

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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DAY ON TEST	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	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 NG/KG	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	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	2	3	4	5	6	7	8	9	0	1	2	3	4	5	
* TOTALS																

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

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

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 1	0 0 0 2	0 0 0 3	0 0 0 4	0 0 0 5	0 0 0 6	0 0 0 7	0 0 0 8	0 0 0 9	0 0 0 0	0 0 0 1	0 0 0 2	0 0 0 3	0 0 0 4	0 0 0 5	
Infiltration Cellular, Mononuclear Cell			1				1			1			1			4 1.0
Tongue	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
CARDIOVASCULAR SYSTEM																
Blood Vessel	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
Cardiomyopathy		1			1	1	1		1	1		1	1		9 1.0	
ENDOCRINE SYSTEM																
Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
Parathyroid Gland	+	+	M	+	+	+	+	+	+	+	+	+	+	+	M	13
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
GENERAL BODY SYSTEM																
NONE																
GENITAL SYSTEM																
Clitoral Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
Ovary	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15

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

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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		
Periovarian Tissue, Cyst																1	1	1.0
Uterus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		15	
Vagina	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		15	
HEMATOPOIETIC SYSTEM																		
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 1.0 6 1.2
Spleen Pigmentation, Hemosiderin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		15	15 1.1
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		15	
INTEGUMENTARY SYSTEM																		
Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		15	
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		15	
MUSCULOSKELETAL SYSTEM																		
Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		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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First Dose M/F: NA / 10/13/03

Lab: BAT

FISCHER 344 RATS FEMALE 0 NG/KG	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	
		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		* TOTALS

NERVOUS SYSTEM

Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15
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RESPIRATORY SYSTEM

Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	15		
Alveolar Epithelium, Hyperplasia															2		1	2.0
Alveolus, Infiltration Cellular, Histiocyte				1	1										1		3	1.0
Interstitial, 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	1		15	1.0
Nephropathy											1	1					2	1.0

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

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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	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

+ .. Tissue examined microscopically

X .. Lesion present

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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		
	* TOTALS										

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

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

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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	0	0	
1000 NG/KG 66	ANIMAL ID	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	
		0	0	0	0	0	0	0	0	0	0	
		1	1	1	1	1	1	1	1	1	1	
		0	0	0	0	0	0	0	0	0	1	
		1	2	3	4	5	6	7	8	9	0	
											* TOTALS	

RESPIRATORY SYSTEM

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

SPECIAL SENSES SYSTEM

Harderian Gland	+	+	+	+	+	+	+	+	+	+	10	
Infiltration Cellular, Mononuclear Cell	1											1 1.0

URINARY SYSTEM

Kidney	+	+	+	+	+	+	+	+	+	+	10	
Mineralization			1	1	1	1		1	1	1		7 1.0
Nephropathy									1			1 1.0

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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	0
	9	9	9	9	9	9	9	9	9	9	9
	4	4	4	4	4	4	4	4	4	4	4
	<hr/>										
10,000 NG/KG 66	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	9	0

* TOTALS

ALIMENTARY SYSTEM

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

CARDIOVASCULAR SYSTEM

Heart	+	+	+	+	+	+	+	+	+	+	10
Cardiomyopathy	1	1		1		1	1		1	1	7 1.0

ENDOCRINE SYSTEM

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

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

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X .. Lesion present

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Lab: BAT

FISCHER 344 RATS FEMALE 10,000 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 1 1 1	
	1	1	1	1	1	1	1	1	1	1	1 1 1 1 1 1	
	2	3	4	5	6	7	8	9	0			
												* TOTALS

Thyroid Gland	+	+	+	+	+	+	+	+	+	+		10
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GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Ovary	+	+	+	+	+	+	+	+	+	+		10
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Uterus	+	+	+	+	+	+	+	+	+	+		10
--------	---	---	---	---	---	---	---	---	---	---	--	-----------

Vagina	+	+	+	+	+	+	+	+	+	+		10
--------	---	---	---	---	---	---	---	---	---	---	--	-----------

HEMATOPOIETIC SYSTEM

Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+		10	
Infiltration Cellular, Histiocyte	1	1	1			1	1			1		6	1.0

Spleen	+	+	+	+	+	+	+	+	+	+		10	
Pigmentation, Hemosiderin	1	1	1	1	1	1	1	1	1	1		10	1.0

Thymus	+	+	+	+	+	+	+	+	+	+		10
--------	---	---	---	---	---	---	---	---	---	---	--	-----------

INTEGUMENTARY SYSTEM

Mammary Gland	+	+	+	+	+	+	+	+	+	+		10
---------------	---	---	---	---	---	---	---	---	---	---	--	-----------

Skin	+	+	+	+	+	+	+	+	+	+		10
------	---	---	---	---	---	---	---	---	---	---	--	-----------

MUSCULOSKELETAL 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

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	DAY ON TEST	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
		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
10,000 NG/KG 66	ANIMAL ID	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	1	1	1	1
		1	1	1	1	1	1	1	1	1	1	1	2	1
		1	2	3	4	5	6	7	8	9	0			

* TOTALS

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
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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

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Time Report Requested: 09:31:49

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

Lab: BAT

FISCHER 344 RATS FEMALE	DAY ON TEST										* TOTALS
	0	0	0	0	0	0	0	0	0	0	
50,000 NG/KG 66	ANIMAL ID										* TOTALS
	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	

ALIMENTARY SYSTEM

Intestine Large, Colon											+	1	
Serosa, Cyst											2		1 2.0
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+		10	
Liver	+	+	+	+	+	+	+	+	+	+		10	
Fatty Change													1 1.0
Hepatodiaphragmatic Nodule				X									1
Inflammation, Chronic Active	1	1	1	1	1		1	2	1	1			9 1.1
Pigmentation				1									1 1.0
Hepatocyte, Hypertrophy			1	1	1	1							4 1.0
Pancreas	+	+	+	+	+	+	+	+	+	+		10	
Infiltration Cellular, Mononuclear Cell	1			1	1	1		1	1				6 1.0
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+		10	

CARDIOVASCULAR SYSTEM

Heart	+	+	+	+	+	+	+	+	+	+		10	
Cardiomyopathy			1	1	1	1	1		1	1			7 1.0

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+		10	
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+		10	

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

+ .. Tissue examined microscopically

X .. Lesion present

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M .. Missing tissue

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Species/Strain: RATS/F 344/N

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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	
FISCHER 344 RATS FEMALE	4	4	4	4	4	4	4	4	4	4	
50,000 NG/KG 66	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	
* TOTALS											

Pituitary Gland	+	+	+	+	+	+	+	+	+	+	10
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	10

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

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

HEMATOPOIETIC SYSTEM

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

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
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Test Type: 90-DAY

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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 50,000 NG/KG 66	DAY ON TEST	0	0	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	0
		9	9	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	4	4
		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
		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	3
		1	2	3	4	5	6	7	8	9	0								
* TOTALS																			

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

Skin + + + + + + + + + + 10

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

Lung + + + + + + + + + + 10

Inflammation, Chronic Active 1 1.0

Alveolar Epithelium, Hyperplasia 1 1.0

Alveolus, Infiltration Cellular, Histiocyte 1 1 1 3 1.0

SPECIAL SENSES SYSTEM

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

Infiltration Cellular, Mononuclear Cell 1 1 2 1.0

URINARY SYSTEM

Kidney + + + + + + + + + + 10

Mineralization 1 1 1 1 1 7 1.0

Nephropathy 1 1 1 1 1 3 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

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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

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	0
	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
100,000 NG/KG 66		9	9	9	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	4	4	4
		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
		3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	4
		1	2	3	4	5	6	7	8	9	0									
* TOTALS																				

ALIMENTARY SYSTEM

Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	10		
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	10		
Clear Cell Focus																						1
Fatty Change	1	2		1	1		1	1		1	1		1								7	1.1
Hepatocyte, Multinucleate	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		10	1.1
Hepatodiaphragmatic Nodule				X																	1	
Inflammation, Granulomatous	1	1	2	1	1	1	1	1	1												8	1.1
Inflammation, Chronic Active	1	1		1	1	1	1	1	2	1	1										9	1.1
Necrosis, Focal					1																1	1.0
Toxic Hepatopathy	1	1		1	1	1	1	1	1	1	1										8	1.0
Hepatocyte, Hypertrophy	2	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		10	2.1
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	10		
Infiltration Cellular, Mononuclear Cell			1						1	1											3	1.0
Acinus, Atrophy, Focal																					1	1.0
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	10		

CARDIOVASCULAR SYSTEM

Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	10		
Cardiomyopathy			1			1	1														4	1.0

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	10		
Inflammation, Histiocytic				2																	1	2.0

* .. 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

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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	ANIMAL ID		
	0	0	0	0	0	0	0	0	0	0			
FISCHER 344 RATS FEMALE	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			
	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			
											* TOTALS		
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+		10	
Pituitary Gland Cyst	+	+	+	+	+	+	+	+	+	+	1	10	1 1.0
Thyroid Gland	+	+	+	+	+	+	+	+	+	+		10	
GENERAL BODY SYSTEM													
NONE													
GENITAL SYSTEM													
Ovary	+	+	+	+	+	+	+	+	+	+		10	
Uterus	+	+	+	+	+	+	+	+	+	+		10	
Vagina	+	+	+	+	+	+	+	+	+	+		10	
HEMATOPOIETIC SYSTEM													
Lymph Node, Mesenteric Hyperplasia, Lymphoid Infiltration Cellular, Histiocyte	+	+	+	+	+	+	+	+	+	+	2	10	1 2.0
	1	2	1	3		2	1	1	1	1			9 1.4
Spleen Pigmentation, Hemosiderin	+	+	+	+	+	+	+	+	+	+		10	
	1	1	1	1	1	1	1	1	1	1			10 1.0
Thymus Atrophy	+	+	+	+	+	+	+	+	+	+		10	
				1				1					2 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

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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

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

INTEGUMENTARY SYSTEM

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

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

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

SPECIAL SENSES SYSTEM

Harderian Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	10
Infiltration Cellular, Mononuclear Cell																		1	1 1.0

URINARY SYSTEM

Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	10
Mineralization	1			1		1	1	1											5 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

		0	0	0	0	0	0	0	0	0	
FISCHER 344 RATS FEMALE	DAY ON TEST	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	
		4	4	4	4	4	4	4	4	4	
100,000 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	
		3	3	3	3	3	3	3	3	4	
		1	2	3	4	5	6	7	8	9	0
* TOTALS											
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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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	
FISCHER 344 RATS FEMALE		0	0	0	0	0	0	0	0	0	
200,000 NG/KG 66		9	9	9	9	8	8	9	9	9	
ANIMAL ID		4	4	4	4	7	2	4	4	4	
		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	
		4	4	4	4	4	4	4	4	5	
		1	2	3	4	5	6	7	8	9	
* TOTALS											

ALIMENTARY SYSTEM

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

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

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

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

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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

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Lab: BAT

DAY ON TEST		0	0	0	0	0	0	0	0	0	
FISCHER 344 RATS FEMALE		0	0	0	0	0	0	0	0	0	
		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
* TOTALS											

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	M	+	+	+	+	9
Adrenal Medulla	+	+	+	+	+	M	+	+	+	+	9
Parathyroid Gland	+	+	+	+	+	M	+	+	+	+	9
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	10
Thyroid Gland	+	+	+	+	+	M	+	+	+	+	9

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Clitoral Gland	+	+	+	+	+	+	+	+	+	+	10
Ovary	+	+	+	+	+	M	+	+	+	+	9
Atrophy	2	1	1	1	1		2	1	1	1	9 1.2
Uterus	+	+	+	+	+	M	+	+	+	+	9
Atrophy	2	2	2	2	2		2	2	1	2	9 1.9
Vagina	+	M	+	+	+	+	+	+	+	+	9

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	10
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	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 1 4 1	0 0 4 2	0 0 4 3	0 0 4 4	0 0 4 5	0 0 4 6	0 0 4 7	0 0 4 8	0 0 4 9	0 0 5 0		
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M	0	
Lymph Node, Mesenteric Atrophy	+	+	+	+	+	M	+	+	+	+	9	
Infiltration Cellular, Histiocyte	2						1	1	1	1	4	1.3
Infiltration Cellular, Plasma Cell			2							1	3	1.3
				2							1	2.0
Spleen Pigmentation, Hemosiderin	+	+	+	+	+	M	+	+	+	+	9	
		1	1	1	1		1	1	1	1	8	1.0
Thymus Atrophy	+	+	+	+	+	+	+	+	+	+	10	
	4	4	4	4	4	4	4	3	4	3	10	3.8
INTEGUMENTARY SYSTEM												
Mammary Gland	+	+	+	+	+	+	+	+	+	+	10	
Skin	+	+	+	+	+	+	+	+	+	+	10	
MUSCULOSKELETAL SYSTEM												
Bone	+	+	+	+	+	+	+	+	+	+	10	
NERVOUS SYSTEM												
Brain	+	+	+	+	+	+	+	+	+	+	10	
RESPIRATORY SYSTEM												
Lung Alveolus, Infiltration Cellular, Histiocyte	+	+	+	+	+	+	+	+	+	+	10	
	1	1		1			1	2	1		6	1.2

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DAY ON TEST		0	0	0	0	0	0	0	0	0	
FISCHER 344 RATS FEMALE		0	0	0	0	0	0	0	0	0	
		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
* TOTALS											
Nose		+	+	+	+	+	+	+	+	+	10
Trachea		+	+	+	+	+	+	+	+	+	10
SPECIAL SENSES SYSTEM											
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
URINARY SYSTEM											
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 ***

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