Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

Lab: BAT

F2\_R2

NTP Study Number: C99032

**Lock Date:** 09/07/2007

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Study Gender: Both

**TDMSE Version:** 2.6.0.0\_007

**PWG Approval Date:** 12/19/2009

Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

### P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
Disposition Summary				
Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	17	14	15	17
Natural Death	10	8	7	5
Survivors				
Natural Death		2		
Terminal Sacrifice	23	26	28	28
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Periesophageal Tissue, Hemorrhage	1 (2%)			
Periesophageal Tissue, Inflammation	1 (2%)			
Intestine Large, Cecum	(49)	(50)	(50)	(50)
Inflammation	·	2 (4%)	·	·
Necrosis		1 (2%)		
Thrombosis		1 (2%)	1 (2%)	
Intestine Large, Colon	(50)	(50)	(50)	(50)
Hyperplasia, Lymphoid		1 (2%)		
Parasite Metazoan	2 (4%)		1 (2%)	6 (12%)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Parasite Metazoan	4 (8%)	5 (10%)	3 (6%)	4 (8%)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Inflammation			1 (2%)	
Ulcer			1 (2%)	
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Inflammation			1 (2%)	
Epithelium, Dysplasia	1 (2%)			
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Inflammation				1 (2%)
Peyer's Patch, Inflammation, Granulomatous		1 (2%)		
Liver	(50)	(50)	(50)	(50)
Angiectasis	3 (6%)	2 (4%)		1 (2%)

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

### P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

Experiment Number: 99032 - 03

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Basophilic Focus	8 (16%)	8 (16%)	11 (22%)	8 (16%)	
Clear Cell Focus	18 (36%)	17 (34%)	21 (42%)	21 (42%)	
Congestion, Acute	1 (2%)				
Degeneration, Cystic	1 (2%)	6 (12%)	1 (2%)	1 (2%)	
Eosinophilic Focus	3 (6%)	2 (4%)		2 (4%)	
Fatty Change	1 (2%)	3 (6%)	1 (2%)	3 (6%)	
Hematopoietic Cell Proliferation				2 (4%)	
Hemorrhage			1 (2%)		
Hepatodiaphragmatic Nodule	3 (6%)	2 (4%)	5 (10%)	4 (8%)	
Inflammation	19 (38%)	17 (34%)	17 (34%)	17 (34%)	
Mixed Cell Focus	8 (16%)	6 (12%)	6 (12%)	5 (10%)	
Bile Duct, Cyst			1 (2%)		
Bile Duct, Hyperplasia	28 (56%)	24 (48%)	27 (54%)	26 (52%)	
Centrilobular, Fibrosis	1 (2%)		1 (2%)		
Hepatocyte, Atrophy		1 (2%)	1 (2%)		
Hepatocyte, Degeneration	1 (2%)	1 (2%)			
Hepatocyte, Necrosis	1 (2%)	5 (10%)	4 (8%)	5 (10%)	
Hepatocyte, Regeneration	1 (2%)		1 (2%)		
Hepatocyte, Vacuolization Cytoplasmic	19 (38%)	20 (40%)	24 (48%)	18 (36%)	
Kupffer Cell, Pigmentation				1 (2%)	
Portal, Fibrosis	3 (6%)	6 (12%)	9 (18%)	6 (12%)	
Vein, Thrombosis		1 (2%)			
Mesentery	(9)	(2)	(3)	(5)	
Necrosis	7 (78%)	2 (100%)	3 (100%)	4 (80%)	
Oral Mucosa	(2)	(1)	(4)	(3)	
Gingival, Inflammation	2 (100%)	1 (100%)	2 (50%)	3 (100%)	
Pharyngeal, Hyperplasia			2 (50%)		
Pancreas	(50)	(50)	(50)	(50)	
Acinus, Atrophy	28 (56%)	31 (62%)	28 (56%)	31 (62%)	
Acinus, Hyperplasia	3 (6%)	8 (16%)	4 (8%)	1 (2%)	
Duct, Cyst	5 (10%)	4 (8%)	3 (6%)	4 (8%)	
Salivary Glands	(50)	(50)	(50)	(50)	
Hyperplasia		1 (2%)			
Inflammation			1 (2%)	1 (2%)	
Duct, Cyst			1 (2%)		
Stomach, Forestomach	(50)	(50)	(50)	(50)	

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

Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

### P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
			<u>-</u>	
		( (224)	- (()	
2 (4%)		1 (2%)	5 (10%)	
(50)		(50)	(50)	
	, ,			
2 (4%)	4 (8%)		3 (6%)	
	4 (8%)		3 (6%)	
		1 (2%)		
	2 (4%)	1 (2%)		
	1 (2%)	1 (2%)		
(1)			(2)	
. ,	• *	. ,	1 (50%)	
(50) (50) 46 (92%)	(50) (50) 45 (90%) 2 (4%)	(50) (50) 46 (92%)	(50) (50) 47 (94%) 1 (2%) 1 (2%) 1 (2%) 2 (4%)	
(50)	(50)	(50)	(50)	
	•	•	1 (2%)	
	1 (2%)	1 (2%)		
	, ,			
	1 (2%)			
19 (38%)			20 (40%)	
. ( ,	. 0 (=0,0)	. 0 (=0,0)		
	1 (2%) 2 (4%) 4 (8%) 2 (4%) (50) 2 (4%)  (1)  (50) (50) (50) 46 (92%)	1 (2%) 2 (4%) 1 (2%) 4 (8%) 6 (12%) 2 (4%) (50) (50) 1 (2%) 2 (4%) 4 (8%)  2 (4%) 4 (8%)  2 (4%) 1 (2%) (1)  (50) (50) (50) (50) (50) (50) 46 (92%) (50) (50) (50) (50) (50) (50) (50) (50	1 (2%) 2 (4%) 1 (2%) 1 (2%) 4 (8%) 6 (12%) 7 (14%) 2 (4%) (50) (50) (50) (50) 1 (2%) 2 (4%) 4 (8%) 4 (8%) 4 (8%)  1 (2%) 2 (4%) 1 (2%) 2 (4%) 1 (2%) 1 (2%) 1 (2%) (1) (50) (50) (50) (50) (50) (50) (50) (50	1 (2%) 2 (4%) 1 (2%) 1 (2%) 1 (2%) 4 (8%) 6 (12%) 7 (14%) 4 (8%) 6 (12%) 7 (14%) 4 (8%) 6 (12%) 6 (50) (50) (50) (50) (50) (50) (4 (8%) 4 (8%) 3 (6%) 4 (8%) 3 (6%) 4 (8%) 3 (6%) 4 (8%) 3 (6%)  1 (2%) 2 (4%) 1 (2%) 1 (2%) 1 (2%) (1) (0) (50) (50) (50) (50) (50) (50) (50)

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

Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

# P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

Lab: BAT

ISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Necrosis			1 (2%)	1 (2%)	
Vacuolization Cytoplasmic	27 (54%)	18 (36%)	23 (46%)	19 (38%)	
Capsule, Fibrosis, Focal	,	,	,	1 (2%)	
Adrenal Medulla	(50)	(50)	(50)	(50)	
Angiectasis	, ,	, ,	, ,	1 (2%)	
Hemorrhage		1 (2%)		1 (2%)	
Hyperplasia	16 (32%)	18 (36%)	20 (40%)	18 (36%)	
Infiltration Cellular, Mononuclear Cell	, ,	, ,	, ,	1 (2%)	
Mineralization				1 (2%)	
Necrosis			1 (2%)		
Islets, Pancreatic	(50)	(50)	(50)	(50)	
Hyperplasia				1 (2%)	
Parathyroid Gland	(50)	(49)	(47)	(49)	
Cyst		1 (2%)			
Hyperplasia		3 (6%)			
Pituitary Gland	(50)	(49)	(50)	(50)	
Hemorrhage		1 (2%)		2 (4%)	
Pigmentation, Hemosiderin				1 (2%)	
Pars Distalis, Atrophy	1 (2%)			3 (6%)	
Pars Distalis, Cyst		2 (4%)		4 (8%)	
Pars Distalis, Hyperplasia	11 (22%)	10 (20%)	12 (24%)	13 (26%)	
Pars Intermedia, Hyperplasia		1 (2%)	1 (2%)		
Thyroid Gland	(50)	(50)	(50)	(50)	
Cyst		1 (2%)			
Inflammation				1 (2%)	
C-cell, Hyperplasia	18 (36%)	19 (38%)	21 (42%)	18 (36%)	

#### **GENERAL BODY SYSTEM**

None

GENITAL SYSTEM	GEI	NITAL	$_{\rm SYS}$	ΤΕМ
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Coagulating Gland	(1)	(0)	(0)	(0)
Epididymis	(50)	(50)	(50)	(50)

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

Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

# P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Inflammation		1 (2%)	2 (4%)		
Penis	(0)	(0)	(1)	(0)	
Congestion			1 (100%)		
Preputial Gland	(50)	(50)	(50)	(50)	
Inflammation	2 (4%)	8 (16%)	5 (10%)	7 (14%)	
Duct, Hyperplasia, Squamous				1 (2%)	
Prostate	(50)	(50)	(50)	(50)	
Inflammation	44 (88%)	45 (90%)	48 (96%)	44 (88%)	
Epithelium, Hyperplasia	4 (8%)	8 (16%)	5 (10%)	5 (10%)	
Epithelium, Metaplasia, Squamous			1 (2%)	1 (2%)	
Seminal Vesicle	(50)	(50)	(50)	(50)	
Inflammation		1 (2%)			
Bilateral, Atrophy			1 (2%)		
Testes	(50)	(50)	(50)	(50)	
Cyst			2 (4%)	1 (2%)	
Mineralization			2 (4%)		
Arteriole, Inflammation		1 (2%)			
Bilateral, Germinal Epithelium, Atrophy		3 (6%)		1 (2%)	
Germinal Epithelium, Atrophy	5 (10%)	4 (8%)	7 (14%)	9 (18%)	
Interstitial Cell, Hyperplasia	11 (22%)	13 (26%)	5 (10%)	8 (16%)	
HEMATOPOIETIC SYSTEM					
Bone Marrow	(50)	(50)	(50)	(50)	
Hemorrhage		1 (2%)		- 4	
Hyperplasia	10 (20%)	11 (22%)	11 (22%)	9 (18%)	
Infiltration Cellular, Histiocyte				1 (2%)	
Myelofibrosis		1 (2%)	1 (2%)		
Lymph Node	(10)	(8)	(4)	(7)	
Degeneration, Cystic			1 (25%)		
Deep Cervical, Degeneration, Cystic		1 (13%)		- ()	
Deep Cervical, Hemorrhage	- 4			2 (29%)	
Mediastinal, Degeneration, Cystic	2 (20%)	1 (13%)			
Mediastinal, Hemorrhage		2 (25%)			
Mediastinal, Hyperplasia		1 (13%)			

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

Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

# P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Mediastinal, Hyperplasia, Lymphoid		1 (13%)			
Mediastinal, Hyperplasia, Plasma Cell	2 (20%)	1 (13%)	1 (25%)		
Pancreatic, Degeneration, Cystic	1 (10%)				
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)	
Degeneration, Cystic		4 (8%)	1 (2%)	5 (10%)	
Hemorrhage				2 (4%)	
Hyperplasia, Histiocytic			2 (4%)		
Hyperplasia, Plasma Cell			1 (2%)		
Infiltration Cellular, Histiocyte			, ,	1 (2%)	
Necrosis, Lymphoid		2 (4%)		, ,	
Spleen	(50)	(50)	(50)	(50)	
Congestion	,	,	1 (2%)	,	
Hematopoietic Cell Proliferation			,	1 (2%)	
Hyperplasia, Lymphoid	3 (6%)	3 (6%)	1 (2%)	2 (4%)	
Infarct	2 (4%)	2 (4%)	3 (6%)	1 (2%)	
Necrosis, Lymphoid	,	1 (2%)	, ,	,	
Necrosis, Focal		1 (2%)			
Thrombosis		,		1 (2%)	
Capsule, Fibrosis		1 (2%)		1 (2%)	
Capsule, Inflammation		,		1 (2%)	
Lymphoid Follicle, Atrophy		1 (2%)	2 (4%)	,	
Lymphoid Follicle, Depletion Cellular		1 (2%)	,		
Thymus	(47)	(48)	(48)	(47)	
Cyst	,	( - /	1 (2%)	,	
Ectopic Parathyroid Gland			( /	1 (2%)	
Fibrosis			1 (2%)	( /	
Epithelial Cell, Hyperplasia			,	1 (2%)	
INTEGUMENTARY SYSTEM					
Mammary Gland	(50)	(49)	(50)	(50)	
Inflammation	` '	1 (2%)	` '	,	
Duct, Cyst	1 (2%)	,			
Duct, Dilatation	1 (2%)				
Skin	(50)	(50)	(50)	(50)	

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

Test Type: CHRONIC
Route: SKIN APPLICATION
Species/Strain: RATS/F 344/N

### P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Abscess		1 (2%)			
Fibrosis		, ,		1 (2%)	
Hyperkeratosis				1 (2%)	
Hyperplasia				2 (4%)	
Inflammation				1 (2%)	
Ulcer			1 (2%)	1 (2%)	
Control, Hyperkeratosis			, ,	1 (2%)	
Control, Hyperplasia				1 (2%)	
Control, Inflammation				1 (2%)	
Control, Sebaceous Gland, Hyperplasia				1 (2%)	
Sebaceous Gland, Site Of Application, Hyperplasia			12 (24%)	48 (96%)	
Site Of Application, Hyperkeratosis		2 (4%)	21 (42%)	48 (96%)	
Site Of Application, Hyperplasia		6 (12%)	20 (40%)	50 (100%)	
Site Of Application, Inflammation				46 (92%)	
Site Of Application, Ulcer				1 (2%)	
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	
Fibrosis				1 (2%)	
Hemorrhage		1 (2%)			
Osteopetrosis				1 (2%)	
Epiphysis, Femur, Cyst		1 (2%)		, ,	
Mandible, Cyst		, ,	1 (2%)		
NERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(50)	
Hemorrhage	3 (6%)	4 (8%)	(30)	2 (4%)	
Hydrocephalus	2 (4%)	3 (6%)	4 (8%)	_ ( ,	
Cerebrum, Inflammation	_ ( 1,0)	0 (0 /0)	. (070)	1 (2%)	
				. (=/-/	

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

Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

# P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
RESPIRATORY SYSTEM					
Lung	(50)	(50)	(50)	(50)	
Congestion	1 (2%)		1 (2%)		
Hemorrhage	1 (2%)	3 (6%)	, ,		
Hyperplasia	` ,	, ,	1 (2%)		
Inflammation	6 (12%)	12 (24%)	13 (26%)	8 (16%)	
Metaplasia, Squamous	,	,	1 (2%)	,	
Pigmentation, Hemosiderin		1 (2%)	,		
Thrombosis	2 (4%)	1 (2%)			
Alveolar Epithelium, Hyperplasia	9 (18%)	7 (14%)	10 (20%)	6 (12%)	
Alveolus, Infiltration Cellular, Histiocyte	6 (12%)	6 (12%)	5 (10%)	4 (8%)	
Bronchiole, Fibrosis	,	,	1 (2%)	,	
Serosa, Hyperplasia	1 (2%)		()		
Nose	(50)	(50)	(50)	(50)	
Inflammation	21 (42%)	28 (56%)	21 (42%)	18 (36%)	
Metaplasia, Squamous	1 (2%)	- ()	( /	- ()	
Polyp, Inflammatory	( )	1 (2%)			
Thrombosis		2 (4%)			
Nasolacrimal Duct, Inflammation		()		1 (2%)	
Trachea	(50)	(50)	(50)	(50)	
Infiltration Cellular, Mononuclear Cell	()	1 (2%)	()	()	
Inflammation	1 (2%)	(-7-7)	2 (4%)		
Metaplasia, Squamous	. (= /*)		1 (2%)		
SPECIAL SENSES SYSTEM					
Eye	(50)	(50)	(50)	(50)	
Cataract		2 (4%)		1 (2%)	
Anterior Chamber, Inflammation	1 (2%)				
Cornea, Inflammation	1 (2%)				
Retina, Atrophy	1 (2%)	3 (6%)		1 (2%)	
Retina, Developmental Malformation	` ,	, ,	1 (2%)	, ,	
Harderian Gland	(50)	(50)	(50)	(50)	
Hyperplasia	1 (2%)	1 (2%)	2 (4%)	` ,	

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

Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

### P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
Inflammation	1 (2%)	1 (2%)	1 (2%)	2 (4%)
Zymbal's Gland	(1)	(0)	(0)	(0)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Cyst, Multiple				1 (2%)
Hyperplasia, Tubular			2 (4%)	3 (6%)
Inflammation	1 (2%)	1 (2%)		2 (4%)
Nephropathy	45 (90%)	47 (94%)	49 (98%)	48 (96%)
Thrombosis			1 (2%)	
Pelvis, Calculus Micro Observation Only				1 (2%)
Transitional Epithelium, Hyperplasia				1 (2%)
Urethra	(0)	(0)	(0)	(1)
Bulbourethral Gland, Hyperplasia				1 (100%)
Urinary Bladder	(50)	(50)	(50)	(50)
Hemorrhage				1 (2%)
Inflammation		1 (2%)		
Transitional Epithelium, Hyperplasia			1 (2%)	1 (2%)

<sup>\*\*\*</sup> END OF MALE \*\*\*

Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
Disposition Summary				
Animals Initially In Study	50	50	50	50
Early Deaths				
Accidentally Killed		1		
Moribund Sacrifice	12	7	18	9
Natural Death	9	9	6	10
Survivors				
Natural Death			1	
Terminal Sacrifice	29	33	25	31
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Erosion	1 (2%)	. ,	. ,	. ,
Inflammation	1 (2%)		1 (2%)	2 (4%)
Thrombosis			1 (2%)	•
Ulcer	1 (2%)	1 (2%)	1 (2%)	
Intestine Large, Colon	(50)	(50)	(50)	(50)
Inflammation	1 (2%)	·		•
Parasite Metazoan	2 (4%)	5 (10%)	2 (4%)	1 (2%)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Parasite Metazoan	3 (6%)	8 (16%)	5 (10%)	5 (10%)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Parasite Metazoan	1 (2%)			
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Inflammation		1 (2%)	1 (2%)	
Parasite Metazoan			1 (2%)	
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Peyer's Patch, Hyperplasia	1 (2%)			
Serosa, Fibrosis	1 (2%)			
Liver	(50)	(50)	(50)	(50)
Angiectasis	1 (2%)	2 (4%)		3 (6%)
Atypia Cellular, Focal			1 (2%)	

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

### P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

Experiment Number: 99032 - 03

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Basophilic Focus	31 (62%)	34 (68%)	28 (56%)	34 (68%)	
Clear Cell Focus	9 (18%)	1 (2%)	2 (4%)	4 (8%)	
Congestion, Diffuse	, ,	, ,	` ,	1 (2%)	
Degeneration, Cystic		1 (2%)	1 (2%)	,	
Eosinophilic Focus	2 (4%)	4 (8%)	2 (4%)	1 (2%)	
Fatty Change	4 (8%)	1 (2%)	6 (12%)	4 (8%)	
Hematopoietic Cell Proliferation		1 (2%)			
Hemorrhage			1 (2%)	1 (2%)	
Hepatodiaphragmatic Nodule	1 (2%)	6 (12%)	3 (6%)	7 (14%)	
Inflammation	23 (46%)	26 (52%)	10 (20%)	16 (32%)	
Mixed Cell Focus	5 (10%)	5 (10%)	3 (6%)	4 (8%)	
Bile Duct, Hyperplasia	10 (20%)	7 (14%)	7 (14%)	7 (14%)	
Hepatocyte, Hypertrophy		1 (2%)			
Hepatocyte, Necrosis	1 (2%)	1 (2%)	3 (6%)		
Hepatocyte, Regeneration		, ,	1 (2%)	1 (2%)	
Hepatocyte, Vacuolization Cytoplasmic	12 (24%)	15 (30%)	8 (16%)	6 (12%)	
Hepatocyte, Midzonal, Degeneration	1 (2%)				
Portal, Fibrosis	4 (8%)	1 (2%)	3 (6%)	1 (2%)	
Serosa, Fibrosis				1 (2%)	
Mesentery	(8)	(11)	(13)	(10)	
Necrosis	6 (75%)	11 (100%)	13 (100%)	10 (100%)	
Oral Mucosa	(2)	(2)	(0)	(0)	
Gingival, Cyst	1 (50%)	1 (50%)			
Gingival, Inflammation	1 (50%)	1 (50%)			
Pancreas	(50)	(50)	(50)	(50)	
Basophilic Focus		1 (2%)			
Acinus, Atrophy	16 (32%)	13 (26%)	17 (34%)	15 (30%)	
Acinus, Hyperplasia	3 (6%)	8 (16%)	1 (2%)	5 (10%)	
Duct, Cyst	4 (8%)	2 (4%)	2 (4%)	2 (4%)	
Salivary Glands	(50)	(50)	(50)	(50)	
Hyperplasia			1 (2%)		
Inflammation			1 (2%)		
Mineralization			1 (2%)		
Stomach, Forestomach	(50)	(50)	(50)	(50)	
Inflammation	1 (2%)	• •	2 (4%)	3 (6%)	
Ulcer	5 (10%)	3 (6%)	7 (14%)	3 (6%)	

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

Test Type: CHRONIC
Route: SKIN APPLICATION
Species/Strain: RATS/F 344/N

### P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Epithelium, Hyperplasia	3 (6%)		1 (2%)	3 (6%)	
Stomach, Glandular	(50)	(50)	(50)	(50)	
Erosion	1 (2%)	1 (2%)	1 (2%)		
Inflammation	2 (4%)		1 (2%)	2 (4%)	
Ulcer			1 (2%)		
Epithelium, Cyst				1 (2%)	
CARDIOVASCULAR SYSTEM					
Blood Vessel	(50)	(50)	(50)	(50)	
Thrombosis			1 (2%)		
Heart	(50)	(50)	(50)	(50)	
Cardiomyopathy	44 (88%)	45 (90%)	46 (92%)	45 (90%)	
Inflammation	1 (2%)				
Atrium, Thrombosis	1 (2%)	1 (2%)	1 (2%)		
Myocardium, Inflammation		1 (2%)			
ENDOCRINE SYSTEM					
Adrenal Cortex	(50)	(50)	(50)	(50)	
Angiectasis			1 (2%)		
Atrophy			1 (2%)	1 (2%)	
Atypia Cellular			1 (2%)		
Degeneration, Cystic	8 (16%)	4 (8%)	4 (8%)	2 (4%)	
Hematopoietic Cell Proliferation	1 (2%)			1 (2%)	
Hemorrhage				2 (4%)	
Hyperplasia	29 (58%)	24 (48%)	26 (52%)	29 (58%)	
Hypertrophy	17 (34%)	15 (30%)	24 (48%)	21 (42%)	
Necrosis			1 (2%)		
Thrombosis			1 (2%)		
Vacuolization Cytoplasmic	14 (28%)	13 (26%)	13 (26%)	18 (36%)	
Adrenal Medulla	(50)	(50)	(50)	(50)	
Hyperplasia	5 (10%)	1 (2%)	6 (12%)	4 (8%)	
Infiltration Cellular, Mononuclear Cell				1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)	

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

Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

### P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Parathyroid Gland	(49)	(49)	(50)	(49)	
Hyperplasia			2 (4%)		
Pituitary Gland	(50)	(50)	(50)	(50)	
Angiectasis			1 (2%)		
Cyst			1 (2%)	1 (2%)	
Hemorrhage	1 (2%)			2 (4%)	
Pars Distalis, Cyst	4 (8%)	8 (16%)	7 (14%)	7 (14%)	
Pars Distalis, Hyperplasia	19 (38%)	16 (32%)	17 (34%)	19 (38%)	
Pars Distalis, Inflammation		1 (2%)			
Thyroid Gland	(50)	(50)	(50)	(50)	
Cyst				1 (2%)	
C-cell, Hyperplasia	22 (44%)	31 (62%)	23 (46%)	31 (62%)	
Follicle, Cyst		1 (2%)	·	·	
Follicular Cell, Hyperplasia		. ,		1 (2%)	

#### **GENERAL BODY SYSTEM**

None

Clitoral Gland	(50)	(50)	(50)	(50)
Atrophy			1 (2%)	
Fibrosis			1 (2%)	
Hyperplasia	3 (6%)	1 (2%)	4 (8%)	1 (2%)
Inflammation	3 (6%)	4 (8%)	6 (12%)	6 (12%)
Duct, Dilatation	1 (2%)		2 (4%)	
Ovary	(50)	(50)	(50)	(50)
Cyst	3 (6%)	3 (6%)	6 (12%)	1 (2%)
Uterus	(50)	(50)	(50)	(50)
Hemorrhage		1 (2%)		
Hyperplasia, Adenomatous				1 (2%)
Inflammation	3 (6%)			1 (2%)
Cervix, Fibrosis	1 (2%)			
Endometrium, Cyst			1 (2%)	

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Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

# P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Endometrium, Edema			1 (2%)		
Endometrium, Hyperplasia, Cystic	5 (10%)	5 (10%)	4 (8%)		
Vagina	(0)	(1)	(0)	(0)	
Inflammation		1 (100%)			
HEMATOPOIETIC SYSTEM					
Bone Marrow	(50)	(50)	(50)	(50)	
Fibrosis	1 (2%)				
Hyperplasia	10 (20%)	6 (12%)	10 (20%)	10 (20%)	
Myelofibrosis			2 (4%)	1 (2%)	
Lymph Node	(3)	(2)	(4)	(2)	
Hemorrhage			1 (25%)		
Deep Cervical, Hyperplasia, Plasma Cell	1 (33%)				
Mediastinal, Congestion		1 (50%)			
Mediastinal, Hemorrhage	2 (67%)		1 (25%)		
Mediastinal, Hyperplasia, Plasma Cell	1 (33%)	1 (50%)	1 (25%)		
Pancreatic, Hemorrhage			1 (25%)		
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)	
Degeneration, Cystic	3 (6%)			1 (2%)	
Hyperplasia, Lymphoid				1 (2%)	
Hyperplasia, Plasma Cell			1 (2%)	1 (2%)	
Infiltration Cellular, Histiocyte		1 (2%)			
Inflammation		2 (4%)			
Spleen	(50)	(50)	(50)	(50)	
Accessory Spleen			1 (2%)	1 (2%)	
Hematopoietic Cell Proliferation		3 (6%)	1 (2%)		
Hyperplasia, Lymphoid		1 (2%)	1 (2%)	2 (4%)	
Infarct		2 (4%)	4 (8%)	1 (2%)	
Pigmentation, Hemosiderin		1 (2%)		1 (2%)	
Capsule, Hyperplasia			1 (2%)		
Capsule, Inflammation			1 (2%)		
Lymphoid Follicle, Atrophy		1 (2%)	1 (2%)	1 (2%)	
Thymus	(50)	(50)	(49)	(50)	
Cyst				1 (2%)	

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Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

### P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
INTEGUMENTARY SYSTEM					
Mammary Gland	(50)	(50)	(50)	(50)	
Inflammation	1 (2%)	4 (8%)		1 (2%)	
Duct, Cyst	1 (2%)	1 (2%)	1 (2%)	5 (10%)	
Duct, Hyperplasia, Cystic	1 (2%)				
Skin	(50)	(50)	(50)	(50)	
Hyperkeratosis	. ,	2 (4%)		, ,	
Hyperplasia		, ,		1 (2%)	
Ulcer				1 (2%)	
Control, Hyperplasia			1 (2%)	,	
Control, Inflammation			1 (2%)		
Sebaceous Gland, Site Of Application, Hyperplasia			5 (10%)	41 (82%)	
Site Of Application, Hyperkeratosis		6 (12%)	23 (46%)	49 (98%)	
Site Of Application, Hyperplasia		9 (18%)	11 (22%)	49 (98%)	
Site Of Application, Inflammation		3 (6%)	6 (12%)	49 (98%)	
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	
Osteopetrosis	(00)	(00)	1 (2%)	(33)	
Osteosclerosis	1 (2%)		(270)		
Fibula, Tibia, Fracture	1 (2%)				
Skeletal Muscle	(0)	(0)	(2)	(0)	
NERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(50)	
Hemorrhage	1 (2%)	1 (2%)	(50)	1 (2%)	
Hydrocephalus	1 (2%)	3 (6%)	3 (6%)	3 (6%)	
Thrombosis	1 (2/0)	3 (0/0)	1 (2%)	3 (0 /0)	
	1 (20/.)		I (∠ /0)		
Cerebellum, Gliosis	1 (2%)				

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Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

# P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Cerebrum, Necrosis	1 (2%)				
Peripheral Nerve	(0)	(0)	(1)	(0)	
Spinal Cord	(0)	(0)	(1)	(0)	
RESPIRATORY SYSTEM					
Larynx	(0)	(1)	(0)	(0)	
Foreign Body	( )	1 (100%)	( )	( )	
Inflammation		1 (100%)			
Lung	(50)	(50)	(50)	(50)	
Congestion	,	1 (2%)	1 (2%)	1 (2%)	
Fibrosis	2 (4%)	,	,	,	
Hemorrhage	, ,	2 (4%)			
Inflammation	8 (16%)	9 (18%)	2 (4%)	10 (20%)	
Thrombosis	1 (2%)				
Alveolar Epithelium, Hyperplasia	6 (12%)	11 (22%)	5 (10%)	12 (24%)	
Alveolus, Infiltration Cellular, Histiocyte	2 (4%)	3 (6%)	2 (4%)	6 (12%)	
Alveolus, Pigmentation, Hemoglobin				1 (2%)	
Bronchiole, Hyperplasia				1 (2%)	
Serosa, Fibrosis		1 (2%)			
Nose	(50)	(50)	(50)	(50)	
Inflammation	11 (22%)	10 (20%)	12 (24%)	8 (16%)	
Metaplasia, Squamous	1 (2%)	1 (2%)			
Thrombosis	1 (2%)	1 (2%)	1 (2%)		
Goblet Cell, Hyperplasia	2 (4%)	2 (4%)			
Nasolacrimal Duct, Inflammation		1 (2%)			
Nasolacrimal Duct, Squamous Epithelium, Hyperplasia	1 (2%)				
Nasopharyngeal Duct, Inflammation			2 (4%)		
Olfactory Epithelium, Hyperplasia			1 (2%)		
Respiratory Epithelium, Necrosis		1 (2%)			
Squamous Epithelium, Necrosis		1 (2%)			
Vomeronasal Organ, Necrosis		1 (2%)			
Trachea	(50)	(50)	(50)	(50)	
Infiltration Cellular, Mononuclear Cell	1 (2%)				

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Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

# P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol CAS Number: 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Inflammation	1 (2%)		1 (2%)		
SPECIAL SENSES SYSTEM					
Eye	(50)	(50)	(50)	(50)	
Cataract	3 (6%)	4 (8%)	1 (2%)	1 (2%)	
Synechia	1 (2%)	1 (2%)			
Anterior Chamber, Exudate				1 (2%)	
Bilateral, Retina, Atrophy		1 (2%)			
Optic Nerve, Atrophy	1 (2%)		1 (2%)		
Posterior Chamber, Exudate				1 (2%)	
Retina, Atrophy	3 (6%)	3 (6%)	2 (4%)		
Retina, Developmental Malformation	1 (2%)				
Retina, Dysplasia		1 (2%)		1 (2%)	
Harderian Gland	(50)	(50)	(50)	(50)	
Hyperplasia	1 (2%)	2 (4%)	4 (8%)	3 (6%)	
Inflammation	2 (4%)	4 (8%)		4 (8%)	
Metaplasia, Squamous	1 (2%)				
Pigmentation, Porphyrin		3 (6%)	6 (12%)	1 (2%)	
URINARY SYSTEM					
Kidney	(50)	(50)	(50)	(50)	
Accumulation, Hyaline Droplet	` '	2 (4%)	` ,	, ,	
Atrophy		, ,	1 (2%)		
Cyst		1 (2%)	1 (2%)		
Hypertrophy			1 (2%)		
Infiltration Cellular, Lipocyte		1 (2%)	. ,		
Inflammation	1 (2%)	, ,	3 (6%)		
Nephropathy	46 (92%)	42 (84%)	42 (84%)	44 (88%)	
Papilla, Necrosis	•	, ,	1 (2%)	,	
Transitional Epithelium, Hyperplasia			1 (2%)		
Urinary Bladder	(50)	(50)	(50)	(49)	
Transitional Epithelium, Hyperplasia		1 (2%)	1 (2%)		

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Test Type: CHRONIC

Route: SKIN APPLICATION
Species/Strain: RATS/F 344/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pyrogallol

**CAS Number:** 87-66-1

Date Report Requested: 05/30/2012 Time Report Requested: 11:40:45 First Dose M/F: 09/15/04 / 09/16/04

Lab: BAT

FISCHER 344 RATS FEMALE 0 MG/KG 5 MG/KG 20 MG/KG 75 MG/KG

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