**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

**Page:** 54

Report Date: 05/18/2011

Species: RATS Strain: F 344/N

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

# **Study Summary**

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

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: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			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%)	
verall Incidence	Total	65/100 (65%)	Mean 65%	SD 4.24%	Total	30/100 (30%)	Mean 30%	SD 14.14%
All Organs: Malignant and Benign Tun								
		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%)	
verall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
All Organs: Hemangiosarcoma or Hen	nangioma	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%
Trei all Illiciaence	IUIAI	1/100 (1/0)	IVICALL 1/0	JD 1.41/0	i Ulai	0/100 (0/8)	IVICALI U/0	30 0/0

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

<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

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Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

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

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

<sup>#:</sup> 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: GAVAGE

Vehicle: METHYLCELLULOSE

Strain: F 344/N Length of Study: CHRONIC

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

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

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

Species: RATS

Contract/Lab: All Laboratories

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Strain: F 344/N

			Male				Female	
#Bone: Chordoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Osteoma		0/50 (0%)	0/50 (00/)			0/50 (0%)	0/50 (/00/)	
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%
#Bone: Osteosarcoma								
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Bone: Osteosarcoma or Osteoma		1/50 (2%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Brain: Astrocytoma Malignant								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Ependymoma Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

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

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

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Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female			
*Brain: Ependymoma Malignant										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Brain: Glioma		(20)	(201)			2/52 (221)	0.770 (001)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Brain: Glioma Benign			•••••			•••••				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Brain: Glioma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
*Brain: Granular Cell Tumor Benig										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Brain: Oligodendroglioma Benign	1	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		

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

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

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 61

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Strain: F 344/N Length of Study: CHRONIC

			Male				Female	
Brain: Oligodendroglioma 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%
Brain: Oligodendroglioma, Gliom								
	_	1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
verall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Brain: Osteosarcoma								
		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%
Brain: Schwannoma Malignant								
verall 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								
		3/50 (6%)	2/49 (4%)			12/50 (24%)	12/50 (24%)	
verall Incidence	Total	5/99 (5.05%)	Mean 5.04%	SD 1.36%	Total	24/100 (24%)	Mean 24%	SD 0%
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)	1/49 (2%)			1/50 (2%)	2/50 (4%)	
verall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	3/100 (3%)	Mean 3%	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

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		Male			Female			
	3/50 (6%)	3/49 (6%)			13/50 (26%)	14/50 (28%)		
Total	6/99 (6.06%)			Total	, ,	Mean 27%	SD 1.41%	
	, ,	, ,	05 00/		, ,	0/50 (0%)	25	
Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
T-1-1	` '	` '	OD 00/	T-1-1	, ,	` ,	00.00/	
ı otai	0/100 (0%)	wean u%	SD 0%	ı otal	0/100 (0%)	Mean 0%	SD 0%	
	2(72 (224)	2(72 (22))			(201)	0(50 (00))		
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
	0/50 (00/)	0/50 (0%)			0/50 (09/)	0/50 (09/)		
Total	` '	` ,	SD 0%	Total	` '	` ,	SD 0%	
	Total  Total	Total 6/99 (6.06%)  O/50 (0%)  Total 0/99 (0%)  Total 0/50 (0%)  Total 0/100 (0%)  Total 0/100 (0%)  Total 0/100 (0%)  Total 0/50 (0%)  Total 0/100 (0%)	Total 6/99 (6.06%) Mean 6.06%  0/50 (0%) 0/49 (0%)  Total 0/99 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0%  Total 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%	Total 6/99 (6.06%) Mean 6.06% SD 0.09%    O/50 (0%)	Total         6/99 (6.06%)         Mean 6.06%         SD 0.09%         Total           0/50 (0%)         0/49 (0%)         SD 0%         Total           Total         0/99 (0%)         0/50 (0%)         SD 0%         Total           Total         0/100 (0%)         0/50 (0%)         SD 0%         Total	Total         6/99 (6.06%)         Mean 6.06%         SD 0.09%         Total         27/100 (27%)           0/50 (0%)         0/49 (0%)         SD 0%         Total         1/50 (2%)           Total         0/99 (0%)         Mean 0%         SD 0%         Total         1/100 (1%)           Total         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/100 (0%)         0/100 (0%)           Total         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/100 (0%)         0/50 (0%)           Total         0/100 (0%)         Mean 0%         SD 0%         Total         0/100 (0%)           Total         0/100 (0%)         Mean 0%         SD 0%         Total         0/100 (0%)           0/50 (0%)         0/50 (0%)         SD 0%         Total         0/100 (0%)	Total 6/99 (6.06%) Mean 6.06% SD 0.09% Total 27/100 (27%) Mean 27%    0/50 (0%) 0/49 (0%)	

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

<sup>#:</sup> 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: GAVAGE

Vehicle: METHYLCELLULOSE

Strain: F 344/N 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									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Harderian Gland: Carcinoma									
Overall Incidence	Total	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 or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Heart: Schwannoma Benign									
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*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%	

<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

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Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

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

<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	
#Intestine Small: Ileum: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Jejunum: Granular Cell Tumor Malig	nant	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma						0(50 (00))	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unspec	cified:							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

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

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 66

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

nor incluence for Selected Cor

Length of Study: CHRONIC

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

<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**

**Page:** 67

Report Date: 05/18/2011

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

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

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

<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: 68

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Parity CAVAC

Length of Study: CHRONIC

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

<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**: 69

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

*Kidney: Renal Tubule:  Mesenchymal Tumor Malignant  0/49 (0%) 0/48 (0%)  Overall Incidence  Total  0/97 (0%)  Mean 0%  SD 0%  Total  1/94 (1.06%)  *Kidney: Renal Tubule: Nephroblastoma  0/49 (0%)  0/48 (0%)  Overall Incidence  Total  0/97 (0%)  Mean 0%  SD 0%  Total  0/50 (0%)  0/50 (0%)  0/50 (0%)  *Kidney: Renal Tubule: Sarcoma  0/49 (0%)  0/48 (0%)  Overall Incidence  Total  0/97 (0%)  Mean 0%  SD 0%  Total  0/50 (0%)  0/50 (0%)  Overall Incidence  Total  0/97 (0%)  Mean 0%  SD 0%  Total  0/94 (0%)  Total  0/94 (0%)	
Overall Incidence         Total         0/97 (0%)         Mean 0%         SD 0%         Total         1/94 (1.06%)           *Kidney: Renal Tubule: Nephroblastoma         0/49 (0%)         0/48 (0%)         0/50 (0%)           Overall Incidence         Total         0/97 (0%)         Mean 0%         SD 0%         Total         0/94 (0%)           *Kidney: Renal Tubule: Sarcoma         0/49 (0%)         0/48 (0%)         0/50 (0%)           Overall Incidence         Total         0/97 (0%)         Mean 0%         SD 0%         Total         0/94 (0%)	
*Kidney: Renal Tubule: Nephroblastoma  0/49 (0%) 0/48 (0%)  Overall Incidence Total 0/97 (0%) Mean 0% SD 0% Total 0/94 (0%)  *Kidney: Renal Tubule: Sarcoma 0/49 (0%) 0/48 (0%)  Overall Incidence Total 0/97 (0%) Mean 0% SD 0% Total 0/50 (0%)  Overall Incidence Total 0/97 (0%) Mean 0% SD 0% Total 0/94 (0%)	1/44 (2%)
*Kidney: Renal Tubule: Nephroblastoma  0/49 (0%) 0/48 (0%)  Overall Incidence Total 0/97 (0%) Mean 0% SD 0%  *Kidney: Renal Tubule: Sarcoma  0/49 (0%) 0/48 (0%)  Overall Incidence Total 0/97 (0%) Mean 0%  SD 0%  Total 0/94 (0%)  Overall Incidence Total 0/97 (0%)  Mean 0%  SD 0%  Total 0/94 (0%)	Mean 1.14% SD 1.61%
Overall Incidence         Total         0/97 (0%)         Mean 0%         SD 0%         Total         0/94 (0%)           *Kidney: Renal Tubule: Sarcoma           0/49 (0%)         0/48 (0%)         0/50 (0%)           Overall Incidence         Total         0/97 (0%)         Mean 0%         SD 0%         Total         0/94 (0%)	
*Kidney: Renal Tubule: Sarcoma  0/49 (0%) 0/48 (0%)  Overall Incidence Total 0/97 (0%) Mean 0% SD 0% Total 0/94 (0%)	0/44 (0%)
Sarcoma           0/49 (0%)         0/48 (0%)         0/50 (0%)           Overall Incidence         Total         0/97 (0%)         Mean 0%         SD 0%         Total         0/94 (0%)	Mean 0% SD 0%
Overall Incidence         Total         0/97 (0%)         Mean 0%         SD 0%         Total         0/94 (0%)	
	0/44 (0%)
¥1 5	Mean 0% SD 0%
*Liver: Cholangioma	0(50 (00))
0/50         (0%)         0/50         (0%)         0/50         (0%)           Overall Incidence         Total         0/100 (0%)         Mean 0%         SD 0%         Total         0/100 (0%)	0/50 (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%) 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

**Page:** 70

		Male				Female	
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
or Hepatobla	ıstoma						
•	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
or Hepatocel		0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
Hepatocellu	•				0/50 (0%)	0/50 (0%)	
Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
oma	0/50 /00/	4/50 (00)			0/50 (00%)	0/50 (0%)	
Total	` '		SD 1 410/	Total	` ,	` '	SD 0%
	Total  Total  Total  Total  Hepatocellul  Total  Total	Total 0/100 (0%)  or Hepatoblastoma  0/50 (0%)  Total 0/100 (0%)  or Hepatocellular Adenoma 2/50 (4%)  Total 2/100 (2%)  Hepatocellular Adenoma, or Hepatob 2/50 (4%)  Total 2/100 (2%)  Total 2/100 (2%)  O/50 (0%)  Total 1/100 (1%)	Total 0/100 (0%) Mean 0%  Or Hepatoblastoma  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  Or Hepatocellular Adenoma  2/50 (4%) 0/50 (0%)  Total 2/100 (2%) Mean 2%  Hepatocellular Adenoma, or Hepatoblastoma  2/50 (4%) 0/50 (0%)  Total 2/100 (2%) Mean 2%  O/50 (0%)  Total 1/100 (1%) Mean 1%  Oma  0/50 (0%) 1/50 (2%)	Total 0/100 (0%) Mean 0% SD 0%  Or Hepatoblastoma  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0%  Or Hepatocellular Adenoma  2/50 (4%) 0/50 (0%)  Total 2/100 (2%) Mean 2% SD 2.83%  Hepatocellular Adenoma, or Hepatoblastoma  2/50 (4%) 0/50 (0%)  Total 2/100 (2%) Mean 2% SD 2.83%  Total 2/100 (2%) Mean 2% SD 2.83%  O/50 (0%) 1/50 (2%)  Total 1/100 (1%) Mean 1% SD 1.41%	Total 0/100 (0%) Mean 0% SD 0% Total  or Hepatoblastoma  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total  or Hepatocellular Adenoma  2/50 (4%) 0/50 (0%)  Total 2/100 (2%) Mean 2% SD 2.83% Total  Hepatocellular Adenoma, or Hepatoblastoma  2/50 (4%) 0/50 (0%)  Total 2/100 (2%) Mean 2% SD 2.83% Total  O/50 (0%)  Total 1/100 (1%) Mean 1% SD 1.41% Total  O/50 (0%) 1/50 (2%)	Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  or Hepatoblastoma  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  or Hepatocellular Adenoma  2/50 (4%) 0/50 (0%)  Total 2/100 (2%) Mean 2% SD 2.83% Total 0/100 (0%)  Hepatocellular Adenoma, or Hepatoblastoma  2/50 (4%) 0/50 (0%)  Total 2/100 (2%) Mean 2% SD 2.83% Total 0/100 (0%)  Total 2/100 (2%) Mean 2% SD 2.83% Total 0/100 (0%)  Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%)  O/50 (0%)  Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%)	Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  or Hepatoblastoma  0/50 (0%) 0/50 (0%) SD 0%  Total 0/100 (0%) Mean 0%  Or Hepatocellular Adenoma  2/50 (4%) 0/50 (0%)  Total 2/100 (2%) Mean 2%  SD 2.83%  Total 0/100 (0%) 0/50 (0%)  Total 2/100 (2%) Mean 2%  SD 2.83%  Total 0/100 (0%) 0/50 (0%)  Mean 0%  Hepatocellular Adenoma, or Hepatoblastoma  2/50 (4%) 0/50 (0%)  Total 2/100 (2%) Mean 2%  SD 2.83%  Total 0/100 (0%) 0/50 (0%)  Total 2/100 (2%) Mean 2%  SD 2.83%  Total 0/100 (0%) 0/50 (0%)  Total 1/100 (1%) Mean 1%  SD 1.41%  Total 0/100 (0%) 0/50 (0%)  Mean 0%  O/50 (0%) 0/50 (0%)  Mean 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:** 71

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
Lung: Alveolar/Bronchiolar Carcii	noma							
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
Lung: Alveolar/Bronchiolar Carcii		eolar/Bronchiolar Adenon	na					
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
Lung: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Lung: Hemangiosarcoma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/30 (2%)	0/50 (0%) Mean 1%	SD 1.41%	Total	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%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangiosarcoma							0/50 (00)	
Normall In al January	<b>T</b> -1-1	1/50 (2%)	0/50 (0%)	OD 4 440/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

<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:** 72

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Mammary Gland: Adenolipoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)			2/50 (4%)	2/50 (4%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	4/100 (4%)	Mean 4%	SD 0%
Mammary Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			3/50 (6%)	3/50 (6%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	6/100 (6%)	Mean 6%	SD 0%
Mammary Gland: Fibroadenoma								
		2/50 (4%)	3/50 (6%)			35/50 (70%)	26/50 (52%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	61/100 (61%)	Mean 61%	SD 12.73%
Mammary Gland: Fibroma		(00)						
		1/50 (2%)	0/50 (0%)	25		0/50 (0%)	1/50 (2%)	00
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					
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma												
		3/50 (6%)	3/50 (6%)			36/50 (72%)	28/50 (56%)					
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 0%	Total	64/100 (64%)	Mean 64%	SD 11.31%				
#Mammary Gland: Fibroma, Fibroadenoma, C	Carcinoma, or	Adenoma										
		3/50 (6%)	3/50 (6%)			37/50 (74%)	30/50 (60%)					
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 0%	Total	67/100 (67%)	Mean 67%	SD 9.9%				
#Mesentery: Fibrous Histiocytoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Mesentery: Hemangiosarcoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Mesentery: Lipoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Mesentery: Schwannoma Malignant												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

<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: 74

			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 Carcino	oma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Oral Cavity (Oral Mucos Papilloma Squamous o		ynx, Tooth, Gingiva):	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Oral Cavity (Oral Mucos Squamous Cell Carcing	a, Tongue, Phary											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Oral Cavity (Oral Mucos	a, Tongue, Phary		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%				
			•••••									
#Oral Mucosa: Squamous Cell Carcino	oma	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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

**Page:** 75

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

<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: 76

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: **Granulosa-Theca Tumor Benign** 0/50 (0%)0/50 (0%)Overall Incidence Total 0/100 (0%) Mean 0% SD 0% ..... \*Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)0/50 (0%)Overall Incidence Total 0/100 (0%) Mean 0% SD 0% \*Ovary: **Schwannoma Malignant** 0/50 (0%)0/50 (0%)Overall Incidence Total 0/100 (0%) Mean 0% SD 0% ..... \*Ovary: **Tubulostromal Adenoma** 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% \*Pancreas: Adenoma 3/50 (6%)0/50 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 3/100 (3%) Mean 3% SD 4.24% Total 0/99 (0%) Mean 0% SD 0% ...... \*Pancreas: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total Mean 0% SD 0% Mean 0% SD 0% 0/100 (0%) Total 0/99 (0%)

<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: 77

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

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

<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: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma												
		19/50 (38%)	24/50 (48%)			19/50 (38%)	26/50 (52%)					
Overall Incidence	Total	43/100 (43%)	Mean 43%	SD 7.07%	Total	45/100 (45%)	Mean 45%	SD 9.9%				
*Pituitary Gland: Pars Distal Ganglioneuroma	is or Unspec	ified Site:										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Pituitary Gland: Pars Interm Adenoma	nedia:											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	nedia:	0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Pituitary Gland: Pars Nervo Craniopharyngioma	sa:											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Prostate: Adenoma												
		0/50 (0%)	2/50 (4%)									
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%								

<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: 79

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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

<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: 80

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

		Male				Female	
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (00)	(201)			(00)	(22)	
Total	` '	` '	CD 00/	Total	` ,	` '	CD 00/
	` '				, ,		SD 0%
	, ,	, ,	<b>OD</b>		` '	` '	00.00/
	` ,		SD 0%	l otal	0/100 (0%)	Mean 0%	SD 0%
Rhabdomyoma		0/50 (00/)			0/50 (00/)	0/50 (00/)	
Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
asosquamous	Tumor Benign						
	0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
	Total  Total  Total  Total  Total  Total	Total 0/100 (0%)    0/50 (0%)     Total 0/100 (0%)     0/50 (0%)     Total 0/100 (0%)     Total 0/100 (0%)     Total 0/100 (0%)     Total 1/100 (1%)     asosquamous Tumor Benign 0/50 (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%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  thabdomyoma 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  10/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1%  asosquamous Tumor Benign 0/50 (0%) 1/50 (2%)	Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%    0/50 (0%) 0/50 (0%) SD 0%   Total 0/100 (0%) Mean 0% SD 0%    Total 0/100 (0%) Mean 0% SD 0%    Total 0/100 (0%) Mean 0% SD 0%    Chabdomyoma	Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total  thabdomyoma 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total  1/100 (1%) Mean 0% SD 0% Total  1/100 (1%) Mean 1% SD 1.41% Total  asosquamous Tumor Benign 0/50 (0%) 1/50 (2%)	O/50 (0%)   O/50 (0%)   O/50 (0%)   O/50 (0%)     Total	O/50 (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: 81

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female			
#Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma										
	-	0/50 (0%)	3/50 (6%)			0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
#Skin: Basal Cell Carcinoma										
		1/50 (2%)	1/50 (2%)			0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
#Skin:										
Basal Cell Carcinoma	or Basosquamοι	is Tumor (malignant or NO	OS)							
		1/50 (2%)	1/50 (2%)			0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
#Skin: Basal Cell Carcinoma, NOS), or Trichoepithel		oma, Basosquamous Tun	nor (benign, maligna	nt or						
		1/50 (2%)	4/50 (8%)			0/50 (0%)	2/50 (4%)			
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 4.24%	Total	2/100 (2%)	Mean 2%	SD 2.83%		
		a, Basosq. Tumor (M or B ratoacanthoma, Trichoep	ithelioma	ma,						
		5/50 (10%)	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										
Fibroma		5/50 (10%)	11/50 (22%)			3/50 (6%)	2/50 (4%)			

<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: 82

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

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

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

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

Species: RATS

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 83

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Strain: F 344/N Length of Study: CHRONIC

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

<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** 

Page: 84

Report Date: 05/18/2011

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

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Skin: Neurofibrosarcoma or Sch	vannoma (m	nalignant 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, Neurof								
,		0/50 (0%)	0/50 (0%)			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 Malignant								
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
		` ,				( /		

<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: 85

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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

<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: 86

			Male			Female           Total         0/50 (0%) 0/50 (0%) 0/50 (0%)           Total         0/50 (0%) 0/50 (0%) 0/50 (0%)           Total         0/100 (0%) 0/50 (0%) 0/50 (0%)			
#Skin: Sebaceous Gland: Adenoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Skin: Sebaceous Gland: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)			` ,	( )		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Spinal Cord: Astrocytoma Benign		0/50 (00/)	0/50 /00/\			0/50 (09/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	( )	SD 0%	
		, ,			·····				
#Spinal Cord: Astrocytoma Malignant		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Spinal Cord: Glioma Malignant									
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Spleen: Fibrosarcoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/40 (000)		
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%)	0/48 (0%) Mean 0%	SD 0%	
Overall incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	iviean u%	3D 0%	

<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:** 87

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

<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

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Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papillom	a Squamous						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Lipoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Sarcoma		2/22	2/ /22/				(201)	
Occupation of desire	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%

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

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Contract/Lab: All Laboratories

Species: RATS

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

**Page:** 89

(0%)

SD 0%

Mean 0%

0/48

(0%)

0/50

0/98 (0%)

Total

Report Date: 05/18/2011

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

SD 0%

(0%)

0/44

Mean 0%

Total

0/50

0/94 (0%)

(0%)

Thymoma: Benign, Malignant, NOS

**Overall Incidence** 

<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:** 90

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

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

<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:** 91

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

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

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

Species: RATS

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 92

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Strain: F 344/N Length of Study: CHRONIC

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

<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: 93

Report Date: 05/18/2011

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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

<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

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

#Zymbal's Gland: Adenoma

**Overall Incidence** 

#Zymbal's Gland: Carcinoma

**#Uterus:** 

#Vagina: Polyp

#Vagina: Sarcoma

#Vagina:

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Total

Total

Total

Total

Length of Study: CHRONIC

Schwannoma Malignant

......

**Schwannoma Malignant** 

Contract/Lab: All Laboratories

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

(0%)

(0%)

(0%)

0/100 (0%)

0/50

0/50

0/50

0/100 (0%)

0/100 (0%)

0/100 (0%)

**Page:** 94

Mean 0%

Mean 0%

Mean 0%

Mean 0%

(0%)

(0%)

(0%)

0/50

0/50

0/50

Report Date: 05/18/2011

SD 0%

SD 0%

SD 0%

SD 0%

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

Total

.....

0/50

0/100 (0%)

0/50

(0%)

(0%)

0/50

0/50

Mean 0%

Mean 0%

(0%)

(0%)

SD 0%

SD 0%

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

Species: RATS

#Zymbal's Gland:

Overall Incidence

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Strain: F 344/N Length of Study: CHRONIC

Carcinoma or Adenoma

Vehicle: METHYLCELLULOSE

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

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Report Date: 05/18/2011

Total

0/50

0/100 (0%)

(0%)

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

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