

Experiment Number: 99020-03
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

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

Test Compound: Pulegone
CAS Number: 89-82-7

Date Report Requested: 10/20/2014
Time Report Requested: 05:18:33
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

Experiment Number: 99020-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

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

Test Compound: Pulegone

CAS Number: 89-82-7

Date Report Requested: 10/20/2014

Time Report Requested: 05:18:33

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
Disposition Summary						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
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					
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 [1.0]	10 [2.0]
Hepatocyte, Hypertrophy					10 [1.0]	10 [1.9]
Hepatocyte, Necrosis, Focal						6 [1.0]
Hepatodiaphragmatic Nodule		2	2	2		
Inflammation, Chronic Active	1 [1.0]			1 [1.0]	1 [1.0]	1 [2.0]
Mineralization				1 [1.0]		1 [1.0]
Oval Cell, Hyperplasia						10 [1.0]
Periportal, Fibrosis						10 [1.0]
Pigmentation						1 [1.0]
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Basophilic Focus						1 [1.0]
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)

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)

Experiment Number: 99020-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

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

Test Compound: Pulegone

CAS Number: 89-82-7

Date Report Requested: 10/20/2014

Time Report Requested: 05:18:33

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
Metaplasia, Squamous, Focal						1 [1.0]
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(10)	(10)	(10)	(10)	(10)
Mineralization	5 [1.0]	3 [1.0]	5 [1.8]	2 [1.0]	3 [1.0]	9 [1.1]
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(10)	(10)	(10)	(10)	(10)
Cardiomyopathy	9 [1.1]	8 [1.1]	8 [1.1]	9 [1.0]	7 [1.0]	7 [1.0]
Mineralization	1 [1.0]			1 [1.0]		6 [1.0]
Myocardium, Pigmentation, Hemosiderin	1 [1.0]					
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Accessory Adrenal Cortical Nodule						1 [1.0]
Capsule, Fibrosis	1 [1.0]					
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 [1.0]					
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Cyst						1
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Granulomatous						1 [2.0]
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)

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)

Experiment Number: 99020-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

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

Test Compound: Pulegone

CAS Number: 89-82-7

Date Report Requested: 10/20/2014

Time Report Requested: 05:18:33

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
Infiltration Cellular, Mononuclear CI						1 [1.0]
Inflammation, Chronic Active						2 [1.0]
Inflammation, Suppurative	1 [1.0]					
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Suppurative						1 [1.0]
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(2)	(0)	(0)	(0)	(10)
Germinal Epith, Degeneration		2 [2.5]				
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia	3 [1.0]	1 [1.0]	5 [1.0]	9 [1.2]	10 [1.9]	10 [2.7]
Lymph Node	(1)	(0)	(0)	(0)	(0)	(0)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Necrosis, Lymphoid						1 [1.0]
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(10)	(10)	(10)
Atrophy	2 [1.5]				1 [1.0]	1 [1.0]
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(10)	(10)	(10)	(10)	(10)
RESPIRATORY SYSTEM						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte	6 [1.0]		5 [1.0]	4 [1.0]	2 [1.0]	8 [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)

Experiment Number: 99020-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

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

Test Compound: Pulegone

CAS Number: 89-82-7

Date Report Requested: 10/20/2014

Time Report Requested: 05:18:34

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
Interstitial, Infiltration Cellular, Lymphocyte	7 [1.0]			1 [1.0]	2 [1.0]	1 [1.0]
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Acute						1 [1.0]
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Acute						1 [1.0]
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Accumulation, Hyaline Droplet	3 [1.0]		1 [1.0]	1 [1.0]		
Glomerulopathy, Hyaline					2 [1.0]	10 [1.0]
Infiltration Cellular, Lymphocyte	1 [1.0]		1 [1.0]	1 [1.0]		
Mineralization	6 [1.0]	8 [1.0]	8 [1.0]	7 [1.0]	9 [1.0]	7 [1.0]
Renal Tubule, Casts Protein	7 [1.0]	4 [1.5]	6 [1.0]	6 [1.0]	4 [1.0]	10 [2.7]
Renal Tubule, Regeneration	9 [1.0]	9 [1.0]	10 [1.0]	10 [1.0]	3 [1.0]	9 [1.0]
Urinary Bladder	(9)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular	1 [1.0]					
Mineralization						1 [1.0]

END OF MALE DATA

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)

Experiment Number: 99020-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

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

Test Compound: Pulegone

CAS Number: 89-82-7

Date Report Requested: 10/20/2014

Time Report Requested: 05:18:34

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
Disposition Summary						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Natural Death						1
Survivors						
Terminal Sacrifice	10	10	10	10	10	9
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic	1 [1.0]					
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					
Bile Duct, Hyperplasia					1 [1.0]	10 [1.7]
Hepatocyte, Hypertrophy						10 [1.9]
Hepatodiaphragmatic Nodule	1	2	2	2		1
Inflammation, Chronic Active		1 [1.0]				
Oval Cell, Hyperplasia						9 [1.0]
Periportal, Fibrosis						9 [1.0]
Serosa, Fibrosis	1 [1.0]					
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)

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)

Experiment Number: 99020-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

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

Test Compound: Pulegone

CAS Number: 89-82-7

Date Report Requested: 10/20/2014

Time Report Requested: 05:18:34

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
Stomach, Glandular Mineralization	(10)	(10) 3 [1.0]	(10) 2 [1.0]	(10) 2 [1.0]	(10) 6 [1.0]	(10) 7 [1.0]
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(10)	(10)	(10)	(10)	(10)
Cardiomyopathy	6 [1.0]	3 [1.0]		4 [1.0]	5 [1.0]	2 [1.0]
Mineralization						1 [1.0]
ENDOCRINE SYSTEM						
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
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active						1 [1.0]
Ovary	(10)	(10)	(10)	(10)	(10)	(10)
Cyst	1	2	2	2	3	6
Uterus	(10)	(10)	(10)	(10)	(10)	(10)
Dilatation	2 [2.5]					
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia	1 [1.0]	1 [1.0]	1 [1.0]	1 [1.0]	10 [1.3]	9 [1.9]

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)

Experiment Number: 99020-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

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

Test Compound: Pulegone

CAS Number: 89-82-7

Date Report Requested: 10/20/2014

Time Report Requested: 05:18:34

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
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(0)	(10)	(10)
Atrophy	1 [2.0]					
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(9)	(10)	(10)	(10)	(10)	(10)
Brain, Cerebellum	(1)	(0)	(0)	(0)	(0)	(0)
Dysplasia	1 [2.0]					
RESPIRATORY SYSTEM						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte	1 [1.0]			2 [1.0]	2 [1.0]	6 [1.0]
Interstitial, Infiltration Cellular, Lymphocyte	4 [1.0]					
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Glomerulopathy, Hyaline						8 [1.0]
Mineralization	6 [1.0]	10 [1.0]	9 [1.0]	9 [1.0]	10 [1.0]	9 [1.1]
Nephropathy						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)

Experiment Number: 99020-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

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

Test Compound: Pulegone

CAS Number: 89-82-7

Date Report Requested: 10/20/2014

Time Report Requested: 05:18:34

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
Renal Tubule, Casts Protein	1 [1.0]				2 [1.0]	6 [1.0]
Renal Tubule, Regeneration		1 [1.0]				
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)
Mineralization	1 [1.0]					

**** 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)