

Experiment Number: 20306 - 03

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

Date Report Requested: 08/27/2015

Test Type: 90-DAY

PCN 66/67 comparison study

Time Report Requested: 09:31:49

Route: GAVAGE

CAS Number: PCNCOMPARISN

First Dose M/F: NA / 10/13/03

Species/Strain: RATS/F 344/N

Lab: BAT

F1_Rev.1_PCN66

NTP Study Number: C20306

Lock Date: 10/07/2004

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include 001 0 NG/KG

Include 002 1000 NG/KG 66

Include 003 10,000 NG/KG 66

Include 004 50,000 NG/KG 66

Include 005 100,000 NG/KG 66

Include 006 200,000 NG/KG 66

Study Gender: Female

TDMSE Version: 3.0.2.2_002

PWG Approval Date: NONE

Test Type: 90-DAY

PCN 66/67 comparison study

Time Report Requested: 09:31:49

Route: GAVAGE

CAS Number: PCNCOMPARISN

First Dose M/F: NA / 10/13/03

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 NG/KG	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
-------------------------	---------	---------------	-----------------	-----------------	------------------	------------------

Disposition Summary

Animals Initially In Study	15	10	10	10	10	10
Early Deaths						
Natural Death						2
Survivors						
Terminal Sacrifice	15	10	10	10	10	8
Animals Examined Microscopically	15	10	10	10	10	10

ALIMENTARY SYSTEM

Esophagus	(15)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(15)	(0)	(0)	(0)	(0)	(9)
Intestine Large, Colon	(15)	(0)	(0)	(1)	(0)	(10)
Serosa, Cyst				1 [2.0]		
Intestine Large, Rectum	(15)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(15)	(10)	(10)	(10)	(10)	(9)
Intestine Small, Ileum	(15)	(0)	(0)	(0)	(0)	(9)
Intestine Small, Jejunum	(15)	(0)	(0)	(0)	(0)	(9)
Liver	(15)	(10)	(10)	(10)	(10)	(9)
Clear Cell Focus					1	
Fatty Change				1 [1.0]	7 [1.1]	9 [1.8]
Hematopoietic Cell Proliferation						1 [1.0]
Hepatocyte, Multinucleate					10 [1.1]	9 [1.9]
Hepatodiaphragmatic Nodule	1	2	3	1	1	2
Inflammation, Suppurative						3 [1.0]
Inflammation, Granulomatous					8 [1.1]	
Inflammation, Chronic Active	7 [1.0]	6 [1.0]	8 [1.0]	9 [1.1]	9 [1.1]	8 [1.0]
Necrosis, Focal					1 [1.0]	
Pigmentation				1 [1.0]		4 [1.0]
Toxic Hepatopathy					8 [1.0]	9 [2.8]
Bile Duct, Cyst						1 [3.0]
Bile Duct, Hyperplasia						6 [1.2]
Hepatocyte, Degeneration						4 [1.0]
Hepatocyte, Glandular Structures						5 [2.0]
Hepatocyte, Hyperplasia						6 [1.5]

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)

Test Type: 90-DAY

PCN 66/67 comparison study

Time Report Requested: 09:31:49

Route: GAVAGE

CAS Number: PCNCOMPARISN

First Dose M/F: NA / 10/13/03

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 NG/KG	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Hepatocyte, Hypertrophy	1 [1.0]			4 [1.0]	10 [2.1]	9 [3.8]
Oval Cell, Hyperplasia						8 [1.1]
Portal Vein, Fibrosis, Focal						2 [2.0]
Mesentery	(0)	(0)	(1)	(0)	(0)	(0)
Fat, Necrosis			1 [1.0]			
Pancreas	(15)	(10)	(10)	(10)	(10)	(9)
Infiltration Cellular, Mononuclear Cell	7 [1.0]	5 [1.0]	4 [1.0]	6 [1.0]	3 [1.0]	6 [1.0]
Acinus, Atrophy, Focal					1 [1.0]	
Acinus, Vacuolization Cytoplasmic						1 [1.0]
Salivary Glands	(15)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(15)	(10)	(10)	(10)	(10)	(9)
Infiltration Cellular, Mononuclear Cell	1 [1.0]					
Epithelium, Hyperplasia, Squamous						1 [1.0]
Stomach, Glandular	(15)	(0)	(0)	(0)	(0)	(9)
Infiltration Cellular, Mononuclear Cell	4 [1.0]					2 [1.0]
Glands, Ectasia						1 [1.0]
Tongue	(15)	(0)	(0)	(0)	(0)	(10)

CARDIOVASCULAR SYSTEM

Blood Vessel	(15)	(0)	(0)	(0)	(0)	(10)
Aorta, Thrombus						3 [2.7]
Pulmonary Artery, Thrombus						1 [3.0]
Heart	(15)	(10)	(10)	(10)	(10)	(10)
Cardiomyopathy	9 [1.0]	8 [1.0]	7 [1.0]	7 [1.0]	4 [1.0]	4 [1.0]
Myocardium, Inflammation						3 [2.7]
Valve, Thrombus						1 [3.0]
Ventricle, Thrombus						2 [2.5]

ENDOCRINE SYSTEM

Adrenal Cortex	(15)	(10)	(10)	(10)	(10)	(9)
Infiltration Cellular, Mixed Cell			1 [1.0]			
Inflammation, Histiocytic					1 [2.0]	
Zona Fasciculata, Vacuolization Cytoplasmic			1 [1.0]			

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)

Test Type: 90-DAY

PCN 66/67 comparison study

Time Report Requested: 09:31:49

Route: GAVAGE

CAS Number: PCNCOMPARISN

First Dose M/F: NA / 10/13/03

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 NG/KG	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Adrenal Medulla	(15)	(10)	(10)	(10)	(10)	(9)
Parathyroid Gland	(13)	(0)	(0)	(0)	(0)	(9)
Pituitary Gland	(15)	(10)	(10)	(10)	(10)	(10)
Cyst					1 [1.0]	
Thyroid Gland	(15)	(10)	(10)	(10)	(10)	(9)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(15)	(0)	(0)	(0)	(0)	(10)
Ovary	(15)	(10)	(10)	(10)	(10)	(9)
Atrophy						9 [1.2]
Periovarian Tissue, Cyst	1 [1.0]					
Uterus	(15)	(10)	(10)	(10)	(10)	(9)
Atrophy						9 [1.9]
Vagina	(15)	(10)	(10)	(10)	(10)	(9)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(15)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mesenteric	(15)	(10)	(10)	(10)	(10)	(9)
Atrophy	1 [1.0]			1 [1.0]		4 [1.3]
Hyperplasia, Lymphoid					1 [2.0]	
Infiltration Cellular, Histiocyte	6 [1.2]	6 [1.0]	6 [1.0]	5 [1.2]	9 [1.4]	3 [1.3]
Infiltration Cellular, Plasma Cell						1 [2.0]
Spleen	(15)	(10)	(10)	(10)	(10)	(9)
Hematopoietic Cell Proliferation				1 [1.0]		
Pigmentation, Hemosiderin	15 [1.1]	10 [1.0]	10 [1.0]	10 [1.2]	10 [1.0]	8 [1.0]
Thymus	(15)	(10)	(10)	(10)	(10)	(10)
Atrophy				1 [1.0]	2 [1.0]	10 [3.8]

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)

Test Type: 90-DAY

PCN 66/67 comparison study

Time Report Requested: 09:31:49

Route: GAVAGE

CAS Number: PCNCOMPARISN

First Dose M/F: NA / 10/13/03

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 NG/KG	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
INTEGUMENTARY SYSTEM						
Mammary Gland	(15)	(10)	(10)	(10)	(10)	(10)
Skin	(15)	(10)	(10)	(10)	(10)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(15)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(15)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY SYSTEM						
Lung	(15)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active Metaplasia, Squamous		1 [1.0]	1 [1.0]	1 [1.0]	1 [1.0]	1 [1.0]
Alveolar Epithelium, Hyperplasia	1 [2.0]	2 [1.0]	1 [1.0]	1 [1.0]		
Alveolus, Infiltration Cellular, Histiocyte	3 [1.0]	2 [1.0]	2 [1.0]	3 [1.0]	6 [1.0]	6 [1.2]
Interstitial, Inflammation, Granulomatous	1 [1.0]				1 [1.0]	
Nose	(15)	(0)	(0)	(0)	(0)	(10)
Trachea	(15)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
Eye	(15)	(0)	(0)	(0)	(0)	(10)
Harderian Gland	(15)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Mononuclear Cell Duct, Metaplasia, Squamous		1 [1.0]		2 [1.0]	1 [1.0]	8 [1.9] 1 [2.0]
URINARY SYSTEM						

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)

Experiment Number: 20306 - 03

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

Date Report Requested: 08/27/2015

Test Type: 90-DAY

PCN 66/67 comparison study

Time Report Requested: 09:31:49

Route: GAVAGE

CAS Number: PCNCOMPARISN

First Dose M/F: NA / 10/13/03

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 NG/KG	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Kidney	(15)	(10)	(10)	(10)	(10)	(9)
Mineralization	15 [1.0]	7 [1.0]	10 [1.0]	7 [1.0]	5 [1.0]	7 [1.0]
Nephropathy	2 [1.0]	1 [1.0]	1 [1.0]	3 [1.0]	4 [1.0]	4 [1.0]
Urinary Bladder	(15)	(0)	(0)	(0)	(0)	(9)
Infiltration Cellular, Lymphocyte	1 [1.0]					

*** END OF REPORT ***

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)