

TDMS No. 20214 - 01

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Date Report Reqsted: 04/02/2008

Test Type: 90-DAY

5-Amino-o-cresol

Time Report Reqsted: 09:24:09

Route: SKIN APPLICATION

CAS Number: 2835-95-2

First Dose M/F: 05/08/06 / 05/09/06

Species/Strain: RATS/F344/N Tac

Lab: BAT

F1_RD

C Number: C20214

Lock Date: 12/04/2006

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

TDMSE Version: 1.9.1

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Lab: BAT

Fischer 344-Taconic RATS MALE	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
Disposition Summary						
Animals Initially in Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Parasite Metazoan						2 [1.0]
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Hepatodiaphragmatic Nodule				1		
Inflammation, Chronic Active	9 [1.0]			1 [1.0]		9 [1.0]
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	1 [1.0]					
Acinus, Atrophy						2 [1.0]
CARDIOVASCULAR SYSTEM						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy	10 [1.0]					10 [1.0]
ENDOCRINE SYSTEM						
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular, Mononuclear Cell	1 [1.0]					2 [1.0]
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Cyst	1 [1.0]					
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Mononuclear Cell						1 [1.0]
GENERAL BODY SYSTEM						
None						

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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Fischer 344-Taconic RATS MALE	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
GENITAL SYSTEM						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular, Mononuclear Cell Inflammation, Chronic Active	1 [1.0]					2 [1.0]
HEMATOPOIETIC SYSTEM						
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Histiocytic						1 [1.0]
INTEGUMENTARY SYSTEM						
None						
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte Inflammation, Chronic Active	2 [1.0] 3 [1.3]					4 [1.0] 5 [1.2]
Metaplasia, Osseous Interstitialium, Inflammation, Chronic Active	2 [1.0]	5 [1.0]	7 [1.0]	8 [1.0]	6 [1.2]	1 [1.0]
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular, Mononuclear Cell	5 [1.0]					3 [1.0]
SPECIAL SENSES SYSTEM						

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Fischer 344-Taconic RATS MALE	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular, Mononuclear Cell						1 [1.0]
Inflammation, Chronic Active	1 [3.0]					1 [3.0]
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular, Mononuclear Cell	1 [1.0]					1 [1.0]
Mineralization	6 [1.0]					6 [1.0]
Nephropathy	10 [1.0]					10 [1.0]

*** END OF MALE ***

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Species/Strain: RATS/F344/N Tac

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Fischer 344-Taconic RATS FEMALE	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
Disposition Summary						
Animals Initially in Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Parasite Metazoan	1 [1.0]					
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Hematopoietic Cell Proliferation				1 [1.0]		
Hepatodiaphragmatic Nodule	2	3	2	3	2	1
Inflammation, Chronic Active	10 [1.1]	1 [1.0]	2 [1.0]	2 [1.0]	2 [1.0]	10 [1.5]
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Acinus, Atrophy	2 [1.0]					1 [1.0]
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular, Mononuclear Cell						1 [1.0]
CARDIOVASCULAR SYSTEM						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy	10 [1.0]					9 [1.0]
ENDOCRINE SYSTEM						
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Mononuclear Cell						1 [1.0]
GENERAL BODY SYSTEM						
None						

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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Fischer 344-Taconic RATS FEMALE	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
GENITAL SYSTEM						
Ovary	(10)	(0)	(0)	(1)	(0)	(10)
Left, Cyst				1 [2.0]		
Left, Inflammation				1 [2.0]		
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular, Histiocyte						1 [2.0]
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Histiocytic						5 [2.0]
INTEGUMENTARY SYSTEM						
None						
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte						1 [1.0]
Inflammation, Chronic Active	2 [1.0]					6 [1.0]
Interstitial, Inflammation, Chronic Active		2 [1.0]	6 [1.7]	3 [1.3]	5 [1.2]	
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active						2 [2.0]
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular, Mononuclear Cell	3 [1.0]					1 [1.0]

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Fischer 344-Taconic RATS FEMALE	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
SPECIAL SENSES SYSTEM						
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular, Mononuclear Cell						2 [1.0]
Inflammation, Chronic Active	1 [1.0]					3 [1.0]
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular, Lipocyte	1 [1.0]					
Infiltration Cellular, Mononuclear Cell	1 [1.0]					
Mineralization	7 [1.0]					7 [1.0]
Nephropathy	3 [1.0]					
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular, Mononuclear Cell	1 [1.0]					1 [1.0]

*** END OF REPORT ***