

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
ISOEUGENOL  
CAS Number: 97-54-1  
Pathologist: Blackshear, P. - GRUMBEIN, S.  
F1\_M3

Date Report Requested: 10/04/2006  
Time Report Requested: 13:47:31  
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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**FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES EXAMINED.  
IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.**

Adrenal Cortex  
Adrenal Medulla  
Bone Marrow  
Clitoral/Preputial Gland  
Heart  
Kidney  
Liver  
Lung  
Ovary  
Pituitary Gland  
Spleen  
Testes  
Thyroid Gland

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

### MALE MICE

#### Organ

Harderian Gland  
Liver

All Organs

#### Morphology

Carcinoma or Adenoma  
Hepatocellular Adenoma  
Hepatocellular Carcinoma  
Hepatocellular Carcinoma or Hepatoblastoma  
Hepatocellular Carcinoma or Hepatocellular Adenoma  
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma  
Benign Tumors  
Malignant Tumors  
Malignant and Benign Tumors

### FEMALE MICE

#### Organ

Liver

Skin

All Organs

#### Morphology

Hepatocellular Adenoma  
Hepatocellular Carcinoma  
Hepatocellular Carcinoma or Hepatoblastoma  
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous  
Histiocytoma  
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma  
Sarcoma  
Histiocytic Sarcoma  
Malignant and Benign Tumors

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Adrenal Cortex  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	3/50 (6%)	0/50 (0%)	3/50 (6%)	0/49 (0%)
POLY-3 RATE (b)	3/44.38	0/45.3	3/45.85	0/38.1
POLY-3 PERCENT (g)	6.8%	0%	6.5%	0%
TERMINAL (d)	3/39 (8%)	0/38 (0%)	3/36 (8%)	0/27 (0%)
FIRST INCIDENCE	728 (T)	---	728 (T)	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.243N	P=0.126N	P=0.626	P=0.193N
POLY 3	P=0.202N	P=0.115N	P=0.647N	P=0.148N
POLY 1.5	P=0.188N	P=0.116N	P=0.650N	P=0.137N
POLY 6	P=0.219N	P=0.114N	P=0.649N	P=0.162N
LOGISTIC REGRESSION	P=0.243N	(e)	P=0.626	(e)
COCH-ARM / FISHERS	P=0.167N	P=0.121N	P=0.661N	P=0.125N
ORDER RESTRICTED	P=0.076N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.098N	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
<b>Harderian Gland Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	8/50 (16%)	4/50 (8%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	8/44.49	4/45.3	3/45.85	3/38.27
POLY-3 PERCENT (g)	18%	8.8%	6.5%	7.8%
TERMINAL (d)	7/39 (18%)	4/38 (11%)	3/36 (8%)	3/27 (11%)
FIRST INCIDENCE	700	728 (T)	728 (T)	728 (T)
<b>STATISTICAL TESTS</b>				
LIFE TABLE	P=0.184N	P=0.190N	P=0.125N	P=0.254N
POLY 3	P=0.102N	P=0.167N	P=0.089N	P=0.152N
POLY 1.5	P=0.093N	P=0.169N	P=0.091N	P=0.128N
POLY 6	P=0.114N	P=0.166N	P=0.089N	P=0.182N
LOGISTIC REGRESSION	P=0.159N	P=0.168N	P=0.097N	P=0.212N
COCH-ARM / FISHERS	P=0.078N	P=0.178N	P=0.100N	P=0.100N
ORDER RESTRICTED	P=0.088N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.112N	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Harderian Gland  
 Carcinoma**

**TUMOR RATES**

	#	#	#	#
OVERALL (a)	4/50 (8%)	3/50 (6%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	4/45.11	3/46.49	2/45.85	1/38.27
POLY-3 PERCENT (g)	8.9%	6.5%	4.4%	2.6%
TERMINAL (d)	3/39 (8%)	1/38 (3%)	2/36 (6%)	1/27 (4%)
FIRST INCIDENCE	468	441	728 (T)	728 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.185N	P=0.501N	P=0.367N	P=0.287N
POLY 3	P=0.148N	P=0.484N	P=0.330N	P=0.233N
POLY 1.5	P=0.135N	P=0.488N	P=0.330N	P=0.210N
POLY 6	P=0.163N	P=0.480N	P=0.333N	P=0.259N
LOGISTIC REGRESSION	P=0.091N	P=0.557N	P=0.349N	P=0.184N
COCH-ARM / FISHERS	P=0.114N	P=0.500N	P=0.339N	P=0.181N
ORDER RESTRICTED	P=0.184N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.219N	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Harderian Gland  
 Carcinoma or Adenoma**

**TUMOR RATES**

	#	#	#	#
OVERALL (a)	12/50 (24%)	7/50 (14%)	5/50 (10%)	4/50 (8%)
POLY-3 RATE (b)	12/45.22	7/46.49	5/45.85	4/38.27
POLY-3 PERCENT (g)	26.5%	15.1%	10.9%	10.5%
TERMINAL (d)	10/39 (26%)	5/38 (13%)	5/36 (14%)	4/27 (15%)
FIRST INCIDENCE	468	441	728 (T)	728 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.073N	P=0.170N	P=0.075N	P=0.118N
POLY 3	P=0.034N*	P=0.135N	P=0.048N*	P=0.055N
POLY 1.5	P=0.027N*	P=0.140N	P=0.048N*	P=0.041N*
POLY 6	P=0.042N*	P=0.131N	P=0.049N*	P=0.076N
LOGISTIC REGRESSION	P=0.028N*	P=0.155N	P=0.048N*	P=0.059N
COCH-ARM / FISHERS	P=0.019N*	P=0.154N	P=0.054N	P=0.027N*
ORDER RESTRICTED	P=0.035N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.052N	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Intestine Small: Site Unspecified  
 Carcinoma or Adenoma**

**TUMOR RATES**

	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.38	0/45.3	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)



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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Liver  
 Hemangiosarcoma

**TUMOR RATES**

OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/44.38	2/46.22	1/46.03	0/38.27
POLY-3 PERCENT (g)	2.3%	4.3%	2.2%	0%
TERMINAL (d)	1/39 (3%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	728 (T)	510	682	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.300N	P=0.502	P=0.757	P=0.573N
POLY 3	P=0.281N	P=0.514	P=0.752N	P=0.529N
POLY 1.5	P=0.268N	P=0.510	P=0.754N	P=0.517N
POLY 6	P=0.295N	P=0.518	P=0.752N	P=0.543N
LOGISTIC REGRESSION	P=0.212N	P=0.460	P=0.759N	(e)
COCH-ARM / FISHERS	P=0.247N	P=0.500	P=0.753N	P=0.500N
ORDER RESTRICTED	P=0.265N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.297N	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
<b>Liver</b>				
<b>Hepatoblastoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	3/44.82	1/45.3	0/45.85	2/38.59
POLY-3 PERCENT (g)	6.7%	2.2%	0%	5.2%
TERMINAL (d)	2/39 (5%)	1/38 (3%)	0/36 (0%)	1/27 (4%)
FIRST INCIDENCE	599	728 (T)	---	640
<b>STATISTICAL TESTS</b>				
LIFE TABLE	P=0.555N	P=0.310N	P=0.130N	P=0.630N
POLY 3	P=0.449N	P=0.301N	P=0.115N	P=0.568N
POLY 1.5	P=0.449N	P=0.301N	P=0.115N	P=0.540N
POLY 6	P=0.447N	P=0.303N	P=0.116N	P=0.597N
LOGISTIC REGRESSION	P=0.459N	P=0.303N	P=0.123N	P=0.529N
COCH-ARM / FISHERS	P=0.444N	P=0.309N	P=0.121N	P=0.500N
ORDER RESTRICTED	P=0.226N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.258N	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Liver  
 Hepatocellular Adenoma

**TUMOR RATES**

OVERALL (a)	24/50 (48%)	35/50 (70%)	37/50 (74%)	33/50 (66%)
POLY-3 RATE (b)	24/45.3	35/46.22	37/48.11	33/42.46
POLY-3 PERCENT (g)	53%	75.7%	76.9%	77.7%
TERMINAL (d)	22/39 (56%)	31/38 (82%)	29/36 (81%)	23/27 (85%)
FIRST INCIDENCE	469	646	491	408

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.013*	P=0.003**	P<0.001**
POLY 3	P=0.012*	P=0.015*	P=0.010**	P=0.009**
POLY 1.5	P=0.026*	P=0.017*	P=0.009**	P=0.019*
POLY 6	P=0.006**	P=0.015*	P=0.011*	P=0.005**
LOGISTIC REGRESSION	P=0.005**	P=0.021*	P=0.010**	P=0.006**
COCH-ARM / FISHERS	P=0.077	P=0.021*	P=0.007**	P=0.053
ORDER RESTRICTED	P=0.005**	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.007**	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Liver  
 Hepatocellular Carcinoma

**TUMOR RATES**

OVERALL (a)	8/50 (16%)	18/50 (36%)	19/50 (38%)	18/50 (36%)
POLY-3 RATE (b)	8/46.08	18/47.53	19/49.15	18/44.56
POLY-3 PERCENT (g)	17.4%	37.9%	38.7%	40.4%
TERMINAL (d)	5/39 (13%)	10/38 (26%)	9/36 (25%)	5/27 (19%)
FIRST INCIDENCE	469	481	491	385

**STATISTICAL TESTS**

LIFE TABLE	P=0.008**	P=0.031*	P=0.019*	P=0.007**
POLY 3	P=0.027*	P=0.022*	P=0.017*	P=0.012*
POLY 1.5	P=0.032*	P=0.020*	P=0.015*	P=0.014*
POLY 6	P=0.023*	P=0.024*	P=0.019*	P=0.010**
LOGISTIC REGRESSION	P=0.101	P=0.018*	P=0.006**	P=0.045*
COCH-ARM / FISHERS	P=0.042*	P=0.020*	P=0.012*	P=0.020*
ORDER RESTRICTED	P=0.013*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.017*	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Liver  
 Hepatocellular Carcinoma or Hepatoblastoma

**TUMOR RATES**

OVERALL (a)	11/50 (22%)	19/50 (38%)	19/50 (38%)	20/50 (40%)
POLY-3 RATE (b)	11/46.52	19/47.53	19/49.15	20/44.88
POLY-3 PERCENT (g)	23.7%	40%	38.7%	44.6%
TERMINAL (d)	7/39 (18%)	11/38 (29%)	9/36 (25%)	6/27 (22%)
FIRST INCIDENCE	469	481	491	385

**STATISTICAL TESTS**

LIFE TABLE	P=0.011*	P=0.085	P=0.077	P=0.013*
POLY 3	P=0.042*	P=0.068	P=0.085	P=0.027*
POLY 1.5	P=0.050*	P=0.066	P=0.078	P=0.032*
POLY 6	P=0.036*	P=0.071	P=0.091	P=0.023*
LOGISTIC REGRESSION	P=0.135	P=0.058	P=0.039*	P=0.082
COCH-ARM / FISHERS	P=0.063	P=0.063	P=0.063	P=0.041*
ORDER RESTRICTED	P=0.026*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.032*	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Liver  
 Hepatocellular Carcinoma or Hepatocellular Adenoma

**TUMOR RATES**

OVERALL (a)	28/50 (56%)	43/50 (86%)	43/50 (86%)	43/50 (86%)
POLY-3 RATE (b)	28/46.27	43/47.79	43/49.82	43/47.63
POLY-3 PERCENT (g)	60.5%	90%	86.3%	90.3%
TERMINAL (d)	24/39 (62%)	34/38 (90%)	30/36 (83%)	24/27 (89%)
FIRST INCIDENCE	469	481	491	385

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.003**	P=0.003**	P<0.001**
POLY 3	P<0.001**	P<0.001**	P=0.003**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P=0.002**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P=0.004**	P<0.001**
LOGISTIC REGRESSION	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P=0.002**	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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Liver  
 Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

**TUMOR RATES**

OVERALL (a)	30/50 (60%)	43/50 (86%)	43/50 (86%)	43/50 (86%)
POLY-3 RATE (b)	30/46.71	43/47.79	43/49.82	43/47.63
POLY-3 PERCENT (g)	64.2%	90%	86.3%	90.3%
TERMINAL (d)	25/39 (64%)	34/38 (90%)	30/36 (83%)	24/27 (89%)
FIRST INCIDENCE	469	481	491	385

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.009**	P=0.008**	P<0.001**
POLY 3	P=0.003**	P=0.002**	P=0.008**	P<0.001**
POLY 1.5	P=0.003**	P=0.002**	P=0.006**	P=0.002**
POLY 6	P=0.003**	P=0.002**	P=0.012*	P<0.001**
LOGISTIC REGRESSION	P<0.001**	P=0.004**	P=0.004**	P=0.002**
COCH-ARM / FISHERS	P=0.005**	P=0.003**	P=0.003**	P=0.003**
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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
<b>Liver</b>				
<b>Hepatocolangiocarcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/45.37	1/45.3	0/45.85	1/38.54
POLY-3 PERCENT (g)	4.4%	2.2%	0%	2.6%
TERMINAL (d)	0/39 (0%)	1/38 (3%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	515	728 (T)	---	656
<b>STATISTICAL TESTS</b>				
LIFE TABLE	P=0.426N	P=0.498N	P=0.228N	P=0.560N
POLY 3	P=0.370N	P=0.501N	P=0.235N	P=0.556N
POLY 1.5	P=0.370N	P=0.499N	P=0.234N	P=0.534N
POLY 6	P=0.370N	P=0.504N	P=0.238N	P=0.581N
LOGISTIC REGRESSION	P=0.312N	P=0.546N	P=0.324N	P=0.438N
COCH-ARM / FISHERS	P=0.366N	P=0.500N	P=0.247N	P=0.500N
ORDER RESTRICTED	P=0.270N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.304N	(e)	(e)	(e)



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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Lung  
 Alveolar/Bronchiolar Adenoma

**TUMOR RATES**

OVERALL (a)	6/50 (12%)	5/49 (10%)	2/50 (4%)	8/50 (16%)
POLY-3 RATE (b)	6/44.85	5/44.56	2/45.85	8/39.14
POLY-3 PERCENT (g)	13.4%	11.2%	4.4%	20.4%
TERMINAL (d)	5/39 (13%)	4/37 (11%)	2/36 (6%)	5/27 (19%)
FIRST INCIDENCE	589	658	728 (T)	607

**STATISTICAL TESTS**

LIFE TABLE	P=0.132	P=0.525N	P=0.157N	P=0.177
POLY 3	P=0.254	P=0.505N	P=0.126N	P=0.284
POLY 1.5	P=0.274	P=0.505N	P=0.127N	P=0.324
POLY 6	P=0.235	P=0.505N	P=0.128N	P=0.246
LOGISTIC REGRESSION	P=0.224	P=0.504N	P=0.125N	P=0.284
COCH-ARM / FISHERS	P=0.311	P=0.514N	P=0.134N	P=0.387
ORDER RESTRICTED	P=0.102	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.128	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Lung  
 Alveolar/Bronchiolar Carcinoma**

**TUMOR RATES**

OVERALL (a)	2/50 (4%)	7/49 (14%)	7/50 (14%)	2/50 (4%)
POLY-3 RATE (b)	2/44.38	7/45.32	7/45.92	2/38.27
POLY-3 PERCENT (g)	4.5%	15.5%	15.2%	5.2%
TERMINAL (d)	2/39 (5%)	4/37 (11%)	6/36 (17%)	2/27 (7%)
FIRST INCIDENCE	728 (T)	510	710	728 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.525	P=0.080	P=0.065	P=0.556
POLY 3	P=0.530N	P=0.083	P=0.087	P=0.640
POLY 1.5	P=0.476N	P=0.081	P=0.086	P=0.662
POLY 6	P=0.525	P=0.086	P=0.086	P=0.614
LOGISTIC REGRESSION	P=0.495N	P=0.076	P=0.076	P=0.556
COCH-ARM / FISHERS	P=0.397N	P=0.075	P=0.080	P=0.691N
ORDER RESTRICTED	P=0.199	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.232	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Lung  
 Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma

**TUMOR RATES**

OVERALL (a)	7/50 (14%)	12/49 (24%)	9/50 (18%)	10/50 (20%)
POLY-3 RATE (b)	7/44.85	12/45.58	9/45.92	10/39.14
POLY-3 PERCENT (g)	15.6%	26.3%	19.6%	25.6%
TERMINAL (d)	6/39 (15%)	8/37 (22%)	8/36 (22%)	7/27 (26%)
FIRST INCIDENCE	589	510	710	607

**STATISTICAL TESTS**

LIFE TABLE	P=0.127	P=0.146	P=0.337	P=0.102
POLY 3	P=0.253	P=0.160	P=0.412	P=0.195
POLY 1.5	P=0.302	P=0.154	P=0.411	P=0.233
POLY 6	P=0.206	P=0.166	P=0.405	P=0.160
LOGISTIC REGRESSION	P=0.254	P=0.147	P=0.417	P=0.180
COCH-ARM / FISHERS	P=0.387	P=0.142	P=0.393	P=0.298
ORDER RESTRICTED	P=0.221	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.253	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
ISOEUGENOL  
CAS Number: 97-54-1  
Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
Time Report Reqsted: 13:47:31  
First Dose M/F: 05/09/02 / 05/08/02  
Lab: BNW

STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 or Unspecified Site  
Adenoma

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/48 (0%)	0/50 (0%)	0/48 (0%)
POLY-3 RATE (b)	0/44.38	0/43.51	0/45.85	0/37.89
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/37 (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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Skin**  
 Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.38	1/45.6	1/45.96	0/38.27
POLY-3 PERCENT (g)	0%	2.2%	2.2%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	646	700	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.656N	P=0.519	P=0.500	(e)
POLY 3	P=0.630N	P=0.505	P=0.507	(e)
POLY 1.5	P=0.616N	P=0.504	P=0.506	(e)
POLY 6	P=0.645N	P=0.507	P=0.507	(e)
LOGISTIC REGRESSION	P=0.584N	P=0.483	P=0.502	(e)
COCH-ARM / FISHERS	P=0.595N	P=0.500	P=0.500	(e)
ORDER RESTRICTED	P=0.417	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.445	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Skin  
 Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.38	1/45.6	1/45.96	0/38.27
POLY-3 PERCENT (g)	0%	2.2%	2.2%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	646	700	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.656N	P=0.519	P=0.500	(e)
POLY 3	P=0.630N	P=0.505	P=0.507	(e)
POLY 1.5	P=0.616N	P=0.504	P=0.506	(e)
POLY 6	P=0.645N	P=0.507	P=0.507	(e)
LOGISTIC REGRESSION	P=0.584N	P=0.483	P=0.502	(e)
COCH-ARM / FISHERS	P=0.595N	P=0.500	P=0.500	(e)
ORDER RESTRICTED	P=0.417	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.445	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
<b>Skin</b>				
<b>Sarcoma</b>				
<b>TUMOR RATES</b>				
	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.38	0/45.3	1/45.96	0/38.27
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	0/36 (0%)	0/27 (0%)
FIRST INCIDENCE	---	---	700	---
<b>STATISTICAL TESTS</b>				
LIFE TABLE	P=0.662	(e)	P=0.500	(e)
POLY 3	P=0.619	(e)	P=0.507	(e)
POLY 1.5	P=0.650	(e)	P=0.506	(e)
POLY 6	P=0.583	(e)	P=0.507	(e)
LOGISTIC REGRESSION	P=0.688	(e)	P=0.502	(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=0.417	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Stomach, Forestomach  
 Squamous Cell Papilloma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.38	2/45.3	2/45.85	0/38.27
POLY-3 PERCENT (g)	0%	4.4%	4.4%	0%
TERMINAL (d)	0/39 (0%)	2/38 (5%)	2/36 (6%)	0/27 (0%)
FIRST INCIDENCE	---	728 (T)	728 (T)	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.610N	P=0.233	P=0.221	(e)
POLY 3	P=0.566N	P=0.242	P=0.244	(e)
POLY 1.5	P=0.539N	P=0.241	P=0.243	(e)
POLY 6	P=0.595N	P=0.242	P=0.244	(e)
LOGISTIC REGRESSION	(e)	P=0.233	P=0.221	(e)
COCH-ARM / FISHERS	P=0.500N	P=0.247	P=0.247	(e)
ORDER RESTRICTED	P=0.289	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.321	(e)	(e)	(e)



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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Testes  
 Adenoma

**TUMOR RATES**

OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/45.02	1/45.3	1/45.85	0/38.27
POLY-3 PERCENT (g)	4.4%	2.2%	2.2%	0%
TERMINAL (d)	1/39 (3%)	1/38 (3%)	1/36 (3%)	0/27 (0%)
FIRST INCIDENCE	515	728 (T)	728 (T)	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.198N	P=0.508N	P=0.514N	P=0.288N
POLY 3	P=0.173N	P=0.498N	P=0.494N	P=0.275N
POLY 1.5	P=0.166N	P=0.497N	P=0.494N	P=0.259N
POLY 6	P=0.181N	P=0.499N	P=0.497N	P=0.293N
LOGISTIC REGRESSION	P=0.143N	P=0.521N	P=0.542N	P=0.206N
COCH-ARM / FISHERS	P=0.153N	P=0.500N	P=0.500N	P=0.247N
ORDER RESTRICTED	P=0.148N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.181N	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

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 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**All Organs  
 Hemangiosarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	4/50 (8%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	3/44.38	4/46.22	2/46.03	1/39.1
POLY-3 PERCENT (g)	6.8%	8.7%	4.4%	2.6%
TERMINAL (d)	3/39 (8%)	2/38 (5%)	1/36 (3%)	0/27 (0%)
FIRST INCIDENCE	728 (T)	510	682	408

**STATISTICAL TESTS**

LIFE TABLE	P=0.250N	P=0.494	P=0.525N	P=0.414N
POLY 3	P=0.198N	P=0.522	P=0.483N	P=0.352N
POLY 1.5	P=0.183N	P=0.515	P=0.487N	P=0.332N
POLY 6	P=0.215N	P=0.529	P=0.483N	P=0.375N
LOGISTIC REGRESSION	P=0.134N	P=0.495	P=0.487N	P=0.279N
COCH-ARM / FISHERS	P=0.162N	P=0.500	P=0.500N	P=0.309N
ORDER RESTRICTED	P=0.258N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.286N	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
ISOEUGENOL  
CAS Number: 97-54-1  
Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
Time Report Reqsted: 13:47:31  
First Dose M/F: 05/09/02 / 05/08/02  
Lab: BNW

STATISTICAL ANALYSIS OF PRIMARY TUMORS 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

---

All Organs  
Histiocytic Sarcoma

---

TUMOR RATES

	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.38	0/45.3	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	---	---	---	---

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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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**All Organs  
 Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	0/44.38	0/45.3	3/46.32	2/38.27
POLY-3 PERCENT (g)	0%	0%	6.5%	5.2%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	1/36 (3%)	2/27 (7%)
FIRST INCIDENCE	---	---	629	728 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.050*	(e)	P=0.125	P=0.162
POLY 3	P=0.063	(e)	P=0.127	P=0.206
POLY 1.5	P=0.074	(e)	P=0.125	P=0.218
POLY 6	P=0.052	(e)	P=0.127	P=0.192
LOGISTIC REGRESSION	P=0.075	(e)	P=0.114	P=0.162
COCH-ARM / FISHERS	P=0.097	(e)	P=0.121	P=0.247
ORDER RESTRICTED	P=0.089	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.098	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**All Organs  
 Benign Tumors**

**TUMOR RATES**

	#	#	#	#
OVERALL (a)	33/50 (66%)	37/50 (74%)	37/50 (74%)	36/50 (72%)
POLY-3 RATE (b)	33/46.53	37/46.22	37/48.11	36/42.84
POLY-3 PERCENT (g)	70.9%	80.1%	76.9%	84%
TERMINAL (d)	28/39 (72%)	33/38 (87%)	29/36 (81%)	25/27 (93%)
FIRST INCIDENCE	469	646	491	408

**STATISTICAL TESTS**

LIFE TABLE	P=0.002**	P=0.216	P=0.163	P=0.005**
POLY 3	P=0.107	P=0.208	P=0.329	P=0.095
POLY 1.5	P=0.180	P=0.233	P=0.314	P=0.170
POLY 6	P=0.060	P=0.186	P=0.333	P=0.050*
LOGISTIC REGRESSION	P=0.056	P=0.299	P=0.330	P=0.081
COCH-ARM / FISHERS	P=0.346	P=0.257	P=0.257	P=0.333
ORDER RESTRICTED	P=0.092	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.107	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**All Organs  
 Malignant Tumors**

**TUMOR RATES**

	#	#	#	#
OVERALL (a)	20/50 (40%)	27/50 (54%)	29/50 (58%)	28/50 (56%)
POLY-3 RATE (b)	20/48.25	27/49.23	29/49.79	28/45.98
POLY-3 PERCENT (g)	41.5%	54.9%	58.2%	60.9%
TERMINAL (d)	13/39 (33%)	16/38 (42%)	16/36 (44%)	12/27 (44%)
FIRST INCIDENCE	468	441	491	385

**STATISTICAL TESTS**

LIFE TABLE	P=0.009**	P=0.156	P=0.077	P=0.015*
POLY 3	P=0.046*	P=0.131	P=0.071	P=0.043*
POLY 1.5	P=0.062	P=0.127	P=0.066	P=0.056
POLY 6	P=0.034*	P=0.138	P=0.075	P=0.033*
LOGISTIC REGRESSION	P=0.195	P=0.093	P=0.035*	P=0.142
COCH-ARM / FISHERS	P=0.090	P=0.115	P=0.055	P=0.080
ORDER RESTRICTED	P=0.041*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.051	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**All Organs  
 Malignant and Benign Tumors**

**TUMOR RATES**

	#	#	#	#
OVERALL (a)	43/50 (86%)	48/50 (96%)	46/50 (92%)	46/50 (92%)
POLY-3 RATE (b)	43/49.02	48/49.23	46/50	46/47.63
POLY-3 PERCENT (g)	87.7%	97.5%	92%	96.6%
TERMINAL (d)	33/39 (85%)	37/38 (97%)	32/36 (89%)	27/27 (100%)
FIRST INCIDENCE	468	441	491	385

**STATISTICAL TESTS**

LIFE TABLE	P=0.002**	P=0.189	P=0.234	P=0.004**
POLY 3	P=0.128	P=0.067	P=0.355	P=0.097
POLY 1.5	P=0.200	P=0.075	P=0.341	P=0.158
POLY 6	P=0.072	P=0.059	P=0.358	P=0.051
LOGISTIC REGRESSION	P=0.194	P=0.098	P=0.283	P=0.154
COCH-ARM / FISHERS	P=0.319	P=0.080	P=0.262	P=0.262
ORDER RESTRICTED	P=0.050*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.057	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Adrenal Cortex  
 Adenoma**

**TUMOR RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.691	(e)	P=0.522	(e)
POLY 3	P=0.651	(e)	P=0.521	(e)
POLY 1.5	P=0.672	(e)	P=0.516	(e)
POLY 6	P=0.626	(e)	P=0.524	(e)
LOGISTIC REGRESSION	(e)	(e)	P=0.522	(e)
COCH-ARM / FISHERS	P=0.698	(e)	P=0.505	(e)
ORDER RESTRICTED	P=0.399	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.412	(e)	(e)	(e)



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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
<b>Harderian Gland Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/49 (6%)	3/50 (6%)	2/50 (4%)	5/50 (10%)
POLY-3 RATE (b)	3/42.59	3/46.47	2/46.55	5/41.46
POLY-3 PERCENT (g)	7%	6.5%	4.3%	12.1%
TERMINAL (d)	3/34 (9%)	3/39 (8%)	2/38 (5%)	3/33 (9%)
FIRST INCIDENCE	727 (T)	727 (T)	727 (T)	553
<b>STATISTICAL TESTS</b>				
LIFE TABLE	P=0.227	P=0.599N	P=0.449N	P=0.334
POLY 3	P=0.248	P=0.622N	P=0.460N	P=0.341
POLY 1.5	P=0.258	P=0.629N	P=0.469N	P=0.354
POLY 6	P=0.239	P=0.618N	P=0.453N	P=0.326
LOGISTIC REGRESSION	P=0.240	P=0.599N	P=0.449N	P=0.348
COCH-ARM / FISHERS	P=0.271	P=0.651N	P=0.490N	P=0.369
ORDER RESTRICTED	P=0.232	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.242	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Harderian Gland  
 Carcinoma**

**TUMOR RATES**

	#	#	#	#
OVERALL (a)	1/49 (2%)	2/50 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/42.59	2/46.97	2/46.68	1/40.48
POLY-3 PERCENT (g)	2.4%	4.3%	4.3%	2.5%
TERMINAL (d)	1/34 (3%)	1/39 (3%)	1/38 (3%)	1/33 (3%)
FIRST INCIDENCE	727 (T)	577	695	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.593N	P=0.544	P=0.540	P=0.755
POLY 3	P=0.580N	P=0.534	P=0.532	P=0.749
POLY 1.5	P=0.566N	P=0.527	P=0.524	P=0.757
POLY 6	P=0.594N	P=0.539	P=0.538	P=0.740
LOGISTIC REGRESSION	P=0.561N	P=0.484	P=0.534	P=0.755
COCH-ARM / FISHERS	P=0.550N	P=0.508	P=0.508	P=0.747N
ORDER RESTRICTED	P=0.578	(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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Harderian Gland  
 Carcinoma or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	4/49 (8%)	5/50 (10%)	4/50 (8%)	5/50 (10%)
POLY-3 RATE (b)	4/42.59	5/46.97	4/46.68	5/41.46
POLY-3 PERCENT (g)	9.4%	10.7%	8.6%	12.1%
TERMINAL (d)	4/34 (12%)	4/39 (10%)	3/38 (8%)	3/33 (9%)
FIRST INCIDENCE	727 (T)	577	695	553

**STATISTICAL TESTS**

LIFE TABLE	P=0.413	P=0.583	P=0.580N	P=0.473
POLY 3	P=0.436	P=0.561	P=0.592N	P=0.483
POLY 1.5	P=0.454	P=0.548	P=0.604N	P=0.498
POLY 6	P=0.420	P=0.569	P=0.582N	P=0.467
LOGISTIC REGRESSION	P=0.449	P=0.549	P=0.580N	P=0.485
COCH-ARM / FISHERS	P=0.477	P=0.513	P=0.631N	P=0.513
ORDER RESTRICTED	P=0.545	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.553	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 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 PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Intestine Small: Site Unspecified  
 Carcinoma or Adenoma**

**TUMOR 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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Liver  
 Hemangiosarcoma

**TUMOR RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.416N	P=0.269	(e)	(e)
POLY 3	P=0.396N	P=0.257	(e)	(e)
POLY 1.5	P=0.396N	P=0.253	(e)	(e)
POLY 6	P=0.397N	P=0.259	(e)	(e)
LOGISTIC REGRESSION	(e)	P=0.269	(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)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 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 PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Liver  
 Hepatoblastoma

**TUMOR 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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 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 PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Liver  
 Hepatocellular Adenoma

**TUMOR RATES**

OVERALL (a)	11/49 (22%)	10/50 (20%)	9/49 (18%)	4/50 (8%)
POLY-3 RATE (b)	11/42.86	10/48.19	9/46.61	4/40.59
POLY-3 PERCENT (g)	25.7%	20.8%	19.3%	9.9%
TERMINAL (d)	8/34 (24%)	5/39 (13%)	8/38 (21%)	3/33 (9%)
FIRST INCIDENCE	699	577	693	698

**STATISTICAL TESTS**

LIFE TABLE	P=0.050N*	P=0.384N	P=0.300N	P=0.062N
POLY 3	P=0.048N*	P=0.380N	P=0.321N	P=0.053N
POLY 1.5	P=0.039N*	P=0.410N	P=0.342N	P=0.046N*
POLY 6	P=0.059N	P=0.355N	P=0.308N	P=0.063N
LOGISTIC REGRESSION	P=0.039N*	P=0.450N	P=0.294N	P=0.067N
COCH-ARM / FISHERS	P=0.030N*	P=0.479N	P=0.401N	P=0.041N*
ORDER RESTRICTED	P=0.053N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.065N	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Liver  
 Hepatocellular Carcinoma

**TUMOR RATES**

OVERALL (a)	3/49 (6%)	8/50 (16%)	9/49 (18%)	6/50 (12%)
POLY-3 RATE (b)	3/43.63	8/46.47	9/46.85	6/40.48
POLY-3 PERCENT (g)	6.9%	17.2%	19.2%	14.8%
TERMINAL (d)	1/34 (3%)	8/39 (21%)	6/38 (16%)	6/33 (18%)
FIRST INCIDENCE	423	727 (T)	647	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.257	P=0.147	P=0.098	P=0.227
POLY 3	P=0.231	P=0.119	P=0.077	P=0.205
POLY 1.5	P=0.267	P=0.117	P=0.072	P=0.226
POLY 6	P=0.195	P=0.117	P=0.080	P=0.182
LOGISTIC REGRESSION	P=0.259	P=0.105	P=0.049*	P=0.238
COCH-ARM / FISHERS	P=0.319	P=0.106	P=0.060	P=0.254
ORDER RESTRICTED	P=0.149	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.169	(e)	(e)	(e)



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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Liver  
 Hepatocellular Carcinoma or Hepatoblastoma

**TUMOR RATES**

OVERALL (a)	3/49 (6%)	8/50 (16%)	9/49 (18%)	6/50 (12%)
POLY-3 RATE (b)	3/43.63	8/46.47	9/46.85	6/40.48
POLY-3 PERCENT (g)	6.9%	17.2%	19.2%	14.8%
TERMINAL (d)	1/34 (3%)	8/39 (21%)	6/38 (16%)	6/33 (18%)
FIRST INCIDENCE	423	727 (T)	647	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.257	P=0.147	P=0.098	P=0.227
POLY 3	P=0.231	P=0.119	P=0.077	P=0.205
POLY 1.5	P=0.267	P=0.117	P=0.072	P=0.226
POLY 6	P=0.195	P=0.117	P=0.080	P=0.182
LOGISTIC REGRESSION	P=0.259	P=0.105	P=0.049*	P=0.238
COCH-ARM / FISHERS	P=0.319	P=0.106	P=0.060	P=0.254
ORDER RESTRICTED	P=0.149	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.169	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Liver  
 Hepatocellular Carcinoma or Hepatocellular Adenoma

**TUMOR RATES**

OVERALL (a)	13/49 (27%)	16/50 (32%)	15/49 (31%)	9/50 (18%)
POLY-3 RATE (b)	13/43.9	16/48.19	15/46.98	9/40.59
POLY-3 PERCENT (g)	29.6%	33.2%	31.9%	22.2%
TERMINAL (d)	8/34 (24%)	11/39 (28%)	11/38 (29%)	8/33 (24%)
FIRST INCIDENCE	423	577	647	698

**STATISTICAL TESTS**

LIFE TABLE	P=0.216N	P=0.481	P=0.546	P=0.281N
POLY 3	P=0.229N	P=0.442	P=0.495	P=0.297N
POLY 1.5	P=0.185N	P=0.417	P=0.474	P=0.258N
POLY 6	P=0.285N	P=0.462	P=0.509	P=0.349N
LOGISTIC REGRESSION	P=0.176N	P=0.361	P=0.476	P=0.279N
COCH-ARM / FISHERS	P=0.136N	P=0.353	P=0.412	P=0.218N
ORDER RESTRICTED	P=0.281N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.303N	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Liver  
 Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

**TUMOR RATES**

OVERALL (a)	13/49 (27%)	16/50 (32%)	15/49 (31%)	9/50 (18%)
POLY-3 RATE (b)	13/43.9	16/48.19	15/46.98	9/40.59
POLY-3 PERCENT (g)	29.6%	33.2%	31.9%	22.2%
TERMINAL (d)	8/34 (24%)	11/39 (28%)	11/38 (29%)	8/33 (24%)
FIRST INCIDENCE	423	577	647	698

**STATISTICAL TESTS**

LIFE TABLE	P=0.216N	P=0.481	P=0.546	P=0.281N
POLY 3	P=0.229N	P=0.442	P=0.495	P=0.297N
POLY 1.5	P=0.185N	P=0.417	P=0.474	P=0.258N
POLY 6	P=0.285N	P=0.462	P=0.509	P=0.349N
LOGISTIC REGRESSION	P=0.176N	P=0.361	P=0.476	P=0.279N
COCH-ARM / FISHERS	P=0.136N	P=0.353	P=0.412	P=0.218N
ORDER RESTRICTED	P=0.281N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.303N	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Liver  
 Hepatocholangiocarcinoma

**TUMOR 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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Lung  
 Alveolar/Bronchiolar Adenoma

**TUMOR RATES**

OVERALL (a)	4/48 (8%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	4/41.83	2/46.81	1/46.55	1/40.48
POLY-3 PERCENT (g)	9.6%	4.3%	2.2%	2.5%
TERMINAL (d)	4/34 (12%)	1/39 (3%)	1/38 (3%)	1/33 (3%)
FIRST INCIDENCE	727 (T)	632	727 (T)	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.119N	P=0.279N	P=0.147N	P=0.187N
POLY 3	P=0.115N	P=0.287N	P=0.148N	P=0.188N
POLY 1.5	P=0.111N	P=0.295N	P=0.153N	P=0.177N
POLY 6	P=0.119N	P=0.282N	P=0.144N	P=0.202N
LOGISTIC REGRESSION	P=0.119N	P=0.292N	P=0.147N	P=0.187N
COCH-ARM / FISHERS	P=0.104N	P=0.319N	P=0.168N	P=0.168N
ORDER RESTRICTED	P=0.095N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.106N	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Lung  
 Alveolar/Bronchiolar Carcinoma**

**TUMOR RATES**

OVERALL (a)	0/48 (0%)	2/50 (4%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	0/41.83	2/46.77	3/47.05	1/40.48
POLY-3 PERCENT (g)	0%	4.3%	6.4%	2.5%
TERMINAL (d)	0/34 (0%)	1/39 (3%)	2/38 (5%)	1/33 (3%)
FIRST INCIDENCE	---	647	577	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.405	P=0.266	P=0.143	P=0.494
POLY 3	P=0.401	P=0.263	P=0.141	P=0.493
POLY 1.5	P=0.426	P=0.259	P=0.137	P=0.501
POLY 6	P=0.372	P=0.265	P=0.145	P=0.484
LOGISTIC REGRESSION	P=0.455	P=0.237	P=0.116	P=0.494
COCH-ARM / FISHERS	P=0.456	P=0.258	P=0.129	P=0.510
ORDER RESTRICTED	P=0.212	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.226	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Lung  
 Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma**

**TUMOR RATES**

OVERALL (a)	4/48 (8%)	4/50 (8%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	4/41.83	4/47.11	4/47.05	2/40.48
POLY-3 PERCENT (g)	9.6%	8.5%	8.5%	4.9%
TERMINAL (d)	4/34 (12%)	2/39 (5%)	3/38 (8%)	2/33 (6%)
FIRST INCIDENCE	727 (T)	632	577	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.292N	P=0.570N	P=0.581N	P=0.350N
POLY 3	P=0.283N	P=0.577N	P=0.577N	P=0.352N
POLY 1.5	P=0.265N	P=0.588N	P=0.590N	P=0.335N
POLY 6	P=0.303N	P=0.569N	P=0.567N	P=0.373N
LOGISTIC REGRESSION	P=0.262N	P=0.599N	P=0.595N	P=0.350N
COCH-ARM / FISHERS	P=0.241N	P=0.619N	P=0.619N	P=0.319N
ORDER RESTRICTED	P=0.363N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.375N	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Ovary  
 Cystadenoma

**TUMOR RATES**

OVERALL (a)	3/48 (6%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/41.83	0/46.47	1/46.55	1/40.48
POLY-3 PERCENT (g)	7.2%	0%	2.2%	2.5%
TERMINAL (d)	3/34 (9%)	0/39 (0%)	1/38 (3%)	1/33 (3%)
FIRST INCIDENCE	727 (T)	---	727 (T)	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.309N	P=0.098N	P=0.266N	P=0.315N
POLY 3	P=0.303N	P=0.101N	P=0.268N	P=0.317N
POLY 1.5	P=0.298N	P=0.103N	P=0.274N	P=0.304N
POLY 6	P=0.305N	P=0.100N	P=0.264N	P=0.333N
LOGISTIC REGRESSION	P=0.309N	(e)	P=0.266N	P=0.315N
COCH-ARM / FISHERS	P=0.286N	P=0.114N	P=0.293N	P=0.293N
ORDER RESTRICTED	P=0.101N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.112N	(e)	(e)	(e)



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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 or Unspecified Site  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	4/47 (9%)	0/48 (0%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	4/41.29	0/44.88	4/46.55	1/40.48
POLY-3 PERCENT (g)	9.7%	0%	8.6%	2.5%
TERMINAL (d)	3/34 (9%)	0/38 (0%)	4/38 (11%)	1/33 (3%)
FIRST INCIDENCE	699	---	727 (T)	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.282N	P=0.052N	P=0.582N	P=0.197N
POLY 3	P=0.284N	P=0.050N*	P=0.576N	P=0.184N
POLY 1.5	P=0.266N	P=0.052N	P=0.584N	P=0.172N
POLY 6	P=0.302N	P=0.050N*	P=0.574N	P=0.200N
LOGISTIC REGRESSION	P=0.293N	P=0.052N	P=0.572N	P=0.204N
COCH-ARM / FISHERS	P=0.240N	P=0.056N	P=0.607N	P=0.162N
ORDER RESTRICTED	P=0.114N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.126N	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Skin**  
 Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma

TUMOR RATES	#	#	#	#
OVERALL (a)	3/49 (6%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/43.7	0/46.47	1/47.03	0/40.48
POLY-3 PERCENT (g)	6.9%	0%	2.1%	0%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	342	---	587	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.093N	P=0.109N	P=0.278N	P=0.133N
POLY 3	P=0.089N	P=0.108N	P=0.280N	P=0.133N
POLY 1.5	P=0.087N	P=0.109N	P=0.285N	P=0.125N
POLY 6	P=0.090N	P=0.108N	P=0.275N	P=0.143N
LOGISTIC REGRESSION	P=0.083N	P=0.196N	P=0.418N	P=0.109N
COCH-ARM / FISHERS	P=0.084N	P=0.117N	P=0.301N	P=0.117N
ORDER RESTRICTED	P=0.025N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.035N*	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Skin  
 Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	3/49 (6%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/43.7	0/46.47	1/47.03	0/40.48
POLY-3 PERCENT (g)	6.9%	0%	2.1%	0%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	342	---	587	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.093N	P=0.109N	P=0.278N	P=0.133N
POLY 3	P=0.089N	P=0.108N	P=0.280N	P=0.133N
POLY 1.5	P=0.087N	P=0.109N	P=0.285N	P=0.125N
POLY 6	P=0.090N	P=0.108N	P=0.275N	P=0.143N
LOGISTIC REGRESSION	P=0.083N	P=0.196N	P=0.418N	P=0.109N
COCH-ARM / FISHERS	P=0.084N	P=0.117N	P=0.301N	P=0.117N
ORDER RESTRICTED	P=0.025N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.035N*	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Skin  
 Sarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	3/49 (6%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/43.7	0/46.47	1/47.03	0/40.48
POLY-3 PERCENT (g)	6.9%	0%	2.1%	0%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	0/33 (0%)
FIRST INCIDENCE	342	---	587	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.093N	P=0.109N	P=0.278N	P=0.133N
POLY 3	P=0.089N	P=0.108N	P=0.280N	P=0.133N
POLY 1.5	P=0.087N	P=0.109N	P=0.285N	P=0.125N
POLY 6	P=0.090N	P=0.108N	P=0.275N	P=0.143N
LOGISTIC REGRESSION	P=0.083N	P=0.196N	P=0.418N	P=0.109N
COCH-ARM / FISHERS	P=0.084N	P=0.117N	P=0.301N	P=0.117N
ORDER RESTRICTED	P=0.025N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.035N*	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 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 PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Stomach, Forestomach  
 Squamous Cell Papilloma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/49 (2%)	1/50 (2%)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	1/42.59	1/46.47	5/46.69	3/40.48
POLY-3 PERCENT (g)	2.4%	2.2%	10.7%	7.4%
TERMINAL (d)	1/34 (3%)	1/39 (3%)	3/38 (8%)	3/33 (9%)
FIRST INCIDENCE	727 (T)	727 (T)	693	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.136	P=0.731N	P=0.137	P=0.294
POLY 3	P=0.126	P=0.741N	P=0.124	P=0.287
POLY 1.5	P=0.142	P=0.745N	P=0.119	P=0.299
POLY 6	P=0.111	P=0.739N	P=0.129	P=0.272
LOGISTIC REGRESSION	P=0.118	P=0.731N	P=0.129	P=0.294
COCH-ARM / FISHERS	P=0.166	P=0.747N	P=0.107	P=0.316
ORDER RESTRICTED	P=0.143	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.156	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
<b>Uterus</b>				
<b>Polyp Stromal</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/42.59	0/46.47	2/47.47	1/40.48
POLY-3 PERCENT (g)	0%	0%	4.2%	2.5%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	1/38 (3%)	1/33 (3%)
FIRST INCIDENCE	---	---	313	727 (T)
<b>STATISTICAL TESTS</b>				
LIFE TABLE	P=0.235	(e)	P=0.259	P=0.494
POLY 3	P=0.210	(e)	P=0.262	P=0.490
POLY 1.5	P=0.226	(e)	P=0.256	P=0.497
POLY 6	P=0.193	(e)	P=0.266	P=0.482
LOGISTIC REGRESSION	P=0.287	(e)	P=0.116	P=0.494
COCH-ARM / FISHERS	P=0.249	(e)	P=0.253	P=0.505
ORDER RESTRICTED	P=0.190	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.206	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Uterus  
 Sarcoma Stromal or Polyp Stromal

TUMOR RATES	#	#	#	#
OVERALL (a)	1/49 (2%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/42.59	0/46.47	2/47.47	1/40.48
POLY-3 PERCENT (g)	2.4%	0%	4.2%	2.5%
TERMINAL (d)	1/34 (3%)	0/39 (0%)	1/38 (3%)	1/33 (3%)
FIRST INCIDENCE	727 (T)	---	313	727 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.488	P=0.473N	P=0.533	P=0.755
POLY 3	P=0.457	P=0.483N	P=0.538	P=0.749
POLY 1.5	P=0.477	P=0.486N	P=0.529	P=0.757
POLY 6	P=0.437	P=0.481N	P=0.544	P=0.740
LOGISTIC REGRESSION	P=0.535	(e)	P=0.392	P=0.755
COCH-ARM / FISHERS	P=0.505	P=0.495N	P=0.508	P=0.747N
ORDER RESTRICTED	P=0.396	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.409	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**All Organs  
 Hemangiosarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/49 (2%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/42.98	2/46.47	1/46.55	1/40.59
POLY-3 PERCENT (g)	2.3%	4.3%	2.2%	2.5%
TERMINAL (d)	0/34 (0%)	2/39 (5%)	1/38 (3%)	0/33 (0%)
FIRST INCIDENCE	616	727 (T)	727 (T)	698

**STATISTICAL TESTS**

LIFE TABLE	P=0.566N	P=0.537	P=0.738N	P=0.725
POLY 3	P=0.544N	P=0.527	P=0.743N	P=0.748
POLY 1.5	P=0.535N	P=0.523	P=0.746N	P=0.756
POLY 6	P=0.553N	P=0.528	P=0.741N	P=0.738
LOGISTIC REGRESSION	P=0.538N	P=0.503	P=0.757	P=0.755N
COCH-ARM / FISHERS	P=0.525N	P=0.508	P=0.747N	P=0.747N
ORDER RESTRICTED	P=0.606N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.613N	(e)	(e)	(e)



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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**All Organs  
 Histiocytic Sarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/49 (0%)	1/50 (2%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	0/42.59	1/46.89	1/46.94	4/41.36
POLY-3 PERCENT (g)	0%	2.1%	2.1%	9.7%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/38 (0%)	2/33 (6%)
FIRST INCIDENCE	---	605	616	538

**STATISTICAL TESTS**

LIFE TABLE	P=0.012*	P=0.522	P=0.518	P=0.061
POLY 3	P=0.015*	P=0.519	P=0.519	P=0.056
POLY 1.5	P=0.016*	P=0.515	P=0.515	P=0.059
POLY 6	P=0.014*	P=0.522	P=0.524	P=0.053
LOGISTIC REGRESSION	P=0.026*	P=0.415	P=0.456	P=0.067
COCH-ARM / FISHERS	P=0.018*	P=0.505	P=0.505	P=0.061
ORDER RESTRICTED	P=0.011*	(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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**All Organs**  
**Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type**

TUMOR RATES	#	#	#	#
OVERALL (a)	11/49 (22%)	10/50 (20%)	8/50 (16%)	7/50 (14%)
POLY-3 RATE (b)	11/44.02	10/47.62	8/46.55	7/40.9
POLY-3 PERCENT (g)	25%	21%	17.2%	17.1%
TERMINAL (d)	7/34 (21%)	7/39 (18%)	8/38 (21%)	6/33 (18%)
FIRST INCIDENCE	569	518	727 (T)	605

**STATISTICAL TESTS**

LIFE TABLE	P=0.212N	P=0.384N	P=0.225N	P=0.275N
POLY 3	P=0.211N	P=0.419N	P=0.257N	P=0.267N
POLY 1.5	P=0.184N	P=0.431N	P=0.262N	P=0.235N
POLY 6	P=0.244N	P=0.419N	P=0.261N	P=0.311N
LOGISTIC REGRESSION	P=0.174N	P=0.489N	P=0.253N	P=0.236N
COCH-ARM / FISHERS	P=0.150N	P=0.479N	P=0.288N	P=0.204N
ORDER RESTRICTED	P=0.300N	(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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 ISOEUGENOL  
 CAS Number: 97-54-1  
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Reqsted: 10/04/2006  
 Time Report Reqsted: 13:47:31  
 First Dose M/F: 05/09/02 / 05/08/02  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**All Organs  
 Benign Tumors**

**TUMOR RATES**

	#	#	#	#
OVERALL (a)	20/49 (41%)	18/50 (36%)	22/50 (44%)	13/50 (26%)
POLY-3 RATE (b)	20/42.86	18/48.53	22/47.61	13/41.58
POLY-3 PERCENT (g)	46.7%	37.1%	46.2%	31.3%
TERMINAL (d)	17/34 (50%)	12/39 (31%)	19/38 (50%)	10/33 (30%)
FIRST INCIDENCE	699	577	313	553

**STATISTICAL TESTS**

LIFE TABLE	P=0.168N	P=0.253N	P=0.553N	P=0.131N
POLY 3	P=0.150N	P=0.237N	P=0.567N	P=0.105N
POLY 1.5	P=0.121N	P=0.282N	P=0.560	P=0.093N
POLY 6	P=0.188N	P=0.199N	P=0.542N	P=0.123N
LOGISTIC REGRESSION	P=0.138N	P=0.300N	P=0.575	P=0.157N
COCH-ARM / FISHERS	P=0.091N	P=0.387N	P=0.453	P=0.088N
ORDER RESTRICTED	P=0.122N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.132N	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 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 PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**All Organs  
 Malignant Tumors**

**TUMOR RATES**

	#	#	#	#
OVERALL (a)	21/49 (43%)	27/50 (54%)	25/50 (50%)	20/50 (40%)
POLY-3 RATE (b)	21/46.95	27/49.24	25/48.86	20/41.9
POLY-3 PERCENT (g)	44.7%	54.8%	51.2%	47.7%
TERMINAL (d)	10/34 (29%)	19/39 (49%)	16/38 (42%)	16/33 (49%)
FIRST INCIDENCE	342	518	577	538

**STATISTICAL TESTS**

LIFE TABLE	P=0.491N	P=0.361	P=0.465	P=0.551
POLY 3	P=0.505	P=0.216	P=0.336	P=0.472
POLY 1.5	P=0.455N	P=0.213	P=0.330	P=0.570
POLY 6	P=0.384	P=0.208	P=0.336	P=0.361
LOGISTIC REGRESSION	P=0.310N	P=0.123	P=0.252	P=0.493N
COCH-ARM / FISHERS	P=0.296N	P=0.182	P=0.305	P=0.466N
ORDER RESTRICTED	P=0.426	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.449	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 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 PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**All Organs  
 Malignant and Benign Tumors**

**TUMOR RATES**

	#	#	#	#
OVERALL (a)	34/49 (69%)	33/50 (66%)	37/50 (74%)	26/50 (52%)
POLY-3 RATE (b)	34/47.06	33/49.65	37/49.91	26/42.46
POLY-3 PERCENT (g)	72.3%	66.5%	74.1%	61.2%
TERMINAL (d)	22/34 (65%)	24/39 (62%)	26/38 (68%)	21/33 (64%)
FIRST INCIDENCE	342	518	313	538

**STATISTICAL TESTS**

LIFE TABLE	P=0.209N	P=0.253N	P=0.509N	P=0.171N
POLY 3	P=0.218N	P=0.347N	P=0.508	P=0.183N
POLY 1.5	P=0.124N	P=0.362N	P=0.483	P=0.109N
POLY 6	P=0.356N	P=0.351N	P=0.516	P=0.307N
LOGISTIC REGRESSION	P=0.062N	P=0.460N	P=0.377	P=0.079N
COCH-ARM / FISHERS	P=0.047N*	P=0.442N	P=0.387	P=0.059N
ORDER RESTRICTED	P=0.211N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.237N	(e)	(e)	(e)

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

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
ISOEUGENOL  
CAS Number: 97-54-1  
Pathologist: Blackshear, P. - GRUMBEIN, S.

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

## 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 \*\*\*