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: PERINATAL AND POSTNATAL

Vehicle: FEED

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Report Date: 06/05/2013

# **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	059901305	05/12/05	726	50(3)	36(685)	522.7	Styrene-acrylonitrile trimer
					Female		
Battelle Columbus Laboratory	059901305	05/13/05	727	50(5)	41(699)	371.2	Styrene-acrylonitrile trimer

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male			Female			
#All Organs: Benign Tumors									
		46/50 (92%)				42/50 (84%)			
Overall Incidence	Total	46/50 (92%)	Mean 92%	SD 0%	Total	42/50 (84%)	Mean 84%	SD 0%	
#All Organs: Malignant Tumors									
		22/50 (44%)				19/50 (38%)			
Overall Incidence	Total	22/50 (44%)	Mean 44%	SD 0%	Total	19/50 (38%)	Mean 38%	SD 0%	
#All Organs: Malignant and Benign Tu	ımors	49/50 (98%)				44/50 (88%)			
Overall Incidence	Total	49/50 (98%)	Mean 98%	SD 0%	Total	44/50 (88%)	Mean 88%	SD 0%	
#All Organs: Hemangioma		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									
		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	emangioma	0/50 (00)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	Total	0/50 (0%)			Total	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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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SD 0%

SD 0%

			Male	Female				
#All Organs: Histiocytic Sarcoma								
		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:								
	c, Monocytic, Ma	ononuclear, or Undiffere	ntiated					
		15/50 (30%)				13/50 (26%)		
Overall Incidence	Total	15/50 (30%)	Mean 30%	SD 0%	Total	13/50 (26%)	Mean 26%	SD 0%
#All Organs:								
Malignant Lymphoma:	Histiocytic, Lym	phocytic, Mixed, NOS, o	r Undifferentiated Ce	II Type				
		0/50 (0%)				0/50 (0%)		
	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Overall Incidence		,		02 070				
		,		02 070				
#All Organs:				02 070				
				02 070				

SD 0%

SD 0%

0/50

0/50

0/50 (0%)

0/50 (0%)

Total

Total

(0%)

(0%)

Mean 0%

Mean 0%

Total

......

Total

4/50

4/50 (8%)

0/50

0/50 (0%)

(8%)

(0%)

Mean 8%

Mean 0%

Mesothelioma: Malignant

**Overall Incidence** 

**Overall Incidence** 

#All Organs: Osteoma

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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				Male				Female			
#All Organs: Osteosarcoma		0/50 (0					0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Osteosarcoma or Osteoma		0/50 ((	0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Adrenal Cortex: Adenoma		0/50 ((	0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	070)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Adrenal Cortex: Carcinoma		0/50 ((	0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma Benign		4/50 (8	00/\				0/50 (0%)				
Overall Incidence	Total	4/50 (8%)	8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma Comple	ex	0/50 ((	0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	<i>- ,</i> 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

**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: PERINATAL AND POSTNATAL

Vehicle: FEED

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				Male			Female			
*Adrenal Medulla: Pheochromocytoma Malig	nant	0/50	(09/)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Adrenal Medulla: Pheochromocytoma: Beni	gn, Complex,	_					4/50 (20/)			
Overall Incidence	Total	4/50 4/50 (8%)	(8%)	Mean 8%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Blood Vessel: Leiomyosarcoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Chordoma	Total		(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteoma			(0%)				( ,			
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(3,0)	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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Bone: Osteosarcoma or Osteoma	a							
Overall Incidence	Total	0/50 (0° 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Glioma								
Overall Incidence	Total	0/50 (0° 0/50 (0%)	%) Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Brain: Glioma Benign		0/50 (0 <sup>4</sup>	0/)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Glioma 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%
*Brain: Oligodendroglioma, Gliom		toma						
Overall Incidence	Total	0/50 (0° 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Osteosarcoma		0/50 /0/	0(1)			0/50 (09/.)		
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

Adenoma

Carcinoma

Sarcoma

#Ear:

#Eye:

Melanoma Benign

**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: PERINATAL AND POSTNATAL

Vehicle: FEED

Male **Female** \*Clitoral/Preputial Gland: 1/50 (2%)3/50 (6%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 3/50 (6%) Mean 6% SD 0% \*Clitoral/Preputial Gland: 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% \*Clitoral/Preputial Gland: Carcinoma or Adenoma 2/50 (4%)3/50 (6%)**Overall Incidence** Total 2/50 (4%) Mean 4% SD 0% Total 3/50 (6%) Mean 6% SD 0% ..... \*Clitoral/Preputial Gland: 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) **Neural Crest Tumor** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%

0/50

0/50 (0%)

Total

(0%)

Mean 0%

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SD 0%

0/50

(0%)

Mean 0%

SD 0%

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

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

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Eye: Melanoma 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%
#Harderian Gland: Adenoma		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%
#Harderian Gland: 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%
#Harderian Gland: Carcinoma or 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%
*Heart: Schwannoma Benign								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Heart: 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

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female			
#Intestine Large: Colon/Rectu Adenoma	m:	1/50 (2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Colon/Rectu Carcinoma or Adenoma	m:									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Leiomyoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: 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%		
#Intestine Small: Ileum: Adenoma						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: Jejunum: 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%		

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Intestine Small: Jejunum: Leiomyoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspo Adenoma	ecified:							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe 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%
#Intestine Small: Site Unspe Carcinoma or 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%
#Intestine Small: Site Unspo Leiomyoma								
		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

Length of Study: CHRONIC

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female			
#Intestine Small: Site Unspe Leiomyosarcoma	cified:									
•		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Unspe 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%		
*Islets, Pancreatic: 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%		
*Islets, Pancreatic: 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%		
Overall incluence	10lal	0/50 (0%)			ı Olai	0/30 (0%)	iviean 0%	3D 0%		
*Islets, Pancreatic: Carcinoma or Adenoma										
	<b>-</b>	0/50 (0%)	14 00/	OD 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%		
*Kidney: Pelvis and Transition Papilloma	onal Epitheliu									
		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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Vehicle: FEED

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Report Date: 06/05/2013

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Length of Study: CHRONIC

Male **Female** \*Kidney: Renal Tubule: Adenoma 1/50 (2%)0/50 (0%)1/50 (2%) **Overall Incidence** Total Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% \*Kidney: Renal Tubule: 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% \*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 0/50 (0%)0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% ..... \*Kidney: Renal Tubule: **Mesenchymal 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% \*Kidney: Renal Tubule: Sarcoma 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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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Mean 0%

Mean 0%

SD 0%

SD 0%

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Male **Female** \*Liver: Hepatocellular 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% \*Liver: **Hepatocellular 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% \*Liver: Hepatocellular Carcinoma or Hepatoblastoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% ...... \*Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) \*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 0/50 (0%)0/50 (0%)

SD 0%

SD 0%

Total

Total

0/50 (0%)

0/50

0/50 (0%)

(0%)

Total

Total

0/50 (0%)

0/50

0/50 (0%)

(0%)

Mean 0%

Mean 0%

**Overall Incidence** 

**Overall Incidence** 

**Ito Cell Tumor Benign** 

\*Liver:

<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: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Lung: Alveolar/Bronchiolar A		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar C	arcinoma							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar C	arcinoma or Alve	eolar/Bronchiolar Adenon 1/50 (2%)	na			0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Fibrosarcoma		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: Adenolipoma		0/50 (0%)				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%
#Mammary 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%

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Mammary Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Mammary Gland: Carcinoma or Adenoma		0/50 (00)				0/50 (40/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Mammary Gland: Fibroadenoma		4/50 (00()				00/50 /700/		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	36/50 (72%) 36/50 (72%)	Mean 72%	SD 0%
#Mammary Gland: Fibroma		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: Fibroma, Fibroadenoma o	or Adenoma			•••••				
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	36/50 (72%) 36/50 (72%)	Mean 72%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, (						36/50 (72%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	36/50 (72%)	Mean 72%	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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Mesentery: Fibrous Histiocytoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Schwannoma Malignar	nt	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%
*Nose: Adenoma		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%
#Oral Cavity (Oral Mucos Papilloma Squamous o	a, Tongue, Phary	nx, Tooth, Gingiva):  0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcine	a, Tongue, Phary							
-		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phary					1/50 (2%)		
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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 192

			Male Female				1/50 (2%) Total 1/50 (2%) Mean 2% SD 0%  0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%  0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%		
#Oral Mucosa: Squamous Cell Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		1/50 (2%)		SD 0%	
#Oral Mucosa: Squamous Cell Papilloma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%	
*Ovary: Cystadenoma									
Overall Incidence					Total	, ,	Mean 0%	SD 0%	
*Ovary: Fibrosarcoma						0/50 (00/)			
Overall Incidence						0/50 (0%)		SD 0%	
*Ovary: Granulosa Cell Tumor Beniq									
Overall Incidence					Total	` ,	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor Malig	ınant								
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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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Mean 2%

SD 0%

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Length of Study: CHRONIC

Vehicle: FEED

Male Female \*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% ..... \*Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% \*Ovary: **Schwannoma Malignant** 0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% ..... \*Ovary: **Sertoli Cell Tumor Malignant** 0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/50 (0%) \*Ovary: **Tubulostromal Adenoma** 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% \*Pancreas: Adenoma 1/50 (2%)1/50 (2%)

SD 0%

Total

1/50 (2%)

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

**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: PERINATAL AND POSTNATAL

Vehicle: FEED

**Page:** 194

		Male Female				1/50 (2%) Total 1/50 (2%) Mean 2% SD  0/50 (0%) Total 0/50 (0%) Mean 0% SD  0/48 (0%) Total 0/48 (0%) Mean 0% SD  22/50 (44%) Total 22/50 (44%) Mean 44% SD		
*Pancreas: Carcinoma or Adenoma								
Overell lesidence	Tatal	1/50 (2%)	Mana 20/	CD 00/	Tatal	` '	Mana 20/	CD 00/
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	ı otal	1/50 (2%)	Wean 2%	SD 0%
*Pancreas: Mixed Tumor Benign								
		1/50 (2%)				` '		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma		0/25 (00/)				0/40 (00/)		
Overall Incidence	Total	0/35 (0%) 0/35 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Pituitary Gland: Pars Distali Adenoma Overall Incidence	is or Unspeci Total	fied Site: 16/50 (32%) 16/50 (32%)	Mean 32%	SD 0%	Total	22/50 (44%) 22/50 (44%)		SD 0%
*Pituitary Gland: Pars Distali 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%
*Pituitary Gland: Pars Distali Carcinoma or Adenoma								
		16/50 (32%)				22/50 (44%)		
Overall Incidence	Total	16/50 (32%)	Mean 32%	SD 0%	Total	22/50 (44%)	Mean 44%	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: PERINATAL AND POSTNATAL

Vehicle: FEED

**Page:** 195

		Male				Female	
alis or Unspecif	ied Site:						
	0/50 (0%)				0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
rmedia:							
	0/50 (0%)				0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
rmedia:	0/50 (00)				0/50 (00)		
Total	` '	Maan 00/	CD 00/	Total	` '	Maan 00/	SD 0%
	` '		3D 0%	ı Olal	0/50 (0%)	iviean 0%	3D 0%
vosa:	0/50 (0%)				0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	0/50 (0%)						
Total	0/50 (0%)	Mean 0%	SD 0%				
	0/50 (09/)						
Total	, ,	Mean 0%	SD 0%				
	Total  Total  Total  Total  Total  Total  Total	Total 0/50 (0%)  rmedia:  0/50 (0%)  Total 0/50 (0%)  rmedia:  0/50 (0%)  Total 0/50 (0%)  //osa:  0/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)  0/50 (0%)	Alis or Unspecified Site:    0/50 (0%)	Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Tmedia:  0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%	Alis or Unspecified Site:    Total	Alis or Unspecified Site:    Total	Alis or Unspecified Site:    Total   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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 196

		Male Female				0/50 (0%) 0% Total 0/50 (0%) Mean 0%  0/50 (0%) 0% Total 0/50 (0%) Mean 0%  0/50 (0%) 0% Total 0/50 (0%) Mean 0%  0/50 (0%) 0% Total 0/50 (0%) Mean 0%		
*Salivary Glands: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%
*Salivary Glands: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Salivary Glands: Sarcoma		0/50 (0%)				0/50 (09/)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	, ,	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%
#Seminal Vesicle: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Fibrous Histiocytoma		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

Length of Study: CHRONIC

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

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Report Date: 06/05/2013

SD 0%

Mean 0%

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Male **Female #Skeletal Muscle:** Lipoma 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** 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, Basosquamous Tumor Benign, or Trichoepithelioma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) #Skin: **Basal 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% #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 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

## **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: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 198

			Male				Female	
#Skin: Basal Cell Carcinoma, NOS), or Trichoepithel		oma, Basosquamous Tu	mor (benign, maligna	ant or				
,, ,		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:								
		a, Basosq. Tumor (M or ratoacanthoma, Trichoe		ma,		4/50 (00/)		
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
		4/50 (6%)	0%	 		1/50 (2%)	2%	
#Skin: Fibroma								
		5/50 (10%)				0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcom	a, Sarcoma, Myx	oma, Myxosarcoma, or F 5/50 (10%)	ibrous Histiocytoma	1		0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma								
	<b>-</b>	0/50 (0%)		00.00/	<b></b>	0/50 (0%)		00.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcon	na, Myxosarcoma	ı, or Fibrous Histiocytom	na					
		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

**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: PERINATAL AND POSTNATAL

Vehicle: FEED

**Page:** 199

	Male Female				0/50 (0%)  Mean 0%  0/50 (0%)  Mean 0%  7otal 0/50 (0%)  Mean 0%  1/50 (2%)  Total 1/50 (2%)  Mean 2%  0/50 (0%)  Mean 0%				
#Skin: Fibrous Histiocytoma								,	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		` '		SD 0%	
#Skin: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%	
#Skin: Keratoacanthoma									
		2/50 (4%)				1/50 (2%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Skin: Lipoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%		0/50 (0%)	Mean 0%	SD 0%	
#Skin: Liposarcoma									
		0/50 (0%)				` '			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Neural Crest Tumor		0(50 (00))				0/50 (00/)			
Overall Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan OO/	CD 00/	
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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 200

			Male				Female	
#Skin: Neurofibroma or Schwa	nnoma benign							
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:								
Neurofibrosarcoma or \$	Schwannoma (m	•						
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin:								
-	urofibroma, or S	chwannoma (benign, ma	lignant or NOS)					
•	,	0/50 (0%)	,			1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin:								
Sarcoma								
		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 Benign		0/50 (0%)				0/50 (0%)		
	<b>-</b>	` ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Overall Incidence	Lotal	0/50 (0%)						
Overall Incidence	Total	0/50 (0%)						
Overall Incidence  #Skin: Schwannoma Malignan		0/50 (0%)	iviean 0%		····			
#Skin:		0/50 (0%)	wean 0%	35 0/8	1000	1/50 (2%)		

<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: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 201

		Male				0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%  0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0%  0/50 (0%) Mean 0% SD 0%  1/50 (0%) Mean 0% SD 0%			Female				
#Skin: Squamous Cell Carcino	oma												
•		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:													
Squamous Cell Carcino or Carcinoma	oma, Basal Cell C	Carcinoma, Basosquamo	us Tumor (malignar	nt 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: Squamous Cell Papillo	ma			•••••	•••••	•••••							
•		2/50 (4%)				0/50 (0%)							
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%					
#Skin: Squamous Cell Papillo	ma or Papilloma			•••••	•••••	•••••							
	•	2/50 (4%)				0/50 (0%)							
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%					
#Skin: Squamous Cell Papillo	ma, Papilloma, S	quamous Cell Carcinom	a or Keratoacanthor	na									
		4/50 (8%)				1/50 (2%)							
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%					
#Skin: Squamous Cell Papillo	ma, Papilloma, o	r Keratoacanthoma 4/50 (8%)				1/50 (2%)							
Overall Incidence	Total	4/50 (8%)	Mean 8%	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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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(0%)

Mean 0%

0/50

Total

0/50 (0%)

Report Date: 06/05/2013

SD 0%

	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%
#Skin: Sebaceous 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%
#Skin: Sebaceous Gland: 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%
#Spinal Cord: Glioma 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%
#Stomach, Glandular: 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%
#Stomach, Glandular: Carcinoma or Adenoma								

SD 0%

Total

(0%)

Mean 0%

0/50

0/50 (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: 06/05/2013

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

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

			Male		Female			
#Stomach, Glandular: Sarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Testes: Adenoma		41/50 (82%)						
Overall Incidence	Total	41/50 (82%)	Mean 82%	SD 0%				
*Testes: Hemangioma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Benign		1/48 (2%)				0/50 (0%)		
Overall Incidence	Total	1/48 (2.08%)	Mean 2.08%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
Overall Incidence	Total	1/48 (2%) 1/48 (2.08%)	Mean 2.08%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Thymus: Thymoma NOS		0/48 (0%)				0/50 (0%)		
Overall Incidence	Total	0/48 (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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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Report Date: 06/05/2013

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

		Male Fe						
*Thymus: Thymoma: Benign, Malig	nant, NOS	2/48 (4%)				1/50 (2%)		
Overall Incidence	Total	2/48 (4.17%)	Mean 4.17%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Thyroid Gland: C-Cell: Adenoma		12/50 (24%)				6/50 (12%)		
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%
*Thyroid Gland: C-Cell: 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%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
Overall Incidence	Total	12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%	Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%
*Thyroid Gland: Follicular ( Adenoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Thyroid Gland: Follicular ( Carcinoma	Cell:				•••••			
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

**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: PERINATAL AND POSTNATAL

Vehicle: FEED

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	Male						Female			
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:									
		1/50	(2%)				1/50 (2%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Tongue: Squamous 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%	
#Tongue: Squamous Cell Carcinoma o	r Papilloma	a Squamous 0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Papilloma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	` '	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tooth: Adamantinoma 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%	
*Urinary Bladder: 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

**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: PERINATAL AND POSTNATAL

Vehicle: FEED

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*Urinary Bladder: Carcinoma or Papilloma	Male					Female			
		1/50 (	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	(270)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma		0/50 (	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(U70)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Papilloma		0/50 /	(00/)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma							0/50 (09/)		
Overall Incidence						Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma		•••••					0/50 (00)		
Overall Incidence						Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma									
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

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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	Male			Female			
#Uterus: Polyp Stromal							
Overall Incidence		Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%		
#Uterus: Sarcoma				•••••			
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Sarcoma Stromal							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Sarcoma Stromal or Polyp Stromal							
Overall Incidence		Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%		
#Uterus: Schwannoma Malignant							
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Vagina: Polyp							
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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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

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

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