

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Pulegone
CAS Number: 89-82-7

Date Report Requested: 04/23/2009
Time Report Requested: 10:38:13
First Dose M/F: 04/15/03 / 04/14/03
Lab: BAT

F1_Rev1_M3

C Number:	C99020		
Lock Date:	12/21/2005		
Cage Range:	ALL		
Date Range:	ALL		
Reasons For Removal:	25022 ACCK	25021 TSAC	25020 NATD
	25019 MSAC	25018 DACC	
Removal Date Range:	ALL		
Treatment Groups:	Include ALL		
Study Gender:	Both		
TDMSE Version:	2.1.0		

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SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF PULEGONE

MALE MICE

Organ

Adrenal Cortex
Adrenal Cortex: Subcapsular
Epididymis
Harderian Gland
Heart
Islets, Pancreatic
Kidney

Kidney: Glomerulus
Liver

Liver: Bile Duct

Liver: Hepatocyte, Centrilobular
Liver: Oval Cell
Liver: Vein
Lung
Lung: Alveolar Epithelium
Lymph Node, Mesenteric
Nose
Nose: Nerve
Nose: Olfactory Epithelium

Morphology

Hypertrophy
Hyperplasia
Inflammation
Infiltration Cellular Mononuclear Cell
Infiltration Cellular Mononuclear Cell
Hyperplasia
Cyst
Glomerulopathy Hyaline
Mineralization
Nephropathy
Congestion
Clear Cell Focus
Eosinophilic Focus
Fatty Change Diffuse
Fatty Change Focal
Hematopoietic Cell Proliferation
Mixed Cell Focus
Necrosis
Pigmentation
Cyst
Fibrosis
Hyperplasia
Hypertrophy
Hyperplasia
Intravascular Hepatocyte
Inflammation
Hyperplasia
Atrophy
Inflammation
Atrophy
Degeneration
Metaplasia

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SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF PULEGONE

Preputial Gland
Prostate
Prostate: Epithelium
Salivary Glands
Spleen
Stomach, Forestomach

Cyst
Infiltration Cellular Mononuclear Cell
Hyperplasia
Infiltration Cellular Mononuclear Cell
Hematopoietic Cell Proliferation
Hyperplasia
Inflammation
Ulcer
Infiltration Cellular Mononuclear Cell

Urinary Bladder

FEMALE MICE

Organ

Bone Marrow
Clitoral Gland
Eye
Eye: Anterior Chamber
Eye: Cornea
Harderian Gland
Harderian Gland: Epithelium
Heart

Islets, Pancreatic
Kidney

Kidney: Glomerulus
Kidney: Papilla
Liver

Morphology

Hyperplasia
Inflammation
Atrophy
Inflammation
Inflammation
Infiltration Cellular Mononuclear Cell
Hyperplasia
Cardiomyopathy
Mineralization
Necrosis
Hyperplasia
Accumulation, Hyaline Droplet
Glomerulopathy Hyaline
Mineralization
Nephropathy
Congestion
Necrosis
Angiectasis
Clear Cell Focus
Eosinophilic Focus
Fatty Change Diffuse
Fatty Change Focal
Fibrosis

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Liver: Bile Duct	Inflammation
Liver: Hepatocyte, Centrilobular	Mixed Cell Focus
Liver: Oval Cell	Necrosis
Liver: Vein	Pigmentation
Lung: Alveolar Epithelium	Tension Lipidosis
Mesentery	Cyst
Mesentery: Fat	Hyperplasia
Nose	Hypertrophy
Nose: Nerve	Hyperplasia
Nose: Olfactory Epithelium	Intravascular Hepatocyte
Ovary	Hyperplasia
Salivary Glands	Necrosis
Spleen	Necrosis
Stomach, Forestomach	Inflammation
Thymus	Atrophy
Uterus	Degeneration
	Metaplasia
	Atrophy
	Infiltration Cellular Mononuclear Cell
	Hematopoietic Cell Proliferation
	Pigmentation
	Hyperplasia
	Inflammation
	Ulcer
	Atrophy
	Angiectasis

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Adrenal Cortex Hypertrophy				
LESION RATES				
OVERALL (a)	17/50 (34%)	9/50 (18%)	8/50 (16%)	4/50 (8%)
POLY-3 RATE (b)	17/44.22	9/45.21	8/47.72	4/45.98
POLY-3 PERCENT (g)	38.4%	19.9%	16.8%	8.7%
TERMINAL (d)	17/38 (45%)	8/36 (22%)	8/42 (19%)	4/41 (10%)
FIRST INCIDENCE	730 (T)	693	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.042N*	P=0.016N*	P<0.001N**
POLY 1.5	P<0.001N**	P=0.048N*	P=0.020N*	P<0.001N**
POLY 6	P<0.001N**	P=0.037N*	P=0.013N*	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.055N	P=0.032N*	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.026N*	P=0.011N*	P<0.001N**

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Adrenal Cortex: Subcapsular Hyperplasia				
LESION RATES				
OVERALL (a)	39/50 (78%)	40/50 (80%)	47/50 (94%)	44/50 (88%)
POLY-3 RATE (b)	39/48.13	40/47.40	47/49.29	44/48.95
POLY-3 PERCENT (g)	81%	84.4%	95.4%	89.9%
TERMINAL (d)	30/38 (79%)	32/36 (89%)	41/42 (98%)	37/41 (90%)
FIRST INCIDENCE	331	428	597	332
STATISTICAL TESTS				
POLY 3	P=0.080	P=0.434	P=0.023*	P=0.166
POLY 1.5	P=0.061	P=0.433	P=0.021*	P=0.136
POLY 6	P=0.111	P=0.421	P=0.023*	P=0.206
COCH-ARM / FISHERS	P=0.062	P=0.500	P=0.020*	P=0.143
MAX-ISO-POLY-3	P=0.055	P=0.329	P=0.010**	P=0.105

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Adrenal Medulla Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/44.22	2/45.07	1/47.72	2/45.98
POLY-3 PERCENT (g)	0%	4.4%	2.1%	4.4%
TERMINAL (d)	0/38 (0%)	2/36 (6%)	1/42 (2%)	2/41 (5%)
FIRST INCIDENCE	---	730 (T)	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.261	P=0.241	P=0.515	P=0.246
POLY 1.5	P=0.253	P=0.239	P=0.510	P=0.241
POLY 6	P=0.271	P=0.243	P=0.519	P=0.252
COCH-ARM / FISHERS	P=0.245	P=0.247	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.174	P=0.080	P=0.177	P=0.084

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TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Bone Marrow Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Bone Marrow				
Myelofibrosis				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	2/44.22	0/45.07	3/47.72	1/45.98
POLY-3 PERCENT (g)	4.5%	0%	6.3%	2.2%
TERMINAL (d)	2/38 (5%)	0/36 (0%)	3/42 (7%)	1/41 (2%)
FIRST INCIDENCE	730 (T)	---	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.544N	P=0.233N	P=0.535	P=0.486N
POLY 1.5	P=0.550N	P=0.236N	P=0.523	P=0.494N
POLY 6	P=0.534N	P=0.231N	P=0.544	P=0.477N
COCH-ARM / FISHERS	P=0.556N	P=0.247N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.436N	P=0.076N	P=0.360	P=0.273N

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TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Epididymis				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	23/50 (46%)	27/50 (54%)	20/50 (40%)	20/50 (40%)
POLY-3 RATE (b)	23/44.94	27/47.37	20/49.13	20/46.09
POLY-3 PERCENT (g)	51.2%	57%	40.7%	43.4%
TERMINAL (d)	20/38 (53%)	19/36 (53%)	15/42 (36%)	19/41 (46%)
FIRST INCIDENCE	573	444	597	702
STATISTICAL TESTS				
POLY 3	P=0.147N	P=0.361	P=0.208N	P=0.295N
POLY 1.5	P=0.164N	P=0.314	P=0.254N	P=0.324N
POLY 6	P=0.129N	P=0.412	P=0.167N	P=0.264N
COCH-ARM / FISHERS	P=0.181N	P=0.274	P=0.343N	P=0.343N
MAX-ISO-POLY-3	P=0.204N	P=0.291	P=0.164N	P=0.230N

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TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Epididymis Inflammation				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.55	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	4.5%	0%	0%	0%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	640	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.113N	P=0.235N	P=0.222N	P=0.230N
POLY 1.5	P=0.113N	P=0.237N	P=0.227N	P=0.234N
POLY 6	P=0.114N	P=0.234N	P=0.219N	P=0.225N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.032N*	P=0.076N	P=0.076N	P=0.076N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Esophagus Inflammation				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/44.29	0/45.07	1/47.72	1/45.98
POLY-3 PERCENT (g)	4.5%	0%	2.1%	2.2%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	1/42 (2%)	1/41 (2%)
FIRST INCIDENCE	714	---	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.494N	P=0.233N	P=0.474N	P=0.487N
POLY 1.5	P=0.496N	P=0.236N	P=0.483N	P=0.495N
POLY 6	P=0.491N	P=0.232N	P=0.467N	P=0.478N
COCH-ARM / FISHERS	P=0.500N	P=0.247N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.268N	P=0.076N	P=0.266N	P=0.273N

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Eye Atrophy				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	1/46.50
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	---	570
STATISTICAL TESTS				
POLY 3	P=0.205	(e)	(e)	P=0.510
POLY 1.5	P=0.202	(e)	(e)	P=0.505
POLY 6	P=0.209	(e)	(e)	P=0.517
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.141	(e)	(e)	P=0.171

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TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

Eye: Anterior Chamber
Inflammation

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Eye: Cornea Inflammation				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/44.22	0/45.07	1/48.17	3/45.98
POLY-3 PERCENT (g)	2.3%	0%	2.1%	6.5%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	0/42 (0%)	3/41 (7%)
FIRST INCIDENCE	730 (T)	---	597	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.101	P=0.496N	P=0.741N	P=0.319
POLY 1.5	P=0.099	P=0.499N	P=0.748N	P=0.311
POLY 6	P=0.104	P=0.495N	P=0.735N	P=0.329
COCH-ARM / FISHERS	P=0.097	P=0.500N	P=0.753N	P=0.309
MAX-ISO-POLY-3	P=0.098	P=0.158N	P=0.476N	P=0.169

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TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Gallbladder				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.22	0/44.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	1/37 (3%)	0/35 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	730 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.305N	P=0.496N	P=0.480N	P=0.488N
POLY 1.5	P=0.303N	P=0.499N	P=0.486N	P=0.492N
POLY 6	P=0.308N	P=0.495N	P=0.476N	P=0.482N
COCH-ARM / FISHERS	P=0.303N	P=0.500N	P=0.495N	P=0.495N
MAX-ISO-POLY-3	P=0.122N	P=0.158N	P=0.157N	P=0.157N

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 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Harderian Gland Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	34/50 (68%)	27/50 (54%)	23/50 (46%)	17/50 (34%)
POLY-3 RATE (b)	34/47.52	27/46.32	23/48.42	17/46.76
POLY-3 PERCENT (g)	71.6%	58.3%	47.5%	36.4%
TERMINAL (d)	28/38 (74%)	20/36 (56%)	20/42 (48%)	15/41 (37%)
FIRST INCIDENCE	331	646	639	473
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.124N	P=0.012N*	P<0.001N**
POLY 1.5	P<0.001N**	P=0.127N	P=0.014N*	P<0.001N**
POLY 6	P<0.001N**	P=0.121N	P=0.010N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.109N	P=0.021N*	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.087N	P=0.007N**	P<0.001N**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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 Pulegone
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Harderian Gland: Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	3/50 (6%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/44.36	3/46.18	1/47.72	3/45.98
POLY-3 PERCENT (g)	2.3%	6.5%	2.1%	6.5%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	1/42 (2%)	3/41 (7%)
FIRST INCIDENCE	695	428	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.329	P=0.320	P=0.744N	P=0.318
POLY 1.5	P=0.321	P=0.313	P=0.750N	P=0.311
POLY 6	P=0.338	P=0.325	P=0.740N	P=0.327
COCH-ARM / FISHERS	P=0.313	P=0.309	P=0.753N	P=0.309
MAX-ISO-POLY-3	P=0.270	P=0.169	P=0.479N	P=0.168

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Heart				
Cardiomyopathy				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.74	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	573	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.306N	P=0.499N	P=0.487N	P=0.495N
POLY 1.5	P=0.305N	P=0.500N	P=0.491N	P=0.498N
POLY 6	P=0.308N	P=0.498N	P=0.484N	P=0.490N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.124N	P=0.158N	P=0.158N	P=0.159N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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 CAS Number: 89-82-7

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Heart				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	4/50 (8%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	4/44.94	0/45.07	1/47.72	1/45.98
POLY-3 PERCENT (g)	8.9%	0%	2.1%	2.2%
TERMINAL (d)	3/38 (8%)	0/36 (0%)	1/42 (2%)	1/41 (2%)
FIRST INCIDENCE	479	---	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.157N	P=0.060N	P=0.161N	P=0.172N
POLY 1.5	P=0.159N	P=0.061N	P=0.167N	P=0.177N
POLY 6	P=0.155N	P=0.059N	P=0.156N	P=0.165N
COCH-ARM / FISHERS	P=0.163N	P=0.059N	P=0.181N	P=0.181N
MAX-ISO-POLY-3	P=0.036N*	P=0.019N*	P=0.079N	P=0.082N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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 CAS Number: 89-82-7

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Heart Mineralization				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	1/44.94	1/45.15	1/48.05	4/46.93
POLY-3 PERCENT (g)	2.2%	2.2%	2.1%	8.5%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	2/41 (5%)
FIRST INCIDENCE	477	709	639	332
STATISTICAL TESTS				
POLY 3	P=0.073	P=0.760N	P=0.745N	P=0.192
POLY 1.5	P=0.070	P=0.760	P=0.751N	P=0.186
POLY 6	P=0.076	P=0.759N	P=0.741N	P=0.200
COCH-ARM / FISHERS	P=0.067	P=0.753N	P=0.753N	P=0.181
MAX-ISO-POLY-3	P=0.093	P=0.498N	P=0.481N	P=0.097

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 04/23/2009
Time Report Requested: 10:38:13
First Dose M/F: 04/15/03 / 04/14/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Heart Necrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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 Pulegone
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Date Report Requested: 04/23/2009
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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Islets, Pancreatic Hyperplasia				
LESION RATES				
OVERALL (a)	20/50 (40%)	17/50 (34%)	21/50 (42%)	2/50 (4%)
POLY-3 RATE (b)	20/45.71	17/45.89	21/48.63	2/46.88
POLY-3 PERCENT (g)	43.8%	37.1%	43.2%	4.3%
TERMINAL (d)	16/38 (42%)	13/36 (36%)	17/42 (41%)	1/41 (2%)
FIRST INCIDENCE	477	648	588	332
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.329N	P=0.560N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.341N	P=0.569	P<0.001N**
POLY 6	P<0.001N**	P=0.324N	P=0.534N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.339N	P=0.500	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.257N	P=0.477N	P<0.001N**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney				
Accumulation, Hyaline Droplet				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.94	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	477	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.305N	P=0.499N	P=0.488N	P=0.495N
POLY 1.5	P=0.304N	P=0.501N	P=0.492N	P=0.499N
POLY 6	P=0.307N	P=0.499N	P=0.485N	P=0.491N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.124N	P=0.159N	P=0.158N	P=0.159N

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 Test Type: CHRONIC
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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney Cyst				
LESION RATES				
OVERALL (a)	9/50 (18%)	3/50 (6%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	9/44.53	3/45.07	4/47.72	0/45.98
POLY-3 PERCENT (g)	20.2%	6.7%	8.4%	0%
TERMINAL (d)	8/38 (21%)	3/36 (8%)	4/42 (10%)	0/41 (0%)
FIRST INCIDENCE	646	730 (T)	730 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.002N**	P=0.056N	P=0.090N	P<0.001N**
POLY 1.5	P=0.002N**	P=0.058N	P=0.099N	P=0.002N**
POLY 6	P<0.001N**	P=0.055N	P=0.084N	P<0.001N**
COCH-ARM / FISHERS	P=0.002N**	P=0.061N	P=0.117N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.029N*	P=0.056N	P<0.001N**

TDMS No. 99020 - 06
 Test Type: CHRONIC
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 Species/Strain: MICE/B6C3F1

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney				
Glomerulopathy Hyaline				
LESION RATES				
OVERALL (a)	1/50 (2%)	19/50 (38%)	30/50 (60%)	44/50 (88%)
POLY-3 RATE (b)	1/44.22	19/46.33	30/48.60	44/47.00
POLY-3 PERCENT (g)	2.3%	41%	61.7%	93.6%
TERMINAL (d)	1/38 (3%)	13/36 (36%)	26/42 (62%)	40/41 (98%)
FIRST INCIDENCE	730 (T)	646	646	570
STATISTICAL TESTS				
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**

TDMS No. 99020 - 06
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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney Infarct				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.22	0/45.07	0/47.72	1/45.98
POLY-3 PERCENT (g)	2.3%	0%	0%	2.2%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	0/42 (0%)	1/41 (2%)
FIRST INCIDENCE	730 (T)	---	---	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.599	P=0.496N	P=0.485N	P=0.752N
POLY 1.5	P=0.597	P=0.499N	P=0.490N	P=0.757N
POLY 6	P=0.603	P=0.495N	P=0.481N	P=0.746N
COCH-ARM / FISHERS	P=0.595	P=0.500N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.400N	P=0.158N	P=0.158N	P=0.488N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney				
Metaplasia Osseous				
LESION RATES				
OVERALL (a)	3/50 (6%)	2/50 (4%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	3/44.55	2/45.07	2/47.95	4/46.30
POLY-3 PERCENT (g)	6.7%	4.4%	4.2%	8.6%
TERMINAL (d)	2/38 (5%)	2/36 (6%)	1/42 (2%)	3/41 (7%)
FIRST INCIDENCE	640	730 (T)	668	640
STATISTICAL TESTS				
POLY 3	P=0.376	P=0.495N	P=0.467N	P=0.521
POLY 1.5	P=0.367	P=0.499N	P=0.478N	P=0.509
POLY 6	P=0.388	P=0.494N	P=0.458N	P=0.536
COCH-ARM / FISHERS	P=0.357	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.395	P=0.320N	P=0.301N	P=0.369

TDMS No. 99020 - 06
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 Species/Strain: MICE/B6C3F1

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney Mineralization				
LESION RATES				
OVERALL (a)	30/50 (60%)	34/50 (68%)	41/50 (82%)	38/50 (76%)
POLY-3 RATE (b)	30/45.63	34/46.23	41/48.59	38/47.66
POLY-3 PERCENT (g)	65.8%	73.6%	84.4%	79.7%
TERMINAL (d)	25/38 (66%)	29/36 (81%)	38/42 (91%)	33/41 (81%)
FIRST INCIDENCE	549	606	597	473
STATISTICAL TESTS				
POLY 3	P=0.061	P=0.274	P=0.025*	P=0.093
POLY 1.5	P=0.044*	P=0.256	P=0.020*	P=0.071
POLY 6	P=0.087	P=0.281	P=0.028*	P=0.124
COCH-ARM / FISHERS	P=0.038*	P=0.266	P=0.013*	P=0.066
MAX-ISO-POLY-3	P=0.047*	P=0.204	P=0.016*	P=0.063

TDMS No. 99020 - 06
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 Species/Strain: MICE/B6C3F1

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney				
Nephropathy				
LESION RATES				
OVERALL (a)	45/50 (90%)	45/50 (90%)	49/50 (98%)	49/50 (98%)
POLY-3 RATE (b)	45/47.91	45/47.20	49/49.52	49/49.01
POLY-3 PERCENT (g)	93.9%	95.3%	98.9%	100%
TERMINAL (d)	37/38 (97%)	36/36 (100%)	42/42 (100%)	41/41 (100%)
FIRST INCIDENCE	479	606	597	332
STATISTICAL TESTS				
POLY 3	P=0.029*	P=0.566	P=0.180	P=0.096
POLY 1.5	P=0.020*	P=0.553	P=0.146	P=0.065
POLY 6	P=0.049*	P=0.592	P=0.214	P=0.156
COCH-ARM / FISHERS	P=0.035*	P=0.630N	P=0.102	P=0.102
MAX-ISO-POLY-3	P=0.032*	P=0.366	P=0.063	P=0.025*

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

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 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney Pigmentation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	2/47.92	0/45.98
POLY-3 PERCENT (g)	0%	0%	4.2%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	695	---
STATISTICAL TESTS				
POLY 3	P=0.610	(e)	P=0.256	(e)
POLY 1.5	P=0.601	(e)	P=0.249	(e)
POLY 6	P=0.624	(e)	P=0.262	(e)
COCH-ARM / FISHERS	P=0.595	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.275	(e)	P=0.094	(e)

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 04/23/2009
Time Report Requested: 10:38:13
First Dose M/F: 04/15/03 / 04/14/03
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney				
Vacuolization Cytoplasmic				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 04/23/2009
Time Report Requested: 10:38:13
First Dose M/F: 04/15/03 / 04/14/03
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney: Glomerulus Congestion				
LESION RATES				
OVERALL (a)	9/50 (18%)	14/50 (28%)	17/50 (34%)	44/50 (88%)
POLY-3 RATE (b)	9/46.61	14/46.13	17/48.02	44/46.52
POLY-3 PERCENT (g)	19.3%	30.4%	35.4%	94.6%
TERMINAL (d)	4/38 (11%)	10/36 (28%)	16/42 (38%)	40/41 (98%)
FIRST INCIDENCE	535	646	646	638
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.161	P=0.062	P<0.001**
POLY 1.5	P<0.001**	P=0.161	P=0.060	P<0.001**
POLY 6	P<0.001**	P=0.157	P=0.060	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.171	P=0.055	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.109	P=0.040*	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney: Papilla Necrosis				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.36	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	695	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.307N	P=0.497N	P=0.485N	P=0.493N
POLY 1.5	P=0.305N	P=0.499N	P=0.490N	P=0.497N
POLY 6	P=0.310N	P=0.496N	P=0.482N	P=0.488N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.124N	P=0.158N	P=0.158N	P=0.158N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney: Pelvis Inflammation				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/44.94	0/45.07	0/47.72	2/46.88
POLY-3 PERCENT (g)	2.2%	0%	0%	4.3%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	1/41 (2%)
FIRST INCIDENCE	477	---	---	332
STATISTICAL TESTS				
POLY 3	P=0.252	P=0.499N	P=0.488N	P=0.515
POLY 1.5	P=0.250	P=0.501N	P=0.492N	P=0.507
POLY 6	P=0.256	P=0.499N	P=0.485N	P=0.523
COCH-ARM / FISHERS	P=0.246	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.151	P=0.159N	P=0.158N	P=0.297

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Angiectasis				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	2/45.21	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	4.4%	0%	0%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	693	---	---
STATISTICAL TESTS				
POLY 3	P=0.391N	P=0.242	(e)	(e)
POLY 1.5	P=0.398N	P=0.239	(e)	(e)
POLY 6	P=0.384N	P=0.244	(e)	(e)
COCH-ARM / FISHERS	P=0.405N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.255N	P=0.081	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Basophilic Focus				
LESION RATES				
OVERALL (a)	4/50 (8%)	5/50 (10%)	4/50 (8%)	6/50 (12%)
POLY-3 RATE (b)	4/45.59	5/45.52	4/47.72	6/46.31
POLY-3 PERCENT (g)	8.8%	11%	8.4%	13%
TERMINAL (d)	0/38 (0%)	3/36 (8%)	4/42 (10%)	5/41 (12%)
FIRST INCIDENCE	547	646	730 (T)	638
STATISTICAL TESTS				
POLY 3	P=0.341	P=0.499	P=0.618N	P=0.380
POLY 1.5	P=0.333	P=0.497	P=0.624N	P=0.372
POLY 6	P=0.349	P=0.496	P=0.617N	P=0.387
COCH-ARM / FISHERS	P=0.327	P=0.500	P=0.643N	P=0.370
MAX-ISO-POLY-3	P=0.416	P=0.362	P=0.473N	P=0.263

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Clear Cell Focus				
LESION RATES				
OVERALL (a)	15/50 (30%)	27/50 (54%)	28/50 (56%)	34/50 (68%)
POLY-3 RATE (b)	15/44.22	27/45.07	28/48.17	34/45.98
POLY-3 PERCENT (g)	33.9%	59.9%	58.1%	74%
TERMINAL (d)	15/38 (40%)	27/36 (75%)	27/42 (64%)	34/41 (83%)
FIRST INCIDENCE	730 (T)	730 (T)	597	730 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.009**	P=0.014*	P<0.001**
POLY 1.5	P<0.001**	P=0.009**	P=0.011*	P<0.001**
POLY 6	P<0.001**	P=0.009**	P=0.018*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.013*	P=0.007**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.005**	P=0.010**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Eosinophilic Focus				
LESION RATES				
OVERALL (a)	7/50 (14%)	12/50 (24%)	20/50 (40%)	36/50 (72%)
POLY-3 RATE (b)	7/45.11	12/45.25	20/47.85	36/46.41
POLY-3 PERCENT (g)	15.5%	26.5%	41.8%	77.6%
TERMINAL (d)	5/38 (13%)	10/36 (28%)	19/42 (45%)	33/41 (81%)
FIRST INCIDENCE	547	693	695	640
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.152	P=0.004**	P<0.001**
POLY 1.5	P<0.001**	P=0.150	P=0.003**	P<0.001**
POLY 6	P<0.001**	P=0.150	P=0.004**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.154	P=0.003**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.099	P=0.002**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Fatty Change Diffuse				
LESION RATES				
OVERALL (a)	38/50 (76%)	27/50 (54%)	21/50 (42%)	3/50 (6%)
POLY-3 RATE (b)	38/45.98	27/45.87	21/48.17	3/47.26
POLY-3 PERCENT (g)	82.7%	58.9%	43.6%	6.4%
TERMINAL (d)	33/38 (87%)	26/36 (72%)	20/42 (48%)	0/41 (0%)
FIRST INCIDENCE	479	428	597	332
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.007N**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.010N**	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P=0.006N**	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.018N*	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.003N**	P<0.001N**	P<0.001N**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Fatty Change Focal				
LESION RATES				
OVERALL (a)	3/50 (6%)	8/50 (16%)	20/50 (40%)	23/50 (46%)
POLY-3 RATE (b)	3/44.55	8/45.26	20/48.17	23/46.03
POLY-3 PERCENT (g)	6.7%	17.7%	41.5%	50%
TERMINAL (d)	2/38 (5%)	6/36 (17%)	19/42 (45%)	22/41 (54%)
FIRST INCIDENCE	640	690	597	716
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.103	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.100	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.104	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.100	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.057	P<0.001**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Fibrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	3/44.22	0/45.07	1/47.85	2/45.98
POLY-3 PERCENT (g)	6.8%	0%	2.1%	4.4%
TERMINAL (d)	3/38 (8%)	0/36 (0%)	0/42 (0%)	2/41 (5%)
FIRST INCIDENCE	730 (T)	---	695	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.549N	P=0.115N	P=0.278N	P=0.482N
POLY 1.5	P=0.551N	P=0.118N	P=0.287N	P=0.493N
POLY 6	P=0.546N	P=0.114N	P=0.269N	P=0.470N
COCH-ARM / FISHERS	P=0.556N	P=0.121N	P=0.309N	P=0.500N
MAX-ISO-POLY-3	P=0.183N	P=0.038N*	P=0.145N	P=0.312N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver Inflammation				
LESION RATES				
OVERALL (a)	24/50 (48%)	21/50 (42%)	20/50 (40%)	29/50 (58%)
POLY-3 RATE (b)	24/46.40	21/45.96	20/48.79	29/46.14
POLY-3 PERCENT (g)	51.7%	45.7%	41%	62.9%
TERMINAL (d)	18/38 (47%)	18/36 (50%)	17/42 (41%)	27/41 (66%)
FIRST INCIDENCE	547	606	588	702
STATISTICAL TESTS				
POLY 3	P=0.130	P=0.354N	P=0.198N	P=0.189
POLY 1.5	P=0.128	P=0.356N	P=0.220N	P=0.188
POLY 6	P=0.132	P=0.367N	P=0.189N	P=0.188
COCH-ARM / FISHERS	P=0.135	P=0.344N	P=0.273N	P=0.212
MAX-ISO-POLY-3	P=0.081	P=0.281N	P=0.151N	P=0.137

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Mixed Cell Focus				
LESION RATES				
OVERALL (a)	18/50 (36%)	20/50 (40%)	19/50 (38%)	34/50 (68%)
POLY-3 RATE (b)	18/44.42	20/45.38	19/48.40	34/46.42
POLY-3 PERCENT (g)	40.5%	44.1%	39.3%	73.3%
TERMINAL (d)	16/38 (42%)	19/36 (53%)	17/42 (41%)	32/41 (78%)
FIRST INCIDENCE	695	646	597	638
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.449	P=0.535N	P<0.001**
POLY 1.5	P<0.001**	P=0.429	P=0.581N	P<0.001**
POLY 6	P<0.001**	P=0.460	P=0.493N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.418	P=0.500	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.366	P=0.451N	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Necrosis				
LESION RATES				
OVERALL (a)	1/50 (2%)	8/50 (16%)	5/50 (10%)	26/50 (52%)
POLY-3 RATE (b)	1/44.83	8/45.64	5/48.20	26/45.98
POLY-3 PERCENT (g)	2.2%	17.5%	10.4%	56.6%
TERMINAL (d)	0/38 (0%)	4/36 (11%)	4/42 (10%)	26/41 (63%)
FIRST INCIDENCE	535	646	588	730 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.017*	P=0.119	P<0.001**
POLY 1.5	P<0.001**	P=0.016*	P=0.113	P<0.001**
POLY 6	P<0.001**	P=0.017*	P=0.125	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.015*	P=0.102	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.007**	P=0.061	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Pigmentation				
LESION RATES				
OVERALL (a)	3/50 (6%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	3/45.12	0/45.07	2/47.72	1/45.98
POLY-3 PERCENT (g)	6.7%	0%	4.2%	2.2%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	2/42 (5%)	1/41 (2%)
FIRST INCIDENCE	547	---	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.330N	P=0.119N	P=0.475N	P=0.299N
POLY 1.5	P=0.333N	P=0.120N	P=0.482N	P=0.304N
POLY 6	P=0.324N	P=0.120N	P=0.470N	P=0.293N
COCH-ARM / FISHERS	P=0.337N	P=0.121N	P=0.500N	P=0.309N
MAX-ISO-POLY-3	P=0.187N	P=0.038N*	P=0.306N	P=0.151N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Tension Lipidosis				
LESION RATES				
OVERALL (a)	5/50 (10%)	6/50 (12%)	7/50 (14%)	2/50 (4%)
POLY-3 RATE (b)	5/45.39	6/46.43	7/47.72	2/46.88
POLY-3 PERCENT (g)	11%	12.9%	14.7%	4.3%
TERMINAL (d)	2/38 (5%)	3/36 (8%)	7/42 (17%)	1/41 (2%)
FIRST INCIDENCE	477	444	730 (T)	332
STATISTICAL TESTS				
POLY 3	P=0.153N	P=0.516	P=0.415	P=0.203N
POLY 1.5	P=0.161N	P=0.507	P=0.404	P=0.210N
POLY 6	P=0.145N	P=0.521	P=0.420	P=0.197N
COCH-ARM / FISHERS	P=0.169N	P=0.500	P=0.380	P=0.218N
MAX-ISO-POLY-3	P=0.150N	P=0.389	P=0.305	P=0.114N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver: Bile Duct Cyst				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	3/50 (6%)	14/50 (28%)
POLY-3 RATE (b)	0/44.22	0/45.07	3/47.78	14/46.13
POLY-3 PERCENT (g)	0%	0%	6.3%	30.4%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	2/42 (5%)	12/41 (29%)
FIRST INCIDENCE	---	---	714	702
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.133	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.128	P<0.001**
POLY 6	P<0.001**	(e)	P=0.138	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.121	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.050*	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver: Bile Duct Fibrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	2/45.98
POLY-3 PERCENT (g)	0%	0%	0%	4.4%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	2/41 (5%)
FIRST INCIDENCE	---	---	---	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.047*	(e)	(e)	P=0.246
POLY 1.5	P=0.046*	(e)	(e)	P=0.241
POLY 6	P=0.048*	(e)	(e)	P=0.252
COCH-ARM / FISHERS	P=0.046*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.039*	(e)	(e)	P=0.084

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver: Bile Duct Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	35/50 (70%)
POLY-3 RATE (b)	0/44.22	0/45.07	1/47.72	35/45.98
POLY-3 PERCENT (g)	0%	0%	2.1%	76.1%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	1/42 (2%)	35/41 (85%)
FIRST INCIDENCE	---	---	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.515	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.510	P<0.001**
POLY 6	P<0.001**	(e)	P=0.519	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.177	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver: Hepatocyte, Centrilobular Hypertrophy				
LESION RATES				
OVERALL (a)	0/50 (0%)	11/50 (22%)	23/50 (46%)	46/50 (92%)
POLY-3 RATE (b)	0/44.22	11/45.53	23/48.63	46/48.72
POLY-3 PERCENT (g)	0%	24.2%	47.3%	94.4%
TERMINAL (d)	0/38 (0%)	9/36 (25%)	20/42 (48%)	40/41 (98%)
FIRST INCIDENCE	---	646	639	141
STATISTICAL TESTS				
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver: Oval Cell Hyperplasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	36/50 (72%)
POLY-3 RATE (b)	1/44.54	0/45.07	1/47.72	36/45.98
POLY-3 PERCENT (g)	2.2%	0%	2.1%	78.3%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	1/42 (2%)	36/41 (88%)
FIRST INCIDENCE	641	---	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.498N	P=0.745N	P<0.001**
POLY 1.5	P<0.001**	P=0.499N	P=0.750N	P<0.001**
POLY 6	P<0.001**	P=0.497N	P=0.741N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500N	P=0.753N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.158N	P=0.480N	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver: Vein				
Intravascular Hepatocyte				
LESION RATES				
OVERALL (a)	3/50 (6%)	1/50 (2%)	15/50 (30%)	47/50 (94%)
POLY-3 RATE (b)	3/44.22	1/45.23	15/47.72	47/47.95
POLY-3 PERCENT (g)	6.8%	2.2%	31.4%	98%
TERMINAL (d)	3/38 (8%)	0/36 (0%)	15/42 (36%)	41/41 (100%)
FIRST INCIDENCE	730 (T)	690	730 (T)	332
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.297N	P=0.002**	P<0.001**
POLY 1.5	P<0.001**	P=0.302N	P=0.002**	P<0.001**
POLY 6	P<0.001**	P=0.293N	P=0.003**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.309N	P=0.002**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.151N	P<0.001**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lung Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	5/50 (10%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/44.22	5/46.28	2/47.72	1/46.88
POLY-3 PERCENT (g)	0%	10.8%	4.2%	2.1%
TERMINAL (d)	0/38 (0%)	2/36 (6%)	2/42 (5%)	0/41 (0%)
FIRST INCIDENCE	---	444	730 (T)	332
STATISTICAL TESTS				
POLY 3	P=0.460N	P=0.034*	P=0.255	P=0.512
POLY 1.5	P=0.478N	P=0.033*	P=0.249	P=0.506
POLY 6	P=0.442N	P=0.036*	P=0.260	P=0.518
COCH-ARM / FISHERS	P=0.500N	P=0.028*	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.154	P=0.013*	P=0.093	P=0.173

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lung: Alveolar Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	7/50 (14%)	2/50 (4%)	9/50 (18%)
POLY-3 RATE (b)	2/44.74	7/45.36	2/47.72	9/46.70
POLY-3 PERCENT (g)	4.5%	15.4%	4.2%	19.3%
TERMINAL (d)	1/38 (3%)	6/36 (17%)	2/42 (5%)	8/41 (20%)
FIRST INCIDENCE	573	652	730 (T)	473
STATISTICAL TESTS				
POLY 3	P=0.044*	P=0.082	P=0.670N	P=0.030*
POLY 1.5	P=0.041*	P=0.080	P=0.678N	P=0.027*
POLY 6	P=0.048*	P=0.082	P=0.665N	P=0.033*
COCH-ARM / FISHERS	P=0.040*	P=0.080	P=0.691N	P=0.026*
MAX-ISO-POLY-3	P=0.019*	P=0.041*	P=0.474N	P=0.015*

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lung: Alveolus Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	2/50 (4%)	4/50 (8%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	2/44.22	4/45.81	3/47.72	3/45.98
POLY-3 PERCENT (g)	4.5%	8.7%	6.3%	6.5%
TERMINAL (d)	2/38 (5%)	1/36 (3%)	3/42 (7%)	3/41 (7%)
FIRST INCIDENCE	730 (T)	646	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.524	P=0.354	P=0.535	P=0.518
POLY 1.5	P=0.511	P=0.344	P=0.523	P=0.507
POLY 6	P=0.539	P=0.363	P=0.544	P=0.530
COCH-ARM / FISHERS	P=0.500	P=0.339	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.498	P=0.218	P=0.360	P=0.342

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lung: Cervix Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	2/46.21	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	59	---	---
STATISTICAL TESTS				
POLY 3	P=0.388N	P=0.247	(e)	(e)
POLY 1.5	P=0.395N	P=0.244	(e)	(e)
POLY 6	P=0.381N	P=0.249	(e)	(e)
COCH-ARM / FISHERS	P=0.405N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.260N	P=0.086	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lymph Node, Mandibular Atrophy				
LESION RATES				
OVERALL (a)	1/50 (2%)	4/50 (8%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	1/44.22	4/45.98	3/48.59	2/46.88
POLY-3 PERCENT (g)	2.3%	8.7%	6.2%	4.3%
TERMINAL (d)	1/38 (3%)	1/36 (3%)	0/42 (0%)	1/41 (2%)
FIRST INCIDENCE	730 (T)	646	639	332
STATISTICAL TESTS				
POLY 3	P=0.582	P=0.191	P=0.340	P=0.520
POLY 1.5	P=0.565	P=0.184	P=0.327	P=0.511
POLY 6	P=0.578N	P=0.198	P=0.353	P=0.531
COCH-ARM / FISHERS	P=0.544	P=0.181	P=0.309	P=0.500
MAX-ISO-POLY-3	P=0.329	P=0.095	P=0.189	P=0.303

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lymph Node, Mandibular Hyperplasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.29	1/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	4.5%	2.2%	0%	0%
TERMINAL (d)	1/38 (3%)	1/36 (3%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	714	730 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.098N	P=0.494N	P=0.221N	P=0.229N
POLY 1.5	P=0.099N	P=0.498N	P=0.227N	P=0.234N
POLY 6	P=0.097N	P=0.492N	P=0.217N	P=0.223N
COCH-ARM / FISHERS	P=0.101N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.077N	P=0.277N	P=0.076N	P=0.076N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lymph Node, Mandibular Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.29	1/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	2.3%	2.2%	0%	0%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	714	730 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.232N	P=0.757N	P=0.485N	P=0.493N
POLY 1.5	P=0.233N	P=0.759N	P=0.490N	P=0.497N
POLY 6	P=0.230N	P=0.756N	P=0.481N	P=0.487N
COCH-ARM / FISHERS	P=0.236N	P=0.753N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.255N	P=0.494N	P=0.158N	P=0.158N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lymph Node, Mesenteric Atrophy				
LESION RATES				
OVERALL (a)	0/47 (0%)	1/49 (2%)	2/45 (4%)	3/44 (7%)
POLY-3 RATE (b)	0/41.54	1/44.68	2/43.59	3/41.78
POLY-3 PERCENT (g)	0%	2.2%	4.6%	7.2%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	1/39 (3%)	1/37 (3%)
FIRST INCIDENCE	---	646	668	332
STATISTICAL TESTS				
POLY 3	P=0.059	P=0.515	P=0.248	P=0.119
POLY 1.5	P=0.055	P=0.511	P=0.241	P=0.113
POLY 6	P=0.064	P=0.517	P=0.255	P=0.126
COCH-ARM / FISHERS	P=0.051	P=0.510	P=0.237	P=0.109
MAX-ISO-POLY-3	P=0.064	P=0.174	P=0.089	P=0.041*

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 04/23/2009
Time Report Requested: 10:38:13
First Dose M/F: 04/15/03 / 04/14/03
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Mesentery				
Necrosis				
<hr/>				
LESION RATES				
OVERALL (a)	0/4 (0%)	0/2 (0%)	0/3 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/3.07	0/1.86	0/2.94	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/2 (0%)	0/1 (0%)	0/2 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 04/23/2009
Time Report Requested: 10:38:13
First Dose M/F: 04/15/03 / 04/14/03
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

Mesentery: Fat
Necrosis

LESION RATES

OVERALL (a)	3/4 (75%)	1/2 (50%)	3/3 (100%)	0/0 (0%)
POLY-3 RATE (b)	3/3.39	1/1.86	3/3.00	0/0.00
POLY-3 PERCENT (g)	88.4%	53.9%	100%	0%
TERMINAL (d)	2/2 (100%)	1/1 (100%)	2/2 (100%)	0/0 (0%)
FIRST INCIDENCE	640	730 (T)	714	---

STATISTICAL TESTS

POLY 3	(e)	P=0.575N	P=0.925	(e)
POLY 1.5	(e)	P=0.584N	P=0.740	(e)
POLY 6	(e)	P=0.592N	P=1.000	(e)
COCH-ARM / FISHERS	P=0.581	P=0.600N	P=0.571	(e)
MAX-ISO-POLY-3	(e)	P=0.207N	P=0.203	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Nose Inflammation				
LESION RATES				
OVERALL (a)	2/50 (4%)	3/50 (6%)	2/50 (4%)	22/50 (44%)
POLY-3 RATE (b)	2/44.53	3/45.07	2/47.72	22/46.36
POLY-3 PERCENT (g)	4.5%	6.7%	4.2%	47.5%
TERMINAL (d)	1/38 (3%)	3/36 (8%)	2/42 (5%)	20/41 (49%)
FIRST INCIDENCE	646	730 (T)	730 (T)	638
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.506	P=0.669N	P<0.001**
POLY 1.5	P<0.001**	P=0.501	P=0.677N	P<0.001**
POLY 6	P<0.001**	P=0.506	P=0.663N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.691N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.329	P=0.472N	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Nose				
Polyp, Inflammatory				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	2/45.21	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	4.4%	0%	0%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	693	---	---
STATISTICAL TESTS				
POLY 3	P=0.391N	P=0.242	(e)	(e)
POLY 1.5	P=0.398N	P=0.239	(e)	(e)
POLY 6	P=0.384N	P=0.244	(e)	(e)
COCH-ARM / FISHERS	P=0.405N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.255N	P=0.081	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Nose: Nerve Atrophy				
LESION RATES				
OVERALL (a)	1/50 (2%)	3/50 (6%)	3/50 (6%)	45/50 (90%)
POLY-3 RATE (b)	1/44.53	3/45.21	3/47.72	45/47.33
POLY-3 PERCENT (g)	2.3%	6.6%	6.3%	95.1%
TERMINAL (d)	0/38 (0%)	2/36 (6%)	3/42 (7%)	40/41 (98%)
FIRST INCIDENCE	646	693	730 (T)	570
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.311	P=0.331	P<0.001**
POLY 1.5	P<0.001**	P=0.307	P=0.322	P<0.001**
POLY 6	P<0.001**	P=0.312	P=0.337	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.309	P=0.309	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.160	P=0.180	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Nose: Olfactory Epithelium Degeneration				
LESION RATES				
OVERALL (a)	3/50 (6%)	3/50 (6%)	11/50 (22%)	46/50 (92%)
POLY-3 RATE (b)	3/44.94	3/45.21	11/48.43	46/48.90
POLY-3 PERCENT (g)	6.7%	6.6%	22.7%	94.1%
TERMINAL (d)	2/38 (5%)	2/36 (6%)	9/42 (21%)	40/41 (98%)
FIRST INCIDENCE	477	693	588	332
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.660N	P=0.028*	P<0.001**
POLY 1.5	P<0.001**	P=0.661	P=0.025*	P<0.001**
POLY 6	P<0.001**	P=0.658N	P=0.032*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.661N	P=0.020*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.496N	P=0.017*	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Nose: Olfactory Epithelium Metaplasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	5/50 (10%)	3/50 (6%)	44/50 (88%)
POLY-3 RATE (b)	1/44.53	5/45.25	3/47.72	44/48.05
POLY-3 PERCENT (g)	2.3%	11.1%	6.3%	91.6%
TERMINAL (d)	0/38 (0%)	3/36 (8%)	3/42 (7%)	38/41 (93%)
FIRST INCIDENCE	646	693	730 (T)	473
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.105	P=0.331	P<0.001**
POLY 1.5	P<0.001**	P=0.103	P=0.322	P<0.001**
POLY 6	P<0.001**	P=0.106	P=0.337	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.102	P=0.309	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.047*	P=0.180	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Nose: Respiratory Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	38/50 (76%)	38/50 (76%)	42/50 (84%)	40/50 (80%)
POLY-3 RATE (b)	38/45.78	38/47.01	42/48.98	40/48.37
POLY-3 PERCENT (g)	83%	80.8%	85.8%	82.7%
TERMINAL (d)	33/38 (87%)	31/36 (86%)	37/42 (88%)	35/41 (85%)
FIRST INCIDENCE	477	428	597	141
STATISTICAL TESTS				
POLY 3	P=0.515	P=0.499N	P=0.465	P=0.596N
POLY 1.5	P=0.438	P=0.558N	P=0.366	P=0.543
POLY 6	P=0.517N	P=0.453N	P=0.562	P=0.517N
COCH-ARM / FISHERS	P=0.299	P=0.592N	P=0.227	P=0.405
MAX-ISO-POLY-3	P=0.596	P=0.386N	P=0.353	P=0.482N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Pancreas				
Cytoplasmic Alteration Focal				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/44.22	2/45.21	1/47.72	1/45.98
POLY-3 PERCENT (g)	0%	4.4%	2.1%	2.2%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	1/42 (2%)	1/41 (2%)
FIRST INCIDENCE	---	693	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.519	P=0.242	P=0.515	P=0.508
POLY 1.5	P=0.508	P=0.239	P=0.510	P=0.503
POLY 6	P=0.532	P=0.244	P=0.519	P=0.513
COCH-ARM / FISHERS	P=0.500	P=0.247	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.294	P=0.081	P=0.177	P=0.168

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Pancreas				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	5/50 (10%)	5/50 (10%)	4/50 (8%)	7/50 (14%)
POLY-3 RATE (b)	5/44.55	5/45.23	4/47.72	7/45.98
POLY-3 PERCENT (g)	11.2%	11.1%	8.4%	15.2%
TERMINAL (d)	4/38 (11%)	4/36 (11%)	4/42 (10%)	7/41 (17%)
FIRST INCIDENCE	640	690	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.327	P=0.621N	P=0.457N	P=0.401
POLY 1.5	P=0.317	P=0.627N	P=0.471N	P=0.388
POLY 6	P=0.340	P=0.618N	P=0.447N	P=0.417
COCH-ARM / FISHERS	P=0.306	P=0.630N	P=0.500N	P=0.380
MAX-ISO-POLY-3	P=0.375	P=0.489N	P=0.329N	P=0.292

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Pituitary Gland				
Angiectasis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 04/23/2009
Time Report Requested: 10:38:13
First Dose M/F: 04/15/03 / 04/14/03
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

Pituitary Gland: Pars Distalis
Cyst

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Pituitary Gland: Pars Distalis Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	1/47.72	0/45.98
POLY-3 PERCENT (g)	0%	0%	2.1%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	1/42 (2%)	0/41 (0%)
FIRST INCIDENCE	---	---	730 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.705	(e)	P=0.515	(e)
POLY 1.5	P=0.698	(e)	P=0.510	(e)
POLY 6	P=0.715	(e)	P=0.519	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.407	(e)	P=0.177	(e)

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 04/23/2009
Time Report Requested: 10:38:13
First Dose M/F: 04/15/03 / 04/14/03
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Preputial Gland Cyst				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	2/45.98
POLY-3 PERCENT (g)	0%	0%	0%	4.4%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	2/41 (5%)
FIRST INCIDENCE	---	---	---	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.047*	(e)	(e)	P=0.246
POLY 1.5	P=0.046*	(e)	(e)	P=0.241
POLY 6	P=0.048*	(e)	(e)	P=0.252
COCH-ARM / FISHERS	P=0.046*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.039*	(e)	(e)	P=0.084

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Preputial Gland				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	10/50 (20%)	15/50 (30%)	12/50 (24%)	7/50 (14%)
POLY-3 RATE (b)	10/44.75	15/45.33	12/48.18	7/46.31
POLY-3 PERCENT (g)	22.4%	33.1%	24.9%	15.1%
TERMINAL (d)	7/38 (18%)	12/36 (33%)	10/42 (24%)	6/41 (15%)
FIRST INCIDENCE	641	693	639	638
STATISTICAL TESTS				
POLY 3	P=0.119N	P=0.182	P=0.482	P=0.269N
POLY 1.5	P=0.134N	P=0.177	P=0.456	P=0.285N
POLY 6	P=0.104N	P=0.182	P=0.502	P=0.252N
COCH-ARM / FISHERS	P=0.149N	P=0.178	P=0.405	P=0.298N
MAX-ISO-POLY-3	P=0.130N	P=0.128	P=0.389	P=0.193N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Preputial Gland Inflammation				
LESION RATES				
OVERALL (a)	4/50 (8%)	4/50 (8%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	4/44.22	4/45.36	3/47.72	4/45.98
POLY-3 PERCENT (g)	9.1%	8.8%	6.3%	8.7%
TERMINAL (d)	4/38 (11%)	3/36 (8%)	3/42 (7%)	4/41 (10%)
FIRST INCIDENCE	730 (T)	652	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.532N	P=0.629N	P=0.459N	P=0.622N
POLY 1.5	P=0.543N	P=0.638N	P=0.473N	P=0.634N
POLY 6	P=0.519N	P=0.623N	P=0.447N	P=0.607N
COCH-ARM / FISHERS	P=0.554N	P=0.643N	P=0.500N	P=0.643N
MAX-ISO-POLY-3	P=0.618N	P=0.484N	P=0.317N	P=0.476N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Preputial Gland: Duct Ectasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	1/44.54	1/45.07	3/47.78	3/46.70
POLY-3 PERCENT (g)	2.2%	2.2%	6.3%	6.4%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	2/42 (5%)	2/41 (5%)
FIRST INCIDENCE	641	730 (T)	714	473
STATISTICAL TESTS				
POLY 3	P=0.181	P=0.758N	P=0.331	P=0.323
POLY 1.5	P=0.173	P=0.760N	P=0.322	P=0.314
POLY 6	P=0.191	P=0.758N	P=0.337	P=0.332
COCH-ARM / FISHERS	P=0.165	P=0.753N	P=0.309	P=0.309
MAX-ISO-POLY-3	P=0.276	P=0.496N	P=0.180	P=0.172

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Prostate				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	23/50 (46%)	30/50 (60%)	23/50 (46%)	14/50 (28%)
POLY-3 RATE (b)	23/46.50	30/46.01	23/47.92	14/46.56
POLY-3 PERCENT (g)	49.5%	65.2%	48%	30.1%
TERMINAL (d)	18/38 (47%)	25/36 (69%)	21/42 (50%)	12/41 (29%)
FIRST INCIDENCE	479	646	695	570
STATISTICAL TESTS				
POLY 3	P=0.006N**	P=0.089	P=0.525N	P=0.042N*
POLY 1.5	P=0.007N**	P=0.092	P=0.539N	P=0.046N*
POLY 6	P=0.004N**	P=0.083	P=0.526N	P=0.038N*
COCH-ARM / FISHERS	P=0.009N**	P=0.115	P=0.579N	P=0.048N*
MAX-ISO-POLY-3	P=0.005N**	P=0.060	P=0.442N	P=0.026N*

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Prostate: Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	6/50 (12%)	3/50 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	6/44.22	3/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	13.6%	6.7%	0%	0%
TERMINAL (d)	6/38 (16%)	3/36 (8%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.003N**	P=0.232N	P=0.012N*	P=0.013N*
POLY 1.5	P=0.003N**	P=0.239N	P=0.013N*	P=0.014N*
POLY 6	P=0.002N**	P=0.228N	P=0.011N*	P=0.012N*
COCH-ARM / FISHERS	P=0.003N**	P=0.243N	P=0.013N*	P=0.013N*
MAX-ISO-POLY-3	P=0.002N**	P=0.142N	P=0.004N**	P=0.005N**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Salivary Glands				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	40/50 (80%)	32/50 (64%)	30/50 (60%)	33/50 (66%)
POLY-3 RATE (b)	40/47.82	32/47.04	30/49.16	33/46.56
POLY-3 PERCENT (g)	83.7%	68%	61%	70.9%
TERMINAL (d)	33/38 (87%)	24/36 (67%)	26/42 (62%)	31/41 (76%)
FIRST INCIDENCE	331	606	588	570
STATISTICAL TESTS				
POLY 3	P=0.131N	P=0.056N	P=0.009N**	P=0.100N
POLY 1.5	P=0.134N	P=0.064N	P=0.013N*	P=0.105N
POLY 6	P=0.125N	P=0.045N*	P=0.006N**	P=0.090N
COCH-ARM / FISHERS	P=0.125N	P=0.059N	P=0.024N*	P=0.088N
MAX-ISO-POLY-3	P=0.042N*	P=0.034N*	P=0.005N**	P=0.064N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Skin Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	1/45.50	2/47.72	0/45.98
POLY-3 PERCENT (g)	0%	2.2%	4.2%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	2/42 (5%)	0/41 (0%)
FIRST INCIDENCE	---	606	730 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.602N	P=0.506	P=0.255	(e)
POLY 1.5	P=0.610N	P=0.502	P=0.249	(e)
POLY 6	P=0.591N	P=0.508	P=0.260	(e)
COCH-ARM / FISHERS	P=0.616N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.346N	P=0.166	P=0.093	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Skin				
Ulcer				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	1/45.50	2/47.72	0/45.98
POLY-3 PERCENT (g)	0%	2.2%	4.2%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	2/42 (5%)	0/41 (0%)
FIRST INCIDENCE	---	606	730 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.602N	P=0.506	P=0.255	(e)
POLY 1.5	P=0.610N	P=0.502	P=0.249	(e)
POLY 6	P=0.591N	P=0.508	P=0.260	(e)
COCH-ARM / FISHERS	P=0.616N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.346N	P=0.166	P=0.093	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Spleen				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	29/50 (58%)	32/50 (64%)	23/50 (46%)	23/50 (46%)
POLY-3 RATE (b)	29/46.35	32/47.49	23/48.68	23/47.02
POLY-3 PERCENT (g)	62.6%	67.4%	47.3%	48.9%
TERMINAL (d)	24/38 (63%)	24/36 (67%)	19/42 (45%)	21/41 (51%)
FIRST INCIDENCE	535	444	597	141
STATISTICAL TESTS				
POLY 3	P=0.043N*	P=0.391	P=0.095N	P=0.128N
POLY 1.5	P=0.047N*	P=0.357	P=0.113N	P=0.138N
POLY 6	P=0.040N*	P=0.425	P=0.082N	P=0.119N
COCH-ARM / FISHERS	P=0.060N	P=0.341	P=0.158N	P=0.158N
MAX-ISO-POLY-3	P=0.067N	P=0.312	P=0.069N	P=0.090N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Spleen				
Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	2/50 (4%)	3/50 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.22	3/45.84	0/47.72	0/45.98
POLY-3 PERCENT (g)	4.5%	6.5%	0%	0%
TERMINAL (d)	2/38 (5%)	2/36 (6%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	730 (T)	444	---	---
STATISTICAL TESTS				
POLY 3	P=0.067N	P=0.516	P=0.221N	P=0.229N
POLY 1.5	P=0.069N	P=0.508	P=0.226N	P=0.234N
POLY 6	P=0.064N	P=0.522	P=0.216N	P=0.223N
COCH-ARM / FISHERS	P=0.073N	P=0.500	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.088N	P=0.341	P=0.076N	P=0.076N

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 04/23/2009
Time Report Requested: 10:38:13
First Dose M/F: 04/15/03 / 04/14/03
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

Spleen
Pigmentation

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Spleen: Lymphoid Follicle Atrophy				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/44.74	0/45.07	1/47.72	3/47.26
POLY-3 PERCENT (g)	2.2%	0%	2.1%	6.4%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	1/42 (2%)	0/41 (0%)
FIRST INCIDENCE	573	---	730 (T)	332
STATISTICAL TESTS				
POLY 3	P=0.104	P=0.499N	P=0.746N	P=0.325
POLY 1.5	P=0.101	P=0.500N	P=0.751N	P=0.316
POLY 6	P=0.108	P=0.498N	P=0.743N	P=0.336
COCH-ARM / FISHERS	P=0.097	P=0.500N	P=0.753N	P=0.309
MAX-ISO-POLY-3	P=0.104	P=0.158N	P=0.481N	P=0.175

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Spleen: Red Pulp Atrophy				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/44.74	0/45.07	1/48.05	3/47.26
POLY-3 PERCENT (g)	2.2%	0%	2.1%	6.4%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	573	---	639	332
STATISTICAL TESTS				
POLY 3	P=0.104	P=0.499N	P=0.744N	P=0.325
POLY 1.5	P=0.101	P=0.500N	P=0.750N	P=0.316
POLY 6	P=0.108	P=0.498N	P=0.740N	P=0.336
COCH-ARM / FISHERS	P=0.097	P=0.500N	P=0.753N	P=0.309
MAX-ISO-POLY-3	P=0.104	P=0.158N	P=0.479N	P=0.175

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Stomach, Forestomach Hyperplasia				
LESION RATES				
OVERALL (a)	7/50 (14%)	10/50 (20%)	27/50 (54%)	41/50 (82%)
POLY-3 RATE (b)	7/45.73	10/45.64	27/48.68	41/48.28
POLY-3 PERCENT (g)	15.3%	21.9%	55.5%	84.9%
TERMINAL (d)	4/38 (11%)	6/36 (17%)	23/42 (55%)	34/41 (83%)
FIRST INCIDENCE	535	646	646	332
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.294	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.292	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.293	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.298	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.210	P<0.001**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Stomach, Forestomach Inflammation				
LESION RATES				
OVERALL (a)	3/50 (6%)	9/50 (18%)	24/50 (48%)	39/50 (78%)
POLY-3 RATE (b)	3/44.55	9/45.64	24/48.51	39/48.28
POLY-3 PERCENT (g)	6.7%	19.7%	49.5%	80.8%
TERMINAL (d)	2/38 (5%)	5/36 (14%)	20/42 (48%)	32/41 (78%)
FIRST INCIDENCE	640	646	646	332
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.064	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.061	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.067	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.061	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.035*	P<0.001**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Stomach, Forestomach Ulcer				
LESION RATES				
OVERALL (a)	0/50 (0%)	3/50 (6%)	9/50 (18%)	22/50 (44%)
POLY-3 RATE (b)	0/44.22	3/45.30	9/48.00	22/47.43
POLY-3 PERCENT (g)	0%	6.6%	18.8%	46.4%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	8/42 (19%)	17/41 (42%)
FIRST INCIDENCE	---	693	654	332
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.123	P=0.003**	P<0.001**
POLY 1.5	P<0.001**	P=0.120	P=0.002**	P<0.001**
POLY 6	P<0.001**	P=0.125	P=0.003**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.121	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.041*	P<0.001**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Stomach, Glandular Mineralization				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.22	1/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	4.5%	2.2%	0%	0%
TERMINAL (d)	2/38 (5%)	1/36 (3%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.098N	P=0.493N	P=0.221N	P=0.229N
POLY 1.5	P=0.099N	P=0.498N	P=0.226N	P=0.234N
POLY 6	P=0.097N	P=0.491N	P=0.216N	P=0.223N
COCH-ARM / FISHERS	P=0.101N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.077N	P=0.277N	P=0.076N	P=0.076N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Stomach, Glandular: Glands Cyst				
LESION RATES				
OVERALL (a)	4/50 (8%)	4/50 (8%)	3/50 (6%)	5/50 (10%)
POLY-3 RATE (b)	4/44.22	4/45.07	3/47.72	5/45.98
POLY-3 PERCENT (g)	9.1%	8.9%	6.3%	10.9%
TERMINAL (d)	4/38 (11%)	4/36 (11%)	3/42 (7%)	5/41 (12%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.455	P=0.633N	P=0.459N	P=0.524
POLY 1.5	P=0.442	P=0.639N	P=0.473N	P=0.510
POLY 6	P=0.470	P=0.630N	P=0.447N	P=0.541
COCH-ARM / FISHERS	P=0.430	P=0.643N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.512	P=0.488N	P=0.317N	P=0.387

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Testes				
Mineralization				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	2/45.84	1/47.72	0/45.98
POLY-3 PERCENT (g)	0%	4.4%	2.1%	0%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	1/42 (2%)	0/41 (0%)
FIRST INCIDENCE	---	444	730 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.443N	P=0.245	P=0.515	(e)
POLY 1.5	P=0.453N	P=0.241	P=0.510	(e)
POLY 6	P=0.433N	P=0.248	P=0.519	(e)
COCH-ARM / FISHERS	P=0.461N	P=0.247	P=0.500	(e)
MAX-ISO-POLY-3	P=0.339N	P=0.084	P=0.177	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Testes: Germinal Epithelium Atrophy				
LESION RATES				
OVERALL (a)	2/50 (4%)	2/50 (4%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	2/44.22	2/46.15	3/48.02	0/45.98
POLY-3 PERCENT (g)	4.5%	4.3%	6.3%	0%
TERMINAL (d)	2/38 (5%)	0/36 (0%)	2/42 (5%)	0/41 (0%)
FIRST INCIDENCE	730 (T)	444	646	---
STATISTICAL TESTS				
POLY 3	P=0.189N	P=0.678N	P=0.537	P=0.229N
POLY 1.5	P=0.195N	P=0.686N	P=0.524	P=0.234N
POLY 6	P=0.181N	P=0.673N	P=0.549	P=0.223N
COCH-ARM / FISHERS	P=0.199N	P=0.691N	P=0.500	P=0.247N
MAX-ISO-POLY-3	P=0.178N	P=0.482N	P=0.363	P=0.076N

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 04/23/2009
Time Report Requested: 10:38:13
First Dose M/F: 04/15/03 / 04/14/03
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Thymus Atrophy				
LESION RATES				
OVERALL (a)	36/49 (73%)	35/46 (76%)	32/45 (71%)	30/42 (71%)
POLY-3 RATE (b)	36/46.08	35/43.54	32/44.55	30/39.95
POLY-3 PERCENT (g)	78.1%	80.4%	71.8%	75.1%
TERMINAL (d)	28/37 (76%)	27/33 (82%)	26/38 (68%)	27/36 (75%)
FIRST INCIDENCE	535	444	588	640
STATISTICAL TESTS				
POLY 3	P=0.338N	P=0.498	P=0.325N	P=0.470N
POLY 1.5	P=0.368N	P=0.472	P=0.376N	P=0.498N
POLY 6	P=0.315N	P=0.505	P=0.293N	P=0.451N
COCH-ARM / FISHERS	P=0.403N	P=0.478	P=0.490N	P=0.506N
MAX-ISO-POLY-3	P=0.430N	P=0.393	P=0.244N	P=0.371N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Thymus				
Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	0/49 (0%)	2/46 (4%)	0/45 (0%)	0/42 (0%)
POLY-3 RATE (b)	0/43.22	2/41.23	0/42.95	0/39.45
POLY-3 PERCENT (g)	0%	4.9%	0%	0%
TERMINAL (d)	0/37 (0%)	2/33 (6%)	0/38 (0%)	0/36 (0%)
FIRST INCIDENCE	---	730 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.416N	P=0.226	(e)	(e)
POLY 1.5	P=0.424N	P=0.224	(e)	(e)
POLY 6	P=0.409N	P=0.228	(e)	(e)
COCH-ARM / FISHERS	P=0.434N	P=0.232	(e)	(e)
MAX-ISO-POLY-3	P=0.262N	P=0.072	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Thymus				
Necrosis Lymphoid				
LESION RATES				
OVERALL (a)	0/49 (0%)	2/46 (4%)	0/45 (0%)	0/42 (0%)
POLY-3 RATE (b)	0/43.22	2/42.39	0/42.95	0/39.45
POLY-3 PERCENT (g)	0%	4.7%	0%	0%
TERMINAL (d)	0/37 (0%)	0/33 (0%)	0/38 (0%)	0/36 (0%)
FIRST INCIDENCE	---	59	---	---
STATISTICAL TESTS				
POLY 3	P=0.412N	P=0.233	(e)	(e)
POLY 1.5	P=0.421N	P=0.229	(e)	(e)
POLY 6	P=0.404N	P=0.235	(e)	(e)
COCH-ARM / FISHERS	P=0.434N	P=0.232	(e)	(e)
MAX-ISO-POLY-3	P=0.267N	P=0.075	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Tooth Dysplasia				
LESION RATES				
OVERALL (a)	37/37 (100%)	37/37 (100%)	35/35 (100%)	20/20 (100%)
POLY-3 RATE (b)	37/37.00	37/37.00	35/35.00	20/20.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	34/34 (100%)	32/32 (100%)	33/33 (100%)	19/19 (100%)
FIRST INCIDENCE	646	652	668	640
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Urinary Bladder				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	28/50 (56%)	19/50 (38%)	19/50 (38%)	31/50 (62%)
POLY-3 RATE (b)	28/45.49	19/45.86	19/48.56	31/47.25
POLY-3 PERCENT (g)	61.6%	41.4%	39.1%	65.6%
TERMINAL (d)	24/38 (63%)	15/36 (42%)	15/42 (36%)	26/41 (63%)
FIRST INCIDENCE	549	646	639	473
STATISTICAL TESTS				
POLY 3	P=0.201	P=0.039N*	P=0.022N*	P=0.424
POLY 1.5	P=0.179	P=0.046N*	P=0.030N*	P=0.375
POLY 6	P=0.231	P=0.035N*	P=0.017N*	P=0.482
COCH-ARM / FISHERS	P=0.163	P=0.054N	P=0.054N	P=0.342
MAX-ISO-POLY-3	P=0.057	P=0.025N*	P=0.015N*	P=0.343

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Adrenal Cortex Hypertrophy				
LESION RATES				
OVERALL (a)	0/49 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/45.13	1/46.68	1/45.32	1/44.78
POLY-3 PERCENT (g)	0%	2.1%	2.2%	2.2%
TERMINAL (d)	0/35 (0%)	1/41 (2%)	0/38 (0%)	1/37 (3%)
FIRST INCIDENCE	---	729 (T)	667	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.377	P=0.507	P=0.501	P=0.498
POLY 1.5	P=0.378	P=0.506	P=0.501	P=0.499
POLY 6	P=0.375	P=0.509	P=0.502	P=0.498
COCH-ARM / FISHERS	P=0.388	P=0.505	P=0.505	P=0.505
MAX-ISO-POLY-3	P=0.336	P=0.166	P=0.160	P=0.160

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Adrenal Cortex: Subcapsular Hyperplasia				
LESION RATES				
OVERALL (a)	49/49 (100%)	50/50 (100%)	49/50 (98%)	49/50 (98%)
POLY-3 RATE (b)	49/49.00	50/50.00	49/49.42	49/49.00
POLY-3 PERCENT (g)	100%	100%	99.2%	100%
TERMINAL (d)	35/35 (100%)	41/41 (100%)	38/38 (100%)	37/37 (100%)
FIRST INCIDENCE	450	493	268	404
STATISTICAL TESTS				
POLY 3	P=0.924N	(e)	P=0.920N	P=0.505N
POLY 1.5	P=0.804N	(e)	P=0.711N	P=1.000N
POLY 6	P=1.000N	(e)	P=1.000N	P=0.505N
COCH-ARM / FISHERS	P=0.238N	(e)	P=0.505N	P=0.505N
MAX-ISO-POLY-3	P=0.391N	(e)	P=0.162N	P=0.163N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Adrenal Medulla Hyperplasia				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.23	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	702	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.303N	P=0.494N	P=0.501N	P=0.502N
POLY 1.5	P=0.303N	P=0.495N	P=0.500N	P=0.501N
POLY 6	P=0.304N	P=0.492N	P=0.501N	P=0.503N
COCH-ARM / FISHERS	P=0.303N	P=0.495N	P=0.495N	P=0.495N
MAX-ISO-POLY-3	P=0.128N	P=0.157N	P=0.161N	P=0.162N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Bone Marrow Hyperplasia				
LESION RATES				
OVERALL (a)	2/49 (4%)	9/50 (18%)	4/50 (8%)	5/50 (10%)
POLY-3 RATE (b)	2/45.32	9/48.76	4/46.65	5/45.58
POLY-3 PERCENT (g)	4.4%	18.5%	8.6%	11%
TERMINAL (d)	0/35 (0%)	4/41 (10%)	1/38 (3%)	1/37 (3%)
FIRST INCIDENCE	695	493	439	591
STATISTICAL TESTS				
POLY 3	P=0.433	P=0.034*	P=0.351	P=0.218
POLY 1.5	P=0.431	P=0.032*	P=0.348	P=0.217
POLY 6	P=0.438	P=0.038*	P=0.356	P=0.221
COCH-ARM / FISHERS	P=0.448	P=0.028*	P=0.349	P=0.226
MAX-ISO-POLY-3	P=0.159	P=0.019*	P=0.213	P=0.122

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 04/23/2009
Time Report Requested: 10:38:13
First Dose M/F: 04/15/03 / 04/14/03
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Bone Marrow				
Myelofibrosis				
LESION RATES				
OVERALL (a)	20/49 (41%)	17/50 (34%)	17/50 (34%)	14/50 (28%)
POLY-3 RATE (b)	20/45.58	17/47.00	17/45.52	14/45.45
POLY-3 PERCENT (g)	43.9%	36.2%	37.4%	30.8%
TERMINAL (d)	19/35 (54%)	16/41 (39%)	15/38 (40%)	12/37 (32%)
FIRST INCIDENCE	598	640	667	589
STATISTICAL TESTS				
POLY 3	P=0.137N	P=0.292N	P=0.336N	P=0.139N
POLY 1.5	P=0.138N	P=0.301N	P=0.333N	P=0.142N
POLY 6	P=0.135N	P=0.276N	P=0.328N	P=0.133N
COCH-ARM / FISHERS	P=0.120N	P=0.311N	P=0.311N	P=0.129N
MAX-ISO-POLY-3	P=0.156N	P=0.226N	P=0.263N	P=0.098N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Clitoral Gland Inflammation				
LESION RATES				
OVERALL (a)	0/47 (0%)	1/50 (2%)	1/49 (2%)	3/49 (6%)
POLY-3 RATE (b)	0/43.45	1/46.68	1/44.67	3/44.25
POLY-3 PERCENT (g)	0%	2.1%	2.2%	6.8%
TERMINAL (d)	0/35 (0%)	1/41 (2%)	0/38 (0%)	3/37 (8%)
FIRST INCIDENCE	---	729 (T)	667	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.053	P=0.514	P=0.506	P=0.122
POLY 1.5	P=0.053	P=0.514	P=0.506	P=0.122
POLY 6	P=0.052	P=0.516	P=0.507	P=0.121
COCH-ARM / FISHERS	P=0.056	P=0.515	P=0.510	P=0.129
MAX-ISO-POLY-3	P=0.042*	P=0.173	P=0.163	P=0.039*

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Esophagus Inflammation				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Eye Atrophy				
LESION RATES				
OVERALL (a)	0/49 (0%)	2/50 (4%)	1/49 (2%)	3/50 (6%)
POLY-3 RATE (b)	0/45.13	2/47.09	1/44.33	3/45.65
POLY-3 PERCENT (g)	0%	4.3%	2.3%	6.6%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	1/38 (3%)	0/37 (0%)
FIRST INCIDENCE	---	640	729 (T)	589
STATISTICAL TESTS				
POLY 3	P=0.104	P=0.247	P=0.496	P=0.121
POLY 1.5	P=0.103	P=0.245	P=0.497	P=0.120
POLY 6	P=0.105	P=0.251	P=0.497	P=0.123
COCH-ARM / FISHERS	P=0.106	P=0.253	P=0.500	P=0.125
MAX-ISO-POLY-3	P=0.062	P=0.084	P=0.159	P=0.039*

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Eye: Anterior Chamber Inflammation				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/49 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/44.33	2/44.78
POLY-3 PERCENT (g)	0%	0%	0%	4.5%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	2/37 (5%)
FIRST INCIDENCE	---	---	---	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.045*	(e)	(e)	P=0.235
POLY 1.5	P=0.045*	(e)	(e)	P=0.236
POLY 6	P=0.044*	(e)	(e)	P=0.235
COCH-ARM / FISHERS	P=0.047*	(e)	(e)	P=0.253
MAX-ISO-POLY-3	P=0.033*	(e)	(e)	P=0.077

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Eye: Cornea Inflammation				
LESION RATES				
OVERALL (a)	2/49 (4%)	0/50 (0%)	0/49 (0%)	9/50 (18%)
POLY-3 RATE (b)	2/45.20	0/46.68	0/44.33	9/45.94
POLY-3 PERCENT (g)	4.4%	0%	0%	19.6%
TERMINAL (d)	1/35 (3%)	0/41 (0%)	0/38 (0%)	6/37 (16%)
FIRST INCIDENCE	710	---	---	589
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.230N	P=0.241N	P=0.026*
POLY 1.5	P<0.001**	P=0.231N	P=0.241N	P=0.026*
POLY 6	P<0.001**	P=0.228N	P=0.241N	P=0.028*
COCH-ARM / FISHERS	P<0.001**	P=0.242N	P=0.247N	P=0.028*
MAX-ISO-POLY-3	P<0.001**	P=0.075N	P=0.080N	P=0.012*

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Gallbladder				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	1/48 (2%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.13	2/46.68	0/45.08	1/44.78
POLY-3 PERCENT (g)	2.3%	4.3%	0%	2.2%
TERMINAL (d)	1/34 (3%)	2/41 (5%)	0/38 (0%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.496N	P=0.520	P=0.496N	P=0.757N
POLY 1.5	P=0.495N	P=0.517	P=0.495N	P=0.757N
POLY 6	P=0.496N	P=0.524	P=0.495N	P=0.758N
COCH-ARM / FISHERS	P=0.490N	P=0.515	P=0.490N	P=0.742N
MAX-ISO-POLY-3	P=0.394N	P=0.300	P=0.156N	P=0.495N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Harderian Gland Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	30/49 (61%)	22/50 (44%)	17/49 (35%)	15/50 (30%)
POLY-3 RATE (b)	30/46.35	22/47.00	17/45.30	15/45.19
POLY-3 PERCENT (g)	64.7%	46.8%	37.5%	33.2%
TERMINAL (d)	23/35 (66%)	21/41 (51%)	14/38 (37%)	13/37 (35%)
FIRST INCIDENCE	598	640	541	666
STATISTICAL TESTS				
POLY 3	P=0.002N**	P=0.058N	P=0.006N**	P<0.001N**
POLY 1.5	P=0.002N**	P=0.059N	P=0.006N**	P<0.001N**
POLY 6	P=0.002N**	P=0.058N	P=0.006N**	P=0.002N**
COCH-ARM / FISHERS	P<0.001N**	P=0.065N	P=0.007N**	P=0.002N**
MAX-ISO-POLY-3	P=0.002N**	P=0.037N*	P=0.003N**	P<0.001N**

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 04/23/2009
Time Report Requested: 10:38:13
First Dose M/F: 04/15/03 / 04/14/03
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Harderian Gland: Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	3/49 (6%)	0/50 (0%)	0/49 (0%)	4/50 (8%)
POLY-3 RATE (b)	3/45.13	0/46.68	0/44.33	4/45.09
POLY-3 PERCENT (g)	6.7%	0%	0%	8.9%
TERMINAL (d)	3/35 (9%)	0/41 (0%)	0/38 (0%)	2/37 (5%)
FIRST INCIDENCE	729 (T)	---	---	676
STATISTICAL TESTS				
POLY 3	P=0.233	P=0.113N	P=0.122N	P=0.499
POLY 1.5	P=0.234	P=0.114N	P=0.122N	P=0.499
POLY 6	P=0.231	P=0.111N	P=0.121N	P=0.502
COCH-ARM / FISHERS	P=0.242	P=0.117N	P=0.121N	P=0.511
MAX-ISO-POLY-3	P=0.077	P=0.037N*	P=0.040N*	P=0.347

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 04/23/2009
Time Report Requested: 10:38:13
First Dose M/F: 04/15/03 / 04/14/03
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Heart				
Cardiomyopathy				
LESION RATES				
OVERALL (a)	1/49 (2%)	2/50 (4%)	1/50 (2%)	5/50 (10%)
POLY-3 RATE (b)	1/45.13	2/46.68	1/45.08	5/44.88
POLY-3 PERCENT (g)	2.2%	4.3%	2.2%	11.1%
TERMINAL (d)	1/35 (3%)	2/41 (5%)	1/38 (3%)	4/37 (11%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	703
STATISTICAL TESTS				
POLY 3	P=0.045*	P=0.512	P=0.760	P=0.100
POLY 1.5	P=0.045*	P=0.510	P=0.760N	P=0.101
POLY 6	P=0.044*	P=0.515	P=0.761N	P=0.099
COCH-ARM / FISHERS	P=0.049*	P=0.508	P=0.747N	P=0.107
MAX-ISO-POLY-3	P=0.040*	P=0.293	P=0.499	P=0.045*

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Heart				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.39	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	659	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.303N	P=0.494N	P=0.501N	P=0.503N
POLY 1.5	P=0.302N	P=0.495N	P=0.500N	P=0.502N
POLY 6	P=0.303N	P=0.493N	P=0.502N	P=0.504N
COCH-ARM / FISHERS	P=0.303N	P=0.495N	P=0.495N	P=0.495N
MAX-ISO-POLY-3	P=0.129N	P=0.157N	P=0.162N	P=0.163N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Heart Mineralization				
LESION RATES				
OVERALL (a)	2/49 (4%)	0/50 (0%)	2/50 (4%)	8/50 (16%)
POLY-3 RATE (b)	2/45.44	0/46.68	2/45.73	8/45.75
POLY-3 PERCENT (g)	4.4%	0%	4.4%	17.5%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	5/37 (14%)
FIRST INCIDENCE	666	---	544	566
STATISTICAL TESTS				
POLY 3	P=0.002**	P=0.231N	P=0.692N	P=0.046*
POLY 1.5	P=0.002**	P=0.232N	P=0.691N	P=0.046*
POLY 6	P=0.002**	P=0.230N	P=0.691N	P=0.047*
COCH-ARM / FISHERS	P=0.003**	P=0.242N	P=0.684N	P=0.049*
MAX-ISO-POLY-3	P=0.002**	P=0.075N	P=0.497N	P=0.022*

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Heart Necrosis				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	2/45.36
POLY-3 PERCENT (g)	0%	0%	0%	4.4%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	566
STATISTICAL TESTS				
POLY 3	P=0.045*	(e)	(e)	P=0.238
POLY 1.5	P=0.045*	(e)	(e)	P=0.238
POLY 6	P=0.045*	(e)	(e)	P=0.239
COCH-ARM / FISHERS	P=0.047*	(e)	(e)	P=0.253
MAX-ISO-POLY-3	P=0.033*	(e)	(e)	P=0.077

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Islets, Pancreatic Hyperplasia				
LESION RATES				
OVERALL (a)	5/49 (10%)	2/50 (4%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	5/45.23	2/46.68	3/45.67	1/44.98
POLY-3 PERCENT (g)	11.1%	4.3%	6.6%	2.2%
TERMINAL (d)	4/35 (11%)	2/41 (5%)	2/38 (5%)	0/37 (0%)
FIRST INCIDENCE	702	729 (T)	544	676
STATISTICAL TESTS				
POLY 3	P=0.097N	P=0.204N	P=0.351N	P=0.102N
POLY 1.5	P=0.097N	P=0.206N	P=0.351N	P=0.102N
POLY 6	P=0.098N	P=0.200N	P=0.348N	P=0.102N
COCH-ARM / FISHERS	P=0.091N	P=0.210N	P=0.346N	P=0.098N
MAX-ISO-POLY-3	P=0.063N	P=0.113N	P=0.227N	P=0.046N*

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney				
Accumulation, Hyaline Droplet				
LESION RATES				
OVERALL (a)	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/45.26	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	4.4%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	710	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.112N	P=0.230N	P=0.238N	P=0.239N
POLY 1.5	P=0.112N	P=0.231N	P=0.237N	P=0.239N
POLY 6	P=0.113N	P=0.229N	P=0.238N	P=0.240N
COCH-ARM / FISHERS	P=0.113N	P=0.242N	P=0.242N	P=0.242N
MAX-ISO-POLY-3	P=0.035N*	P=0.075N	P=0.078N	P=0.079N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney Cyst				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	2/46.06	0/44.78
POLY-3 PERCENT (g)	0%	0%	4.3%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	439	---
STATISTICAL TESTS				
POLY 3	P=0.581	(e)	P=0.242	(e)
POLY 1.5	P=0.583	(e)	P=0.241	(e)
POLY 6	P=0.577	(e)	P=0.244	(e)
COCH-ARM / FISHERS	P=0.598	(e)	P=0.253	(e)
MAX-ISO-POLY-3	P=0.258	(e)	P=0.079	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney				
Glomerulopathy Hyaline				
LESION RATES				
OVERALL (a)	0/49 (0%)	3/50 (6%)	15/50 (30%)	41/50 (82%)
POLY-3 RATE (b)	0/45.13	3/46.82	15/45.28	41/48.01
POLY-3 PERCENT (g)	0%	6.4%	33.1%	85.4%
TERMINAL (d)	0/35 (0%)	2/41 (5%)	14/38 (37%)	32/37 (87%)
FIRST INCIDENCE	---	694	677	404
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.125	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.124	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.128	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.125	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.043*	P<0.001**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney Infarct				
LESION RATES				
OVERALL (a)	3/49 (6%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/45.13	2/46.68	1/45.08	1/44.98
POLY-3 PERCENT (g)	6.7%	4.3%	2.2%	2.2%
TERMINAL (d)	3/35 (9%)	2/41 (5%)	1/38 (3%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	676
STATISTICAL TESTS				
POLY 3	P=0.202N	P=0.485N	P=0.306N	P=0.306N
POLY 1.5	P=0.201N	P=0.487N	P=0.304N	P=0.306N
POLY 6	P=0.202N	P=0.480N	P=0.305N	P=0.305N
COCH-ARM / FISHERS	P=0.194N	P=0.490N	P=0.301N	P=0.301N
MAX-ISO-POLY-3	P=0.226N	P=0.312N	P=0.156N	P=0.157N

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 04/23/2009
Time Report Requested: 10:38:13
First Dose M/F: 04/15/03 / 04/14/03
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney				
Metaplasia Osseous				
LESION RATES				
OVERALL (a)	1/49 (2%)	2/50 (4%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	1/45.13	2/46.99	2/45.08	4/44.98
POLY-3 PERCENT (g)	2.2%	4.3%	4.4%	8.9%
TERMINAL (d)	1/35 (3%)	1/41 (2%)	2/38 (5%)	3/37 (8%)
FIRST INCIDENCE	729 (T)	645	729 (T)	676
STATISTICAL TESTS				
POLY 3	P=0.109	P=0.514	P=0.500	P=0.178
POLY 1.5	P=0.110	P=0.511	P=0.501	P=0.178
POLY 6	P=0.108	P=0.519	P=0.500	P=0.178
COCH-ARM / FISHERS	P=0.116	P=0.508	P=0.508	P=0.187
MAX-ISO-POLY-3	P=0.117	P=0.295	P=0.281	P=0.084

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney Mineralization				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	3/50 (6%)	20/50 (40%)
POLY-3 RATE (b)	1/45.13	0/46.68	3/45.08	20/45.94
POLY-3 PERCENT (g)	2.2%	0%	6.7%	43.5%
TERMINAL (d)	1/35 (3%)	0/41 (0%)	3/38 (8%)	17/37 (46%)
FIRST INCIDENCE	729 (T)	---	729 (T)	589
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.493N	P=0.305	P<0.001**
POLY 1.5	P<0.001**	P=0.494N	P=0.306	P<0.001**
POLY 6	P<0.001**	P=0.491N	P=0.305	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.495N	P=0.316	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.157N	P=0.155	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney				
Nephropathy				
LESION RATES				
OVERALL (a)	13/49 (27%)	19/50 (38%)	12/50 (24%)	25/50 (50%)
POLY-3 RATE (b)	13/45.99	19/46.82	12/45.25	25/45.26
POLY-3 PERCENT (g)	28.3%	40.6%	26.5%	55.2%
TERMINAL (d)	10/35 (29%)	18/41 (44%)	10/38 (26%)	22/37 (60%)
FIRST INCIDENCE	500	694	701	676
STATISTICAL TESTS				
POLY 3	P=0.010**	P=0.150	P=0.519N	P=0.006**
POLY 1.5	P=0.011*	P=0.152	P=0.507N	P=0.007**
POLY 6	P=0.008**	P=0.150	P=0.524N	P=0.005**
COCH-ARM / FISHERS	P=0.019*	P=0.157	P=0.477N	P=0.014*
MAX-ISO-POLY-3	P=0.005**	P=0.105	P=0.425N	P=0.003**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney Pigmentation				
LESION RATES				
OVERALL (a)	1/49 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.80	1/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	2.2%	2.1%	0%	0%
TERMINAL (d)	0/35 (0%)	1/41 (2%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	500	729 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.237N	P=0.756N	P=0.503N	P=0.505N
POLY 1.5	P=0.236N	P=0.756N	P=0.501N	P=0.503N
POLY 6	P=0.238N	P=0.755N	P=0.504N	P=0.506N
COCH-ARM / FISHERS	P=0.233N	P=0.747N	P=0.495N	P=0.495N
MAX-ISO-POLY-3	P=0.265N	P=0.494N	P=0.164N	P=0.165N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney				
Vacuolization Cytoplasmic				
LESION RATES				
OVERALL (a)	0/49 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	1/46.77	2/45.67	0/44.78
POLY-3 PERCENT (g)	0%	2.1%	4.4%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	1/38 (3%)	0/37 (0%)
FIRST INCIDENCE	---	706	544	---
STATISTICAL TESTS				
POLY 3	P=0.624N	P=0.507	P=0.240	(e)
POLY 1.5	P=0.623N	P=0.506	P=0.240	(e)
POLY 6	P=0.626N	P=0.510	P=0.241	(e)
COCH-ARM / FISHERS	P=0.612N	P=0.505	P=0.253	(e)
MAX-ISO-POLY-3	P=0.337	P=0.166	P=0.077	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney: Glomerulus Congestion				
LESION RATES				
OVERALL (a)	5/49 (10%)	2/50 (4%)	12/50 (24%)	37/50 (74%)
POLY-3 RATE (b)	5/45.23	2/47.05	12/45.98	37/45.97
POLY-3 PERCENT (g)	11.1%	4.3%	26.1%	80.5%
TERMINAL (d)	4/35 (11%)	1/41 (2%)	10/38 (26%)	32/37 (87%)
FIRST INCIDENCE	702	624	544	589
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.201N	P=0.055	P<0.001**
POLY 1.5	P<0.001**	P=0.204N	P=0.055	P<0.001**
POLY 6	P<0.001**	P=0.195N	P=0.057	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.210N	P=0.059	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.112N	P=0.031*	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Kidney: Papilla Necrosis				
LESION RATES				
OVERALL (a)	3/49 (6%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/45.24	1/46.92	1/45.08	0/44.78
POLY-3 PERCENT (g)	6.6%	2.1%	2.2%	0%
TERMINAL (d)	1/35 (3%)	0/41 (0%)	1/38 (3%)	0/37 (0%)
FIRST INCIDENCE	715	666	729 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.074N	P=0.292N	P=0.306N	P=0.120N
POLY 1.5	P=0.073N	P=0.295N	P=0.305N	P=0.120N
POLY 6	P=0.075N	P=0.288N	P=0.307N	P=0.121N
COCH-ARM / FISHERS	P=0.071N	P=0.301N	P=0.301N	P=0.117N
MAX-ISO-POLY-3	P=0.044N*	P=0.148N	P=0.157N	P=0.040N*

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 04/23/2009
Time Report Requested: 10:38:13
First Dose M/F: 04/15/03 / 04/14/03
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

Kidney: Pelvis
Inflammation

LESION RATES

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Angiectasis				
LESION RATES				
OVERALL (a)	0/49 (0%)	1/50 (2%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	0/45.13	1/46.68	3/45.19	1/44.78
POLY-3 PERCENT (g)	0%	2.1%	6.6%	2.2%
TERMINAL (d)	0/35 (0%)	1/41 (2%)	2/38 (5%)	1/37 (3%)
FIRST INCIDENCE	---	729 (T)	701	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.338	P=0.507	P=0.119	P=0.498
POLY 1.5	P=0.340	P=0.506	P=0.120	P=0.499
POLY 6	P=0.336	P=0.509	P=0.119	P=0.498
COCH-ARM / FISHERS	P=0.356	P=0.505	P=0.125	P=0.505
MAX-ISO-POLY-3	P=0.160	P=0.166	P=0.039*	P=0.160

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Basophilic Focus				
LESION RATES				
OVERALL (a)	1/49 (2%)	3/50 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.13	3/46.68	0/45.08	1/44.78
POLY-3 PERCENT (g)	2.2%	6.4%	0%	2.2%
TERMINAL (d)	1/35 (3%)	3/41 (7%)	0/38 (0%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.411N	P=0.318	P=0.500N	P=0.759
POLY 1.5	P=0.411N	P=0.315	P=0.499N	P=0.759
POLY 6	P=0.411N	P=0.321	P=0.500N	P=0.759
COCH-ARM / FISHERS	P=0.404N	P=0.316	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.284N	P=0.166	P=0.160N	P=0.497

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Clear Cell Focus				
LESION RATES				
OVERALL (a)	0/49 (0%)	6/50 (12%)	23/50 (46%)	32/50 (64%)
POLY-3 RATE (b)	0/45.13	6/46.68	23/45.19	32/44.78
POLY-3 PERCENT (g)	0%	12.9%	50.9%	71.5%
TERMINAL (d)	0/35 (0%)	6/41 (15%)	22/38 (58%)	32/37 (87%)
FIRST INCIDENCE	---	729 (T)	701	729 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.017*	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.017*	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.018*	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.014*	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.006**	P<0.001**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Eosinophilic Focus				
LESION RATES				
OVERALL (a)	3/49 (6%)	7/50 (14%)	10/50 (20%)	31/50 (62%)
POLY-3 RATE (b)	3/45.13	7/46.68	10/45.08	31/45.48
POLY-3 PERCENT (g)	6.7%	15%	22.2%	68.2%
TERMINAL (d)	3/35 (9%)	7/41 (17%)	10/38 (26%)	29/37 (78%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	591
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.171	P=0.034*	P<0.001**
POLY 1.5	P<0.001**	P=0.169	P=0.035*	P<0.001**
POLY 6	P<0.001**	P=0.175	P=0.033*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.167	P=0.039*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.102	P=0.017*	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Fatty Change Diffuse				
LESION RATES				
OVERALL (a)	36/49 (73%)	31/50 (62%)	34/50 (68%)	3/50 (6%)
POLY-3 RATE (b)	36/47.48	31/47.79	34/47.42	3/45.97
POLY-3 PERCENT (g)	75.8%	64.9%	71.7%	6.5%
TERMINAL (d)	30/35 (86%)	27/41 (66%)	28/38 (74%)	0/37 (0%)
FIRST INCIDENCE	450	575	439	566
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.166N	P=0.409N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.166N	P=0.400N	P<0.001N**
POLY 6	P<0.001N**	P=0.154N	P=0.400N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.157N	P=0.353N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.115N	P=0.320N	P<0.001N**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Fatty Change Focal				
LESION RATES				
OVERALL (a)	1/49 (2%)	2/50 (4%)	20/50 (40%)	12/50 (24%)
POLY-3 RATE (b)	1/45.39	2/46.68	20/45.89	12/45.25
POLY-3 PERCENT (g)	2.2%	4.3%	43.6%	26.5%
TERMINAL (d)	0/35 (0%)	2/41 (5%)	18/38 (47%)	11/37 (30%)
FIRST INCIDENCE	659	729 (T)	584	589
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.510	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.509	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.512	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.508	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.291	P<0.001**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver Fibrosis				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	2/45.36
POLY-3 PERCENT (g)	0%	0%	0%	4.4%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	566
STATISTICAL TESTS				
POLY 3	P=0.045*	(e)	(e)	P=0.238
POLY 1.5	P=0.045*	(e)	(e)	P=0.238
POLY 6	P=0.045*	(e)	(e)	P=0.239
COCH-ARM / FISHERS	P=0.047*	(e)	(e)	P=0.253
MAX-ISO-POLY-3	P=0.033*	(e)	(e)	P=0.077

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.18	0/46.68	0/45.08	1/45.25
POLY-3 PERCENT (g)	2.2%	0%	0%	2.2%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	715	---	---	591
STATISTICAL TESTS				
POLY 3	P=0.593	P=0.494N	P=0.500N	P=0.760N
POLY 1.5	P=0.593	P=0.495N	P=0.500N	P=0.760N
POLY 6	P=0.592	P=0.492N	P=0.500N	P=0.760N
COCH-ARM / FISHERS	P=0.598	P=0.495N	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.405N	P=0.157N	P=0.160N	P=0.499N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver Inflammation				
LESION RATES				
OVERALL (a)	40/49 (82%)	40/50 (80%)	14/50 (28%)	31/50 (62%)
POLY-3 RATE (b)	40/48.08	40/48.10	14/46.27	31/46.37
POLY-3 PERCENT (g)	83.2%	83.2%	30.3%	66.9%
TERMINAL (d)	32/35 (91%)	36/41 (88%)	12/38 (32%)	26/37 (70%)
FIRST INCIDENCE	450	513	268	589
STATISTICAL TESTS				
POLY 3	P=0.003N**	P=0.610N	P<0.001N**	P=0.048N*
POLY 1.5	P=0.003N**	P=0.575N	P<0.001N**	P=0.043N*
POLY 6	P=0.003N**	P=0.598	P<0.001N**	P=0.051N
COCH-ARM / FISHERS	P=0.004N**	P=0.520N	P<0.001N**	P=0.025N*
MAX-ISO-POLY-3	P<0.001N**	P=0.498N	P<0.001N**	P=0.031N*

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Mixed Cell Focus				
LESION RATES				
OVERALL (a)	4/49 (8%)	8/50 (16%)	16/50 (32%)	20/50 (40%)
POLY-3 RATE (b)	4/45.13	8/46.77	16/45.08	20/45.16
POLY-3 PERCENT (g)	8.9%	17.1%	35.5%	44.3%
TERMINAL (d)	4/35 (11%)	7/41 (17%)	16/38 (42%)	18/37 (49%)
FIRST INCIDENCE	729 (T)	706	729 (T)	676
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.194	P=0.002**	P<0.001**
POLY 1.5	P<0.001**	P=0.191	P=0.002**	P<0.001**
POLY 6	P<0.001**	P=0.200	P=0.002**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.188	P=0.003**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.124	P<0.001**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Necrosis				
LESION RATES				
OVERALL (a)	5/49 (10%)	2/50 (4%)	4/50 (8%)	27/50 (54%)
POLY-3 RATE (b)	5/45.94	2/47.01	4/46.04	27/46.32
POLY-3 PERCENT (g)	10.9%	4.3%	8.7%	58.3%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	1/38 (3%)	21/37 (57%)
FIRST INCIDENCE	659	666	439	589
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.207N	P=0.499N	P<0.001**
POLY 1.5	P<0.001**	P=0.208N	P=0.496N	P<0.001**
POLY 6	P<0.001**	P=0.206N	P=0.502N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.210N	P=0.487N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.114N	P=0.362N	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Pigmentation				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	46/50 (92%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	46/47.19
POLY-3 PERCENT (g)	0%	0%	0%	97.5%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	37/37 (100%)
FIRST INCIDENCE	---	---	---	589
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	(e)	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	P<0.001**
POLY 6	P<0.001**	(e)	(e)	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver				
Tension Lipidosis				
LESION RATES				
OVERALL (a)	5/49 (10%)	5/50 (10%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	5/45.58	5/46.77	4/46.03	0/44.78
POLY-3 PERCENT (g)	11%	10.7%	8.7%	0%
TERMINAL (d)	4/35 (11%)	4/41 (10%)	3/38 (8%)	0/37 (0%)
FIRST INCIDENCE	598	706	268	---
STATISTICAL TESTS				
POLY 3	P=0.026N*	P=0.614N	P=0.494N	P=0.032N*
POLY 1.5	P=0.025N*	P=0.615N	P=0.491N	P=0.031N*
POLY 6	P=0.027N*	P=0.610N	P=0.496N	P=0.032N*
COCH-ARM / FISHERS	P=0.023N*	P=0.617N	P=0.487N	P=0.027N*
MAX-ISO-POLY-3	P=0.040N*	P=0.482N	P=0.357N	P=0.011N*

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver: Bile Duct Cyst				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	4/50 (8%)	38/50 (76%)
POLY-3 RATE (b)	0/45.13	0/46.68	4/45.28	38/45.17
POLY-3 PERCENT (g)	0%	0%	8.8%	84.1%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	3/38 (8%)	35/37 (95%)
FIRST INCIDENCE	---	---	677	666
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.061	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.061	P<0.001**
POLY 6	P<0.001**	(e)	P=0.061	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.061	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.020*	P<0.001**

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

Liver: Bile Duct
Fibrosis

LESION RATES

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver: Bile Duct Hyperplasia				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	47/50 (94%)
POLY-3 RATE (b)	0/45.13	0/46.68	2/45.19	47/47.70
POLY-3 PERCENT (g)	0%	0%	4.4%	98.5%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	1/38 (3%)	37/37 (100%)
FIRST INCIDENCE	---	---	701	566
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.237	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.238	P<0.001**
POLY 6	P<0.001**	(e)	P=0.238	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.253	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.077	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver: Hepatocyte, Centrilobular Hypertrophy				
LESION RATES				
OVERALL (a)	0/49 (0%)	4/50 (8%)	12/50 (24%)	29/50 (58%)
POLY-3 RATE (b)	0/45.13	4/46.68	12/45.33	29/47.02
POLY-3 PERCENT (g)	0%	8.6%	26.5%	61.7%
TERMINAL (d)	0/35 (0%)	4/41 (10%)	11/38 (29%)	24/37 (65%)
FIRST INCIDENCE	---	729 (T)	662	404
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.065	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.064	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.066	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.061	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.022*	P<0.001**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

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 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver: Oval Cell Hyperplasia				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	3/50 (6%)	46/50 (92%)
POLY-3 RATE (b)	0/45.13	0/46.68	3/45.19	46/47.23
POLY-3 PERCENT (g)	0%	0%	6.6%	97.4%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	2/38 (5%)	37/37 (100%)
FIRST INCIDENCE	---	---	701	566
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.119	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.120	P<0.001**
POLY 6	P<0.001**	(e)	P=0.119	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.125	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.039*	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Liver: Vein				
Intravascular Hepatocyte				
LESION RATES				
OVERALL (a)	0/49 (0%)	2/50 (4%)	20/50 (40%)	46/50 (92%)
POLY-3 RATE (b)	0/45.13	2/46.68	20/45.46	46/47.42
POLY-3 PERCENT (g)	0%	4.3%	44%	97%
TERMINAL (d)	0/35 (0%)	2/41 (5%)	18/38 (47%)	37/37 (100%)
FIRST INCIDENCE	---	729 (T)	642	589
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.245	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.244	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.247	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.253	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.082	P<0.001**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lung Inflammation				
LESION RATES				
OVERALL (a)	2/49 (4%)	4/50 (8%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/45.58	4/46.68	2/45.51	0/44.78
POLY-3 PERCENT (g)	4.4%	8.6%	4.4%	0%
TERMINAL (d)	1/35 (3%)	4/41 (10%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	598	729 (T)	642	---
STATISTICAL TESTS				
POLY 3	P=0.117N	P=0.348	P=0.693	P=0.241N
POLY 1.5	P=0.115N	P=0.348	P=0.693N	P=0.240N
POLY 6	P=0.118N	P=0.350	P=0.694N	P=0.243N
COCH-ARM / FISHERS	P=0.108N	P=0.349	P=0.684N	P=0.242N
MAX-ISO-POLY-3	P=0.107N	P=0.211	P=0.499	P=0.081N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lung: Alveolar Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	1/49 (2%)	3/50 (6%)	2/50 (4%)	7/50 (14%)
POLY-3 RATE (b)	1/45.20	3/46.68	2/45.40	7/44.78
POLY-3 PERCENT (g)	2.2%	6.4%	4.4%	15.6%
TERMINAL (d)	0/35 (0%)	3/41 (7%)	1/38 (3%)	7/37 (19%)
FIRST INCIDENCE	710	729 (T)	642	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.013*	P=0.317	P=0.502	P=0.029*
POLY 1.5	P=0.013*	P=0.315	P=0.502	P=0.029*
POLY 6	P=0.012*	P=0.320	P=0.503	P=0.028*
COCH-ARM / FISHERS	P=0.015*	P=0.316	P=0.508	P=0.032*
MAX-ISO-POLY-3	P=0.010**	P=0.165	P=0.282	P=0.012*

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lung: Alveolus Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lung: Cervix Inflammation				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lymph Node, Mandibular Atrophy				
LESION RATES				
OVERALL (a)	0/49 (0%)	1/50 (2%)	0/49 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.13	1/46.77	0/44.33	2/46.06
POLY-3 PERCENT (g)	0%	2.1%	0%	4.3%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	706	---	404
STATISTICAL TESTS				
POLY 3	P=0.141	P=0.507	(e)	P=0.242
POLY 1.5	P=0.141	P=0.506	(e)	P=0.240
POLY 6	P=0.142	P=0.510	(e)	P=0.244
COCH-ARM / FISHERS	P=0.142	P=0.505	(e)	P=0.253
MAX-ISO-POLY-3	P=0.082	P=0.166	(e)	P=0.079

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lymph Node, Mandibular Hyperplasia				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/44.33	0/44.78
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lymph Node, Mandibular Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	2/49 (4%)	0/50 (0%)	1/49 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/45.13	0/46.68	1/44.33	2/45.36
POLY-3 PERCENT (g)	4.4%	0%	2.3%	4.4%
TERMINAL (d)	2/35 (6%)	0/41 (0%)	1/38 (3%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	589
STATISTICAL TESTS				
POLY 3	P=0.466	P=0.230N	P=0.506N	P=0.692N
POLY 1.5	P=0.467	P=0.231N	P=0.505N	P=0.693N
POLY 6	P=0.466	P=0.227N	P=0.504N	P=0.690N
COCH-ARM / FISHERS	P=0.474	P=0.242N	P=0.500N	P=0.684N
MAX-ISO-POLY-3	P=0.419N	P=0.075N	P=0.287N	P=0.497N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Lymph Node, Mesenteric Atrophy				
LESION RATES				
OVERALL (a)	0/47 (0%)	0/49 (0%)	2/50 (4%)	1/49 (2%)
POLY-3 RATE (b)	0/43.31	0/45.68	2/45.28	1/45.06
POLY-3 PERCENT (g)	0%	0%	4.4%	2.2%
TERMINAL (d)	0/34 (0%)	0/40 (0%)	1/38 (3%)	0/37 (0%)
FIRST INCIDENCE	---	---	677	596
STATISTICAL TESTS				
POLY 3	P=0.250	(e)	P=0.247	P=0.508
POLY 1.5	P=0.248	(e)	P=0.248	P=0.507
POLY 6	P=0.251	(e)	P=0.248	P=0.509
COCH-ARM / FISHERS	P=0.252	(e)	P=0.263	P=0.510
MAX-ISO-POLY-3	P=0.181	(e)	P=0.082	P=0.166

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Mesentery Necrosis				
LESION RATES				
OVERALL (a)	2/6 (33%)	0/12 (0%)	0/11 (0%)	0/2 (0%)
POLY-3 RATE (b)	2/5.79	0/10.81	0/9.73	0/2.00
POLY-3 PERCENT (g)	34.5%	0%	0%	0%
TERMINAL (d)	2/4 (50%)	0/8 (0%)	0/7 (0%)	0/2 (0%)
FIRST INCIDENCE	729 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.096N	P=0.082N	P=0.099N	P=0.491N
POLY 1.5	P=0.091N	P=0.079N	P=0.095N	P=0.495N
POLY 6	P=0.102N	P=0.084N	P=0.102N	P=0.482N
COCH-ARM / FISHERS	P=0.106N	P=0.098N	P=0.110N	P=0.536N
MAX-ISO-POLY-3	P=0.093N	P=0.023N*	P=0.026N*	P=0.229N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Mesentery: Fat Necrosis				
LESION RATES				
OVERALL (a)	4/6 (67%)	11/12 (92%)	10/11 (91%)	1/2 (50%)
POLY-3 RATE (b)	4/6.00	11/11.35	10/10.22	1/2.00
POLY-3 PERCENT (g)	66.7%	96.9%	97.9%	50%
TERMINAL (d)	2/4 (50%)	8/8 (100%)	7/7 (100%)	1/2 (50%)
FIRST INCIDENCE	695	645	642	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.745N	P=0.131	P=0.132	P=0.644N
POLY 1.5	P=0.713N	P=0.174	P=0.176	P=0.644N
POLY 6	P=0.758	P=0.099	P=0.108	P=0.644N
COCH-ARM / FISHERS	P=0.647N	P=0.245	P=0.272	P=0.643N
MAX-ISO-POLY-3	P=0.112N	P=0.043*	P=0.040*	P=0.380N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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 Pulegone
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 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Nose Inflammation				
LESION RATES				
OVERALL (a)	2/49 (4%)	1/50 (2%)	4/50 (8%)	27/50 (54%)
POLY-3 RATE (b)	2/45.37	1/46.68	4/45.32	27/46.13
POLY-3 PERCENT (g)	4.4%	2.1%	8.8%	58.5%
TERMINAL (d)	1/35 (3%)	1/41 (2%)	3/38 (8%)	21/37 (57%)
FIRST INCIDENCE	666	729 (T)	667	566
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.490N	P=0.337	P<0.001**
POLY 1.5	P<0.001**	P=0.491N	P=0.339	P<0.001**
POLY 6	P<0.001**	P=0.488N	P=0.337	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.492N	P=0.349	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.274N	P=0.202	P<0.001**

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<hr/>				
Nose				
Polyp, Inflammatory				
<hr/>				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Nose: Nerve Atrophy				
LESION RATES				
OVERALL (a)	0/49 (0%)	1/50 (2%)	2/50 (4%)	49/50 (98%)
POLY-3 RATE (b)	0/45.13	1/47.37	2/45.08	49/49.00
POLY-3 PERCENT (g)	0%	2.1%	4.4%	100%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	2/38 (5%)	37/37 (100%)
FIRST INCIDENCE	---	493	729 (T)	404
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.510	P=0.237	P<0.001**
POLY 1.5	P<0.001**	P=0.507	P=0.238	P<0.001**
POLY 6	P<0.001**	P=0.513	P=0.237	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.505	P=0.253	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.169	P=0.077	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Nose: Olfactory Epithelium Degeneration				
LESION RATES				
OVERALL (a)	0/49 (0%)	5/50 (10%)	22/50 (44%)	48/50 (96%)
POLY-3 RATE (b)	0/45.13	5/47.51	22/45.81	48/48.17
POLY-3 PERCENT (g)	0%	10.5%	48%	99.7%
TERMINAL (d)	0/35 (0%)	3/41 (7%)	19/38 (50%)	37/37 (100%)
FIRST INCIDENCE	---	493	631	566
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.035*	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.034*	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.037*	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.030*	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.013*	P<0.001**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Nose: Olfactory Epithelium Metaplasia				
LESION RATES				
OVERALL (a)	1/49 (2%)	2/50 (4%)	4/50 (8%)	49/50 (98%)
POLY-3 RATE (b)	1/45.13	2/46.68	4/45.08	49/49.00
POLY-3 PERCENT (g)	2.2%	4.3%	8.9%	100%
TERMINAL (d)	1/35 (3%)	2/41 (5%)	4/38 (11%)	37/37 (100%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	404
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.512	P=0.178	P<0.001**
POLY 1.5	P<0.001**	P=0.510	P=0.180	P<0.001**
POLY 6	P<0.001**	P=0.515	P=0.178	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.508	P=0.187	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.293	P=0.085	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Nose: Respiratory Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Ovary Atrophy				
LESION RATES				
OVERALL (a)	11/49 (22%)	10/49 (20%)	24/50 (48%)	39/50 (78%)
POLY-3 RATE (b)	11/47.64	10/45.91	24/46.32	39/46.23
POLY-3 PERCENT (g)	23.1%	21.8%	51.8%	84.4%
TERMINAL (d)	1/35 (3%)	8/40 (20%)	21/38 (55%)	33/37 (89%)
FIRST INCIDENCE	450	694	541	591
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.538N	P=0.003**	P<0.001**
POLY 1.5	P<0.001**	P=0.522N	P=0.004**	P<0.001**
POLY 6	P<0.001**	P=0.559N	P=0.002**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500N	P=0.007**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.440N	P=0.002**	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Ovary Cyst				
LESION RATES				
OVERALL (a)	6/49 (12%)	7/49 (14%)	9/50 (18%)	7/50 (14%)
POLY-3 RATE (b)	6/45.99	7/46.56	9/45.28	7/45.47
POLY-3 PERCENT (g)	13.1%	15%	19.9%	15.4%
TERMINAL (d)	3/35 (9%)	5/40 (13%)	8/38 (21%)	5/37 (14%)
FIRST INCIDENCE	500	575	677	591
STATISTICAL TESTS				
POLY 3	P=0.414	P=0.509	P=0.275	P=0.491
POLY 1.5	P=0.421	P=0.505	P=0.283	P=0.494
POLY 6	P=0.409	P=0.518	P=0.271	P=0.490
COCH-ARM / FISHERS	P=0.452	P=0.500	P=0.303	P=0.516
MAX-ISO-POLY-3	P=0.446	P=0.391	P=0.193	P=0.374

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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 CAS Number: 89-82-7

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Pancreas				
Cytoplasmic Alteration Focal				
LESION RATES				
OVERALL (a)	1/49 (2%)	2/50 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/45.13	2/46.68	0/45.08	2/44.78
POLY-3 PERCENT (g)	2.2%	4.3%	0%	4.5%
TERMINAL (d)	1/35 (3%)	2/41 (5%)	0/38 (0%)	2/37 (5%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.465	P=0.512	P=0.500N	P=0.497
POLY 1.5	P=0.466	P=0.510	P=0.499N	P=0.498
POLY 6	P=0.464	P=0.515	P=0.500N	P=0.497
COCH-ARM / FISHERS	P=0.475	P=0.508	P=0.495N	P=0.508
MAX-ISO-POLY-3	P=0.416	P=0.293	P=0.160N	P=0.280

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Pancreas				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	12/49 (24%)	16/50 (32%)	15/50 (30%)	11/50 (22%)
POLY-3 RATE (b)	12/45.80	16/47.47	15/45.19	11/45.63
POLY-3 PERCENT (g)	26.2%	33.7%	33.2%	24.1%
TERMINAL (d)	11/35 (31%)	14/41 (34%)	14/38 (37%)	8/37 (22%)
FIRST INCIDENCE	500	513	701	589
STATISTICAL TESTS				
POLY 3	P=0.373N	P=0.286	P=0.308	P=0.504N
POLY 1.5	P=0.371N	P=0.280	P=0.319	P=0.505N
POLY 6	P=0.369N	P=0.298	P=0.304	P=0.497N
COCH-ARM / FISHERS	P=0.334N	P=0.272	P=0.349	P=0.478N
MAX-ISO-POLY-3	P=0.379N	P=0.218	P=0.235	P=0.408N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Pituitary Gland				
Angiectasis				
LESION RATES				
OVERALL (a)	3/49 (6%)	3/50 (6%)	1/49 (2%)	2/49 (4%)
POLY-3 RATE (b)	3/45.13	3/46.68	1/44.33	2/43.78
POLY-3 PERCENT (g)	6.7%	6.4%	2.3%	4.6%
TERMINAL (d)	3/35 (9%)	3/41 (7%)	1/38 (3%)	2/36 (6%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.358N	P=0.647N	P=0.312N	P=0.514N
POLY 1.5	P=0.357N	P=0.649N	P=0.311N	P=0.512N
POLY 6	P=0.360N	P=0.642N	P=0.310N	P=0.515N
COCH-ARM / FISHERS	P=0.346N	P=0.651N	P=0.309N	P=0.500N
MAX-ISO-POLY-3	P=0.399N	P=0.482N	P=0.161N	P=0.338N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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 Pulegone
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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Pituitary Gland: Pars Distalis Cyst				
LESION RATES				
OVERALL (a)	0/49 (0%)	2/50 (4%)	0/49 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/45.13	2/46.68	0/44.33	0/43.78
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/35 (0%)	2/41 (5%)	0/38 (0%)	0/36 (0%)
FIRST INCIDENCE	---	729 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.410N	P=0.245	(e)	(e)
POLY 1.5	P=0.410N	P=0.244	(e)	(e)
POLY 6	P=0.409N	P=0.247	(e)	(e)
COCH-ARM / FISHERS	P=0.406N	P=0.253	(e)	(e)
MAX-ISO-POLY-3	P=0.269N	P=0.082	(e)	(e)

TDMS No. 99020 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

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Pulegone
CAS Number: 89-82-7

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Pituitary Gland: Pars Distalis Hyperplasia				
LESION RATES				
OVERALL (a)	7/49 (14%)	4/50 (8%)	5/49 (10%)	4/49 (8%)
POLY-3 RATE (b)	7/45.13	4/46.92	5/44.33	4/43.78
POLY-3 PERCENT (g)	15.5%	8.5%	11.3%	9.1%
TERMINAL (d)	7/35 (20%)	3/41 (7%)	5/38 (13%)	4/36 (11%)
FIRST INCIDENCE	729 (T)	666	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.287N	P=0.239N	P=0.391N	P=0.278N
POLY 1.5	P=0.284N	P=0.244N	P=0.390N	P=0.277N
POLY 6	P=0.292N	P=0.230N	P=0.387N	P=0.279N
COCH-ARM / FISHERS	P=0.265N	P=0.251N	P=0.380N	P=0.262N
MAX-ISO-POLY-3	P=0.282N	P=0.155N	P=0.282N	P=0.185N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Salivary Glands				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	39/49 (80%)	29/50 (58%)	28/49 (57%)	26/50 (52%)
POLY-3 RATE (b)	39/48.74	29/48.23	28/46.29	26/45.90
POLY-3 PERCENT (g)	80%	60.1%	60.5%	56.7%
TERMINAL (d)	28/35 (80%)	24/41 (59%)	24/38 (63%)	23/37 (62%)
FIRST INCIDENCE	450	493	268	589
STATISTICAL TESTS				
POLY 3	P=0.019N*	P=0.024N*	P=0.027N*	P=0.010N**
POLY 1.5	P=0.015N*	P=0.021N*	P=0.021N*	P=0.007N**
POLY 6	P=0.027N*	P=0.029N*	P=0.037N*	P=0.016N*
COCH-ARM / FISHERS	P=0.008N**	P=0.017N*	P=0.014N*	P=0.003N**
MAX-ISO-POLY-3	P=0.014N*	P=0.015N*	P=0.018N*	P=0.007N**

TDMS No. 99020 - 06
 Test Type: CHRONIC
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 Species/Strain: MICE/B6C3F1

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Skin Inflammation				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Skin				
Ulcer				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Spleen				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	24/49 (49%)	29/50 (58%)	25/50 (50%)	40/50 (80%)
POLY-3 RATE (b)	24/46.66	29/47.38	25/46.57	40/46.75
POLY-3 PERCENT (g)	51.4%	61.2%	53.7%	85.6%
TERMINAL (d)	18/35 (51%)	26/41 (63%)	22/38 (58%)	33/37 (89%)
FIRST INCIDENCE	500	640	439	589
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.225	P=0.496	P<0.001**
POLY 1.5	P<0.001**	P=0.231	P=0.509	P<0.001**
POLY 6	P<0.001**	P=0.222	P=0.480	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.243	P=0.540	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.168	P=0.412	P<0.001**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Spleen				
Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	6/49 (12%)	3/50 (6%)	9/50 (18%)	3/50 (6%)
POLY-3 RATE (b)	6/45.13	3/46.68	9/45.57	3/44.78
POLY-3 PERCENT (g)	13.3%	6.4%	19.8%	6.7%
TERMINAL (d)	6/35 (17%)	3/41 (7%)	8/38 (21%)	3/37 (8%)
FIRST INCIDENCE	729 (T)	729 (T)	584	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.349N	P=0.225N	P=0.293	P=0.245N
POLY 1.5	P=0.345N	P=0.229N	P=0.294	P=0.245N
POLY 6	P=0.353N	P=0.220N	P=0.298	P=0.245N
COCH-ARM / FISHERS	P=0.323N	P=0.233N	P=0.303	P=0.233N
MAX-ISO-POLY-3	P=0.266N	P=0.137N	P=0.205	P=0.151N

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Spleen Pigmentation				
LESION RATES				
OVERALL (a)	0/49 (0%)	1/50 (2%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	0/45.13	1/46.82	3/45.40	2/45.61
POLY-3 PERCENT (g)	0%	2.1%	6.6%	4.4%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	2/38 (5%)	1/37 (3%)
FIRST INCIDENCE	---	694	642	404
STATISTICAL TESTS				
POLY 3	P=0.162	P=0.507	P=0.120	P=0.239
POLY 1.5	P=0.161	P=0.506	P=0.120	P=0.239
POLY 6	P=0.161	P=0.510	P=0.121	P=0.240
COCH-ARM / FISHERS	P=0.167	P=0.505	P=0.125	P=0.253
MAX-ISO-POLY-3	P=0.112	P=0.167	P=0.039*	P=0.077

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Spleen: Lymphoid Follicle Atrophy				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	1/45.61
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	404
STATISTICAL TESTS				
POLY 3	P=0.198	(e)	(e)	P=0.502
POLY 1.5	P=0.198	(e)	(e)	P=0.501
POLY 6	P=0.198	(e)	(e)	P=0.503
COCH-ARM / FISHERS	P=0.200	(e)	(e)	P=0.505
MAX-ISO-POLY-3	P=0.125	(e)	(e)	P=0.160

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Spleen: Red Pulp Atrophy				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.89	0/46.68	0/45.08	1/45.61
POLY-3 PERCENT (g)	2.2%	0%	0%	2.2%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	450	---	---	404
STATISTICAL TESTS				
POLY 3	P=0.593	P=0.497N	P=0.504N	P=0.759
POLY 1.5	P=0.594	P=0.497N	P=0.502N	P=0.760
POLY 6	P=0.592	P=0.495N	P=0.504N	P=0.759
COCH-ARM / FISHERS	P=0.598	P=0.495N	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.407	P=0.157N	P=0.164N	P=0.497

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
 Time Report Requested: 10:38:13
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Stomach, Forestomach Hyperplasia				
LESION RATES				
OVERALL (a)	13/49 (27%)	1/50 (2%)	10/50 (20%)	26/50 (52%)
POLY-3 RATE (b)	13/47.47	1/46.68	10/46.21	26/47.10
POLY-3 PERCENT (g)	27.4%	2.1%	21.6%	55.2%
TERMINAL (d)	5/35 (14%)	1/41 (2%)	7/38 (18%)	20/37 (54%)
FIRST INCIDENCE	450	729 (T)	544	404
STATISTICAL TESTS				
POLY 3	P<0.001**	P<0.001N**	P=0.343N	P=0.004**
POLY 1.5	P<0.001**	P<0.001N**	P=0.329N	P=0.005**
POLY 6	P<0.001**	P<0.001N**	P=0.357N	P=0.004**
COCH-ARM / FISHERS	P<0.001**	P<0.001N**	P=0.298N	P=0.008**
MAX-ISO-POLY-3	P<0.001**	P<0.001N**	P=0.264N	P=0.002**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Stomach, Forestomach Inflammation				
LESION RATES				
OVERALL (a)	10/49 (20%)	0/50 (0%)	7/50 (14%)	20/50 (40%)
POLY-3 RATE (b)	10/46.97	0/46.68	7/46.15	20/46.57
POLY-3 PERCENT (g)	21.3%	0%	15.2%	43%
TERMINAL (d)	4/35 (11%)	0/41 (0%)	5/38 (13%)	15/37 (41%)
FIRST INCIDENCE	450	---	544	404
STATISTICAL TESTS				
POLY 3	P<0.001**	P<0.001N**	P=0.311N	P=0.019*
POLY 1.5	P<0.001**	P<0.001N**	P=0.303N	P=0.021*
POLY 6	P<0.001**	P<0.001N**	P=0.316N	P=0.018*
COCH-ARM / FISHERS	P<0.001**	P<0.001N**	P=0.282N	P=0.028*
MAX-ISO-POLY-3	P<0.001**	P<0.001N**	P=0.227N	P=0.011*

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Stomach, Forestomach Ulcer				
LESION RATES				
OVERALL (a)	8/49 (16%)	0/50 (0%)	4/50 (8%)	10/50 (20%)
POLY-3 RATE (b)	8/46.97	0/46.68	4/45.57	10/45.69
POLY-3 PERCENT (g)	17%	0%	8.8%	21.9%
TERMINAL (d)	2/35 (6%)	0/41 (0%)	3/38 (8%)	7/37 (19%)
FIRST INCIDENCE	450	---	584	591
STATISTICAL TESTS				
POLY 3	P=0.088	P=0.004N**	P=0.192N	P=0.372
POLY 1.5	P=0.089	P=0.004N**	P=0.185N	P=0.381
POLY 6	P=0.087	P=0.004N**	P=0.198N	P=0.364
COCH-ARM / FISHERS	P=0.102	P=0.003N**	P=0.168N	P=0.416
MAX-ISO-POLY-3	P=0.034*	P<0.001N**	P=0.124N	P=0.282

TDMS No. 99020 - 06
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 Species/Strain: MICE/B6C3F1

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Date Report Requested: 04/23/2009
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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Stomach, Glandular Mineralization				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	1/45.28	0/44.78
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	677	---
STATISTICAL TESTS				
POLY 3	P=0.684	(e)	P=0.501	(e)
POLY 1.5	P=0.686	(e)	P=0.501	(e)
POLY 6	P=0.682	(e)	P=0.502	(e)
COCH-ARM / FISHERS	P=0.697	(e)	P=0.505	(e)
MAX-ISO-POLY-3	P=0.390	(e)	P=0.160	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Stomach, Glandular: Glands Cyst				
LESION RATES				
OVERALL (a)	2/49 (4%)	3/50 (6%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	2/45.13	3/46.68	3/45.08	2/44.98
POLY-3 PERCENT (g)	4.4%	6.4%	6.7%	4.5%
TERMINAL (d)	2/35 (6%)	3/41 (7%)	3/38 (8%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	676
STATISTICAL TESTS				
POLY 3	P=0.551N	P=0.515	P=0.500	P=0.693
POLY 1.5	P=0.549N	P=0.513	P=0.501	P=0.693
POLY 6	P=0.551N	P=0.520	P=0.500	P=0.694
COCH-ARM / FISHERS	P=0.536N	P=0.510	P=0.510	P=0.684N
MAX-ISO-POLY-3	P=0.603	P=0.339	P=0.324	P=0.498

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Thymus Atrophy				
LESION RATES				
OVERALL (a)	28/48 (58%)	21/49 (43%)	20/49 (41%)	13/46 (28%)
POLY-3 RATE (b)	28/46.72	21/47.33	20/46.96	13/43.53
POLY-3 PERCENT (g)	59.9%	44.4%	42.6%	29.9%
TERMINAL (d)	20/35 (57%)	15/40 (38%)	12/37 (32%)	7/35 (20%)
FIRST INCIDENCE	598	575	439	404
STATISTICAL TESTS				
POLY 3	P=0.003N**	P=0.094N	P=0.068N	P=0.003N**
POLY 1.5	P=0.003N**	P=0.094N	P=0.068N	P=0.003N**
POLY 6	P=0.003N**	P=0.091N	P=0.066N	P=0.003N**
COCH-ARM / FISHERS	P=0.003N**	P=0.093N	P=0.064N	P=0.003N**
MAX-ISO-POLY-3	P=0.003N**	P=0.064N	P=0.045N*	P=0.002N**

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Thymus				
Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	4/48 (8%)	5/49 (10%)	2/49 (4%)	1/46 (2%)
POLY-3 RATE (b)	4/44.89	5/45.68	2/44.08	1/41.41
POLY-3 PERCENT (g)	8.9%	11%	4.5%	2.4%
TERMINAL (d)	4/35 (11%)	5/40 (13%)	2/37 (5%)	1/35 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.095N	P=0.511	P=0.345N	P=0.204N
POLY 1.5	P=0.094N	P=0.511	P=0.341N	P=0.203N
POLY 6	P=0.095N	P=0.514	P=0.347N	P=0.203N
COCH-ARM / FISHERS	P=0.086N	P=0.513	P=0.329N	P=0.194N
MAX-ISO-POLY-3	P=0.141N	P=0.373	P=0.210N	P=0.105N

TDMS No. 99020 - 06
Test Type: CHRONIC
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Species/Strain: MICE/B6C3F1

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Thymus Necrosis Lymphoid				
LESION RATES				
OVERALL (a)	0/48 (0%)	0/49 (0%)	0/49 (0%)	0/46 (0%)
POLY-3 RATE (b)	0/44.89	0/45.68	0/44.08	0/41.41
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/40 (0%)	0/37 (0%)	0/35 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Pulegone
 CAS Number: 89-82-7

Date Report Requested: 04/23/2009
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 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Tooth Dysplasia				
LESION RATES				
OVERALL (a)	3/3 (100%)	1/1 (100%)	2/2 (100%)	1/1 (100%)
POLY-3 RATE (b)	3/3.00	1/1.00	2/2.00	1/1.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	3/3 (100%)	1/1 (100%)	2/2 (100%)	1/1 (100%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Urinary Bladder Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	37/49 (76%)	33/49 (67%)	30/50 (60%)	30/50 (60%)
POLY-3 RATE (b)	37/47.24	33/46.38	30/46.82	30/45.86
POLY-3 PERCENT (g)	78.3%	71.2%	64.1%	65.4%
TERMINAL (d)	30/35 (86%)	31/40 (78%)	25/38 (66%)	26/37 (70%)
FIRST INCIDENCE	450	624	544	591
STATISTICAL TESTS				
POLY 3	P=0.094N	P=0.281N	P=0.090N	P=0.115N
POLY 1.5	P=0.090N	P=0.272N	P=0.090N	P=0.109N
POLY 6	P=0.093N	P=0.279N	P=0.079N	P=0.115N
COCH-ARM / FISHERS	P=0.063N	P=0.251N	P=0.075N	P=0.075N
MAX-ISO-POLY-3	P=0.118N	P=0.207N	P=0.059N	P=0.079N

TDMS No. 99020 - 06
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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Uterus				
Angiectasis				
LESION RATES				
OVERALL (a)	3/49 (6%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/45.13	0/45.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	6.7%	0%	0%	0%
TERMINAL (d)	3/35 (9%)	0/40 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.044N*	P=0.116N	P=0.119N	P=0.120N
POLY 1.5	P=0.044N*	P=0.118N	P=0.118N	P=0.120N
POLY 6	P=0.045N*	P=0.115N	P=0.118N	P=0.120N
COCH-ARM / FISHERS	P=0.046N*	P=0.121N	P=0.117N	P=0.117N
MAX-ISO-POLY-3	P=0.010N**	P=0.038N*	P=0.039N*	P=0.040N*

TDMS No. 99020 - 06
Test Type: CHRONIC
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Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Uterus: Endometrium Hyperplasia Cystic				
LESION RATES				
OVERALL (a)	32/49 (65%)	32/49 (65%)	40/50 (80%)	35/50 (70%)
POLY-3 RATE (b)	32/45.99	32/46.51	40/48.86	35/47.21
POLY-3 PERCENT (g)	69.6%	68.8%	81.9%	74.1%
TERMINAL (d)	28/35 (80%)	29/40 (73%)	31/38 (82%)	28/37 (76%)
FIRST INCIDENCE	598	624	268	404
STATISTICAL TESTS				
POLY 3	P=0.262	P=0.559N	P=0.114	P=0.395
POLY 1.5	P=0.240	P=0.570N	P=0.097	P=0.370
POLY 6	P=0.290	P=0.536N	P=0.145	P=0.429
COCH-ARM / FISHERS	P=0.265	P=0.584N	P=0.078	P=0.388
MAX-ISO-POLY-3	P=0.259	P=0.466N	P=0.078	P=0.308

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LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
 - (b) Number of tumor-bearing animals/Poly-3 number
 - (d) Observed incidence at terminal kill.
 - (e) Value of Statistic cannot be computed.
 - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
 - (g) Poly-3 adjusted lifetime tumor incidence.
 - (I) Interim sacrifice
 - (T) Terminal sacrifice
 - # Tumor rates based on numbers of animals necropsied.
 - * To the right of any statistical result, indicates significance at ($P \leq 0.05$).
 - ** To the right of any statistical result, indicates significance at ($P \leq 0.01$).
 - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***