

TDMS No. 88105-04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
ISOEUGENOL  
CAS Number: 97-54-1  
Pathologist: Blackshear, P. - GRUMBEIN, S.  
F1\_M3

Date Report Requested: 10/04/2006  
Time Report Requested: 13:50:37  
First Dose M/F: 05/09/02 / 05/08/02  
Lab: BNW

<b>C Number:</b>	C88105		
<b>Lock Date:</b>	03/10/2005		
<b>Cage Range:</b>	1 - 9999		
<b>Date Range:</b>	1-JAN-1940 to 17-SEP-2040		
<b>Reasons For Removal:</b>	25022 Accidentally Killed	25021 Terminal Sacrifice	25020 Natural Death
	25019 Moribund Sacrifice		
<b>Removal Date Range:</b>	JAN /1 /1940 - SEP /17 /2040		
<b>Treatment Groups:</b>	Include 1 0 MG/KG	Include 2 0 MG/KG	Include 3 75 MG/KG
	Include 4 75 MG/KG	Include 5 150 MG/KG	Include 6 150 MG/KG
	Include 7 300 MG/KG	Include 8 300 MG/KG	

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## SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF ISOEUGENOL

### MALE MICE

#### Organ

Islets, Pancreatic  
Kidney  
Liver  
  
Nose: Glands  
Nose: Olfactory Epithelium

Spleen  
Stomach, Forestomach

Stomach, Glandular

Testes

### FEMALE MICE

#### Organ

Kidney  
Kidney: Bilateral, Papilla  
Kidney: Papilla  
Kidney: Renal Tubule  
Liver

Nose: Glands  
Nose: Olfactory Epithelium

#### Morphology

Hyperplasia  
Nephropathy  
Clear Cell Focus  
Necrosis  
Hyperplasia  
Accumulation, Hyaline Droplet  
Atrophy  
Degeneration  
Respiratory Metaplasia  
Depletion Cellular  
Hyperplasia  
Inflammation  
Ulcer  
Inflammation  
Inflammation Acute  
Ulcer  
Atrophy

#### Morphology

Nephropathy  
Necrosis  
Necrosis  
Necrosis  
Fatty Change  
Mineralization  
Necrosis  
Hyperplasia  
Accumulation, Hyaline Droplet  
Atrophy  
Respiratory Metaplasia

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

Spleen  
Stomach, Forestomach  
  
Stomach, Glandular

Depletion Cellular  
Hyperplasia  
Inflammation  
Inflammation  
Ulcer

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Adrenal Cortex  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	13/50 (26%)	16/50 (32%)	12/50 (24%)	7/49 (14%)
POLY-3 RATE (b)	13/45.22	16/46.79	12/45.94	7/39.50
POLY-3 PERCENT (g)	28.8%	34.2%	26.1%	17.7%
TERMINAL (d)	11/39 (28%)	14/38 (37%)	11/36 (31%)	5/27 (19%)
FIRST INCIDENCE	468	443	707	436

**STATISTICAL TESTS**

LIFE TABLE	P=0.220N	P=0.306	P=0.580N	P=0.326N
POLY 3	P=0.098N	P=0.368	P=0.482N	P=0.174N
POLY 1.5	P=0.076N	P=0.359	P=0.482N	P=0.146N
POLY 6	P=0.129N	P=0.372	P=0.492N	P=0.212N
LOGISTIC REGRESSION	P=0.075N	P=0.339	P=0.463N	P=0.146N
COCH-ARM / FISHERS	P=0.052N	P=0.330	P=0.500N	P=0.115N
ORDER RESTRICTED	P=0.125N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.149N	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Adrenal Cortex  
 Hypertrophy**

**LESION RATES**

OVERALL (a)	13/50 (26%)	13/50 (26%)	14/50 (28%)	6/49 (12%)
POLY-3 RATE (b)	13/44.82	13/46.73	14/46.35	6/38.94
POLY-3 PERCENT (g)	29%	27.8%	30.2%	15.4%
TERMINAL (d)	12/39 (31%)	11/38 (29%)	10/36 (28%)	5/27 (19%)
FIRST INCIDENCE	599	443	682	394

**STATISTICAL TESTS**

LIFE TABLE	P=0.226N	P=0.565	P=0.427	P=0.230N
POLY 3	P=0.110N	P=0.542N	P=0.541	P=0.109N
POLY 1.5	P=0.083N	P=0.555N	P=0.533	P=0.089N
POLY 6	P=0.148N	P=0.535N	P=0.544	P=0.141N
LOGISTIC REGRESSION	P=0.087N	P=0.576N	P=0.539	P=0.115N
COCH-ARM / FISHERS	P=0.055N	P=0.590N	P=0.500	P=0.068N
ORDER RESTRICTED	P=0.130N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.154N	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Adrenal Medulla  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	0/44.38	1/45.44	2/46.32	0/38.10
POLY-3 PERCENT (g)	0%	2.2%	4.3%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	1/36 (3%)	0/27 (0%)
FIRST INCIDENCE	---	693	591	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.628	P=0.505	P=0.238	(e)
POLY 3	P=0.606	P=0.505	P=0.247	(e)
POLY 1.5	P=0.639	P=0.504	P=0.245	(e)
POLY 6	P=0.566	P=0.506	P=0.247	(e)
LOGISTIC REGRESSION	P=0.605N	P=0.500	P=0.208	(e)
COCH-ARM / FISHERS	P=0.621N	P=0.500	P=0.247	(e)
ORDER RESTRICTED	P=0.338	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.366	(e)	(e)	(e)

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 104 WEEKS

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DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

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Brain  
Demyelination

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LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.38	0/45.30	0/45.85	0/38.27
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

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LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Brain  
 Necrosis**

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.38	2/46.21	0/45.85	0/38.27
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	443	---	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.446N	P=0.242	(e)	(e)
POLY 3	P=0.416N	P=0.246	(e)	(e)
POLY 1.5	P=0.411N	P=0.244	(e)	(e)
POLY 6	P=0.423N	P=0.248	(e)	(e)
LOGISTIC REGRESSION	P=0.345N	P=0.166	(e)	(e)
COCH-ARM / FISHERS	P=0.405N	P=0.247	(e)	(e)
ORDER RESTRICTED	P=0.285N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.317N	(e)	(e)	(e)



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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Harderian Gland  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	3/49 (6%)	4/50 (8%)	4/50 (8%)	4/49 (8%)
POLY-3 RATE (b)	3/43.99	4/45.60	4/46.13	4/37.80
POLY-3 PERCENT (g)	6.8%	8.8%	8.7%	10.6%
TERMINAL (d)	2/39 (5%)	3/38 (8%)	2/36 (6%)	3/27 (11%)
FIRST INCIDENCE	678	646	674	650

**STATISTICAL TESTS**

LIFE TABLE	P=0.261	P=0.497	P=0.479	P=0.323
POLY 3	P=0.350	P=0.520	P=0.526	P=0.418
POLY 1.5	P=0.385	P=0.519	P=0.524	P=0.451
POLY 6	P=0.314	P=0.519	P=0.523	P=0.382
LOGISTIC REGRESSION	P=0.350	P=0.517	P=0.523	P=0.398
COCH-ARM / FISHERS	P=0.443	P=0.511	P=0.511	P=0.500
ORDER RESTRICTED	P=0.445	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.469	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Heart  
 Cardiomyopathy**

**LESION RATES**

OVERALL (a)	9/50 (18%)	11/50 (22%)	14/50 (28%)	12/50 (24%)
POLY-3 RATE (b)	9/44.49	11/46.17	14/46.25	12/39.19
POLY-3 PERCENT (g)	20.2%	23.8%	30.3%	30.6%
TERMINAL (d)	8/39 (21%)	7/38 (18%)	11/36 (31%)	8/27 (30%)
FIRST INCIDENCE	700	611	674	607

**STATISTICAL TESTS**

LIFE TABLE	P=0.055	P=0.396	P=0.134	P=0.088
POLY 3	P=0.143	P=0.437	P=0.195	P=0.199
POLY 1.5	P=0.185	P=0.426	P=0.190	P=0.241
POLY 6	P=0.109	P=0.451	P=0.195	P=0.162
LOGISTIC REGRESSION	P=0.109	P=0.421	P=0.183	P=0.142
COCH-ARM / FISHERS	P=0.266	P=0.402	P=0.171	P=0.312
ORDER RESTRICTED	P=0.232	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.231	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Heart  
 Inflammation**

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/44.85	0/45.30	1/46.21	0/38.27
POLY-3 PERCENT (g)	2.2%	0%	2.2%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	589	---	629	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.444N	P=0.496N	P=0.745N	P=0.539N
POLY 3	P=0.427N	P=0.498N	P=0.754N	P=0.531N
POLY 1.5	P=0.420N	P=0.498N	P=0.755N	P=0.519N
POLY 6	P=0.435N	P=0.499N	P=0.755N	P=0.546N
LOGISTIC REGRESSION	P=0.356N	P=0.548N	P=0.707	P=0.462N
COCH-ARM / FISHERS	P=0.405N	P=0.500N	P=0.753N	P=0.500N
ORDER RESTRICTED	P=0.284N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.317N	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Heart  
 Mineralization**

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/44.85	0/45.30	0/45.85	2/39.70
POLY-3 PERCENT (g)	2.2%	0%	0%	5%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	589	---	---	408

**STATISTICAL TESTS**

LIFE TABLE	P=0.217	P=0.496N	P=0.491N	P=0.457
POLY 3	P=0.233	P=0.498N	P=0.496N	P=0.458
POLY 1.5	P=0.237	P=0.498N	P=0.496N	P=0.475
POLY 6	P=0.228	P=0.499N	P=0.497N	P=0.437
LOGISTIC REGRESSION	P=0.363	P=0.548N	P=0.581N	P=0.608
COCH-ARM / FISHERS	P=0.246	P=0.500N	P=0.500N	P=0.500
ORDER RESTRICTED	P=0.103	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.126	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Heart  
 Thrombosis**

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/44.85	1/46.07	1/46.21	0/38.27
POLY-3 PERCENT (g)	2.2%	2.2%	2.2%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	589	443	629	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.346N	P=0.758N	P=0.745N	P=0.539N
POLY 3	P=0.344N	P=0.755N	P=0.754N	P=0.531N
POLY 1.5	P=0.332N	P=0.756N	P=0.755N	P=0.519N
POLY 6	P=0.357N	P=0.755N	P=0.755N	P=0.546N
LOGISTIC REGRESSION	P=0.242N	P=0.679	P=0.707	P=0.462N
COCH-ARM / FISHERS	P=0.311N	P=0.753N	P=0.753N	P=0.500N
ORDER RESTRICTED	P=0.360N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.390N	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Heart: Artery  
 Inflammation Chronic

**LESION RATES**

OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.38	2/46.07	0/45.85	1/38.27
POLY-3 PERCENT (g)	2.3%	4.3%	0%	2.6%
TERMINAL (d)	1/39 (3%)	1/38 (3%)	0/36 (0%)	1/27 (4%)
FIRST INCIDENCE	728 (T)	443	---	728 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.590N	P=0.494	P=0.516N	P=0.678
POLY 3	P=0.513N	P=0.513	P=0.493N	P=0.727
POLY 1.5	P=0.508N	P=0.510	P=0.495N	P=0.741
POLY 6	P=0.517N	P=0.515	P=0.494N	P=0.710
LOGISTIC REGRESSION	P=0.462N	P=0.460	(e)	P=0.678
COCH-ARM / FISHERS	P=0.500N	P=0.500	P=0.500N	P=0.753N
ORDER RESTRICTED	P=0.423N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.450N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Islets, Pancreatic  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)	0/49 (0%)
POLY-3 RATE (b)	3/44.38	0/45.30	1/45.85	0/38.10
POLY-3 PERCENT (g)	6.8%	0%	2.2%	0%
TERMINAL (d)	3/39 (8%)	0/38 (0%)	1/36 (3%)	0/27 (0%)
FIRST INCIDENCE	728 (T)	---	728 (T)	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.122N	P=0.126N	P=0.334N	P=0.193N
POLY 3	P=0.093N	P=0.115N	P=0.294N	P=0.148N
POLY 1.5	P=0.091N	P=0.116N	P=0.296N	P=0.137N
POLY 6	P=0.096N	P=0.114N	P=0.294N	P=0.162N
LOGISTIC REGRESSION	P=0.122N	(e)	P=0.334N	(e)
COCH-ARM / FISHERS	P=0.088N	P=0.121N	P=0.309N	P=0.125N
ORDER RESTRICTED	P=0.032N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.048N*	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Kidney  
 Infarct**

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	1/49 (2%)
POLY-3 RATE (b)	1/44.38	1/46.07	2/46.67	1/38.10
POLY-3 PERCENT (g)	2.3%	2.2%	4.3%	2.6%
TERMINAL (d)	1/39 (3%)	0/38 (0%)	0/36 (0%)	1/27 (4%)
FIRST INCIDENCE	728 (T)	443	591	728 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.512	P=0.757	P=0.509	P=0.678
POLY 3	P=0.516	P=0.752N	P=0.518	P=0.726
POLY 1.5	P=0.543	P=0.754N	P=0.513	P=0.739
POLY 6	P=0.485	P=0.751N	P=0.521	P=0.710
LOGISTIC REGRESSION	P=0.582N	P=0.719	P=0.448	P=0.678
COCH-ARM / FISHERS	P=0.584	P=0.753N	P=0.500	P=0.747
ORDER RESTRICTED	P=0.572	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.585	(e)	(e)	(e)



TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Kidney  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	2/49 (4%)
POLY-3 RATE (b)	0/44.38	2/46.38	0/45.85	2/38.34
POLY-3 PERCENT (g)	0%	4.3%	0%	5.2%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	1/27 (4%)
FIRST INCIDENCE	---	443	---	666

**STATISTICAL TESTS**

LIFE TABLE	P=0.186	P=0.250	(e)	P=0.172
POLY 3	P=0.216	P=0.247	(e)	P=0.206
POLY 1.5	P=0.226	P=0.244	(e)	P=0.217
POLY 6	P=0.206	P=0.250	(e)	P=0.194
LOGISTIC REGRESSION	P=0.305	P=0.150	(e)	P=0.208
COCH-ARM / FISHERS	P=0.242	P=0.247	(e)	P=0.242
ORDER RESTRICTED	P=0.094	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.118	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Kidney  
 Nephropathy**

**LESION RATES**

OVERALL (a)	47/50 (94%)	48/50 (96%)	47/50 (94%)	47/49 (96%)
POLY-3 RATE (b)	47/48.38	48/49.70	47/49.89	47/48.77
POLY-3 PERCENT (g)	97.2%	96.6%	94.2%	96.4%
TERMINAL (d)	38/39 (97%)	37/38 (97%)	34/36 (94%)	26/27 (96%)
FIRST INCIDENCE	468	441	491	324

**STATISTICAL TESTS**

LIFE TABLE	P=0.003**	P=0.440	P=0.386	P=0.010**
POLY 3	P=0.503N	P=0.672N	P=0.410N	P=0.648N
POLY 1.5	P=0.548N	P=0.707N	P=0.473N	P=0.691N
POLY 6	P=0.485N	P=0.674N	P=0.376N	P=0.641N
LOGISTIC REGRESSION	P=0.380	P=0.613	P=0.516N	P=0.408
COCH-ARM / FISHERS	P=0.466	P=0.500	P=0.661N	P=0.510
ORDER RESTRICTED	P=0.492N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.498N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Requested: 10/04/2006  
 Time Report Requested: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Kidney: Bilateral, Papilla  
 Necrosis**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/44.38	0/45.30	0/45.85	0/38.10
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Kidney: Papilla  
 Necrosis**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/44.38	0/45.30	0/45.85	0/38.10
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Kidney: Renal Tubule  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	2/49 (4%)
POLY-3 RATE (b)	2/44.73	2/45.30	1/45.85	2/38.10
POLY-3 PERCENT (g)	4.5%	4.4%	2.2%	5.3%
TERMINAL (d)	1/39 (3%)	2/38 (5%)	1/36 (3%)	2/27 (7%)
FIRST INCIDENCE	631	728 (T)	728 (T)	728 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.497	P=0.692	P=0.511N	P=0.571
POLY 3	P=0.571	P=0.689N	P=0.491N	P=0.635
POLY 1.5	P=0.591	P=0.689N	P=0.492N	P=0.657
POLY 6	P=0.549	P=0.691N	P=0.494N	P=0.608
LOGISTIC REGRESSION	P=0.558	P=0.691N	P=0.500N	P=0.641
COCH-ARM / FISHERS	P=0.586N	P=0.691N	P=0.500N	P=0.684
ORDER RESTRICTED	P=0.569	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.584	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

---

**Kidney: Renal Tubule  
 Necrosis**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/44.38	0/45.30	0/45.85	0/38.10
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Liver  
 Angiectasis

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.38	0/45.30	1/45.85	0/38.27
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	1/36 (3%)	0/27 (0%)
FIRST INCIDENCE	---	---	728 (T)	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.655	(e)	P=0.484	(e)
POLY 3	P=0.619	(e)	P=0.507	(e)
POLY 1.5	P=0.650	(e)	P=0.505	(e)
POLY 6	P=0.583	(e)	P=0.506	(e)
LOGISTIC REGRESSION	(e)	(e)	P=0.484	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
ORDER RESTRICTED	P=0.390	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.416	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Liver  
 Basophilic Focus

**LESION RATES**

OVERALL (a)	5/50 (10%)	5/50 (10%)	3/50 (6%)	7/50 (14%)
POLY-3 RATE (b)	5/45.17	5/45.96	3/46.05	7/39.73
POLY-3 PERCENT (g)	11.1%	10.9%	6.5%	17.6%
TERMINAL (d)	3/39 (8%)	4/38 (11%)	1/36 (3%)	5/27 (19%)
FIRST INCIDENCE	599	510	700	385

**STATISTICAL TESTS**

LIFE TABLE	P=0.158	P=0.623	P=0.374N	P=0.206
POLY 3	P=0.254	P=0.619N	P=0.346N	P=0.291
POLY 1.5	P=0.278	P=0.620N	P=0.346N	P=0.328
POLY 6	P=0.228	P=0.622N	P=0.351N	P=0.251
LOGISTIC REGRESSION	P=0.340	P=0.623	P=0.358N	P=0.386
COCH-ARM / FISHERS	P=0.316	P=0.630N	P=0.357N	P=0.380
ORDER RESTRICTED	P=0.194	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.224	(e)	(e)	(e)



TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Requested: 10/04/2006  
 Time Report Requested: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Liver  
 Clear Cell Focus

**LESION RATES**

OVERALL (a)	16/50 (32%)	26/50 (52%)	29/50 (58%)	13/50 (26%)
POLY-3 RATE (b)	16/44.38	26/46.28	29/46.10	13/38.88
POLY-3 PERCENT (g)	36.1%	56.2%	62.9%	33.4%
TERMINAL (d)	16/39 (41%)	23/38 (61%)	27/36 (75%)	12/27 (44%)
FIRST INCIDENCE	728 (T)	510	692	533

**STATISTICAL TESTS**

LIFE TABLE	P=0.337	P=0.023*	P<0.001**	P=0.390
POLY 3	P=0.405N	P=0.039*	P=0.007**	P=0.492N
POLY 1.5	P=0.291N	P=0.037*	P=0.007**	P=0.423N
POLY 6	P=0.533	P=0.042*	P=0.006**	P=0.572N
LOGISTIC REGRESSION	P=0.541N	P=0.036*	P=0.003**	P=0.536
COCH-ARM / FISHERS	P=0.166N	P=0.034*	P=0.008**	P=0.330N
ORDER RESTRICTED	P=0.064N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.085N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Liver  
 Eosinophilic Focus

**LESION RATES**

OVERALL (a)	8/50 (16%)	13/50 (26%)	11/50 (22%)	5/50 (10%)
POLY-3 RATE (b)	8/45.22	13/46.02	11/46.25	5/38.71
POLY-3 PERCENT (g)	17.7%	28.3%	23.8%	12.9%
TERMINAL (d)	6/39 (15%)	11/38 (29%)	7/36 (19%)	2/27 (7%)
FIRST INCIDENCE	468	510	692	656

**STATISTICAL TESTS**

LIFE TABLE	P=0.391N	P=0.155	P=0.269	P=0.511N
POLY 3	P=0.258N	P=0.170	P=0.323	P=0.383N
POLY 1.5	P=0.207N	P=0.170	P=0.321	P=0.339N
POLY 6	P=0.317N	P=0.170	P=0.320	P=0.431N
LOGISTIC REGRESSION	P=0.224N	P=0.170	P=0.325	P=0.353N
COCH-ARM / FISHERS	P=0.141N	P=0.163	P=0.306	P=0.277N
ORDER RESTRICTED	P=0.201N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.235N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

---

Liver  
 Fatty Change

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.38	0/45.30	0/45.85	0/38.27
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Liver  
 Hepatodiaphragmatic Nodule

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.38	0/45.30	2/45.85	0/38.27
POLY-3 PERCENT (g)	0%	0%	4.4%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	2/36 (6%)	0/27 (0%)
FIRST INCIDENCE	---	---	728 (T)	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.523	(e)	P=0.221	(e)
POLY 3	P=0.499	(e)	P=0.244	(e)
POLY 1.5	P=0.538	(e)	P=0.243	(e)
POLY 6	P=0.455	(e)	P=0.244	(e)
LOGISTIC REGRESSION	(e)	(e)	P=0.221	(e)
COCH-ARM / FISHERS	P=0.595	(e)	P=0.247	(e)
ORDER RESTRICTED	P=0.257	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.289	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
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 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Liver  
 Infarct

**LESION RATES**

OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.38	1/45.30	0/45.85	0/38.27
POLY-3 PERCENT (g)	4.5%	2.2%	0%	0%
TERMINAL (d)	2/39 (5%)	1/38 (3%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	---	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.134N	P=0.509N	P=0.256N	P=0.322N
POLY 3	P=0.101N	P=0.493N	P=0.230N	P=0.272N
POLY 1.5	P=0.102N	P=0.494N	P=0.231N	P=0.257N
POLY 6	P=0.101N	P=0.492N	P=0.230N	P=0.288N
LOGISTIC REGRESSION	P=0.134N	P=0.509N	(e)	(e)
COCH-ARM / FISHERS	P=0.101N	P=0.500N	P=0.247N	P=0.247N
ORDER RESTRICTED	P=0.098N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.123N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

---

Liver  
 Mineralization

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.38	0/45.30	0/45.85	0/38.27
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Liver  
 Necrosis

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	5/50 (10%)
POLY-3 RATE (b)	1/44.85	0/45.30	2/46.41	5/40.51
POLY-3 PERCENT (g)	2.2%	0%	4.3%	12.3%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	589	---	642	532

**STATISTICAL TESTS**

LIFE TABLE	P=0.007**	P=0.496N	P=0.524	P=0.075
POLY 3	P=0.010**	P=0.498N	P=0.512	P=0.079
POLY 1.5	P=0.011*	P=0.498N	P=0.509	P=0.087
POLY 6	P=0.009**	P=0.499N	P=0.512	P=0.072
LOGISTIC REGRESSION	P=0.036*	P=0.548N	P=0.424	P=0.148
COCH-ARM / FISHERS	P=0.014*	P=0.500N	P=0.500	P=0.102
ORDER RESTRICTED	P=0.009**	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.014*	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Lung: Alveolar Epithelium  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	3/50 (6%)	4/49 (8%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	3/44.38	4/44.44	4/45.94	2/38.65
POLY-3 PERCENT (g)	6.8%	9%	8.7%	5.2%
TERMINAL (d)	3/39 (8%)	3/37 (8%)	3/36 (8%)	1/27 (4%)
FIRST INCIDENCE	728 (T)	693	707	621

**STATISTICAL TESTS**

LIFE TABLE	P=0.546N	P=0.477	P=0.463	P=0.647N
POLY 3	P=0.442N	P=0.501	P=0.519	P=0.563N
POLY 1.5	P=0.412N	P=0.498	P=0.515	P=0.538N
POLY 6	P=0.474N	P=0.503	P=0.518	P=0.589N
LOGISTIC REGRESSION	P=0.466N	P=0.498	P=0.502	P=0.576N
COCH-ARM / FISHERS	P=0.364N	P=0.489	P=0.500	P=0.500N
ORDER RESTRICTED	P=0.487N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.509N	(e)	(e)	(e)



TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Mesentery: Fat  
 Necrosis

**LESION RATES**

OVERALL (a)	5/5 (100%)	3/4 (75%)	4/4 (100%)	0/1 (0%)
POLY-3 RATE (b)	5/5.00	3/4.00	4/4.00	0/1.00
POLY-3 PERCENT (g)	100%	75%	100%	0%
TERMINAL (d)	5/5 (100%)	2/3 (67%)	3/3 (100%)	0/1 (0%)
FIRST INCIDENCE	728 (T)	693	674	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.219N	P=0.705N	(e)	P=0.186N
POLY 3	P=0.068N	P=0.455N	(e)	P=0.167N
POLY 1.5	P=0.068N	P=0.455N	(e)	P=0.167N
POLY 6	P=0.068N	P=0.455N	(e)	P=0.167N
LOGISTIC REGRESSION	P=0.219N	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.122N	P=0.444N	(e)	P=0.167N
ORDER RESTRICTED	P=0.101N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.007N**	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Nose: Glands  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	3/50 (6%)	34/50 (68%)	49/50 (98%)	48/50 (96%)
POLY-3 RATE (b)	3/44.38	34/48.42	49/50.00	48/50.00
POLY-3 PERCENT (g)	6.8%	70.2%	98%	96%
TERMINAL (d)	3/39 (8%)	26/38 (68%)	35/36 (97%)	25/27 (93%)
FIRST INCIDENCE	728 (T)	441	491	324

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P<0.001**	P<0.001**	P<0.001**
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**
LOGISTIC REGRESSION	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**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Nose: Olfactory Epithelium  
 Accumulation, Hyaline Droplet

**LESION RATES**

OVERALL (a)	0/50 (0%)	6/50 (12%)	26/50 (52%)	19/50 (38%)
POLY-3 RATE (b)	0/44.38	6/46.49	26/49.05	19/42.80
POLY-3 PERCENT (g)	0%	12.9%	53%	44.4%
TERMINAL (d)	0/39 (0%)	4/38 (11%)	16/36 (44%)	11/27 (41%)
FIRST INCIDENCE	---	441	491	385

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.019*	P<0.001**	P<0.001**
POLY 3	P<0.001**	P=0.018*	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**
LOGISTIC REGRESSION	P<0.001**	P=0.014*	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.013*	P<0.001**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
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 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Nose: Olfactory Epithelium  
 Atrophy

**LESION RATES**

OVERALL (a)	5/50 (10%)	13/50 (26%)	36/50 (72%)	41/50 (82%)
POLY-3 RATE (b)	5/44.38	13/47.27	36/49.13	41/46.91
POLY-3 PERCENT (g)	11.3%	27.5%	73.3%	87.4%
TERMINAL (d)	5/39 (13%)	7/38 (18%)	25/36 (69%)	23/27 (85%)
FIRST INCIDENCE	728 (T)	481	491	324

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.040*	P<0.001**	P<0.001**
POLY 3	P<0.001**	P=0.043*	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.039*	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.048*	P<0.001**	P<0.001**
LOGISTIC REGRESSION	P<0.001**	P=0.034*	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.033*	P<0.001**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
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 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Nose: Olfactory Epithelium  
 Degeneration**

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	7/50 (14%)	6/50 (12%)
POLY-3 RATE (b)	1/44.93	1/45.30	7/47.09	6/41.09
POLY-3 PERCENT (g)	2.2%	2.2%	14.9%	14.6%
TERMINAL (d)	0/39 (0%)	1/38 (3%)	4/36 (11%)	2/27 (7%)
FIRST INCIDENCE	557	728 (T)	522	324

**STATISTICAL TESTS**

LIFE TABLE	P=0.006**	P=0.757	P=0.035*	P=0.039*
POLY 3	P=0.009**	P=0.759N	P=0.035*	P=0.042*
POLY 1.5	P=0.011*	P=0.758N	P=0.034*	P=0.048*
POLY 6	P=0.007**	P=0.760N	P=0.036*	P=0.036*
LOGISTIC REGRESSION	P=0.047*	P=0.745	P=0.020*	P=0.107
COCH-ARM / FISHERS	P=0.016*	P=0.753N	P=0.030*	P=0.056
ORDER RESTRICTED	P=0.025*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.013*	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Nose: Olfactory Epithelium  
 Metaplasia**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/44.38	0/45.30	2/46.62	1/38.27
POLY-3 PERCENT (g)	0%	0%	4.3%	2.6%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	1/27 (4%)
FIRST INCIDENCE	---	---	522	728 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.195	(e)	P=0.249	P=0.427
POLY 3	P=0.186	(e)	P=0.248	P=0.471
POLY 1.5	P=0.209	(e)	P=0.245	P=0.483
POLY 6	P=0.163	(e)	P=0.250	P=0.457
LOGISTIC REGRESSION	P=0.285	(e)	P=0.159	P=0.427
COCH-ARM / FISHERS	P=0.246	(e)	P=0.247	P=0.500
ORDER RESTRICTED	P=0.181	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.214	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Nose: Olfactory Epithelium  
 Respiratory Metaplasia

**LESION RATES**

OVERALL (a)	4/50 (8%)	31/50 (62%)	47/50 (94%)	49/50 (98%)
POLY-3 RATE (b)	4/44.57	31/47.04	47/49.41	49/49.38
POLY-3 PERCENT (g)	9%	65.9%	95.1%	99.2%
TERMINAL (d)	3/39 (8%)	25/38 (66%)	34/36 (94%)	27/27 (100%)
FIRST INCIDENCE	678	443	491	324

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P<0.001**	P<0.001**	P<0.001**
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**
LOGISTIC REGRESSION	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**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

---

**Pancreas  
 Amyloid Deposition**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/44.38	0/45.30	0/45.85	0/38.10
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---



TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
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 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Pancreas  
 Atrophy**

**LESION RATES**

OVERALL (a)	2/50 (4%)	1/50 (2%)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	2/44.38	1/45.30	2/45.85	0/38.10
POLY-3 PERCENT (g)	4.5%	2.2%	4.4%	0%
TERMINAL (d)	2/39 (5%)	1/38 (3%)	2/36 (6%)	0/27 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	728 (T)	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.281N	P=0.509N	P=0.666	P=0.322N
POLY 3	P=0.239N	P=0.493N	P=0.682N	P=0.272N
POLY 1.5	P=0.225N	P=0.494N	P=0.684N	P=0.259N
POLY 6	P=0.254N	P=0.492N	P=0.683N	P=0.288N
LOGISTIC REGRESSION	P=0.281N	P=0.509N	P=0.666	(e)
COCH-ARM / FISHERS	P=0.204N	P=0.500N	P=0.691N	P=0.253N
ORDER RESTRICTED	P=0.186N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.217N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
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 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

---

**Pancreas  
 Basophilic Focus**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/44.38	0/45.30	0/45.85	0/38.10
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Pituitary Gland: Pars Distalis  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	1/50 (2%)	3/48 (6%)	3/50 (6%)	0/48 (0%)
POLY-3 RATE (b)	1/44.38	3/43.51	3/46.28	0/37.89
POLY-3 PERCENT (g)	2.3%	6.9%	6.5%	0%
TERMINAL (d)	1/39 (3%)	3/37 (8%)	1/36 (3%)	0/27 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	642	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.391N	P=0.286	P=0.302	P=0.573N
POLY 3	P=0.344N	P=0.298	P=0.320	P=0.531N
POLY 1.5	P=0.320N	P=0.297	P=0.317	P=0.522N
POLY 6	P=0.374N	P=0.299	P=0.322	P=0.543N
LOGISTIC REGRESSION	P=0.328N	P=0.286	P=0.307	(e)
COCH-ARM / FISHERS	P=0.288N	P=0.293	P=0.309	P=0.510N
ORDER RESTRICTED	P=0.191N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.222N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Preputial Gland  
 Ectasia**

**LESION RATES**

OVERALL (a)	5/50 (10%)	4/50 (8%)	5/50 (10%)	6/50 (12%)
POLY-3 RATE (b)	5/44.38	4/45.44	5/46.17	6/38.86
POLY-3 PERCENT (g)	11.3%	8.8%	10.8%	15.4%
TERMINAL (d)	5/39 (13%)	3/38 (8%)	4/36 (11%)	3/27 (11%)
FIRST INCIDENCE	728 (T)	693	642	579

**STATISTICAL TESTS**

LIFE TABLE	P=0.176	P=0.513N	P=0.590	P=0.278
POLY 3	P=0.292	P=0.485N	P=0.605N	P=0.407
POLY 1.5	P=0.323	P=0.489N	P=0.611N	P=0.444
POLY 6	P=0.263	P=0.482N	P=0.604N	P=0.369
LOGISTIC REGRESSION	P=0.254	P=0.488N	P=0.613N	P=0.362
COCH-ARM / FISHERS	P=0.375	P=0.500N	P=0.630N	P=0.500
ORDER RESTRICTED	P=0.360	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.387	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Skin  
 Inflammation Chronic**

**LESION RATES**

OVERALL (a)	0/50 (0%)	3/50 (6%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/44.38	3/45.46	1/46.06	2/38.41
POLY-3 PERCENT (g)	0%	6.6%	2.2%	5.2%
TERMINAL (d)	0/39 (0%)	1/38 (3%)	0/36 (0%)	1/27 (4%)
FIRST INCIDENCE	---	702	674	692

**STATISTICAL TESTS**

LIFE TABLE	P=0.229	P=0.124	P=0.510	P=0.171
POLY 3	P=0.282	P=0.123	P=0.507	P=0.206
POLY 1.5	P=0.303	P=0.122	P=0.506	P=0.218
POLY 6	P=0.260	P=0.124	P=0.508	P=0.194
LOGISTIC REGRESSION	P=0.287	P=0.124	P=0.487	P=0.195
COCH-ARM / FISHERS	P=0.337	P=0.121	P=0.500	P=0.247
ORDER RESTRICTED	P=0.161	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.193	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Spleen  
 Depletion Cellular**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/49 (4%)
POLY-3 RATE (b)	0/44.38	0/45.30	0/45.85	2/39.32
POLY-3 PERCENT (g)	0%	0%	0%	5.1%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	---	---	533

**STATISTICAL TESTS**

LIFE TABLE	P=0.037*	(e)	(e)	P=0.212
POLY 3	P=0.040*	(e)	(e)	P=0.211
POLY 1.5	P=0.041*	(e)	(e)	P=0.220
POLY 6	P=0.039*	(e)	(e)	P=0.201
LOGISTIC REGRESSION	P=0.082	(e)	(e)	P=0.276
COCH-ARM / FISHERS	P=0.045*	(e)	(e)	P=0.242
ORDER RESTRICTED	P=0.021*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.031*	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Spleen  
 Hematopoietic Cell Proliferation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/49 (2%)
POLY-3 RATE (b)	0/44.38	0/45.30	1/45.85	1/38.93
POLY-3 PERCENT (g)	0%	0%	2.2%	2.6%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	1/36 (3%)	0/27 (0%)
FIRST INCIDENCE	---	---	728 (T)	408

**STATISTICAL TESTS**

LIFE TABLE	P=0.196	(e)	P=0.484	P=0.487
POLY 3	P=0.199	(e)	P=0.507	P=0.474
POLY 1.5	P=0.213	(e)	P=0.505	P=0.483
POLY 6	P=0.185	(e)	P=0.506	P=0.463
LOGISTIC REGRESSION	P=0.298	(e)	P=0.484	P=0.506
COCH-ARM / FISHERS	P=0.231	(e)	P=0.500	P=0.495
ORDER RESTRICTED	P=0.226	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.252	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Stomach, Forestomach  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	7/50 (14%)	8/49 (16%)	8/50 (16%)	14/49 (29%)
POLY-3 RATE (b)	7/45.37	8/45.86	8/47.56	14/41.98
POLY-3 PERCENT (g)	15.4%	17.5%	16.8%	33.4%
TERMINAL (d)	5/39 (13%)	5/38 (13%)	4/36 (11%)	6/27 (22%)
FIRST INCIDENCE	515	611	491	385

**STATISTICAL TESTS**

LIFE TABLE	P=0.009**	P=0.500	P=0.477	P=0.022*
POLY 3	P=0.025*	P=0.509	P=0.539	P=0.041*
POLY 1.5	P=0.029*	P=0.502	P=0.530	P=0.049*
POLY 6	P=0.021*	P=0.516	P=0.543	P=0.034*
LOGISTIC REGRESSION	P=0.064	P=0.477	P=0.443	P=0.081
COCH-ARM / FISHERS	P=0.036*	P=0.483	P=0.500	P=0.063
ORDER RESTRICTED	P=0.027*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.035*	(e)	(e)	(e)



TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Stomach, Forestomach  
 Inflammation**

**LESION RATES**

OVERALL (a)	5/50 (10%)	8/49 (16%)	9/50 (18%)	14/49 (29%)
POLY-3 RATE (b)	5/44.73	8/45.86	9/48.03	14/41.98
POLY-3 PERCENT (g)	11.2%	17.5%	18.7%	33.4%
TERMINAL (d)	4/39 (10%)	5/38 (13%)	4/36 (11%)	6/27 (22%)
FIRST INCIDENCE	631	611	491	385

**STATISTICAL TESTS**

LIFE TABLE	P=0.002**	P=0.284	P=0.192	P=0.006**
POLY 3	P=0.007**	P=0.292	P=0.235	P=0.011*
POLY 1.5	P=0.008**	P=0.283	P=0.222	P=0.013*
POLY 6	P=0.006**	P=0.301	P=0.244	P=0.009**
LOGISTIC REGRESSION	P=0.022*	P=0.271	P=0.156	P=0.023*
COCH-ARM / FISHERS	P=0.011*	P=0.264	P=0.194	P=0.017*
ORDER RESTRICTED	P=0.006**	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.009**	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Stomach, Forestomach  
 Ulcer

**LESION RATES**

OVERALL (a)	1/50 (2%)	4/49 (8%)	4/50 (8%)	9/49 (18%)
POLY-3 RATE (b)	1/44.73	4/45.45	4/46.55	9/40.77
POLY-3 PERCENT (g)	2.2%	8.8%	8.6%	22.1%
TERMINAL (d)	0/39 (0%)	2/38 (5%)	3/36 (8%)	4/27 (15%)
FIRST INCIDENCE	631	646	491	436

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.193	P=0.177	P=0.004**
POLY 3	P=0.003**	P=0.183	P=0.191	P=0.005**
POLY 1.5	P=0.003**	P=0.181	P=0.189	P=0.006**
POLY 6	P=0.002**	P=0.186	P=0.190	P=0.004**
LOGISTIC REGRESSION	P=0.009**	P=0.166	P=0.144	P=0.013*
COCH-ARM / FISHERS	P=0.004**	P=0.175	P=0.181	P=0.007**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.003**	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Stomach, Glandular  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/49 (2%)	3/49 (6%)	3/44 (7%)
POLY-3 RATE (b)	0/44.38	1/45.15	3/46.34	3/36.38
POLY-3 PERCENT (g)	0%	2.2%	6.5%	8.3%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	693	491	532

**STATISTICAL TESTS**

LIFE TABLE	P=0.043*	P=0.505	P=0.132	P=0.097
POLY 3	P=0.039*	P=0.503	P=0.127	P=0.086
POLY 1.5	P=0.042*	P=0.501	P=0.123	P=0.090
POLY 6	P=0.036*	P=0.505	P=0.129	P=0.082
LOGISTIC REGRESSION	P=0.090	P=0.495	P=0.053	P=0.121
COCH-ARM / FISHERS	P=0.050*	P=0.495	P=0.117	P=0.099
ORDER RESTRICTED	P=0.051	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.060	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Stomach, Glandular  
 Inflammation Acute**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/49 (0%)	1/49 (2%)	2/44 (5%)
POLY-3 RATE (b)	0/44.38	0/45.01	1/45.17	2/36.13
POLY-3 PERCENT (g)	0%	0%	2.2%	5.5%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	---	710	532

**STATISTICAL TESTS**

LIFE TABLE	P=0.052	(e)	P=0.495	P=0.216
POLY 3	P=0.049*	(e)	P=0.504	P=0.193
POLY 1.5	P=0.051	(e)	P=0.502	P=0.199
POLY 6	P=0.047*	(e)	P=0.504	P=0.188
LOGISTIC REGRESSION	P=0.087	(e)	P=0.502	P=0.244
COCH-ARM / FISHERS	P=0.057	(e)	P=0.495	P=0.216
ORDER RESTRICTED	P=0.050*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.066	(e)	(e)	(e)

TDMS No. 88105-04  
 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 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Stomach, Glandular  
 Ulcer**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/49 (2%)	4/49 (8%)	5/44 (11%)
POLY-3 RATE (b)	0/44.38	1/45.15	4/46.41	5/37.42
POLY-3 PERCENT (g)	0%	2.2%	8.6%	13.4%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	693	491	532

**STATISTICAL TESTS**

LIFE TABLE	P=0.005**	P=0.505	P=0.070	P=0.025*
POLY 3	P=0.004**	P=0.503	P=0.066	P=0.018*
POLY 1.5	P=0.005**	P=0.501	P=0.064	P=0.019*
POLY 6	P=0.004**	P=0.505	P=0.068	P=0.017*
LOGISTIC REGRESSION	P=0.017*	P=0.495	P=0.029*	P=0.033*
COCH-ARM / FISHERS	P=0.006**	P=0.495	P=0.056	P=0.020*
ORDER RESTRICTED	P=0.007**	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.007**	(e)	(e)	(e)

TDMS No. 88105-04  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Testes  
 Atrophy

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	1/44.38	1/45.30	0/45.85	4/39.27
POLY-3 PERCENT (g)	2.3%	2.2%	0%	10.2%
TERMINAL (d)	1/39 (3%)	1/38 (3%)	0/36 (0%)	1/27 (4%)
FIRST INCIDENCE	728 (T)	728 (T)	---	436

**STATISTICAL TESTS**

LIFE TABLE	P=0.031*	P=0.756	P=0.516N	P=0.111
POLY 3	P=0.053	P=0.756N	P=0.493N	P=0.143
POLY 1.5	P=0.056	P=0.757N	P=0.495N	P=0.157
POLY 6	P=0.051	P=0.756N	P=0.494N	P=0.129
LOGISTIC REGRESSION	P=0.069	P=0.756	(e)	P=0.184
COCH-ARM / FISHERS	P=0.062	P=0.753N	P=0.500N	P=0.181
ORDER RESTRICTED	P=0.021*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.032*	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Thyroid Gland: Follicular Cell  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/49 (4%)	0/50 (0%)	1/49 (2%)
POLY-3 RATE (b)	0/44.38	2/44.50	0/45.85	1/38.10
POLY-3 PERCENT (g)	0%	4.5%	0%	2.6%
TERMINAL (d)	0/39 (0%)	0/37 (0%)	0/36 (0%)	1/27 (4%)
FIRST INCIDENCE	---	693	---	728 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.453	P=0.242	(e)	P=0.427
POLY 3	P=0.497	P=0.238	(e)	P=0.470
POLY 1.5	P=0.513	P=0.237	(e)	P=0.481
POLY 6	P=0.478	P=0.239	(e)	P=0.457
LOGISTIC REGRESSION	P=0.498	P=0.235	(e)	P=0.427
COCH-ARM / FISHERS	P=0.536	P=0.242	(e)	P=0.495
ORDER RESTRICTED	P=0.298	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.329	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Adrenal Cortex  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	4/48 (8%)	2/50 (4%)	4/49 (8%)	2/50 (4%)
POLY-3 RATE (b)	4/41.83	2/46.52	4/46.47	2/40.48
POLY-3 PERCENT (g)	9.6%	4.3%	8.6%	4.9%
TERMINAL (d)	4/34 (12%)	1/39 (3%)	4/38 (11%)	2/33 (6%)
FIRST INCIDENCE	727 (T)	714	727 (T)	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.372N	P=0.277N	P=0.582N	P=0.350N
POLY 3	P=0.375N	P=0.289N	P=0.584N	P=0.352N
POLY 1.5	P=0.357N	P=0.296N	P=0.597N	P=0.335N
POLY 6	P=0.395N	P=0.287N	P=0.577N	P=0.373N
LOGISTIC REGRESSION	P=0.387N	P=0.286N	P=0.582N	P=0.350N
COCH-ARM / FISHERS	P=0.329N	P=0.319N	P=0.631N	P=0.319N
ORDER RESTRICTED	P=0.336N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.351N	(e)	(e)	(e)



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 Species/Strain: MICE/B6C3F1

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Adrenal Cortex  
 Hypertrophy**

**LESION RATES**

OVERALL (a)	0/48 (0%)	1/50 (2%)	3/49 (6%)	1/50 (2%)
POLY-3 RATE (b)	0/41.83	1/46.47	3/46.47	1/40.48
POLY-3 PERCENT (g)	0%	2.2%	6.5%	2.5%
TERMINAL (d)	0/34 (0%)	1/39 (3%)	3/38 (8%)	1/33 (3%)
FIRST INCIDENCE	---	727 (T)	727 (T)	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.326	P=0.527	P=0.141	P=0.494
POLY 3	P=0.307	P=0.521	P=0.139	P=0.493
POLY 1.5	P=0.330	P=0.518	P=0.134	P=0.501
POLY 6	P=0.281	P=0.522	P=0.141	P=0.484
LOGISTIC REGRESSION (e)		P=0.527	P=0.141	P=0.494
COCH-ARM / FISHERS	P=0.360	P=0.510	P=0.125	P=0.510
ORDER RESTRICTED	P=0.173	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.189	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Adrenal Medulla  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	1/48 (2%)	0/50 (0%)	1/49 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/41.83	0/46.47	1/46.47	2/40.48
POLY-3 PERCENT (g)	2.4%	0%	2.2%	4.9%
TERMINAL (d)	1/34 (3%)	0/39 (0%)	1/38 (3%)	2/33 (6%)
FIRST INCIDENCE	727 (T)	---	727 (T)	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.225	P=0.473N	P=0.737N	P=0.490
POLY 3	P=0.230	P=0.479N	P=0.737N	P=0.489
POLY 1.5	P=0.240	P=0.482N	P=0.742N	P=0.501
POLY 6	P=0.221	P=0.478N	P=0.734N	P=0.473
LOGISTIC REGRESSION	P=0.225	(e)	P=0.737N	P=0.490
COCH-ARM / FISHERS	P=0.255	P=0.490N	P=0.747N	P=0.515
ORDER RESTRICTED	P=0.207	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.222	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Brain  
 Demyelination**

**LESION RATES**

OVERALL (a)	0/49 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.59	2/46.63	0/46.55	0/40.48
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	701	---	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.425N	P=0.266	(e)	(e)
POLY 3	P=0.396N	P=0.258	(e)	(e)
POLY 1.5	P=0.396N	P=0.254	(e)	(e)
POLY 6	P=0.398N	P=0.260	(e)	(e)
LOGISTIC REGRESSION	P=0.414N	P=0.252	(e)	(e)
COCH-ARM / FISHERS	P=0.402N	P=0.253	(e)	(e)
ORDER RESTRICTED	P=0.275N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.291N	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Brain  
 Necrosis**

**LESION RATES**

OVERALL (a)	0/49 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.59	1/46.47	0/46.55	1/40.48
POLY-3 PERCENT (g)	0%	2.2%	0%	2.5%
TERMINAL (d)	0/34 (0%)	1/39 (3%)	0/38 (0%)	1/33 (3%)
FIRST INCIDENCE	---	727 (T)	---	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.389	P=0.527	(e)	P=0.494
POLY 3	P=0.393	P=0.517	(e)	P=0.490
POLY 1.5	P=0.401	P=0.514	(e)	P=0.497
POLY 6	P=0.384	P=0.519	(e)	P=0.482
LOGISTIC REGRESSION	(e)	P=0.527	(e)	P=0.494
COCH-ARM / FISHERS	P=0.408	P=0.505	(e)	P=0.505
ORDER RESTRICTED	P=0.241	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.257	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Harderian Gland  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	5/46 (11%)	5/50 (10%)	6/49 (12%)	2/48 (4%)
POLY-3 RATE (b)	5/40.92	5/46.62	6/46.08	2/39.83
POLY-3 PERCENT (g)	12.2%	10.7%	13%	5%
TERMINAL (d)	3/34 (9%)	4/39 (10%)	5/38 (13%)	1/33 (3%)
FIRST INCIDENCE	617	688	693	553

**STATISTICAL TESTS**

LIFE TABLE	P=0.210N	P=0.552N	P=0.576	P=0.248N
POLY 3	P=0.206N	P=0.546N	P=0.583	P=0.226N
POLY 1.5	P=0.189N	P=0.550N	P=0.573	P=0.212N
POLY 6	P=0.227N	P=0.552N	P=0.585	P=0.246N
LOGISTIC REGRESSION	P=0.186N	P=0.549N	P=0.580	P=0.204N
COCH-ARM / FISHERS	P=0.168N	P=0.575N	P=0.545	P=0.200N
ORDER RESTRICTED	P=0.243N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.253N	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Heart  
 Cardiomyopathy**

**LESION RATES**

OVERALL (a)	2/49 (4%)	2/50 (4%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	2/42.59	2/46.47	0/46.55	3/40.48
POLY-3 PERCENT (g)	4.7%	4.3%	0%	7.4%
TERMINAL (d)	2/34 (6%)	2/39 (5%)	0/38 (0%)	3/33 (9%)
FIRST INCIDENCE	727 (T)	727 (T)	---	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.394	P=0.645N	P=0.214N	P=0.486
POLY 3	P=0.411	P=0.662N	P=0.218N	P=0.477
POLY 1.5	P=0.418	P=0.668N	P=0.222N	P=0.493
POLY 6	P=0.404	P=0.660N	P=0.214N	P=0.458
LOGISTIC REGRESSION	P=0.394	P=0.645N	(e)	P=0.486
COCH-ARM / FISHERS	P=0.429	P=0.684N	P=0.242N	P=0.510
ORDER RESTRICTED	P=0.248	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.263	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Heart  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/49 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.59	1/46.88	0/46.55	2/41.20
POLY-3 PERCENT (g)	0%	2.1%	0%	4.9%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	609	---	531

**STATISTICAL TESTS**

LIFE TABLE	P=0.119	P=0.518	(e)	P=0.232
POLY 3	P=0.135	P=0.519	(e)	P=0.230
POLY 1.5	P=0.138	P=0.515	(e)	P=0.236
POLY 6	P=0.132	P=0.522	(e)	P=0.223
LOGISTIC REGRESSION	P=0.172	P=0.420	(e)	P=0.249
COCH-ARM / FISHERS	P=0.142	P=0.505	(e)	P=0.253
ORDER RESTRICTED	P=0.069	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.079	(e)	(e)	(e)

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 Species/Strain: MICE/B6C3F1

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Heart  
 Mineralization**

**LESION RATES**

OVERALL (a)	3/49 (6%)	2/50 (4%)	2/50 (4%)	5/50 (10%)
POLY-3 RATE (b)	3/43.44	2/47.30	2/46.94	5/43.02
POLY-3 PERCENT (g)	6.9%	4.2%	4.3%	11.6%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	1/38 (3%)	0/33 (0%)
FIRST INCIDENCE	594	605	616	538

**STATISTICAL TESTS**

LIFE TABLE	P=0.159	P=0.463N	P=0.457N	P=0.304
POLY 3	P=0.199	P=0.461N	P=0.465N	P=0.351
POLY 1.5	P=0.206	P=0.468N	P=0.471N	P=0.360
POLY 6	P=0.193	P=0.459N	P=0.462N	P=0.339
LOGISTIC REGRESSION	P=0.276	P=0.620N	P=0.540N	P=0.389
COCH-ARM / FISHERS	P=0.216	P=0.490N	P=0.490N	P=0.369
ORDER RESTRICTED	P=0.181	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.190	(e)	(e)	(e)



TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Heart  
 Thrombosis**

**LESION RATES**

OVERALL (a)	0/49 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.59	1/46.88	0/46.55	2/41.20
POLY-3 PERCENT (g)	0%	2.1%	0%	4.9%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	609	---	531

**STATISTICAL TESTS**

LIFE TABLE	P=0.119	P=0.518	(e)	P=0.232
POLY 3	P=0.135	P=0.519	(e)	P=0.230
POLY 1.5	P=0.138	P=0.515	(e)	P=0.236
POLY 6	P=0.132	P=0.522	(e)	P=0.223
LOGISTIC REGRESSION	P=0.172	P=0.420	(e)	P=0.249
COCH-ARM / FISHERS	P=0.142	P=0.505	(e)	P=0.253
ORDER RESTRICTED	P=0.069	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.079	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Heart: Artery  
 Inflammation Chronic

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.59	0/46.47	0/46.55	0/40.48
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Islets, Pancreatic  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	1/47 (2%)	1/50 (2%)	1/48 (2%)	2/49 (4%)
POLY-3 RATE (b)	1/41.35	1/46.67	1/45.86	2/40.09
POLY-3 PERCENT (g)	2.4%	2.1%	2.2%	5%
TERMINAL (d)	1/34 (3%)	0/39 (0%)	1/38 (3%)	2/33 (6%)
FIRST INCIDENCE	727 (T)	675	727 (T)	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.321	P=0.734N	P=0.737N	P=0.490
POLY 3	P=0.332	P=0.733N	P=0.737N	P=0.489
POLY 1.5	P=0.343	P=0.736N	P=0.742N	P=0.502
POLY 6	P=0.319	P=0.733N	P=0.734N	P=0.473
LOGISTIC REGRESSION	P=0.318	P=0.745N	P=0.737N	P=0.490
COCH-ARM / FISHERS	P=0.358	P=0.737N	P=0.747N	P=0.516
ORDER RESTRICTED	P=0.378	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.390	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Kidney  
 Infarct**

**LESION RATES**

OVERALL (a)	0/47 (0%)	0/50 (0%)	0/49 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/41.35	0/46.47	0/46.47	0/40.16
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Kidney  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/47 (0%)	0/50 (0%)	0/49 (0%)	1/49 (2%)
POLY-3 RATE (b)	0/41.35	0/46.47	0/46.47	1/40.27
POLY-3 PERCENT (g)	0%	0%	0%	2.5%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	698

**STATISTICAL TESTS**

LIFE TABLE	P=0.177	(e)	(e)	P=0.478
POLY 3	P=0.189	(e)	(e)	P=0.495
POLY 1.5	P=0.194	(e)	(e)	P=0.502
POLY 6	P=0.184	(e)	(e)	P=0.486
LOGISTIC REGRESSION	P=0.195	(e)	(e)	P=0.499
COCH-ARM / FISHERS	P=0.200	(e)	(e)	P=0.510
ORDER RESTRICTED	P=0.115	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.125	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Kidney  
 Nephropathy**

**LESION RATES**

OVERALL (a)	23/47 (49%)	30/50 (60%)	22/49 (45%)	33/49 (67%)
POLY-3 RATE (b)	23/43.80	30/49.34	22/47.63	33/47.38
POLY-3 PERCENT (g)	52.5%	60.8%	46.2%	69.7%
TERMINAL (d)	16/34 (47%)	22/39 (56%)	16/38 (42%)	20/33 (61%)
FIRST INCIDENCE	342	518	577	379

**STATISTICAL TESTS**

LIFE TABLE	P=0.042*	P=0.318	P=0.328N	P=0.044*
POLY 3	P=0.090	P=0.275	P=0.347N	P=0.069
POLY 1.5	P=0.087	P=0.252	P=0.360N	P=0.063
POLY 6	P=0.092	P=0.288	P=0.352N	P=0.073
LOGISTIC REGRESSION	P=0.090	P=0.191	P=0.389N	P=0.054
COCH-ARM / FISHERS	P=0.078	P=0.187	P=0.424N	P=0.052
ORDER RESTRICTED	P=0.074	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.083	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Kidney: Bilateral, Papilla  
 Necrosis**

**LESION RATES**

OVERALL (a)	0/47 (0%)	1/50 (2%)	0/49 (0%)	4/49 (8%)
POLY-3 RATE (b)	0/41.35	1/46.47	0/46.47	4/41.31
POLY-3 PERCENT (g)	0%	2.2%	0%	9.7%
TERMINAL (d)	0/34 (0%)	1/39 (3%)	0/38 (0%)	1/33 (3%)
FIRST INCIDENCE	---	727 (T)	---	531

**STATISTICAL TESTS**

LIFE TABLE	P=0.010**	P=0.527	(e)	P=0.058
POLY 3	P=0.012*	P=0.523	(e)	P=0.059
POLY 1.5	P=0.012*	P=0.521	(e)	P=0.063
POLY 6	P=0.011*	P=0.523	(e)	P=0.056
LOGISTIC REGRESSION	P=0.019*	P=0.527	(e)	P=0.071
COCH-ARM / FISHERS	P=0.014*	P=0.515	(e)	P=0.064
ORDER RESTRICTED	P=0.006**	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.007**	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Kidney: Papilla  
 Necrosis**

**LESION RATES**

OVERALL (a)	0/47 (0%)	1/50 (2%)	1/49 (2%)	18/49 (37%)
POLY-3 RATE (b)	0/41.35	1/46.47	1/46.61	18/43.27
POLY-3 PERCENT (g)	0%	2.2%	2.2%	41.6%
TERMINAL (d)	0/34 (0%)	1/39 (3%)	0/38 (0%)	11/33 (33%)
FIRST INCIDENCE	---	727 (T)	693	531

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.527	P=0.529	P<0.001**
POLY 3	P<0.001**	P=0.523	P=0.524	P<0.001**
POLY 1.5	P<0.001**	P=0.521	P=0.520	P<0.001**
POLY 6	P<0.001**	P=0.523	P=0.526	P<0.001**
LOGISTIC REGRESSION	P<0.001**	P=0.527	P=0.504	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.515	P=0.510	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)



TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Kidney: Renal Tubule  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/47 (0%)	0/50 (0%)	0/49 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/41.35	0/46.47	0/46.47	0/40.16
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Kidney: Renal Tubule  
 Necrosis**

**LESION RATES**

OVERALL (a)	0/47 (0%)	1/50 (2%)	0/49 (0%)	6/49 (12%)
POLY-3 RATE (b)	0/41.35	1/46.62	0/46.47	6/43.10
POLY-3 PERCENT (g)	0%	2.1%	0%	13.9%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	688	---	531

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.520	(e)	P=0.016*
POLY 3	P<0.001**	P=0.524	(e)	P=0.017*
POLY 1.5	P<0.001**	P=0.522	(e)	P=0.018*
POLY 6	P<0.001**	P=0.524	(e)	P=0.017*
LOGISTIC REGRESSION	P=0.003**	P=0.508	(e)	P=0.018*
COCH-ARM / FISHERS	P<0.001**	P=0.515	(e)	P=0.015*
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Liver  
 Angiectasis

**LESION RATES**

OVERALL (a)	2/49 (4%)	2/50 (4%)	2/49 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/42.70	2/46.47	2/46.47	0/40.48
POLY-3 PERCENT (g)	4.7%	4.3%	4.3%	0%
TERMINAL (d)	1/34 (3%)	2/39 (5%)	2/38 (5%)	0/33 (0%)
FIRST INCIDENCE	701	727 (T)	727 (T)	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.173N	P=0.647N	P=0.652N	P=0.256N
POLY 3	P=0.181N	P=0.663N	P=0.663N	P=0.249N
POLY 1.5	P=0.172N	P=0.668N	P=0.671N	P=0.241N
POLY 6	P=0.191N	P=0.661N	P=0.658N	P=0.259N
LOGISTIC REGRESSION	P=0.181N	P=0.661N	P=0.656N	P=0.255N
COCH-ARM / FISHERS	P=0.161N	P=0.684N	P=0.691N	P=0.242N
ORDER RESTRICTED	P=0.199N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.218N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Liver  
 Basophilic Focus

**LESION RATES**

OVERALL (a)	5/49 (10%)	4/50 (8%)	8/49 (16%)	4/50 (8%)
POLY-3 RATE (b)	5/42.59	4/46.47	8/46.58	4/40.48
POLY-3 PERCENT (g)	11.7%	8.6%	17.2%	9.9%
TERMINAL (d)	5/34 (15%)	4/39 (10%)	6/38 (16%)	4/33 (12%)
FIRST INCIDENCE	727 (T)	727 (T)	703	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.564N	P=0.414N	P=0.356	P=0.519N
POLY 3	P=0.538	P=0.446N	P=0.336	P=0.532N
POLY 1.5	P=0.549N	P=0.456N	P=0.319	P=0.510N
POLY 6	P=0.502	P=0.441N	P=0.349	P=0.558N
LOGISTIC REGRESSION	P=0.538	P=0.414N	P=0.357	P=0.519N
COCH-ARM / FISHERS	P=0.506N	P=0.487N	P=0.276	P=0.487N
ORDER RESTRICTED	P=0.486	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.499	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Liver  
 Clear Cell Focus

**LESION RATES**

OVERALL (a)	1/49 (2%)	1/50 (2%)	2/49 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/42.59	1/46.47	2/46.47	0/40.48
POLY-3 PERCENT (g)	2.4%	2.2%	4.3%	0%
TERMINAL (d)	1/34 (3%)	1/39 (3%)	2/38 (5%)	0/33 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	727 (T)	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.381N	P=0.731N	P=0.539	P=0.506N
POLY 3	P=0.394N	P=0.741N	P=0.530	P=0.510N
POLY 1.5	P=0.381N	P=0.745N	P=0.522	P=0.503N
POLY 6	P=0.408N	P=0.739N	P=0.536	P=0.518N
LOGISTIC REGRESSION	P=0.381N	P=0.731N	P=0.539	(e)
COCH-ARM / FISHERS	P=0.363N	P=0.747N	P=0.500	P=0.495N
ORDER RESTRICTED	P=0.303N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.321N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
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 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Liver  
 Eosinophilic Focus

**LESION RATES**

OVERALL (a)	5/49 (10%)	5/50 (10%)	4/49 (8%)	1/50 (2%)
POLY-3 RATE (b)	5/42.70	5/46.47	4/46.48	1/40.48
POLY-3 PERCENT (g)	11.7%	10.8%	8.6%	2.5%
TERMINAL (d)	4/34 (12%)	5/39 (13%)	3/38 (8%)	1/33 (3%)
FIRST INCIDENCE	699	727 (T)	725	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.075N	P=0.546N	P=0.430N	P=0.116N
POLY 3	P=0.081N	P=0.576N	P=0.447N	P=0.113N
POLY 1.5	P=0.074N	P=0.586N	P=0.462N	P=0.105N
POLY 6	P=0.090N	P=0.573N	P=0.438N	P=0.124N
LOGISTIC REGRESSION	P=0.080N	P=0.565N	P=0.426N	P=0.126N
COCH-ARM / FISHERS	P=0.065N	P=0.617N	P=0.500N	P=0.098N
ORDER RESTRICTED	P=0.108N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.123N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
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 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Liver  
 Fatty Change

**LESION RATES**

OVERALL (a)	3/49 (6%)	1/50 (2%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/43.28	1/46.47	1/46.47	0/40.48
POLY-3 PERCENT (g)	6.9%	2.2%	2.2%	0%
TERMINAL (d)	1/34 (3%)	1/39 (3%)	1/38 (3%)	0/33 (0%)
FIRST INCIDENCE	594	727 (T)	727 (T)	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.080N	P=0.270N	P=0.275N	P=0.148N
POLY 3	P=0.078N	P=0.280N	P=0.280N	P=0.131N
POLY 1.5	P=0.076N	P=0.283N	P=0.286N	P=0.123N
POLY 6	P=0.081N	P=0.281N	P=0.278N	P=0.141N
LOGISTIC REGRESSION	P=0.070N	P=0.315N	P=0.331N	P=0.114N
COCH-ARM / FISHERS	P=0.072N	P=0.301N	P=0.309N	P=0.117N
ORDER RESTRICTED	P=0.044N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.057N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Liver  
 Hepatodiaphragmatic Nodule

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.59	0/46.47	0/46.47	0/40.48
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)



TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

---

Liver  
 Infarct

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.59	0/46.47	0/46.47	0/40.48
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
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 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Liver  
 Mineralization**

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/49 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.59	0/46.47	0/46.47	2/41.58
POLY-3 PERCENT (g)	0%	0%	0%	4.8%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	554

**STATISTICAL TESTS**

LIFE TABLE	P=0.033*	(e)	(e)	P=0.209
POLY 3	P=0.044*	(e)	(e)	P=0.232
POLY 1.5	P=0.045*	(e)	(e)	P=0.237
POLY 6	P=0.043*	(e)	(e)	P=0.226
LOGISTIC REGRESSION	P=0.073	(e)	(e)	P=0.242
COCH-ARM / FISHERS	P=0.047*	(e)	(e)	P=0.253
ORDER RESTRICTED	P=0.027*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.033*	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Liver  
 Necrosis

**LESION RATES**

OVERALL (a)	3/49 (6%)	0/50 (0%)	1/49 (2%)	8/50 (16%)
POLY-3 RATE (b)	3/44.57	0/46.47	1/46.56	8/44.97
POLY-3 PERCENT (g)	6.7%	0%	2.2%	17.8%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	292	---	705	538

**STATISTICAL TESTS**

LIFE TABLE	P=0.006**	P=0.114N	P=0.283N	P=0.096
POLY 3	P=0.007**	P=0.111N	P=0.290N	P=0.100
POLY 1.5	P=0.007**	P=0.112N	P=0.294N	P=0.102
POLY 6	P=0.007**	P=0.112N	P=0.287N	P=0.101
LOGISTIC REGRESSION	P=0.014*	P=0.390N	P=0.709N	P=0.097
COCH-ARM / FISHERS	P=0.008**	P=0.117N	P=0.309N	P=0.106
ORDER RESTRICTED	P=0.002**	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.003**	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
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 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Lung: Alveolar Epithelium  
 Hyperplasia

**LESION RATES**

OVERALL (a)	2/48 (4%)	1/50 (2%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	2/41.83	1/46.47	4/46.55	0/40.48
POLY-3 PERCENT (g)	4.8%	2.2%	8.6%	0%
TERMINAL (d)	2/34 (6%)	1/39 (3%)	4/38 (11%)	0/33 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	727 (T)	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.294N	P=0.452N	P=0.389	P=0.245N
POLY 3	P=0.314N	P=0.463N	P=0.388	P=0.244N
POLY 1.5	P=0.294N	P=0.468N	P=0.379	P=0.236N
POLY 6	P=0.337N	P=0.462N	P=0.393	P=0.255N
LOGISTIC REGRESSION	P=0.294N	P=0.452N	P=0.389	(e)
COCH-ARM / FISHERS	P=0.268N	P=0.485N	P=0.359	P=0.237N
ORDER RESTRICTED	P=0.189N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.203N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

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 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Mesentery: Fat  
 Necrosis

**LESION RATES**

OVERALL (a)	14/15 (93%)	14/14 (100%)	13/14 (93%)	6/6 (100%)
POLY-3 RATE (b)	14/14.65	14/14.00	13/14.00	6/6.00
POLY-3 PERCENT (g)	95.5%	100%	92.9%	100%
TERMINAL (d)	12/12 (100%)	11/11 (100%)	12/13 (92%)	6/6 (100%)
FIRST INCIDENCE	617	610	709	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.107N	P=0.547	P=0.289N	P=0.273N
POLY 3	P=0.694	P=0.707	P=0.695N	P=0.845
POLY 1.5	P=0.635	P=0.604	P=0.721N	P=0.762
POLY 6	P=0.756N	P=0.908	P=0.644N	P=0.968
LOGISTIC REGRESSION	P=0.749N	P=0.560	P=0.550N	P=0.273N
COCH-ARM / FISHERS	P=0.570	P=0.517	P=0.741N	P=0.714
ORDER RESTRICTED	P=0.533	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.520	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
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 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Nose: Glands  
 Hyperplasia

**LESION RATES**

OVERALL (a)	6/48 (13%)	38/50 (76%)	49/50 (98%)	49/50 (98%)
POLY-3 RATE (b)	6/41.90	38/49.44	49/49.08	49/49.06
POLY-3 PERCENT (g)	14.3%	76.9%	99.8%	99.9%
TERMINAL (d)	5/34 (15%)	29/39 (74%)	38/38 (100%)	33/33 (100%)
FIRST INCIDENCE	709	518	577	379

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P<0.001**	P<0.001**	P<0.001**
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**
LOGISTIC REGRESSION	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**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Nose: Olfactory Epithelium  
 Accumulation, Hyaline Droplet

**LESION RATES**

OVERALL (a)	0/48 (0%)	4/50 (8%)	18/50 (36%)	12/50 (24%)
POLY-3 RATE (b)	0/41.83	4/47.21	18/47.34	12/42.71
POLY-3 PERCENT (g)	0%	8.5%	38%	28.1%
TERMINAL (d)	0/34 (0%)	2/39 (5%)	14/38 (37%)	8/33 (24%)
FIRST INCIDENCE	---	518	587	553

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.083	P<0.001**	P<0.001**
POLY 3	P<0.001**	P=0.077	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.074	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.079	P<0.001**	P<0.001**
LOGISTIC REGRESSION	P<0.001**	P=0.049*	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.064	P<0.001**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
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 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Nose: Olfactory Epithelium  
 Atrophy**

**LESION RATES**

OVERALL (a)	3/48 (6%)	8/50 (16%)	36/50 (72%)	43/50 (86%)
POLY-3 RATE (b)	3/42.88	8/46.97	36/47.66	43/47.48
POLY-3 PERCENT (g)	7%	17%	75.5%	90.6%
TERMINAL (d)	1/34 (3%)	7/39 (18%)	30/38 (79%)	30/33 (91%)
FIRST INCIDENCE	292	577	587	379

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.147	P<0.001**	P<0.001**
POLY 3	P<0.001**	P=0.129	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.125	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.130	P<0.001**	P<0.001**
LOGISTIC REGRESSION	P<0.001**	P=0.080	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.113	P<0.001**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)



TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Nose: Olfactory Epithelium  
 Degeneration**

**LESION RATES**

OVERALL (a)	0/48 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/41.83	0/46.47	1/46.55	2/41.89
POLY-3 PERCENT (g)	0%	0%	2.2%	4.8%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	1/38 (3%)	0/33 (0%)
FIRST INCIDENCE	---	---	727 (T)	379

**STATISTICAL TESTS**

LIFE TABLE	P=0.063	(e)	P=0.522	P=0.236
POLY 3	P=0.065	(e)	P=0.521	P=0.237
POLY 1.5	P=0.068	(e)	P=0.518	P=0.243
POLY 6	P=0.062	(e)	P=0.524	P=0.230
LOGISTIC REGRESSION	P=0.100	(e)	P=0.522	P=0.209
COCH-ARM / FISHERS	P=0.073	(e)	P=0.510	P=0.258
ORDER RESTRICTED	P=0.074	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.079	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

---

Nose: Olfactory Epithelium  
 Metaplasia

**LESION RATES**

OVERALL (a)	0/48 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/41.83	0/46.47	0/46.55	0/40.48
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
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 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Nose: Olfactory Epithelium  
 Respiratory Metaplasia**

**LESION RATES**

OVERALL (a)	6/48 (13%)	37/50 (74%)	49/50 (98%)	50/50 (100%)
POLY-3 RATE (b)	6/42.71	37/49.44	49/49.08	50/50.00
POLY-3 PERCENT (g)	14.1%	74.8%	99.8%	100%
TERMINAL (d)	4/34 (12%)	28/39 (72%)	38/38 (100%)	33/33 (100%)
FIRST INCIDENCE	423	518	577	277

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P<0.001**	P<0.001**	P<0.001**
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**
LOGISTIC REGRESSION	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**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Ovary  
 Angiectasis**

**LESION RATES**

OVERALL (a)	2/48 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/41.83	0/46.47	0/46.55	1/40.48
POLY-3 PERCENT (g)	4.8%	0%	0%	2.5%
TERMINAL (d)	2/34 (6%)	0/39 (0%)	0/38 (0%)	1/33 (3%)
FIRST INCIDENCE	727 (T)	---	---	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.476N	P=0.209N	P=0.214N	P=0.510N
POLY 3	P=0.453N	P=0.214N	P=0.214N	P=0.511N
POLY 1.5	P=0.456N	P=0.217N	P=0.218N	P=0.499N
POLY 6	P=0.448N	P=0.213N	P=0.211N	P=0.527N
LOGISTIC REGRESSION	P=0.476N	(e)	(e)	P=0.510N
COCH-ARM / FISHERS	P=0.452N	P=0.237N	P=0.237N	P=0.485N
ORDER RESTRICTED	P=0.132N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.144N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Ovary  
 Cyst

**LESION RATES**

OVERALL (a)	5/48 (10%)	12/50 (24%)	5/50 (10%)	4/50 (8%)
POLY-3 RATE (b)	5/41.83	12/47.16	5/46.69	4/42.15
POLY-3 PERCENT (g)	12%	25.4%	10.7%	9.5%
TERMINAL (d)	5/34 (15%)	9/39 (23%)	4/38 (11%)	1/33 (3%)
FIRST INCIDENCE	727 (T)	632	693	553

**STATISTICAL TESTS**

LIFE TABLE	P=0.216N	P=0.100	P=0.557N	P=0.524N
POLY 3	P=0.172N	P=0.088	P=0.560N	P=0.495N
POLY 1.5	P=0.164N	P=0.081	P=0.573N	P=0.484N
POLY 6	P=0.182N	P=0.093	P=0.550N	P=0.509N
LOGISTIC REGRESSION	P=0.174N	P=0.085	P=0.551N	P=0.473N
COCH-ARM / FISHERS	P=0.161N	P=0.065	P=0.603N	P=0.474N
ORDER RESTRICTED	P=0.170N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.177N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Pancreas  
 Amyloid Deposition**

**LESION RATES**

OVERALL (a)	0/47 (0%)	2/50 (4%)	0/47 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/41.35	2/46.77	0/44.95	0/40.09
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/34 (0%)	1/39 (3%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	647	---	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.424N	P=0.266	(e)	(e)
POLY 3	P=0.396N	P=0.265	(e)	(e)
POLY 1.5	P=0.395N	P=0.262	(e)	(e)
POLY 6	P=0.399N	P=0.266	(e)	(e)
LOGISTIC REGRESSION	P=0.398N	P=0.241	(e)	(e)
COCH-ARM / FISHERS	P=0.401N	P=0.263	(e)	(e)
ORDER RESTRICTED	P=0.278N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.292N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Pancreas  
 Atrophy**

**LESION RATES**

OVERALL (a)	0/47 (0%)	1/50 (2%)	1/47 (2%)	0/49 (0%)
POLY-3 RATE (b)	0/41.35	1/46.77	1/44.95	0/40.09
POLY-3 PERCENT (g)	0%	2.1%	2.2%	0%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	1/38 (3%)	0/33 (0%)
FIRST INCIDENCE	---	647	727 (T)	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.620N	P=0.519	P=0.522	(e)
POLY 3	P=0.606N	P=0.525	P=0.517	(e)
POLY 1.5	P=0.598N	P=0.522	P=0.512	(e)
POLY 6	P=0.616N	P=0.525	P=0.519	(e)
LOGISTIC REGRESSION	P=0.587N	P=0.471	P=0.522	(e)
COCH-ARM / FISHERS	P=0.591N	P=0.515	P=0.500	(e)
ORDER RESTRICTED	P=0.425	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.437	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Pancreas  
 Basophilic Focus**

**LESION RATES**

OVERALL (a)	1/47 (2%)	2/50 (4%)	1/47 (2%)	1/49 (2%)
POLY-3 RATE (b)	1/41.35	2/46.47	1/44.95	1/40.09
POLY-3 PERCENT (g)	2.4%	4.3%	2.2%	2.5%
TERMINAL (d)	1/34 (3%)	2/39 (5%)	1/38 (3%)	1/33 (3%)
FIRST INCIDENCE	727 (T)	727 (T)	727 (T)	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.553N	P=0.548	P=0.737N	P=0.755
POLY 3	P=0.539N	P=0.541	P=0.742N	P=0.754
POLY 1.5	P=0.532N	P=0.537	P=0.747N	P=0.760N
POLY 6	P=0.548N	P=0.540	P=0.739N	P=0.744
LOGISTIC REGRESSION	P=0.553N	P=0.548	P=0.737N	P=0.755
COCH-ARM / FISHERS	P=0.523N	P=0.523	P=0.753N	P=0.742N
ORDER RESTRICTED	P=0.609N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.615N	(e)	(e)	(e)



TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Pituitary Gland: Pars Distalis  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	9/47 (19%)	17/48 (35%)	6/50 (12%)	9/50 (18%)
POLY-3 RATE (b)	9/41.18	17/45.72	6/46.55	9/41.19
POLY-3 PERCENT (g)	21.9%	37.2%	12.9%	21.9%
TERMINAL (d)	9/34 (27%)	14/38 (37%)	6/38 (16%)	7/33 (21%)
FIRST INCIDENCE	727 (T)	632	727 (T)	605

**STATISTICAL TESTS**

LIFE TABLE	P=0.299N	P=0.100	P=0.207N	P=0.565
POLY 3	P=0.234N	P=0.091	P=0.204N	P=0.605N
POLY 1.5	P=0.213N	P=0.082	P=0.214N	P=0.575N
POLY 6	P=0.259N	P=0.098	P=0.199N	P=0.572
LOGISTIC REGRESSION	P=0.299N	P=0.085	P=0.207N	P=0.545
COCH-ARM / FISHERS	P=0.197N	P=0.060	P=0.245N	P=0.545N
ORDER RESTRICTED	P=0.135N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.143N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Skin  
 Inflammation Chronic**

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.59	0/46.47	1/46.69	0/40.48
POLY-3 PERCENT (g)	0%	0%	2.1%	0%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	693	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.687	(e)	P=0.529	(e)
POLY 3	P=0.651	(e)	P=0.518	(e)
POLY 1.5	P=0.671	(e)	P=0.514	(e)
POLY 6	P=0.628	(e)	P=0.522	(e)
LOGISTIC REGRESSION	P=0.697	(e)	P=0.505	(e)
COCH-ARM / FISHERS	P=0.697	(e)	P=0.505	(e)
ORDER RESTRICTED	P=0.397	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.411	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Spleen  
 Depletion Cellular**

**LESION RATES**

OVERALL (a)	0/48 (0%)	0/50 (0%)	0/49 (0%)	9/50 (18%)
POLY-3 RATE (b)	0/41.83	0/46.47	0/46.47	9/45.79
POLY-3 PERCENT (g)	0%	0%	0%	19.7%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	379

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	(e)	(e)	P=0.003**
POLY 3	P<0.001**	(e)	(e)	P=0.003**
POLY 1.5	P<0.001**	(e)	(e)	P=0.003**
POLY 6	P<0.001**	(e)	(e)	P=0.003**
LOGISTIC REGRESSION	P<0.001**	(e)	(e)	P=0.002**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.002**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Spleen  
 Hematopoietic Cell Proliferation**

**LESION RATES**

OVERALL (a)	1/48 (2%)	5/50 (10%)	2/49 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/41.99	5/47.52	2/46.68	0/40.48
POLY-3 PERCENT (g)	2.4%	10.5%	4.3%	0%
TERMINAL (d)	0/34 (0%)	2/39 (5%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	686	609	693	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.194N	P=0.136	P=0.543	P=0.527N
POLY 3	P=0.174N	P=0.133	P=0.537	P=0.507N
POLY 1.5	P=0.163N	P=0.127	P=0.529	P=0.500N
POLY 6	P=0.189N	P=0.137	P=0.542	P=0.517N
LOGISTIC REGRESSION	P=0.151N	P=0.086	P=0.507	P=0.497N
COCH-ARM / FISHERS	P=0.157N	P=0.112	P=0.508	P=0.490N
ORDER RESTRICTED	P=0.117N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.131N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
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 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Stomach, Forestomach  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	2/48 (4%)	8/50 (16%)	5/49 (10%)	8/50 (16%)
POLY-3 RATE (b)	2/43.22	8/47.99	5/47.11	8/42.41
POLY-3 PERCENT (g)	4.6%	16.7%	10.6%	18.9%
TERMINAL (d)	0/34 (0%)	3/39 (8%)	3/38 (8%)	4/33 (12%)
FIRST INCIDENCE	292	518	577	497

**STATISTICAL TESTS**

LIFE TABLE	P=0.069	P=0.077	P=0.262	P=0.043*
POLY 3	P=0.081	P=0.065	P=0.253	P=0.041*
POLY 1.5	P=0.090	P=0.061	P=0.245	P=0.046*
POLY 6	P=0.073	P=0.068	P=0.258	P=0.037*
LOGISTIC REGRESSION	P=0.147	P=0.012*	P=0.075	P=0.059
COCH-ARM / FISHERS	P=0.105	P=0.053	P=0.226	P=0.053
ORDER RESTRICTED	P=0.036*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.044*	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Stomach, Forestomach  
 Inflammation**

**LESION RATES**

OVERALL (a)	2/48 (4%)	8/50 (16%)	5/49 (10%)	8/50 (16%)
POLY-3 RATE (b)	2/43.22	8/47.99	5/47.36	8/41.87
POLY-3 PERCENT (g)	4.6%	16.7%	10.6%	19.1%
TERMINAL (d)	0/34 (0%)	3/39 (8%)	3/38 (8%)	5/33 (15%)
FIRST INCIDENCE	292	518	577	497

**STATISTICAL TESTS**

LIFE TABLE	P=0.070	P=0.077	P=0.259	P=0.045*
POLY 3	P=0.078	P=0.065	P=0.255	P=0.039*
POLY 1.5	P=0.088	P=0.061	P=0.246	P=0.044*
POLY 6	P=0.069	P=0.068	P=0.262	P=0.034*
LOGISTIC REGRESSION	P=0.144	P=0.012*	P=0.060	P=0.060
COCH-ARM / FISHERS	P=0.105	P=0.053	P=0.226	P=0.053
ORDER RESTRICTED	P=0.035*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.043*	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
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 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Stomach, Forestomach  
 Ulcer

**LESION RATES**

OVERALL (a)	2/48 (4%)	4/50 (8%)	3/49 (6%)	4/50 (8%)
POLY-3 RATE (b)	2/43.22	4/47.15	3/47.36	4/41.87
POLY-3 PERCENT (g)	4.6%	8.5%	6.3%	9.6%
TERMINAL (d)	0/34 (0%)	1/39 (3%)	1/38 (3%)	1/33 (3%)
FIRST INCIDENCE	292	605	577	497

**STATISTICAL TESTS**

LIFE TABLE	P=0.273	P=0.384	P=0.533	P=0.308
POLY 3	P=0.307	P=0.378	P=0.542	P=0.322
POLY 1.5	P=0.323	P=0.373	P=0.532	P=0.337
POLY 6	P=0.291	P=0.381	P=0.549	P=0.307
LOGISTIC REGRESSION	P=0.420	P=0.158	P=0.170	P=0.364
COCH-ARM / FISHERS	P=0.346	P=0.359	P=0.510	P=0.359
ORDER RESTRICTED	P=0.314	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.329	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Stomach, Glandular  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/46 (0%)	1/48 (2%)	1/47 (2%)	6/48 (13%)
POLY-3 RATE (b)	0/40.42	1/45.15	1/44.95	6/43.37
POLY-3 PERCENT (g)	0%	2.2%	2.2%	13.8%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	1/38 (3%)	0/33 (0%)
FIRST INCIDENCE	---	701	727 (T)	531

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.520	P=0.522	P=0.016*
POLY 3	P=0.002**	P=0.522	P=0.521	P=0.019*
POLY 1.5	P=0.002**	P=0.519	P=0.517	P=0.019*
POLY 6	P=0.002**	P=0.523	P=0.524	P=0.019*
LOGISTIC REGRESSION	P=0.002**	P=0.513	P=0.522	P=0.008**
COCH-ARM / FISHERS	P=0.002**	P=0.511	P=0.505	P=0.015*
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.002**	(e)	(e)	(e)



TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

---

**Stomach, Glandular  
 Inflammation Acute**

**LESION RATES**

OVERALL (a)	0/46 (0%)	0/48 (0%)	0/47 (0%)	0/48 (0%)
POLY-3 RATE (b)	0/40.42	0/45.05	0/44.95	0/39.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
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 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Stomach, Glandular  
 Ulcer**

**LESION RATES**

OVERALL (a)	0/46 (0%)	1/48 (2%)	1/47 (2%)	7/48 (15%)
POLY-3 RATE (b)	0/40.42	1/45.15	1/44.95	7/43.93
POLY-3 PERCENT (g)	0%	2.2%	2.2%	15.9%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	1/38 (3%)	0/33 (0%)
FIRST INCIDENCE	---	701	727 (T)	531

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.520	P=0.522	P=0.009**
POLY 3	P<0.001**	P=0.522	P=0.521	P=0.010**
POLY 1.5	P<0.001**	P=0.519	P=0.517	P=0.010**
POLY 6	P<0.001**	P=0.523	P=0.524	P=0.010**
LOGISTIC REGRESSION	P<0.001**	P=0.513	P=0.522	P=0.004**
COCH-ARM / FISHERS	P<0.001**	P=0.511	P=0.505	P=0.007**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:50:37  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

**Thyroid Gland: Follicular Cell  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	1/48 (2%)	0/50 (0%)	0/49 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/41.83	0/46.47	0/46.47	1/40.48
POLY-3 PERCENT (g)	2.4%	0%	0%	2.5%
TERMINAL (d)	1/34 (3%)	0/39 (0%)	0/38 (0%)	1/33 (3%)
FIRST INCIDENCE	727 (T)	---	---	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.584	P=0.473N	P=0.478N	P=0.755
POLY 3	P=0.583	P=0.479N	P=0.479N	P=0.753
POLY 1.5	P=0.589	P=0.482N	P=0.484N	P=0.760N
POLY 6	P=0.578	P=0.478N	P=0.476N	P=0.743
LOGISTIC REGRESSION	P=0.584	(e)	(e)	P=0.755
COCH-ARM / FISHERS	P=0.601	P=0.490N	P=0.495N	P=0.742N
ORDER RESTRICTED	P=0.378	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.391	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

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 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Uterus  
 Angiectasis

**LESION RATES**

OVERALL (a)	2/48 (4%)	3/50 (6%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/41.83	3/46.88	2/46.55	0/40.48
POLY-3 PERCENT (g)	4.8%	6.4%	4.3%	0%
TERMINAL (d)	2/34 (6%)	2/39 (5%)	2/38 (5%)	0/33 (0%)
FIRST INCIDENCE	727 (T)	609	727 (T)	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.146N	P=0.558	P=0.655N	P=0.245N
POLY 3	P=0.145N	P=0.552	P=0.655N	P=0.244N
POLY 1.5	P=0.137N	P=0.543	P=0.662N	P=0.236N
POLY 6	P=0.155N	P=0.556	P=0.651N	P=0.255N
LOGISTIC REGRESSION	P=0.138N	P=0.535	P=0.655N	(e)
COCH-ARM / FISHERS	P=0.127N	P=0.520	P=0.676N	P=0.237N
ORDER RESTRICTED	P=0.160N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.173N	(e)	(e)	(e)

TDMS No. 88105-04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG

Uterus: Endometrium  
 Hyperplasia Cystic

**LESION RATES**

OVERALL (a)	24/48 (50%)	32/50 (64%)	19/50 (38%)	21/50 (42%)
POLY-3 RATE (b)	24/42.51	32/47.36	19/47.11	21/42.44
POLY-3 PERCENT (g)	56.5%	67.6%	40.3%	49.5%
TERMINAL (d)	20/34 (59%)	28/39 (72%)	15/38 (40%)	17/33 (52%)
FIRST INCIDENCE	616	632	632	553

**STATISTICAL TESTS**

LIFE TABLE	P=0.185N	P=0.251	P=0.105N	P=0.415N
POLY 3	P=0.101N	P=0.188	P=0.091N	P=0.331N
POLY 1.5	P=0.086N	P=0.169	P=0.108N	P=0.297N
POLY 6	P=0.123N	P=0.191	P=0.081N	P=0.383N
LOGISTIC REGRESSION	P=0.184N	P=0.189	P=0.082N	P=0.429N
COCH-ARM / FISHERS	P=0.078N	P=0.116	P=0.160N	P=0.277N
ORDER RESTRICTED	P=0.075N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.081N	(e)	(e)	(e)

TDMS No. 88105-04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
ISOEUGENOL  
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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.
  - (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. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death.
  - (e) Value of Statistic cannot be computed.
  - (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
- Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors.  
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

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