

TDMS No. 88105 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

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

ISOEUGENOL

CAS Number: 97-54-1

Pathologist: Blackshear, P. - GRUMBEIN, S.

F1_R2

Date Report Reqsted: 09/28/2006

Time Report Reqsted: 17:46:24

First Dose M/F: 04/22/02 / 04/23/02

Lab: BNW

C Number: C88105
Lock Date: 01/21/2005
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident		1		2
Moribund Sacrifice	14	9	14	11
Natural Death	1	6	3	7
Survivors				
Terminal Sacrifice	35	34	33	30
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Perforation				2 [3.5]
Intestine Large, Cecum	(49)	(46)	(50)	(45)
Inflammation, Acute		1 [2.0]		
Intestine Large, Colon	(50)	(46)	(50)	(47)
Parasite Metazoan	1	1	2	
Intestine Large, Rectum	(50)	(46)	(50)	(48)
Parasite Metazoan	4	1		
Intestine Small, Duodenum	(50)	(46)	(50)	(45)
Inflammation, Acute				1 [1.0]
Intestine Small, Ileum	(50)	(46)	(50)	(45)
Intestine Small, Jejunum	(50)	(46)	(50)	(45)
Inflammation, Chronic			1 [4.0]	
Liver	(50)	(50)	(50)	(48)
Angiectasis	1 [2.0]			2 [2.5]
Basophilic Focus	43	34	26	18
Clear Cell Focus	27	20	19	14
Degeneration, Cystic	4 [2.0]	1 [2.0]	2 [2.0]	4 [1.3]
Eosinophilic Focus	8	2		2
Fatty Change	2 [3.0]	1 [2.0]	2 [3.0]	2 [3.0]
Hematopoietic Cell Proliferation		1 [2.0]		
Hepatodiaphragmatic Nodule	5	3	3	3
Infarct				1 [2.0]
Malformation		1		
Mixed Cell Focus	6	4	6	2

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Necrosis	1 [2.0]			
Bile Duct, Hyperplasia	39 [1.5]	39 [1.5]	32 [1.4]	24 [1.2]
Centrilobular, Necrosis	2 [2.0]	1 [3.0]		1 [2.0]
Hepatocyte, Vacuolization Cytoplasmic				1 [1.0]
Mesentery	(12)	(18)	(7)	(11)
Fat, Hemorrhage	1 [3.0]			
Fat, Necrosis	10 [2.1]	17 [2.1]	7 [2.0]	9 [2.0]
Oral Mucosa	(1)	(0)	(1)	(3)
Pancreas	(50)	(50)	(50)	(49)
Basophilic Focus	1 [2.0]	1 [4.0]		
Metaplasia, Hepatocyte	1 [1.0]			
Acinus, Atrophy	22 [1.5]	21 [1.3]	17 [1.4]	10 [1.1]
Acinus, Hyperplasia	21 [2.5]	12 [2.6]	13 [2.5]	19 [2.6]
Salivary Glands	(50)	(50)	(49)	(50)
Hyperplasia	1 [2.0]			
Stomach, Forestomach	(50)	(49)	(50)	(49)
Hyperplasia, Squamous	2 [2.5]	1 [1.0]	3 [2.3]	5 [2.2]
Inflammation	1 [2.0]			
Ulcer	3 [2.3]	1 [2.0]	4 [2.5]	2 [2.5]
Stomach, Glandular	(50)	(46)	(50)	(45)
Atrophy	2 [2.0]	3 [2.3]	2 [1.5]	3 [1.7]
Inflammation, Chronic Active			1 [4.0]	
Mineralization				1 [1.0]
Necrosis		1 [2.0]	1 [2.0]	
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	48 [1.4]	44 [1.6]	47 [1.6]	46 [1.7]
Thrombosis	1 [2.0]	2 [2.5]		
Pericardium, Inflammation, Acute				1 [3.0]
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(49)
Degeneration, Cystic	2 [2.0]			
Hyperplasia	31 [1.9]	22 [2.0]	21 [2.0]	31 [2.0]
Hypertrophy	5 [1.6]	1 [2.0]	4 [1.8]	1 [2.0]
Vacuolization Cytoplasmic		2 [2.0]		

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Adrenal Medulla	(50)	(50)	(50)	(49)
Hyperplasia	24 [2.0]	18 [2.5]	16 [2.4]	15 [2.2]
Islets, Pancreatic	(50)	(49)	(50)	(49)
Hyperplasia	1 [2.0]		1 [2.0]	
Pituitary Gland	(50)	(48)	(47)	(47)
Hemorrhage				1 [2.0]
Pars Distalis, Angiectasis	6 [2.8]		3 [2.7]	2 [3.0]
Pars Distalis, Hyperplasia	18 [2.4]	20 [2.3]	15 [2.3]	16 [2.4]
Thyroid Gland	(50)	(49)	(50)	(47)
C-cell, Hyperplasia	9 [2.2]	5 [2.0]	7 [2.3]	9 [2.2]
Follicular Cell, Hyperplasia	3 [1.3]	3 [2.0]		5 [1.4]

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm		1 [1.0]		
Preputial Gland	(50)	(49)	(50)	(50)
Cyst		1		
Hyperplasia	1 [2.0]	2 [3.0]	1 [2.0]	4 [1.8]
Inflammation, Chronic Active		1 [4.0]		
Prostate	(50)	(49)	(50)	(50)
Hyperplasia	10 [2.0]	9 [2.2]	15 [2.8]	11 [2.2]
Inflammation, Chronic Active	3 [1.7]	1 [2.0]		3 [2.7]
Seminal Vesicle	(50)	(49)	(50)	(49)
Hyperplasia				1 [3.0]
Testes	(50)	(50)	(50)	(50)
Atrophy	1 [3.0]	4 [3.0]	3 [2.7]	
Interstitial Cell, Hyperplasia	7 [1.9]	2 [2.5]	4 [1.5]	1 [1.0]

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(49)	(50)	(50)
Hyperplasia, Reticulum Cell			1 [3.0]	
Lymph Node	(3)	(4)	(4)	(4)

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Deep Cervical, Hyperplasia, Lymphoid Mediastinal, Ectasia	1 [2.0]		1 [1.0]	
Pancreatic, Inflammation, Chronic Active			1 [4.0]	
Lymph Node, Mesenteric	(50)	(48)	(50)	(47)
Spleen	(50)	(46)	(50)	(47)
Fibrosis	2 [2.0]		2 [2.5]	
Hematopoietic Cell Proliferation	3 [2.7]	3 [3.3]	1 [3.0]	2 [3.0]
Hemorrhage	1 [4.0]			
Hyperplasia, Lymphoid		1 [3.0]		
Inflammation, Acute		1 [2.0]		
Necrosis	2 [2.0]	1 [3.0]	1 [4.0]	
Thymus	(47)	(43)	(49)	(48)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(49)	(50)	(50)
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion		2		2
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(2)	(0)	(1)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Hydrocephalus	2 [2.5]			
Thrombosis		1 [2.0]		
Meninges, Hemorrhage			1 [3.0]	
Peripheral Nerve	(0)	(1)	(1)	(0)
Spinal Cord	(0)	(1)	(1)	(0)
Hemorrhage			1 [3.0]	
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Foreign Body			3	1

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Inflammation, Chronic Active		1 [3.0]	1 [2.0]	
Metaplasia, Squamous	1 [2.0]	2 [3.0]		
Thrombosis		1 [3.0]		
Alveolar Epithelium, Hyperplasia	27 [1.6]	20 [1.6]	16 [1.7]	25 [1.7]
Alveolus, Infiltration Cellular, Histiocyte				1 [2.0]
Bronchiole, Hyperplasia		1 [2.0]	1 [1.0]	1 [1.0]
Perivascular, Inflammation, Chronic Active		1 [4.0]		
Nose	(50)	(48)	(49)	(49)
Foreign Body	3		3	4
Inflammation, Suppurative	12 [1.3]	11 [1.3]	13 [1.4]	12 [1.5]
Inflammation, Chronic	2 [1.0]	1 [2.0]	2 [1.5]	2 [2.0]
Thrombosis			1 [3.0]	
Glands, Dilatation		2 [1.5]	1 [2.0]	2 [2.0]
Nasolacrimal Duct, Cyst			1	
Nasolacrimal Duct, Inflammation				1 [2.0]
Olfactory Epithelium, Accumulation, Hyaline Droplet	50 [1.4]	37 [1.2]	42 [1.2]	42 [1.2]
Olfactory Epithelium, Atrophy	1 [1.0]	5 [1.2]	9 [1.0]	13 [1.0]
Olfactory Epithelium, Degeneration	1 [1.0]		2 [1.0]	6 [1.2]
Olfactory Epithelium, Hyperplasia				1 [2.0]
Olfactory Epithelium, Hyperplasia, Basal Cell			1 [1.0]	
Olfactory Epithelium, Metaplasia, Respiratory	4 [1.0]	6 [1.3]	10 [1.7]	15 [1.9]
Olfactory Epithelium, Metaplasia, Squamous	1 [1.0]	1 [2.0]		
Respiratory Epithelium, Accumulation, Hyaline Droplet	3 [2.0]	5 [1.6]	1 [1.0]	2 [1.0]
Respiratory Epithelium, Hyperplasia	12 [1.6]	3 [1.7]	14 [1.6]	8 [1.8]
Respiratory Epithelium, Metaplasia, Squamous	1 [1.0]	4 [2.0]	3 [1.3]	5 [2.0]
Pleura	(0)	(0)	(0)	(2)
Inflammation, Acute				2 [4.0]
Trachea	(50)	(49)	(50)	(48)
Epithelium, Necrosis		1 [3.0]		

SPECIAL SENSES SYSTEM

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Eye	(50)	(46)	(50)	(45)
Cataract		1 [4.0]		2 [3.0]
Retina, Atrophy		1 [4.0]	1 [3.0]	2 [3.0]
Harderian Gland	(50)	(47)	(50)	(45)
Hyperplasia	1 [2.0]	5 [2.4]	5 [1.6]	1 [2.0]
Inflammation, Chronic Active	1 [3.0]			
Zymbal's Gland	(2)	(1)	(0)	(0)
URINARY SYSTEM				
Kidney	(50)	(48)	(50)	(49)
Cyst				1 [3.0]
Degeneration, Mucoïd, Focal				1 [3.0]
Hyperplasia, Oncocytic				1 [1.0]
Inflammation, Suppurative				1 [2.0]
Nephropathy	49 [1.6]	46 [1.4]	47 [1.6]	47 [2.1]
Renal Tubule, Degeneration, Hyaline				1 [4.0]
Transitional Epithelium, Hyperplasia		1 [2.0]		2 [2.5]
Urinary Bladder	(50)	(48)	(50)	(47)

*** END OF MALE ***

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FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident		1		
Moribund Sacrifice	15	8	9	9
Natural Death	2	6	7	10
Survivors				
Moribund Sacrifice				1
Terminal Sacrifice	33	35	34	30
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Perforation		1 [4.0]		
Intestine Large, Colon	(50)	(48)	(47)	(48)
Parasite Metazoan	2	1	1	
Intestine Large, Rectum	(49)	(48)	(47)	(48)
Parasite Metazoan	1	1	1	2
Intestine Small, Ileum	(49)	(47)	(45)	(45)
Parasite Metazoan			1	
Liver	(50)	(50)	(50)	(50)
Angiectasis			2 [2.0]	3 [2.3]
Basophilic Focus	50	49	48	46
Clear Cell Focus	12	9	9	10
Degeneration, Cystic	1 [2.0]			
Eosinophilic Focus	2	2	5	5
Fatty Change	2 [2.5]		1 [2.0]	
Hepatodiaphragmatic Nodule	8	11	7	4
Mixed Cell Focus	5	7	3	3
Necrosis		1 [4.0]		
Bile Duct, Hyperplasia	3 [1.7]	4 [2.0]	4 [1.3]	4 [1.5]
Hepatocyte, Mitotic Alteration				1 [3.0]
Mesentery	(11)	(11)	(11)	(14)
Fat, Hemorrhage	1 [2.0]			
Fat, Necrosis	11 [2.0]	10 [2.0]	11 [2.1]	13 [2.0]
Oral Mucosa	(0)	(1)	(0)	(1)

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FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Pancreas	(50)	(49)	(48)	(50)
Basophilic Focus	1 [2.0]			
Acinus, Atrophy	9 [1.1]	4 [1.3]	2 [1.0]	4 [1.3]
Acinus, Hyperplasia	5 [2.0]	2 [2.0]		5 [2.6]
Salivary Glands	(49)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(49)	(50)
Hyperplasia, Squamous	2 [1.0]		1 [2.0]	2 [2.0]
Inflammation	1 [2.0]			1 [2.0]
Ulcer	1 [3.0]		2 [2.0]	2 [1.5]
Stomach, Glandular	(50)	(47)	(46)	(47)
Atrophy	1 [1.0]	3 [1.7]		3 [2.0]
Mineralization	3 [1.0]	1 [1.0]	2 [1.0]	1 [2.0]
Tongue	(0)	(0)	(1)	(0)
Tooth	(0)	(1)	(0)	(0)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	41 [1.1]	42 [1.1]	38 [1.1]	39 [1.2]
Pericardium, Inflammation, Granulomatous				1 [4.0]
Pericardium, Inflammation, Acute		1 [3.0]		1 [2.0]
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(47)	(49)
Degeneration, Cystic		2 [2.5]	4 [2.3]	3 [2.3]
Hyperplasia	25 [2.0]	17 [2.1]	18 [2.0]	18 [2.0]
Hypertrophy	4 [1.8]	3 [2.0]	2 [2.0]	2 [2.0]
Necrosis	1 [3.0]	2 [2.0]	1 [3.0]	
Vacuolization Cytoplasmic				1 [4.0]
Adrenal Medulla	(50)	(50)	(46)	(49)
Hyperplasia	5 [2.4]	6 [2.0]	5 [1.6]	5 [1.8]
Islets, Pancreatic	(50)	(49)	(47)	(49)
Parathyroid Gland	(47)	(44)	(48)	(44)
Hyperplasia	1 [2.0]			
Pituitary Gland	(50)	(48)	(49)	(49)
Cyst	1 [2.0]			
Pars Distalis, Angiectasis	3 [2.0]	2 [2.5]	2 [2.0]	3 [2.0]

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FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Pars Distalis, Hyperplasia	17 [2.6]	21 [2.4]	21 [2.6]	20 [2.5]
Thyroid Gland	(50)	(46)	(46)	(48)
C-cell, Hyperplasia	9 [2.6]	4 [2.0]	7 [2.1]	6 [2.2]
Follicular Cell, Hyperplasia	2 [1.5]	2 [3.0]		
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(48)	(50)	(49)	(50)
Hyperplasia	7 [1.7]	5 [1.8]	5 [2.0]	4 [1.8]
Inflammation, Chronic Active		1 [1.0]		1 [3.0]
Ovary	(50)	(50)	(49)	(50)
Cyst	1 [2.0]	6 [3.0]	1 [2.0]	4 [3.0]
Uterus	(50)	(50)	(49)	(50)
Inflammation, Acute			1 [2.0]	
Necrosis	1 [3.0]			
Endometrium, Hyperplasia, Cystic	2 [2.5]		1 [3.0]	
Vagina	(1)	(0)	(1)	(0)
Inflammation, Suppurative			1 [2.0]	
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(49)	(49)	(49)
Hyperplasia, Reticulum Cell	1 [4.0]	1 [1.0]	1 [2.0]	
Lymph Node	(0)	(3)	(3)	(3)
Deep Cervical, Ectasia		1 [3.0]		1 [3.0]
Deep Cervical, Hemorrhage				1 [2.0]
Lymph Node, Mesenteric	(50)	(49)	(48)	(49)
Spleen	(50)	(49)	(49)	(49)
Hematopoietic Cell Proliferation		1 [3.0]	2 [3.0]	3 [3.0]
Inflammation, Granulomatous			1 [3.0]	1 [4.0]
Necrosis				1 [3.0]
Thymus	(47)	(47)	(46)	(49)
Inflammation, Acute				1 [3.0]

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FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
INTEGUMENTARY SYSTEM				
Mammary Gland	(49)	(50)	(50)	(49)
Galactoceles				1
Hyperplasia	1 [3.0]			
Skin	(50)	(50)	(50)	(50)
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Hyperostosis			1 [3.0]	
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Hemorrhage			1 [3.0]	
Hydrocephalus	1 [2.0]			
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Cyst				1 [4.0]
Inflammation, Acute	1 [2.0]			3 [1.7]
Inflammation, Chronic Active	2 [1.0]	4 [2.0]	3 [1.3]	2 [1.5]
Alveolar Epithelium, Hyperplasia	17 [1.2]	11 [1.3]	16 [1.4]	14 [1.0]
Alveolus, Infiltration Cellular, Histiocyte				1 [3.0]
Bronchiole, Hyperplasia	1 [1.0]		1 [2.0]	1 [1.0]
Nose	(50)	(49)	(49)	(49)
Foreign Body	1			
Inflammation, Suppurative	3 [1.3]	5 [1.6]	2 [2.5]	3 [1.3]
Inflammation, Chronic	5 [1.6]	4 [1.5]		2 [2.0]
Thrombosis	1 [2.0]	1 [2.0]	1 [3.0]	
Glands, Dilatation	2 [1.5]			2 [2.0]
Glands, Hyperplasia		1 [2.0]	1 [1.0]	1 [2.0]
Olfactory Epithelium, Accumulation, Hyaline Droplet	48 [1.2]	36 [1.5]	37 [1.2]	33 [1.2]
Olfactory Epithelium, Atrophy				4 [1.0]
Olfactory Epithelium, Degeneration			1 [1.0]	

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: CHRONIC

Time Report Requested: 17:46:24

Route: GAVAGE

CAS Number: 97-54-1

First Dose M/F: 04/22/02 / 04/23/02

Species/Strain: RATS/F 344

Pathologist: Blackshear, P. - GRUMBEIN, S.

Lab: BNW

FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Olfactory Epithelium, Metaplasia, Respiratory	5 [1.6]	5 [1.8]	9 [1.8]	12 [1.3]
Olfactory Epithelium, Metaplasia, Squamous	3 [1.7]			1 [2.0]
Respiratory Epithelium, Accumulation, Hyaline Droplet	4 [1.3]	3 [1.7]	2 [1.5]	
Respiratory Epithelium, Hyperplasia	6 [1.7]	9 [1.7]	4 [2.0]	6 [2.0]
Respiratory Epithelium, Metaplasia, Squamous	2 [1.5]	2 [2.0]		2 [1.5]
Respiratory Epithelium, Necrosis		1 [1.0]		
Pleura	(0)	(0)	(0)	(1)
Inflammation, Suppurative				1 [3.0]
Trachea	(50)	(49)	(48)	(49)
Inflammation, Suppurative				1 [2.0]
SPECIAL SENSES SYSTEM				
Eye	(49)	(46)	(47)	(48)
Cataract			3 [3.7]	
Cornea, Inflammation, Acute		1 [3.0]		
Cornea, Mineralization	1 [2.0]			
Retina, Atrophy	1 [2.0]		3 [4.0]	1 [2.0]
Zymbal's Gland	(0)	(1)	(0)	(1)
URINARY SYSTEM				
Kidney	(50)	(49)	(47)	(50)
Infarct		1 [2.0]		1 [4.0]
Inflammation, Suppurative				2 [3.5]
Nephropathy	41 [1.1]	39 [1.0]	40 [1.2]	40 [1.2]
Renal Tubule, Necrosis	1 [4.0]			
Transitional Epithelium, Hyperplasia	1 [4.0]		1 [3.0]	2 [3.5]
Urinary Bladder	(50)	(50)	(48)	(49)
Inflammation, Chronic Active				1 [2.0]

*** END OF REPORT ***

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)