepatocellular Adenoma 2/50 (4%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%)			, ,			Total	0/94 (0%)	Mean 0%	SD 0%
Overall Incidence Total 0/97 (0%) Mean 0% SD 0% Total 0/94 (0%) Mean 0% SD 0% *Liver: Cholangioma	*Kidney: Renal Tubule: Sarcoma								
*Liver: Cholangioma 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: Hemangiosarcoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Liver: Hepatocellular Adenoma 2/50 (4%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)			0/49 (0%)	0/48 (0%)			` ,	` ,	
Cholangioma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Liver: Hemangiosarcoma Overall Incidence Total 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0% *Liver: Hepatocellular Adenoma 2/50 (4%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/94 (0%)	Mean 0%	SD 0%
Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Liver: Hemangiosarcoma Overall Incidence Total 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0% *Liver: Hepatocellular Adenoma 2/50 (4%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	*Liver: Cholangioma		0(50 (00())	0/50 (00/)			0/50 (00)	0/50 (00/)	
Hemangiosarcoma 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Liver: Hepatocellular Adenoma 2/50 (4%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Overall Incidence	Total	` '	, ,	SD 0%	Total	` ,	` ,	SD 0%
Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Liver: Hepatocellular Adenoma 2/50 (4%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	*Liver: Hemangiosarcoma								
*Liver: Hepatocellular Adenoma 2/50 (4%) 0/50 (0%) 0/50 (0%) 0/50 (0%)			` '	, ,			` '	` ,	
Hepatocellular Adenoma 2/50 (4%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	*Liver: Hepatocellular Adenoma								
Overall Incidence Total 2/100 (2%) Mean 2% SD 2.83% Total 0/100 (0%) Mean 0% SD 0%			2/50 (4%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
	Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 70

			Male			Female			
*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	or Hepatobla	astoma							
•	•	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	or Hepatoce	Ilular Adenoma 2/50 (4%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Carcinoma	, Hepatocellu	lar Adenoma, or Hepatob	lastoma 0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Liver: Ito Cell Tumor Benign									
		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 Aden	ioma	0/50 (0%)	4/50 (00)			0/50 (000)	0/50 /00/		
Overall Instidence	Tatal	0/50 (0%)	1/50 (2%)	CD 4 440/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 71

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
Lung: Alveolar/Bronchiolar Carcii	noma							
		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 Carcii		eolar/Bronchiolar Adenon	na					
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
Lung: 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%
Lung: Hemangiosarcoma		1/50 (2%)				0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
		` '				` '		
Lung: Squamous Cell Carcinoma								
		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%
Lymph Node: Hemangiosarcoma							0/50 (00)	
Sec	T-1-1	1/50 (2%)	0/50 (0%)	OD 4 440/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 72

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Mammary Gland: Adenolipoma								
		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%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)			2/50 (4%)	2/50 (4%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	4/100 (4%)	Mean 4%	SD 0%
Mammary Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			3/50 (6%)	3/50 (6%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	6/100 (6%)	Mean 6%	SD 0%
Mammary Gland: Fibroadenoma								
		2/50 (4%)	3/50 (6%)			35/50 (70%)	26/50 (52%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	61/100 (61%)	Mean 61%	SD 12.73%
Mammary Gland: Fibroma								
		1/50 (2%)	0/50 (0%)	25		0/50 (0%)	1/50 (2%)	00 4 4404
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 73

			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma o	r Adenoma							
		3/50 (6%)	3/50 (6%)			36/50 (72%)	28/50 (56%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 0%	Total	64/100 (64%)	Mean 64%	SD 11.31%
#Mammary Gland: Fibroma, Fibroadenoma, C	Carcinoma, or	Adenoma						
		3/50 (6%)	3/50 (6%)			37/50 (74%)	30/50 (60%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 0%	Total	67/100 (67%)	Mean 67%	SD 9.9%
#Mesentery: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: 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%
#Mesentery: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 74

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male			Female 0/50 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)		
*Nose: Adenoma		0/50 (0%)	0/50 (00/)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total		(/	SD 0%
*Nose: Squamous Cell Carcinom	na	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	` '	` '	SD 0%
#Oral Cavity (Oral Mucosa, Papilloma Squamous or F	Tongue, Phary	ynx, Tooth, Gingiva):						
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	` '	` '	SD 0%
#Oral Cavity (Oral Mucosa, Squamous Cell Carcinom	Tongue, Phary	ynx, Tooth, Gingiva):						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` '	SD 0%
#Oral Cavity (Oral Mucosa, Squamous Cell Carcinom	•	Squamous, or Papilloma	0/50 (00/)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	` '	` '	SD 0%
#Oral Mucosa: Squamous Cell Carcinom	na							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

Page: 75

			Male				Female	
#Oral Mucosa: Squamous Cell Papillom	a							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma								
						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Fibrosarcoma								
						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Be	enign					0/50 (00/)	0/50 /00/)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Ma								
						0/50 (0%)	1/50 (2%)	
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%
*Ovary: Granulosa Cell Tumor: B	enign, Maligna	ant, NOS						
One will be add a second					T-1-1	0/50 (0%)	1/50 (2%)	OD 4 440/
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 76

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: **Granulosa-Theca Tumor Benign** 0/50 (0%)0/50 (0%)Overall Incidence Total 0/100 (0%) Mean 0% SD 0% *Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)0/50 (0%)Overall Incidence Total 0/100 (0%) Mean 0% SD 0% *Ovary: **Schwannoma 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 3/50 (6%)0/50 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 3/100 (3%) Mean 3% SD 4.24% Total 0/99 (0%) Mean 0% SD 0% *Pancreas: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total Mean 0% SD 0% Mean 0% SD 0% 0/100 (0%) Total 0/99 (0%)

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 77

Report Date: 05/18/2011

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

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
Pancreas: Carcinoma or Adenoma								
• " " "	.	3/50 (6%)	0/50 (0%)	00 4 0 40/	-	0/50 (0%)	0/49 (0%)	05.00/
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	0/99 (0%)	Mean 0%	SD 0%
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 (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%
Parathyroid Gland: Adenoma								
Duranell Inclidence	Tatal	0/48 (0%)	0/48 (0%)	CD 00/	Tatal	0/49 (0%)	0/47 (0%)	SD 0%
Overall Incidence	Total	0/96 (0%)	Mean 0%	SD 0%	Total	0/96 (0%)	Mean 0%	
Pituitary Gland: Pars Distal Adenoma	lis or Unspec	ified Site:						
		19/50 (38%)	24/50 (48%)			19/50 (38%)	25/50 (50%)	
Overall Incidence	Total	43/100 (43%)	Mean 43%	SD 7.07%	Total	44/100 (44%)	Mean 44%	SD 8.49%
Pituitary Gland: Pars Distal Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 78

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female				
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma											
		19/50 (38%)	24/50 (48%)			19/50 (38%)	26/50 (52%)				
Overall Incidence	Total	43/100 (43%)	Mean 43%	SD 7.07%	Total	45/100 (45%)	Mean 45%	SD 9.9%			
*Pituitary Gland: Pars Distal Ganglioneuroma	is or Unspec	ified Site:									
		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%			
*Pituitary Gland: Pars Interm Adenoma	nedia:										
		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%			
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	nedia:	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%			
*Pituitary Gland: Pars Nervo Craniopharyngioma	sa:										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
*Prostate: Adenoma											
		0/50 (0%)	2/50 (4%)								
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%							

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 79

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Prostate: Carcinoma or Adenoma 0/50 (0%)2/50 (4%)**Overall Incidence** Total 2/100 (2%) Mean 2% SD 2.83% *Salivary Glands: 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% *Salivary Glands: 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% *Salivary Glands: Sarcoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% *Salivary Glands: **Schwannoma Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% **#Seminal Vesicle:** Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/100 (0%)

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 80

			Male				Female	
#Skeletal Muscle: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	05.00/		0/50 (0%)	0/50 (0%)	05 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (00)	2(22)			(201)	0/50 (001)	
Overall Insidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or F	Rhabdomyoma							
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%)	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%
#Skin: Basal Cell Adenoma or B		Tumor Benign						
• " " " "	+	0/50 (0%)	1/50 (2%)	05 4 440/		0/50 (0%)	1/50 (2%)	05 4 440/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 81

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female				
#Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma											
		0/50 (0%)	3/50 (6%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
#Skin: Basal Cell Carcinoma											
		1/50 (2%)	1/50 (2%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
#Skin:											
Basal Cell Carcinoma	or Basosquamou	is Tumor (malignant or No	OS)								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
#Skin: Basal Cell Carcinoma, NOS), or Trichoepithel		oma, Basosquamous Tun	nor (benign, maligna	nt or							
		1/50 (2%)	4/50 (8%)			0/50 (0%)	2/50 (4%)				
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 4.24%	Total	2/100 (2%)	Mean 2%	SD 2.83%			
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	inoma, Carcinom Sq Papilloma, Ke	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 5/50 (10%)), Basal Cell Adenor ithelioma 9/50 (18%)	na,		0/50 (0%)	2/50 (4%)				
Overall Incidence	Total	14/100 (14%)	Mean 14%	SD 5.66%	Total	2/100 (2%)	Mean 2%	SD 2.83%			
#Skin: Fibroma											
#Skin: Fibroma Overall Incidence	Total	5/50 (10%) 16/100 (16%)	11/50 (22%) Mean 16%	SD 8.49%	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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 82

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female				
#Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma											
		6/50 (12%)	16/50 (32%)			3/50 (6%)	2/50 (4%)				
Overall Incidence	Total	22/100 (22%)	Mean 22%	SD 14.14%	Total	5/100 (5%)	Mean 5%	SD 1.41%			
#Skin: Fibrosarcoma											
		1/50 (2%)	3/50 (6%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Fibrosarcoma, Sarcoma,	Myxosarcoma	a, or Fibrous Histiocytoma 1/50 (2%)	a 6/50 (12%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	7/100 (7%)	Mean 7%	SD 7.07%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Fibrous Histiocytoma		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: 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%			
#Skin: Hemangiosarcoma											
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 83

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Strain: F 344/N Length of Study: CHRONIC

			Male				Female	
#Skin: Keratoacanthoma								
Overall Incidence	Total	3/50 (6%) 8/100 (8%)	5/50 (10%) Mean 8%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Lipoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Liposarcoma		•••••						
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		0/50 (09/)	0/50 (09/)			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%
#Skin: Neural Crest Tumor, Mal	lignant							
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: Neurofibroma or Schwa								
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

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 84

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Strain: F 344/N Length of Study: CHRONIC

Male					Female						
#Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS)											
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
ırofibroma, or S		-			0/50 (0%)	0/50 (0%)					
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
	0/50 (0%)	3/50 (6%)			0/50 (0%)	0/50 (0%)					
	` '		SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%				
					0/50 (0%)	0/50 (0%)					
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
T-1-1	` '	` '	OD 00/	T-1-1	` '	` '	00.00/				
ı otaı	0/100 (0%)	iviean u%	SD 0%	ı otaı	U/100 (U%)	iviean u%	SD 0%				
ma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Total	` '	` '	SD 0%	Total	` '	` '	SD 0%				
	Total Irofibroma, or \$ Total Total Total	0/50 (0%) Total 0/100 (0%) Irofibroma, or Schwannoma (benign, ma 0/50 (0%) Total 0/100 (0%) 0/50 (0%) Total 3/100 (3%) Total 0/50 (0%) Total 0/100 (0%) Total 0/100 (0%) Total 0/50 (0%) 0/50 (0%)	Chwannoma (malignant or NOS) 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% Irofibroma, or Schwannoma (benign, malignant or NOS) 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 3/50 (6%) Total 3/100 (3%) Mean 3% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% Total 0/100 (0%) Mean 0% Total 0/100 (0%) Mean 0%	Chwannoma (malignant or NOS) 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Irrofibroma, or Schwannoma (benign, malignant or NOS) 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% 0/50 (0%) 3/50 (6%) Total 3/100 (3%) Mean 3% SD 4.24% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0%	Chwannoma (malignant or NOS) 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total Profibroma, or Schwannoma (benign, malignant or NOS) 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/50 (0%) 3/50 (6%) Total 3/100 (3%) Mean 3% SD 4.24% Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total	chwannoma (malignant or NOS)	chwannoma (malignant or NOS) 0/50 (0%) 0/				

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 85

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 2/100 (2%) Mean 2% SD 0% Total 1/100 (1%) Mean 1% SD 1.41% **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% 0/100 (0%) Mean 0% SD 0% Total #Skin: **Squamous Cell Papilloma or Papilloma** 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) SD 0% #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma 4/50 (8%)5/50 (10%) 0/50 (0%)0/50 (0%)Mean 9% 0/100 (0%) Overall Incidence Total 9/100 (9%) SD 1.41% Total Mean 0% SD 0% #Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 4/50 (8%)5/50 (10%) 0/50 0/50 (0%)Overall Incidence Total 9/100 (9%) Mean 9% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% #Skin: Trichoepithelioma (0%)(4%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 2/100 (2%) Mean 2% SD 2.83% Total 0/100 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 86

			Male				Female	
#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 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 (00/)	0/50 /00/			0/50 (09/)	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%
		, ,			·····			
#Spinal Cord: Astrocytoma Malignant		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%
#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 (00/)	0/50 (00/)			0/50 (00/)	0/40 (000)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%)	0/48 (0%) Mean 0%	SD 0%
Overall incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	iviean u%	3D 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 87

			Male				Female	
*Spleen: Fibrous Histiocytoma								
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Spleen: Leiomyosarcoma		0/50 (00)	0/50 (00)			0/50 (00/)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 00/	Total	0/50 (0%)	0/48 (0%) Mean 0%	CD 00/
Overall incidence		0/100 (0%)	wean 0%	SD 0%	ı olal	0/98 (0%)	wiean 0%	SD 0%
*Spleen: Sarcoma		0/50 (00/)	0/50 (00()			0/50 (00/)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
	.	0/50 (0%)	0/50 (0%)	OD 00/	-	0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 88

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female				
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Stomach, Glandular: 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%			
#Stomach, Glandular: 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%			
#Stomach, Glandular: Lipoma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Stomach, Glandular: Sarcoma		2/22	2/ /22/				(201)				
Occupation of decision	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Contract/Lab: All Laboratories

Species: RATS

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

Page: 89

(0%)

SD 0%

Mean 0%

0/48

(0%)

0/50

0/98 (0%)

Total

Report Date: 05/18/2011

			Male				Female	
*Testes: Adenoma		42/50 (84%)	35/50 (70%)					
Overall Incidence	Total	77/100 (77%)	Mean 77%	SD 9.9%				
*Testes: Hemangioma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Benign		0/50 (0%)	0/44 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/50 (0%)	0/44 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma NOS								
Overall Incidence	Total	0/50 (0%) 0/94 (0%)	0/44 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%
*Thymus:								

SD 0%

(0%)

0/44

Mean 0%

Total

0/50

0/94 (0%)

(0%)

Thymoma: Benign, Malignant, NOS

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 90

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Thyroid Gland: C-Cell: Adenoma								
Overall Incidence	Total	3/50 (6%) 9/96 (9.38%)	6/46 (13%) Mean 9.52%	SD 4.98%	Total	4/50 (8%) 8/92 (8.7%)	4/42 (10%) Mean 8.76%	SD 1.08%
*Thyroid Gland: C-Cell: Carcinoma								
Overall Incidence	Total	1/50 (2%) 1/96 (1.04%)	0/46 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 3/92 (3.26%)	3/42 (7%) Mean 3.57%	SD 5.05%
'Thyroid Gland: C-Cell: Carcinoma or Adenoma								
Overall Incidence	Total	4/50 (8%) 10/96 (10.42%)	6/46 (13%) Mean 10.52%	SD 3.57%	Total	4/50 (8%) 11/92 (11.96%)	7/42 (17%) Mean 12.33%	SD 6.13%
Thyroid Gland: Follicular Cell Adenoma								
Overall Incidence	Total	3/50 (6%) 3/96 (3.12%)	0/46 (0%) Mean 3%	SD 4.24%	Total	0/50 (0%) 0/92 (0%)	0/42 (0%) Mean 0%	SD 0%
Thyroid Gland: Follicular Cell Carcinoma			•••••					•••••
Overall Incidence	Total	0/50 (0%) 0/96 (0%)	0/46 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/92 (0%)	0/42 (0%) Mean 0%	SD 0%
Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:	2/50 /(20/)	0/40 (00/)			0/50 (0%)	0/40 (00/)	
Overall Incidence	Total	3/50 (6%) 3/96 (3.12%)	0/46 (0%) Mean 3%	SD 4.24%	Total	0/50 (0%) 0/92 (0%)	0/42 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 91

			Male				Female	
#Tissue NOS: Paraganglioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinor	ma							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinor	ma or Papilloma	=	0/50 (0%)			0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)			` '	` '	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
		1/100 (1%)	Mean 1%		Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue:		1/100 (1%)	Mean 1%		Total Total	` '	` '	SD 0% SD 0%
#Tongue: Squamous Cell Papillom	n a Total	1/100 (1%) 1/50 (2%) 1/100 (1%)	Mean 1% 0/50 (0%) Mean 1%			0/100 (0%) 0/50 (0%) 0/100 (0%)	Mean 0%	
#Tongue: Squamous Cell Papillom Overall Incidence #Tooth: Adamantinoma Malignar	na Total	1/100 (1%) 1/50 (2%) 1/100 (1%) 0/50 (0%)	Mean 1% 0/50 (0%) Mean 1% 0/50 (0%)	SD 1.41%	Total	0/100 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%)	Mean 0% 0/50 (0%) Mean 0% 0/50 (0%)	SD 0%
#Tongue: Squamous Cell Papillom Overall Incidence #Tooth:	n a Total	1/100 (1%) 1/50 (2%) 1/100 (1%)	Mean 1% 0/50 (0%) Mean 1%			0/100 (0%) 0/50 (0%) 0/100 (0%)	Mean 0% 0/50 (0%) Mean 0%	
#Tongue: Squamous Cell Papillom Overall Incidence #Tooth: Adamantinoma Malignar	na Total	1/100 (1%) 1/50 (2%) 1/100 (1%) 0/50 (0%)	Mean 1% 0/50 (0%) Mean 1% 0/50 (0%)	SD 1.41%	Total	0/100 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%)	Mean 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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 92

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Strain: F 344/N Length of Study: CHRONIC

			Male				Female	
*Urinary Bladder: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Urinary Bladder: Carcinoma or Papilloma								
		0/50 (0%)	0/50 (0%)	25 20/		0/50 (0%)	0/50 (0%)	00.00/
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Urinary Bladder: Papilloma								
		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%
Uterus: Adenoma								
						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
Uterus: Carcinoma	•••••							
						0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 93

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus:** Deciduoma Benign 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Uterus: Leiomyosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Uterus: **Polyp Stromal** 9/50 (18%) 17/50 (34%) **Overall Incidence** Total 26/100 (26%) Mean 26% SD 11.31% #Uterus: Sarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Uterus: Sarcoma Stromal 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% **#Uterus:** Sarcoma Stromal or Polyp Stromal 9/50 (18%)17/50 (34%)**Overall Incidence** 26/100 (26%) Mean 26% SD 11.31% Total

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

#Zymbal's Gland: Adenoma

Overall Incidence

#Zymbal's Gland: Carcinoma

#Uterus:

#Vagina: Polyp

#Vagina: Sarcoma

#Vagina:

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Total

Total

Total

Total

Length of Study: CHRONIC

Schwannoma Malignant

......

Schwannoma Malignant

Contract/Lab: All Laboratories

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

(0%)

(0%)

(0%)

0/100 (0%)

0/50

0/50

0/50

0/100 (0%)

0/100 (0%)

0/100 (0%)

Page: 94

Mean 0%

Mean 0%

Mean 0%

Mean 0%

(0%)

(0%)

(0%)

0/50

0/50

0/50

Report Date: 05/18/2011

SD 0%

SD 0%

SD 0%

SD 0%

Overall Incidence	Total	0/100 (0%)
*: Denominator is number of animals		

Total

.....

0/50

0/100 (0%)

0/50

(0%)

(0%)

0/50

0/50

Mean 0%

Mean 0%

(0%)

(0%)

SD 0%

SD 0%

^{#:} Denominator is number of animals necropsied

Species: RATS

#Zymbal's Gland:

Overall Incidence

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Strain: F 344/N Length of Study: CHRONIC

Carcinoma or Adenoma

Vehicle: METHYLCELLULOSE

Male				Female	
0/50 (00/)			0/50 (00/)	0/50 (00/)	
0/50 (0%)			0/50 (0%)	0/50 (0%)	
Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

Page: 95

Report Date: 05/18/2011

Total

0/50

0/100 (0%)

(0%)

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 96

Report Date: 05/18/2011

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

Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory Battelle Columbus Laboratory	052000505 059501107	01/21/04 03/06/02	727 727	50(3) 50(3)	30(679) 22(673)	498.5 510.3	Ginseng 5-(Hydroxymethyl)-2-furfural
					Female		
Battelle Columbus Laboratory Battelle Columbus Laboratory	052000505 059501107	01/22/04 03/07/02	728 728	50(5) 50(5)	36(700) 31(679)	355.0 332.2	Ginseng 5-(Hydroxymethyl)-2-furfural

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 97

			Male				Female	
#All Organs: Benign Tumors		49/50 (98%)	50/50 (100%)			42/50 (84%)	46/50 (92%)	
Overall Incidence	Total	99/100 (99%)	Mean 99%	SD 1.41%	Total	88/100 (88%)	Mean 88%	SD 5.66%
#All Organs: Malignant Tumors		26/50 (52%)	35/50 (70%)			10/50 (20%)	16/50 (32%)	
Overall Incidence	Total	61/100 (61%)	Mean 61%	SD 12.73%	Total	26/100 (26%)	Mean 26%	SD 8.49%
#All Organs: Malignant and Benign To								
Overall Incidence	Total	49/50 (98%) 99/100 (99%)	50/50 (100%) Mean 99%	SD 1.41%	Total	45/50 (90%) 93/100 (93%)	48/50 (96%) Mean 93%	SD 4.24%
#All Organs: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma					•••••			
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: Hemangiosarcoma or He								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 98

			Male			Female			
#All Organs: Histiocytic 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%	
#All Organs: Leukemia: Erythrocytic									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#All Organs: Leukemia: Lymphocytic, M	Monocytic, M	18/50 (36%)	28/50 (56%)			6/50 (12%)	9/50 (18%)		
Overall Incidence	Total	46/100 (46%)	Mean 46%	SD 14.14%	Total	15/100 (15%)	Mean 15%	SD 4.24%	
#All Organs: Malignant Lymphoma: His						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									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#All Organs: Mesothelioma: Benign, Ma		3							
		2/50 (4%)	2/50 (4%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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

			Male		Female			
#All Organs: Mesothelioma: Malignant								
		2/50 (4%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
	.	1/50 (2%)	0/50 (0%)	00 4 440/	-	0/50 (0%)	1/50 (2%)	05 4 440/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#All Organs: Osteosarcoma or Osteoma								
O	T-1-1	1/50 (2%)	0/50 (0%)	OD 4 440/	T-1-1	0/50 (0%)	1/50 (2%)	00 4 440/
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 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Adrenal Cortex: Carcinoma		0/50 (00/)	0/50 /00()			0/50 (00()	0/50 /00/	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
	Total	0/100 (0%)	Mean 0%		Total	0/100 (0%)		

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

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 100

			Male				Female	
*Adrenal Medulla: Ganglioneuroma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*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 Benign		4/50 (8%)	5/50 (10%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Adrenal Medulla: Pheochromocytoma Comple		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 Maligna								
		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: Benign			5/50 (10%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Overali incidence		, ,				` ,		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

> Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Report Date: 05/18/2011

Page: 101

			Male	Female					
#Bone: Chordoma		2(20)	- ()				2/22 (22)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Bone: Osteoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Bone: Osteosarcoma									
Overall Incidence	Total	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%	
#Bone: Osteosarcoma or Osteoma									
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%	
*Brain: Astrocytoma Malignant									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Brain: Ependymoma Benign									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 102

			Male				Female	
*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								
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 Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Glioma Malignant						0/50 /00/\	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Granular Cell Tumor Benigi								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Oligodendroglioma 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	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 103

			Male				Female				
*Brain: Oligodendroglioma 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%			
		0/100 (0%)			10lai						
*Brain: Oligodendroglioma, GI	ioma, or Astrocy	rtoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
*Brain: Osteosarcoma											
	-	0/50 (0%)	0/50 (0%)	00.00/	+	0/50 (0%)	0/50 (0%)	OD 00/			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
*Brain: Schwannoma Malignar	nt	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	:										
		0/50 (0%)	5/50 (10%)			1/50 (2%)	3/50 (6%)				
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 7.07%	Total	4/100 (4%)	Mean 4%	SD 2.83%			
*Clitoral/Preputial Gland: Carcinoma	:										
		0/50 (0%)	1/50 (2%)			1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 104

			Male				Female	
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 6/100 (6%)	6/50 (12%) Mean 6%	SD 8.49%	Total	2/50 (4%) 5/100 (5%)	3/50 (6%) Mean 5%	SD 1.41%
				30 0.4970		3/100 (3/0)		
*Clitoral/Preputial Gland: Sarcoma		0/50 (00)	0/50 (00/)			0/50 (00()	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Ear: Neural Crest Tumor		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Esophagus: 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%
#Eye: Melanoma Benign		- (a)	(00)			2/22 (221)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Eye: Melanoma Malignant								
-		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 105

#Eye: Schwannoma Malignant			Male		Female				
		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%	
#Harderian Gland: Adenoma	•••••								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Harderian Gland: Carcinoma									
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Harderian Gland: Carcinoma or Adenoma		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%	
*Heart: Schwannoma Benign									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Heart: Schwannoma Malignant		272 (221)				0/20 (00)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 106

Report Date: 05/18/2011

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 107

			Male				Female	
#Intestine Small: Ileum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Granular Cell Tumor Maligr	nant	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma						0/50 (0%)	0/50 (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%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Adenoma	ified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 108

Report Date: 05/18/2011

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Small: Site Unspecified: Carcinoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Carcinoma or Adenoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: **Granular Cell Tumor 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% #Intestine Small: Site Unspecified: Leiomyoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 1/100 (1%) Mean 1% SD 1.41% #Intestine Small: Site Unspecified: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: **Schwannoma Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/100 (0%) Mean 0% SD 0% 0/100 (0%) Total

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 109

Report Date: 05/18/2011

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Islets, Pancreatic: Adenoma 0/50 (0%)2/50 (4%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 2/100 (2%) Mean 2% SD 2.83% Total 1/100 (1%) Mean 1% SD 1.41% *Islets, Pancreatic: Carcinoma 0/50 0/50 (0%)2/50 (4%)0/50 (0%)(0%)**Overall Incidence** Total 2/100 (2%) Mean 2% SD 2.83% Total 0/100 (0%) Mean 0% SD 0% *Islets, Pancreatic: Carcinoma or Adenoma 0/50 (0%)4/50 (8%)1/50 (2%)0/50 (0%)**Overall Incidence** 4/100 (4%) Mean 4% SD 5.66% Total 1/100 (1%) Mean 1% SD 1.41% Total *Kidney: Pelvis and Transitional Epithelium: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: **Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% 0/100 (0%) Mean 0% SD 0% Total

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 110 Report Date: 05/18/2011

			Male				Female	
*Kidney: Renal Tubule: Adenoma								
		1/50 (2%)	0/50 (0%)	05		0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma		4/50 (001)	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%
*Kidney: Renal Tubule: Carcinoma or Adenoma		2/50 (4%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma						•••••		•••••
·		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Benigi	n	- (ac.)	- (as::				(00)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/
	Total	0/100 (0%)		SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 111

			Male				Female	
*Kidney: Renal Tubule: Mesenchymal 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%
*Kidney: Renal Tubule: Nephroblastoma		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%
*Kidney: Renal Tubule: 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%
*Liver: Cholangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma		•••••						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatocellular 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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 112

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Liver: Hepatocellular Carcinoma Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma	or Hepatobla							
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%
*Liver: Hepatocellular Carcinoma						0/50 /00/\	0/50 (0%)	
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%
*Liver: Hepatocellular Carcinoma,								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Ito 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%
*Lung: Alveolar/Bronchiolar Aden								
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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 113

Report Date: 05/18/2011

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

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Hemangiosarcoma

Squamous Cell Carcinoma

......

Overall Incidence

Overall Incidence

Overall Incidence

#Lymph Node: Hemangiosarcoma

*Lung:

Male **Female** *Lung: Alveolar/Bronchiolar Carcinoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% *Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 1/100 (1%) Mean 1% SD 1.41% *Lung: 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% *Lung:

SD 0%

SD 0%

SD 0%

0/50

0/50

0/50

0/100 (0%)

0/100 (0%)

0/100 (0%)

Total

Total

Total

(0%)

(0%)

(0%)

0/50

0/50

0/50

(0%)

(0%)

(0%)

SD 0%

SD 0%

SD 0%

Mean 0%

Mean 0%

Mean 0%

*: Denominator is number of animals with tissues examined microscopically

Total

Total

Total

0/50

0/100 (0%)

0/50

0/100 (0%)

0/50

0/100 (0%)

(0%)

(0%)

(0%)

0/50

0/50

0/50

Mean 0%

Mean 0%

Mean 0%

(0%)

(0%)

(0%)

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Control Animal Groups Report Date: 05/18/2011 /AGE

Page: 114

			Male				Female	
#Mammary Gland: Adenolipoma								
	.	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%
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	05 00/		2/50 (4%)	2/50 (4%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	4/100 (4%)	Mean 4%	SD 0%
#Mammary Gland: Carcinoma								
	.	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%
#Mammary Gland: Carcinoma or Adenoma		0/50 (00)	0/50 (00/)			0/50 /40/)	0/50 (40()	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%
#Mammary Gland: Fibroadenoma								
		2/50 (4%)	1/50 (2%)			32/50 (64%)	29/50 (58%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	61/100 (61%)	Mean 61%	SD 4.24%
#Mammary Gland: Fibroma	•••••							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 115

			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma	or Adenoma							
Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	33/50 (66%) 63/100 (63%)	30/50 (60%) Mean 63%	SD 4.24%
#Mammary Gland: Fibroma, Fibroadenoma,	. Carcinoma. or	Adenoma						
Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	33/50 (66%) 63/100 (63%)	30/50 (60%) Mean 63%	SD 4.24%
#Mesentery: Fibrous Histiocytoma								
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			•••••					
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: 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%
#Mesentery: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 116

			Male				Female	
*Nose: Adenoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Nose: Squamous Cell Carcin	oma							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o		ynx, Tooth, Gingiva): 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Phary							
	-	0/50 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucos Squamous Cell Carcin		Squamous, or Papilloma	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%
	ı Olai				10tai	0/100 (0%)	ivicali 070	
#Oral Mucosa: Squamous Cell Carcin	oma		0/50 (00:			(00:)	2/22 (22%)	
O	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	00, 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 117

		Male				Female	
1							
Total	0/100 (0%)	Mean 0%	SD 0%	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%
				Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
nign							
Ū				Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
lignant							
9				Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
	NOS						
enign, Maligna	ant, NOS				0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	
	nign	0/50 (0%) Total 0/100 (0%)	n	a 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%	Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total Total Total Total Total Total Total	1	a

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female

Page: 118

		Male				Female	
Benign							
				Total	0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
Malignant							
				Total	0/99 (0%)	Mean 0%	SD 0%
				Total	0/99 (0%)	Mean 0%	SD 0%
				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%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	0/50 (001)	0/50 (05:)			0/50 (001)	0(50 (00))	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	Malignant Total	Malignant 0/50 (0%) Total 1/100 (1%) 0/50 (0%) Total 0/100 (0%)	3enign Malignant 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%	Benign Malignant 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%	Total Total Total Total	Malignant	Total O/50 (0%) O/49 (0%) Mean 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 119

			Male				Female	
*Pancreas: Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pancreas: Mixed Tumor Benign								
		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%
*Pancreas: Mixed Tumor 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%
*Parathyroid Gland: Adenoma		0/50 (0%)	0/49 (0%)			0/48 (0%)	0/48 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/96 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distali Adenoma								
		20/50 (40%)	15/50 (30%)			16/50 (32%)	24/50 (48%)	
Overall Incidence	Total	35/100 (35%)	Mean 35%	SD 7.07%	Total	40/100 (40%)	Mean 40%	SD 11.31%
*Pituitary Gland: Pars Distali Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 120

Report Date: 05/18/2011

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male				Female				
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma											
		20/50 (40%)	15/50 (30%)			16/50 (32%)	25/50 (50%)				
Overall Incidence	Total	35/100 (35%)	Mean 35%	SD 7.07%	Total	41/100 (41%)	Mean 41%	SD 12.73%			
*Pituitary Gland: Pars Distalis Ganglioneuroma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
*Pituitary Gland: Pars Interme 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%			
*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%			
*Pituitary Gland: Pars Nervos Craniopharyngioma	a:										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
*Prostate: Adenoma											
		1/50 (2%)	0/50 (0%)								
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%							

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

^{#:} Denominator is number of animals necropsied

*Salivary Glands: Sarcoma

Overall Incidence

*Salivary Glands:

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Schwannoma Malignant

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 121

Report Date: 05/18/2011

			Male			Female				
Prostate: Carcinoma or Adenoma		4/50 (00/)	0/50 (00/)							
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%						
Salivary Glands: 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%		
Salivary Glands: 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%		

0/50

0/50

0/100 (0%)

Total

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0%

SD 0%

SD 0%

Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% **#Seminal Vesicle:**

(0%)

(0%)

SD 0%

0/50

0/50

Mean 0%

Adenoma

1/50 (2%)0/50

(0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41%

0/50

0/100 (0%)

0/50

(0%)

(0%)

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: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 122

			Male		0/50 (0%) 0/50 (0%) 7 Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0% 1/50 (2%) 0/50 (0%)			Female			
#Skeletal Muscle: Fibrous Histiocytoma											
		0/50 (0%)	0/50 (0%)			` ,	` ,				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skeletal Muscle: Hemangiosarcoma		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%			
#Skeletal Muscle: Rhabdomyosarcoma											
	-	0/50 (0%)	0/50 (0%)	00.00/	-	` '	` '	00.00/			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	l otal	0/100 (0%)	Mean 0%	SD 0%			
#Skeletal Muscle: Rhabdomyosarcoma or F	Rhabdomyoma	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%			
#Skin: Basal Cell Adenoma	•••••										
		1/50 (2%)	1/50 (2%)			` '	` ,				
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
#Skin: Basal Cell Adenoma or B	asosquamous	Tumor Benign 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%			

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 123

			Male				Female	
#Skin: Basal Cell Adenoma, E	Basosquamous T	umor Benign, or Trichoep	oithelioma					
	•	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%
#Skin: Basal Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma	or Basosquamou	us Tumor (malignant or NO	OS) 0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma, NOS), or Trichoepithel		oma, Basosquamous Tun	, , ,	nt or		1/50 (2%)	0/50 (09/)	
Overall Incidence	Total	2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	1/30 (2%)	0/50 (0%) Mean 1%	SD 1.41%
		a, Basosq. Tumor (M or B ratoacanthoma, Trichoep 2/50 (4%)		na,		3/50 (6%)	0/50 (0%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 2.83%	Total	3/100 (3%)	Mean 3%	SD 4.24%
#Skin: Fibroma		0/50 (40/)	F/F0 (400)			0/50 (00/)	4/50 (00/)	
Overall Incidence	Total	2/50 (4%) 7/100 (7%)	5/50 (10%) Mean 7%	SD 4.24%	Total	0/50 (0%)	1/50 (2%) Mean 1%	SD 1.41%
Overall incidence	iolai	1/100 (1%)	IVICALI 1%	SD 4.24%	Total	1/100 (1%)	iviedii 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

ol Animal Groups Report Date: 05/18/2011

Page: 124

			Male				Female	
#Skin: Fibroma, Fibrosarcoma	, Sarcoma, Myxo	oma, Myxosarcoma, or Fil						
Overall Incidence	Total	3/50 (6%) 9/100 (9%)	6/50 (12%) Mean 9%	SD 4.24%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Skin: Fibrosarcoma								
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%
·	. •	, or Fibrous Histiocytoma	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibrous Histiocytoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Hemangiosarcoma			(05.1)			2/20 (00)	(00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 125

			Male			0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD (0%) 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD (0%) Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD (0%)			Female				
#Skin: Keratoacanthoma													
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	, ,	` ,	SD 2.83%					
#Skin: Lipoma													
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` ,	SD 0%					
#Skin: Liposarcoma	••••••												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	, ,	` ,	SD 0%					
#Skin: Neural Crest Tumor						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%					
#Skin: Neural Crest Tumor, Mali	ignant												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` ,	SD 0%					
#Skin: Neurofibroma or Schwar	nnoma benign	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: F 344/N **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 126

Report Date: 05/18/2011

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS) 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% #Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) 0/50 0/50 (0%)1/50 (2%)**Overall Incidence** 1/100 (1%) Mean 1% SD 1.41% Total 1/100 (1%) Mean 1% SD 1.41% Total #Skin: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total #Skin: Schwannoma Benign (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/100 (0%) SD 0% 0/100 (0%) Mean 0% #Skin: **Schwannoma Malignant** 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% #Skin: **Squamous Cell Carcinoma** 1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 2% SD 0% Mean 0% SD 0% 2/100 (2%) Total 0/100 (0%)

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

^{#:} Denominator is number of animals necropsied

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: WATER

Page: 127

			Male				Female	
#Skin: Squamous Cell Carcino or Carcinoma	oma, Basal Cell (Carcinoma, Basosquamou	, ,	or NOS),				
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Squamous Cell Papillor	ma	0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Squamous Cell Papillor	na or Papilloma	0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin:		quamous Cell Carcinoma 1/50 (2%) 4/100 (4%)		a SD 2.83%	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%
#Skin: Squamous Cell Papillor		0/50 (0%)	2/50 (4%)			3/50 (6%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	3/100 (3%)	Mean 3%	SD 4.24%
#Skin: Trichoepithelioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 128

			Male		0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 1/50 (2%) 0/50 (0%)			
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%)	0/50 (0%)			` ,	` '	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
• " "	T	0/50 (0%)	0/50 (0%)	00.00/	-	` ,	` ,	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	l otal	0/100 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Benign		0.470 (001)	0.750 (001)				2/22 (221)	
Overell Incidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	` ,	` ,	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	ı otal	0/100 (0%)	wean 0%	SD 0%
#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	` ,	` '	SD 0%
#Spinal Cord: Glioma Malignant								
		0/50 (0%)	0/50 (0%)	OD .00/		` '	` ,	00 4 4404
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	l otal	1/100 (1%)	Mean 1%	SD 1.41%
*Spleen: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 129

			Male				Female	
*Spleen: Fibrous Histiocytoma		0/50 (0%)	0/50 (00/)			0/50 (00/)	0/50 (00()	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Spleen: Leiomyosarcoma		0/50 (09/)	1/50 /20/			0/50 (09/)	0/50 (09/)	
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%
*Spleen: 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%
#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			(25.)					
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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 130

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinon	na or Papilloma	a Squamous						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Stomach, Forestomach: Squamous Cell Papilloma	a							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: 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, Glandular: 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%
#Stomach, Glandular: Lipoma								
·		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Sarcoma		- (ac)				2/20 (00:)		
O	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 131

			Male			Total 1/96 (1.04%) 0/48 (0%) Total 1/96 (1.04%) Mean 1.04% SD 1.47% 1/48 (2%) 0/48 (0%) Total 1/96 (1.04%) Mean 1.04% SD 1.47% 0/48 (0%) 0/48 (0%) Total 0/96 (0%) Mean 0% SD 0%		
*Testes: Adenoma Overall Incidence	Total	45/50 (90%) 93/100 (93%)	48/50 (96%) Mean 93%	SD 4.24%				
*Testes: Hemangioma	-	0/50 (0%)	0/50 (0%)	00.00				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Benign		0/50 (0%)	0/48 (0%)			0/48 (0%)	1/48 (2%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	` '	` '	SD 1.47%
*Thymus: Thymoma Malignant Overall Incidence	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	` '	` '	SD 1 479/
	10tai	0/96 (0%)	Weall 0%	SD 0%		1/96 (1.04%)	IVIEAN 1.04%	
*Thymus: Thymoma NOS								
Overall Incidence	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	` '	` '	SD 0%
*Thymus: Thymoma: Benign, Maliç		0/50 (0%)	0/48 (0%)			1/48 (2%)	1/48 (2%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	2/96 (2.08%)	Mean 2.08%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: WATER

Page: 132

		Male				Female				
Thyroid Gland: C-Cell: Adenoma						,				
		11/50 (22%)	1/50 (2%)			6/50 (12%)	11/50 (22%)			
Overall Incidence	Total	12/100 (12%)	Mean 12%	SD 14.14%	Total	17/100 (17%)	Mean 17%	SD 7.07%		
Thyroid Gland: C-Cell: Carcinoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
Thyroid Gland: C-Cell: Carcinoma or Adenoma			./=-				(2.10)			
Overall Incidence	Total	11/50 (22%) 12/100 (12%)	1/50 (2%) Mean 12%	SD 14.14%	Total	6/50 (12%)	12/50 (24%) Mean 18%	SD 8.49%		
		` '		SD 14.14%		18/100 (18%)		SD 6.49%		
Гhyroid Gland: Follicular Cell: Adenoma	:									
	T-1-1	0/50 (0%)	1/50 (2%)	OD 4 440/	T-1-1	0/50 (0%)	1/50 (2%)	OD 4 440/		
verall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
Thyroid Gland: Follicular Cell: Carcinoma	:									
		1/50 (2%)	2/50 (4%)			0/50 (0%)	2/50 (4%)			
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%		
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma	:				•••••					
		1/50 (2%)	3/50 (6%)			0/50 (0%)	2/50 (4%)			
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	2/100 (2%)	Mean 2%	SD 2.83%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 133

			Male Female				0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE		
#Tissue NOS: Paraganglioma									
		0/50 (0%)	0/50 (0%)			` '	()		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		` '		SD 0%	
#Tongue: Squamous Cell Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 0%	
#Tongue: Squamous Cell Carcinoma of	or Papillom	a Squamous 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Tooth: Adamantinoma Malignant									
_		0/50 (0%)	0/50 (0%)			(,	` ,		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Tooth: Odontoma						0.50	2/ (00/)		
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Strain: F 344/N Length of Study: CHRONIC Page: 134

			Male				Female	
*Urinary Bladder: 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%
*Urinary Bladder: Carcinoma or Papilloma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma		0/50 (00/)	0/50 (004)			0(50 (00))	0/50 (004)	
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: Papilloma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Adenoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 135

	Male			Female	
#Uterus: Deciduoma Benign					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Leiomyosarcoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Polyp Stromal					
Overall Incidence		Total	8/50 (16%) 16/100 (16%)	8/50 (16%) Mean 16%	SD 0%
fUterus: Sarcoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					
Overall Incidence		Total	8/50 (16%) 16/100 (16%)	8/50 (16%) Mean 16%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

GAVAGE WATER **Page:** 136

			Male				Female	
#Uterus: Schwannoma Malignant						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
#Vagina: Polyp							(201)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Sarcoma						0(50 (00))	0/50 (00)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Schwannoma Malignant						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 05/18/2011

Page: 137

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

Length of Study: CHRONIC

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

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 138

Report Date: 05/18/2011

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

Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Northwest	052001105	07/14/03	729	50(5)	23(678)	526.9	1-Bromopropane
Battelle Northwest	059901705	08/25/03	729	50(5)	28(686)	525.6	Diethylamine
Battelle Northwest	059302507	06/16/03	729	50(5)	20(668)	536.2	Tetralin
					Female		
Battelle Northwest	052001105	07/14/03	730	50(5)	34(702)	386.5	1-Bromopropane
Battelle Northwest	059901705	08/25/03	730	50(5)	31(687)	378.3	Diethylamine
Battelle Northwest	059302507	06/16/03	730	50(5)	31(682)	370.8	Tetralin

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 139

Report Date: 05/18/2011

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** #All Organs: **Benign Tumors** 48/50 (96%)44/50 (88%)48/50 (96%)45/50 (90%)43/50 (86%)40/50 (80%)**Overall Incidence** Total 140/150 (93.33%) Mean 93.33% SD 4.62% Total 128/150 (85.33%) Mean 85.33% SD 5.03% #All Organs: **Malignant Tumors** 38/50 (76%)31/50 (62%)33/50 (66%)26/50 (52%)24/50 (48%)25/50 (50%)**Overall Incidence** Total 102/150 (68%) Mean 68% SD 7.21% Total 75/150 (50%) Mean 50% SD 2% #All Organs: **Malignant and Benign Tumors** 50/50 (100%) 49/50 (98%)50/50 (100%) 49/50 (98%)48/50 (96%)46/50 (92%)Overall Incidence Total 149/150 (99.33%) Mean 99.33% SD 1.15% 143/150 (95.33%) Mean 95.33% SD 3.06% Total #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 (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% **#All Organs:** Hemangiosarcoma or Hemangioma 0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Mean 1.33% 0/150 (0%) Mean 0% SD 0% Total 2/150 (1.33%) SD 1.15% Total

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 140

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: **Histiocytic Sarcoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 2/150 (1.33%) Mean 1.33% SD 2.31% #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 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated 29/50 (58%)25/50 (50%)25/50 (50%)16/50 (32%)15/50 (30%) 17/50 (34%)**Overall Incidence** 79/150 (52.67%) Mean 52.67% SD 4.62% Total 48/150 (32%) Mean 32% SD 2% Total #All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% **#All Organs:** Mesothelioma: Benign 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% **#All Organs:** Mesothelioma: Benign, Malignant, NOS

0/50

SD 0%

(0%)

0/50

0/150 (0%)

Total

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

0/50

0/150 (0%)

(0%)

0/50

Mean 0%

(0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 141

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: Mesothelioma: 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% #All Organs: Osteoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #All Organs: Osteosarcoma 2/50 (4%)0/50 (0%)3/50 (6%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 5/150 (3.33%) Mean 3.33% SD 3.06% Total 0/150 (0%) Mean 0% SD 0% #All Organs: Osteosarcoma or Osteoma (0%) 2/50 (4%)0/50 (0%)3/50 (6%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** Total 5/150 (3.33%) Mean 3.33% SD 3.06% Total 0/150 (0%) Mean 0% SD 0% *Adrenal Cortex: Adenoma 1/50 (2%)1/50 (2%)0/50 (0%)3/50 (6%)4/50 (8%)8/50 (16%) **Overall Incidence** Total 2/150 (1.33%) Mean 1.33% SD 1.15% Total 15/150 (10%) Mean 10% SD 5.29% *Adrenal Cortex: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/150 (0%) Mean 0% SD 0% 0/150 (0%) Total

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 142

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male			Female			
Adrenal Medulla: Ganglioneuroma									
		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: Hemangioma									
		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%	
Adrenal Medulla: Pheochromocytoma Benign									
		10/50 (20%)	7/50 (14%)	9/50 (18%)		2/50 (4%)	0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	26/150 (17.33%)	Mean 17.33%	SD 3.06%	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	
Adrenal Medulla: Pheochromocytoma Comple									
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	2/50 (4%) Mean 2%	0/50 (0%) SD 2%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	
		G, 100 (270)				,			
Adrenal Medulla: Pheochromocytoma Maligna	nt								
		0/50 (0%)	1/50 (2%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
verall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 4.16%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
Adrenal Medulla: Pheochromocytoma: Benigr	, Comple	x, Malignant, NOS							
-	-	11/50 (22%)	10/50 (20%)	12/50 (24%)		3/50 (6%)	0/50 (0%)	3/50 (6%)	
Overall Incidence	Total	33/150 (22%)	Mean 22%	SD 2%	Total	6/150 (4%)	Mean 4%	SD 3.46%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 143

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male			Female			
#Bone: Chordoma									
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%	
Bone: 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%	
Bone: Osteosarcoma									
Overall Incidence	Total	1/50 (2%) 4/150 (2.67%)	0/50 (0%) Mean 2.67%	3/50 (6%) SD 3.06%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Bone: Osteosarcoma or Osteoma									
Overall Incidence	Total	1/50 (2%) 4/150 (2.67%)	0/50 (0%) Mean 2.67%	3/50 (6%) SD 3.06%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Brain: 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%	
Brain: Ependymoma Benign		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%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 144

			Male				Female	
*Brain: Ependymoma Malignant		2(20)	2/22 (221)	2/52		(20)	2/52 (221)	2(72)
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		0/50 (0%)	0/50 (0%)	0/50 (09	%)	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 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: Glioma Malignant	Total	0/50 (0%)	0/50 (0%)	0/50 (09		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%
*Brain: Granular Cell Tumor Benign		0/50 (0%)	0/50 (0%)	0/50 (09	'	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 (0%)	0/50 (0%)	0/50 (09	-/	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: F 344/N

Toxicology Data Management System

Page: 145

Report Date: 05/18/2011

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** *Brain: Oligodendroglioma 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: Oligodendroglioma, Glioma, or Astrocytoma 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% 1/150 (0.67%) Mean 0.67% SD 1.15% Total *Brain: Osteosarcoma 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% 0/150 (0%) Mean 0% SD 0% Total *Brain: **Schwannoma Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% 0/150 (0%) *Clitoral/Preputial Gland: Adenoma 4/50 (8%)0/50 (0%)0/50 (0%)3/49 (6%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 4/150 (2.67%) Mean 2.67% SD 4.62% Total 4/149 (2.68%) Mean 2.71% SD 3.12% *Clitoral/Preputial Gland: Carcinoma 2/50 (4%)1/50 (2%)0/50 (0%)1/49 (2%)0/50 (0%)4/50 (8%)**Overall Incidence** Total Mean 2% SD 2% Mean 3.35% SD 4.16% 3/150 (2%) Total 5/149 (3.36%)

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Page: 146

			Male			Female			
Clitoral/Preputial Gland: Carcinoma or Adenoma									
		6/50 (12%)	1/50 (2%)	0/50 (0%)		4/49 (8%)	1/50 (2%)	4/50 (8%)	
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 6.43%	Total	9/149 (6.04%)	Mean 6.05%	SD 3.51%	
Clitoral/Preputial Gland: Sarcoma									
		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%	
Ear: Neural Crest Tumor									
		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%	
Esophagus: 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%	
Eye: Melanoma Benign									
		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: 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%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 147

			Male			Female				
#Eye: Schwannoma Malignant										
Overall Incidence	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%		
	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Harderian 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%		
#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										
Sec	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%		
Heart: Schwannoma Benign										
		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 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%		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 148

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Large: Colon/Rectum: 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: 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 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Duodenum: Leiomyoma 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% #Intestine Small: Duodenum: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/150 (0%) Mean 0% SD 0% 0/150 (0%) Total

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Contract/Lab: All Laboratories

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

Vehicle: AIR

Page: 149

			Male			Female			
#Intestine Small: Ileum: Adenoma									
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
		0/150 (0%)		SD 0%	Total	0/150 (0%)		ט עס	
#Intestine Small: Jejunum: 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%	
#Intestine Small: Jejunum: Granular Cell Tumor Malign	nant								
		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: Jejunum: 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: 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 Unspec Adenoma	ified:				•••••				
		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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 150

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Small: Site Unspecified: 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% #Intestine Small: Site Unspecified: 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 Small: Site Unspecified: **Granular Cell 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% #Intestine Small: Site Unspecified: Leiomyoma 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% #Intestine Small: Site Unspecified: Leiomyosarcoma

0/50

SD 0%

0/50

SD 0%

(0%)

(0%)

Total

Total

0/50

0/50

0/150 (0%)

0/150 (0%)

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0%

Mean 0%

0/50

0/50

SD 0%

SD 0%

(0%)

(0%)

Total

Total

0/50

0/150 (0%)

0/50

0/150 (0%)

(0%)

(0%)

0/50

0/50

Mean 0%

Mean 0%

(0%)

(0%)

#Intestine Small: Site Unspecified: Schwannoma Malignant

Overall Incidence

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 151

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Islets, Pancreatic: Adenoma 0/50 (0%)6/50 (12%)3/50 (6%)0/50 (0%)2/50 (4%)0/50 (0%)**Overall Incidence** Total 9/150 (6%) Mean 6% SD 6% 2/150 (1.33%) Mean 1.33% SD 2.31% Total *Islets, Pancreatic: Carcinoma 3/50 (6%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 5/150 (3.33%) Mean 3.33% SD 2.31% 1/150 (0.67%) Mean 0.67% SD 1.15% Total *Islets, Pancreatic: Carcinoma or Adenoma 7/50 (14%) 3/50 (6%)4/50 (8%) 1/50 (2%)2/50 (4%)0/50 (0%)**Overall Incidence** 14/150 (9.33%) Mean 9.33% SD 4.16% 3/150 (2%) Mean 2% SD 2% Total Total *Kidney: Pelvis and Transitional Epithelium: Carcinoma (0%) 0/50 (0%)0/50 (0%)0/50 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% *Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma 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% *Kidney: Pelvis and Transitional Epithelium: **Papilloma** 1/50 (2%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% Mean 0% SD 0% SD 1.15% Total 0/149 (0%)

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 152

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Kidney: Renal Tubule: Adenoma 1/50 (2%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/149 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/149 (0.67%) Mean 0.68% SD 1.18% *Kidney: Renal Tubule: Carcinoma or Adenoma 1/50 (2%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% 1/149 (0.67%) Mean 0.68% SD 1.18% Total *Kidney: Renal Tubule: Hemangiosarcoma (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/149 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Lipoma 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% *Kidney: Renal Tubule: Mesenchymal Tumor Benign 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Mean 0% SD 0% 0/150 (0%) Total 0/149 (0%)

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Page: 153

			Male			Female			
Kidney: Renal Tubule: Mesenchymal Tumor Malig	nant								
		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%	
Kidney: Renal Tubule: Nephroblastoma									
		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%	
'Kidney: Renal Tubule: Sarcoma									
		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%	
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%)	1/50 (2%)		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%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 154

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female				
*Liver: Hepatocellular Carcinoma											
Overall Incidence	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%			
*Liver:								•••••			
Hepatocellular Carcinom	a or Hepatobi	astoma 2/50 (4%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%			
*Liver: Hepatocellular Carcinom			0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)			
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%			
Liver: Hepatocellular Carcinom				1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)			
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%			
Liver: Ito Cell Tumor Benign											
•		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: Alveolar/Bronchiolar Ade											
		2/50 (4%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 155

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Lung: Alveolar/Bronchiolar Carcinoma 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% *Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 3/50 (6%)1/50 (2%)1/50 (2%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 5/150 (3.33%) Mean 3.33% SD 2.31% 2/150 (1.33%) Mean 1.33% SD 2.31% Total *Lung: 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 0/150 (0%) Mean 0% SD 0% *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: **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%

0/50

SD 0%

(0%)

0/50

0/150 (0%)

Total

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

0/50

0/150 (0%)

(0%)

0/50

Mean 0%

(0%)

#Lymph Node: Hemangiosarcoma

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 156

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female				
#Mammary Gland: Adenolipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Adenoma									
		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%	
#Mammary Gland: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		4/50 (8%)	9/50 (18%)	3/50 (6%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	16/150 (10.67%)	Mean 10.67%	SD 6.43%	
#Mammary Gland: Carcinoma or Adenoma				0/50 (00/)		4/50 (00()	40/50 (00%)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	4/50 (8%) 17/150 (11.33%)	10/50 (20%) Mean 11.33%	3/50 (6%) SD 7.57%	
#Mammary Gland: Fibroadenoma									
		2/50 (4%)	2/50 (4%)	1/50 (2%)		25/50 (50%)	27/50 (54%)	14/50 (28%)	
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 1.15%	Total	66/150 (44%)	Mean 44%	SD 14%	
#Mammary Gland: Fibroma									
		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

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Strain: F 344/N Length of Study: CHRONIC Page: 157

			Male			Female					
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma											
Overall Incidence	Total	2/50 (4%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	1/50 (2%) SD 1.15%	Total	25/50 (50%) 66/150 (44%)	27/50 (54%) Mean 44%	14/50 (28%) SD 14%			
Mammary Gland: Fibroma, Fibroadenoma,	Carcinoma, or	· Adenoma									
Overall Incidence	Total	2/50 (4%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	1/50 (2%) SD 1.15%	Total	27/50 (54%) 73/150 (48.67%)	30/50 (60%) Mean 48.67%	16/50 (32%) SD 14.74%			
Mesentery: Fibrous Histiocytoma											
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%			
Mesentery: 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: 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%			

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 158

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female			
*Nose: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (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: Squamous Cell Carcinor	na	0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	0/49 (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%	
Oral Cavity (Oral Mucosa, Papilloma Squamous or	Tongue, Phar	ynx, Tooth, Gingiva):							
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%	
Oral Cavity (Oral Mucosa, Squamous Cell Carcinor	Tongue, Phar								
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%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	
Oral Cavity (Oral Mucosa, Squamous Cell Carcinon	•	Squamous, or Papilloma							
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%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	
Oral Mucosa: Squamous Cell Carcinor	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%) 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

Version: May2011
Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 159

Mean 0%

SD 0%

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female #Oral Mucosa: Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)SD 0% SD 0% **Overall Incidence** Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 0% *Ovary: Cystadenoma 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% *Ovary: **Fibrosarcoma** 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% *Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% *Ovary: **Granulosa Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)0/50 (0%)

Total

0/150 (0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Groups

Report Date: 05/18/2011

Page: 160

Length of Study: CHRONIC

			Male			Female			
Ovary: Granulosa-Theca Tumor Ben	ign								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Ovary: Granulosa-Theca Tumor Mali	ignant		•••••						
Overall Incidence					Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%	
Ovary: Schwannoma Malignant			•••••				•••••		
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Ovary: Tubulostromal Adenoma									
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%) 0/149 (0%)	0/49 (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%	
Pancreas: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 161

			Male		Female				
Pancreas: Carcinoma or Adenoma									
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (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%	
Pancreas: Mixed Tumor Benign									
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (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%	
Pancreas: Mixed Tumor Malignant		0/50 (00/)	0/40 /02/	0/50 /00/		0/50 (0%)	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (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									
Overall Incidence	Total	0/46 (0%) 0/142 (0%)	0/48 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/47 (0%) 1/139 (0.72%)	1/43 (2%) Mean 0.78%	0/49 (0%) SD 1.34%	
Pituitary Gland: Pars Dist Adenoma		cified Site:							
Overall Incidence	Total	37/50 (74%) 104/150 (69.33%)	31/50 (62%) Mean 69.33%	36/50 (72%) SD 6.43%	Total	35/50 (70%) 100/149 (67.11%)	29/50 (58%) Mean 67.16%	36/49 (73%) SD 8.12%	
Pituitary Gland: Pars Dist Carcinoma	alis or Unspe								
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%) 2/149 (1.34%)	2/50 (4%) Mean 1.33%	0/49 (0%) SD 2.31%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 162

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Strain: F 344/N Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female			
*Pituitary Gland: Pars Distalis Carcinoma or Adenoma	s or Unspec	cified Site:							
Overall Incidence	Total	37/50 (74%) 105/150 (70%)	31/50 (62%) Mean 70%	37/50 (74%) SD 6.93%	Total	35/50 (70%) 102/149 (68.46%)	31/50 (62%) Mean 68.49%	36/49 (73%) SD 5.88%	
*Pituitary Gland: Pars Distalis Ganglioneuroma	s or Unspec	cified Site:							
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%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	
*Pituitary Gland: Pars Interme Adenoma	edia:								
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%	
*Pituitary Gland: Pars Interme 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%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	
*Pituitary Gland: Pars Nervos Craniopharyngioma			•••••			•••••			
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%	
*Prostate: Adenoma									
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: F 344/N

Toxicology Data Management System

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Page: 163

			Male				Female			
Prostate: Carcinoma or Adenoma										
		0/50 (0%)	0/50 (0%)	0/50	(0%)					
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%						
Salivary Glands: 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%	
Salivary Glands: Carcinoma or Adenoma		- (aa)	0.70	0/50	(004)		2(-2)	2/-2	(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%	
Salivary Glands: Sarcoma										
		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%	
Salivary Glands: Schwannoma 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	0/150 (0%)	Mean 0%	SD 0%	
Seminal Vesicle: Adenoma										
		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: F 344/N

Toxicology Data Management System

Page: 164

Report Date: 05/18/2011

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male			Female			
#Skeletal Muscle: 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%	
#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: Rhabdomyosarcoma									
		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: Rhabdomyosarcoma or F	Rhabdomyom	a							
		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									
		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:									
Basal Cell Adenoma or B	asosquamous	•	0/50 (00/)	4/50 (20/)		0/50 (00/)	0/50 (00/)	0/50 (00/)	
Overell Insidence	Tatal	0/50 (0%)	0/50 (0%)	1/50 (2%)	Tatal	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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

le: AIR

Page: 165

			Male				Female	
#Skin:		T D T T	-tdP					
Basai Celi Adenoma, E	sasosquamous	Tumor Benign, or Trichoe 0/50 (0%)		1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	3/50 (6%) SD 3.06%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Basal Cell Carcinoma	or Basosquamo	us Tumor (malignant or N	,					
Overall Incidence	Total	0/50 (0%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	3/50 (6%) SD 3.06%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Basal Cell Carcinoma, NOS), or Trichoepithel		noma, Basosquamous Tui	, , ,					
Overall Incidence	Total	0/50 (0%) 5/150 (3.33%)	1/50 (2%) Mean 3.33%	4/50 (8%) SD 4.16%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		na, Basosq. Tumor (M or I eratoacanthoma, Trichoep 1/50 (2%)	3), Basal Cell Adenon	na, 5/50 (10%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 4.62%	Total	3/150 (2%)	Mean 2%	SD 0%
#Skin: Fibroma								
		3/50 (6%)	1/50 (2%)	3/50 (6%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 2.31%	Total	3/150 (2%)	Mean 2%	SD 2%

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 166

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male		Female				
#Skin: Fibroma, Fibrosarcoma, S	Sarcoma, Myx	koma, Myxosarcoma, or F	ibrous Histiocytoma						
Occupation of the second	Tarak	3/50 (6%)	2/50 (4%)	6/50 (12%)	T . (.)	2/50 (4%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	11/150 (7.33%)	Mean 7.33%	SD 4.16%	Total	3/150 (2%)	Mean 2%	SD 2%	
#Skin: Fibrosarcoma									
	-	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: Fibrosarcoma, Sarcoma,	Myxosarcom	a, or Fibrous Histiocytom 0/50 (0%)	a 1/50 (2%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Skin: 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%	
#Skin: 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%	
#Skin: Hemangiosarcoma		0/50 (00/)	0/50 /00/)	4/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00/)	
O	T-1-1	0/50 (0%)	0/50 (0%)	1/50 (2%)	T-1-1	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

Strain: F 344/N

Toxicology Data Management System

Page: 167

Report Date: 05/18/2011

Contract/Lab: All Laboratories

Species: RATS

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

			Male			Female			
#Skin: Keratoacanthoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	
≇Skin: Lipoma		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/30 (4%)	Mean 1.33%	SD 2.31%	Total	0/30 (0%)	Mean 0%	SD 0%	
#Skin: Liposarcoma 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	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	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%	
		,				1/130 (0.07/6)			
#Skin: Neural Crest Tumor, Malignan	nt	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: Neurofibroma or Schwannom	a benign							0/50	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	

SD 0%

0/150 (0%)

Total

Mean 0%

SD 0%

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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 05/18/2011

Page: 168

			Male			Female					
#Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS)											
		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: Neurofibrosarcoma, Neurof											
		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: 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%			
Skin: Schwannoma Benign											
		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: Schwannoma 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%			
#Skin: Squamous Cell Carcinoma											
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	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

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

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 1/50 (2%)1/50 (2%)3/50 (6%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 5/150 (3.33%) Mean 3.33% SD 2.31% Total 1/150 (0.67%) Mean 0.67% SD 1.15% **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% #Skin: Squamous Cell Papilloma or Papilloma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) SD 0% #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma 1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)1/50 (2%)Mean 1.33% **Overall Incidence** Total 2/150 (1.33%) SD 1.15% Total 3/150 (2%) Mean 2% SD 0% #Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 0/50 (0%)0/50 1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)Overall Incidence Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 2/150 (1.33%) Mean 1.33% SD 1.15% #Skin: Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% 0/150 (0%) SD 0% Total

Page: 169

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

^{#:} Denominator is number of animals necropsied

y2011 Toxicology Data Mai

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 170

			Male				Female	
#Skin: Sebaceous Gland: Adenoma		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/30 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	1/50 (2%)	2/50 (4%)		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%
#Spinal Cord: Astrocytoma Benign						0(50 (004)	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	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Spinal Cord: Glioma 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%
*Spleen: Fibrosarcoma		(201)				2(-2)	2/22 (221)	(20)
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: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 171

			Male				Female	
Spleen: Fibrous Histiocytoma								
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								
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: Leiomyosarcoma		0/50 (00/)	0/50 /00/	0/50 /00	<i>(</i>)	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%	∕₀) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Spleen: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	6) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Stomach, Forestomach: 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, Forestomach: Squamous Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	6) 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: F 344/N **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 172

Mean 0%

SD 0%

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (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%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Stomach, Glandular: 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, Glandular: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% 0/150 (0%) #Stomach, Glandular: 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% #Stomach, Glandular: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

0/150 (0%)

Mean 0%

Total

0/150 (0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 173

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Testes: Adenoma 34/50 (68%)36/50 (72%)29/50 (58%)**Overall Incidence** Total 99/150 (66%) Mean 66% SD 7.21% *Testes: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% *Thymus: Thymoma Benign 0/43 (0%)0/44 (0%)0/47 (0%)1/46 (2%)0/48 (0%)0/44 (0%)**Overall Incidence** Total 0/134 (0%) Mean 0% SD 0% Total 1/138 (0.72%) Mean 0.72% SD 1.26% *Thymus: **Thymoma Malignant** 0/43 (0%)0/44 (0%)0/47 (0%)0/46 (0%)0/48 (0%)0/44 (0%)**Overall Incidence** Total 0/134 (0%) Mean 0% SD 0% Total 0/138 (0%) Mean 0% SD 0% *Thymus: Thymoma NOS 0/43 (0%)0/44 (0%)0/47 (0%)0/46 (0%)1/48 (2%)0/44 (0%)**Overall Incidence** Total 0/134 (0%) Mean 0% SD 0% Total 1/138 (0.72%) Mean 0.69% SD 1.2% *Thymus: Thymoma: Benign, Malignant, NOS 1/46 0/43 (0%)0/44 (0%)0/47 (0%)(2%)1/48 (2%)0/44 (0%)**Overall Incidence** Mean 0% SD 0% 2/138 (1.45%) Mean 1.42% SD 1.23% Total 0/134 (0%) Total

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female

Page: 174

			waie				Female	
*Thyroid Gland: C-Cell: Adenoma		5/50 (10%)	7/50 (14%)	5/50 (10%)		3/50 (6%)	4/50 (8%)	3/50 (6%)
Overall Incidence	Total	17/150 (11.33%)	Mean 11.33%	SD 2.31%	Total	10/150 (6.67%)	Mean 6.67%	SD 1.15%
Thyroid Gland: C-Cell: Carcinoma								
Overall Incidence	Total	4/50 (8%) 7/150 (4.67%)	1/50 (2%) Mean 4.67%	2/50 (4%) SD 3.06%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
Overall Incidence	Total	9/50 (18%) 23/150 (15.33%)	8/50 (16%) Mean 15.33%	6/50 (12%) SD 3.06%	Total	4/50 (8%) 11/150 (7.33%)	4/50 (8%) Mean 7.33%	3/50 (6%) SD 1.15%
Thyroid Gland: Follicular 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%
Thyroid Gland: Follicular Cell: 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%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma			0/50 (001)	0/50 (00/)		0/50 (000)	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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 175

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Tissue NOS:** Paraganglioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Tongue: **Squamous Cell Carcinoma** 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(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% #Tongue: Squamous Cell Carcinoma or Papilloma Squamous 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% #Tongue: Squamous Cell Papilloma (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Tooth: **Adamantinoma 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% #Tooth: Odontoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/150 (0%) Mean 0% SD 0% 0/150 (0%) Total

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 176

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)SD 0% **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% *Urinary Bladder: Carcinoma or Papilloma 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% *Urinary Bladder: Hemangiosarcoma 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% *Urinary Bladder: **Papilloma** 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)SD 0% **Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0% #Uterus: Adenoma 0/50 (0%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 2/150 (1.33%) Mean 1.33% SD 1.15% #Uterus: Carcinoma 0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** 1/150 (0.67%) Mean 0.67% SD 1.15% Total

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 177

Report Date: 05/18/2011

Route: INHALATION Vehicle: AIR

Strain: F 344/N Length of Study: CHRONIC

	Male		Female	
#Uterus: Deciduoma Benign				
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%) 22/150 (14.67%)	8/50 (16%) Mean 14.67%	6/50 (12%) SD 2.31%
#Uterus: Sarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Sarcoma Stromal				
Overall Incidence	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
#Uterus: Sarcoma Stromal or Polyp Stromal				
Overall Incidence	Total	10/50 (20%) 24/150 (16%)	8/50 (16%) Mean 16%	6/50 (12%) SD 4%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 178

Report Date: 05/18/2011

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female					
#Uterus: Schwannoma Malignant						0/50 (00)	2/22 (221)				
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
#Vagina: Polyp											
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
#Vagina: Sarcoma											
Overall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%			
#Vagina: 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%			
#Zymbal's Gland: Adenoma								•••••			
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) 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%			
#Zymbal's Gland: Carcinoma											
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	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

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 179

			Male				Female	
#Zymbal's Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%	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

Toxicology Data Management System

Page: 180

Report Date: 05/18/2011

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

Route: ORAL Vehicle: FEED

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Southern Research Institute	059902703	08/12/02	729	50(3)	37(705)	452.8	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517405	08/05/02	729	50(3)	33(703)	510.0	Cresols
Southern Research Institute	059900705	04/21/03	729	50(3)	33(679)	460.9	Goldenseal root powder
Southern Research Institute	052000803	03/04/03	729	50(3)	36(704)	452.1	Milk thistle extract
					Female		
Southern Research Institute	059902703	08/12/02	733	50(5)	36(702)	314.7	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517405	N/A	N/A	0(0)	0(0)	N/A	Cresols
Southern Research Institute	059900705	04/21/03	731	50(5)	30(699)	326.0	Goldenseal root powder
Southern Research Institute	052000803	03/04/03	732	50(5)	38(693)	328.4	Milk thistle extract

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 181

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#All Organs: Benign Tumors								
3		49/50 (98%) 50/50 (100%)	50/50 (100%)	47/50 (94%)		45/50 (90%) 39/50 (78%)		46/50 (92%)
Overall Incidence	Total	196/200 (98%)	Mean 98%	SD 2.83%	Total	130/150 (86.67%)	Mean 86.67%	SD 7.57%
#All Organs: Malignant Tumors								
		27/50 (54%) 26/50 (52%)	23/50 (46%)	29/50 (58%)		15/50 (30%) 18/50 (36%)		19/50 (38%)
Overall Incidence	Total	105/200 (52.5%)	Mean 52.5%	SD 5%	Total	52/150 (34.67%)	Mean 34.67%	SD 4.16%
#All Organs: Malignant and Benign T								
		50/50 (100%) 50/50 (100%)	50/50 (100%)	50/50 (100%)		47/50 (94%) 46/50 (92%)		48/50 (96%)
Overall Incidence	Total	200/200 (100%)	Mean 100%	SD 0%	Total	141/150 (94%)	Mean 94%	SD 2%
#All Organs: Hemangioma								
		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	0/150 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
-		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 182

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: Hemangiosarcoma or Hemangioma 2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/150 (0%) Overall Incidence Total 3/200 (1.5%) Mean 1.5% SD 1.91% Total Mean 0% SD 0% #All Organs: **Histiocytic Sarcoma** (2%) 0/50 (0%)0/50 (0%)0/50 (0%)1/50 1/50 (2%)3/50 (6%)0/50 (0%)Overall Incidence Total 3/200 (1.5%) Mean 1.5% SD 3% Total 2/150 (1.33%) Mean 1.33% SD 1.15% **#All Organs:** Leukemia: Erythrocytic 0/50 (0%)0/50 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 1/150 (0.67%) Mean 0.67% SD 1.15% **#All Organs:** Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated 19/50 (38%)15/50 (30%)21/50 (42%)9/50 (18%)9/50 (18%)17/50 (34%)6/50 (12%)**Overall Incidence** Total 72/200 (36%) Mean 36% SD 5.16% Total 24/150 (16%) Mean 16% SD 3.46% **#All Organs:** Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 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 0/150 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 183

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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%)Overall Incidence Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #All Organs: Mesothelioma: Benign, Malignant, NOS 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 0/150 (0%) Mean 0% SD 0% **#All Organs:** Mesothelioma: Malignant 1/50 (2%)0/50 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 0/150 (0%) Mean 0% SD 0% #All Organs: Osteoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)1/50 (2%)0/50 (0%)0/150 (0%) **Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total Mean 0% SD 0% #All Organs: Osteosarcoma 0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/200 (1%) Mean 1% SD 2% 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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 184

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female
#All Organs: Osteosarcoma or Osteoma							
		0/50 (0%) 1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5% SD	1.91%	Total 0/	/150 (0%)	Mean 0% SD 0%
*Adrenal Cortex: Adenoma							
		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		2/50 (4%) 0/48 (0%)	1/50 (2%)
Overall Incidence	Total	2/200 (1%)		SD 2%	Total 3/1	48 (2.03%) N	Mean 2% SD 2%
*Adrenal Cortex: Carcinoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/48 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% S	SD 0%	Total 0/	/148 (0%) N	Mean 0% SD 0%
*Adrenal Medulla: Ganglioneuroma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% S	SD 0%	Total 0/	(146 (0%)	Mean 0% SD 0%
*Adrenal Medulla: Hemangioma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% S	SD 0%	Total 0/	/146 (0%) N	Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 185

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Adrenal Medulla: Pheochromocytoma Be	enign							
		8/50 (16%) 5/50 (10%)	8/50 (16%)	5/49 (10%)		1/50 (2%) 1/48 (2%)		0/48 (0%)
Overall Incidence	Total	26/199 (13.07%)	Mean 13.05%	SD 3.41%	Total	2/146 (1.37%)	Mean 1.36%	SD 1.18%
*Adrenal Medulla: Pheochromocytoma Co	omplex							
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/48 (2%)		0/48 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/146 (0.68%)	Mean 0.69%	SD 1.2%
*Adrenal Medulla: Pheochromocytoma Ma								
		3/50 (6%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		2/50 (4%) 0/48 (0%)		0/48 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 2.83%	Total	2/146 (1.37%)	Mean 1.33%	SD 2.31%
*Adrenal Medulla: Pheochromocytoma: B	enign, Comple	x, Malignant, NOS						
		11/50 (22%) 6/50 (12%)	8/50 (16%)	6/49 (12%)		3/50 (6%) 2/48 (4%)		0/48 (0%)
Overall Incidence	Total	31/199 (15.58%)	Mean 15.56%	SD 4.67%	Total	5/146 (3.42%)	Mean 3.39%	SD 3.07%
#Bone: Chordoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 186

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Bone: Osteoma								
		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	0/150 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma	ı							
		0/50 (0%) 1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/150 (0%)	Mean 0%	SD 0%
*Brain: Astrocytoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Brain: Ependymoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/199 (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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 187

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Brain: Ependymoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Glioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Glioma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/199 (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%)	0/49 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Benign								
		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	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: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Page: 188

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** *Brain: Oligodendroglioma Benign 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 0/150 (0%) Mean 0% SD 0% *Brain: Oligodendroglioma Malignant 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)Mean 0% **Overall Incidence** Total 0/199 (0%) SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% *Brain: Oligodendroglioma, Glioma, or Astrocytoma 0/50 (0%)0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% *Brain: Osteosarcoma 0/50 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 0/150 (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%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 189

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Clitoral/Preputial Gland: Adenoma								
		1/50 (2%) 1/50 (2%)	5/50 (10%)	0/50 (0%)		10/50 (20%) 11/50 (22%)		5/50 (10%)
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 4.43%	Total	26/150 (17.33%)	Mean 17.33%	SD 6.43%
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%) 2/50 (4%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 3/50 (6%)		4/50 (8%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.31%	Total	7/150 (4.67%)	Mean 4.67%	SD 4.16%
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		1/50 (2%) 3/50 (6%)	5/50 (10%)	2/50 (4%)		10/50 (20%) 14/50 (28%)		9/50 (18%)
Overall Incidence	Total	11/200 (5.5%)	Mean 5.5%	SD 3.42%	Total	33/150 (22%)	Mean 22%	SD 5.29%
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%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Ear: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 190

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Esophagus: Lipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Eye: Melanoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Eye: Melanoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Eye: Schwannoma Malignant								
		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	0/150 (0%)	Mean 0%	SD 0%
Harderian Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 191

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Harderian Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (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%)		0/50 (0%)
Overall Incidence	Total	0/200 (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%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Malignant								
		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		1/50 (2%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Large: Colon/Rect Adenoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 192

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Large: Colon/Rectum: Carcinoma or Adenoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% #Intestine Large: Colon/Rectum: Hemangioma (0%) 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)Mean 0.5% Overall Incidence Total 1/200 (0.5%) SD 1% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Duodenum: Carcinoma 1/50 (2%)0/50 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 0/150 (0%) Mean 0% SD 0% #Intestine Small: Duodenum: Leiomyoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/150 (0%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Intestine Small: Duodenum: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 193

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Small: Ileum: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (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%)Mean 0% **Overall Incidence** Total 0/200 (0%) SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: **Granular Cell Tumor Malignant** 0/50 (0%)0/50 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 0/150 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 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%)0/50 (0%)**Overall Incidence** Total 0/200 (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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 194

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Small: Site Unspecified: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Carcinoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0.5% Overall Incidence Total 1/200 (0.5%) SD 1% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Carcinoma or Adenoma 1/50 (2%)0/50 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 0/150 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: **Granular Cell Tumor Malignant** 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 195

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
fIntestine Small: Site Unspection	cified:							
		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	0/150 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspec Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Adenoma								
		1/50 (2%) 3/50 (6%)	1/49 (2%)	7/50 (14%)		2/49 (4%) 0/48 (0%)		0/49 (0%)
Overall Incidence	Total	12/199 (6.03%)	Mean 6.01%	SD 5.65%	Total	2/146 (1.37%)	Mean 1.36%	SD 2.36%
slets, Pancreatic: Carcinoma								
		1/50 (2%) 1/50 (2%)	1/49 (2%)	0/50 (0%)		0/49 (0%) 0/48 (0%)		0/49 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	0/146 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Carcinoma or Adenoma								
		2/50 (4%) 4/50 (8%)	2/49 (4%)	7/50 (14%)		2/49 (4%) 0/48 (0%)		0/49 (0%)
Overall Incidence	Total	15/199 (7.54%)	Mean 7.52%	SD 4.71%	Total	2/146 (1.37%)	Mean 1.36%	SD 2.36%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 196

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male			Female	
*Kidney: Pelvis and Transiti Carcinoma	onal Epitheliu	ım:					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/47 (0%) 0/49 (0%) 0/48 (0%)	
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/144 (0%) Mean 0% SD 0%	
*Kidney: Pelvis and Transiti Carcinoma or Adenoma	onal Epitheliu	ım:					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/47 (0%) 0/49 (0%) 0/48 (0%)	
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/144 (0%) Mean 0% SD 0%	
*Kidney: Pelvis and Transiti Papilloma	onal Epitheliu	ım:					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%) 0/48 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/144 (0%) Mean 0% SD 0%	
*Kidney: Renal Tubule: Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%) 0/48 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/144 (0%) Mean 0% SD 0%	
*Kidney: Renal Tubule: Carcinoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%) 0/48 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/144 (0%) Mean 0% SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 197

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male	Female
*Kidney: Renal Tubule: Carcinoma or Adenoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/47 (0%) 0/49 (0%) 0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Lipoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/47 (0%) 0/49 (0%) 0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Beni	gn			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/47 (0%) 0/49 (0%) 0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Malig	gnant			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/47 (0%) 0/49 (0%) 0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 198

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
*Kidney: Renal Tubule: Nephroblastoma				
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Sarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0%) 0/47 (0%) 1/49 (2%) 0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 1/144 (0.69%) Mean 0.68% SD 1.18%
*Liver: Cholangioma				
		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
*Liver: Hemangiosarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Liver: Hepatocellular Adenoma	••••			
		1/50 (2%) 3/50 (6%)	0/50 (0%) 1/50 (2%	2%) 2/50 (4%) 0/50 (0%) 2/50 (4%)
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5% SD 2.52%	Total 4/150 (2.67%) Mean 2.67% SD 2.31%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 199

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Liver: **Hepatocellular Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/150 (0%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total Mean 0% SD 0% *Liver: Hepatocellular Carcinoma or Hepatoblastoma (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/200 (0%) SD 0% Total 0/150 (0%) Mean 0% SD 0% *Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma (2%)0/50 1/50 2/50 (4%)0/50 (0%)3/50 (6%)2/50 (4%)**Overall Incidence** Total 5/200 (2.5%) Mean 2.5% SD 2.52% Total 4/150 (2.67%) Mean 2.67% SD 2.31% *Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 1/50 (2%)0/50 (0%)1/50 (2%)2/50 (4%)0/50 (0%)3/50 (6%)2/50 (4%)**Overall Incidence** Total 5/200 (2.5%) Mean 2.5% SD 2.52% Total 4/150 (2.67%) Mean 2.67% SD 2.31% *Liver: Ito 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 0/200 (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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 200

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Lung: Alveolar/Bronchiolar A	Adenoma							
		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%) 0/50 (0%)		1/50 (2%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
Lung: Alveolar/Bronchiolar C	Carcinoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 1/50 (2%)		0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Lung: Alveolar/Bronchiolar C Overall Incidence	Carcinoma or Alv Total	veolar/Bronchiolar Adeno 0/50 (0%) 1/50 (2%) 3/200 (1.5%)	Mean 1.5%	1/50 (2%) SD 1%	Total	1/50 (2%) 1/50 (2%) 3/150 (2%)	Mean 2%	1/50 (2%) SD 0%
Lung: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lung: Hemangiosarcoma		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%)
Overall Incidence	Total	0/200 (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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 201

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Lung: **Squamous Cell Carcinoma** 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 0/150 (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%)Mean 0% Overall Incidence Total 0/200 (0%) SD 0% Total 0/150 (0%) Mean 0% SD 0% **#Mammary Gland:** Adenolipoma 0/50 (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 0/150 (0%) Mean 0% SD 0% #Mammary Gland: Adenoma 0/50 2/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)(4%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 3/150 (2%) Mean 2% SD 2% #Mammary Gland: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)4/50 (8%)0/50 (0%)4/50 (8%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 8/150 (5.33%) Mean 5.33% SD 4.62%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 202

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Mammary Gland: Carcinoma or Adenoma 0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)6/50 (12%) 0/50 (0%)(8%)11/150 (7.33%) **Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total Mean 7.33% SD 5.03% #Mammary Gland: Fibroadenoma 2/50 (4%)0/50 (0%)1/50 (2%)29/50 (58%)(60%)0/50 (0%)28/50 (56%)Overall Incidence Total 3/200 (1.5%) Mean 1.5% SD 1.91% Total 87/150 (58%) Mean 58% SD 2% **#Mammary Gland: Fibroma** 0/50 (0%)0/50 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 0/150 (0%) SD 0% Mean 0% **#Mammary Gland:** Fibroma, Fibroadenoma or Adenoma 2/50 (4%)1/50 (2%)30/50 (60%)30/50 (60%)1/50 (2%)0/50 (0%)28/50 (56%)**Overall Incidence** Total 4/200 (2%) Mean 2% SD 1.63% Total 88/150 (58.67%) Mean 58.67% SD 2.31% #Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma (4%)1/50 (2%)1/50 (2%)30/50 (60%)31/50 (62%)0/50 (0%)28/50 (56%)**Overall Incidence** Total 4/200 (2%) Mean 2% SD 1.63% Total 89/150 (59.33%) Mean 59.33%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 203

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Mesentery: **Fibrous Histiocytoma** 0/50 (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 0/150 (0%) Mean 0% SD 0% #Mesentery: Hemangiosarcoma 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 0/150 (0%) Mean 0% SD 0% #Mesentery: Lipoma 0/50 (0%)0/50 1/50 (2%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% #Mesentery: Schwannoma Malignant 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/150 (0%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total Mean 0% SD 0% *Nose: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 204

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Nose: Squamous Cell Carcino	oma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucos Papilloma Squamous o	. •	ynx, Tooth, Gingiva):						
		1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)		1/50 (2%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Squamous Cell Carcino Overall Incidence	Total	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%) 0/150 (0%)	Mean 0%	0/50 (0%) SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phar	ynx, Tooth, Gingiva): Squamous, or Papilloma		0/50 (40/)		0/50 (00()		4/50 (00/)
		1/50 (2%) 1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)		1/50 (2%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Oral Mucosa: Squamous Cell Carcino	oma	0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)		0/50 (0%)
Overell In eldense	Tatal	0/50 (0%)	Mana 0 50/	CD 40/	Tatal	0/50 (0%)	Maara 00/	CD 00%
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 205

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Oral Mucosa: Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Ovary: Cystadenoma 0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/150 (0%) SD 0% *Ovary: **Fibrosarcoma** 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% *Ovary: **Granulosa Cell Tumor Benign** 0/50 0/50 (0%)(0%)

0/50

0/50

2/50

2/150 (1.33%)

0/150 (0%)

Total

Total

(0%)

(0%)

(4%)

Mean 0%

Mean 1.33%

SD 0%

SD 2.31%

(0%)

0/50

.....

Granulosa Cell Tumor Malignant

Overall Incidence

Overall Incidence

*Ovary:

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 206

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

	Male			Female	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS					
			0/50 (0%) 2/50 (4%)		0/50 (0%)
Overall Incidence		Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
Ovary:					
Granulosa-Theca Tumor Benign			1/50 (2%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Ovary: Granulosa-Theca Tumor Malignant					
3			0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%
Ovary: Schwannoma Malignant				•••••	
3			0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma					
			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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 207

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Pancreas: Adenoma 0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/49 (0%)2/50 (4%)0/48 (0%)**Overall Incidence** Total 2/198 (1.01%) Mean 1% SD 2% Total 0/146 (0%) Mean 0% SD 0% *Pancreas: Carcinoma 0/49(0%)0/49 (0%)0/50 (0%)0/49(0%)0/49 (0%)0/50 (0%)0/48 (0%)Mean 0% Overall Incidence Total 0/198 (0%) SD 0% Total 0/146 (0%) Mean 0% SD 0% *Pancreas: Carcinoma or Adenoma 0/49 (0%)0/49 0/50 (0%)0/49 (0%)0/49 (0%)2/50 (4%)0/48 (0%)**Overall Incidence** Total 2/198 (1.01%) Mean 1% SD 2% Total 0/146 (0%) Mean 0% SD 0% *Pancreas: **Mixed Tumor Benign** 0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/48 (0%)**Overall Incidence** Total 0/198 (0%) Mean 0% SD 0% Total 0/146 (0%) Mean 0% SD 0% *Pancreas: **Mixed Tumor Malignant** 0/49 (0%)0/49 (0%)1/50 (2%)0/49 (0%)0/49 (0%)0/50 (0%)0/48 (0%)**Overall Incidence** Total 1/198 (0.51%) Mean 0.5% SD 1% Total 0/146 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 208

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Parathyroid Gland: Adenoma 1/45 (2%)1/46 (2%)0/49 (0%)0/48 (0%)0/49 (0%)0/49 0/50 (0%)(0%)Mean 0% **Overall Incidence** Total 2/190 (1.05%) Mean 1.1% SD 1.27% Total 0/146 (0%) SD 0% *Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 10/50 (20%)20/50 (40%)8/50 (16%)24/49 (49%)(50%)13/50 (26%)20/50 (40%)Overall Incidence Total 51/200 (25.5%) Mean 25.5% SD 10.5% Total 69/149 (46.31%) Mean 46.33% SD 5.5% *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/50 (0%)0/50 0/50 1/49 (2%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 2/149 (1.34%) Mean 1.35% SD 1.17% *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 10/50 (20%)20/50 (40%)8/50 (16%)25/49 (51%)25/50 (50%)13/50 (26%)21/50 (42%)**Overall Incidence** Total 51/200 (25.5%) Mean 25.5% SD 10.5% Total 71/149 (47.65%) Mean 47.67% SD 4.94% *Pituitary Gland: Pars Distalis or Unspecified Site: Ganglioneuroma 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 0/149 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 209

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Pituitary Gland: Pars Inte	rmedia:							
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/149 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Intel								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/149 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Nerv Craniopharyngioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				
*Prostate: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 210

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Salivary Glands: Carcinoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 0/197 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Salivary Glands: Carcinoma or Adenoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/197 (0%) SD 0% Total 0/150 (0%) Mean 0% SD 0% *Salivary Glands: Sarcoma 0/50 (0%)0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 0/197 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Salivary Glands: Schwannoma Malignant 0/50 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)(0%)0/48 (0%)0/50 (0%)Overall Incidence Total 0/197 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% **#Seminal Vesicle:** Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 211

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Skeletal Muscle: Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% Overall Incidence Total 0/200 (0%) SD 0% Total 0/150 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Rhabdomyosarcoma 0/50 (0%)0/50 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 0/150 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Rhabdomyosarcoma or Rhabdomyoma 0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% #Skin: **Basal Cell Adenoma** 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% 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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 212

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Basal Cell Adenoma or Basosquamous Tumor Benign (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/150 (0%) **Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total Mean 0% SD 0% #Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/150 (0.67%) **Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total Mean 0.67% SD 1.15% #Skin: **Basal Cell Carcinoma** 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% 0/150 (0%) SD 0% Total Mean 0% #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 2/200 (1%) Mean 1% 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

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 213

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 4/50 (8%)2/50 0/50 (0%)1/50 (2%)(2%)(4%)(12%) 6/50 1/50 (2%)Overall Incidence Total 13/200 (6.5%) Mean 6.5% SD 4.43% Total 2/150 (1.33%) Mean 1.33% SD 1.15% #Skin: Fibroma 4/50 (8%)1/50 (2%)5/50 (10%)0/50 (0%)1/50 (2%)3/50 (6%)1/50 (2%)13/200 (6.5%) SD 3.42% 2/150 (1.33%) SD 1.15% **Overall Incidence** Total Mean 6.5% Total Mean 1.33% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma (8%)(8%) (10%)0/50 (0%)3/50 (6%)(8%) (2%)4/50 1/50 **Overall Incidence** Total 17/200 (8.5%) Mean 8.5% SD 1% Total 4/150 (2.67%) Mean 2.67% SD 3.06% #Skin: **Fibrosarcoma** 0/50 (0%)2/50 0/50 (0%)0/50 (0%)0/50 (0%)(4%)(2%)0/50 (0%)1/50 **Overall Incidence** Total 2/200 (1%) Mean 1% SD 2% Total 1/150 (0.67%) Mean 0.67% SD 1.15% #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 (0%)3/50 0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 4/200 (2%) Mean 2% SD 2.83% Total 3/150 (2%) Mean 2% SD 2%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Page: 214

Report Date: 05/18/2011

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male				Female	
#Skin: Fibrous Histiocytoma								
		0/50 (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	0/150 (0%)	Mean 0%	SD 0%
tSkin: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Keratoacanthoma								
		3/50 (6%) 4/50 (8%)	1/50 (2%)	2/50 (4%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	10/200 (5%)	Mean 5%	SD 2.58%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Lipoma	•							
		0/50 (0%) 1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	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: F 344/N

Toxicology Data Management System

Page: 215

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Skin: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		1/50 (2%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Neural Crest Tumor, Ma								
		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	0/150 (0%)	Mean 0%	SD 0%
#Skin: Neurofibroma or Schwi								
		0/50 (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	0/150 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or								
	`	0/50 (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	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 216

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Skin: Neurofibrosarcoma, Neurofi	broma, or s	Schwannoma (benign, ma	alignant or NOS)					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
≇Skin: Sarcoma								
		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		2/50 (4%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
#Skin: Schwannoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
έSkin: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)		0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	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

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Vehicle: FEED

Page: 217

			Male				Female					
#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma												
		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)		0/50 (0%)				
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
#Skin: Squamous Cell Papillo	oma											
		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	0/150 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papillo	oma or Papilloma		2/52 (221)	2/22 (221)		0/50		2/-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	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papillo	oma, Papilloma, S	Squamous Cell Carcinom 3/50 (6%) 6/50 (12%)	a or Keratoacanthom 1/50 (2%)	a 2/50 (4%)		0/50 (0%) 1/50 (2%)		0/50 (0%)				
Overall Incidence	Total	12/200 (6%)	Mean 6%	SD 4.32%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
#Skin: Squamous Cell Papillo	oma, Papilloma, c		4/50 (001)	0/50 (404)		0/50 (00/)		0/50 (00)				
		3/50 (6%) 5/50 (10%)	1/50 (2%)	2/50 (4%)		0/50 (0%) 0/50 (0%)		0/50 (0%)				
Overall Incidence	Total	11/200 (5.5%)	Mean 5.5%	SD 3.42%	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

Page: 218

Report Date: 05/18/2011

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male	Female
#Skin: Trichoepithelioma				
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 1/150 (0.67%) Mean 0.67% SD 1.15%
#Skin: Sebaceous Gland: Adenoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/150 (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%) 0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/150 (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%)
Overall Incidence	Total	0/200 (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: F 344/N

Toxicology Data Management System

Page: 219

Report Date: 05/18/2011

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

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Male **Female #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%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Spleen: **Fibrosarcoma** 0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)Mean 0% **Overall Incidence** Total 0/198 (0%) SD 0% Total 0/148 (0%) Mean 0% SD 0% *Spleen: **Fibrous Histiocytoma** 0/50 (0%)0/49 1/49 (2%)0/50 (0%)0/49 (0%)(0%)0/50 0/49 (0%)**Overall Incidence** Total 1/198 (0.51%) Mean 0.51% SD 1.02% Total 0/148 (0%) Mean 0% SD 0% *Spleen: Hemangiosarcoma 0/49 1/50 (2%)0/49 (0%)0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 1/198 (0.51%) Mean 0.5% SD 1% Total 0/148 (0%) Mean 0% SD 0% *Spleen: Leiomyosarcoma 1/50 (2%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 1/198 (0.51%) Mean 0.5% SD 1% Total 0/148 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 220

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male			Female
*Spleen: Sarcoma						
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/49 (0%)	0/50 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total 0/148 (0%)	Mean 0% SD 0%
#Stomach, Forestomach: Leiomyosarcoma						
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	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%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0% SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papillom	a Squamous				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (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%)	1/50 (2%)
Overall Incidence	Total	0/200 (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: F 344/N

Toxicology Data Management System

Page: 221

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Stomach, Glandular: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Lipoma							•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Testes: Adenoma								
		46/50 (92%) 46/50 (92%)	49/50 (98%)	42/50 (84%)				
Overall Incidence	Total	183/200 (91.5%)	Mean 91.5%	SD 5.74%				

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 222

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Testes: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% *Thymus: **Thymoma Benign** 0/48(0%)(0%)1/48 (2%)0/46 (0%)0/49 (0%)0/41 (0%)0/50 (0%)Overall Incidence Total 1/184 (0.54%) Mean 0.52% SD 1.04% Total 0/145 (0%) Mean 0% SD 0% *Thymus: **Thymoma Malignant** 0/48 (0%)0/47 0/48 (0%)0/46 (0%)0/49 (0%)0/41 (0%)0/50 (0%)**Overall Incidence** Total 0/184 (0%) Mean 0% SD 0% Total 0/145 (0%) Mean 0% SD 0% *Thymus: **Thymoma NOS** 0/49 0/48 (0%)0/47 (0%)0/48 (0%)0/46 (0%)(0%)0/41 (0%)0/50 (0%)**Overall Incidence** Total 0/184 (0%) Mean 0% SD 0% Total 0/145 (0%) Mean 0% SD 0% *Thymus: Thymoma: Benign, Malignant, NOS 0/48 (0%)0/47 (0%)1/48 (2%)0/46 (0%)0/49 (0%)0/41 (0%)0/50 (0%)**Overall Incidence** Total 1/184 (0.54%) Mean 0.52% SD 1.04% Total 0/145 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 223

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Thyroid Gland: C-Cell: Adenoma								
		5/50 (10%) 5/48 (10%)	6/50 (12%)	7/50 (14%)		3/49 (6%) 2/47 (4%)		4/50 (8%)
Overall Incidence	Total	23/198 (11.62%)	Mean 11.6%	SD 1.81%	Total	9/146 (6.16%)	Mean 6.13%	SD 1.87%
Thyroid Gland: C-Cell: Carcinoma								
		4/50 (8%) 1/48 (2%)	1/50 (2%)	1/50 (2%)		1/49 (2%) 0/47 (0%)		1/50 (2%)
Overall Incidence	Total	7/198 (3.54%)	Mean 3.52%	SD 2.99%	Total	2/146 (1.37%)	Mean 1.35%	SD 1.17%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		9/50 (18%) 6/48 (13%)	7/50 (14%)	8/50 (16%)		4/49 (8%) 2/47 (4%)		5/50 (10%)
Overall Incidence	Total	30/198 (15.15%)	Mean 15.12%	SD 2.39%	Total	11/146 (7.53%)	Mean 7.47%	SD 2.93%
Thyroid Gland: Follicular Cell: Adenoma								
		2/50 (4%) 0/48 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/47 (0%)		0/50 (0%)
Overall Incidence	Total	2/198 (1.01%)	Mean 1%	SD 2%	Total	0/146 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell: Carcinoma								
		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 1/47 (2%)		0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/146 (0.68%)	Mean 0.71%	SD 1.23%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 224

Report Date: 05/18/2011

1/50

1/50

SD 1.15%

SD 1.15%

Mean 0.67%

Mean 0.67%

(2%)

(2%)

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma 2/50 (4%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/48 (0%)1/47 (2%)Overall Incidence Total 2/198 (1.01%) Mean 1% SD 2% Total 1/146 (0.68%) Mean 0.71% SD 1.23% **#Tissue NOS:** Paraganglioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)Mean 0.5% Overall Incidence Total 1/200 (0.5%) SD 1% Total 0/150 (0%) Mean 0% SD 0% #Tongue: **Squamous Cell Carcinoma** 0/50 (0%)0/50 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 0/150 (0%) Mean 0% SD 0% #Tongue: Squamous Cell Carcinoma or Papilloma Squamous

1/50

SD 1%

1/50

SD 1%

(2%)

(2%)

0/50

0/50

0/50

0/50

1/150 (0.67%)

1/150 (0.67%)

Total

Total

(0%)

(0%)

(0%)

(0%)

Total

Total

(2%)

(2%)

(2%)

(2%)

1/50

3/200 (1.5%)

1/50

1/50

3/200 (1.5%)

0/50

0/50

Mean 1.5%

Mean 1.5%

(0%)

(0%)

Overall Incidence

Overall Incidence

Squamous Cell Papilloma

#Tongue:

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 225

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Tooth: Adamantinoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (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 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Urinary Bladder: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Urinary Bladder: Carcinoma or Papilloma								
		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/150 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma								
		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	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 226

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: **Papilloma** 0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/199 (0.5%) Mean 0.51% SD 1.02% Total 0/150 (0%) Mean 0% SD 0% #Uterus: Adenoma 0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% #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 0/50 (0%)(0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% #Uterus: Leiomyosarcoma 0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** 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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 227

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

	Male		Female	
#Uterus:				
Polyp Stromal		10/50 (20%)		14/50 (28%)
		10/50 (20%)		14/30 (20/0)
Overall Incidence	То	tal 34/150 (22.67%)	Mean 22.67%	SD 4.62%
Uterus: Sarcoma				
		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	То		Mean 0%	SD 0%
fUterus: Sarcoma Stromal				
		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	То	tal 0/150 (0%)	Mean 0%	SD 0%
Uterus: Sarcoma Stromal or Polyp Stromal				
77		10/50 (20%) 10/50 (20%)		14/50 (28%)
Overall Incidence	То	,	Mean 22.67%	SD 4.62%
fUterus: Schwannoma Malignant				
		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	То		Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 228

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

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%)Mean 0% **Overall Incidence** Total 0/150 (0%) SD 0% #Vagina: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% #Zymbal's Gland: Adenoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (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%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% 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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 229

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

Tumor Incidence for Selected Control Animal Groups

Page: 230

Report Date: 05/18/2011

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

Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory Southern Research Institute	052000903 052011407	11/18/04 10/02/02	726 730	50(3) 50(3)	33(668) 28(696)	516.1 532.4	beta-Picoline Sodium dichromate dihydrate (VI)
					Female		
Battelle Columbus Laboratory Southern Research Institute	052000903 052011407	11/19/04 10/02/02	727 735	50(5) 50(5)	30(688) 33(700)	352.7 351.2	beta-Picoline Sodium dichromate dihydrate (VI)

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 231

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male		Female				
#All Organs: Benign Tumors									
		45/50 (90%)	49/50 (98%)			47/50 (94%)	47/50 (94%)		
Overall Incidence	Total	94/100 (94%)	Mean 94%	SD 5.66%	Total	94/100 (94%)	Mean 94%	SD 0%	
#All Organs: Malignant Tumors		22/52 (40%)	20/50 /50%			47/50 (040()	20/50 (400/)		
Overall Incidence	Total	23/50 (46%) 52/100 (52%)	29/50 (58%) Mean 52%	SD 8.49%	Total	17/50 (34%) 37/100 (37%)	20/50 (40%) Mean 37%	SD 4.24%	
#All Organs: Malignant and Benign T	umors	•••••							
		48/50 (96%)	50/50 (100%)			49/50 (98%)	49/50 (98%)		
Overall Incidence	Total	98/100 (98%)	Mean 98%	SD 2.83%	Total	98/100 (98%)	Mean 98%	SD 0%	
#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									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma or H	emangioma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 232

Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: **Histiocytic 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% #All Organs: Leukemia: Erythrocytic 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated 14/50 (28%)26/50 (52%)12/50 (24%)8/50 (16%) Overall Incidence Total 40/100 (40%) Mean 40% SD 16.97% Total 20/100 (20%) Mean 20% SD 5.66% #All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% **#All Organs:** Mesothelioma: 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% **#All Organs:** Mesothelioma: Benign, Malignant, NOS 4/50 (8%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 6% SD 2.83% 0/100 (0%) Mean 0% SD 0% 6/100 (6%) Total

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 233

Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: Mesothelioma: Malignant 4/50 (8%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 6/100 (6%) Mean 6% SD 2.83% Total 0/100 (0%) Mean 0% SD 0% #All Organs: Osteoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #All Organs: Osteosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #All Organs: Osteosarcoma or 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% *Adrenal Cortex: Adenoma 1/50 (2%)0/50 (0%)2/50 (4%)1/50 (2%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 3/100 (3%) Mean 3% SD 1.41% *Adrenal Cortex:

SD 0%

0/50

Total

0/100 (0%)

(0%)

0/50

(0%)

SD 0%

Mean 0%

Total

0/50

0/100 (0%)

(0%)

0/50

Mean 0%

(0%)

Carcinoma

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 234

Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WA

			Male		Female				
*Adrenal Medulla: Ganglioneuroma									
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	
*Adrenal Medulla: Hemangioma									
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Beni	ign	E/EO /400/\	6/40 (400/)			2/50 /40/\	2/40 (49/)		
Overall Incidence	Total	5/50 (10%) 11/99 (11.11%)	6/49 (12%) Mean 11.12%	SD 1.59%	Total	2/50 (4%) 4/99 (4.04%)	2/49 (4%) Mean 4.04%	SD 0.06%	
*Adrenal Medulla: Pheochromocytoma Com	nplex	4/50 (00)	0/40 /00/		•••••	0/50 (00/)	0/40 (00/)		
Overall Incidence	Total	1/50 (2%) 1/99 (1.01%)	0/49 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Mali									
Overall Incidence	Total	0/50 (0%) 1/99 (1.01%)	1/49 (2%) Mean 1.02%	SD 1.44%	Total	0/50 (0%) 1/99 (1.01%)	1/49 (2%) Mean 1.02%	SD 1.44%	
*Adrenal Medulla: Pheochromocytoma: Ben									
Overall Incidence	Total	6/50 (12%) 13/99 (13.13%)	7/49 (14%) Mean 13.14%	SD 1.62%	Total	2/50 (4%) 5/99 (5.05%)	3/49 (6%) Mean 5.06%	SD 1.5%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 235

			Male				Female	
#Bone: Chordoma								
		0/50 (0%)	0/50 (0%)	25 22/		0/50 (0%)	0/50 (0%)	05 007
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Osteoma		0/50 (00()	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Bone: Osteosarcoma		0/50 (00)	0/50 (001)			0/50 (00/)	0(50 (00))	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Bone: Osteosarcoma or 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%
*Brain: 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%
*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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 236

			Male		Female			
*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								
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 Benign			(201)			(70)	(20)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Brain: Glioma Malignant		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%
*Brain: Granular Cell Tumor Benigr								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Oligodendroglioma Benign		- (ac)	(00)			(20)	(00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 237

			Male				Female					
*Brain: Oligodendroglioma Malignant 0/50 (0%) 0/50 (0%) 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%				
Brain: Oligodendroglioma, Glion	ma, or Astrocy	rtoma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%				
Brain: Osteosarcoma		0(50 (00))	0/50 (00/)			0/50 (001)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
Brain: Schwannoma Malignant		0/50 (00/)	0/50 (00/)			0/50 (00()	0/50 (0%)					
overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
Clitoral/Preputial Gland: Adenoma												
Normall In add on a c	Tatal	0/50 (0%)	4/50 (8%)	CD F 000/	Takal	7/50 (14%)	2/50 (4%)	CD 7 070/				
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 5.66%	Total	9/100 (9%)	Mean 9%	SD 7.07%				
Clitoral/Preputial Gland: Carcinoma		2/50 (40/)	1/50 (20/)			0/50 (09/)	9/50 (469/)					
Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	0/50 (0%) 8/100 (8%)	8/50 (16%) Mean 8%	SD 11.31%				

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 238

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male			Female		
*Clitoral/Preputial Gland: Carcinoma or Adenoma		2/50 (4%)	4/50 (8%)			7/50 (14%)	10/50 (20%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 2.83%	Total	17/100 (17%)	Mean 17%	SD 4.24%
*Clitoral/Preputial Gland: Sarcoma		0.75	2/52 (221)			(20)	(201)	
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%
#Ear: Neural Crest Tumor		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%
#Esophagus: 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	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Eye: Melanoma Benign		2(20)				2(20)	(201)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Eye: Melanoma Malignant								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 239

Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #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 0/100 (0%) Mean 0% SD 0% #Harderian 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% #Harderian Gland: Carcinoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% #Harderian Gland: Carcinoma or Adenoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% *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%)1/50 (2%)**Overall Incidence** Total Mean 0% SD 0% 1/100 (1%) Mean 1% SD 1.41% 0/100 (0%) Total

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 240

Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Intestine Large: Colon/Rectu Adenoma	m:							
		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%
#Intestine Large: Colon/Rectu Carcinoma or Adenoma	m:							
		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%
#Intestine Large: Colon/Rectu Hemangioma	m:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma		2/22 (221)	(201)			27-2 (221)	(20)	
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		` '						
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Duodenum: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 241

Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Small: Ileum: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Intestine Small: 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 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% #Intestine Small: Jejunum: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% 0/100 (0%) Mean 0% SD 0% Total

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 242

Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Site Unsp	ecified:							
		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 Unsp Carcinoma or Adenoma	ecified:	0/50 (00)	0/50 (00)			0/50 (001)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unsp Granular Cell Tumor Mal								
Owner Haller and America	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Leiomyoma	ecified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Site Unsp Leiomyosarcoma	ecified:							
·		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 Unsp Schwannoma Malignant	ecified:							
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 243

Report Date: 05/18/2011

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

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female** *Islets, Pancreatic: Adenoma 4/50 (8%)4/50 (8%) 0/50 (0%)2/50 (4%)**Overall Incidence** Total 8/100 (8%) Mean 8% SD 0% Total 2/100 (2%) Mean 2% SD 2.83% *Islets, Pancreatic: 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% *Islets, Pancreatic: Carcinoma or Adenoma 4/50 (8%)4/50 (8%)0/50 (0%)2/50 (4%) **Overall Incidence** 8/100 (8%) Mean 8% SD 0% Total 2/100 (2%) Mean 2% SD 2.83% Total *Kidney: Pelvis and Transitional Epithelium: Carcinoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: **Papilloma** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Mean 0% SD 0% Total 0/99 (0%)

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 244

Report Date: 05/18/2011

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

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female** *Kidney: Renal Tubule: Adenoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Lipoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: **Mesenchymal Tumor Benign** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Mean 0% SD 0% Total 0/99 (0%)

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 245

Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Kidney: Renal Tubule: Mesenchymal Tumor Mali	gnant	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Cholangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma								
Overall Incidence	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%
Overall includince	iolai	3/100 (3/0)	IVICALI 3/0	JD 4.2470	i Otai	3/100 (3/0)	IVICALL 3/0	JD 1.4170

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 246

		Male Female					0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 09 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 09 2/50 (4%) 1/50 (2%) Total 3/100 (3%) Mean 3% SD 1.4: 2/50 (4%) 1/50 (2%) Total 3/100 (3%) Mean 3% SD 1.4: 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 09		
*Liver: Hepatocellular Carcino	ma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Carcino	ma or Hepatobla	ıstoma							
•	•	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 Carcino Overall Incidence	ma or Hepatocel	Ilular Adenoma 3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	(,	` ,	SD 1.41%	
*Liver:		lar Adenoma, or Hepatob 3/50 (6%) 3/100 (3%)		SD 4.24%		` '	` ,	SD 1.41%	
*Liver: Ito Cell Tumor Benign		0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%	
*Lung: Alveolar/Bronchiolar Ad		3/50 (6%)	4/50 (8%)			0/50 (0%)	4/50 (8%)		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 247

			Male				Female	
*Lung: Alveolar/Bronchiolar Carci Overall Incidence	noma 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 Carci	noma or Alve		na 4/50 (8%)			0/50 (0%)	4/50 (8%)	
Overall Incidence	Total	7/100 (7%)	Mean 7%	SD 1.41%	Total	4/100 (4%)	Mean 4%	SD 5.66%
*Lung: 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%
*Lung: Hemangiosarcoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Lung: 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%
#Lymph Node: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 248

Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male			Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% 0/50 (0%) 2/50 (4%) Total 2/100 (2%) Mean 2% SD 2.83% 2/50 (4%) 0/50 (0%) Total 2/100 (2%) Mean 2% SD 2.83% 2/50 (4%) 2/50 (4%) Total 4/100 (4%) Mean 4% SD 0% 34/50 (68%) 37/50 (74%) Total 71/100 (71%) Mean 71% SD 4.24%			Female				
#Mammary Gland: Adenolipoma													
		0/50 (0%)	0/50 (0%)			` ,	, ,						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%					
#Mammary Gland: Adenoma													
	-	0/50 (0%)	0/50 (0%)	00.00/	-	(,	` '	00.000/					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	l otal	2/100 (2%)	Mean 2%	SD 2.83%					
#Mammary Gland: Carcinoma													
		0/50 (0%)	1/50 (2%)			` ,	()						
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%					
#Mammary Gland: Carcinoma or Adenoma		- (aa)	(704)			2/-2 (///)	0.50						
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%		` ,	` ,	SD 0%					
#Mammary Gland: Fibroadenoma													
		1/50 (2%)	2/50 (4%)			` ,	, ,						
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	71/100 (71%)	Mean 71%	SD 4.24%					
#Mammary Gland: Fibroma													
		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

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Vehicle: WATER

Page: 249

			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma o	r Adenoma							
		1/50 (2%)	2/50 (4%)			34/50 (68%)	37/50 (74%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	71/100 (71%)	Mean 71%	SD 4.24%
#Mammary Gland: Fibroma, Fibroadenoma, C	Carcinoma, o	r Adenoma						
		1/50 (2%)	3/50 (6%)			34/50 (68%)	37/50 (74%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	71/100 (71%)	Mean 71%	SD 4.24%
#Mesentery: Fibrous Histiocytoma		0/50 (0%)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		, ,						
#Mesentery: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: 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%
#Mesentery: Schwannoma Malignant		0/50 (00/)	0/50 (00)			0/50 /00()	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incluence	ı olal	0/100 (0%)	IVICALI U%	0% עכ		0/100 (0%)	iviedii U%	3D 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 250

Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Nose: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Nose: **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% **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):** Papilloma Squamous or Papilloma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** 0/100 (0%) Mean 0% SD 0% Total 1/100 (1%) Mean 1% SD 1.41% Total **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): 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% #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%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 1/100 (1%) Mean 1% SD 1.41% **#Oral Mucosa: Squamous Cell Carcinoma**

SD 0%

0/50

Total

0/100 (0%)

(0%)

0/50

(0%)

SD 0%

Mean 0%

Total

0/50

0/100 (0%)

(0%)

0/50

Mean 0%

(0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Control Animal Groups Report Date: 05/18/2011
AL

Page: 251

			Male				Female			
#Oral Mucosa: Squamous Cell Papilloma	ı									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
Ovary: Cystadenoma										
•						0/50 (0%)	0/49 (0%)			
Overall Incidence					Total	0/99 (0%)	Mean 0%	SD 0%		
Ovary: Fibrosarcoma										
						0/50 (0%)	0/49 (0%)			
Overall Incidence					Total	0/99 (0%)	Mean 0%	SD 0%		
Ovary: Granulosa Cell Tumor Be										
Overall Incidence					Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%		
Ovary: Granulosa Cell Tumor Ma										
	_					0/50 (0%)	0/49 (0%)			
Overall Incidence					Total	0/99 (0%)	Mean 0%	SD 0%		
'Ovary: Granulosa Cell Tumor: Be	enign, Maligna	ant, NOS								
						0/50 (0%)	0/49 (0%)			
Overall Incidence					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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 252 Report Date: 05/18/2011

			Male				Female	
*Ovary: Granulosa-Theca Tumor Beni	gn					0/50 (0%)	0/49 (0%)	
Overall Incidence					Total	0/99 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malig	ınant							
Overall Incidence					Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Ovary: Schwannoma Malignant							0/40 (00/)	
Overall Incidence					Total	1/50 (2%) 1/99 (1.01%)	0/49 (0%) Mean 1%	SD 1.41%
Ovary: Tubulostromal Adenoma						0/50 (0%)	0/49 (0%)	
Overall Incidence					Total	0/99 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma		4/40 (20/)	4/50 (20/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	1/49 (2%) 2/99 (2.02%)	1/50 (2%) Mean 2.02%	SD 0.03%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Pancreas: Carcinoma								
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: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 253

Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Pancreas: Carcinoma or Adenoma 1/49 (2%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/99 (2.02%) Mean 2.02% SD 0.03% Total 0/100 (0%) Mean 0% SD 0% *Pancreas: **Mixed Tumor Benign** 0/50 0/49 (0%)0/50 (0%)0/50 (0%)(0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Pancreas: **Mixed Tumor Malignant** 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% *Parathyroid Gland: Adenoma 0/50 (0%)0/46 (0%)0/47 (0%)0/46 (0%)**Overall Incidence** Total 0/96 (0%) Mean 0% SD 0% Total 0/93 (0%) Mean 0% SD 0% *Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 28/50 (56%)16/50 (32%)30/50 (60%)28/50 (56%) **Overall Incidence** Total 44/100 (44%) Mean 44% SD 16.97% Total 58/100 (58%) Mean 58% SD 2.83% *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% 2/100 (2%) Mean 2% SD 2.83% Total

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 254

Report Date: 05/18/2011

Route: ORAL

Contract/Lab: All Laboratories

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

	Male					Female			
*Pituitary Gland: Pars Distal Carcinoma or Adenoma	is or Unspec	ified Site:							
		28/50 (56%)	16/50 (32%)			30/50 (60%)	30/50 (60%)		
Overall Incidence	Total	44/100 (44%)	Mean 44%	SD 16.97%	Total	60/100 (60%)	Mean 60%	SD 0%	
*Pituitary Gland: Pars Distal Ganglioneuroma	is or Unspec								
		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 Intern 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 Interm Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Pituitary Gland: Pars Nervo Craniopharyngioma	sa:								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Prostate: Adenoma									
Occupation of the sec	T-1-1	0/49 (0%)	2/50 (4%)	OD 0.000/					
Overall Incidence	Total	2/99 (2.02%)	Mean 2%	SD 2.83%					

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 255

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

				Female 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) 0/50 (0%) Mean 0% SD 0%			Female			
*Prostate: Carcinoma or Adenoma										
		0/49 (0%)	2/50 (4%)							
Overall Incidence	Total	2/99 (2.02%)	Mean 2%	SD 2.83%						
*Salivary Glands: 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%		
*Salivary Glands: Carcinoma or Adenoma										
		0/50 (0%)	0/50 (0%)			` ,	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%		
*Salivary Glands: Sarcoma										
		0/50 (0%)	0/50 (0%)			` '	, ,			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Salivary Glands: Schwannoma Malignant										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Seminal Vesicle: Adenoma		0/50 (00%)	0/50 /05()							
	-	0/50 (0%)	0/50 (0%)	00.00/						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%						

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

^{#:} Denominator is number of animals necropsied

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

Page: 256

Report Date: 05/18/2011

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

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Skeletal Muscle: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma		0/50 (00)	(-()	
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	SD 00/
Overali incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or I	Rhabdomyoma		0/50 (00)			0(50 (00))	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
		1/50 (2%)	2/50 (4%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin:								
Basal Cell Adenoma or B	Basosquamous	Tumor Benign						
		1/50 (2%)	2/50 (4%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

mal Groups Report Date: 05/18/2011

Page: 257

			Male				Female			
#Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma 1/50 (2%) 2/50 (4%) 1/50 (2%) 0/50 (0%)										
Overall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%		
#Skin: Basal Cell Carcinoma		0/50 (0%)	0/50 (00/)			0/50 (0%)	0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Skin: Basal Cell Carcinoma o	or Basosquamou	us Tumor (malignant or No	OS) 0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Basal Cell Carcinoma, I NOS), or Trichoepitheli		oma, Basosquamous Tun 1/50 (2%) 3/100 (3%)	nor (benign, malignal 2/50 (4%) Mean 3%	nt or SD 1.41%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%		
#Skin: Basal or Sq. Cell Carcir Adenoma, Papilloma, S	noma, Carcinom q Papilloma, Ke	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 6/50 (12%)	i), Basal Cell Adenon ithelioma 5/50 (10%)			1/50 (2%)	1/50 (2%)			
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 0%		
#Skin: Fibroma		3/50 (6%)	8/50 (16%)			2/50 (4%)	1/50 (2%)			
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 7.07%	Total	3/100 (3%)	Mean 3%	SD 1.41%		

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Page: 258

			Male				Female			
#Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 4/50 (8%) 11/50 (22%) 2/50 (4%) 1/50 (2%)										
Overall Incidence	Total	15/100 (15%)	Mean 15%	SD 9.9%	Total	3/100 (3%)	Mean 3%	SD 1.41%		
#Skin: Fibrosarcoma										
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Skin: Fibrosarcoma, Sarcoma	, Myxosarcoma	a, or Fibrous Histiocytoma 1/50 (2%)	a 3/50 (6%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Fibrous Histiocytoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Skin: Hemangioma	Total				·····		wear 078			
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: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	0/30 (0%) Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 259

		Male Female					0/50 (0%) 1/50 (2%)		
#Skin: Keratoacanthoma Overall Incidence	Total	5/50 (10%) 7/100 (7%)	2/50 (4%) Mean 7%	SD 4.24%	Total	` '	` '	SD 1.41%	
#Skin: Lipoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` '	SD 0%	
#Skin: Liposarcoma	Total	0/50 (0%)	0/50 (0%)		i Olai			30 0%	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Skin: Neural Crest Tumor Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` ,	SD 0%	
#Skin: Neural Crest Tumor, Mali		0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		0/100 (0%)	Mean 0%		
#Skin: Neurofibroma or Schwan		0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 260

Report Date: 05/18/2011

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Neurofibrosarcoma or Schwannoma (malignant or 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% #Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) 0/50 (0%)0/50 (0%)**Overall Incidence** 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total #Skin: Sarcoma 0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** 2/100 (2%) Mean 2% SD 2.83% Total 0/100 (0%) Mean 0% SD 0% Total #Skin: Schwannoma Benign (0%)(0%) 0/50 (0%)0/50 (0%)0/50 0/50 **Overall Incidence** Total Mean 0% SD 0% Total 0/100 (0%) SD 0% 0/100 (0%) Mean 0% #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%

SD 1.41%

0/50

Total

0/100 (0%)

(0%)

0/50

(0%)

SD 0%

Mean 0%

Total

0/50

1/100 (1%)

(0%)

1/50

Mean 1%

(2%)

Squamous Cell Carcinoma

#Skin:

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

te: ORAL le: WATER Page: 261

			Male				Female				
#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma											
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papilloma		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	0/30 (0 <i>%</i>) Mean 0%	SD 0%			
#Skin: Squamous Cell Papilloma o	or Papilloma										
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	00.007			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papilloma,	Papilloma, S	Squamous Cell Carcinoma 5/50 (10%)	or Keratoacanthom 4/50 (8%)	a		0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
#Skin: Squamous Cell Papilloma,	Papilloma, o	or Keratoacanthoma 5/50 (10%)	3/50 (6%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
#Skin: Trichoepithelioma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 262

			Male			0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.419 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%		Female		
#Skin: Sebaceous Gland: Adenoma										
		0/50 (0%)	0/50 (0%)			` '	` '			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
#Skin: Sebaceous Gland: Carcinoma or Adenoma										
Overall Insidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	` '	, ,	CD 4 440/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	ı отаі 	1/100 (1%)	Mean 1%	SD 1.41%		
#Spinal Cord: Astrocytoma Benign		-4								
Occupation of desires	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	` '	` ,	00, 00/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%		
#Spinal Cord: Astrocytoma Malignant		0/50 (09/)	0/50 (00/)			0/50 (09/)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	, ,	` '	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 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00)			
Overell Insidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	, ,	` ,	CD 00/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	ıotaı	0/100 (0%)	wean 0%	3D 0%		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 263

Report Date: 05/18/2011

Route: ORAL

Contract/Lab: All Laboratories

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

			Male			Female		
*Spleen: Fibrous Histiocytoma								
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%
*Spleen: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Spleen: 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%
*Spleen: 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%
#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								
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

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 264

Report Date: 05/18/2011

Route: ORAL

Length of Study: CHRONIC

Vehicle: WATER

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinoma	a or Papilloma	a Squamous						
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 Papilloma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Glandular: 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%
#Stomach, Glandular: 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%
#Stomach, Glandular: Lipoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Glandular: Sarcoma		- (ac)	(00)				2/20 (004)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 265

Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Testes: Adenoma 35/50 (70%)48/50 (96%)**Overall Incidence** Total 83/100 (83%) Mean 83% SD 18.38% *Testes: Hemangioma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% *Thymus: Thymoma Benign 0/49 (0%)0/48 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/97 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% SD 0% *Thymus: **Thymoma Malignant** 0/49 (0%)0/48 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/97 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% SD 0% *Thymus:

SD 0%

SD 0%

0/49

0/49

0/99 (0%)

0/99 (0%)

Total

Total

(0%)

(0%)

0/50

0/50

(0%)

(0%)

SD 0%

SD 0%

Mean 0%

Mean 0%

Total

Total

0/49

0/97 (0%)

0/49

0/97 (0%)

(0%)

(0%)

0/48

0/48

Mean 0%

Mean 0%

(0%)

(0%)

Thymoma: Benign, Malignant, NOS

Thymoma NOS

Overall Incidence

Overall Incidence

*Thymus:

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 266

			Male				Female	
*Thyroid Gland: C-Cell: Adenoma					10/50 (20%) 8/50 (16 9.9% Total 18/100 (18%) Mean 18 1/50 (2%) 2/50 (4 0% Total 3/100 (3%) Mean 3 11/50 (22%) 10/50 (20 9.9% Total 21/100 (21%) Mean 21 0/50 (0%) 0/50 (0 0% Total 0/100 (0%) Mean 0			
		12/50 (24%)	5/50 (10%)			10/50 (20%)	8/50 (16%)	
Overall Incidence	Total	17/100 (17%)	Mean 17%	SD 9.9%	Total	18/100 (18%)	Mean 18%	SD 2.83%
*Thyroid Gland: C-Cell: Carcinoma								
		1/50 (2%)	1/50 (2%)			(,	` ,	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		42/50 (200/)	6/50 (400)			44/50 (220/)	10/50 (20%)	
Overall Incidence	Total	13/50 (26%) 19/100 (19%)	6/50 (12%) Mean 19%	SD 9.9%	Total	` '	Mean 21%	SD 1.41%
		` '				, ,		
*Thyroid Gland: Follicular Cell: Adenoma	:	0(50 (00))	0 (50 (00))			0(50 (004)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%		` ,	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	` ,	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 267

			Male		0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 09 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 09			
#Tissue NOS: Paraganglioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` ,	SD 0%
#Tongue: Squamous Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` ,	SD 0%
#Tongue: Squamous Cell Carcinoma	or Papillom	a Squamous 0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` ,	` ,	SD 1.41%
#Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	(,	` ,	SD 1.41%
#Tooth: Adamantinoma Malignant		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	` '	` ,	SD 0%
#Tooth: Odontoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

ORAL

Page: 268

			Male				Female		
*Urinary Bladder: 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%	
*Urinary Bladder: Carcinoma or Papilloma									
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%	
*Urinary Bladder: Hemangiosarcoma									
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%	
*Urinary Bladder: Papilloma									
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%	
#Uterus: Adenoma									
Overall Incidence					Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	
#Uterus: Carcinoma									
Overall Incidence					Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Page: 269

Male			Female	
#Uterus: Deciduoma Benign				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Leiomyosarcoma				
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Uterus: Polyp Stromal				
Overall Incidence	Total	8/50 (16%) 18/100 (18%)	10/50 (20%) Mean 18%	SD 2.83%
#Uterus: Sarcoma				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal				
Overall Incidence	Total	8/50 (16%) 18/100 (18%)	10/50 (20%) Mean 18%	SD 2.83%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 270

			Male			Female			
#Uterus: Schwannoma Malignant						0/50 (0%)	0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Vagina: Polyp									
Overall Incidence					Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	
#Vagina: Sarcoma									
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Vagina: Schwannoma Malignant						0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%	
#Zymbal's Gland: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma									
Overall Incidence	Total	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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 271

Report Date: 05/18/2011

Route: ORAL
Vehicle: WATER

Length of Study: CHRONIC

			Male			Female			
#Zymbal's Gland: Carcinoma or Adenoma									
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 272

Report Date: 05/18/2011

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	059901305	05/12/05	726	50(3)	36(685)	522.7	Styrene-acrylonitrile trimer
					Female		
Battelle Columbus Laboratory	059901305	05/13/05	727	50(5)	41(699)	371.2	Styrene-acrylonitrile trimer

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 273

			Male				Female	
#All Organs: Benign Tumors Overall Incidence	Total	46/50 (92%) 46/50 (92%)	Mean 92%	SD 0%	Total	42/50 (84%) 42/50 (84%)	Mean 84%	SD 0%
#All Organs: Malignant Tumors	•••••							
Overall Incidence	Total	22/50 (44%) 22/50 (44%)	Mean 44%	SD 0%	Total	19/50 (38%) 19/50 (38%)	Mean 38%	SD 0%
#All Organs: Malignant and Benign Tu	ımors	49/50 (98%)				44/50 (88%)		
Overall Incidence	Total	49/50 (98%)	Mean 98%	SD 0%	Total	44/50 (88%)	Mean 88%	SD 0%
#All Organs: Hemangioma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma or He	mangioma	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 274

			Male				Female	
#All Organs: Histiocytic Sarcoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Erythrocytic								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic, Overall Incidence	Monocytic, Mo	ononuclear, or Undifferer 15/50 (30%) 15/50 (30%)	ntiated Mean 30%	SD 0%	Total	13/50 (26%) 13/50 (26%)	Mean 26%	SD 0%
Overali incidence	Total	13/30 (30/0)	Wicaii 0070	OD 070	iotai	13/30 (20/0)	Wicaii 2070	OD 070
#All Organs: Malignant Lymphoma: H					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs:	istiocytic, Lym	phocytic, Mixed, NOS, or 0/50 (0%) 0/50 (0%)	Undifferentiated Ce	II Туре		0/50 (0%) 0/50 (0%)		
#All Organs: Malignant Lymphoma: H Overall Incidence #All Organs:	istiocytic, Lym	phocytic, Mixed, NOS, or	Undifferentiated Ce	II Туре		0/50 (0%)		
#All Organs: Malignant Lymphoma: H Overall Incidence #All Organs: Mesothelioma: Benign	istiocytic, Lym Total	phocytic, Mixed, NOS, or 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Undifferentiated Ce	II Type SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 275

			Male				Female	
#All Organs: Mesothelioma: Malignant								
_		4/50 (8%)				0/50 (0%)		
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma		0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		` '				, ,		טעט ענ 0%
#All Organs: Osteosarcoma or Osteoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Adrenal Cortex: Carcinoma		0/50 (00)				0/50 (00/)		
Overell Institutes	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Mann 00/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 276

				Male				Female	
*Adrenal Medulla: Ganglioneuroma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Hemangioma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benigr		4/50	(8%)				0/50 (0%)		
Overall Incidence	Total	4/50 (8%)	(070)	Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Compl		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Malign									
		0/50	(0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Adrenal Medulla: Pheochromocytoma: Benig		Malignant, NOS					1/50 (2%)		
Overall Incidence	Total	4/50 (8%)	` ,	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 277

			Ma	ale			Female	
#Bone: Chordoma						27-2 (201)		
Overall Incidence	Total	0/50 (0° 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
Overall Incidence	Total	0/50 (0° 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma		0/50 /00	27.			0/50 (/0//)		
Overall Incidence	Total	0/50 (0° 0/50 (0%)	Mean 0%		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma		0/50 (0º				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%		Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Astrocytoma Malignant								
Overall Incidence	Total	0/50 (0° 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Ependymoma Benign		0/50 (0 ^o	24)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 278

			Male				Female	
*Brain: Ependymoma Malignant		0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Glioma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Brain: Glioma Benign		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Glioma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Benign								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Benign		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 279

			Male				Female					
*Brain: Oligodendroglioma Malignant 0/50 (0%) Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%												
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Brain: Oligodendroglioma, Glid	oma, or Astrocy	toma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Brain: Osteosarcoma		0/50 (0 ⁹	%)			0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Brain: Schwannoma Malignant		0/50 (09				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Clitoral/Preputial Gland: Adenoma												
Overall Incidence	Total	1/50 (29 1/50 (2%)	%) Mean 2%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%				
*Clitoral/Preputial Gland: Carcinoma		1/50 (29	9 <u>/</u> .)			0/50 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 280

			Male			Female Total 3/50 (6%) Mean 6% SD 0% Total 0/50 (0%) Mean 0% SD 0%			
*Clitoral/Preputial Gland: Carcinoma or Adenoma									
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	` '	Moon 6%	SD 0%	
	10tai	2/30 (4/0)	4 /0		10tai		Weall 076	30 0/6	
*Clitoral/Preputial Gland: Sarcoma									
• " ' '	-	0/50 (0%)		OD 00/	-	` '	NA 00/	00.00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	l otal	0/50 (0%)	Mean 0%	SD 0%	
#Ear: Neural Crest Tumor		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%	
#Esophagus: Lipoma		0/50 (0%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)			
#Eye: Melanoma Benign									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Eye: Melanoma Malignant									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		, ,				` '			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 281

			Male			0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%		
#Eye: Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)		
#Harderian Gland: Adenoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
#Harderian Gland: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma	Total	0/50 (0%)	Macro 00/	SD 00/	Total	` '	Magn 00/	SD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Heart: Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 282

				Male				Female	
#Intestine Large: Colon/Rectu Adenoma	m:								
	.	1/50	(2%)		OD 00/		0/50 (0%)		OD 00/
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Carcinoma or Adenoma	m:								
		1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Hemangioma	m:	0/50	(00()				0/50 (00)		
Overell Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Maan 00/	SD 0%
Overall Incidence	Total	0/50 (0%)		iviean 0%	3D 0%	ıolaı	0/50 (0%)	Mean 0%	טט טא טא
#Intestine Small: Duodenum: Carcinoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyoma									
•		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Schwannoma Malignant		0/25	(224)				(00)		
		0/50	(0%)		05 00/		0/50 (0%)		00.007
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

Page: 283

Report Date: 05/18/2011

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

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Ileum: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Granular Cell Tumor Maligi		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 284

Report Date: 05/18/2011

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Small: Site Unspe Carcinoma	cified:							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Carcinoma or Adenoma	cified:							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Granular Cell Tumor Malig		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Leiomyoma	cified:	0/50 (00)				0/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Leiomyosarcoma	cified:	0/50 (0%)				0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Schwannoma Malignant	cified:							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 285

			Male			Total 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% O/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0%				
*Islets, Pancreatic: Adenoma							1/50 (2%) 1/50 (2%) Mean 2% SD 0% 0/50 (0%) 0/50 (0%) Mean 0% SD 0% 1/50 (2%) 1/50 (2%) Mean 2% SD 0% 0/50 (0%) 0/50 (0%) Mean 0% SD 0% SD 0%			
		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		(,		SD 0%		
*Islets, Pancreatic: Carcinoma										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Islets, Pancreatic: Carcinoma or Adenoma		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 2%	SD 0%		
*Kidney: Pelvis and Transitio Carcinoma		m:				0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)				
*Kidney: Pelvis and Transitio Carcinoma or Adenoma				•••••						
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,		/-		
*Kidney: Pelvis and Transitio Papilloma										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incid

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 286

			Male		Female 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%				
*Kidney: Renal Tubule: Adenoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		0/50 (0%)		SD 0%	
*Kidney: Renal Tubule: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma or Adenoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	` '	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Hemangiosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Lipoma						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%	
*Kidney: Renal Tubule: Mesenchymal Tumor Benig	n	0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 287

Report Date: 05/18/2011

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Kidney: Renal Tubule: Mesenchymal Tumor Malig	jnant	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma		0/50 (0%)				0/50 /00/		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma		0/50 (09/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Liver: Cholangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

Page: 288

Report Date: 05/18/2011

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

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

			Male				Female				
*Liver: Hepatocellular Carcinoma 0/50 (0%) 0/50 (0%)											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Liver:	o ar Hanatabla										
Hepatocellular Carcinoma	а ог ператоріа	0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Carcinoma	a or Hepatocel	0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Carcinoma Overall Incidence				SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Liver: Ito Cell Tumor Benign		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Lung: Alveolar/Bronchiolar Ade	noma										
		1/50 (2%)				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 289

			Male				Female	
*Lung: Alveolar/Bronchiolar Ca	ırcinoma							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Ca								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Fibrosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Hemangiosarcoma	•••••	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Squamous Cell Carcino								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 290

Report Date: 05/18/2011

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Mammary Gland: Adenolipoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
		, ,						
#Mammary Gland:								
Carcinoma or Adenoma		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Mammary Gland: Fibroadenoma								
		1/50 (2%)				36/50 (72%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	36/50 (72%)	Mean 72%	SD 0%
#Mammary Gland: Fibroma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 291

				Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma o	or Adenoma	,							
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	36/50 (72%) 36/50 (72%)	Mean 72%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma,	Carcinoma or	Adenoma						•••••	
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	36/50 (72%) 36/50 (72%)	Mean 72%	SD 0%
#Mesentery: Fibrous Histiocytoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	, ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Lipoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Schwannoma Malignant		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 292

			Male				Female	
*Nose: Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Nose: Squamous Cell Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, To Papilloma Squamous or Pa Overall Incidence		ynx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, To Squamous Cell Carcinoma	ongue, Phary	ynx, Tooth, Gingiva): 0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Oral Cavity (Oral Mucosa, To Squamous Cell Carcinoma,	•					1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Oral Mucosa: Squamous Cell Carcinoma				•••••				
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 293

Report Date: 05/18/2011

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female		
#Oral Mucosa: Squamous Cell Papillor	ma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Cystadenoma		` '				` '			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Fibrosarcoma						0/50 (00)			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor E									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor M	M alignant								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor:									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 294

Report Date: 05/18/2011

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Ovary: **Granulosa-Theca Tumor Benign** 0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% *Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% *Ovary: **Schwannoma Malignant** 0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% *Ovary: **Tubulostromal Adenoma** 0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/50 (0%) *Pancreas: Adenoma 1/50 (2%)1/50 (2%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2% SD 0% *Pancreas: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%)

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 295

Report Date: 05/18/2011

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Pancreas: Carcinoma or Adenoma 1/50 (2%)1/50 (2%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2% SD 0% *Pancreas: **Mixed Tumor Benign** 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Pancreas: **Mixed Tumor Malignant** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Parathyroid Gland: Adenoma 0/35 (0%)0/48 (0%)**Overall Incidence** Total 0/35 (0%) Mean 0% SD 0% Total 0/48 (0%) Mean 0% SD 0% *Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 16/50 (32%)22/50 (44%)**Overall Incidence** Total 16/50 (32%) Mean 32% SD 0% Total 22/50 (44%) Mean 44% SD 0% *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) SD 0% Mean 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 296

Report Date: 05/18/2011

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 16/50 (32%)22/50 (44%)**Overall Incidence** Total 16/50 (32%) Mean 32% SD 0% Total 22/50 (44%) Mean 44% SD 0% *Pituitary Gland: Pars Distalis or Unspecified Site: Ganglioneuroma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Pituitary Gland: Pars Intermedia: Adenoma 0/50 (0%)0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Pituitary Gland: Pars Nervosa: Craniopharyngioma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Prostate: Adenoma 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

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 297

			Male				Female	
*Prostate: Carcinoma or Adenoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma		0/50 (0%)	•••••			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Sarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma		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

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 298

eport	Date:	U5/	10/2011	

			Male				Female	
#Skeletal Muscle: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)				0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or F						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or B	asosquamous	Tumor Benign 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 299

Report Date: 05/18/2011

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Skin: **Basal Cell Carcinoma** 0/50 (0%)0/50 (0%)**Overall Incidence** 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) SD 0% Total Mean 0% #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 0/50 (0%)**Overall Incidence** 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%)0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 4/50 (8%)1/50 Overall Incidence Total 4/50 (8%) Mean 8% SD 0% Total 1/50 (2%) Mean 2% SD 0% #Skin: **Fibroma** (10%)0/50 (0%)**Overall Incidence** Total 5/50 (10%) Mean 10% SD 0% Total 0/50 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

Page: 300

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female				
#Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 5/50 (10%) 0/50 (0%)											
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Fibrosarcoma		0/50 (00/)				0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Skin: Fibrosarcoma, Sarcoma		, or Fibrous Histiocytoma 0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Fibrous Histiocytoma	•••••	0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Hemangioma	•••••										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Skin: Hemangiosarcoma	•••••										
		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

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 301

			Male				Female	
#Skin: Keratoacanthoma								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Lipoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor, Mali								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Neurofibroma or Schwar	nnoma benign	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 302

			Male				Female	
#Skin: Neurofibrosarcoma or Sch	wannoma (m	-				(201)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Neurofibrosarcoma, Neuro	fibroma, or S	schwannoma (benign, ma 0/50 (0%)	alignant or NOS)			1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Sarcoma		0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Benign		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Squamous Cell Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female

Page: 303

			Maie				Female		
#Skin: Squamous Cell Carcin or Carcinoma	oma, Basal Cell C	Carcinoma, Basosquam	ous Tumor (malignar	nt or NOS),					
Overell Inclidence	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Papillo	oma	2/50 (40/)				0/50 (00/)			
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		, ,							
#Skin: Squamous Cell Papillo	oma or Papilloma	0/50 /40/)				0/50 (00/)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Overall incluence	Total	2/50 (4%)				0/50 (0%)			
#Skin: Squamous Cell Papillo	oma, Papilloma, S	quamous Cell Carcinon 4/50 (8%)	na or Keratoacanthor	ma		1/50 (2%)			
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Skin: Squamous Cell Papillo		r Keratoacanthoma 4/50 (8%)				1/50 (2%)			
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Skin: Trichoepithelioma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 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

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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 304

			Male				Female	
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Spinal Cord: Astrocytoma Benign		0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
		0/50 (0%)			TOTAL	0/50 (0%)	wean 0%	3D 0%
#Spinal Cord: Astrocytoma Malignant		2/20 (00)				2(72)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
						` '		
#Spinal Cord: Glioma Malignant								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Spleen: Fibrosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Contract/Lab: All Laboratories

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Ve

Page: 305

			Male				Female	
*Spleen: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Spleen: Leiomyosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Spleen: Sarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 306

				Male		Female Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0%					
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous 0/50 (0%) 0/50 (0%)											
Overall Incidence	Total	0/50 (0%)	(076)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%		
#Stomach, Forestomach: Squamous Cell Papilloma		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(078)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%		
#Stomach, Glandular: Carcinoma		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	, ,	Mean 0%	SD 0%		
#Stomach, Glandular: Carcinoma or Adenoma Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	, ,	Mean 0%	SD 0%		
#Stomach, Glandular: Lipoma		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Stomach, Glandular: Sarcoma		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 307

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Testes: Adenoma 41/50 (82%)**Overall Incidence** Total 41/50 (82%) Mean 82% SD 0% *Testes: Hemangioma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Thymus: **Thymoma Benign** 1/48 (2%)0/50 (0%)Overall Incidence Total 1/48 (2.08%) Mean 2.08% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Thymus: **Thymoma Malignant** 1/48 (2%)1/50 (2%)**Overall Incidence** SD 0% Total 1/48 (2.08%) Mean 2.08% SD 0% Total 1/50 (2%) Mean 2% *Thymus: Thymoma NOS 0/48 (0%)0/50 (0%)**Overall Incidence** Total 0/48 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Thymus: Thymoma: Benign, Malignant, NOS

SD 0%

1/50

1/50 (2%)

Total

(2%)

Mean 2%

SD 0%

Total

2/48

2/48 (4.17%)

(4%)

Mean 4.17%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

Page: 308

Report Date: 05/18/2011

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

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

			Male			0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 6/50 (12%)		
*Thyroid Gland: C-Cell: Adenoma								
Overall Incidence	Total	12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%	Total	` ,	Mean 12%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		12/50 (24%)				6/50 (129/.)		
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	` '	Mean 12%	SD 0%
*Thyroid Gland: Follicular Ce Adenoma	II:							
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	` '	Mean 2%	SD 0%
*Thyroid Gland: Follicular Ce Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Contract/Lab: All Laboratories

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 309

				Male				Female	
#Tissue NOS: Paraganglioma									
Overall Incidence	Total	0/50 (0%)	0%) Me	an 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma									
Overall Incidence	Total	0/50 (0%)	0%) Me	an 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma	-	0/50 (0	0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		an 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma Overall Incidence	Total	0/50 (0%)		an 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tooth: Adamantinoma Malignant			0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	,	an 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		0/50 ((0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	,	an 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 310

Report Date: 05/18/2011

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: Carcinoma 1/50 (2%)0/50 (0%)1/50 (2%) SD 0% SD 0% **Overall Incidence** Total Mean 2% Total 0/50 (0%) Mean 0% *Urinary Bladder: Carcinoma or Papilloma 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Urinary Bladder: Hemangiosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Urinary Bladder: **Papilloma** 0/50 (0%)0/50 (0%)SD 0% **Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% #Uterus: Adenoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% #Uterus: Carcinoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 311

Report Date: 05/18/2011

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male			Female	
#Uterus: Deciduoma Benign					
3			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma					
•			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal					
			6/50 (12%)		
Overall Incidence		Total	6/50 (12%)	Mean 12%	SD 0%
#Uterus: Sarcoma					
			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal					
			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					
			6/50 (12%)		
Overall Incidence		Total	6/50 (12%)	Mean 12%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 312

Report Date: 05/18/2011

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female 1/50 (2%) Mean 2% SD 0% 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Mean 0% SD 0%			
#Uterus: Schwannoma Malignant									
Overall Incidence					Total	` ,	Mean 2%	SD 0%	
#Vagina:									
Polyp						0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	
#Vagina: Sarcoma				•••••					
						, ,			
Overall Incidence					Total	(,			
#Vagina: Schwannoma Malignant						0.50			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Zymbal's Gland: Adenoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma									
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 313

			Male			Female				
#Zymbal's Gland: Carcinoma or Adenoma		4/50 (00/)				0(50 (00))				
		1/50 (2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 314

Report Date: 05/18/2011

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

Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Southern Research Institute	058813307	01/18/05	729	50(1)	23(681)	516.1	Trimethylolpropane triacrylate
					Female		
Southern Research Institute	058813307	01/18/05	731	50(1)	27(688)	352.8	Trimethylolpropane triacrylate

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 315

Report Date: 05/18/2011

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			21/50 (42%) Total 21/50 (42%) Mean 42% SD 0% 47/50 (94%) Total 47/50 (94%) Mean 94% SD 0% 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%			Female			
#All Organs: Benign Tumors												
-		48/50 (96%)				43/50 (86%)						
Overall Incidence	Total	48/50 (96%)	Mean 96%	SD 0%	Total	43/50 (86%)	Mean 86%	SD 0%				
#All Organs: Malignant Tumors		30/50 (60%)				21/50 (42%)						
Overall Incidence	Total	30/50 (60%)	Mean 60%	SD 0%	Total	` ,	Mean 42%	SD 0%				
#All Organs: Malignant and Benign To												
		50/50 (100%)				, ,						
Overall Incidence	Total	50/50 (100%)	Mean 100%	SD 0%	Total	47/50 (94%)	Mean 94%	SD 0%				
#All Organs: Hemangioma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%				
#All Organs: Hemangiosarcoma												
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#All Organs: Hemangiosarcoma or He	emangioma											
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

Page: 316

			Male				Mean 0% SD 0% Mean 0% SD 0% 4%) Mean 24% SD 0% Mean 0% SD 0% Mean 0% SD 0% SD 0%		
#All Organs: Histiocytic Sarcoma									
• " ' '	-	0/50 (0%)		OD 00/	+	0/50 (0%)		OD 00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)			
#All Organs: Leukemia: Erythrocytic		0/50 (00/)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		` '							
#All Organs: Leukemia: Lymphocytic, I	Monocytic, Mo	ononuclear, or Undiffere	ntiated			12/50 (24%)			
Overall Incidence	Total	26/50 (52%)	Mean 52%	SD 0%	Total	12/50 (24%)	Mean 24%	SD 0%	
#All Organs: Malignant Lymphoma: His						0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Mesothelioma: Benign									
_		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)		SD 0%	
#All Organs: Mesothelioma: Benign, Ma		;							
Overell Incidence	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Maan 00/	CD 00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 317

Report Date: 05/18/2011

Route: SKIN

Vehicle: ACETONE

Length of Study: CHRONIC

			Male				Female	
#All Organs: Mesothelioma: Malignant								
_		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma		0/50 (00/)				0/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma		2/50 (4%)						
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall incluence	ı Ulal	0/30 (070)	IVICALI U70	עט עט	ı Ulai	0/30 (0%)	IVIEAN U70	3D 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

Page: 318

			Male	Female					
*Adrenal Medulla: Ganglioneuroma									
•		0/49 (0%)				0/48 (0%)			
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Hemangioma		0/49 (0%)				0/48 (0%)			
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Benign									
		11/49 (22%)				0/48 (0%)			
Overall Incidence	Total	11/49 (22.45%)	Mean 22.45%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Comple	ex	0/49 (0%)				0/48 (0%)			
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Malign									
		1/49 (2%)				0/48 (0%)			
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma: Benig						0/48 (0%)			
Overall Incidence	Total	12/49 (24.49%)	Mean 24.49%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	
		(/)				(- / - /			

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

Page: 319

			Male	Female				
#Bone: Chordoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Astrocytoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Ependymoma Benign								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

Route: SKIN

Length of Study: CHRONIC

Vehicle: ACETONE

Page: 320

			Male	Female				
*Brain: Ependymoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Glioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Glioma Benign		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Glioma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Benig		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Benigr	1	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 321

		Male						Female			
*Brain: Oligodendroglioma Malignant											
	•	0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Brain: Oligodendroglioma, Glic											
,	,		(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	, ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Brain: Osteosarcoma	•••••	0/50	(004)				(201)				
			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Brain: Schwannoma Malignant		2/52	(201)				(201)				
Overall Incidence	Total	0/50 (0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Clitoral/Preputial Gland: Adenoma											
		3/50	(6%)				4/50 (8%)				
Overall Incidence	Total	3/50 (6%)		Mean 6%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%		
*Clitoral/Preputial Gland: Carcinoma											
			(0%)				7/50 (14%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 322

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Clitoral/Preputial Gland: Carcinoma or Adenoma		(201)				(220)		
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	10/50 (20%) 10/50 (20%)	Mean 20%	SD 0%
*Clitoral/Preputial Gland: Sarcoma		0/50 (09/)				0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Ear: Neural Crest Tumor		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Esophagus: Lipoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Benign		2/22 (224)				0.750 (001)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 323

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

			Male	Female				
#Eye: Schwannoma Malignant								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma		(201)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
·····		` '				, ,		
#Harderian Gland: Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign				•••••				
_		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant		0/50 (00()			•••••	0/50 (00/)		
Overall Incidence	Total	` '	Moon 09/	SD 00/	Total	` '	Moon 09/	CD 00/
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0°

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

Route: SKIN

Length of Study: CHRONIC

Vehicle: ACETONE

Page: 324

				Male		Female					
#Intestine Large: Colon/Rectum: Adenoma											
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Colon/Rectu Carcinoma or Adenoma	ım:										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Colon/Rectu Hemangioma	ım:	0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Carcinoma											
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Leiomyoma											
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Schwannoma Malignant							0/50 (00/)				
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

Page: 325

			Male				Female			
#Intestine Small: Ileum: Adenoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Carcinoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Granular Cell Tumor Maligi		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Leiomyoma		0/50 (0%)	M	OD 00/	T-1-1	0/50 (0%)	M 00/	05.0%		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Leiomyosarcoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Unspec Adenoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 326

Report Date: 05/18/2011

Vehicle: ACETONE

Length of Study: CHRONIC

			Male				Female			
#Intestine Small: Site Uns	specified:									
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Uns Carcinoma or Adenoma	•	0/50 (00/)				0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Uns Granular Cell Tumor Ma	specified:									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
		, ,				, ,				
#Intestine Small: Site Uns Leiomyoma	specified:									
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Uns Leiomyosarcoma										
,		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Uns Schwannoma Malignan	•									
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 327

Report Date: 05/18/2011

Route: SKIN

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female				
*Islets, Pancreatic: Adenoma								
		18/50 (36%)				3/50 (6%)		
Overall Incidence	Total	18/50 (36%)	Mean 36%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
*Islets, Pancreatic: Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
		18/50 (36%)				3/50 (6%)		
Overall Incidence	Total	18/50 (36%)	Mean 36%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
*Kidney: Pelvis and Transitic Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Pelvis and Transitio Carcinoma or Adenoma		ım:						
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Pelvis and Transition Papilloma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

IN .

Page: 328

				Male			Female			
*Kidney: Renal Tubule: Adenoma		0/50 ((0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma		0/50 //	00/\				0/50 (09/)			
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 ((0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Hemangiosarcoma			0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Lipoma				•••••						
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Mesenchymal Tumor Benig			0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 329

			Male			Female					
*Kidney: Renal Tubule: Mesenchymal Tumor Malignant											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Nephroblastoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Sarcoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)) Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
*Liver: Cholangioma Overall Incidence	Total	0/50 (0% 0/50 (0%)		SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hemangiosarcoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Adenoma		1/50 (2%				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 330

Report Date: 05/18/2011

Vehicle: ACETONE

Length of Study: CHRONIC

			Male			Female			
*Liver: Hepatocellular Carcinom	na								
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver:									
Hepatocellular Carcinom	na or Hepatobla					0/50 (00/)			
		1/50 (2%)		OD		0/50 (0%)	• • • • • • • • • • • • • • • • • • • •	05.00/	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Carcinom	na or Hepatocel	lular Adenoma							
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Carcinom						0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Ito Cell Tumor Benign									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Lung: Alveolar/Bronchiolar Ad	enoma	4/50 (00()				0/50 (00/)			
Overell Incidence	Tatal	1/50 (2%)	Mana 20/	CD 00/	Tatal	0/50 (0%)	Mann 00/	CD 00/	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 331

Report Date: 05/18/2011

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female					
*Lung: Alveolar/Bronchiolar Carcinoma											
		1/50 (2	2%)			0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
Lung: Alveolar/Bronchiolar Carcii		eolar/Bronchiolar	Adenoma								
		,	4%)			0/50 (0%)					
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
Lung: Fibrosarcoma											
		`	0%)	OD O		0/50 (0%)	••	05.00/			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
Lung: Hemangiosarcoma		0/50 ((0%)			0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
Lung: Squamous Cell Carcinoma											
		0/50 (0	0%)			0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
¥Lymph Node: Hemangiosarcoma			0%)			0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
		` ,	iviean 0%			` '					

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 332

			Male			Female			
#Mammary Gland: Adenolipoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	
#Mammary Gland: Carcinoma		0/50 (0%)				3/50 (6%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
#Mammary Gland: Carcinoma or Adenoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%	
#Mammary Gland: Fibroadenoma		1/50 (2%)				22/50 (44%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	22/50 (44%)	Mean 44%	SD 0%	
#Mammary Gland: Fibroma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 333

				Male				Female			
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma											
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	25/50 (50%) 25/50 (50%)	Mean 50%	SD 0%		
		1/50 (2%)		2%	טע עס	ı olal	25/50 (50%)		งบ บ‰ 		
#Mammary Gland: Fibroma, Fibroadenoma, C	Carcinoma, or	Adenoma									
		1/50	(2%)				25/50 (50%)				
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	25/50 (50%)	Mean 50%	SD 0%		
#Mesentery: Fibrous Histiocytoma											
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
·····		, ,					, ,				
#Mesentery: Hemangiosarcoma		0/50	(00()				0/50 (00/)				
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
		` ,					` ,				
#Mesentery: Lipoma											
		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Mesentery: Schwannoma Malignant											
		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Vehicle: ACETONE

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 334

Report Date: 05/18/2011

Length of Study: CHRONIC

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

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Page: 335

			Male			Female			
#Oral Mucosa: Squamous Cell Papilloma	1	0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Cystadenoma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Fibrosarcoma						0/50 (00)			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor Be	nign					0/50 (09/)			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor Ma	lignant								
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Ovary: Granulosa Cell Tumor: Be	enign, Maligna	nt, NOS				1/50 (2%)			
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

trol Animal Groups Report Date: 05/18/2011

Page: 336

			Male				Female			
*Ovary: Granulosa-Theca Tumor Be	enign									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Granulosa-Theca Tumor Ma										
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Schwannoma Malignant										
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Tubulostromal Adenoma										
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Pancreas: Adenoma										
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Pancreas: Carcinoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 337

Report Date: 05/18/2011

Route: SKIN

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female			
*Pancreas: Carcinoma or Adenoma									
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Mixed Tumor Benign		4/50 (00())				0/50 (00/)			
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Mixed Tumor Malignant									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Parathyroid Gland: Adenoma		0/45 (00/)				0/45 (09/)			
Overall Incidence	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%	
*Pituitary Gland: Pars Dista									
Adenoma		34/49 (69%)				36/50 (72%)			
Overall Incidence	Total	34/49 (69.39%)	Mean 69.39%	SD 0%	Total	36/50 (72%)	Mean 72%	SD 0%	
						•••••			
*Pituitary Gland: Pars Dista Carcinoma	lis or Unspec								
		0/49 (0%)				2/50 (4%)			
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 338

Report Date: 05/18/2011

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 34/49 (69%)38/50 (76%)**Overall Incidence** Total 34/49 (69.39%) Mean 69.39% SD 0% Total 38/50 (76%) Mean 76% SD 0% *Pituitary Gland: Pars Distalis or Unspecified Site: Ganglioneuroma 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/49 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Pituitary Gland: Pars Intermedia: Adenoma 0/49 (0%)1/50 (2%)Overall Incidence Total 0/49 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0% *Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 0/49 (0%)1/50 (2%)Overall Incidence Total 0/49 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0% *Pituitary Gland: Pars Nervosa: Craniopharyngioma 0/49 (0%)1/50 (2%)**Overall Incidence** Total 0/49 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0% *Prostate: Adenoma 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

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Report Date: 05/18/2011

Page: 339

			Male				Female	
*Prostate: Carcinoma or Adenoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Carcinoma	Total	1/50 (2%)	Mars 20/	CD 00/	Tatal	0/50 (0%)	M 00/	CD OW
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Moon 09/	SD 0%
Overall incidence	Total	1/50 (2%)	iviean 2%	3D 0%	Total	0/50 (0%)	Mean 0%	טע ט%
*Salivary Glands: Sarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma		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

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for S

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 340

			Male		0/50 (0%) Total 0/50 (0%) Mean 0% SD 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0/50 (0%) Total 0/50 (0%) Mean 0% SD			
#Skeletal Muscle: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%
#Skeletal Muscle: Hemangiosarcoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or R						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 2%	SD 0%
#Skin: Basal Cell Adenoma or B	asosquamous	Tumor Benign 0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 341

Report Date: 05/18/2011

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Basal Cell Adenoma, B	asosquamous T	umor Benign, or Trichoe	pithelioma					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
	10tai	0/30 (0 /8)		30 0%	10tai	1/30 (2/6)		
#Skin: Basal Cell Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:		- T	100/		•••••			
Basai Celi Carcinoma (or Basosquamou	s Tumor (malignant or N 0/50 (0%)	105)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli	Basal Cell Adend	oma, Basosquamous Tu 0/50 (0%)	mor (benign, maligna	ant or		1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
		a, Basosq. Tumor (M or ratoacanthoma, Trichoe 5/50 (10%)		ma,		1/50 (2%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Fibroma								
		4/50 (8%)		05.00/		0/50 (0%)		00.00
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 342

Report Date: 05/18/2011

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

			Male				Female	
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myxo	oma, Myxosarcoma, or Fi 4/50 (8%)	brous Histiocytoma			0/50 (0%)		
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcoma	a, Myxosarcoma	, or Fibrous Histiocytoma 0/50 (0%)	1			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 343

			Male			Female 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Mean 0% SD 0%		
#Skin: Keratoacanthoma Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin: Lipoma Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin: Liposarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin: Neural Crest Tumor Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)		
#Skin: Neural Crest Tumor, Ma		0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)		
#Skin: Neurofibroma or Schwa		0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 05/18/2011

Page: 344

			Male				Female	
#Skin: Neurofibrosarcoma or Sch	vannama (m	alignant or NOS)						
Neuronbrosarcoma or Sch	varinoma (m	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:								
Neurofibrosarcoma, Neurof	ibroma, or S		alignant or NOS)					
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin:								
Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:								
Schwannoma Benign		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
лен								
#Skin:								
Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Overall incluence	ı olal	0/30 (0%)	IVIEAN U%	3D 0%	ı olal	0/30 (0%)	IVIEAN 070	الله الله الله الله الله الله الله الله
#Skin: Squamous Cell Carcinoma								
equalitous con carolilonia		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
						` '		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 345

Report Date: 05/18/2011

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

0/50 (0%) 0/50 (0%)	Mean 0%	t or NOS), SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%											
0/50 (0%)				0/50 (0%)	Mean 0%												
				, ,	Mean 0%	SD 0%											
1/5() (2%)																	
` ,	Mana 200/	CD 00/	Tatal	, ,	Mana 00/	CD 00/											
1/50 (2%)	Mean 2%	SD 0%	ı otal	0/50 (0%)	Mean 0%	SD 0%											
1/50 (2%)				0/50 (0%)													
1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%											
ous Cell Carcinoma 5/50 (10%)	or Keratoacanthom	na		0/50 (0%)													
5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%											
				0/50 (0%)													
, ,	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%											
0/50 (0%)				0/50 (0%)													
` '	Mean 0%	SD 0%	Total	, ,	Mean 0%	SD 0%											
1	0us Cell Carcinoma	1/50 (2%) Mean 2% 1/50 (2%) Mean 2% Ous Cell Carcinoma or Keratoacanthom 5/50 (10%) Mean 10% Atoacanthoma 5/50 (10%) Mean 10% O/50 (10%) Mean 10%	1/50 (2%) Mean 2% SD 0% 1/50 (2%) Mean 2% SD 0% ous Cell Carcinoma or Keratoacanthoma 5/50 (10%) Mean 10% SD 0% stoacanthoma 5/50 (10%) Mean 10% SD 0% outoacanthoma 5/50 (10%) Mean 10% SD 0%	1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) 1/50 (2%) Mean 2% SD 0% Total ous Cell Carcinoma or Keratoacanthoma 5/50 (10%) 6/50 (10%) Mean 10% SD 0% Total atoacanthoma 5/50 (10%) 6/50 (10%) Mean 10% SD 0% Total	1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Ous Cell Carcinoma or Keratoacanthoma 5/50 (10%) 0/50 (10%) 1/50 (10%) Mean 10% SD 0% Total 0/50 (0%) 1/50 (10%) Mean 10% SD 0% Total 0/50 (0%) 1/50 (10%) Mean 10% SD 0% Total 0/50 (0%) 1/50 (10%) Mean 10% SD 0% Total 0/50 (0%) 1/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)	1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% 1/50 (2%)											

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

> Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Page: 346

			Male		0/50 (0%) Total 0/50 (0%) Mean 0% SD 0 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0			
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		, ,		SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)				` ,		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Benign		0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
		, ,			·····	0/30 (0/8)		
#Spinal Cord: Astrocytoma Malignant		2/20 (201)				2(22)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	, ,	Mean 0%	SD 0%
		` '				` '		
#Spinal Cord: Glioma Malignant								
		0/50 (0%)				` ,		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Spleen: Fibrosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 347

Report Date: 05/18/2011

Route: SKIN

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

				Male			Female Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%		
*Spleen: Fibrous Histiocytoma Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
*Spleen: Leiomyosarcoma Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	()	Mean 0%	SD 0%
*Spleen: Sarcoma Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyosarcoma Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 348

Report Date: 05/18/2011

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papilloma	a Squamous						
	-	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma				•••••				
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Lipoma								
·		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Report Date: 05/18/2011

Page: 349

			Male				Female	
*Testes: Adenoma Overall Incidence	Total	27/50 (54%)	Moon 549/	SD 09/				
Overali incidence	Total	27/50 (54%)	Mean 54%	SD 0%				
*Testes: Hemangioma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Benign								
Overall Incidence	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/45 (0%)				0/47 (0%)		
Overall Incidence	Total	0/45 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma NOS								
Overall Incidence	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Mali	gnant, NOS							
Overall Incidence	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

SKIN

Page: 350

			Male				Female	
*Thyroid Gland: C-Cell: Adenoma Overall Incidence	Total	8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		8/50 (16%)				3/50 (6%)		
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
*Thyroid Gland: Follicular Cell Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 351

				Male			Female			
#Tissue NOS: Paraganglioma										
Occupation of desires	Tatal	0/50	(0%)	Mara 2007	00.00/	Tatal	0/50 (0%)	Marana 00/	00.00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Carcinoma										
		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Carcinoma	or Papilloma	a Squamous 1/50	(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Papilloma		1/50	(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tooth: Adamantinoma Malignant										
		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tooth: Odontoma		0/50	(0%)				0/50 (0%)			

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 352

Report Date: 05/18/2011

Route: SKIN

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Urinary Bladder: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Papilloma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma						0/50 (09/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 353

Report Date: 05/18/2011

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus:** Deciduoma Benign 0/50 (0%)SD 0% **Overall Incidence** Total 0/50 (0%) Mean 0% #Uterus: Leiomyosarcoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% #Uterus: **Polyp Stromal** 9/50 (18%) **Overall Incidence** Total 9/50 (18%) Mean 18% SD 0% **#Uterus:** Sarcoma 0/50 (0%)**Overall Incidence** SD 0% Total 0/50 (0%) Mean 0% #Uterus: Sarcoma Stromal 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% **#Uterus:** Sarcoma Stromal or Polyp Stromal 9/50 (18%)**Overall Incidence**

Total

9/50 (18%)

Mean 18%

SD 0%

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

^{#:} Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Page: 354

			Male				Female	
#Uterus: Schwannoma Malignant						0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Polyp								
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Vagina: Sarcoma						0(50 (00))		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Schwannoma Malignant						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 355

			Male				Female	
#Zymbal's Gland: Carcinoma or Adenoma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} 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: 356

Report Date: 05/18/2011

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

Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	059902805	09/16/02	729	50(1)	21(676)	506.2	bis(2-Chloroethoxy)methane
Battelle Columbus Laboratory	059700307	07/10/02	728	50(1)	25(680)	510.4	1,2-Dibromo-2,4-dicyanobutane
Southern Research Institute	059500305	04/05/04	729	50(1)	27(683)	508.5	Methyl trans-styryl ketone
Battelle Columbus Laboratory	059903203	09/15/04	727	50(1)	23(651)	510.1	Pyrogallol
					Female		
Battelle Columbus Laboratory	059902805	09/17/02	730	50(1)	19(646)	341.0	bis(2-Chloroethoxy)methane
Battelle Columbus Laboratory	059700307	07/11/02	729	50(1)	29(695)	337.8	1,2-Dibromo-2,4-dicyanobutane
Southern Research Institute	059500305	04/05/04	732	50(1)	30(685)	356.2	Methyl trans-styryl ketone
Battelle Columbus Laboratory	059903203	09/16/04	728	50(1)	29(670)	351.0	Pyrogallol

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 05/18/2011

Page: 357

			Male				Female	
#All Organs: Benign Tumors								
		49/50 (98%) 47/50 (94%)	46/50 (92%)	46/50 (92%)		37/50 (74%) 43/50 (86%)	46/50 (92%)	47/50 (94%)
Overall Incidence	Total	188/200 (94%)	Mean 94%	SD 2.83%	Total	173/200 (86.5%)	Mean 86.5%	SD 9%
#All Organs: Malignant Tumors								
		26/50 (52%) 22/50 (44%)	23/50 (46%)	33/50 (66%)		19/50 (38%) 12/50 (24%)	15/50 (30%)	22/50 (44%)
Overall Incidence	Total	104/200 (52%)	Mean 52%	SD 9.93%	Total	68/200 (34%)	Mean 34%	SD 8.79%
#All Organs: Malignant and Benign To	umors	49/50 (98%)	50/50 (100%)	48/50 (96%)		44/50 (88%)	48/50 (96%)	49/50 (98%)
Overall Incidence	Total	49/50 (98%) 196/200 (98%)	Mean 98%	SD 1.63%	Total	45/50 (90%) 186/200 (93%)	Mean 93%	SD 4.76%
#All Organs: Hemangioma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 358

			Male				Female	
#All Organs: Hemangiosarcoma or H	lemangioma							
-	_	1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Histiocytic Sarcoma								
		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	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%
#All Organs: Leukemia: Erythrocytic								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic	c, Monocytic, M	Iononuclear, or Undifferen	ntiated					
		17/50 (34%) 11/50 (22%)	17/50 (34%)	26/50 (52%)		12/50 (24%) 8/50 (16%)	10/50 (20%)	18/50 (36%)
Overall Incidence	Total	71/200 (35.5%)	Mean 35.5%	SD 12.37%	Total	48/200 (24%)	Mean 24%	SD 8.64%
#All Organs: Malignant Lymphoma: I	Histiocytic, Lyn	nphocytic, Mixed, NOS, or	Undifferentiated Cell	Туре				
		0/50 (0%) 0/50 (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

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 359

Report Date: 05/18/2011

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

			Male	Female
#All Organs: Mesothelioma: Benign				
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5% SD 1%	Total 0/200 (0%) Mean 0% SD 0%
#All Organs: Mesothelioma: Benign, Ma	alignant, NOS			
		2/50 (4%) 2/50 (4%)	1/50 (2%) 4/50 (8%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	9/200 (4.5%)	Mean 4.5% SD 2.52%	Total 0/200 (0%) Mean 0% SD 0%
#All Organs: Mesothelioma: Malignant				
		2/50 (4%) 2/50 (4%)	0/50 (0%) 4/50 (8%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	8/200 (4%)	Mean 4% SD 3.27%	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%) 1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 1/200 (0.5%) Mean 0.5% SD 1%
#All Organs: Osteosarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 360

			Male				Female	
All Organs: Osteosarcoma or Osteoma	I.							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Adrenal Cortex: Adenoma								
		0/50 (0%) 0/50 (0%)	3/50 (6%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	4/50 (8%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 3%	Total	5/200 (2.5%)	Mean 2.5%	SD 3.79%
Adrenal Cortex: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Ganglioneuroma								
		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: Hemangioma								
		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%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 05/18/2011

Page: 361

			Male				Female	
*Adrenal Medulla: Pheochromocytoma Be	enign							
		3/50 (6%) 4/50 (8%)	5/50 (10%)	11/49 (22%)		1/50 (2%) 1/50 (2%)	1/50 (2%)	1/49 (2%)
Overall Incidence	Total	23/199 (11.56%)	Mean 11.61%	SD 7.41%	Total	4/199 (2.01%)	Mean 2.01%	SD 0.02%
*Adrenal Medulla: Pheochromocytoma Co								
		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: Pheochromocytoma Ma	alignant	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/50 (2%) 1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma: Bo		x, Malignant, NOS 3/50 (6%) 5/50 (10%)	5/50 (10%)	11/49 (22%)		1/50 (2%) 1/50 (2%)	1/50 (2%)	1/49 (2%)
Overall Incidence	Total	24/199 (12.06%)	Mean 12.11%	SD 7.14%	Total	4/199 (2.01%)	Mean 2.01%	SD 0.02%
#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%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 362

			Male				Female	
Bone: Osteoma								
		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: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Brain: Astrocytoma Malignant								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	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%)	0/50 (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

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL **Page:** 363

			Male				Female	
*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								
		0/50 (0%) 0/50 (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 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%
Brain: 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%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
'Brain: Granular Cell Tumor Benig	jn							
_		0/50 (0%) 0/50 (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: F 344/N

Toxicology Data Management System

Page: 364

Report Date: 05/18/2011

Contract/Lab: All Laboratories Tumor Incidence for 3

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

			Male				Female	
*Brain: Oligodendroglioma Benigr	1							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Malign	ant	0/70 (001)				(50)	2/20 (201)	0.70
		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%
Brain: Oligodendroglioma, Gliom	a, or Astroc	ytoma 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	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
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								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 365

			Male				Female	
*Clitoral/Preputial Gland: Adenoma								
		2/50 (4%) 0/50 (0%)	2/50 (4%)	1/50 (2%)		2/50 (4%) 3/50 (6%)	6/50 (12%)	6/50 (12%)
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 1.91%	Total	17/200 (8.5%)	Mean 8.5%	SD 4.12%
*Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	3/50 (6%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 3%	Total	4/200 (2%)	Mean 2%	SD 2.83%
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		2/50 (4%) 0/50 (0%)	2/50 (4%)	4/50 (8%)		2/50 (4%) 4/50 (8%)	6/50 (12%)	9/50 (18%)
Overall Incidence	Total	8/200 (4%)	Mean 4%	SD 3.27%	Total	21/200 (10.5%)	Mean 10.5%	SD 5.97%
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%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 366

Report Date: 05/18/2011

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

0/50

0/50

0/200 (0%)

0/50

0/50

0/200 (0%)

(0%)

(0%)

(0%)

(0%)

.....

0/50

0/50

Mean 0%

Mean 0%

(0%)

(0%)

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Male **Female** #Esophagus: Lipoma 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 0/200 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% #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%)Mean 0% Overall Incidence Total 0/200 (0%) SD 0% Total 0/200 (0%) Mean 0% SD 0% #Eye: **Melanoma Malignant** 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 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Eye: Schwannoma Malignant

0/50

SD 0%

0/50

SD 0%

(0%)

(0%)

0/50

0/50

0/50

0/50

2/200 (1%)

0/200 (0%)

Total

Total

(0%)

(0%)

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0%

Mean 1%

0/50

2/50

SD 0%

SD 2%

(0%)

(4%)

Total

Total

Overall Incidence

#Harderian Gland: Adenoma

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

Page: 367

			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%)
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%)	2/50 (4%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%
*Heart: Schwannoma Benign								
		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%
'Heart: Schwannoma Malignant								
		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rect								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 368

Report Date: 05/18/2011

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Large: Colon/Rectum: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 2/200 (1%) Mean 1% 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%)0/50 (0%)0/50 (0%)Mean 0% Overall Incidence Total 0/200 (0%) SD 0% Total 0/200 (0%) Mean 0% SD 0% #Intestine Small: Duodenum: Carcinoma 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 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Intestine Small: Duodenum: Leiomyoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(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: 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%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 369
Report Date

			Male				Female	
#Intestine Small: Ileum: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
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 Maligi	nant	1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	,	,		0/50 (0%)	,	,
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma				-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%)
Overall 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%)	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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 370

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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 371

			Male				Female	
#Intestine Small: Site Unspec Leiomyosarcoma	cified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec 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%
*Islets, Pancreatic: Adenoma								
		3/50 (6%) 3/50 (6%)	6/50 (12%)	5/49 (10%)		0/50 (0%) 2/50 (4%)	0/50 (0%)	3/49 (6%)
Overall Incidence	Total	17/199 (8.54%)	Mean 8.55%	SD 3.04%	Total	5/199 (2.51%)	Mean 2.53%	SD 3.05%
'Islets, Pancreatic: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	3/49 (6%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.53%	SD 3.06%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
*Islets, Pancreatic: Carcinoma or Adenoma	•							
		3/50 (6%) 3/50 (6%)	6/50 (12%)	8/49 (16%)		1/50 (2%) 2/50 (4%)	0/50 (0%)	3/49 (6%)
Overall Incidence	Total	20/199 (10.05%)	Mean 10.08%	SD 5.03%	Total	6/199 (3.02%)	Mean 3.03%	SD 2.63%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 372

Report Date: 05/18/2011

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Kidney: Pelvis and Transitional Epithelium: 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% *Kidney: Pelvis and Transitional Epithelium: 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%)Mean 0% Overall Incidence Total 0/200 (0%) SD 0% Total 0/200 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: **Papilloma** 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 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Adenoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma

0/50

SD 0%

(0%)

0/50

0/50

0/200 (0%)

Total

(0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

0/50

0/50

0/200 (0%)

(0%)

(0%)

0/50

Mean 0%

(0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

Page: 373

			Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Kidney: Renal Tubule: Mesenchymal Tumor Benign	1							
		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%
Kidney: Renal Tubule: Mesenchymal Tumor Malign	ant							
		0/50 (0%) 0/50 (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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

Page: 374

			Male				Female	
Kidney: Renal Tubule: Nephroblastoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		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%
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%) 1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	2/200 (1%)	Mean 1%	SD 2%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 375

			Male				Female	
Liver: Hepatocellular Carcinoma	1							
		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	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinoma	or Hepatobla	astoma						
	-	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%
*Liver: Hepatocellular Carcinoma	or Hepatoce	0/50 (0%) 1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	2/200 (1%)	Mean 1%	SD 2%
Liver: Hepatocellular Carcinoma	ı, Hepatocellu	ular Adenoma, or Hepatob 0/50 (0%)	olastoma 1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/30 (2/6)	2/30 (4/0)		2/50 (4%)	0/30 (0/8)	0/30 (0/8)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	2/200 (1%)	Mean 1%	SD 2%
Liver: Ito Cell Tumor Benign		0/50 (00/)	0/50 (00/)	0/50 (0%)		0/50 (09/)	0/50 (00/)	0/50 (09/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

Page: 376

			Male				Female	
*Lung: Alveolar/Bronchiolar A	denoma							
		4/50 (8%) 1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	4/50 (8%)	1/50 (2%)
Overall Incidence	Total	8/200 (4%)	Mean 4%	SD 2.83%	Total	5/200 (2.5%)	Mean 2.5%	SD 3.79%
*Lung: Alveolar/Bronchiolar Ca				2(-2)		2/22 (224)	(20)	2(-2)
		1/50 (2%) 3/50 (6%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Overall Incidence	Total	eolar/Bronchiolar Adend 5/50 (10%) 4/50 (8%) 13/200 (6.5%)	2/50 (4%) Mean 6.5%	2/50 (4%) SD 3%	Total	0/50 (0%) 0/50 (0%) 5/200 (2.5%)	4/50 (8%) Mean 2.5%	1/50 (2%) SD 3.79%
*Lung: Fibrosarcoma		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%
*Lung: 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%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

Page: 377

			Male				Female	
*Lung: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenolipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	4/200 (2%)	Mean 2%	SD 1.63%
#Mammary Gland: Carcinoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	2/50 (4%)	2/50 (4%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	6/200 (3%)	Mean 3%	SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

Page: 378

			Male				Female	
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 3/50 (6%)	3/50 (6%)	3/50 (6%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	10/200 (5%)	Mean 5%	SD 2%
#Mammary Gland: Fibroadenoma								
		3/50 (6%) 0/50 (0%)	1/50 (2%)	2/50 (4%)		16/50 (32%) 24/50 (48%)	14/50 (28%)	19/50 (38%)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2.58%	Total	73/200 (36.5%)	Mean 36.5%	SD 8.7%
#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%
#Mammary Gland: Fibroma, Fibroadenoma o	r Adenoma							
		3/50 (6%) 0/50 (0%)	1/50 (2%)	2/50 (4%)		16/50 (32%) 25/50 (50%)	15/50 (30%)	19/50 (38%)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2.58%	Total	75/200 (37.5%)	Mean 37.5%	SD 9%
#Mammary Gland: Fibroma, Fibroadenoma, C	Carcinoma, o	· Adenoma						
,	, -	3/50 (6%) 1/50 (2%)	1/50 (2%)	2/50 (4%)		17/50 (34%) 26/50 (52%)	17/50 (34%)	21/50 (42%)
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 1.91%	Total	81/200 (40.5%)	Mean 40.5%	SD 8.54%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 379

			Male				Female	
Mesentery: 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%
#Mesentery: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
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%
#Mesentery: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 2%
Nose: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/200 (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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 380

Report Date: 05/18/2011

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

			Male				Female	
*Nose: Squamous Cell Carcino	oma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o	a, Tongue, Phar	ynx, Tooth, Gingiva):						
	•	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Squamous Cell Carcino Overall Incidence	Total	0/50 (0%) 1/50 (2%) 2/200 (1%)	0/50 (0%) Mean 1%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Oral Cavity (Oral Mucos; Squamous Cell Carcing		ynx, Tooth, Gingiva): Squamous, or Papilloma						
		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	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%
#Oral Mucosa: Squamous Cell Carcino	oma							
		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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

ntrol Animal Groups Report Date: 05/18/2011

Page: 381

			Male					Female	
#Oral Mucosa: Squamous Cell Papillom	na								
		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%
Ovary: Cystadenoma									
							0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence						Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Fibrosarcoma									
							0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence						Total	0/200 (0%)	Mean 0%	SD 0%
Ovary: Granulosa Cell Tumor B	enign								
							0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence						Total	2/200 (1%)	Mean 1%	SD 1.15%
*Ovary: Granulosa Cell Tumor M	alignant								
							1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence						Total	1/200 (0.5%)	Mean 0.5%	SD 1%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 382

Male			Female	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
		1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
*Ovary: Granulosa-Theca Tumor Benign				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Schwannoma Malignant				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 383

			Male				Female	
Pancreas: Adenoma								
		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%
Pancreas: 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%
Pancreas: Carcinoma or Adenoma								
		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%
Pancreas: Mixed Tumor Benign								
		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%
Pancreas: Mixed Tumor Malignant								
		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%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

Page: 384

			Male				Female	
Parathyroid Gland:								
		0/49 (0%) 0/50 (0%)	0/49 (0%)	0/49 (0%)		0/43 (0%) 0/49 (0%)	0/46 (0%)	1/50 (2%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	1/188 (0.53%)	Mean 0.5%	SD 1%
Pituitary Gland: Pars Dis Adenoma	stalis or Unspe	cified Site:						
		35/49 (71%) 33/50 (66%)	32/50 (64%)	33/50 (66%)		22/50 (44%) 25/50 (50%)	35/50 (70%)	31/50 (62%)
Overall Incidence	Total	133/199 (66.83%)	Mean 66.86%	SD 3.19%	Total	113/200 (56.5%)	Mean 56.5%	SD 11.7%
*Pituitary Gland: Pars Dis Carcinoma	stalis or Unspe							
		0/49 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	2/200 (1%)	Mean 1%	SD 2%
Pituitary Gland: Pars Dis Carcinoma or Adenom	•	cified Site:						
		35/49 (71%) 33/50 (66%)	32/50 (64%)	35/50 (70%)		22/50 (44%) 25/50 (50%)	35/50 (70%)	33/50 (66%)
Overall Incidence	Total	135/199 (67.84%)	Mean 67.86%	SD 3.45%	Total	115/200 (57.5%)	Mean 57.5%	SD 12.48%
*Pituitary Gland: Pars Dis Ganglioneuroma								
-		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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 385

			Male				Female	
Pituitary Gland: Pars Interm Adenoma	edia:							
		0/49 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Pituitary Gland: Pars Interm Carcinoma or Adenoma								
		0/49 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%	5)	1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Pituitary Gland: Pars Nervos Craniopharyngioma								•••••
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%	b)	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%
Prostate: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				
Prostate: Carcinoma or Adenoma			0/50	0.000				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 386

			Male				Female	
Salivary Glands: 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%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Salivary Glands: 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%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Salivary Glands: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	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%) 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%
#Seminal Vesicle: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 387

			Male				Female	
#Skeletal Muscle: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma							4/50 (00()	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Skeletal Muscle: Rhabdomyosarcoma or R	habdomyoma							
		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%
‡Skin: Basal Cell 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%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 388

Report Date: 05/18/2011

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Basal Cell Adenoma or Basosquamous Tumor Benign (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)0/200 (0%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 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: **Basal Cell Carcinoma** 0/50 (0%)0/50 1/50 (2%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 1/200 (0.5%) SD 1% Mean 0.5% #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) (0%)(0%)1/50 (2%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 1/200 (0.5%) Mean 0.5% SD 1% #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 1/50 (2%)0/50 (0%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 1/50 (2%)**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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 389

			Male				Female					
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma												
		2/50 (4%) 3/50 (6%)	2/50 (4%)	7/50 (14%)		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	14/200 (7%)	Mean 7%	SD 4.76%	Total	2/200 (1%)	Mean 1%	SD 1.15%				
#Skin: Fibroma												
		1/50 (2%) 1/50 (2%)	7/50 (14%)	5/50 (10%)		2/50 (4%) 1/50 (2%)	0/50 (0%)	3/50 (6%)				
Overall Incidence	Total	14/200 (7%)	Mean 7%	SD 6%	Total	6/200 (3%)	Mean 3%	SD 2.58%				
·	a, Sarcoma, Myx	oma, Myxosarcoma, or Fil 3/50 (6%) 1/50 (2%)	8/50 (16%)	7/50 (14%)		2/50 (4%) 1/50 (2%)	0/50 (0%)	3/50 (6%)				
Overall Incidence	Total	19/200 (9.5%)	Mean 9.5%	SD 6.61%	Total	6/200 (3%)	Mean 3%	SD 2.58%				
#Skin: Fibrosarcoma		2/50 (4%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 4/200 (2%)	Mean 2%	SD 2.31%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%				
#Skin: Fibrosarcoma, Sarcom	na, Myxosarcoma	a, or Fibrous Histiocytoma	 I									
		2/50 (4%) 0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 390

			Male	Female
#Skin: Fibrous Histiocytoma				
		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: 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%
#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				
		0/50 (0%) 2/50 (4%)	2/50 (4%) 4/50 (8%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	8/200 (4%)	Mean 4% SD 3.27%	Total 0/200 (0%) Mean 0% SD 0%
#Skin: Lipoma				
		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%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 391

			Male				Female	
#Skin: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	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	vannoma benign							
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or								
	•	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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Report Dat

Report Date: 05/18/2011

Page: 392

			Male				Female					
#Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)												
		1/50 (2%) 0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				
#Skin: 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%				
#Skin: Schwannoma Benign												
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%				
#Skin: Schwannoma Malignant												
		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%				
#Skin: Squamous Cell Carcinoma												
		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 393

			Male				Female						
#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma													
		1/50 (2%) 0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	2/200 (1%)	Mean 1%	SD 1.15%					
#Skin: Squamous Cell Papillo	ma												
		0/50 (0%) 1/50 (2%)	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 Papillo	ma or Papilloma												
	·	0/50 (0%) 1/50 (2%)	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:		quamous Cell Carcinoma	or Keratoacanthoma										
		1/50 (2%) 3/50 (6%)	2/50 (4%)	6/50 (12%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	12/200 (6%)	Mean 6%	SD 4.32%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%					
#Skin: Squamous Cell Papillo	ma, Papilloma, o	r Keratoacanthoma											
•		0/50 (0%) 3/50 (6%)	2/50 (4%)	5/50 (10%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	10/200 (5%)	Mean 5%	SD 4.16%	Total	0/200 (0%)	Mean 0%	SD 0%					

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 394

Report Date: 05/18/2011

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
≴Skin: Trichoepithelioma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Sebaceous Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 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 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								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 395

			Male				Female	
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%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Leiomyosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 396

Report Date: 05/18/2011

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Spleen: Sarcoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% #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%)Mean 0% **Overall Incidence** Total 0/200 (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 or Papilloma Squamous 0/50 (0%)(2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 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% #Stomach, Forestomach: Squamous Cell Papilloma 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%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 397

Report Date: 05/18/2011

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Stomach, Glandular: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% #Stomach, Glandular: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% #Stomach, Glandular: Lipoma 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 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, Glandular: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% *Testes: Adenoma 30/50 (60%)(74%)(68%)37/50 (74%)**Overall Incidence** Total 138/200 (69%) Mean 69% SD 6.63%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Report Date: 05/18/2011

Page: 398

			Male				Female	
*Testes: Hemangioma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				
*Thymus: Thymoma Benign								
		0/49 (0%) 0/47 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%) 1/50 (2%)	0/45 (0%)	1/50 (2%)
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	2/194 (1.03%)	Mean 1%	SD 1.15%
*Thymus: Thymoma Malignant		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/45 (0%)	0/50 (0%)
		0/49 (0%)	0/49 (070)	0/30 (0/0)		0/49 (0%)	0/43 (0 /8)	0/30 (0 /8)
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	0/194 (0%)	Mean 0%	SD 0%
Thymus: Thymoma NOS								
		0/49 (0%) 0/47 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/45 (0%)	0/50 (0%)
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	0/194 (0%)	Mean 0%	SD 0%
'Thymus: Thymoma: Benign, Malig	nant, NOS							
		0/49 (0%) 0/47 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%) 1/50 (2%)	0/45 (0%)	1/50 (2%)
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	2/194 (1.03%)	Mean 1%	SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 399

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Thyroid Gland: C-Cell: Adenoma 10/50 (20%)10/50 (20%)6/46 (13%)6/50 (12%)8/50 (16%) 7/50 (14%)9/50 (18%)7/50 (14%)Mean 14% Overall Incidence Total 35/196 (17.86%) Mean 17.76% SD 3.28% Total 28/200 (14%) SD 1.63% *Thyroid Gland: C-Cell: Carcinoma 1/50 (2%)2/50 (4%)0/46 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)Overall Incidence Total 3/196 (1.53%) Mean 1.5% SD 1.91% Total 1/200 (0.5%) Mean 0.5% SD 1% *Thyroid Gland: C-Cell: Carcinoma or Adenoma 11/50 (22%)12/50 (24%)6/46 (13%)6/50 (12%)8/50 (16%) 8/50 (16%) 9/50 (18%)7/50 (14%)**Overall Incidence** Total 38/196 (19.39%) Mean 19.26% SD 4.84% Total 29/200 (14.5%) Mean 14.5% SD 1.91% *Thyroid Gland: Follicular Cell: Adenoma 0/50 (0%)0/50 (0%)0/46 1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)Overall Incidence Total 0/196 (0%) Mean 0% SD 0% Total 3/200 (1.5%) Mean 1.5% SD 1% *Thyroid Gland: Follicular Cell: Carcinoma 0/50 (0%)1/50 (2%)2/46 (4%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 3/196 (1.53%) Mean 1.59% SD 2.07% Total 1/200 (0.5%) Mean 0.5%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#Tongue:

Overall Incidence

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 400

Report Date: 05/18/2011

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma 0/50 (0%)1/50 (2%)2/46 (4%)2/50 (4%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)Overall Incidence Total 3/196 (1.53%) Mean 1.59% SD 2.07% Total 4/200 (2%) Mean 2% SD 1.63% **#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%)Mean 0% Overall Incidence Total 0/200 (0%) SD 0% Total 0/200 (0%) Mean 0% SD 0% #Tongue: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% #Tongue: Squamous Cell Carcinoma or Papilloma Squamous (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0%

0/50

SD 0%

(0%)

0/50

0/50

0/200 (0%)

Total

(0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

0/50

0/50

0/200 (0%)

(0%)

(0%)

0/50

Mean 0%

(0%)

Squamous Cell Papilloma

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 401

			Male				Female	
≇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%)	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%
Urinary Bladder: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
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

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 402

			Male				Female	
*Urinary Bladder: Papilloma								
•		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%
#Uterus: Adenoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Deciduoma Benign								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 403

Report Date: 05/18/2011

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus: Polyp Stromal** 5/50 (10%)2/50 (4%)(20%)7/50 (14%)**Overall Incidence** Total 24/200 (12%) Mean 12% SD 6.73% #Uterus: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% #Uterus: Sarcoma Stromal 1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/200 (1%) Mean 1% SD 1.15% #Uterus: Sarcoma Stromal or Polyp Stromal 6/50 (12%)3/50 (6%)10/50 (20%)7/50 (14%)**Overall Incidence** Total 26/200 (13%) Mean 13% SD 5.77% #Uterus: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 404

			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%
#Vagina: Schwannoma Malignant						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/50 (0%) 0/200 (0%)	Mean 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%)	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%
Zymbal's Gland: Carcinoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 405

		Male				Female			
#Zymbal's Gland: Carcinoma or Adenoma		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%) 3/200 (1.5%)	Mean 1.5%	SD 1%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied