Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Report Date: 11/11/2014

## **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 Northwest	052060103	09/22/08	729	50(5)	30(672)	606.7	Antimony trioxide
Battelle Northwest	052051503	04/14/08	729	50(5)	33(688)	602.8	Metal working fluids (CIMSTAR 3800)
Battelle Northwest	052052303	07/20/09	729	50(5)	36(696)	622.2	Metal working fluids (Trim VX)
					Female		
Battelle Northwest	052060103	09/22/08	730	50(5)	39(704)	395.6	Antimony trioxide
Battelle Northwest	052051503	04/14/08	731	50(5)	35(700)	384.9	Metal working fluids (CIMSTAR 3800)
Battelle Northwest	052052303	07/20/09	731	50(5)	30(681)	391.1	Metal working fluids (Trim VX)

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Benign Tumors								
Overall Incidence	Total	34/50 (68%) 90/150 (60%)	32/50 (64%) Mean 60%	24/50 (48%) SD 10.58%	Total	33/50 (66%) 117/150 (78%)	42/50 (84%) Mean 78%	42/50 (84%) SD 10.39%
#All Organs: Malignant Tumors								
Overall Incidence	Total	6/50 (12%) 23/150 (15.33%)	13/50 (26%) Mean 15.33%	4/50 (8%) SD 9.45%	Total	17/50 (34%) 41/150 (27.33%)	11/50 (22%) Mean 27.33%	13/50 (26%) SD 6.11%
#All Organs: Malignant and Benign Tu	ımors	36/50 (72%)	37/50 (74%)	26/50 (52%)		40/50 (80%)	43/50 (86%)	47/50 (94%)
Overall Incidence	Total	99/150 (66%)	Mean 66%	SD 12.17%	Total	130/150 (86.67%)	Mean 86.67%	SD 7.02%
#All Organs: Hemangioma		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
Overall Incidence	Total	3/50 (6%) 6/150 (4%)	3/50 (6%) Mean 4%	0/50 (0%) SD 3.46%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%
#All Organs: Hemangiosarcoma or He	emangioma							
Overall Incidence	Total	4/50 (8%) 8/150 (5.33%)	3/50 (6%) Mean 5.33%	1/50 (2%) SD 3.06%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%

<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: Wistar Han

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence To	otal	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
#All Organs: Leukemia: Lymphocytic, Monoc	ytic, Mo	nonuclear, or Undifferer	ntiated					
	•	1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence To	otal	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#All Organs:  Malignant Lymphoma: Histiocy		0/50 (0%)	0/50 (0%)	1/50 (2%)	Taral	0/50 (0%)	2/50 (4%)	1/50 (2%)
Overall Incidence To	otal	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 2%
#All Organs: Mesothelioma: Benign, Maligna	nt, NOS	0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence To	otal	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant								
Mesothelioma: Malignant		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Mesothelioma: Malignant	otal	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
•	otal	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	` '	SD 0%
Mesothelioma: Malignant  Overall Incidence  #All Organs:	otal	` '	` ,	` '	Total	` ,	` '	` ,

<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: Wistar Han

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Osteosarcoma or Osteoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Cortex: Adenoma								
Overall Incidence	Total	3/50 (6%) 6/150 (4%)	2/50 (4%) Mean 4%	1/50 (2%) SD 2%	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%
Adrenal Cortex: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Medulla: Pheochromocytoma Benign		•••••	•••••					
Overall Incidence	Total	1/49 (2%) 5/149 (3.36%)	4/50 (8%) Mean 3.35%	0/50 (0%) SD 4.16%	Total	0/49 (0%) 1/148 (0.68%)	1/49 (2%) Mean 0.68%	0/50 (0%) SD 1.18%
Adrenal Medulla: Pheochromocytoma Comple								
Overall Incidence	Total	1/49 (2%) 1/149 (0.67%)	0/50 (0%) Mean 0.68%	0/50 (0%) SD 1.18%	Total	0/49 (0%) 0/148 (0%)	0/49 (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

Strain: Wistar Han

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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		Male Female						
Adrenal Medulla: Pheochromocytoma Ma	alignant							
•	_	0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/148 (0.68%)	Mean 0.68%	SD 1.18%
Adrenal Medulla: Pheochromocytoma: B	enign, Complex	د, Malignant, NOS						
•		2/49 (4%)	4/50 (8%)	0/50 (0%)		0/49 (0%)	2/49 (4%)	0/50 (0%)
verall Incidence	Total	6/149 (4.03%)	Mean 4.03%	SD 4%	Total	2/148 (1.35%)	Mean 1.36%	SD 2.36%
Blood Vessel: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Bone Marrow: Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Bone: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	Female		
#Bone: Osteosarcoma or Osteoma										
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Bone: Sarcoma										
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
*Brain: Glioma										
O	T-1-1	0/50 (0%)	2/50 (4%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%		
'Brain: Glioma Malignant										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Brain: Granular Cell Tumor Benign	l									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	0/50 (0%)		
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 2%		
*Brain: Granular Cell Tumor Maligna	ant									
Occupation of James	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	1/50 (2%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		

<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

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Species: RATS
Strain: Wistar Han

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				0/50 (0%) 0/50 (0%) 0/50 (0%)				
Brain: Meningioma Malignant		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%			
Brain: Meningioma: Benign, Mali	gnant, NOS		•••••			•••••					
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	` '	` ,	` '			
Brain: Oligodendroglioma, Gliom	a, or Astrocy	rtoma 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
Clitoral/Preputial Gland: Carcinoma		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
Clitoral/Preputial Gland: Carcinoma or Adenoma											
overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Heart: Schwannoma Benign					••••••						
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Heart: Schwannoma NOS								
	<b>-</b>	1/50 (2%)	0/50 (0%)	0/50 (0%)	<b></b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
fIntestine Small: Duodenum: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
fIntestine Small: Duodenum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
fIntestine Small: Jejunum: Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Intestine Small: Jejunum: Leiomyosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
fIntestine Small: Site Unspecit Fibroma								
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (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: Wistar Han

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Intestine Small: Site Uns Leiomyoma	pecified:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Small: Site Uns Leiomyosarcoma	pecified:							
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
'Islets, Pancreatic: Adenoma			- / /					
O	T-1-1	0/50 (0%)	0/50 (0%)	5/50 (10%)	T-1-1	0/50 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 5.77%	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%
Islets, Pancreatic: Carcinoma		2/22 (221)	2/52 (221)	2(72 (724)		- ( ( ( ( ( ( ( ( ( (	2/12 (221)	2/22 (221)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%
		0/150 (0%)			10tai	0/149 (0%)		0% ط
Islets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	5/50 (10%)		0/50 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 5.77%	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%
Kidney: Pelvis and Trans Papilloma	itional Epitheli							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: Wistar Han

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Kidney: Renal Tubule: Carcinoma								
	<b>.</b>	0/50 (0%)	0/50 (0%)	1/50 (2%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (00/)	0/50 (00/)	4/50 (00()		0/50 (00/)	4/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
		,				1/130 (0.07/0)		
Kidney: Renal Tubule: Lipoma		0/50 (001)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
overali incidence		` '				0/150 (0%)		
Kidney: Renal Tubule: Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

<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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Liver: Hepatocellular Carcino	ma or Hepatoce	ellular Adenoma						
•	•	0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Liver:		ılar Adenoma, or Hepatok						
	, торилосон	0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Lung: Alveolar/Bronchiolar Ad	denoma	3/50 (6%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	Total	0/150 (0%)	Mean 0%	SD 0%
Lung:		reolar/Bronchiolar Adeno 3/50 (6%) 4/150 (2.67%)		0/50 (0%) SD 3.06%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node: Hemangioma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenterio	c:							
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: Wistar Han

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Lymph Node, Mesenteric:								
		2/50 (4%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 3.06%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	4/50 (8%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	6/150 (4%)	Mean 4%	SD 4%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		5/50 (10%)	4/50 (8%)	4/50 (8%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	13/150 (8.67%)	Mean 8.67%	SD 1.15%
Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		5/50 (10%)	6/50 (12%)	8/50 (16%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	19/150 (12.67%)	Mean 12.67%	SD 3.06%
Mammary Gland: Fibroadenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		7/50 (14%)	9/50 (18%)	2/50 (4%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	18/150 (12%)	Mean 12%	SD 7.21%
#Mammary Gland: Fibroma, Fibroadenoma or	Adenoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		7/50 (14%)	11/50 (22%)	6/50 (12%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	24/150 (16%)	Mean 16%	SD 5.29%

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

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

Strain: Wistar Han

Species: RATS

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

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Report Date: 11/11/2014

Length of Study: CHRONIC

Vehicle: AIR

			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma, C	arcinoma, o	r Adenoma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		10/50 (20%)	13/50 (26%)	9/50 (18%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	32/150 (21.33%)	Mean 21.33%	SD 4.16%
Mesentery: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Mesentery: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mesentery: Schwannoma Malignant								
S	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Nose: Chondroma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Nose: Olfactory Neuroblastoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Oral Cavity (Oral Mucosa Squamous Cell Carcino		ynx, Tooth, Gingiva):						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Oral Cavity (Oral Mucosa		ynx, Tooth, Gingiva): Squamous, or Papilloma						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Oral Mucosa: Squamous Cell Carcino	oma	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Ovary: Adenoma						2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
Ovary: Cystadenoma								
Overall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
Ovary: Granulosa Cell Tumor E	Benign							
Overall Incidence					Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

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

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

Strain: Wistar Han

Species: RATS

## **Toxicology Data Management System**

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Ovary: Granulosa Cell Tumor Ma	alignant							
Overall Incidence					Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
*Ovary: Granulosa Cell Tumor: B								
Overall Incidence					Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%
*Ovary: Sex Cord Stromal Tumor								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
Pancreas: Adenoma						•••••	•••••	
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%
Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/149 (0%)	0/49 (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

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar Han

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male			Female				
Parathyroid Gland: Adenoma					0/39 (0%) 0/47 (0%) 1/42 Total 1/128 (0.78%) Mean 0.79% SD 1  19/50 (38%) 35/50 (70%) 34/50 Total 88/150 (58.67%) Mean 58.67% SD 17  1/50 (2%) 0/50 (0%) 0/50 Total 1/150 (0.67%) Mean 0.67% SD 1  20/50 (40%) 35/50 (70%) 34/50 Total 89/150 (59.33%) Mean 59.33% SD 16					
		0/44 (0%)	0/43 (0%)	0/39 (0%)		, ,	` ,	( ,		
Overall Incidence	Total	0/126 (0%)	Mean 0%	SD 0%		` ,		SD 1.37%		
Pituitary Gland: Pars Distali Adenoma										
		14/50 (28%)	16/49 (33%)	14/50 (28%)		` '	, ,	34/50 (68%)		
Overall Incidence	Total	44/149 (29.53%)	Mean 29.55%	SD 2.69%	Total	88/150 (58.67%)	Mean 58.67%	SD 17.93%		
Pituitary Gland: Pars Distali Carcinoma	s or Unspec		0/40 (00%)	0/50 (00/)		4/50 (00/)	0/50 (004)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	0/49 (0%) Mean 0%	0/50 (0%)	Total	` ,	` ,	0/50 (0%) SD 1.15%		
	Total	0/149 (0%)		SD 0%		` ,				
Pituitary Gland: Pars Distali Carcinoma or Adenoma	s or Unspec	cified Site:								
		14/50 (28%)	16/49 (33%)	14/50 (28%)		, ,	, ,	34/50 (68%)		
Overall Incidence	Total	44/149 (29.53%)	Mean 29.55%	SD 2.69%		` ,		SD 16.77%		
Pituitary Gland: Pars Interm Adenoma										
		1/50 (2%)	2/49 (4%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	1/50 (2%)		
Overall Incidence	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%		
Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:									
		1/50 (2%)	2/49 (4%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	1/50 (2%)		
Overall Incidence	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%		

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

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

Strain: Wistar Han

Species: RATS

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

**Page:** 78

Report Date: 11/11/2014

Vehicle: AIR

Length of Study: CHRONIC

			Male		Female  0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%  Total 0/150 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%			
*Prostate: Adenoma		1/50 (2%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%				
*Prostate: Carcinoma or Adenoma								
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%				
*Salivary Glands: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` ,	` ,	` '
*Salivary Glands: Carcinoma				2/22 (221)		0/50 (00)	(201)	(201)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` '	` '	` '
*Salivary Glands: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Salivary Glands: Myoepithelioma		(00)						(00)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (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

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page**: 79

			Male				Female	
Salivary Glands: Schwannoma Malignant								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
#Skeletal Muscle: Hemangiosarcoma		2/22 (221)	2/72 (221)	2/22 (221)		2/22 (22)	2/22 (224)	2/22 (221)
Overell Incidence	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or Ba	asosquamous	s Tumor Benign						
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (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: Wistar Han

Species: RATS

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/11/2014

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		Male				Female			
#Skin: Basal Cell Adenoma, Ba	asosquamous 1	Fumor Benign, or Trichoe	oithelioma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Skin: Basal Cell Carcinoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
Skin: Basal Cell Carcinoma o	r Basosguamo	us Tumor (malignant or N	OS)						
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
Skin: Basal Cell Carcinoma, E NOS), or Trichoepithelid		oma, Basosquamous Tur	`						
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
Basal or Sq. Cell Carcin		na, Basosq. Tumor (M or E eratoacanthoma, Trichoep	3), Basal Cell Adenon	na,					
Basal or Sq. Cell Carcin		na, Basosq. Tumor (M or E	3), Basal Cell Adenon	na, 1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Basal or Sq. Cell Carcin Adenoma, Papilloma, Sc		na, Basosq. Tumor (M or E eratoacanthoma, Trichoep	3), Basal Cell Adenon ithelioma	•	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
	q Papilloma, Ke	na, Basosq. Tumor (M or E eratoacanthoma, Trichoep 1/50 (2%)	B), Basal Cell Adenom ithelioma 2/50 (4%)	1/50 (2%)	Total	` ,	()	` '	
Basal or Sq. Cell Carcin Adenoma, Papilloma, So Overall Incidence	q Papilloma, Ke	na, Basosq. Tumor (M or E eratoacanthoma, Trichoep 1/50 (2%)	B), Basal Cell Adenom ithelioma 2/50 (4%)	1/50 (2%)	Total	` ,	()	` '	

<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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Fibroma, Fibrosarcoma	, Sarcoma, Myx	koma, Myxosarcoma, or F	ibrous Histiocytoma					
	-	2/50 (4%)	2/50 (4%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
≮Skin: Fibrosarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcoma	ı, Myxosarcom	a, or Fibrous Histiocytoma 0/50 (0%)	<b>a</b> 1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Hamartoma		0/50 /00/)		0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
¢Skin: Hemangiosarcoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Keratoacanthoma		4/50 (00/)	4/50 (00/)	4/50 /00/		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Jveran incluence	ı Ulai	, ,		3D 0%		` '	IVICALI U/0	JD 0/0

<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: Wistar Han

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Lipoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0 SD 1.15%	)%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		1/150 (0.67%)						
Skin: Liposarcoma								
		0/50 (0%)	0/50 (0%)	`	)%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin: Neurofibrosarcoma or Sch	wannoma (r	malignant or NOS) 0/50 (0%)	0/50 (0%)	0/50 (0	0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Neurofibrosarcoma, Neuro	fibroma, or	Schwannoma (benign, ma	alignant or NOS) 0/50 (0%)	0/50 (0	)%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	`	)%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	`	0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (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: Wistar Han

Species: RATS

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: AIR

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			Male				Female	
#Skin: Squamous Cell Carcinoma or Carcinoma	a, Basal Cell	Carcinoma, Basosquamo	us Tumor (malignant	or NOS),				
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		, ,						
Skin: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/150 (0%)	Mean 0%	0/50 (0%) SD 0%
Skin: Squamous Cell Papilloma	or Papilloma	a						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
∕Skin: Squamous Cell Papilloma	, Papilloma, S	Squamous Cell Carcinom	a or Keratoacanthom 1/50 (2%)	<b>a</b> 1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papilloma	, Papilloma, e		4/50 /00/	1/FO (20/)		0/50 (09/)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Sebaceous Gland: Adenoma								
	<b>T</b>	0/50 (0%)	0/50 (0%)	1/50 (2%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: Wistar Han

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma					O) 0/50 (0%) 0/50 (0%) 0/50 (0°)  Total 0/150 (0%) Mean 0% SD 0%  O) 0/50 (0%) 0/50 (0%) 0/50 (0°)  Total 0/150 (0%) Mean 0% SD 0%  O) 0/50 (0%) 0/50 (0%) 0/50 (0°)  Total 0/150 (0%) 0/50 (0%) 0/50 (0°)  Total 0/150 (0%) Mean 0% SD 0%			
		0/50 (0%)	0/50 (0%)	1/50 (2%)		` ,	` '	` ,
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		, ,		SD 0%
Spleen: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		` ,	` ,	` ,
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Fibrosarcoma		0/50 (00/)	0/50 /00/	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` ,	` ,	` ,
		, ,				0/150 (0%)	Wear 076	SD 0%
Stomach, Forestomach: Leiomyoma								
O II I I I	T-1-1	0/50 (0%)	1/50 (2%)	0/50 (0%)	T-1-1	` ,	` '	` '
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		,		
Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Stomach, Forestomach:								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: Wistar Han

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma	or Papillom	a Squamous						
•	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Fibrosarcoma		0/50 (00/)	0/50 (00/)	0/50 (004)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Glandular: Leiomyosarcoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Stomach, Glandular: Sarcoma		0/50 /00/	4/50 /000	0/50 (0%)		0/50 (0%)	0/50 (00()	0/50 /00/
Overell Incidence	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: Wistar Han

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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	Male					Female			
*Testes: Adenoma									
		6/50 (12%)	2/50 (4%)	0/50 (0%)					
Overall Incidence	Total	8/150 (5.33%)	Mean 5.33%	SD 6.11%					
*Testes: Hemangiosarcoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%					
*Thymus: Sarcoma									
Overall Incidence	Total	0/41 (0%)	0/40 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/46 (0%)	0/48 (0%) Mean 0%	0/48 (0%) SD 0%	
Overall incidence		0/129 (0%)		3D 0%	Total	0/142 (0%)	wiean 0%	טע עס U%	
*Thymus: Thymoma Benign		774	./	2/12 /22/		2(12 (122))	-/ ///	2/42 /4-2/)	
Overall Incidence	Total	3/41 (7%) 7/129 (5.43%)	1/40 (3%) Mean 5.36%	3/48 (6%) SD 2.53%	Total	6/46 (13%) 19/142 (13.38%)	5/48 (10%) Mean 13.38%	8/48 (17%) SD 3.14%	
		1/129 (5.45%)				19/142 (13.30%)		3D 3.14%	
*Thymus: Thymoma: Benign, Malig	ınant, NOS								
		3/41 (7%)	1/40 (3%)	3/48 (6%)		6/46 (13%)	5/48 (10%)	8/48 (17%)	
Overall Incidence	Total	7/129 (5.43%)	Mean 5.36%	SD 2.53%	Total	19/142 (13.38%)	Mean 13.38%	SD 3.14%	
*Thyroid Gland: Carcinoma									
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>+</b>	1/50 (2%)	0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	

<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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male		Female				
*Thyroid Gland: C-Cell: Adenoma		5/50 (10%)	7/50 (14%)	3/50 (6%)		4/50 (8%)	3/50 (6%)	7/49 (14%)	
Overall Incidence	Total	15/150 (10%)	Mean 10%	SD 4%	Total	14/149 (9.4%)	Mean 9.43%	SD 4.32%	
*Thyroid Gland: C-Cell: Carcinoma									
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 1/149 (0.67%)	0/50 (0%) Mean 0.67%	0/49 (0%) SD 1.15%	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
Overall Incidence	Total	6/50 (12%) 16/150 (10.67%)	7/50 (14%) Mean 10.67%	3/50 (6%) SD 4.16%	Total	5/50 (10%) 15/149 (10.07%)	3/50 (6%) Mean 10.1%	7/49 (14%) SD 4.14%	
*Thyroid Gland: Follicular Cell Adenoma	:								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 2/149 (1.34%)	1/50 (2%) Mean 1.33%	0/49 (0%) SD 1.15%	
*Thyroid Gland: Follicular Cell Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 3/149 (2.01%)	1/50 (2%) Mean 2.01%	1/49 (2%) SD 0.02%	
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:		•••••						
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	2/50 (4%) 5/149 (3.36%)	2/50 (4%) Mean 3.35%	1/49 (2%) SD 1.13%	

<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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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	Male					Female			
Urinary Bladder: Carcinoma or Papilloma									
	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b></b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
rinary Bladder: Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Jterus: Adenoma									
						0/50 (0%)	0/50 (0%)	1/50 (2%)	
verall Incidence					Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
lterus: Carcinoma						3/50 (6%)	1/50 (2%)	1/50 (2%)	
verall Incidence					Total	5/150 (3.33%)	Mean 3.33%	SD 2.31%	
Iterus: Granular Cell Tumor Benig	n								
						0/50 (0%)	0/50 (0%)	1/50 (2%)	
verall Incidence					Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
lterus: Hemangiosarcoma									
						1/50 (2%)	0/50 (0%)	0/50 (0%)	
verall Incidence					Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	

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

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

Strain: Wistar Han

Species: RATS

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

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus:** Leiomyosarcoma 1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% #Uterus: **Malignant Mixed Mullerian Tumor** 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% #Uterus: **Polyp Stromal** 2/50 (4%)5/50 (10%) 6/50 (12%) **Overall Incidence** Total 13/150 (8.67%) Mean 8.67% SD 4.16% ..... #Uterus: Sarcoma Stromal 1/50 (2%)2/50 (4%)1/50 (2%)**Overall Incidence** Total 4/150 (2.67%) Mean 2.67% SD 1.15% #Uterus: Sarcoma Stromal or Polyp Stromal 3/50 (6%)6/50 (12%) 7/50 (14%) **Overall Incidence** Total 16/150 (10.67%) Mean 10.67% SD 4.16% **#Uterus: Schwannoma Malignant** 0/50 (0%)0/50 (0%)2/50 (4%)**Overall Incidence** 2/150 (1.33%) Mean 1.33% SD 2.31% Total

<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: Wistar Han

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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		Male						Female			
tUterus: Squamous Cell Papilloma							(20)		2/22 (22)		
Overall Incidence						Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%		
Vagina: Fibrosarcoma											
verall Incidence						Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%		
Vagina: Leiomyoma											
verall Incidence						Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
/agina: Polyp			•••••								
verall Incidence						Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Zymbal's Gland: Carcinoma			•••••								
verall incidence	Total	0/50 (0%) 3/150 (2%)	2/50 (4%) Mean 2%	1/50 SD 2%	(2%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Zymbal's Gland: Carcinoma or Adenoma											
Overall Incidence	Total	0/50 (0%) 3/150 (2%)	2/50 (4%) Mean 2%	1/50 SD 2%	(2%)	Total	0/50 (0%) 0/150 (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