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: METHYLCELLULOSE

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# **Study Summary**

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

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: METHYLCELLULOSE

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			Male				Female	
#All Organs: Benign Tumors								
		47/50 (94%)	44/50 (88%)			44/50 (88%)	46/50 (92%)	
Overall Incidence	Total	91/100 (91%)	Mean 91%	SD 4.24%	Total	90/100 (90%)	Mean 90%	SD 2.83%
#All Organs: Malignant Tumors								
		34/50 (68%)	31/50 (62%)			10/50 (20%)	20/50 (40%)	
Overall Incidence	Total	65/100 (65%)	Mean 65%	SD 4.24%	Total	30/100 (30%)	Mean 30%	SD 14.14%
#All Organs: Malignant and Benign T								
		49/50 (98%)	48/50 (96%)			46/50 (92%)	49/50 (98%)	
Overall Incidence	Total	97/100 (97%)	Mean 97%	SD 1.41%	Total	95/100 (95%)	Mean 95%	SD 4.24%
#All Organs: Hemangioma	•••••				•••••			
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
All Organs: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma or Ho	emangioma							
-	-	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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: METHYLCELLULOSE

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			Male				Female	
#All Organs: Histiocytic Sarcoma								
		1/50 (2%)	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%
#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, N Overall Incidence	lonocytic, Me	ononuclear, or Undifferer 26/50 (52%) 48/100 (48%)	ntiated 22/50 (44%) Mean 48%	SD 5.66%	Total	5/50 (10%) 15/100 (15%)	10/50 (20%) Mean 15%	SD 7.07%
#All Organs: Malignant Lymphoma: His	tiocytic, Lym	nphocytic, Mixed, NOS, or 0/50 (0%)	Undifferentiated Cel	I Туре		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%
#All Organs: Mesothelioma: Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign, Ma	lignant, NOS							
		1/50 (2%) 3/100 (3%)	2/50 (4%)			0/50 (0%) 0/100 (0%)	0/50 (0%)	
Overall Incidence	Total		Mean 3%	SD 1.41%	Total		Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female			
#All Organs: Mesothelioma: Malignant										
		1/50 (2%)	2/50 (4%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		
#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										
O	T-1-1	1/50 (2%)	1/50 (2%)	OD 00/	T-1-1	0/50 (0%)	1/50 (2%)	00 4 440/		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
#All Organs: Osteosarcoma or Osteoma										
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%		
*Adrenal Cortex: Adenoma										
		3/50 (6%)	1/50 (2%)			0/50 (0%)	1/47 (2%)			
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	1/97 (1.03%)	Mean 1.06%	SD 1.5%		
*Adrenal Cortex: Carcinoma										
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/47 (0%)	OD 00/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: METHYLCELLULOSE

**Page:** 58

			Male				Female	
*Adrenal Medulla: Ganglioneuroma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Hemangioma								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%
	10tai	0/100 (0%)	wiean 0%	งบ 0% 	10lai	0/96 (0%)	wiean 0%	3D 0%
*Adrenal Medulla: Pheochromocytoma Benign		7/50 (4.40/)	C/EO (420/)			3/50 (6%)	2/48 (4%)	
Overall Incidence	Total	7/50 (14%) 13/100 (13%)	6/50 (12%) Mean 13%	SD 1.41%	Total	3/50 (6%) 5/98 (5.1%)	Mean 5.08%	SD 1.3%
*Adrenal Medulla: Pheochromocytoma Comple		1/50 (2%)	0/50 (0%)			1/50 (2%)	1/48 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/98 (2.04%)	Mean 2.04%	SD 0.06%
*Adrenal Medulla: Pheochromocytoma Maligna								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma: Benigr			6/50 (12%)			4/50 (8%)	3/48 (6%)	
Overall Incidence	Total	14/100 (14%)	Mean 14%	SD 2.83%	Total	7/98 (7.14%)	Mean 7.13%	SD 1.24%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 59

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

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

**Page:** 60

			Male				Female	
*Brain: Astrocytoma Malignant								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Ependymoma Benign								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Ependymoma Malignant		0/50 (0%)	0/50 (0%)			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: Glioma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Brain: Granular Cell Tumor Benig		•••••						
		0/50 (0%)	0/50 (0%)			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: Medulloblastoma Mal			(20)			2/-2 (221)		
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 09/	Total	0/50 (0%)	0/50 (0%)	CD 09/
Overali incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: METHYLCELLULOSE

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			Male				Female	
*Brain: Oligodendroglioma Beni	gn	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Maliç								
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, Glio		rtoma						
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Brain: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: 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%
*Clitoral/Preputial Gland: Adenoma								
Overall Incidence	Total	3/50 (6%) 5/99 (5.05%)	2/49 (4%) Mean 5.04%	SD 1.36%	Total	12/50 (24%) 24/100 (24%)	12/50 (24%) Mean 24%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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Female

			Male				Female	nale		
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%)	1/49 (2%)			1/50 (2%)	2/50 (4%)			
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	3/100 (3%)	Mean 3%	SD 1.41%		
*Clitoral/Preputial Gland: Carcinoma or Adenoma		3/50 (6%)	3/49 (6%)			13/50 (26%)	14/50 (28%)			
Overall Incidence	Total	6/99 (6.06%)	Mean 6.06%	SD 0.09%	Total	27/100 (27%)	Mean 27%	SD 1.41%		
*Clitoral/Preputial Gland: Fibrosarcoma										
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Clitoral/Preputial Gland: Sarcoma		0/50 (0%)	0/49 (0%)			1/50 (2%)	0/50 (0%)			
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
#Ear: Neural Crest Tumor										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Esophagus: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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

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Report Date: 03/20/2010

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Esophagus: Lipoma		0/50 (0%)	0/50 (00/)			0/50 /00/\	0/50 (09/)	
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Eye: Melanoma 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%
#Eye: 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%
#Harderian Gland: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma								
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 Benign		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Heart: Schwannoma Malignant		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%
#Intestine Large: Colon/Rec Adenoma	tum:							
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%
#Intestine Large: Colon/Rec Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Large: Colon/Rec 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/Rec	tum:					•••••		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenum 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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Vehicle: METHYLCELLULOSE

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

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Mean 0%

SD 0%

Report Date: 03/20/2010

			Male				Female	
#Intestine Small: Duodenum: Leiomyoma		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%
#Intestine Small: Ileum: Adenoma		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%
#Intestine Small: Jejunum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Jejunum: Granular Cell Tumor Malign	ant	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma						0/50 (09/)	0/50 (09/)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	

SD 0%

Total

0/100 (0%)

Total

0/100 (0%)

Mean 0%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: F 344/N

**Toxicology Data Management System** 

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Report Date: 03/20/2010

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

			Male				Female	
#Intestine Small: Site Uns	pecified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns	pecified:	- (a)	(201)			(00)	(00)	
Overall Institutes	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%
#Intestine Small: Site Uns Carcinoma or Adenoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incidence	Total	0/100 (0%)	ivieari 0%	SD 0%	Total	0/100 (0%)	iviean 0%	SD 0%
#Intestine Small: Site Uns Granular Cell Tumor Ma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns	pecified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns	pecified:							
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: METHYLCELLULOSE

Report Date: 03/20/2010

**Page:** 67

			Male				Female	
*Islets, Pancreatic: Adenoma		4/50 (8%)	1/50 (2%)			1/50 (2%)	1/49 (2%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 4.24%	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%
*Islets, Pancreatic: Carcinoma		0/50 (0%)	2/50 (4%)			4/50 /20/\	0/49 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/50 (2%) 1/99 (1.01%)	Mean 1%	SD 1.41%
*Islets, Pancreatic: Carcinoma or Adenoma								
Overall Incidence	Total	4/50 (8%) 7/100 (7%)	3/50 (6%) Mean 7%	SD 1.41%	Total	2/50 (4%) 3/99 (3.03%)	1/49 (2%) Mean 3.02%	SD 1.39%
*Kidney: Pelvis and Transition Carcinoma		m:	0/40 (00/)			0/50 (00/)	0/44 (00%)	
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/94 (0%)	0/44 (0%) Mean 0%	SD 0%
*Kidney: Pelvis and Transition Carcinoma or Adenoma								
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/94 (0%)	0/44 (0%) Mean 0%	SD 0%
*Kidney: Pelvis and Transition		m:						
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/94 (0%)	0/44 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: METHYLCELLULOSE

Page: 68

			Male				Female	
*Kidney: Renal Tubule: Adenoma				SD 0% Total 0/94 (0%)  SD 0% Total 0/94 (0%)  D/50 (0%)  O/50 (0%)  O/50 (0%)  O/94 (0%)  D/50 (0%)  O/50 (0%)  O/50 (0%)  O/50 (0%)  SD 0% Total 0/94 (0%)  O/50 (0%)				
Overall Incidence	Total	0/49 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	` ,	0/44 (0%) Mean 0%	SD 0%
Overall incidence	10lal	0/97 (0%)	wiean 0%	3D 0%	ıoıaı	0/94 (0%)		טיי עכ
*Kidney: Renal Tubule: Carcinoma								
		0/49 (0%)	0/48 (0%)	<b>OD</b> 00/		` ,	0/44 (0%)	00.007
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/94 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/40 (00/)	0/40 (00/)			0/50 (0%)	0/44 (00/)	
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	` ,	0/44 (0%) Mean 0%	SD 0%
		` '			ı Olal	0/94 (0%)		
*Kidney: Renal Tubule: Hemangiosarcoma								
0	T-1-1	0/49 (0%)	0/48 (0%)	00.00/	T-1-1	` ,	0/44 (0%)	OD 00/
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	ı отаі	0/94 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma								
·		0/49 (0%)	0/48 (0%)			` '	0/44 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/94 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Beniç	gn							
		0/49 (0%)	0/48 (0%)	<b>OD</b> 00/		0/50 (0%)	0/44 (0%)	00.007
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/94 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page**: 69

			Male				Female			
*Kidney: Renal Tubule: Mesenchymal Tumor Malignant										
		0/49 (0%)	0/48 (0%)			0/50 (0%)	1/44 (2%)			
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	1/94 (1.06%)	Mean 1.14%	SD 1.61%		
*Kidney: Renal Tubule: Nephroblastoma										
		0/49 (0%)	0/48 (0%)			0/50 (0%)	0/44 (0%)			
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/94 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Sarcoma										
	<b>.</b>	0/49 (0%)	0/48 (0%)	00.00/	<b>T</b>	0/50 (0%)	0/44 (0%)	00.00/		
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/94 (0%)	Mean 0%	SD 0%		
*Liver: Cholangioma										
		0/50 (0%)	0/50 (0%)	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%		
*Liver: 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%		
*Liver: Hepatocellular Adenoma										
		2/50 (4%)	0/50 (0%)	05 0 000/		0/50 (0%)	0/50 (0%)	05.00/		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: METHYLCELLULOSE

**Page:** 70

		Male Female						
*Liver: Hepatocellular Carcinom	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%
*Liver: Hepatocellular Carcinom	a or Hepatobla	stoma						
•	-	0/50 (0%)	0/50 (0%)			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 Carcinom		lular Adenoma					0/50 (00/)	
	<b>-</b>	2/50 (4%)	0/50 (0%)	OD 0.000/	<b>-</b>	0/50 (0%)	0/50 (0%)	<b>OD</b> .00/
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinom	a, Hepatocellu	lar Adenoma, or Hepatob 2/50 (4%)	astoma 0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Benign	•••••							
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Ade	enoma							
		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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

**Page:** 71

			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 Ca	rcinoma or Alve	eolar/Bronchiolar Adenon	na							
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Lung: Fibrosarcoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Lung: Hemangiosarcoma										
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Lung: Squamous Cell Carcino	ma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Lymph Node: Hemangiosarcoma										
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

**Page:** 72

Report Date: 03/20/2010

Species: RATS Strain: F 344/N

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Mammary Gland: Adenolipoma								
		0/50 (0%)	0/50 (0%)	05.00/		0/50 (0%)	0/50 (0%)	<b>05</b> 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%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	<b>OD</b>		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 or Adenoma		0/50 (00/)	0/50 (0%)			2/52 (0%)	2/50 (69/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	3/50 (6%) 6/100 (6%)	3/50 (6%) Mean 6%	SD 0%
#Mammary Gland: Fibroadenoma								
		2/50 (4%)	3/50 (6%)			35/50 (70%)	26/50 (52%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	61/100 (61%)	Mean 61%	SD 12.73%
#Mammary Gland: Fibroma								
		1/50 (2%)	0/50 (0%)			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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 73

		Male Female					36/50 (72%) 28/50 (56%) Total 64/100 (64%) Mean 64% SD 11.31  37/50 (74%) 30/50 (60%) Total 67/100 (67%) Mean 67% SD 9.9%  0/50 (0%) 0/50 (0%)				
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma											
		3/50 (6%)	3/50 (6%)				` ,				
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 0%	Total	64/100 (64%)	Mean 64%	SD 11.31%			
#Mammary Gland: Fibroma, Fibroadenoma	, Carcinoma, or	· Adenoma									
		3/50 (6%)	3/50 (6%)			` '	30/50 (60%)				
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 0%	Total	67/100 (67%)	Mean 67%	SD 9.9%			
#Mesentery: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		` '	` ,	SD 0%			
#Mesentery: Hemangiosarcoma						0/50 (00/)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	, ,	` '	SD 0%			
#Mesentery: Lipoma								•••••			
-		0/50 (0%)	0/50 (0%)			` '	` ,				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Mesentery: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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

Report Date: 03/20/2010

Page: 74

Length of Study: CHRONIC

			Male				Female	
*Nose: 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%
*Nose: Chondroma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Nose: Squamous Cell Carcino	oma	(00)	(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%
#Oral Cavity (Oral Mucosa Papilloma Squamous o	a, Tongue, Phary	ynx, Tooth, Gingiva):						
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phary	ynx, Tooth, Gingiva):						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa Squamous Cell Carcino	a, Tongue, Phary	ynx, Tooth, Gingiva): Squamous, or Papilloma 1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 75

Report Date: 03/20/2010

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Oral Mucosa: 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 Mucosa:** 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% \*Ovary: Cystadenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% ..... \*Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% \*Ovary: **Granulosa Cell Tumor Malignant** 0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41%

0/50

1/100 (1%)

Total

(0%)

1/50

(2%)

SD 1.41%

Mean 1%

Granulosa Cell Tumor: Benign, Malignant, NOS

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 76

			Male				Female	
*Ovary: Granulosa-Theca Tumor B	Benign					0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor N	lalignant							
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma						4/50 (00/)	0/50 (00/)	
Overall Incidence					Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Pancreas: Adenoma								
Overall Incidence	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma		•••••			•••••	•••••		•••••
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/40 (00)	
Overall Incidence	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: METHYLCELLULOSE

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			Male Female					
*Pancreas: Mixed Tumor Benign								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
*Pancreas: Mixed Tumor Malignant	t							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
		0/48 (0%)	0/48 (0%)			0/49 (0%)	0/47 (0%)	
Overall Incidence	Total	0/96 (0%)	Mean 0%	SD 0%	Total	0/96 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Adenoma								
		19/50 (38%)	24/50 (48%)			19/50 (38%)	25/50 (50%)	
Overall Incidence	Total	43/100 (43%)	Mean 43%	SD 7.07%	Total	44/100 (44%)	Mean 44%	SD 8.49%
*Pituitary Gland: Pars Dis								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Pituitary Gland: Pars Dis Carcinoma or Adenoma	talis or Unspec					•••••		
		19/50 (38%)	24/50 (48%)			19/50 (38%)	26/50 (52%)	
Overall Incidence	Total	43/100 (43%)	Mean 43%	SD 7.07%	Total	45/100 (45%)	Mean 45%	SD 9.9%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 78

Report Date: 03/20/2010

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female				
*Pituitary Gland: Pars Distalis or Unspecified Site: Ganglioneuroma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
*Pituitary Gland: Pars Inte Adenoma	rmedia:										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
*Pituitary Gland: Pars Inte Carcinoma or Adenoma		0/50 (09/)	0/50 (00/)			0/50 (00()	4/E0 (20/)				
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%			
*Pituitary Gland: Pars Ner Craniopharyngioma	vosa: 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%			
*Prostate: Adenoma		0/50 (0%)	2/50 (4%)								
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%							
*Prostate: Carcinoma or Adenoma		0/50 (0%)	2/50 (4%)								
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%							

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: F 344/N

**Toxicology Data Management System** 

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Report Date: 03/20/2010

Contract/Lab: All Laboratories

Species: RATS

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC Male **Female** \*Salivary Glands: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% \*Salivary Glands: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% \*Salivary Glands: Sarcoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% ...... \*Salivary Glands: **Schwannoma Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% **#Seminal Vesicle:** Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% **#Skeletal Muscle: Fibrous Histiocytoma** 

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** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male			0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% S  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% S  0/50 (0%) 1/50 (2%)  Total 1/100 (1%) Mean 1% SD  0/50 (0%) 1/50 (2%)  Total 1/100 (1%) Mean 1% SD					
#Skeletal Muscle: Hemangiosarcoma  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)											
Overell In aldeman	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	( ,	` ,	CD 00/			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	ı otal	0/100 (0%)		SD 0%			
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (09/)	0/50 (09/)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` '	` ,	SD 0%			
#Skeletal Muscle: Rhabdomyosarcoma or I	Rhabdomyoma										
		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		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	` ,	` ,	SD 1.41%			
#Skin: Basal Cell Adenoma or E	Basosquamous	Tumor Benign									
		0/50 (0%)	1/50 (2%)			` '	` '				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
#Skin: Basal Cell Adenoma, Bas	sosquamous T	umor Benign, or Trichoep	oithelioma								
	-	0/50 (0%)	3/50 (6%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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Report Date: 03/20/2010

Contract/Lab: All Laboratories

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

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male			Female		
#Skin: Basal Cell Carcinoma								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Basal Cell Carcinoma (	or Basosquamou	us Tumor (malignant or N	OS)					
	•	1/50 (2%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Basal Cell Carcinoma, NOS), or Trichoepithel		oma, Basosquamous Tun 1/50 (2%)	nor (benign, malignal	nt or		0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 4.24%	Total	2/100 (2%)	Mean 2%	SD 2.83%
Adenoma, Papilloma, S	Sq Papilloma, Ke	na, Basosq. Tumor (M or E eratoacanthoma, Trichoep 5/50 (10%)	ithelioma 9/50 (18%)	·		0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	14/100 (14%)	Mean 14%	SD 5.66%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Skin: Fibroma								
		5/50 (10%)	11/50 (22%)			3/50 (6%)	2/50 (4%)	
Overall Incidence	Total	16/100 (16%)	Mean 16%	SD 8.49%	Total	5/100 (5%)	Mean 5%	SD 1.41%
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myx	oma, Myxosarcoma, or Fi	•					
		6/50 (12%)	16/50 (32%)			3/50 (6%)	2/50 (4%)	
Overall Incidence	Total	22/100 (22%)	Mean 22%	SD 14.14%	Total	5/100 (5%)	Mean 5%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: METHYLCELLULOSE

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			Male Female				0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 09  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 09  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 09  Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 09		
#Skin: Fibrosarcoma									
		1/50 (2%)	3/50 (6%)			` '	` '		
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%		, ,		SD 0%	
#Skin: Fibrosarcoma, Sarcoma, l									
.,	,	1/50 (2%)	6/50 (12%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	7/100 (7%)	Mean 7%	SD 7.07%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Skin: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` ,	` '	SD 0%	
#Skin: Hemangioma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%	
#Skin: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)			` '	` '		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Skin: Keratoacanthoma									
	<b>.</b>	3/50 (6%)	5/50 (10%)	00.000/	<b></b>	0/50 (0%)	0/50 (0%)	05.00/	
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

## **Toxicology Data Management System**

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Report Date: 03/20/2010

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			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%)			
#Skin: Lipoma								
Overell In aldenaa	Tatal	1/50 (2%)	0/50 (0%)	CD 4 440/	Tatal	` ,	` '	CD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	` ,		
#Skin: Liposarcoma								
		0/50 (0%)	0/50 (0%)			` '	` '	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	, ,		
#Skin: Neural Crest Tumor								
		0/50 (0%)	0/50 (0%)			` ,	` '	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` '		
#Skin: Neural Crest Tumor, Mal								
		0/50 (0%)	0/50 (0%)			` '	` '	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` '		
Skin: Neurofibroma or Schwar		•••••						
	_	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	()		
#Skin: Neurofibrosarcoma or So			0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
						` '		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Report Date: 03/20/2010

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Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

	Male						Female	
#Skin: Neurofibrosarcoma, Ne	urofibroma, or S	Schwannoma (benign, ma	lignant 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: Sarcoma								
		0/50 (0%)	3/50 (6%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Benign								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignan	t	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%
#Skin: Squamous Cell Carcino	ma							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcino or Carcinoma	ma, Basal Cell (	Carcinoma, Basosquamoı						
		1/50 (2%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: METHYLCELLULOSE

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			Male Female				0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0%					
#Skin: Squamous Cell Papilloma  1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)												
		1/50 (2%)	` ,			` '	( )					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papilloma	a or Papilloma											
	-	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papilloma	a, Papilloma, S	quamous Cell Carcinoma 4/50 (8%)	or Keratoacanthom 5/50 (10%)	a		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 1.41%		0/100 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papilloma			5/50 (10%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Trichoepithelioma		•••••										
		0/50 (0%)	2/50 (4%)			` ,	( )					
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Sebaceous Gland: Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: METHYLCELLULOSE

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			Male			0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE  0/50 (0%) 0/48 (0%) Total 0/98 (0%) Mean 0% SE		
#Skin: Sebaceous Gland: Carcinoma or Adenoma					0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE			
		0/50 (0%)	0/50 (0%)			` ,	( )	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Benign								
		0/50 (0%)	0/50 (0%)			( ,	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Malignant		0/50 (09/)	0/50 (00/)			0/50 (09/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	( )	SD 0%
#Spinal Cord: 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%		0/100 (0%)	Mean 0%	SD 0%
*Spleen: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			` ,	( )	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Spleen: Fibrous Histiocytoma						2/22	(20)	
Owner Haller and James	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/48 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male			0/50 (0%) 0/48 (0%) Total 0/98 (0%) Mean 0% SI  0/50 (0%) 0/48 (0%)  Total 0/98 (0%) Mean 0% SI  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SI			Female			
*Spleen: Hemangiosarcoma												
Occupation of the second	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	,	(/	<b>OD</b> 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	I otal	0/98 (0%)	Mean 0%	SD 0%				
*Spleen: Leiomyosarcoma												
		0/50 (0%)	0/50 (0%)			` '	( )					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%				
*Spleen: Sarcoma												
		0/50 (0%)	0/50 (0%)			` '	( )					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%				
#Stomach, Forestomach: Leiomyosarcoma		0/50 (00/)	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	, ,	` '	SD 0%				
#Stomach, Forestomach: Squamous Cell Carcinoma												
		0/50 (0%)	0/50 (0%)			,	( )					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Stomach, Forestomach: Squamous Cell Carcinoma		a Squamous										
		0/50 (0%)	0/50 (0%)			,	` ,					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male		0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%				
#Stomach, Forestomach: Squamous Cell Papilloma				0/50 (0%)         0/50 (0%)           Mean 0%         SD 0%         Total         0/100 (0%)           0/50 (0%)         0/50 (0%)         0/100 (0%)           Mean 0%         SD 0%         Total         0/100 (0%)           0/50 (0%)         0/50 (0%)         0/50 (0%)           Mean 0%         SD 0%         Total         0/100 (0%)           0/50 (0%)         Total         0/100 (0%)           0/50 (0%)         0/50 (0%)         0/50 (0%)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	` ,	SD 0%	Total	` ,	` ,	SD 0%	
#Stomach, Glandular: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	, ,	SD 0%	Total	` '	` ,	SD 0%	
#Stomach, Glandular: Carcinoma or Adenoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	` '	SD 0%	Total	` ,	` ,	SD 0%	
#Stomach, Glandular: Lipoma		2(22)	(201)			(20)	0.70		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	` '	SD 0%	Total	, ,	` '	SD 0%	
#Stomach, Glandular: Sarcoma				•••••					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	` ,	SD 0%	Total	` '	( )	SD 0%	
*Testes: Adenoma		40/50 (0.4%)	05/50 (70%)						
Overall Incidence	Total	42/50 (84%) 77/100 (77%)	35/50 (70%) Mean 77%	SD 9.9%					

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

## **Toxicology Data Management System**

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Testes: Hemangioma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Benign								
		0/50 (0%)	0/44 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
	<b>-</b>	0/50 (0%)	0/44 (0%)	<b>OD</b> 00/	<b>-</b>	0/50 (0%)	0/48 (0%)	OD 00/
Overall Incidence	Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma NOS		0/50 (00/)	0/44 (00/)			0/50 (09/)	0/49 (00/)	
Overall Incidence	Total	0/50 (0%) 0/94 (0%)	0/44 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligr								
		0/50 (0%)	0/44 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma								
	<b>T</b>	3/50 (6%)	6/46 (13%)	00 4000/	<b>-</b>	4/50 (8%)	4/42 (10%)	00 4 000/
Overall Incidence	Total	9/96 (9.38%)	Mean 9.52%	SD 4.98%	Total	8/92 (8.7%)	Mean 8.76%	SD 1.08%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: METHYLCELLULOSE

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			Male	Male Female				
*Thyroid Gland: C-Cell: Carcinoma								
		1/50 (2%)	0/46 (0%)			0/50 (0%)	3/42 (7%)	
Overall Incidence	Total	1/96 (1.04%)	Mean 1%	SD 1.41%	Total	3/92 (3.26%)	Mean 3.57%	SD 5.05%
'Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		4/50 (8%)	6/46 (13%)			4/50 (8%)	7/42 (17%)	
Overall Incidence	Total	10/96 (10.42%)	Mean 10.52%	SD 3.57%	Total	11/92 (11.96%)	Mean 12.33%	SD 6.13%
Thyroid Gland: Follicular Cell Adenoma								
		3/50 (6%)	0/46 (0%)			0/50 (0%)	0/42 (0%)	
Overall Incidence	Total	3/96 (3.12%)	Mean 3%	SD 4.24%	Total	0/92 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell Carcinoma								
		0/50 (0%)	0/46 (0%)			0/50 (0%)	0/42 (0%)	
Overall Incidence	Total	0/96 (0%)	Mean 0%	SD 0%	Total	0/92 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:							
		3/50 (6%)	0/46 (0%)			0/50 (0%)	0/42 (0%)	
Overall Incidence	Total	3/96 (3.12%)	Mean 3%	SD 4.24%	Total	0/92 (0%)	Mean 0%	SD 0%
#Tissue NOS: Lipoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male			0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0  0/50 (0%) 0/50 (0%)				
#Tissue NOS: Paraganglioma										
		0/50 (0%)	0/50 (0%)			( ,	()			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Tongue: Squamous Cell Carcinoma										
		0/50 (0%)	0/50 (0%)			( ,	` '			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Tongue: Squamous Cell Carcinoma	or Papillom	•	0/50 (00/)			0/50 (00)	0/50 (00)			
Overall Incidence	Tatal	1/50 (2%)	0/50 (0%) Mean 1%	SD 1.41%	Tatal	` ,	` ,	CD 00/		
	Total	1/100 (1%)				, ,				
#Tongue: Squamous Cell Papilloma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	, ,	` '	SD 0%		
#Tooth: Adamantinoma Malignant										
		0/50 (0%)	0/50 (0%)			` ,	` ,			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Tooth: Odontoma										
	<b>.</b>	0/50 (0%)	0/50 (0%)	00.00/	<b>-</b>	( ,	` ,	00.00/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

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Report Date: 03/20/2010

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

				Female				
Urinary Bladder: Carcinoma or Papilloma		0/50 (09/)	0/50 (00/)			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%
Urinary Bladder: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Urinary Bladder: 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%
Urinary Bladder: Papilloma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Uterus: Adenoma						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/30 (0%)	Mean 0%	SD 0%
Uterus: Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

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	Male			Female	
#Uterus: Deciduoma Benign			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Hemangioma				0.50	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Hemangiosarcoma			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma				0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal					
Overall Incidence		Total	9/50 (18%) 26/100 (26%)	17/50 (34%) Mean 26%	SD 11.31%
#Uterus: Sarcoma			0/50 (00)	0/50 /00/	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

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Report Date: 03/20/2010

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Uterus: Sarcoma Stromal								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus:								
Sarcoma Stromal or Polyp	p Stromai					9/50 (18%)	17/50 (34%)	
Overall Incidence					Total	26/100 (26%)	Mean 26%	SD 11.31%
#Uterus: Schwannoma Malignant								
						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
#Vagina: Polyp								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Sarcoma		•••••						
						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
#Zymbal's 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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: METHYLCELLULOSE

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

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied