

**TDMS No.** 88105 - 03  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** RATS/F 344

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**  
ISOEUGENOL  
**CAS Number:** 97-54-1  
**Pathologist:** Blackshear, P. - GRUMBEIN, S.  
F1\_R2

**Date Report Requested:** 09/28/2006  
**Time Report Requested:** 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

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
<b>Disposition Summary</b>				
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
<b>ALIMENTARY SYSTEM</b>				
Esophagus	(50)	(50)	(50)	(50)
Perforation				2 (4%)
Intestine Large, Cecum	(49)	(46)	(50)	(45)
Inflammation, Acute		1 (2%)		
Intestine Large, Colon	(50)	(46)	(50)	(47)
Parasite Metazoan	1 (2%)	1 (2%)	2 (4%)	
Intestine Large, Rectum	(50)	(46)	(50)	(48)
Parasite Metazoan	4 (8%)	1 (2%)		
Intestine Small, Duodenum	(50)	(46)	(50)	(45)
Inflammation, Acute				1 (2%)
Intestine Small, Ileum	(50)	(46)	(50)	(45)
Intestine Small, Jejunum	(50)	(46)	(50)	(45)
Inflammation, Chronic			1 (2%)	
Liver	(50)	(50)	(50)	(48)
Angiectasis	1 (2%)			2 (4%)
Basophilic Focus	43 (86%)	34 (68%)	26 (52%)	18 (38%)
Clear Cell Focus	27 (54%)	20 (40%)	19 (38%)	14 (29%)
Degeneration, Cystic	4 (8%)	1 (2%)	2 (4%)	4 (8%)
Eosinophilic Focus	8 (16%)	2 (4%)		2 (4%)
Fatty Change	2 (4%)	1 (2%)	2 (4%)	2 (4%)
Hematopoietic Cell Proliferation		1 (2%)		
Hepatodiaphragmatic Nodule	5 (10%)	3 (6%)	3 (6%)	3 (6%)
Infarct				1 (2%)
Malformation		1 (2%)		
Mixed Cell Focus	6 (12%)	4 (8%)	6 (12%)	2 (4%)
Necrosis	1 (2%)			

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

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Bile Duct, Hyperplasia	39 (78%)	39 (78%)	32 (64%)	24 (50%)
Centrilobular, Necrosis	2 (4%)	1 (2%)		1 (2%)
Hepatocyte, Vacuolization Cytoplasmic				1 (2%)
Mesentery	(12)	(18)	(7)	(11)
Fat, Hemorrhage	1 (8%)			
Fat, Necrosis	10 (83%)	17 (94%)	7 (100%)	9 (82%)
Oral Mucosa	(1)	(0)	(1)	(3)
Pancreas	(50)	(50)	(50)	(49)
Basophilic Focus	1 (2%)	1 (2%)		
Metaplasia, Hepatocyte	1 (2%)			
Acinus, Atrophy	22 (44%)	21 (42%)	17 (34%)	10 (20%)
Acinus, Hyperplasia	21 (42%)	12 (24%)	13 (26%)	19 (39%)
Salivary Glands	(50)	(50)	(49)	(50)
Hyperplasia	1 (2%)			
Stomach, Forestomach	(50)	(49)	(50)	(49)
Hyperplasia, Squamous	2 (4%)	1 (2%)	3 (6%)	5 (10%)
Inflammation	1 (2%)			
Ulcer	3 (6%)	1 (2%)	4 (8%)	2 (4%)
Stomach, Glandular	(50)	(46)	(50)	(45)
Atrophy	2 (4%)	3 (7%)	2 (4%)	3 (7%)
Inflammation, Chronic Active			1 (2%)	
Mineralization				1 (2%)
Necrosis		1 (2%)	1 (2%)	
<b>CARDIOVASCULAR SYSTEM</b>				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	48 (96%)	44 (88%)	47 (94%)	46 (92%)
Thrombosis	1 (2%)	2 (4%)		
Pericardium, Inflammation, Acute				1 (2%)
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(50)	(50)	(50)	(49)
Degeneration, Cystic	2 (4%)			
Hyperplasia	31 (62%)	22 (44%)	21 (42%)	31 (63%)
Hypertrophy	5 (10%)	1 (2%)	4 (8%)	1 (2%)
Vacuolization Cytoplasmic		2 (4%)		
Adrenal Medulla	(50)	(50)	(50)	(49)
Hyperplasia	24 (48%)	18 (36%)	16 (32%)	15 (31%)

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Islets, Pancreatic	(50)	(49)	(50)	(49)
Hyperplasia	1 (2%)		1 (2%)	
Pituitary Gland	(50)	(48)	(47)	(47)
Hemorrhage				1 (2%)
Pars Distalis, Angiectasis	6 (12%)		3 (6%)	2 (4%)
Pars Distalis, Hyperplasia	18 (36%)	20 (42%)	15 (32%)	16 (34%)
Thyroid Gland	(50)	(49)	(50)	(47)
C-cell, Hyperplasia	9 (18%)	5 (10%)	7 (14%)	9 (19%)
Follicular Cell, Hyperplasia	3 (6%)	3 (6%)		5 (11%)
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				
Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm		1 (2%)		
Preputial Gland	(50)	(49)	(50)	(50)
Cyst		1 (2%)		
Hyperplasia	1 (2%)	2 (4%)	1 (2%)	4 (8%)
Inflammation, Chronic Active		1 (2%)		
Prostate	(50)	(49)	(50)	(50)
Hyperplasia	10 (20%)	9 (18%)	15 (30%)	11 (22%)
Inflammation, Chronic Active	3 (6%)	1 (2%)		3 (6%)
Seminal Vesicle	(50)	(49)	(50)	(49)
Hyperplasia				1 (2%)
Testes	(50)	(50)	(50)	(50)
Atrophy	1 (2%)	4 (8%)	3 (6%)	
Interstitial Cell, Hyperplasia	7 (14%)	2 (4%)	4 (8%)	1 (2%)
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(49)	(50)	(50)
Hyperplasia, Reticulum Cell			1 (2%)	
Lymph Node	(3)	(4)	(4)	(4)
Deep Cervical, Hyperplasia, Lymphoid			1 (25%)	
Mediastinal, Ectasia	1 (33%)			
Pancreatic, Inflammation, Chronic Active			1 (25%)	
Lymph Node, Mesenteric	(50)	(48)	(50)	(47)

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Spleen	(50)	(46)	(50)	(47)
Fibrosis	2 (4%)		2 (4%)	
Hematopoietic Cell Proliferation	3 (6%)	3 (7%)	1 (2%)	2 (4%)
Hemorrhage	1 (2%)			
Hyperplasia, Lymphoid		1 (2%)		
Inflammation, Acute		1 (2%)		
Necrosis	2 (4%)	1 (2%)	1 (2%)	
Thymus	(47)	(43)	(49)	(48)
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(50)	(49)	(50)	(50)
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion		2 (4%)		2 (4%)
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(2)	(0)	(1)
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(50)	(50)	(50)
Hydrocephalus	2 (4%)			
Thrombosis		1 (2%)		
Meninges, Hemorrhage			1 (2%)	
Peripheral Nerve	(0)	(1)	(1)	(0)
Spinal Cord	(0)	(1)	(1)	(0)
Hemorrhage			1 (100%)	
<b>RESPIRATORY SYSTEM</b>				
Lung	(50)	(50)	(50)	(50)
Foreign Body			3 (6%)	1 (2%)
Inflammation, Chronic Active		1 (2%)	1 (2%)	
Metaplasia, Squamous	1 (2%)	2 (4%)		
Thrombosis		1 (2%)		
Alveolar Epithelium, Hyperplasia	27 (54%)	20 (40%)	16 (32%)	25 (50%)
Alveolus, Infiltration Cellular, Histiocyte				1 (2%)

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Bronchiole, Hyperplasia		1 (2%)	1 (2%)	1 (2%)
Perivascular, Inflammation, Chronic Active		1 (2%)		
Nose	(50)	(48)	(49)	(49)
Foreign Body	3 (6%)		3 (6%)	4 (8%)
Inflammation, Suppurative	12 (24%)	11 (23%)	13 (27%)	12 (24%)
Inflammation, Chronic	2 (4%)	1 (2%)	2 (4%)	2 (4%)
Thrombosis			1 (2%)	
Glands, Dilatation		2 (4%)	1 (2%)	2 (4%)
Nasolacrimal Duct, Cyst			1 (2%)	
Nasolacrimal Duct, Inflammation				1 (2%)
Olfactory Epithelium, Accumulation, Hyaline Droplet	50 (100%)	37 (77%)	42 (86%)	42 (86%)
Olfactory Epithelium, Atrophy	1 (2%)	5 (10%)	9 (18%)	13 (27%)
Olfactory Epithelium, Degeneration	1 (2%)		2 (4%)	6 (12%)
Olfactory Epithelium, Hyperplasia				1 (2%)
Olfactory Epithelium, Hyperplasia, Basal Cell			1 (2%)	
Olfactory Epithelium, Metaplasia, Respiratory	4 (8%)	6 (13%)	10 (20%)	15 (31%)
Olfactory Epithelium, Metaplasia, Squamous	1 (2%)	1 (2%)		
Respiratory Epithelium, Accumulation, Hyaline Droplet	3 (6%)	5 (10%)	1 (2%)	2 (4%)
Respiratory Epithelium, Hyperplasia	12 (24%)	3 (6%)	14 (29%)	8 (16%)
Respiratory Epithelium, Metaplasia, Squamous	1 (2%)	4 (8%)	3 (6%)	5 (10%)
Pleura	(0)	(0)	(0)	(2)
Inflammation, Acute				2 (100%)
Trachea	(50)	(49)	(50)	(48)
Epithelium, Necrosis		1 (2%)		
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(50)	(46)	(50)	(45)
Cataract		1 (2%)		2 (4%)
Retina, Atrophy		1 (2%)	1 (2%)	2 (4%)
Harderian Gland	(50)	(47)	(50)	(45)
Hyperplasia	1 (2%)	5 (11%)	5 (10%)	1 (2%)
Inflammation, Chronic Active	1 (2%)			
Zymbal's Gland	(2)	(1)	(0)	(0)
<b>URINARY SYSTEM</b>				

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Kidney	(50)	(48)	(50)	(49)
Cyst				1 (2%)
Degeneration, Muroid, Focal				1 (2%)
Hyperplasia, Oncocytic				1 (2%)
Inflammation, Suppurative				1 (2%)
Nephropathy	49 (98%)	46 (96%)	47 (94%)	47 (96%)
Renal Tubule, Degeneration, Hyaline				1 (2%)
Transitional Epithelium, Hyperplasia		1 (2%)		2 (4%)
Urinary Bladder	(50)	(48)	(50)	(47)

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\*\*\* END OF MALE \*\*\*

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FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
<b>Disposition Summary</b>				
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
<b>ALIMENTARY SYSTEM</b>				
Esophagus	(50)	(50)	(50)	(50)
Perforation		1 (2%)		
Intestine Large, Colon	(50)	(48)	(47)	(48)
Parasite Metazoan	2 (4%)	1 (2%)	1 (2%)	
Intestine Large, Rectum	(49)	(48)	(47)	(48)
Parasite Metazoan	1 (2%)	1 (2%)	1 (2%)	2 (4%)
Intestine Small, Ileum	(49)	(47)	(45)	(45)
Parasite Metazoan			1 (2%)	
Liver	(50)	(50)	(50)	(50)
Angiectasis			2 (4%)	3 (6%)
Basophilic Focus	50 (100%)	49 (98%)	48 (96%)	46 (92%)
Clear Cell Focus	12 (24%)	9 (18%)	9 (18%)	10 (20%)
Degeneration, Cystic	1 (2%)			
Eosinophilic Focus	2 (4%)	2 (4%)	5 (10%)	5 (10%)
Fatty Change	2 (4%)		1 (2%)	
Hepatodiaphragmatic Nodule	8 (16%)	11 (22%)	7 (14%)	4 (8%)
Mixed Cell Focus	5 (10%)	7 (14%)	3 (6%)	3 (6%)
Necrosis		1 (2%)		
Bile Duct, Hyperplasia	3 (6%)	4 (8%)	4 (8%)	4 (8%)
Hepatocyte, Mitotic Alteration				1 (2%)
Mesentery	(11)	(11)	(11)	(14)
Fat, Hemorrhage	1 (9%)			
Fat, Necrosis	11 (100%)	10 (91%)	11 (100%)	13 (93%)
Oral Mucosa	(0)	(1)	(0)	(1)
Pancreas	(50)	(49)	(48)	(50)

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FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Basophilic Focus	1 (2%)			
Acinus, Atrophy	9 (18%)	4 (8%)	2 (4%)	4 (8%)
Acinus, Hyperplasia	5 (10%)	2 (4%)		5 (10%)
Salivary Glands	(49)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(49)	(50)
Hyperplasia, Squamous	2 (4%)		1 (2%)	2 (4%)
Inflammation	1 (2%)			1 (2%)
Ulcer	1 (2%)		2 (4%)	2 (4%)
Stomach, Glandular	(50)	(47)	(46)	(47)
Atrophy	1 (2%)	3 (6%)		3 (6%)
Mineralization	3 (6%)	1 (2%)	2 (4%)	1 (2%)
Tongue	(0)	(0)	(1)	(0)
Tooth	(0)	(1)	(0)	(0)
<b>CARDIOVASCULAR SYSTEM</b>				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	41 (82%)	42 (84%)	38 (76%)	39 (78%)
Pericardium, Inflammation, Granulomatous				1 (2%)
Pericardium, Inflammation, Acute		1 (2%)		1 (2%)
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(50)	(50)	(47)	(49)
Degeneration, Cystic		2 (4%)	4 (9%)	3 (6%)
Hyperplasia	25 (50%)	17 (34%)	18 (38%)	18 (37%)
Hypertrophy	4 (8%)	3 (6%)	2 (4%)	2 (4%)
Necrosis	1 (2%)	2 (4%)	1 (2%)	
Vacuolization Cytoplasmic				1 (2%)
Adrenal Medulla	(50)	(50)	(46)	(49)
Hyperplasia	5 (10%)	6 (12%)	5 (11%)	5 (10%)
Islets, Pancreatic	(50)	(49)	(47)	(49)
Parathyroid Gland	(47)	(44)	(48)	(44)
Hyperplasia	1 (2%)			
Pituitary Gland	(50)	(48)	(49)	(49)
Cyst	1 (2%)			
Pars Distalis, Angiectasis	3 (6%)	2 (4%)	2 (4%)	3 (6%)
Pars Distalis, Hyperplasia	17 (34%)	21 (44%)	21 (43%)	20 (41%)
Thyroid Gland	(50)	(46)	(46)	(48)
C-cell, Hyperplasia	9 (18%)	4 (9%)	7 (15%)	6 (13%)

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FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Follicular Cell, Hyperplasia	2 (4%)	2 (4%)		
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				
Clitoral Gland	(48)	(50)	(49)	(50)
Hyperplasia	7 (15%)	5 (10%)	5 (10%)	4 (8%)
Inflammation, Chronic Active		1 (2%)		1 (2%)
Ovary	(50)	(50)	(49)	(50)
Cyst	1 (2%)	6 (12%)	1 (2%)	4 (8%)
Uterus	(50)	(50)	(49)	(50)
Inflammation, Acute			1 (2%)	
Necrosis	1 (2%)			
Endometrium, Hyperplasia, Cystic	2 (4%)		1 (2%)	
Vagina	(1)	(0)	(1)	(0)
Inflammation, Suppurative			1 (100%)	
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(49)	(49)	(49)
Hyperplasia, Reticulum Cell	1 (2%)	1 (2%)	1 (2%)	
Lymph Node	(0)	(3)	(3)	(3)
Deep Cervical, Ectasia		1 (33%)		1 (33%)
Deep Cervical, Hemorrhage				1 (33%)
Lymph Node, Mesenteric	(50)	(49)	(48)	(49)
Spleen	(50)	(49)	(49)	(49)
Hematopoietic Cell Proliferation		1 (2%)	2 (4%)	3 (6%)
Inflammation, Granulomatous			1 (2%)	1 (2%)
Necrosis				1 (2%)
Thymus	(47)	(47)	(46)	(49)
Inflammation, Acute				1 (2%)
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(49)	(50)	(50)	(49)
Galactocele				1 (2%)

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FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Hyperplasia Skin	1 (2%) (50)	(50)	(50)	(50)
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone Hyperostosis	(50)	(50)	(50) 1 (2%)	(50)
<b>NERVOUS SYSTEM</b>				
Brain Hemorrhage Hydrocephalus	(50)  1 (2%)	(50)	(50) 1 (2%)	(50)
<b>RESPIRATORY SYSTEM</b>				
Lung Cyst Inflammation, Acute Inflammation, Chronic Active Alveolar Epithelium, Hyperplasia Alveolus, Infiltration Cellular, Histiocyte Bronchiole, Hyperplasia Nose Foreign Body Inflammation, Suppurative Inflammation, Chronic Thrombosis Glands, Dilatation Glands, Hyperplasia Olfactory Epithelium, Accumulation, Hyaline Droplet Olfactory Epithelium, Atrophy Olfactory Epithelium, Degeneration Olfactory Epithelium, Metaplasia, Respiratory Olfactory Epithelium, Metaplasia, Squamous Respiratory Epithelium, Accumulation, Hyaline Droplet Respiratory Epithelium, Hyperplasia	(50)  1 (2%) 2 (4%) 17 (34%) 1 (2%) (50) 1 (2%) 3 (6%) 5 (10%) 1 (2%) 2 (4%)  48 (96%)   5 (10%) 3 (6%) 4 (8%) 6 (12%)	(50)   4 (8%) 11 (22%)   (49) 5 (10%) 4 (8%) 1 (2%)  36 (73%)  5 (10%) 3 (6%) 9 (18%) 3 (6%) 3 (6%) 9 (18%)	(50)   3 (6%) 16 (32%)  1 (2%) (49) 2 (4%) 1 (2%)  37 (76%)  1 (2%) 9 (18%) 2 (4%) 4 (8%) 4 (8%)	(50) 1 (2%) 3 (6%) 2 (4%) 14 (28%) 1 (2%) 1 (2%) (49) 3 (6%) 2 (4%)  2 (4%) 1 (2%) 33 (67%) 4 (8%) 12 (24%) 1 (2%) 2 (4%) 6 (12%)

TDMS No. 88105 - 03  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Requested: 09/28/2006  
 Time Report Requested: 17:46:24  
 First Dose M/F: 04/22/02 / 04/23/02  
 Lab: BNW

FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Respiratory Epithelium, Metaplasia, Squamous	2 (4%)	2 (4%)		2 (4%)
Respiratory Epithelium, Necrosis Pleura	(0)	1 (2%) (0)	(0)	(1)
Inflammation, Suppurative Trachea	(50)	(49)	(48)	1 (100%) (49)
Inflammation, Suppurative				1 (2%)
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(49)	(46)	(47)	(48)
Cataract			3 (6%)	
Cornea, Inflammation, Acute		1 (2%)		
Cornea, Mineralization	1 (2%)			
Retina, Atrophy	1 (2%)		3 (6%)	1 (2%)
Zymbal's Gland	(0)	(1)	(0)	(1)
<b>URINARY SYSTEM</b>				
Kidney	(50)	(49)	(47)	(50)
Infarct		1 (2%)		1 (2%)
Inflammation, Suppurative				2 (4%)
Nephropathy	41 (82%)	39 (80%)	40 (85%)	40 (80%)
Renal Tubule, Necrosis	1 (2%)			
Transitional Epithelium, Hyperplasia	1 (2%)		1 (2%)	2 (4%)
Urinary Bladder	(50)	(50)	(48)	(49)
Inflammation, Chronic Active				1 (2%)

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