

TDMS No. 20306 - 02
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: RATS/SD

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
PCN 66/67 COMPARISON STUDY
CAS Number: PCNCOMPARISN
Pathologist: VASCONCELOS, D.
F1 PCN 67

Date Report Reqsted: 12/05/2005
Time Report Reqsted: 12:38:07
First Dose M/F: NA / 10/06/03
Lab: BAT

C 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 007 1000 NG/KG 67

Include 008 10,000 NG/KG 67

Include 009 50,000 NG/KG 67

Include 010 100,000 NG/KG 67

Include 011 200,000 NG/KG 67

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

ALIMENTARY SYSTEM

Esophagus	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	10
Liver	+	+	+	+	+	+	+	+	+	+	10
Hepatodiaphragmatic Nodule			X								1
Inflammation, Chronic Active	1		1	1	1	1	1		1		8 1.0
Necrosis				2							1 2.0
Pancreas	+	+	+	+	+	+	+	+	+	+	10
Salivary Glands	+	+	+	+	+	+	+	+	+	+	10
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	10
Epithelium, Hyperkeratosis						1					1 1.0

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

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1) Minimal 3) Moderate

2) Mild 4) Marked

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		9	9	9	9	9	9	9	9	9	9
		4	4	4	4	4	4	4	4	4	4
SPRAGUE-DAWLEY RATS FEMALE		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
	ANIMAL ID	2	2	2	2	2	2	2	2	2	3
	0 NG/KG	1	2	3	4	5	6	7	8	9	0
* TOTALS											

Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	10
Tongue	+	+	+	+	+	+	+	+	+	+	+	10
Tooth Gingiva, Inflammation						+						1
						1						1 1.0

CARDIOVASCULAR SYSTEM

Blood Vessel	+	+	+	+	+	+	+	+	+	+	10
Heart	+	+	+	+	+	+	+	+	+	+	10

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	10
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	10
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	10
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	10
Thyroid Gland Follicular Cell, Hypertrophy	+	+	+	+	+	+	+	+	+	+	10
	1										1 1.0

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		9	9	9	9	9	9	9	9	9	9
		4	4	4	4	4	4	4	4	4	4
SPRAGUE-DAWLEY RATS FEMALE		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
	ANIMAL ID	2	2	2	2	2	2	2	2	2	3
	0 NG/KG	1	2	3	4	5	6	7	8	9	0
* TOTALS											

GENERAL BODY SYSTEM
 NONE

GENITAL SYSTEM

Clitoral Gland Inflammation, Chronic Active	+	+	+	+	+	+	+	+	+	+	10	6 1.5
Ovary	+	+	+	+	+	+	+	+	+	+	10	
Uterus	+	+	+	+	+	+	+	+	+	+	10	
Vagina	+	+	+	+	+	+	+	+	+	+	10	

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	10	
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	10	
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	10	
Spleen Pigmentation, Hemosiderin	+	+	+	+	+	+	+	+	+	+	10	10 1.0

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		4	4	4	4	4	4	4	4	4	4	
SPRAGUE-DAWLEY RATS FEMALE		0	0	0	0	0	0	0	0	0	0	
ANIMAL ID		0	0	0	0	0	0	0	0	0	0	
0 NG/KG		2	2	2	2	2	2	2	2	2	3	
		1	2	3	4	5	6	7	8	9	0	* TOTALS
Thymus		+	+	+	+	+	+	+	+	+	+	10
INTEGUMENTARY SYSTEM												
Mammary Gland		+	+	+	+	+	+	+	+	+	+	10
Skin		+	+	+	+	+	+	+	+	+	+	10
MUSCULOSKELETAL SYSTEM												
Bone		+	+	+	+	+	+	+	+	+	+	10
NERVOUS SYSTEM												
Brain		+	+	+	+	+	+	+	+	+	+	10
RESPIRATORY SYSTEM												
Lung		+	+	+	+	+	+	+	+	+	+	10
Inflammation, Chronic Active											1	1 1.0
Alveolus, Infiltration Cellular, Histiocyte							1					1 1.0
Nose		+	+	+	+	+	+	+	+	+	+	10
Respiratory Epithelium, Inflammation			2		1							2 1.5

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		9	9	9	9	9	9	9	9	9	9	
		4	4	4	4	4	4	4	4	4	4	
SPRAGUE-DAWLEY RATS		0	0	0	0	0	0	0	0	0	0	
FEMALE		0	0	0	0	0	0	0	0	0	0	
0 NG/KG		0	0	0	0	0	0	0	0	0	0	
ANIMAL ID		2	2	2	2	2	2	2	2	2	3	
		1	2	3	4	5	6	7	8	9	0	* TOTALS
Trachea		+	+	+	+	+	+	+	+	+	+	10
SPECIAL SENSES SYSTEM												
Eye		+	+	+	+	+	+	+	+	+	+	10
Harderian Gland		+	+	+	+	+	+	+	+	+	+	10
Infiltration Cellular, Mononuclear Cell								X				1
URINARY SYSTEM												
Kidney		+	+	+	+	+	+	+	+	+	+	10
Mineralization				1	1	1		1				4 1.0
Nephropathy		1	1			1	1		1		1	6 1.0
Urinary Bladder		+	+	+	+	+	+	+	+	+	+	10

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	9	9	9	9	9	9	9	9	9	9
	4	4	4	4	4	4	4	4	4	4
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0
FEMALE	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	5	5	5	5	5	5	5	5	5	5
1000 NG/KG 67	0	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
Inflammation, Chronic Active	1	1		1	1	1	1	1	1	1	9 1.0
Pancreas	+	+	+	+	+	+	+	+	+	+	10
Inflammation					1						1 1.0
Acinus, Atrophy, Focal								1			1 1.0
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	10

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	10
Hypertrophy		2							1		2 1.5
Zona Fasciculata, Vacuolization								1			1 1.0
Cytoplasmic											
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	10
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	10

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		9	9	9	9	9	9	9	9	9	9
		4	4	4	4	4	4	4	4	4	4
SPRAGUE-DAWLEY RATS FEMALE		0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0
		5	5	5	5	5	5	5	5	5	5
	ANIMAL ID	0	0	0	0	0	0	0	0	0	1
	1000 NG/KG 67	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
-------	---	---	---	---	---	---	---	---	---	---	---	-----------

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

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

HEMATOPOIETIC SYSTEM

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

Thymus	+	+	+	+	+	+	+	+	+	+	+	10
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INTEGUMENTARY SYSTEM

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

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	0	0	0	0	0	0	0	0	0	0	
DAY ON TEST	9	9	9	9	9	9	9	9	9	9	
	4	4	4	4	4	4	4	4	4	4	
.....											
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0	
FEMALE	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	5	5	5	5	5	5	5	5	5	5	
1000 NG/KG 67	0	0	0	0	0	0	0	0	0	1	
	1	2	3	4	5	6	7	8	9	0	* TOTALS
Skin	+	+	+	+	+	+	+	+	+	+	10
MUSCULOSKELETAL SYSTEM											
NONE											
NERVOUS SYSTEM											
NONE											
RESPIRATORY SYSTEM											
.....											
Lung	+	+	+	+	+	+	+	+	+	+	10
Inflammation, Chronic Active				1							1 1.0
SPECIAL SENSES SYSTEM											
NONE											
URINARY SYSTEM											
.....											
Kidney	+	+	+	+	+	+	+	+	+	+	10
Mineralization	1		1		1		1		1	1	5 1.0
Nephropathy	1	2		1		1	1		1		6 1.2

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	9	9	9	9	9	9	9	9	9	9
	4	4	4	4	4	4	4	4	4	4
.....										
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0
FEMALE	0	0	0	0	0	0	0	0	0	0
	5	5	5	5	5	5	5	5	5	5
ANIMAL ID	1	1	1	1	1	1	1	1	1	2
	1	2	3	4	5	6	7	8	9	0
10,000 NG/KG 67										
										* TOTALS

ALIMENTARY SYSTEM

Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	10
Liver	+	+	+	+	+	+	+	+	+	+	10
Inflammation, Chronic Active		1	1	1	1	1	1	1	1		8 1.0
Hepatocyte, Hypertrophy					1						1 1.0
Pancreas	+	+	+	+	+	+	+	+	+	+	10
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	10

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	10
Hypertrophy						1					1 1.0
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	10
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	10
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	10

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	9	9	9	9	9	9	9	9	9	9	
	4	4	4	4	4	4	4	4	4	4	
.....											
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0	
FEMALE	0	0	0	0	0	0	0	0	0	0	
10,000 NG/KG 67	5	5	5	5	5	5	5	5	5	5	
ANIMAL ID	1	1	1	1	1	1	1	1	1	2	
	1	2	3	4	5	6	7	8	9	0	* TOTALS

GENERAL BODY SYSTEM
 NONE

GENITAL SYSTEM

Clitoral Gland	+										1	
Cyst	1										1	1.0
Ovary	+	+	+	+	+	+	+	+	+	+	10	
Uterus	+	+	+	+	+	+	+	+	+	+	10	
Vagina	+	+	+	+	+	+	+	+	+	+	10	

HEMATOPOIETIC SYSTEM

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

INTEGUMENTARY SYSTEM

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

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	9	9	9	9	9	9	9	9	9	9	
	4	4	4	4	4	4	4	4	4	4	
SPRAGUE-DAWLEY RATS FEMALE	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	5	5	5	5	5	5	5	5	5	5	
	1	1	1	1	1	1	1	1	1	2	
	1	2	3	4	5	6	7	8	9	0	
10,000 NG/KG 67											
Skin	+	+	+	+	+	+	+	+	+	+	10

MUSCULOSKELETAL SYSTEM
 NONE

NERVOUS SYSTEM
 NONE

RESPIRATORY SYSTEM

Lung	+	+	+	+	+	+	+	+	+	+	10	
Alveolar Epithelium, Hyperplasia				1								1 1.0
Alveolus, Infiltration Cellular, Histiocyte			1									1 1.0

SPECIAL SENSES SYSTEM
 NONE

URINARY SYSTEM

Kidney	+	+	+	+	+	+	+	+	+	+	10	
Mineralization	1				1	1		1				4 1.0
Nephropathy		2			1					1		3 1.3

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

+ .. Tissue examined microscopically

x .. Lesion present

l .. 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

TDMS No. 20306 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: RATS/SD

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
 PCN 66/67 COMPARISON STUDY
 CAS Number: PCNCOMPARISN
 Pathologist: VASCONCELOS, D.

Date Report Reqsted: 12/05/2005
 Time Report Reqsted: 12:38:07
 First Dose M/F: NA / 10/06/03
 Lab: BAT

DAY ON TEST	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
.....										
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0
FEMALE	0	0	0	0	0	0	0	0	0	0
	5	5	5	5	5	5	5	5	5	5
ANIMAL ID	2	2	2	2	2	2	2	2	2	3
	1	2	3	4	5	6	7	8	9	0
50,000 NG/KG 67										
										* TOTALS

ALIMENTARY SYSTEM

Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	10
Liver	+	+	+	+	+	+	+	+	+	+	10
Inflammation, Chronic Active	1	1	1	1	1	1	1	1	1		9 1.0
Necrosis		3									1 3.0
Hepatocyte, Hypertrophy	1										1 1.0
Pancreas	+	+	+	+	+	+	+	+	+	+	10
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	10

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	10
Hypertrophy				2							1 2.0
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	10
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	10
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	10

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

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TDMS No. 20306 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: RATS/SD

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 Time Report Reqsted: 12:38:07
 First Dose M/F: NA / 10/06/03
 Lab: BAT

DAY ON TEST	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	
.....											
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0	
FEMALE	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	5	5	5	5	5	5	5	5	5	5	
50,000 NG/KG 67	2	2	2	2	2	2	2	2	2	3	
	1	2	3	4	5	6	7	8	9	0	* TOTALS

GENERAL BODY SYSTEM
 NONE

GENITAL SYSTEM

Ovary Atrophy	+	+	+	+	+	+	+	+	+	+	10	1 1.0
Uterus Endometrium, Hyperplasia, Cystic	+	+	+	+	+	+	+	+	+	+	10	1 2.0
Vagina	+	+	+	+	+	+	+	+	+	+	10	

HEMATOPOIETIC SYSTEM

Spleen Pigmentation, Hemosiderin	+	+	+	+	+	+	+	+	+	+	10	10 1.0
Thymus	+	+	+	+	+	+	+	+	+	+	10	

INTEGUMENTARY SYSTEM

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

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

+ .. Tissue examined microscopically

x .. Lesion present

l .. Insufficient tissue

M .. Missing tissue

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1-4 .. Lesion qualified as:

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TDMS No. 20306 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: RATS/SD

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 Lab: BAT

	0	0	0	0	0	0	0	0	0	0	
DAY ON TEST	9	9	9	9	9	9	9	9	9	9	
	4	4	4	4	4	4	4	4	4	4	
.....											
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0	
FEMALE	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	5	5	5	5	5	5	5	5	5	5	
50,000 NG/KG 67	2	2	2	2	2	2	2	2	2	3	
	1	2	3	4	5	6	7	8	9	0	* TOTALS
Skin	+	+	+	+	+	+	+	+	+	+	10
MUSCULOSKELETAL SYSTEM											
NONE											
NERVOUS SYSTEM											
NONE											
RESPIRATORY SYSTEM											
.....											
Lung	+	+	+	+	+	+	+	+	+	+	10
Alveolus, Infiltration Cellular, Histiocyte										1	1 1.0
SPECIAL SENSES SYSTEM											
NONE											
URINARY SYSTEM											
.....											
Kidney	+	+	+	+	+	+	+	+	+	+	10
Mineralization		1	1		1			1	1	1	6 1.0
Nephropathy	1				1	1	1	1		1	6 1.0

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 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
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 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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Page 15

TDMS No. 20306 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: RATS/SD

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
 PCN 66/67 COMPARISON STUDY
 CAS Number: PCNCOMPARISN
 Pathologist: VASCONCELOS, D.

Date Report Reqsted: 12/05/2005
 Time Report Reqsted: 12:38:07
 First Dose M/F: NA / 10/06/03
 Lab: BAT

DAY ON TEST	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
.....										
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0
FEMALE	0	0	0	0	0	0	0	0	0	0
	5	5	5	5	5	5	5	5	5	5
ANIMAL ID	3	3	3	3	3	3	3	3	3	4
100,000 NG/KG 67	1	2	3	4	5	6	7	8	9	0
	* TOTALS									

ALIMENTARY SYSTEM

Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	10
.....											
Liver	+	+	+	+	+	+	+	+	+	+	10
Inflammation, Suppurative						1	1				2 1.0
Inflammation, Chronic Active	1	1	2	1	1	1	1	1	1	1	10 1.1
Necrosis			3								1 3.0
Pigmentation			2				1				2 1.5
Bile Duct, Hyperplasia			2								1 2.0
Hepatocyte, Hypertrophy								1	2	1	3 1.3
Portal Vein, Fibrosis, Focal			2								1 2.0
.....											
Pancreas	+	+	+	+	+	+	+	+	+	+	10
Infiltration Cellular, Mononuclear Cell						X					1
Inflammation			1								1 1.0
.....											
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	10

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	10
Hypertrophy			1								1 1.0

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 l .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
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 2) Mild 4) Marked

Page 16

TDMS No. 20306 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: RATS/SD

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
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 CAS Number: PCNCOMPARISN
 Pathologist: VASCONCELOS, D.

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 Time Report Reqsted: 12:38:07
 First Dose M/F: NA / 10/06/03
 Lab: BAT

DAY ON TEST	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	
SPRAGUE-DAWLEY RATS											
FEMALE											
	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	5	5	5	5	5	5	5	5	5	5	
	3	3	3	3	3	3	3	3	3	4	
	1	2	3	4	5	6	7	8	9	0	
100,000 NG/KG 67											* TOTALS
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	10
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	10
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	10
GENERAL BODY SYSTEM											
NONE											
GENITAL SYSTEM											
Ovary	+	+	+	+	+	+	+	+	+	+	10
Uterus	+	+	+	+	+	+	+	+	+	+	10
Vagina	+	+	+	+	+	+	+	+	+	+	10
HEMATOPOIETIC SYSTEM											
Spleen	+	+	+	+	+	+	+	+	+	+	10
Pigmentation, Hemosiderin	1	1	1	1	1	1	1	1	1	1	10 1.0
Thymus	+	+	+	+	+	+	+	+	+	+	10
INTEGUMENTARY SYSTEM											

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

+ .. Tissue examined microscopically

x .. Lesion present

l .. Insufficient tissue

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1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

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TDMS No. 20306 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: RATS/SD

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 Time Report Reqsted: 12:38:07
 First Dose M/F: NA / 10/06/03
 Lab: BAT

DAY ON TEST	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	
.....											
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0	
FEMALE	0	0	0	0	0	0	0	0	0	0	
100,000 NG/KG 67	5	5	5	5	5	5	5	5	5	5	
ANIMAL ID	3	3	3	3	3	3	3	3	3	4	
	1	2	3	4	5	6	7	8	9	0	* TOTALS

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

MUSCULOSKELETAL SYSTEM

Bone											1
Rib, Fracture											1 1.0

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

Lung	+	+	+	+	+	+	+	+	+	+	10
Inflammation, Chronic Active										1	1 1.0

SPECIAL SENSES SYSTEM

NONE

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
 Page 18

TDMS No. 20306 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: RATS/SD

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
 PCN 66/67 COMPARISON STUDY
 CAS Number: PCNCOMPARISN
 Pathologist: VASCONCELOS, D.

Date Report Reqsted: 12/05/2005
 Time Report Reqsted: 12:38:07
 First Dose M/F: NA / 10/06/03
 Lab: BAT

DAY ON TEST		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	
SPRAGUE-DAWLEY RATS		0	0	0	0	0	0	0	0	0	0	
FEMALE		0	0	0	0	0	0	0	0	0	0	
100,000 NG/KG 67		5	5	5	5	5	5	5	5	5	5	
ANIMAL ID		3	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	1	1	1	1	1	1	7 1.0

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TDMS No. 20306 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: RATS/SD

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
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 First Dose M/F: NA / 10/06/03
 Lab: BAT

DAY ON TEST	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
.....										
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0
FEMALE	0	0	0	0	0	0	0	0	0	0
200,000 NG/KG 67	5	5	5	5	5	5	5	5	5	5
ANIMAL ID	4	4	4	4	4	4	4	4	4	5
	1	2	3	4	5	6	7	8	9	0
	* TOTALS									

ALIMENTARY SYSTEM

Esophagus	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	10
Liver	+	+	+	+	+	+	+	+	+	+	10
Fatty Change	3	3	3	3	3	3	3	3	3	3	10 3.0
Hepatocyte, Multinucleate						1				1	2 1.0
Inflammation, Suppurative	1	1	1	1	1	1	1	1	1	1	10 1.0
Inflammation, Chronic Active	1	2	2	1	1	1	2	2	2	1	10 1.5
Necrosis, Focal	1		1		1	1	1			1	6 1.0
Pigmentation						2					1 2.0
Toxic Hepatopathy	1	2	2	2	2	2	2	2	2	2	10 1.9
Bile Duct, Hyperplasia						2					1 2.0
Hepatocyte, Hypertrophy	2	2	2	2	3	3	2	2	3	2	10 2.3
Oval Cell, Hyperplasia						1					1 1.0

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+ .. Tissue examined microscopically

x .. Lesion present

l .. 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

TDMS No. 20306 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: RATS/SD

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
 PCN 66/67 COMPARISON STUDY
 CAS Number: PCNCOMPARISN
 Pathologist: VASCONCELOS, D.

Date Report Reqsted: 12/05/2005
 Time Report Reqsted: 12:38:07
 First Dose M/F: NA / 10/06/03
 Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	* TOTALS
	9	9	9	9	9	9	9	9	9	9	
	4	4	4	4	4	4	4	4	4	4	
SPRAGUE-DAWLEY RATS FEMALE	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	5	5	5	5	5	5	5	5	5	5	
	4	4	4	4	4	4	4	4	4	5	
200,000 NG/KG 67	1	2	3	4	5	6	7	8	9	0	

Pancreas	+	+	+	+	+	+	+	+	+	+	10
Salivary Glands	+	+	+	+	+	+	+	+	+	+	10
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	10
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	10
Tongue	+	+	+	+	+	+	+	+	+	+	10

CARDIOVASCULAR SYSTEM

Blood Vessel	+	+	+	+	+	+	+	+	+	+	10
Heart	+	+	+	+	+	+	+	+	+	+	10
Cardiomyopathy					1						1 1.0

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	10
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	10
Parathyroid Gland	+	+	M	+	+	+	+	+	M	+	8
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	10

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TDMS No. 20306 - 02
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 Route: GAVAGE
 Species/Strain: RATS/SD

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 First Dose M/F: NA / 10/06/03
 Lab: BAT

DAY ON TEST	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	
.....											
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0	
FEMALE	0	0	0	0	0	0	0	0	0	0	
200,000 NG/KG 67	5	5	5	5	5	5	5	5	5	5	
ANIMAL ID	4	4	4	4	4	4	4	4	4	5	
	1	2	3	4	5	6	7	8	9	0	* TOTALS

Thyroid Gland	+	+	+	+	+	+	+	+	+	+	10
Follicular Cell, Hypertrophy	1		1	1	1	1	1			1	7 1.0

GENERAL BODY SYSTEM
 NONE

GENITAL SYSTEM

Clitoral Gland	+	+	+	+	+	+	+	+	+	+	10
Inflammation, Chronic Active			1	1			2	1	1	1	6 1.2
Ovary	+	+	+	+	+	+	+	+	+	+	10
Uterus	+	+	+	+	+	+	+	+	+	+	10
Vagina	+	+	+	+	+	+	+	+	+	+	10

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	10

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 + .. Tissue examined microscopically
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 First Dose M/F: NA / 10/06/03
 Lab: BAT

DAY ON TEST	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		
SPRAGUE-DAWLEY RATS												
FEMALE												
200,000 NG/KG 67												
ANIMAL ID	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0		
	5	5	5	5	5	5	5	5	5	5		
	4	4	4	4	4	4	4	4	4	4	5	
	1	2	3	4	5	6	7	8	9	0		* TOTALS
Spleen Pigmentation, Hemosiderin	+	+	+	+	+	+	+	+	+	+	10	9 1.0
Thymus Atrophy	+	+	+	+	+	+	+	+	+	+	10	1 1.0
INTEGUMENTARY SYSTEM												
Mammary Gland	+	+	+	+	+	+	+	+	+	+	10	
Skin	+	+	+	+	+	+	+	+	+	+	10	
MUSCULOSKELETAL SYSTEM												
Bone	+	+	+	+	+	+	+	+	+	+	10	
NERVOUS SYSTEM												
Brain	+	+	+	+	+	+	+	+	+	+	10	
RESPIRATORY SYSTEM												
Lung Inflammation, Chronic Active Alveolus, Infiltration Cellular, Histiocyte	+	+	+	+	+	+	+	+	+	+	10	1 1.0 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

Page 23

TDMS No. 20306 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: RATS/SD

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
 PCN 66/67 COMPARISON STUDY
 CAS Number: PCNCOMPARISN
 Pathologist: VASCONCELOS, D.

Date Report Reqsted: 12/05/2005
 Time Report Reqsted: 12:38:07
 First Dose M/F: NA / 10/06/03
 Lab: BAT

	0	0	0	0	0	0	0	0	0	0	
DAY ON TEST	9	9	9	9	9	9	9	9	9	9	
	4	4	4	4	4	4	4	4	4	4	
.....											
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0	
FEMALE	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	5	5	5	5	5	5	5	5	5	5	
200,000 NG/KG 67	4	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
.....											
URINARY SYSTEM											
Kidney	+	+	+	+	+	+	+	+	+	+	10
Mineralization			1	1	1	1	1				5 1.0
Nephropathy		1			1	1	1	1			5 1.0
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	10

*** END OF REPORT ***

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 Page 24