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

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Report Date: 05/18/2011

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

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Male **Female** #Bone: Chordoma 0/50 (0%)0/50 (0%)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: Osteoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Bone: Osteosarcoma 1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 1/100 (1%) Mean 1% SD 1.41% #Bone: Osteosarcoma or Osteoma 1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 1/100 (1%) Mean 1% SD 1.41% *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 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

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 (09/)	0/50 /09/			0/50 /09/\	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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 Ma	llignant							
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%)			ı Olai	0/100 (0%)		3D 0%
*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/	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%
*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%	
*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 (09/)	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%	
#Esophagus: Lipoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (/00/)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Eye: Melanoma 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%	
#Eye: Melanoma Malignant									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 105

			Male				Female	Female		
#Eye: 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%		
#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

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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

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

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 (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								
-		0/50 (0%)	0/50 (0%)			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								
Occupil by althouse	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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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

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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

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Inc

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 110

			Male				Female	
*Kidney: Renal Tubule: Adenoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
Overall Incidence	Total	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								
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: Mesenchymal Tumor Benig	jn	0/50 (0%)	0/50 (0%)			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: 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		lular Adenoma				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	0/100 (0%)			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

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: 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

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:** 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		-1						
		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%
*Parathyroid Gland: Adenoma		0/50 (00/)	2/42 (22/)			0/40 (00/)	0(40 (004)	
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/96 (0%)	0/48 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Distal 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 Distal Carcinoma	is or Unspec							
		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%

Overall	Incidence

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

.....

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				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()				0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma								
	-	0/50 (0%)	0/50 (0%)	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%
#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	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma	•••••							
		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 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

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			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

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: WATER

Length of Study: CHRONIC

ol Animal Groups Report Date: 05/18/2011

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			Male				Female				
#Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma											
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				Female	
#Skin: Keratoacanthoma								
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%
#Skin: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Liposarcoma	••••••							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#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	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	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	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	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

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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

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

Length of Study: CHRONIC

Vehicle: WATER

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			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 Papillo	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	ma 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:		Equamous 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	ma, Papilloma, o	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%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 128

			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								
• " "	T	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%
#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	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%
#Spinal Cord: Astrocytoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Spinal Cord: Glioma Malignant								
		0/50 (0%)	0/50 (0%)	OD		1/50 (2%)	0/50 (0%)	00 4 4404
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	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			(05)						
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

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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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 Carcinoma or Papilloma 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

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			Male				Female	
*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	1/96 (1.04%)	Mean 1.04%	SD 1.47%
*Thymus: Thymoma Malignant Overall Incidence	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	1/48 (2%) 1/96 (1.04%)	0/48 (0%) Mean 1.04%	SD 1.47%
Overall incluence	10tai	0/96 (0%)	Weall 0%	SD 0%		1/96 (1.04%)	IVIEAII 1.04%	
*Thymus: Thymoma NOS								
Overall Incidence	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/96 (0%)	0/48 (0%) Mean 0%	SD 0%
*Thymus: Thymoma: Benign, 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	
#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 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%
#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%)			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

Version: May2011 Contract/Lab: All Laboratories

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

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: WATER

Length of Study: CHRONIC

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	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%
#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%) 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

Strain: F 344/N

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 137

			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