

**Experiment Number:** 20306 - 03  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
PCN 66/67 comparison study  
**CAS Number:** PCNCOMPARISN

**Date Report Requested:** 08/27/2015  
**Time Report Requested:** 09:31:49  
**First Dose M/F:** NA / 10/13/03  
**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

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Lab: BAT

FISCHER 344 RATS FEMALE 0 NG/KG	DAY ON TEST															* TOTALS
	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	
ANIMAL ID	0 0 0 0 1	0 0 0 0 2	0 0 0 0 3	0 0 0 0 4	0 0 0 0 5	0 0 0 0 6	0 0 0 0 7	0 0 0 0 8	0 0 0 0 9	0 0 0 0 0	0 0 0 0 1	0 0 0 0 1	0 0 0 0 2	0 0 0 0 3	0 0 0 0 4	0 0 0 0 5

ALIMENTARY SYSTEM

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15	
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15	
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15	
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15	
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15	
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15	
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15	
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15	
Hepatodiaphragmatic Nodule															X		1
Inflammation, Chronic Active			1	1		1		1				1	1		1		7 1.0
Hepatocyte, Hypertrophy															1		1 1.0
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15	
Infiltration Cellular, Mononuclear Cell	1	1			1			1	1			1		1			7 1.0
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15	
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15	
Infiltration Cellular, Mononuclear Cell												1					1 1.0
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15	

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

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Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	ANIMAL ID				
	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9					
FISCHER 344 RATS FEMALE	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	0	0	0	0	
0 NG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5						
																	* TOTALS				
Infiltration Cellular, Mononuclear Cell	1			1			1			1							4	1.0			
Tongue	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+					15	
<b>CARDIOVASCULAR SYSTEM</b>																					
Blood Vessel	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+					15	
Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+					15	
Cardiomyopathy	1			1			1			1			1							9	1.0
<b>ENDOCRINE SYSTEM</b>																					
Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+					15	
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+					15	
Parathyroid Gland	+	+	M	+	+	+	+	+	+	+	+	+	+	+	M					13	
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+					15	
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+					15	
<b>GENERAL BODY SYSTEM</b>																					
NONE																					
<b>GENITAL SYSTEM</b>																					
Clitoral Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+					15	
Ovary	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+					15	

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

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BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

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Lab: BAT

FISCHER 344 RATS FEMALE 0 NG/KG	DAY ON TEST															* TOTALS
	0 4	0 4	0 4	0 4	0 4	0 4	0 4	0 4	0 4	0 4	0 4	0 4	0 4	0 4	0 4	
ANIMAL ID	0 0 0 0 1	0 0 0 0 2	0 0 0 0 3	0 0 0 0 4	0 0 0 0 5	0 0 0 0 6	0 0 0 0 7	0 0 0 0 8	0 0 0 0 9	0 0 0 0 0	0 0 0 0 1	0 0 0 0 1	0 0 0 0 2	0 0 0 0 3	0 0 0 0 4	0 0 0 0 5
	Periovarian Tissue, Cyst															1
Uterus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
Vagina	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
<b>HEMATOPOIETIC SYSTEM</b>																
Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	0
Lymph Node, Mesenteric Atrophy	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
Infiltration Cellular, Histiocyte			1				1			1	1		2	1		6 1.2
Spleen Pigmentation, Hemosiderin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	15 1.1
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
<b>INTEGUMENTARY SYSTEM</b>																
Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
<b>MUSCULOSKELETAL SYSTEM</b>																
Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15

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 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
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Lab: BAT

FISCHER 344 RATS FEMALE	DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
0 NG/KG		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	
		4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5		<b>* TOTALS</b>

**NERVOUS SYSTEM**

Brain + + + + + + + + + + + + + + + 15

**RESPIRATORY SYSTEM**

Lung + + + + + + + + + + + + + + + 15  
 Alveolar Epithelium, Hyperplasia 2 1 2.0  
 Alveolus, Infiltration Cellular, Histiocyte 1 3 1.0  
 Interstitium, Inflammation, Granulomatous 1 1 1.0

Nose + + + + + + + + + + + + + + + 15

Trachea + + + + + + + + + + + + + + + 15

**SPECIAL SENSES SYSTEM**

Eye + + + + + + + + + + + + + + + 15

Harderian Gland + + + + + + + + + + + + + + + 15

**URINARY SYSTEM**

Kidney + + + + + + + + + + + + + + + 15  
 Mineralization 1 1 1 1 1 1 1 1 1 1 1 1 1 1 15 1.0  
 Nephropathy 1 1 2 1.0

Urinary Bladder + + + + + + + + + + + + + + + 15  
 Infiltration Cellular, Lymphocyte 1 1 1.0

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically M .. Missing tissue  
 X .. Lesion present A .. Autolysis precludes evaluation  
 I .. Insufficient tissue BLANK .. Not examined microscopically

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FISCHER 344 RATS FEMALE	DAY ON TEST	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		9	9	9	9	9	9	9	9	9	
		4	4	4	4	4	4	4	4	4	
1000 NG/KG 66	ANIMAL ID	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		1	1	1	1	1	1	1	1	1	
		0	0	0	0	0	0	0	0	1	
	1	2	3	4	5	6	7	8	9	0	* TOTALS

ALIMENTARY SYSTEM

Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	10
Liver	+	+	+	+	+	+	+	+	+	+	10
Hepatodiaphragmatic Nodule		X						X			2
Inflammation, Chronic Active		1	1	1		1	1		1		6 1.0
Pancreas	+	+	+	+	+	+	+	+	+	+	10
Infiltration Cellular, Mononuclear Cell	1			1	1		1	1			5 1.0
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	10

CARDIOVASCULAR SYSTEM

Heart	+	+	+	+	+	+	+	+	+	+	10
Cardiomyopathy	1		1	1	1	1	1	1	1		8 1.0

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	10
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	10
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	10
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	10

GENERAL BODY SYSTEM

NONE

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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

Lab: BAT

FISCHER 344 RATS FEMALE 1000 NG/KG 66	DAY ON TEST										ANIMAL ID
	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	0 9 4	
	0	0	0	0	0	0	0	0	0	0	0 0 1 0 1
	2	3	4	5	6	7	8	9	0		
	<b>* TOTALS</b>										

GENITAL SYSTEM

Ovary	+	+	+	+	+	+	+	+	+	+	10
Uterus	+	+	+	+	+	+	+	+	+	+	10
Vagina	+	+	+	+	+	+	+	+	+	+	10

HEMATOPOIETIC SYSTEM

Lymph Node, Mesenteric Infiltration Cellular, Histiocyte	+	+	+	+	+	+	+	+	+	+	10	6	1.0
Spleen Pigmentation, Hemosiderin	+	+	+	+	+	+	+	+	+	+	10	10	1.0
Thymus	+	+	+	+	+	+	+	+	+	+	10		

INTEGUMENTARY SYSTEM

Mammary Gland	+	+	+	+	+	+	+	+	+	+	10
Skin	+	+	+	+	+	+	+	+	+	+	10

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

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DAY ON TEST		0	0	0	0	0	0	0	0	0	0
<b>FISCHER 344 RATS FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	9	9	9	9	9	9
	4	4	4	4	4	4	4	4	4	4	4
	<hr/>										
<b>10,000 NG/KG 66</b>	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	1	1	1	2
	1	2	3	4	5	6	7	8	9	0	

**\* TOTALS**

**ALIMENTARY SYSTEM**

Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	<b>10</b>		
Liver	+	+	+	+	+	+	+	+	+	+	<b>10</b>		
Hepatodiaphragmatic Nodule			X				X	X				<b>3</b>	
Inflammation, Chronic Active	1	1	1	1	1	1		1	1			<b>8</b>	<b>1.0</b>
Mesentery			+								<b>1</b>		
Fat, Necrosis			1									<b>1</b>	<b>1.0</b>
Pancreas	+	+	+	+	+	+	+	+	+	+	<b>10</b>		
Infiltration Cellular, Mononuclear Cell		1			1			1	1			<b>4</b>	<b>1.0</b>
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	<b>10</b>		

**CARDIOVASCULAR SYSTEM**

Heart	+	+	+	+	+	+	+	+	+	+	<b>10</b>		
Cardiomyopathy	1	1		1		1	1		1	1		<b>7</b>	<b>1.0</b>

**ENDOCRINE SYSTEM**

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	<b>10</b>		
Infiltration Cellular, Mixed Cell							1					<b>1</b>	<b>1.0</b>
Zona Fasciculata, Vacuolization Cytoplasmic		1										<b>1</b>	<b>1.0</b>
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	<b>10</b>		
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>		

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DAY ON TEST	0	0	0	0	0	0	0	0	0	0	ANIMAL ID
	9	9	9	9	9	9	9	9	9	9	
<b>FISCHER 344 RATS FEMALE</b>	4	4	4	4	4	4	4	4	4	4	
<b>10,000 NG/KG 66</b>	0	0	0	0	0	0	0	0	0	0	
	1	1	1	1	1	1	1	1	1	1	
	1	1	1	1	1	1	1	1	1	2	
	1	2	3	4	5	6	7	8	9	0	<b>* TOTALS</b>

Thyroid Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>
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**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

Ovary	+	+	+	+	+	+	+	+	+	+	<b>10</b>
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Uterus	+	+	+	+	+	+	+	+	+	+	<b>10</b>
--------	---	---	---	---	---	---	---	---	---	---	-----------

Vagina	+	+	+	+	+	+	+	+	+	+	<b>10</b>
--------	---	---	---	---	---	---	---	---	---	---	-----------

**HEMATOPOIETIC SYSTEM**

Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Infiltration Cellular, Histiocyte	1	1	1			1	1			1	<b>6 1.0</b>

Spleen	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Pigmentation, Hemosiderin	1	1	1	1	1	1	1	1	1	1	<b>10 1.0</b>

Thymus	+	+	+	+	+	+	+	+	+	+	<b>10</b>
--------	---	---	---	---	---	---	---	---	---	---	-----------

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>
---------------	---	---	---	---	---	---	---	---	---	---	-----------

Skin	+	+	+	+	+	+	+	+	+	+	<b>10</b>
------	---	---	---	---	---	---	---	---	---	---	-----------

**MUSCULOSKELETAL SYSTEM**

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Lab: BAT

FISCHER 344 RATS FEMALE 10,000 NG/KG 66	DAY ON TEST	0	0	0	0	0	0	0	0	0	0	
	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	
		9	9	9	9	9	9	9	9	9	9	
		4	4	4	4	4	4	4	4	4	4	
		0	0	0	0	0	0	0	0	0	0	
		1	1	1	1	1	1	1	1	1	1	
		1	1	1	1	1	1	1	1	1	2	
		1	2	3	4	5	6	7	8	9	0	
<b>* TOTALS</b>												

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

Lung	+	+	+	+	+	+	+	+	+	+	10	
Inflammation, Chronic Active							1					1 1.0
Alveolar Epithelium, Hyperplasia								1				1 1.0
Alveolus, Infiltration Cellular, Histiocyte	1							1				2 1.0

SPECIAL SENSES SYSTEM

Harderian Gland	+	+	+	+	+	+	+	+	+	+	10	
-----------------	---	---	---	---	---	---	---	---	---	---	----	--

URINARY SYSTEM

Kidney	+	+	+	+	+	+	+	+	+	+	10	
Mineralization	1	1	1	1	1	1	1	1	1	1		10 1.0
Nephropathy			1									1 1.0

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked



Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 09:31:49

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

Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	ANIMAL ID	
	9	9	9	9	9	9	9	9	9	9		
<b>FISCHER 344 RATS FEMALE</b>	4	4	4	4	4	4	4	4	4	4		
<b>50,000 NG/KG 66</b>	0	0	0	0	0	0	0	0	0	0		
	1	1	1	1	1	1	1	1	1	1		
	2	2	2	2	2	2	2	2	2	3		
	1	2	3	4	5	6	7	8	9	0		<b>* TOTALS</b>

Pituitary Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

Ovary	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Uterus	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Vagina	+	+	+	+	+	+	+	+	+	+	<b>10</b>

**HEMATOPOIETIC SYSTEM**

Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Atrophy							1					<b>1 1.0</b>
Infiltration Cellular, Histiocyte		2	1	1				1	1			<b>5 1.2</b>
Spleen	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Hematopoietic Cell Proliferation							1					<b>1 1.0</b>
Pigmentation, Hemosiderin	1	2	1	1	1	1	1	1	1	2		<b>10 1.2</b>
Thymus	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Atrophy	1											<b>1 1.0</b>

**INTEGUMENTARY SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
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Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 09:31:49

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

Lab: BAT

<b>FISCHER 344 RATS FEMALE</b>	DAY ON TEST	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		9	9	9	9	9	9	9	9	9	
		4	4	4	4	4	4	4	4	4	
<b>50,000 NG/KG 66</b>	ANIMAL ID	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		1	1	1	1	1	1	1	1	1	
		2	2	2	2	2	2	2	2	3	
		1	2	3	4	5	6	7	8	9	0

\* TOTALS

Mammary Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>
---------------	---	---	---	---	---	---	---	---	---	---	-----------

Skin	+	+	+	+	+	+	+	+	+	+	<b>10</b>
------	---	---	---	---	---	---	---	---	---	---	-----------

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

Lung	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Inflammation, Chronic Active						1						<b>1 1.0</b>
Alveolar Epithelium, Hyperplasia				1								<b>1 1.0</b>
Alveolus, Infiltration Cellular, Histiocyte				1	1		1					<b>3 1.0</b>

SPECIAL SENSES SYSTEM

Harderian Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Infiltration Cellular, Mononuclear Cell	1			1								<b>2 1.0</b>

URINARY SYSTEM

Kidney	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Mineralization	1	1	1		1	1			1	1		<b>7 1.0</b>
Nephropathy							1	1	1			<b>3 1.0</b>

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

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Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 09:31:49

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

Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	FISCHER 344 RATS FEMALE
	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	9	9	9	9	9	9	9	9	9	9	100,000 NG/KG 66
	4	4	4	4	4	4	4	4	4	4	
	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	1	1	1	1	1	1	1	1	1	1	
	3	3	3	3	3	3	3	3	3	4	
	1	2	3	4	5	6	7	8	9	0	
<b>* TOTALS</b>											

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Skin	+	+	+	+	+	+	+	+	+	+	<b>10</b>

**MUSCULOSKELETAL SYSTEM**

NONE

**NERVOUS SYSTEM**

NONE

**RESPIRATORY SYSTEM**

Lung	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Inflammation, Chronic Active	1											<b>1 1.0</b>
Metaplasia, Squamous				1								<b>1 1.0</b>
Alveolus, Infiltration Cellular, Histiocyte	1	1		1		1			1	1		<b>6 1.0</b>
Interstitialium, Inflammation, Granulomatous			1									<b>1 1.0</b>

**SPECIAL SENSES SYSTEM**

Harderian Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Infiltration Cellular, Mononuclear Cell									1			<b>1 1.0</b>

**URINARY SYSTEM**

Kidney	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Mineralization	1			1		1	1	1				<b>5 1.0</b>

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

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Experiment Number: 20306 - 03

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CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 09:31:49

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

Lab: BAT

		0	0	0	0	0	0	0	0	0	
DAY ON TEST		0	0	0	0	0	0	0	0	0	
FISCHER 344 RATS FEMALE		9	9	9	9	9	9	9	9	9	
		4	4	4	4	4	4	4	4	4	
100,000 NG/KG 66		0	0	0	0	0	0	0	0	0	
ANIMAL ID		0	0	0	0	0	0	0	0	0	
		1	1	1	1	1	1	1	1	1	
		3	3	3	3	3	3	3	3	4	
		1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>											
Nephropathy		1	1			1	1				4 1.0

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

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Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 09:31:49

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

Lab: BAT

DAY ON TEST		0	0	0	0	0	0	0	0	0	
<b>FISCHER 344 RATS FEMALE</b>	0	0	0	0	0	0	0	0	0	0	
	9	9	9	9	8	8	9	9	9	9	
	4	4	4	4	7	2	4	4	4	4	
	<hr/>										
<b>200,000 NG/KG 66</b>	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	1	1	1	1	1	1	1	1	1	1	
	4	4	4	4	4	4	4	4	4	5	
	1	2	3	4	5	6	7	8	9	0	<b>* TOTALS</b>

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Large, Cecum	+	+	+	+	+	M	+	+	+	+	<b>9</b>
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Small, Duodenum	+	+	+	+	+	M	+	+	+	+	<b>9</b>
Intestine Small, Ileum	+	+	+	+	+	M	+	+	+	+	<b>9</b>
Intestine Small, Jejunum	+	+	+	+	+	M	+	+	+	+	<b>9</b>
Liver	+	+	+	+	+	M	+	+	+	+	<b>9</b>
Fatty Change	2	2	2	1	1		2	2	2	2	<b>9 1.8</b>
Hematopoietic Cell Proliferation								1			<b>1 1.0</b>
Hepatocyte, Multinucleate	1	3	3	2	2		1	1	1	3	<b>9 1.9</b>
Hepatodiaphragmatic Nodule			X							X	<b>2</b>
Inflammation, Suppurative		1						1		1	<b>3 1.0</b>
Inflammation, Chronic Active	1	1	1	1			1	1	1	1	<b>8 1.0</b>
Pigmentation		1	1					1	1		<b>4 1.0</b>
Toxic Hepatopathy	3	3	3	3	2		2	3	3	3	<b>9 2.8</b>
Bile Duct, Cyst										3	<b>1 3.0</b>
Bile Duct, Hyperplasia	1	1					1	1	2	1	<b>6 1.2</b>
Hepatocyte, Degeneration		1	1	1						1	<b>4 1.0</b>
Hepatocyte, Glandular Structures	2	2					1	2	3		<b>5 2.0</b>
Hepatocyte, Hyperplasia	2	1		1			1	2	2		<b>6 1.5</b>

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Experiment Number: 20306 - 03

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Route: GAVAGE

Species/Strain: RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 09:31:49

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

Lab: BAT

FISCHER 344 RATS FEMALE 200,000 NG/KG 66	DAY ON TEST										ANIMAL ID			
	0	0	0	0	0	0	0	0	0	0				0
	9	9	9	9	8	8	9	9	9	9				
	4	4	4	4	7	2	4	4	4	4				
	0	0	0	0	0	0	0	0	0	0				
	0	0	0	0	0	0	0	0	0	0				
	1	1	1	1	1	1	1	1	1	1				
	4	4	4	4	4	4	4	4	4	5				
	1	2	3	4	5	6	7	8	9	0				
												<b>* TOTALS</b>		
Hepatocyte, Hypertrophy	4	4	4	4	3		3	4	4	4			<b>9</b>	<b>3.8</b>
Oval Cell, Hyperplasia	1	1		1	1		1	2	1	1			<b>8</b>	<b>1.1</b>
Portal Vein, Fibrosis, Focal								2	2				<b>2</b>	<b>2.0</b>
Pancreas	+	+	+	+	+	M	+	+	+	+			<b>9</b>	
Infiltration Cellular, Mononuclear Cell		1	1	1			1	1	1				<b>6</b>	<b>1.0</b>
Acinus, Vacuolization Cytoplasmic			1										<b>1</b>	<b>1.0</b>
Salivary Glands	+	+	+	+	+	+	+	+	+	+			<b>10</b>	
Stomach, Forestomach	+	+	+	+	+	M	+	+	+	+			<b>9</b>	
Epithelium, Hyperplasia, Squamous									1				<b>1</b>	<b>1.0</b>
Stomach, Glandular	+	+	+	+	+	M	+	+	+	+			<b>9</b>	
Infiltration Cellular, Mononuclear Cell					1					1			<b>2</b>	<b>1.0</b>
Glands, Ectasia								1					<b>1</b>	<b>1.0</b>
Tongue	+	+	+	+	+	+	+	+	+	+			<b>10</b>	
<b>CARDIOVASCULAR SYSTEM</b>														
Blood Vessel	+	+	+	+	+	+	+	+	+	+			<b>10</b>	
Aorta, Thrombus					3	3	2						<b>3</b>	<b>2.7</b>
Pulmonary Artery, Thrombus					3								<b>1</b>	<b>3.0</b>
Heart	+	+	+	+	+	+	+	+	+	+			<b>10</b>	
Cardiomyopathy			1	1				1		1			<b>4</b>	<b>1.0</b>
Myocardium, Inflammation		4			1	3							<b>3</b>	<b>2.7</b>
Valve, Thrombus									3				<b>1</b>	<b>3.0</b>
Ventricle, Thrombus		3				2							<b>2</b>	<b>2.5</b>

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Route: GAVAGE

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CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 09:31:49

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

Lab: BAT

	DAY ON TEST										
<b>FISCHER 344 RATS FEMALE</b>	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	9	9	9	9	8	8	9	9	9	9	
	4	4	4	4	7	2	4	4	4	4	
<b>200,000 NG/KG 66</b>	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	1	1	1	1	1	1	1	1	1	1	
	4	4	4	4	4	4	4	4	4	5	
	1	2	3	4	5	6	7	8	9	0	
											<b>* TOTALS</b>

**ENDOCRINE SYSTEM**

Adrenal Cortex	+	+	+	+	+	M	+	+	+	+	<b>9</b>
Adrenal Medulla	+	+	+	+	+	M	+	+	+	+	<b>9</b>
Parathyroid Gland	+	+	+	+	+	M	+	+	+	+	<b>9</b>
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Thyroid Gland	+	+	+	+	+	M	+	+	+	+	<b>9</b>

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

Clitoral Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Ovary	+	+	+	+	+	M	+	+	+	+	<b>9</b>
Atrophy	2	1	1	1	1		2	1	1	1	<b>9 1.2</b>
Uterus	+	+	+	+	+	M	+	+	+	+	<b>9</b>
Atrophy	2	2	2	2	2		2	2	1	2	<b>9 1.9</b>
Vagina	+	M	+	+	+	+	+	+	+	+	<b>9</b>

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+	+	+	+	+	+	+	+	+	+	<b>10</b>
-------------	---	---	---	---	---	---	---	---	---	---	-----------

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+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 09:31:49

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

Lab: BAT

FISCHER 344 RATS FEMALE 200,000 NG/KG 66	DAY ON TEST										* TOTALS	
	0 9 4	0 9 4	0 9 4	0 9 4	0 8 7	0 8 2	0 9 4	0 9 4	0 9 4	0 9 4		
ANIMAL ID	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0		
	1	1	1	1	1	1	1	1	1	1		
	4	4	4	4	4	4	4	4	4	5		
	1	2	3	4	5	6	7	8	9	0		
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M	0	
Lymph Node, Mesenteric	+	+	+	+	+	M	+	+	+	+	9	
Atrophy	2							1	1	1	4	1.3
Infiltration Cellular, Histiocyte			2					1		1	3	1.3
Infiltration Cellular, Plasma Cell				2							1	2.0
Spleen	+	+	+	+	+	M	+	+	+	+	9	
Pigmentation, Hemosiderin		1	1	1	1		1	1	1	1	8	1.0
Thymus	+	+	+	+	+	+	+	+	+	+	10	
Atrophy	4	4	4	4	4	4	4	3	4	3	10	3.8
<b>INTEGUMENTARY SYSTEM</b>												
Mammary Gland	+	+	+	+	+	+	+	+	+	+	10	
Skin	+	+	+	+	+	+	+	+	+	+	10	
<b>MUSCULOSKELETAL SYSTEM</b>												
Bone	+	+	+	+	+	+	+	+	+	+	10	
<b>NERVOUS SYSTEM</b>												
Brain	+	+	+	+	+	+	+	+	+	+	10	
<b>RESPIRATORY SYSTEM</b>												
Lung	+	+	+	+	+	+	+	+	+	+	10	
Alveolus, Infiltration Cellular, Histiocyte	1	1		1			1	2	1		6	1.2

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

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CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 09:31:49

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

Lab: BAT

		0	0	0	0	0	0	0	0	0	
DAY ON TEST		0	0	0	0	0	0	0	0	0	
FISCHER 344 RATS FEMALE		9	9	9	9	8	8	9	9	9	
		4	4	4	4	7	2	4	4	4	
200,000 NG/KG 66		0	0	0	0	0	0	0	0	0	
ANIMAL ID		0	0	0	0	0	0	0	0	0	
		1	1	1	1	1	1	1	1	1	
		4	4	4	4	4	4	4	4	5	
		1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>											
Nose		+	+	+	+	+	+	+	+	+	10
Trachea		+	+	+	+	+	+	+	+	+	10
<b>SPECIAL SENSES SYSTEM</b>											
Eye		+	+	+	+	+	+	+	+	+	10
Harderian Gland		+	+	+	+	+	+	+	+	+	10
Infiltration Cellular, Mononuclear Cell		2		1	3	1		3	2	1	8 1.9
Duct, Metaplasia, Squamous								2			1 2.0
<b>URINARY SYSTEM</b>											
Kidney		+	+	+	+	+	M	+	+	+	9
Mineralization		1	1	1	1	1		1		1	7 1.0
Nephropathy		1		1				1	1		4 1.0
Urinary Bladder		+	+	+	+	+	M	+	+	+	9

\*\*\* END OF REPORT \*\*\*

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked