

**Experiment Number:** 99020-03

**Test Type:** 90-DAY

**Route:** Gavage

**Species/Strain:** Rat/F 344/N

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

**Test Compound:** Pulegone

**CAS Number:** 89-82-7

**Date Report Requested:** 10/20/2014

**Time Report Requested:** 05:19:07

**First Dose M/F:** NA / NA

**Lab:** BAT

**C Number:** C99020  
**Lock Date:** 09/27/2002  
**Cage Range:** All  
**Date Range:** All  
**Reasons For Removal:** All  
**Removal Date Range:** All  
**Treatment Groups:** All  
**Study Gender:** Both  
**PWG Approval Date** NONE

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**First Dose M/F:** NA / NA  
**Lab:** BAT

F 344/N Rat MALE	0 MG/KG	9.375 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Disposition Summary</b>						
<b>Animals Initially In Study</b>	10	10	10	10	10	10
<b>Early Deaths</b>						
<b>Survivors</b>						
<b>Terminal Sacrifice</b>	10	10	10	10	10	10
<b>Animals Examined Microscopically</b>	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Parasite Metazoan	1 (10%)					
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Bile Duct, Hyperplasia					9 (90%)	10 (100%)
Hepatocyte, Hypertrophy					10 (100%)	10 (100%)
Hepatocyte, Necrosis, Focal						6 (60%)
Hepatodiaphragmatic Nodule		2 (20%)	2 (20%)	2 (20%)		
Inflammation, Chronic Active	1 (10%)			1 (10%)	1 (10%)	1 (10%)
Mineralization				1 (10%)		1 (10%)
Oval Cell, Hyperplasia						10 (100%)
Periportal, Fibrosis						10 (100%)
Pigmentation						1 (10%)
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Basophilic Focus						1 (10%)
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Metaplasia, Squamous, Focal						1 (10%)

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

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F 344/N Rat MALE	0 MG/KG	9.375 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(10)	(10)	(10)	(10)	(10)
Mineralization	5 (50%)	3 (30%)	5 (50%)	2 (20%)	3 (30%)	9 (90%)
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(10)	(10)	(10)	(10)	(10)
Cardiomyopathy	9 (90%)	8 (80%)	8 (80%)	9 (90%)	7 (70%)	7 (70%)
Mineralization	1 (10%)			1 (10%)		6 (60%)
Myocardium, Pigmentation, Hemosiderin	1 (10%)					
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Accessory Adrenal Cortical Nodule						1 (10%)
Capsule, Fibrosis	1 (10%)					
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(9)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Chromophobe CL, Hyperplasia	1 (10%)					
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Cyst						1 (10%)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Granulomatous						1 (10%)
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular, Mononuclear CI						1 (10%)
Inflammation, Chronic Active						2 (20%)

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F 344/N Rat MALE	0 MG/KG	9.375 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Inflammation, Suppurative	1 (10%)					
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Suppurative						1 (10%)
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(2)	(0)	(0)	(0)	(10)
Germinal Epith, Degeneration		2 (100%)				
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia	3 (30%)	1 (10%)	5 (50%)	9 (90%)	10 (100%)	10 (100%)
Lymph Node	(1)	(0)	(0)	(0)	(0)	(0)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Necrosis, Lymphoid						1 (10%)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(10)	(10)	(10)
Atrophy	2 (20%)				1 (10%)	1 (10%)
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(10)	(10)	(10)	(10)	(10)
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte	6 (60%)		5 (50%)	4 (40%)	2 (20%)	8 (80%)
Interstitial, Infiltration Cellular, Lymphocyte	7 (70%)			1 (10%)	2 (20%)	1 (10%)
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)

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**Species/Strain:** Rat/F 344/N

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**Time Report Requested:** 05:19:07

**First Dose M/F:** NA / NA

**Lab:** BAT

F 344/N Rat MALE	0 MG/KG	9.375 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Acute						1 (10%)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Acute						1 (10%)
<b>URINARY SYSTEM</b>						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Accumulation, Hyaline Droplet	3 (30%)		1 (10%)	1 (10%)		
Glomerulopathy, Hyaline					2 (20%)	10 (100%)
Infiltration Cellular, Lymphocyte	1 (10%)		1 (10%)	1 (10%)		
Mineralization	6 (60%)	8 (80%)	8 (80%)	7 (70%)	9 (90%)	7 (70%)
Renal Tubule, Casts Protein	7 (70%)	4 (40%)	6 (60%)	6 (60%)	4 (40%)	10 (100%)
Renal Tubule, Regeneration	9 (90%)	9 (90%)	10 (100%)	10 (100%)	3 (30%)	9 (90%)
Urinary Bladder	(9)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular	1 (11%)					
Mineralization						1 (10%)

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

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**Lab:** BAT

F 344/N Rat FEMALE	0 MG/KG	9.375 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Disposition Summary</b>						
<b>Animals Initially In Study</b>	10	10	10	10	10	10
<b>Early Deaths</b>						1
<b>Natural Death</b>						1
<b>Survivors</b>						
<b>Terminal Sacrifice</b>	10	10	10	10	10	9
<b>Animals Examined Microscopically</b>	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic	1 (10%)					
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Basophilic Focus	1 (10%)					
Bile Duct, Hyperplasia					1 (10%)	10 (100%)
Hepatocyte, Hypertrophy						10 (100%)
Hepatodiaphragmatic Nodule	1 (10%)	2 (20%)	2 (20%)	2 (20%)		1 (10%)
Inflammation, Chronic Active		1 (10%)				
Oval Cell, Hyperplasia						9 (90%)
Periportal, Fibrosis						9 (90%)
Serosa, Fibrosis	1 (10%)					
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(10)	(10)	(10)	(10)	(10)

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**Lab:** BAT

F 344/N Rat FEMALE	0 MG/KG	9.375 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Mineralization		3 (30%)	2 (20%)	2 (20%)	6 (60%)	7 (70%)
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(10)	(10)	(10)	(10)	(10)
Cardiomyopathy	6 (60%)	3 (30%)		4 (40%)	5 (50%)	2 (20%)
Mineralization						1 (10%)
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(9)	(0)	(0)	(0)	(0)	(10)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Cyst						1 (10%)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active						1 (10%)
Ovary	(10)	(10)	(10)	(10)	(10)	(10)
Cyst	1 (10%)	2 (20%)	2 (20%)	2 (20%)	3 (30%)	6 (60%)
Uterus	(10)	(10)	(10)	(10)	(10)	(10)
Dilatation	2 (20%)					
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia	1 (10%)	1 (10%)	1 (10%)	1 (10%)	10 (100%)	9 (90%)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)

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**Lab:** BAT

F 344/N Rat FEMALE	0 MG/KG	9.375 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Thymus Atrophy	(10) 1 (10%)	(0)	(0)	(0)	(10)	(10)
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(9)	(10)	(10)	(10)	(10)	(10)
Brain, Cerebellum	(1)	(0)	(0)	(0)	(0)	(0)
Dysplasia	1 (100%)					
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte	1 (10%)			2 (20%)	2 (20%)	6 (60%)
Interstitial, Infiltration Cellular, Lymphocyte	4 (40%)					
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
<b>URINARY SYSTEM</b>						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Glomerulopathy, Hyaline						8 (80%)
Mineralization	6 (60%)	10 (100%)	9 (90%)	9 (90%)	10 (100%)	9 (90%)
Nephropathy						1 (10%)
Renal Tubule, Casts Protein	1 (10%)				2 (20%)	6 (60%)
Renal Tubule, Regeneration		1 (10%)				

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**Test Compound:** Pulegone

**CAS Number:** 89-82-7

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**Time Report Requested:** 05:19:08

**First Dose M/F:** NA / NA

**Lab:** BAT

F 344/N Rat FEMALE	0 MG/KG	9.375 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Urinary Bladder Mineralization	(10) 1 (10%)	(0)	(0)	(0)	(0)	(10)

\*\* END OF REPORT \*\*

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