Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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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

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Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			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

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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

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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

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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			(20)			(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											
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 an an	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

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Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			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

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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** #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

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Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Large: Colon/Rectum: 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 Large: Colon/Rectum: 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 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%)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 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: 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

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Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			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

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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

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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

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Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		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				
*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 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	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%			
*Liver:		lar Adenoma, or Hepatob 3/50 (6%) 3/100 (3%)		SD 4.24%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%			
*Liver: Ito Cell 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%			
*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

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			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

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Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

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%)	
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%)	00.00/	-	0/50 (0%)	2/50 (4%)	00.000/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Mammary Gland: Carcinoma								
		0/50 (0%)	1/50 (2%)			2/50 (4%)	0/50 (0%)	
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%	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%
#Mammary Gland: Fibroadenoma								
		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								
		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

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		Male				Female					
#Mammary Gland: Fibroma, Fibroadenoma or 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

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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
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			Male		Female 0/50 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) SD 0% 0/50 (0%) 0/49 (0%) 0/99 (0%) 0/49 (0%) 0/49 (0%) SD 0% 0/50 (0%) 0/49 (0%) 0/99 (0%) 0/49 (0%) 0/49 (0%) SD 0% 0/50 (0%) 0/49 (0%) 0/99 (0%) 0/49 (0%) 0/49 (0%) SD 0% 0/50 (0%) 0/99 (0%) Mean 0% SD 0% SD 0%			
#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	, ,		
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	` '	` '	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%)	` ,	
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

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			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

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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

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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

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Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

	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%			
*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**

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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

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: WATER

Contract/Lab: All Laboratories

Strain: F 344/N Length of Study: CHRONIC

	Ma					Female				
#Skin:	_									
Basal Cell Adenoma, B	Basosquamous T	umor Benign, or Trichoer 1/50 (2%)				1/50 (2%)	0/50 (00/)			
Overall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	1/50 (2%)	0/50 (0%) Mean 1%	SD 1.41%		
		3/100 (3/0)								
#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	is Tumor (malignant or No	•							
		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%		
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tun	nor (benign, maligna	nt or						
,,		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%		
		a, Basosq. Tumor (M or B ratoacanthoma, Trichoep	ithelioma	na,						
		6/50 (12%)	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

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			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

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

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

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			Male		0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0% SD 0% 0/50 (0%) 1/50 (2%) 1 1/100 (1%) Mean 1% SD 1.41%			Female		
#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma										
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Skin: Squamous Cell Papillom										
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	` ,	` ,	SD 0%		
#Skin: Squamous Cell Papillom	na or Papilloma									
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	` '	` ,	SD 0%		
Overall Incidence	Total	Squamous Cell Carcinoma 5/50 (10%) 9/100 (9%)	4/50 (8%) Mean 9%	SD 1.41%	Total	1/100 (1%)	Mean 1%			
#Skin: Squamous Cell Papillom			3/50 (6%)							
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 2.83%	Total	` '	` ,	SD 1.41%		
#Skin: Trichoepithelioma			(0.5.2)			(00)	(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%		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

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Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Contract/Lab: All Laboratories

Strain: F 344/N Length of Study: CHRONIC

			Male				Female	
#Skin: Sebaceous Gland: 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%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (00/)	0/50 (00()			0/50 (00/)	4/50 (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%
#Spinal Cord: Astrocytoma Benign								
		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%
#Spinal Cord: Astrocytoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Spinal Cord: Glioma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (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%
Overall illelidelide	1 Ulai	0/100 (0/0)	IVICALI U/0	3D 0/0	ı Ulai	0/100 (0/0)	IVICALI U/0	٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠

^{*:} 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

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Report Date: 05/18/2011

Route: ORAL

Contract/Lab: All Laboratories

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

			Male		0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0%			Female				
*Spleen: Fibrous Histiocytoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%					
*Spleen: Hemangiosarcoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` ,	SD 0%				
*Spleen: Leiomyosarcoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%					
*Spleen: Sarcoma		0/50 (0%)	0/50 (0%)									
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%					
#Stomach, Forestomach: Leiomyosarcoma								•••••				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` '	SD 0%				
#Stomach, Forestomach: Squamous Cell Carcinoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (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

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Report Date: 05/18/2011

Route: ORAL

Length of Study: CHRONIC

Vehicle: WATER

			Male				Female			
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma 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

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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

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			Male				Female	
*Thyroid Gland: C-Cell: Adenoma								
		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%)			1/50 (2%)	2/50 (4%)	
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	11/50 (22%) 21/100 (21%)	10/50 (20%) Mean 21%	SD 1.41%
		` '						
*Thyroid Gland: Follicular Cell: Adenoma	:							
		0/50 (0%)	0/50 (0%)	OD		0/50 (0%)	0/50 (0%)	00.007
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	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%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: 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%

^{*:} 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				Female				
#Tissue NOS: Paraganglioma											
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											
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	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	1/100 (1%)	Mean 1%	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	1/100 (1%)	Mean 1%	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	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	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

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			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

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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	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

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			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								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (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

Overall Incidence

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

SD 1.41%

Strain: F 344/N Length of Study: CHRONIC

Contract/Lab: All Laboratories

| Male | Female | Female | | Female | | Female | | Female | Female

Total

1/100 (1%)

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Mean 1%

Report Date: 05/18/2011

SD 1.41%

Total

1/100 (1%)

Mean 1%

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

^{#:} Denominator is number of animals necropsied