Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

#### Page: 25 Report Da

Report Date: 06/12/2013

#### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	059601405	10/26/06	726	50(3)	19(658)	528.0	Water disinfection byproducts (Bromodichloroacetic acid)
					Female		
Battelle Columbus Laboratory	059601405	10/27/06	727	50(5)	34(694)	352.8	Water disinfection byproducts (Bromodichloroacetic acid)

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 26

			Male			Female			
#All Organs: Benign Tumors									
Overall Incidence	Total	46/50 (92%) 46/50 (92%)	Mean 92%	SD 0%	Total	41/50 (82%) 41/50 (82%)	Mean 82%	SD 0%	
		40/30 (92/0)				41/30 (02/0)			
#All Organs: Malignant Tumors									
		24/50 (48%)				23/50 (46%)			
Overall Incidence	Total	24/50 (48%)	Mean 48%	SD 0%	Total	23/50 (46%)	Mean 46%	SD 0%	
#All Organs: Malignant and Benign Tu	ımors	49/50 (98%)				47/50 (94%)			
Overall Incidence	Total	49/50 (98%)	Mean 98%	SD 0%	Total	47/50 (94%)	Mean 94%	SD 0%	
#All Organs: Hemangioma		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#All Organs: Hemangiosarcoma	•••••								
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma or He	mangioma	0(50 (00))				4/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
		0/50 (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

Report Date: 06/12/2013

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

Length of Study: CHRONIC

			Male		Female			
#All Organs: Leukemia: Lymphocytic, N	-	15/50 (30%)		<b>OD</b> 201		19/50 (38%)		05.00
Overall Incidence	Total	15/50 (30%)	Mean 30%	SD 0%	Total	19/50 (38%)	Mean 38%	SD 0%
#All Organs: Mesothelioma: Benign, Ma	alignant, NOS							
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant						0/50 /00/		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma	a	4/50 (00)				0/50 (00/)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	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

Strain: F 344/N Tac

Species: RATS

**Toxicology Data Management System** 

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Report Date: 06/12/2013

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

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

	Male					Female				
*Adrenal Medulla: Pheochromocytoma Benigr	<b>1</b> Total	10/50 (20%) 10/50 (20%)	Mean 20%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
*Adrenal Medulla: Pheochromocytoma Malign	ant	0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Adrenal Medulla: Pheochromocytoma: Benig	n, Complex	, <b>Malignant, NOS</b> 10/50 (20%) 10/50 (20%)	Mean 20%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%		
#Bone: Osteoma Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Bone: Osteosarcoma or Osteoma		` '				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Brain: Astrocytoma Malignant		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

<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 Tac

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 29

				Male			Female			
*Brain: Fibrous Histiocytoma										
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		, ,								
*Brain: Glioma										
		0/50	(0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Brain: Granular Cell Tumor Benign			(4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	,	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Oligodendroglioma, Glioma,										
	•		(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Adenoma										
		2/50	(4%)				8/50 (16%)			
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	8/50 (16%)	Mean 16%	SD 0%	
*Clitoral/Preputial Gland: Carcinoma										
			(4%)				1/50 (2%)			
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	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 Tac

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 30

				Male			Female			
*Clitoral/Preputial Gland: Carcinoma or Adenoma										
			(8%)				8/50 (16%)			
Overall Incidence	Total	4/50 (8%)		Mean 8%	SD 0%	Total	8/50 (16%)	Mean 16%	SD 0%	
#Ear: Neural Crest Tumor										
			(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Harderian Gland: Carcinoma		4/50	(00()				0/50 (00/)			
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		, ,								
#Harderian Gland: Carcinoma or Adenoma		4/50	(00/)				0/50 (00/)			
Overall Incidence	Total	1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Heart: Schwannoma Malignant										
			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Large: Colon/Rect Adenoma										
	<b>T</b>		(0%)		05.00/	<b>-</b>	1/50 (2%)		00.00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	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 Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 31

			Male			Female			
#Intestine Large: Colon/Re Carcinoma or Adenoma	ectum:								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Intestine Small: Ileum: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Carcinoma	:	0/50 (00/)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unsp Carcinoma						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%	
#Intestine Small: Site Unsp				•••••					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	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 Tac

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 32

			Male			Female			
*Islets, Pancreatic: Carcinoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Carcinoma or Adenoma		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Kidney: Renal Tubule: Adenoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma or Adenoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Lipoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Liver: Fibrous Histiocytoma	•••••	1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	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 Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 33

			Male				Female			
*Liver: Hemangioma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
*Lung: Alveolar/Bronchiolar Ade	enoma	······································				······································				
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Lung: Alveolar/Bronchiolar Car				SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Lung: Fibrous Histiocytoma  Overall Incidence	Total	, ,	Mean 2%		Total	` '	Mean 0%	SD 0%		
*Lung: Squamous Cell Carcinon	ıa	1/50 (2%)				0/50 (0%)				
_	na Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
Squamous Cell Carcinon		( ,	Mean 2%	SD 0%	Total	` '	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 Tac

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 34

			Male			Female			
#Mammary Gland: Adenoma									
		0/50 (0%	,			1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Mammary Gland: Carcinoma									
		0/50 (0%	,			0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Carcinoma or Adenoma	ı	0/50 (0%	<b>(</b> )			1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
		, ,							
#Mammary Gland: Fibroadenoma		0/50 (0%	4)			28/50 (56%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	28/50 (56%)	Mean 56%	SD 0%	
#Mammary Gland: Fibroma, Fibroadenoma									
		0/50 (0%	6)			28/50 (56%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	28/50 (56%)	Mean 56%	SD 0%	
#Mammary Gland: Fibroma, Fibroadenoma	ı, Carcinoma, or	<b>Adenoma</b> 0/50 (0%	4)			28/50 (56%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	28/50 (56%)	Mean 56%	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 Tac

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 35

			Male			Female			
#Oral Cavity (Oral Mucosa Papilloma Squamous or		nx, Tooth, Gingiva):							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Oral Cavity (Oral Mucosa Squamous Cell Carcinor		nx, Tooth, Gingiva):				•••••			
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Oral Cavity (Oral Mucosa Squamous Cell Carcinor Overall Incidence		quamous, or Papilloma 1/50 (2%)	Mann 20/	SD 00/	Total	0/50 (0%)	Magn 00/	SD 0%	
	ı olal	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Oral Mucosa: Squamous Cell Carcinor	na	1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Adenoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Carcinoma or Adenoma		1/EQ (20%)				0/50 (00/)			
		1/50 (2%)				0/50 (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 Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

**Page:** 36

Report Date: 06/12/2013

SD 0%

Mean 0%

Route: ORAL Vehicle: WATER

			Male	Female					
*Pancreas: Mixed Tumor Malignant		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Pituitary Gland: Pars Distali Adenoma									
Overall Incidence	Total	26/50 (52%) 26/50 (52%)	Mean 52%	SD 0%	Total	23/50 (46%) 23/50 (46%)	Mean 46%	SD 0%	
						, ,			
*Pituitary Gland: Pars Distali Carcinoma or Adenoma	s or Unspec					23/50 (46%)			
Overall Incidence	Total	26/50 (52%) 26/50 (52%)	Mean 52%	SD 0%	Total	23/50 (46%)	Mean 46%	SD 0%	
Prostate: Adenoma		1/50 (2%)							
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%					
*Prostate: Carcinoma or Adenoma		1/50 (2%)							
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%					
*Salivary Glands: Adenoma									
		0/50 (0%)				0/50 (0%)			

SD 0%

Total

0/50 (0%)

Total

0/50 (0%)

Mean 0%

**Overall Incidence** 

<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 Tac

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 37

				Male			Female			
*Salivary Glands: Carcinoma or Adenoma		0/50	(00()				0/50 (00/)			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skeletal Muscle: Fibrous Histiocytoma		4/50	(00()				0/50 (00)			
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Basal Cell Adenoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	` '	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Basal Cell Adenoma or	Basosquamous	Tumor Benign 0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Basal Cell Adenoma, Ba	ısosquamous Tı	umor Benign, o	r Trichoe <sub>l</sub>	pithelioma			0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Basal Cell Carcinoma, E NOS), or Trichoepithelic	Basal Cell Adeno	ma, Basosquai	nous Tur							
Overall Incidence	Total	0/50 0/50 (0%)	(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

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Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

Length of Study: CHRONIC

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

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Mean 0%

SD 0%

Report Date: 06/12/2013

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Male **Female** #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 9/50 (18%) 0/50 Mean 0% Overall Incidence Total 9/50 (18%) Mean 18% SD 0% Total 0/50 (0%) SD 0% ..... #Skin: **Fibroma** 4/50 (8%)2/50 (4%)**Overall Incidence** Total 4/50 (8%) Mean 8% SD 0% Total 2/50 (4%) Mean 4% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 6/50 (12%) 2/50 (4%)**Overall Incidence** Total 6/50 (12%) Mean 12% SD 0% Total 2/50 (4%) Mean 4% SD 0% ..... #Skin: **Fibrosarcoma** 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) SD 0% Mean 0% #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 2/50 (4%)0/50 (0%)**Overall Incidence** Total 2/50 (4%) Mean 4% SD 0% Total 0/50 (0%) SD 0% Mean 0% ..... #Skin: **Fibrous Histiocytoma** (2%)0/50 (0%)

SD 0%

Total

0/50 (0%)

Total

1/50 (2%)

Mean 2%

**Overall Incidence** 

<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 Tac

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 39

			Male			Female			
#Skin: Hamartoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Keratoacanthoma									
		7/50 (14%)				0/50 (0%)			
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Lipoma									
		1/50 (2%)				2/50 (4%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
#Skin:	-1	-!'( NOO)							
Neurofibrosarcoma or S	cnwannoma (m	0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin:									
Neurofibrosarcoma, Neu	rofibroma, or S		alignant or NOS)						
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Schwannoma Malignant									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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

Strain: F 344/N Tac

Species: RATS

**Toxicology Data Management System** 

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

AL

**Page:** 40

Report Date: 06/12/2013

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Skin: Squamous Cell Carcino	ma							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcino or Carcinoma	ma, Basal Cell C	Carcinoma, Basosquamo	us Tumor (malignan	t or NOS),				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillon	na	3/50 (6%)				0/50 (0%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillon	na or Papilloma	0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillon				na		0/50 (0%)		
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillon						0/50 (0%)		
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	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

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 41

				Male			Female			
#Skin: Trichoepithelioma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papillom	a Squamous								
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Papilloma		1/50	(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	( )	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Testes: Adenoma		24/50	(600/)							
Overall Incidence	Total	34/50 34/50 (68%	)	Mean 68%	SD 0%					
*Thymus: Thymoma Malignant										
Overall Incidence	Total	0/48 0/48 (0%)	(0%)	Mean 0%	SD 0%	Total	1/48 (2%) 1/48 (2.08%)	Mean 2.08%	SD 0%	
*Thymus: Thymoma: Benign, Maligna	nt, NOS	0/40	(00()				4/40 (00)			
Overall Incidence	Total	0/48 0/48 (0%)	(0%)	Mean 0%	SD 0%	Total	1/48 (2%) 1/48 (2.08%)	Mean 2.08%	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 Tac **Toxicology Data Management System** 

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Report Date: 06/12/2013

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female		
*Thyroid Gland: C-Cell: Adenoma									
		7/50 (14%)				11/50 (22%)			
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	11/50 (22%)	Mean 22%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma									
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		9/50 (469/)				11/50 /229/\			
Overall Incidence	Total	8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%	Total	11/50 (22%) 11/50 (22%)	Mean 22%	SD 0%	
	10lai 	0/30 (10%)			10tai	11/30 (22%)	IVIEAII 2270	JD 0%	
*Thyroid Gland: Follicular Cell Adenoma	:								
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: Follicular Cell Carcinoma	:								
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:								
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<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 Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 43

	Male					Female						
#Tongue: Squamous Cell Carcinoma or Papilloma Squamous												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Tongue: Squamous Cell Papilloma	1											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Uterus: Deciduoma NOS						4/50 (20()						
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
#Uterus: Fibrous Histiocytoma						1/50 (2%)						
Overall Incidence					Total	1/50 (2%)	Mean 2%	SD 0%				
#Uterus: Hemangiosarcoma												
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Uterus: Leiomyoma						0/50 (00/)						
Overall Incidence					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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tac

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 44

Ma							Female		
#Uterus: Leiomyosarcoma									
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Uterus: Polyp Stromal	•••••								
Overall Incidence					Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	
#Uterus: Sarcoma Stromal									
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Uterus: Sarcoma Stromal or Poly									
Overall Incidence					Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	
#Zymbal's Gland: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
·····		` '				, ,			
#Zymbal's Gland: Carcinoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<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 Tac

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 45

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

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

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