

TDMS No. 88105-03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
ISOEUGENOL
CAS Number: 97-54-1
Pathologist: Blackshear, P. - GRUMBEIN, S.
F1_R2

Date Report Reqsted: 09/28/2006
Time Report Reqsted: 17:49:41
First Dose M/F: 04/22/02 / 04/23/02
Lab: BNW

C Number:	C88105		
Lock Date:	01/21/2005		
Cage Range:	1 - 9999		
Date Range:	1-JAN-1940 to 17-SEP-2040		
Reasons For Removal:	ALL		
Removal Date Range:	JAN /1 /1940 - SEP /17 /2040		
Treatment Groups:	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
Brain
Clitoral/Preputial Gland
Islets, Pancreatic
Kidney
Liver
Lung
Nose
Ovary
Pancreas
Pituitary Gland
Prostate
Salivary Glands
Spleen
Testes
Thymus
Thyroid Gland
Urinary Bladder

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

MALE RATS

<u>Organ</u>	<u>Morphology</u>
Clitoral/Preputial Gland	Carcinoma or Adenoma
Mammary Gland	Carcinoma
Pancreas	Adenoma
	Carcinoma or Adenoma
Skin	Keratoacanthoma
	Lipoma
	Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma
	Squamous Cell Papilloma, Papilloma, or Keratoacanthoma
Thymus	Thymoma: Benign, Malignant, NOS

FEMALE RATS

<u>Organ</u>	<u>Morphology</u>
Mammary Gland	Fibroadenoma
Uterus	Polyp Stromal
	Sarcoma Stromal or Polyp Stromal

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Adrenal Medulla
 Pheochromocytoma Benign**

TUMOR RATES

OVERALL (a)	5/50 (10%)	10/50 (20%)	9/50 (18%)	7/49 (14%)
POLY-3 RATE (b)	5/45.7	10/44.22	9/42.11	7/40.79
POLY-3 PERCENT (g)	10.9%	22.6%	21.4%	17.2%
TERMINAL (d)	4/35 (11%)	9/34 (27%)	6/33 (18%)	6/30 (20%)
FIRST INCIDENCE	674	726	607	719

STATISTICAL TESTS

LIFE TABLE	P=0.330	P=0.119	P=0.161	P=0.279
POLY 3	P=0.342	P=0.113	P=0.148	P=0.301
POLY 1.5	P=0.381	P=0.116	P=0.156	P=0.326
POLY 6	P=0.305	P=0.112	P=0.149	P=0.276
LOGISTIC REGRESSION	P=0.324	P=0.125	P=0.148	P=0.267
COCH-ARM / FISHERS	P=0.442	P=0.131	P=0.194	P=0.365
ORDER RESTRICTED	P=0.194	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.219	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Adrenal Medulla
 Pheochromocytoma Malignant**

TUMOR RATES

OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)	1/49 (2%)
POLY-3 RATE (b)	3/45.49	0/44.21	1/41.26	1/40.75
POLY-3 PERCENT (g)	6.6%	0%	2.4%	2.5%
TERMINAL (d)	3/35 (9%)	0/34 (0%)	1/33 (3%)	1/30 (3%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.339N	P=0.126N	P=0.326N	P=0.361N
POLY 3	P=0.313N	P=0.124N	P=0.341N	P=0.346N
POLY 1.5	P=0.307N	P=0.124N	P=0.333N	P=0.333N
POLY 6	P=0.318N	P=0.123N	P=0.343N	P=0.359N
LOGISTIC REGRESSION	P=0.339N	(e)	P=0.326N	P=0.361N
COCH-ARM / FISHERS	P=0.301N	P=0.121N	P=0.309N	P=0.316N
ORDER RESTRICTED	P=0.130N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.149N	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Adrenal Medulla
 Pheochromocytoma: Benign, Complex, Malignant, NOS**

TUMOR RATES

OVERALL (a)	7/50 (14%)	10/50 (20%)	9/50 (18%)	8/49 (16%)
POLY-3 RATE (b)	7/45.7	10/44.22	9/42.11	8/40.79
POLY-3 PERCENT (g)	15.3%	22.6%	21.4%	19.6%
TERMINAL (d)	6/35 (17%)	9/34 (27%)	6/33 (18%)	7/30 (23%)
FIRST INCIDENCE	674	726	607	719

STATISTICAL TESTS

LIFE TABLE	P=0.384	P=0.275	P=0.336	P=0.374
POLY 3	P=0.406	P=0.270	P=0.324	P=0.405
POLY 1.5	P=0.445	P=0.274	P=0.336	P=0.436
POLY 6	P=0.368	P=0.269	P=0.327	P=0.373
LOGISTIC REGRESSION	P=0.375	P=0.292	P=0.316	P=0.361
COCH-ARM / FISHERS	P=0.506	P=0.298	P=0.393	P=0.483
ORDER RESTRICTED	P=0.390	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.409	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Bone
 Hemangiosarcoma**

TUMOR RATES

	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/45.49	0/44.21	2/41.96	0/41.71
POLY-3 PERCENT (g)	0%	0%	4.8%	0%
TERMINAL (d)	0/35 (0%)	0/34 (0%)	1/33 (3%)	0/30 (0%)
FIRST INCIDENCE	---	---	485	---

STATISTICAL TESTS

LIFE TABLE	P=0.577	(e)	P=0.224	(e)
POLY 3	P=0.556	(e)	P=0.220	(e)
POLY 1.5	P=0.574	(e)	P=0.223	(e)
POLY 6	P=0.535	(e)	P=0.219	(e)
LOGISTIC REGRESSION	P=0.616	(e)	P=0.287	(e)
COCH-ARM / FISHERS	P=0.595	(e)	P=0.247	(e)
ORDER RESTRICTED	P=0.232	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.252	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Bone
 Osteosarcoma**

TUMOR RATES

	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/46.32	1/44.82	0/41.26	0/41.71
POLY-3 PERCENT (g)	4.3%	2.2%	0%	0%
TERMINAL (d)	1/35 (3%)	0/34 (0%)	0/33 (0%)	0/30 (0%)
FIRST INCIDENCE	401	533	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.112N	P=0.510N	P=0.256N	P=0.257N
POLY 3	P=0.107N	P=0.512N	P=0.264N	P=0.261N
POLY 1.5	P=0.105N	P=0.511N	P=0.258N	P=0.252N
POLY 6	P=0.109N	P=0.509N	P=0.266N	P=0.270N
LOGISTIC REGRESSION	P=0.075N	P=0.367N	P=0.124N	P=0.124N
COCH-ARM / FISHERS	P=0.101N	P=0.500N	P=0.247N	P=0.247N
ORDER RESTRICTED	P=0.091N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.109N	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Bone
 Osteosarcoma or Osteoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/46.32	2/44.82	0/41.26	0/41.71
POLY-3 PERCENT (g)	4.3%	4.5%	0%	0%
TERMINAL (d)	1/35 (3%)	1/34 (3%)	0/33 (0%)	0/30 (0%)
FIRST INCIDENCE	401	533	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.099N	P=0.681	P=0.256N	P=0.257N
POLY 3	P=0.096N	P=0.682	P=0.264N	P=0.261N
POLY 1.5	P=0.093N	P=0.683	P=0.258N	P=0.252N
POLY 6	P=0.099N	P=0.684	P=0.266N	P=0.270N
LOGISTIC REGRESSION	P=0.068N	P=0.613N	P=0.124N	P=0.124N
COCH-ARM / FISHERS	P=0.086N	P=0.691N	P=0.247N	P=0.247N
ORDER RESTRICTED	P=0.130N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.152N	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Clitoral/Preputial Gland
 Adenoma**

TUMOR RATES

OVERALL (a)	2/50 (4%)	3/49 (6%)	4/50 (8%)	5/50 (10%)
POLY-3 RATE (b)	2/45.49	3/43.21	4/41.63	5/41.71
POLY-3 PERCENT (g)	4.4%	6.9%	9.6%	12%
TERMINAL (d)	2/35 (6%)	3/33 (9%)	3/33 (9%)	5/30 (17%)
FIRST INCIDENCE	729 (T)	729 (T)	624	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.104	P=0.473	P=0.305	P=0.156
POLY 3	P=0.123	P=0.477	P=0.297	P=0.182
POLY 1.5	P=0.135	P=0.478	P=0.305	P=0.195
POLY 6	P=0.111	P=0.478	P=0.297	P=0.169
LOGISTIC REGRESSION	P=0.108	P=0.473	P=0.294	P=0.156
COCH-ARM / FISHERS	P=0.154	P=0.490	P=0.339	P=0.218
ORDER RESTRICTED	P=0.150	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.171	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Clitoral/Preputial Gland
 Carcinoma**

TUMOR RATES

OVERALL (a)	2/50 (4%)	3/49 (6%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	2/45.99	3/43.73	1/41.69	4/43.04
POLY-3 PERCENT (g)	4.4%	6.9%	2.4%	9.3%
TERMINAL (d)	1/35 (3%)	2/33 (6%)	0/33 (0%)	1/30 (3%)
FIRST INCIDENCE	577	568	605	485

STATISTICAL TESTS

LIFE TABLE	P=0.246	P=0.466	P=0.538N	P=0.288
POLY 3	P=0.267	P=0.477	P=0.534N	P=0.307
POLY 1.5	P=0.277	P=0.478	P=0.527N	P=0.318
POLY 6	P=0.258	P=0.478	P=0.536N	P=0.297
LOGISTIC REGRESSION	P=0.318	P=0.519	P=0.442N	P=0.449
COCH-ARM / FISHERS	P=0.295	P=0.490	P=0.500N	P=0.339
ORDER RESTRICTED	P=0.248	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.266	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Clitoral/Preputial Gland
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	4/50 (8%)	5/49 (10%)	5/50 (10%)	9/50 (18%)
POLY-3 RATE (b)	4/45.99	5/43.73	5/42.06	9/43.04
POLY-3 PERCENT (g)	8.7%	11.4%	11.9%	20.9%
TERMINAL (d)	3/35 (9%)	4/33 (12%)	3/33 (9%)	6/30 (20%)
FIRST INCIDENCE	577	568	605	485

STATISTICAL TESTS

LIFE TABLE	P=0.045*	P=0.458	P=0.448	P=0.077
POLY 3	P=0.056	P=0.468	P=0.444	P=0.090
POLY 1.5	P=0.062	P=0.470	P=0.455	P=0.100
POLY 6	P=0.050*	P=0.470	P=0.445	P=0.082
LOGISTIC REGRESSION	P=0.069	P=0.486	P=0.487	P=0.119
COCH-ARM / FISHERS	P=0.074	P=0.487	P=0.500	P=0.117
ORDER RESTRICTED	P=0.062	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.075	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Islets, Pancreatic
 Adenoma**

TUMOR RATES

OVERALL (a)	4/50 (8%)	1/49 (2%)	1/50 (2%)	3/49 (6%)
POLY-3 RATE (b)	4/45.49	1/43.22	1/41.26	3/41.17
POLY-3 PERCENT (g)	8.8%	2.3%	2.4%	7.3%
TERMINAL (d)	4/35 (11%)	1/34 (3%)	1/33 (3%)	3/30 (10%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.593	P=0.187N	P=0.196N	P=0.585N
POLY 3	P=0.550N	P=0.194N	P=0.210N	P=0.554N
POLY 1.5	P=0.542N	P=0.194N	P=0.203N	P=0.538N
POLY 6	P=0.557N	P=0.193N	P=0.211N	P=0.570N
LOGISTIC REGRESSION	P=0.593	P=0.187N	P=0.196N	P=0.585N
COCH-ARM / FISHERS	P=0.529N	P=0.187N	P=0.181N	P=0.511N
ORDER RESTRICTED	P=0.249N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.270N	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

Liver
 Hepatocellular Adenoma

TUMOR RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	2/48 (4%)
POLY-3 RATE (b)	1/45.88	0/44.21	0/41.26	2/40.88
POLY-3 PERCENT (g)	2.2%	0%	0%	4.9%
TERMINAL (d)	0/35 (0%)	0/34 (0%)	0/33 (0%)	2/30 (7%)
FIRST INCIDENCE	617	---	---	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.215	P=0.513N	P=0.533N	P=0.448
POLY 3	P=0.227	P=0.507N	P=0.521N	P=0.460
POLY 1.5	P=0.231	P=0.506N	P=0.516N	P=0.470
POLY 6	P=0.223	P=0.508N	P=0.524N	P=0.450
LOGISTIC REGRESSION	P=0.232	P=0.460N	P=0.450N	P=0.486
COCH-ARM / FISHERS	P=0.236	P=0.500N	P=0.500N	P=0.485
ORDER RESTRICTED	P=0.107	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.125	(e)	(e)	(e)

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 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

Lung
 Alveolar/Bronchiolar Adenoma

TUMOR RATES

OVERALL (a)	3/50 (6%)	3/50 (6%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	3/45.54	3/44.82	2/41.63	2/41.71
POLY-3 PERCENT (g)	6.6%	6.7%	4.8%	4.8%
TERMINAL (d)	2/35 (6%)	2/34 (6%)	1/33 (3%)	2/30 (7%)
FIRST INCIDENCE	715	533	624	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.438N	P=0.649	P=0.534N	P=0.569N
POLY 3	P=0.412N	P=0.655	P=0.541N	P=0.540N
POLY 1.5	P=0.396N	P=0.653	P=0.533N	P=0.524N
POLY 6	P=0.427N	P=0.659	P=0.541N	P=0.556N
LOGISTIC REGRESSION	P=0.392N	P=0.663	P=0.536N	P=0.565N
COCH-ARM / FISHERS	P=0.371N	P=0.661N	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.559N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.571N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Lung
 Alveolar/Bronchiolar Carcinoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/45.49	2/44.32	1/41.26	2/42.53
POLY-3 PERCENT (g)	2.2%	4.5%	2.4%	4.7%
TERMINAL (d)	1/35 (3%)	1/34 (3%)	1/33 (3%)	0/30 (0%)
FIRST INCIDENCE	729 (T)	701	729 (T)	443

STATISTICAL TESTS

LIFE TABLE	P=0.400	P=0.499	P=0.749	P=0.472
POLY 3	P=0.415	P=0.491	P=0.739	P=0.477
POLY 1.5	P=0.427	P=0.491	P=0.743	P=0.486
POLY 6	P=0.404	P=0.493	P=0.737	P=0.467
LOGISTIC REGRESSION	P=0.448	P=0.492	P=0.749	P=0.590
COCH-ARM / FISHERS	P=0.444	P=0.500	P=0.753N	P=0.500
ORDER RESTRICTED	P=0.412	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.428	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 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)	4/50 (8%)	5/50 (10%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	4/45.54	5/44.93	3/41.63	4/42.53
POLY-3 PERCENT (g)	8.8%	11.1%	7.2%	9.4%
TERMINAL (d)	3/35 (9%)	3/34 (9%)	2/33 (6%)	2/30 (7%)
FIRST INCIDENCE	715	533	624	443

STATISTICAL TESTS

LIFE TABLE	P=0.556	P=0.489	P=0.538N	P=0.571
POLY 3	P=0.545N	P=0.491	P=0.549N	P=0.605
POLY 1.5	P=0.528N	P=0.489	P=0.540N	P=0.620
POLY 6	P=0.563N	P=0.499	P=0.549N	P=0.590
LOGISTIC REGRESSION	P=0.513N	P=0.490	P=0.551N	P=0.642
COCH-ARM / FISHERS	P=0.500N	P=0.500	P=0.500N	P=0.643N
ORDER RESTRICTED	P=0.615N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.621N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Mammary Gland Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.49	0/44.21	0/41.26	2/41.71
POLY-3 PERCENT (g)	0%	0%	0%	4.8%
TERMINAL (d)	0/35 (0%)	0/34 (0%)	0/33 (0%)	2/30 (7%)
FIRST INCIDENCE	---	---	---	729 (T)
STATISTICAL TESTS				
LIFE TABLE	P=0.037*	(e)	(e)	P=0.205
POLY 3	P=0.042*	(e)	(e)	P=0.218
POLY 1.5	P=0.043*	(e)	(e)	P=0.226
POLY 6	P=0.040*	(e)	(e)	P=0.211
LOGISTIC REGRESSION	(e)	(e)	(e)	P=0.205
COCH-ARM / FISHERS	P=0.046*	(e)	(e)	P=0.247
ORDER RESTRICTED	P=0.024*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.032*	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Mammary Gland Fibroadenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	4/50 (8%)	3/50 (6%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	4/45.73	3/44.21	1/41.26	1/41.86
POLY-3 PERCENT (g)	8.8%	6.8%	2.4%	2.4%
TERMINAL (d)	2/35 (6%)	3/34 (9%)	1/33 (3%)	0/30 (0%)
FIRST INCIDENCE	688	729 (T)	729 (T)	692
STATISTICAL TESTS				
LIFE TABLE	P=0.122N	P=0.511N	P=0.201N	P=0.230N
POLY 3	P=0.107N	P=0.518N	P=0.211N	P=0.207N
POLY 1.5	P=0.101N	P=0.516N	P=0.204N	P=0.196N
POLY 6	P=0.113N	P=0.519N	P=0.215N	P=0.218N
LOGISTIC REGRESSION	P=0.116N	P=0.512N	P=0.210N	P=0.205N
COCH-ARM / FISHERS	P=0.092N	P=0.500N	P=0.181N	P=0.181N
ORDER RESTRICTED	P=0.139N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.158N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Mammary Gland
 Fibroma, Fibroadenoma, Carcinoma, or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	4/50 (8%)	3/50 (6%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	4/45.73	3/44.21	1/41.26	3/41.86
POLY-3 PERCENT (g)	8.8%	6.8%	2.4%	7.2%
TERMINAL (d)	2/35 (6%)	3/34 (9%)	1/33 (3%)	2/30 (7%)
FIRST INCIDENCE	688	729 (T)	729 (T)	692

STATISTICAL TESTS

LIFE TABLE	P=0.471N	P=0.511N	P=0.201N	P=0.578N
POLY 3	P=0.431N	P=0.518N	P=0.211N	P=0.548N
POLY 1.5	P=0.418N	P=0.516N	P=0.204N	P=0.529N
POLY 6	P=0.443N	P=0.519N	P=0.215N	P=0.567N
LOGISTIC REGRESSION	P=0.462N	P=0.512N	P=0.210N	P=0.561N
COCH-ARM / FISHERS	P=0.397N	P=0.500N	P=0.181N	P=0.500N
ORDER RESTRICTED	P=0.358N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.378N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)
 Squamous Cell Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/45.49	0/44.21	1/42.08	2/41.75
POLY-3 PERCENT (g)	2.2%	0%	2.4%	4.8%
TERMINAL (d)	1/35 (3%)	0/34 (0%)	0/33 (0%)	1/30 (3%)
FIRST INCIDENCE	729 (T)	---	411	719

STATISTICAL TESTS

LIFE TABLE	P=0.224	P=0.506N	P=0.747	P=0.454
POLY 3	P=0.230	P=0.506N	P=0.743	P=0.470
POLY 1.5	P=0.238	P=0.505N	P=0.746	P=0.482
POLY 6	P=0.222	P=0.505N	P=0.743	P=0.459
LOGISTIC REGRESSION	P=0.258	(e)	P=0.681N	P=0.450
COCH-ARM / FISHERS	P=0.247	P=0.500N	P=0.753N	P=0.500
ORDER RESTRICTED	P=0.199	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.221	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)
 Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/45.49	0/44.21	1/42.08	2/41.75
POLY-3 PERCENT (g)	2.2%	0%	2.4%	4.8%
TERMINAL (d)	1/35 (3%)	0/34 (0%)	0/33 (0%)	1/30 (3%)
FIRST INCIDENCE	729 (T)	---	411	719

STATISTICAL TESTS

LIFE TABLE	P=0.224	P=0.506N	P=0.747	P=0.454
POLY 3	P=0.230	P=0.506N	P=0.743	P=0.470
POLY 1.5	P=0.238	P=0.505N	P=0.746	P=0.482
POLY 6	P=0.222	P=0.505N	P=0.743	P=0.459
LOGISTIC REGRESSION	P=0.258	(e)	P=0.681N	P=0.450
COCH-ARM / FISHERS	P=0.247	P=0.500N	P=0.753N	P=0.500
ORDER RESTRICTED	P=0.199	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.221	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
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 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Oral Mucosa
 Squamous Cell Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/45.49	0/44.21	1/42.08	2/41.75
POLY-3 PERCENT (g)	2.2%	0%	2.4%	4.8%
TERMINAL (d)	1/35 (3%)	0/34 (0%)	0/33 (0%)	1/30 (3%)
FIRST INCIDENCE	729 (T)	---	411	719

STATISTICAL TESTS

LIFE TABLE	P=0.224	P=0.506N	P=0.747	P=0.454
POLY 3	P=0.230	P=0.506N	P=0.743	P=0.470
POLY 1.5	P=0.238	P=0.505N	P=0.746	P=0.482
POLY 6	P=0.222	P=0.505N	P=0.743	P=0.459
LOGISTIC REGRESSION	P=0.258	(e)	P=0.681N	P=0.450
COCH-ARM / FISHERS	P=0.247	P=0.500N	P=0.753N	P=0.500
ORDER RESTRICTED	P=0.199	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.221	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
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 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Pancreas
 Adenoma**

TUMOR RATES

OVERALL (a)	7/50 (14%)	1/50 (2%)	1/50 (2%)	5/49 (10%)
POLY-3 RATE (b)	7/45.49	1/44.21	1/41.26	5/41.17
POLY-3 PERCENT (g)	15.4%	2.3%	2.4%	12.1%
TERMINAL (d)	7/35 (20%)	1/34 (3%)	1/33 (3%)	5/30 (17%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.551N	P=0.034N*	P=0.037N*	P=0.490N
POLY 3	P=0.497N	P=0.033N*	P=0.041N*	P=0.450N
POLY 1.5	P=0.487N	P=0.033N*	P=0.039N*	P=0.429N
POLY 6	P=0.505N	P=0.032N*	P=0.042N*	P=0.471N
LOGISTIC REGRESSION	P=0.551N	P=0.034N*	P=0.037N*	P=0.490N
COCH-ARM / FISHERS	P=0.474N	P=0.030N*	P=0.030N*	P=0.394N
ORDER RESTRICTED	P=0.066N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.080N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Pancreas
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	8/50 (16%)	1/50 (2%)	1/50 (2%)	5/49 (10%)
POLY-3 RATE (b)	8/45.49	1/44.21	1/41.26	5/41.17
POLY-3 PERCENT (g)	17.6%	2.3%	2.4%	12.1%
TERMINAL (d)	8/35 (23%)	1/34 (3%)	1/33 (3%)	5/30 (17%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.426N	P=0.019N*	P=0.021N*	P=0.379N
POLY 3	P=0.370N	P=0.017N*	P=0.023N*	P=0.342N
POLY 1.5	P=0.362N	P=0.018N*	P=0.021N*	P=0.322N
POLY 6	P=0.378N	P=0.017N*	P=0.023N*	P=0.362N
LOGISTIC REGRESSION	P=0.426N	P=0.019N*	P=0.021N*	P=0.379N
COCH-ARM / FISHERS	P=0.352N	P=0.015N*	P=0.015N*	P=0.290N
ORDER RESTRICTED	P=0.029N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.039N*	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Requested: 09/28/2006
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 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 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)	19/50 (38%)	13/48 (27%)	19/47 (40%)	15/47 (32%)
POLY-3 RATE (b)	19/46.71	13/44.56	19/39.38	15/40.83
POLY-3 PERCENT (g)	40.7%	29.2%	48.2%	36.7%
TERMINAL (d)	13/35 (37%)	7/34 (21%)	15/30 (50%)	12/30 (40%)
FIRST INCIDENCE	577	477	549	630

STATISTICAL TESTS

LIFE TABLE	P=0.491	P=0.186N	P=0.376	P=0.464N
POLY 3	P=0.513	P=0.175N	P=0.313	P=0.437N
POLY 1.5	P=0.516N	P=0.182N	P=0.352	P=0.397N
POLY 6	P=0.455	P=0.163N	P=0.290	P=0.482N
LOGISTIC REGRESSION	P=0.524N	P=0.181N	P=0.311	P=0.443N
COCH-ARM / FISHERS	P=0.441N	P=0.175N	P=0.485	P=0.340N
ORDER RESTRICTED	P=0.376	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.399	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Prostate
 Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	2/49 (4%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	0/45.49	2/43.38	3/41.26	1/41.71
POLY-3 PERCENT (g)	0%	4.6%	7.3%	2.4%
TERMINAL (d)	0/35 (0%)	1/34 (3%)	3/33 (9%)	1/30 (3%)
FIRST INCIDENCE	---	710	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.388	P=0.239	P=0.110	P=0.469
POLY 3	P=0.394	P=0.227	P=0.102	P=0.483
POLY 1.5	P=0.415	P=0.227	P=0.106	P=0.489
POLY 6	P=0.373	P=0.228	P=0.101	P=0.476
LOGISTIC REGRESSION	P=0.390	P=0.228	P=0.110	P=0.469
COCH-ARM / FISHERS	P=0.447	P=0.242	P=0.121	P=0.500
ORDER RESTRICTED	P=0.168	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.191	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Skin
 Basal Cell Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/45.88	0/44.21	2/41.26	0/41.71
POLY-3 PERCENT (g)	2.2%	0%	4.9%	0%
TERMINAL (d)	0/35 (0%)	0/34 (0%)	2/33 (6%)	0/30 (0%)
FIRST INCIDENCE	617	---	729 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.499N	P=0.513N	P=0.467	P=0.528N
POLY 3	P=0.485N	P=0.507N	P=0.463	P=0.519N
POLY 1.5	P=0.474N	P=0.506N	P=0.472	P=0.511N
POLY 6	P=0.498N	P=0.508N	P=0.459	P=0.527N
LOGISTIC REGRESSION	P=0.468N	P=0.460N	P=0.487	P=0.438N
COCH-ARM / FISHERS	P=0.461N	P=0.500N	P=0.500	P=0.500N
ORDER RESTRICTED	P=0.326N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.349N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

Skin
 Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/45.88	0/44.21	2/41.26	1/41.71
POLY-3 PERCENT (g)	2.2%	0%	4.9%	2.4%
TERMINAL (d)	0/35 (0%)	0/34 (0%)	2/33 (6%)	1/30 (3%)
FIRST INCIDENCE	617	---	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.455	P=0.513N	P=0.467	P=0.727
POLY 3	P=0.466	P=0.507N	P=0.463	P=0.739
POLY 1.5	P=0.481	P=0.506N	P=0.472	P=0.748
POLY 6	P=0.449	P=0.508N	P=0.459	P=0.730
LOGISTIC REGRESSION	P=0.483	P=0.460N	P=0.487	P=0.752N
COCH-ARM / FISHERS	P=0.500	P=0.500N	P=0.500	P=0.753N
ORDER RESTRICTED	P=0.346	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.368	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

Skin
 Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma

TUMOR RATES	#	#	#	#
OVERALL (a)	8/50 (16%)	5/50 (10%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	8/46.15	5/44.32	3/41.26	3/41.71
POLY-3 PERCENT (g)	17.3%	11.3%	7.3%	7.2%
TERMINAL (d)	5/35 (14%)	4/34 (12%)	3/33 (9%)	3/30 (10%)
FIRST INCIDENCE	617	701	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.104N	P=0.296N	P=0.128N	P=0.160N
POLY 3	P=0.084N	P=0.302N	P=0.137N	P=0.133N
POLY 1.5	P=0.076N	P=0.297N	P=0.127N	P=0.118N
POLY 6	P=0.094N	P=0.304N	P=0.143N	P=0.150N
LOGISTIC REGRESSION	P=0.094N	P=0.293N	P=0.131N	P=0.133N
COCH-ARM / FISHERS	P=0.066N	P=0.277N	P=0.100N	P=0.100N
ORDER RESTRICTED	P=0.095N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.115N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Skin				
Fibroma				
TUMOR RATES	#	#	#	#
OVERALL (a)	5/50 (10%)	1/50 (2%)	6/50 (12%)	2/50 (4%)
POLY-3 RATE (b)	5/45.83	1/44.21	6/42.14	2/41.75
POLY-3 PERCENT (g)	10.9%	2.3%	14.2%	4.8%
TERMINAL (d)	4/35 (11%)	1/34 (3%)	2/33 (6%)	1/30 (3%)
FIRST INCIDENCE	635	729 (T)	624	719
STATISTICAL TESTS				
LIFE TABLE	P=0.397N	P=0.111N	P=0.449	P=0.281N
POLY 3	P=0.365N	P=0.110N	P=0.441	P=0.255N
POLY 1.5	P=0.344N	P=0.109N	P=0.451	P=0.240N
POLY 6	P=0.387N	P=0.109N	P=0.444	P=0.272N
LOGISTIC REGRESSION	P=0.355N	P=0.109N	P=0.459	P=0.261N
COCH-ARM / FISHERS	P=0.320N	P=0.102N	P=0.500	P=0.218N
ORDER RESTRICTED	P=0.229N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.251N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 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)	7/50 (14%)	3/50 (6%)	6/50 (12%)	2/50 (4%)
POLY-3 RATE (b)	7/46.25	3/44.92	6/42.14	2/41.75
POLY-3 PERCENT (g)	15.1%	6.7%	14.2%	4.8%
TERMINAL (d)	5/35 (14%)	1/34 (3%)	2/33 (6%)	1/30 (3%)
FIRST INCIDENCE	607	485	624	719

STATISTICAL TESTS

LIFE TABLE	P=0.157N	P=0.179N	P=0.560N	P=0.125N
POLY 3	P=0.136N	P=0.169N	P=0.572N	P=0.105N
POLY 1.5	P=0.122N	P=0.168N	P=0.557N	P=0.094N
POLY 6	P=0.152N	P=0.169N	P=0.573N	P=0.118N
LOGISTIC REGRESSION	P=0.111N	P=0.148N	P=0.534N	P=0.096N
COCH-ARM / FISHERS	P=0.105N	P=0.159N	P=0.500N	P=0.080N
ORDER RESTRICTED	P=0.082N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.100N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 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)	2/50 (4%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/45.91	2/44.92	0/41.26	0/41.71
POLY-3 PERCENT (g)	4.4%	4.5%	0%	0%
TERMINAL (d)	1/35 (3%)	0/34 (0%)	0/33 (0%)	0/30 (0%)
FIRST INCIDENCE	607	485	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.102N	P=0.679	P=0.264N	P=0.272N
POLY 3	P=0.095N	P=0.686	P=0.262N	P=0.259N
POLY 1.5	P=0.092N	P=0.686	P=0.256N	P=0.250N
POLY 6	P=0.099N	P=0.688	P=0.265N	P=0.269N
LOGISTIC REGRESSION	P=0.075N	P=0.651N	P=0.222N	P=0.213N
COCH-ARM / FISHERS	P=0.086N	P=0.691N	P=0.247N	P=0.247N
ORDER RESTRICTED	P=0.130N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.151N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Skin				
Hemangiosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/45.49	0/44.21	2/41.26	0/41.71
POLY-3 PERCENT (g)	0%	0%	4.9%	0%
TERMINAL (d)	0/35 (0%)	0/34 (0%)	2/33 (6%)	0/30 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
STATISTICAL TESTS				
LIFE TABLE	P=0.565	(e)	P=0.225	(e)
POLY 3	P=0.558	(e)	P=0.216	(e)
POLY 1.5	P=0.575	(e)	P=0.220	(e)
POLY 6	P=0.538	(e)	P=0.215	(e)
LOGISTIC REGRESSION	(e)	(e)	P=0.225	(e)
COCH-ARM / FISHERS	P=0.595	(e)	P=0.247	(e)
ORDER RESTRICTED	P=0.228	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.249	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Skin				
Keratoacanthoma				
TUMOR RATES				
	#	#	#	#
OVERALL (a)	7/50 (14%)	5/50 (10%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	7/45.76	5/44.32	1/41.26	1/41.71
POLY-3 PERCENT (g)	15.3%	11.3%	2.4%	2.4%
TERMINAL (d)	5/35 (14%)	4/34 (12%)	1/33 (3%)	1/30 (3%)
FIRST INCIDENCE	681	701	729 (T)	729 (T)
STATISTICAL TESTS				
LIFE TABLE	P=0.016N*	P=0.395N	P=0.042N*	P=0.055N
POLY 3	P=0.012N*	P=0.402N	P=0.042N*	P=0.041N*
POLY 1.5	P=0.010N**	P=0.399N	P=0.039N*	P=0.036N*
POLY 6	P=0.013N*	P=0.400N	P=0.044N*	P=0.046N*
LOGISTIC REGRESSION	P=0.015N*	P=0.392N	P=0.044N*	P=0.047N*
COCH-ARM / FISHERS	P=0.010N**	P=0.380N	P=0.030N*	P=0.030N*
ORDER RESTRICTED	P=0.016N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.017N*	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Skin				
Lipoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/45.49	0/44.21	0/41.26	0/41.71
POLY-3 PERCENT (g)	4.4%	0%	0%	0%
TERMINAL (d)	2/35 (6%)	0/34 (0%)	0/33 (0%)	0/30 (0%)
FIRST INCIDENCE	729 (T)	---	---	---
STATISTICAL TESTS				
LIFE TABLE	P=0.127N	P=0.245N	P=0.251N	P=0.273N
POLY 3	P=0.112N	P=0.244N	P=0.260N	P=0.257N
POLY 1.5	P=0.113N	P=0.243N	P=0.255N	P=0.249N
POLY 6	P=0.112N	P=0.242N	P=0.261N	P=0.265N
LOGISTIC REGRESSION	P=0.127N	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
ORDER RESTRICTED	P=0.036N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.049N*	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

Skin
 Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/45.88	0/44.21	2/41.26	0/41.71
POLY-3 PERCENT (g)	2.2%	0%	4.9%	0%
TERMINAL (d)	0/35 (0%)	0/34 (0%)	2/33 (6%)	0/30 (0%)
FIRST INCIDENCE	617	---	729 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.499N	P=0.513N	P=0.467	P=0.528N
POLY 3	P=0.485N	P=0.507N	P=0.463	P=0.519N
POLY 1.5	P=0.474N	P=0.506N	P=0.472	P=0.511N
POLY 6	P=0.498N	P=0.508N	P=0.459	P=0.527N
LOGISTIC REGRESSION	P=0.468N	P=0.460N	P=0.487	P=0.438N
COCH-ARM / FISHERS	P=0.461N	P=0.500N	P=0.500	P=0.500N
ORDER RESTRICTED	P=0.326N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.349N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Skin
 Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	7/50 (14%)	5/50 (10%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	7/45.76	5/44.32	1/41.26	2/41.71
POLY-3 PERCENT (g)	15.3%	11.3%	2.4%	4.8%
TERMINAL (d)	5/35 (14%)	4/34 (12%)	1/33 (3%)	2/30 (7%)
FIRST INCIDENCE	681	701	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.049N*	P=0.395N	P=0.042N*	P=0.126N
POLY 3	P=0.038N*	P=0.402N	P=0.042N*	P=0.102N
POLY 1.5	P=0.035N*	P=0.399N	P=0.039N*	P=0.093N
POLY 6	P=0.042N*	P=0.400N	P=0.044N*	P=0.113N
LOGISTIC REGRESSION	P=0.046N*	P=0.392N	P=0.044N*	P=0.114N
COCH-ARM / FISHERS	P=0.031N*	P=0.380N	P=0.030N*	P=0.080N
ORDER RESTRICTED	P=0.034N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.047N*	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Skin
 Squamous Cell Papilloma, Papilloma, or Keratoacanthoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	7/50 (14%)	5/50 (10%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	7/45.76	5/44.32	1/41.26	2/41.71
POLY-3 PERCENT (g)	15.3%	11.3%	2.4%	4.8%
TERMINAL (d)	5/35 (14%)	4/34 (12%)	1/33 (3%)	2/30 (7%)
FIRST INCIDENCE	681	701	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.049N*	P=0.395N	P=0.042N*	P=0.126N
POLY 3	P=0.038N*	P=0.402N	P=0.042N*	P=0.102N
POLY 1.5	P=0.035N*	P=0.399N	P=0.039N*	P=0.093N
POLY 6	P=0.042N*	P=0.400N	P=0.044N*	P=0.113N
LOGISTIC REGRESSION	P=0.046N*	P=0.392N	P=0.044N*	P=0.114N
COCH-ARM / FISHERS	P=0.031N*	P=0.380N	P=0.030N*	P=0.080N
ORDER RESTRICTED	P=0.034N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.047N*	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

Testes
 Adenoma

TUMOR RATES

OVERALL (a)	46/50 (92%)	43/50 (86%)	44/50 (88%)	44/50 (88%)
POLY-3 RATE (b)	46/48.24	43/46.73	44/45.75	44/48.83
POLY-3 PERCENT (g)	95.4%	92%	96.2%	90.1%
TERMINAL (d)	35/35 (100%)	33/34 (97%)	33/33 (100%)	27/30 (90%)
FIRST INCIDENCE	556	533	411	415

STATISTICAL TESTS

LIFE TABLE	P=0.168	P=0.429N	P=0.493	P=0.271
POLY 3	P=0.222N	P=0.388N	P=0.644	P=0.257N
POLY 1.5	P=0.285N	P=0.367N	P=0.663	P=0.302N
POLY 6	P=0.146N	P=0.414N	P=0.727	P=0.200N
LOGISTIC REGRESSION	P=0.474	P=0.486N	P=0.313	P=0.539N
COCH-ARM / FISHERS	P=0.397N	P=0.262N	P=0.370N	P=0.370N
ORDER RESTRICTED	P=0.191N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.199N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Requested: 09/28/2006
 Time Report Requested: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

Thymus
 Thymoma: Benign, Malignant, NOS

TUMOR RATES

OVERALL (a)	0/47 (0%)	0/43 (0%)	0/49 (0%)	2/48 (4%)
POLY-3 RATE (b)	0/42.57	0/37.21	0/40.26	2/41.23
POLY-3 PERCENT (g)	0%	0%	0%	4.9%
TERMINAL (d)	0/33 (0%)	0/27 (0%)	0/32 (0%)	1/30 (3%)
FIRST INCIDENCE	---	---	---	719

STATISTICAL TESTS

LIFE TABLE	P=0.043*	(e)	(e)	P=0.220
POLY 3	P=0.047*	(e)	(e)	P=0.230
POLY 1.5	P=0.048*	(e)	(e)	P=0.235
POLY 6	P=0.046*	(e)	(e)	P=0.225
LOGISTIC REGRESSION	P=0.045*	(e)	(e)	P=0.221
COCH-ARM / FISHERS	P=0.050*	(e)	(e)	P=0.253
ORDER RESTRICTED	P=0.027*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.035*	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Thyroid Gland: C-Cell
 Adenoma**

TUMOR RATES

OVERALL (a)	9/50 (18%)	12/49 (24%)	9/50 (18%)	6/47 (13%)
POLY-3 RATE (b)	9/45.78	12/43.69	9/41.71	6/41.12
POLY-3 PERCENT (g)	19.7%	27.5%	21.6%	14.6%
TERMINAL (d)	7/35 (20%)	9/34 (27%)	7/33 (21%)	2/30 (7%)
FIRST INCIDENCE	674	648	624	628

STATISTICAL TESTS

LIFE TABLE	P=0.270N	P=0.297	P=0.542	P=0.404N
POLY 3	P=0.228N	P=0.267	P=0.517	P=0.367N
POLY 1.5	P=0.215N	P=0.269	P=0.534	P=0.356N
POLY 6	P=0.236N	P=0.271	P=0.514	P=0.374N
LOGISTIC REGRESSION	P=0.244N	P=0.266	P=0.509	P=0.370N
COCH-ARM / FISHERS	P=0.193N	P=0.294	P=0.602N	P=0.334N
ORDER RESTRICTED	P=0.243N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.260N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Thyroid Gland: C-Cell
 Carcinoma**

TUMOR RATES

OVERALL (a)	6/50 (12%)	3/49 (6%)	3/50 (6%)	2/47 (4%)
POLY-3 RATE (b)	6/45.65	3/43.22	3/41.69	2/40.1
POLY-3 PERCENT (g)	13.1%	6.9%	7.2%	5%
TERMINAL (d)	5/35 (14%)	3/34 (9%)	2/33 (6%)	2/30 (7%)
FIRST INCIDENCE	688	729 (T)	603	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.154N	P=0.255N	P=0.278N	P=0.188N
POLY 3	P=0.142N	P=0.269N	P=0.288N	P=0.178N
POLY 1.5	P=0.135N	P=0.267N	P=0.279N	P=0.169N
POLY 6	P=0.149N	P=0.269N	P=0.289N	P=0.188N
LOGISTIC REGRESSION	P=0.152N	P=0.256N	P=0.288N	P=0.190N
COCH-ARM / FISHERS	P=0.125N	P=0.254N	P=0.243N	P=0.155N
ORDER RESTRICTED	P=0.132N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.150N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Thyroid Gland: C-Cell
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	15/50 (30%)	15/49 (31%)	11/50 (22%)	8/47 (17%)
POLY-3 RATE (b)	15/45.94	15/43.69	11/42.15	8/41.12
POLY-3 PERCENT (g)	32.7%	34.3%	26.1%	19.5%
TERMINAL (d)	12/35 (34%)	12/34 (35%)	8/33 (24%)	4/30 (13%)
FIRST INCIDENCE	674	648	603	628

STATISTICAL TESTS

LIFE TABLE	P=0.101N	P=0.556	P=0.317N	P=0.163N
POLY 3	P=0.068N	P=0.522	P=0.330N	P=0.123N
POLY 1.5	P=0.063N	P=0.525	P=0.315N	P=0.115N
POLY 6	P=0.072N	P=0.527	P=0.328N	P=0.128N
LOGISTIC REGRESSION	P=0.082N	P=0.528	P=0.347N	P=0.139N
COCH-ARM / FISHERS	P=0.054N	P=0.560	P=0.247N	P=0.103N
ORDER RESTRICTED	P=0.109N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.108N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Thyroid Gland: Follicular Cell
 Carcinoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	2/49 (4%)	2/50 (4%)	1/47 (2%)
POLY-3 RATE (b)	1/45.7	2/43.22	2/41.26	1/40.1
POLY-3 PERCENT (g)	2.2%	4.6%	4.9%	2.5%
TERMINAL (d)	0/35 (0%)	2/34 (6%)	2/33 (6%)	1/30 (3%)
FIRST INCIDENCE	674	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.611	P=0.488	P=0.469	P=0.726
POLY 3	P=0.606N	P=0.481	P=0.464	P=0.731
POLY 1.5	P=0.594N	P=0.482	P=0.472	P=0.737
POLY 6	P=0.597	P=0.480	P=0.461	P=0.724
LOGISTIC REGRESSION	P=0.612	P=0.483	P=0.468	P=0.742
COCH-ARM / FISHERS	P=0.577N	P=0.492	P=0.500	P=0.737
ORDER RESTRICTED	P=0.510	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.526	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Thyroid Gland: Follicular Cell
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	2/50 (4%)	2/49 (4%)	2/50 (4%)	1/47 (2%)
POLY-3 RATE (b)	2/45.75	2/43.22	2/41.26	1/40.1
POLY-3 PERCENT (g)	4.4%	4.6%	4.9%	2.5%
TERMINAL (d)	0/35 (0%)	2/34 (6%)	2/33 (6%)	1/30 (3%)
FIRST INCIDENCE	674	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.431N	P=0.683	P=0.663	P=0.552N
POLY 3	P=0.422N	P=0.673	P=0.656	P=0.546N
POLY 1.5	P=0.411N	P=0.675	P=0.665	P=0.536N
POLY 6	P=0.433N	P=0.673	P=0.652	P=0.556N
LOGISTIC REGRESSION	P=0.429N	P=0.678	P=0.662	P=0.539N
COCH-ARM / FISHERS	P=0.393N	P=0.684	P=0.691N	P=0.523N
ORDER RESTRICTED	P=0.493N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.508N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Zymbal's Gland Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/46.05	1/44.21	0/41.26	0/41.71
POLY-3 PERCENT (g)	4.3%	2.3%	0%	0%
TERMINAL (d)	0/35 (0%)	1/34 (3%)	0/33 (0%)	0/30 (0%)
FIRST INCIDENCE	577	729 (T)	---	---
STATISTICAL TESTS				
LIFE TABLE	P=0.117N	P=0.516N	P=0.261N	P=0.271N
POLY 3	P=0.106N	P=0.514N	P=0.262N	P=0.260N
POLY 1.5	P=0.104N	P=0.512N	P=0.256N	P=0.251N
POLY 6	P=0.108N	P=0.515N	P=0.266N	P=0.270N
LOGISTIC REGRESSION	P=0.098N	P=0.485N	P=0.200N	P=0.191N
COCH-ARM / FISHERS	P=0.101N	P=0.500N	P=0.247N	P=0.247N
ORDER RESTRICTED	P=0.089N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.107N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**All Organs
 Hemangiosarcoma**

TUMOR RATES

	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	1/45.91	0/44.21	4/41.96	0/41.71
POLY-3 PERCENT (g)	2.2%	0%	9.5%	0%
TERMINAL (d)	0/35 (0%)	0/34 (0%)	3/33 (9%)	0/30 (0%)
FIRST INCIDENCE	607	---	485	---

STATISTICAL TESTS

LIFE TABLE	P=0.571N	P=0.518N	P=0.159	P=0.527N
POLY 3	P=0.574N	P=0.508N	P=0.152	P=0.519N
POLY 1.5	P=0.555N	P=0.506N	P=0.158	P=0.512N
POLY 6	P=0.595N	P=0.508N	P=0.150	P=0.527N
LOGISTIC REGRESSION	P=0.516N	P=0.454N	P=0.199	P=0.430N
COCH-ARM / FISHERS	P=0.531N	P=0.500N	P=0.181	P=0.500N
ORDER RESTRICTED	P=0.222N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.245N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

All Organs
 Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated

TUMOR RATES	#	#	#	#
OVERALL (a)	10/50 (20%)	11/50 (22%)	14/50 (28%)	7/50 (14%)
POLY-3 RATE (b)	10/46.57	11/44.85	14/42.85	7/42.16
POLY-3 PERCENT (g)	21.5%	24.5%	32.7%	16.6%
TERMINAL (d)	5/35 (14%)	7/34 (21%)	8/33 (24%)	4/30 (13%)
FIRST INCIDENCE	624	648	549	676

STATISTICAL TESTS

LIFE TABLE	P=0.410N	P=0.484	P=0.201	P=0.425N
POLY 3	P=0.363N	P=0.461	P=0.169	P=0.378N
POLY 1.5	P=0.318N	P=0.468	P=0.182	P=0.345N
POLY 6	P=0.413N	P=0.458	P=0.168	P=0.414N
LOGISTIC REGRESSION	P=0.321N	P=0.477	P=0.192	P=0.354N
COCH-ARM / FISHERS	P=0.259N	P=0.500	P=0.241	P=0.298N
ORDER RESTRICTED	P=0.232N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.255N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

All Organs
 Mesothelioma: Benign, Malignant, NOS

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	3/46.04	1/44.21	2/41.26	4/41.92
POLY-3 PERCENT (g)	6.5%	2.3%	4.9%	9.5%
TERMINAL (d)	2/35 (6%)	1/34 (3%)	2/33 (6%)	3/30 (10%)
FIRST INCIDENCE	556	729 (T)	729 (T)	674

STATISTICAL TESTS

LIFE TABLE	P=0.230	P=0.322N	P=0.535N	P=0.418
POLY 3	P=0.261	P=0.320N	P=0.550N	P=0.449
POLY 1.5	P=0.274	P=0.317N	P=0.538N	P=0.469
POLY 6	P=0.249	P=0.321N	P=0.555N	P=0.430
LOGISTIC REGRESSION	P=0.260	P=0.298N	P=0.521N	P=0.481
COCH-ARM / FISHERS	P=0.292	P=0.309N	P=0.500N	P=0.500
ORDER RESTRICTED	P=0.241	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.262	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**All Organs
 Mesothelioma: Malignant**

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	3/46.04	1/44.21	2/41.26	4/41.92
POLY-3 PERCENT (g)	6.5%	2.3%	4.9%	9.5%
TERMINAL (d)	2/35 (6%)	1/34 (3%)	2/33 (6%)	3/30 (10%)
FIRST INCIDENCE	556	729 (T)	729 (T)	674

STATISTICAL TESTS

LIFE TABLE	P=0.230	P=0.322N	P=0.535N	P=0.418
POLY 3	P=0.261	P=0.320N	P=0.550N	P=0.449
POLY 1.5	P=0.274	P=0.317N	P=0.538N	P=0.469
POLY 6	P=0.249	P=0.321N	P=0.555N	P=0.430
LOGISTIC REGRESSION	P=0.260	P=0.298N	P=0.521N	P=0.481
COCH-ARM / FISHERS	P=0.292	P=0.309N	P=0.500N	P=0.500
ORDER RESTRICTED	P=0.241	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.262	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**All Organs
 Osteosarcoma**

TUMOR RATES

	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/46.32	1/44.82	0/41.26	0/41.71
POLY-3 PERCENT (g)	4.3%	2.2%	0%	0%
TERMINAL (d)	1/35 (3%)	0/34 (0%)	0/33 (0%)	0/30 (0%)
FIRST INCIDENCE	401	533	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.112N	P=0.510N	P=0.256N	P=0.257N
POLY 3	P=0.107N	P=0.512N	P=0.264N	P=0.261N
POLY 1.5	P=0.105N	P=0.511N	P=0.258N	P=0.252N
POLY 6	P=0.109N	P=0.509N	P=0.266N	P=0.270N
LOGISTIC REGRESSION	P=0.075N	P=0.367N	P=0.124N	P=0.124N
COCH-ARM / FISHERS	P=0.101N	P=0.500N	P=0.247N	P=0.247N
ORDER RESTRICTED	P=0.091N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.109N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**All Organs
 Osteosarcoma or Osteoma**

TUMOR RATES

	#	#	#	#
OVERALL (a)	2/50 (4%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/46.32	2/44.82	0/41.26	0/41.71
POLY-3 PERCENT (g)	4.3%	4.5%	0%	0%
TERMINAL (d)	1/35 (3%)	1/34 (3%)	0/33 (0%)	0/30 (0%)
FIRST INCIDENCE	401	533	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.099N	P=0.681	P=0.256N	P=0.257N
POLY 3	P=0.096N	P=0.682	P=0.264N	P=0.261N
POLY 1.5	P=0.093N	P=0.683	P=0.258N	P=0.252N
POLY 6	P=0.099N	P=0.684	P=0.266N	P=0.270N
LOGISTIC REGRESSION	P=0.068N	P=0.613N	P=0.124N	P=0.124N
COCH-ARM / FISHERS	P=0.086N	P=0.691N	P=0.247N	P=0.247N
ORDER RESTRICTED	P=0.130N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.152N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**All Organs
 Benign Tumors**

TUMOR RATES

	#	#	#	#
OVERALL (a)	49/50 (98%)	46/50 (92%)	46/50 (92%)	49/50 (98%)
POLY-3 RATE (b)	49/49.17	46/48.09	46/46.22	49/49.22
POLY-3 PERCENT (g)	99.7%	95.7%	99.5%	99.5%
TERMINAL (d)	35/35 (100%)	33/34 (97%)	33/33 (100%)	30/30 (100%)
FIRST INCIDENCE	556	477	411	415

STATISTICAL TESTS

LIFE TABLE	P=0.087	P=0.446N	P=0.548	P=0.150
POLY 3	P=0.447	P=0.234N	P=1.000N	P=1.000N
POLY 1.5	P=0.460	P=0.238N	P=0.794N	P=0.930N
POLY 6	P=0.458	P=0.271N	P=1.000	P=1.000N
LOGISTIC REGRESSION	P=0.167	P=0.332N	(e)	P=0.827
COCH-ARM / FISHERS	P=0.456	P=0.181N	P=0.181N	P=0.753N
ORDER RESTRICTED	P=0.263	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.268	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**All Organs
 Malignant Tumors**

TUMOR RATES

	#	#	#	#
OVERALL (a)	29/50 (58%)	25/50 (50%)	27/50 (54%)	25/50 (50%)
POLY-3 RATE (b)	29/49.71	25/46.81	27/45.61	25/45.67
POLY-3 PERCENT (g)	58.3%	53.4%	59.2%	54.7%
TERMINAL (d)	16/35 (46%)	16/34 (47%)	16/33 (49%)	13/30 (43%)
FIRST INCIDENCE	401	485	411	415

STATISTICAL TESTS

LIFE TABLE	P=0.484	P=0.359N	P=0.549	P=0.538N
POLY 3	P=0.456N	P=0.389N	P=0.549	P=0.441N
POLY 1.5	P=0.387N	P=0.358N	P=0.578N	P=0.370N
POLY 6	P=0.530N	P=0.422N	P=0.535	P=0.522N
LOGISTIC REGRESSION	P=0.314N	P=0.262N	P=0.424N	P=0.213N
COCH-ARM / FISHERS	P=0.299N	P=0.274N	P=0.420N	P=0.274N
ORDER RESTRICTED	P=0.563N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.575N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 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)	50/50 (100%)	47/50 (94%)	46/50 (92%)	50/50 (100%)
POLY-3 RATE (b)	50/50	47/48.8	46/46.22	50/50
POLY-3 PERCENT (g)	100%	96.3%	99.5%	100%
TERMINAL (d)	35/35 (100%)	33/34 (97%)	33/33 (100%)	30/30 (100%)
FIRST INCIDENCE	401	477	411	415

STATISTICAL TESTS

LIFE TABLE	P=0.096	P=0.449N	P=0.532N	(e)
POLY 3	P=0.446	P=0.259N	P=1.000N	(e)
POLY 1.5	P=0.464	P=0.244N	P=0.599N	(e)
POLY 6	P=0.459	P=0.288N	P=1.000N	(e)
LOGISTIC REGRESSION	P=0.296	P=0.211N	(e)	(e)
COCH-ARM / FISHERS	P=0.474	P=0.121N	P=0.059N	(e)
ORDER RESTRICTED	P=0.248	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.253	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Adrenal Medulla
 Pheochromocytoma Benign**

TUMOR RATES

OVERALL (a)	2/50 (4%)	4/50 (8%)	0/46 (0%)	2/49 (4%)
POLY-3 RATE (b)	2/45.35	4/42.98	0/40.82	2/39.27
POLY-3 PERCENT (g)	4.4%	9.3%	0%	5.1%
TERMINAL (d)	1/33 (3%)	3/35 (9%)	0/33 (0%)	1/31 (3%)
FIRST INCIDENCE	559	708	---	623

STATISTICAL TESTS

LIFE TABLE	P=0.449N	P=0.351	P=0.247N	P=0.649
POLY 3	P=0.450N	P=0.313	P=0.261N	P=0.641
POLY 1.5	P=0.444N	P=0.316	P=0.259N	P=0.649
POLY 6	P=0.455N	P=0.316	P=0.262N	P=0.635
LOGISTIC REGRESSION	P=0.438N	P=0.325	P=0.249N	P=0.697N
COCH-ARM / FISHERS	P=0.417N	P=0.339	P=0.269N	P=0.684
ORDER RESTRICTED	P=0.281N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.313N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Adrenal Medulla
 Pheochromocytoma Malignant**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/46 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/44.8	0/42.9	0/40.82	0/38.89
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/33 (0%)	0/31 (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. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Requested: 09/28/2006
 Time Report Requested: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Adrenal Medulla
 Pheochromocytoma: Benign, Complex, Malignant, NOS**

TUMOR RATES

OVERALL (a)	2/50 (4%)	4/50 (8%)	0/46 (0%)	2/49 (4%)
POLY-3 RATE (b)	2/45.35	4/42.98	0/40.82	2/39.27
POLY-3 PERCENT (g)	4.4%	9.3%	0%	5.1%
TERMINAL (d)	1/33 (3%)	3/35 (9%)	0/33 (0%)	1/31 (3%)
FIRST INCIDENCE	559	708	---	623

STATISTICAL TESTS

LIFE TABLE	P=0.449N	P=0.351	P=0.247N	P=0.649
POLY 3	P=0.450N	P=0.313	P=0.261N	P=0.641
POLY 1.5	P=0.444N	P=0.316	P=0.259N	P=0.649
POLY 6	P=0.455N	P=0.316	P=0.262N	P=0.635
LOGISTIC REGRESSION	P=0.438N	P=0.325	P=0.249N	P=0.697N
COCH-ARM / FISHERS	P=0.417N	P=0.339	P=0.269N	P=0.684
ORDER RESTRICTED	P=0.281N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.313N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Bone
 Hemangiosarcoma**

TUMOR RATES

	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (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. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Bone				
Osteosarcoma				
TUMOR RATES				
	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	1/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/33 (0%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	730 (T)	---	---
STATISTICAL TESTS				
LIFE TABLE	P=0.580N	P=0.512	(e)	(e)
POLY 3	P=0.576N	P=0.491	(e)	(e)
POLY 1.5	P=0.575N	P=0.492	(e)	(e)
POLY 6	P=0.576N	P=0.494	(e)	(e)
LOGISTIC REGRESSION	(e)	P=0.512	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
ORDER RESTRICTED	P=0.396N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.420N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Bone
 Osteosarcoma or Osteoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	1/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/33 (0%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	730 (T)	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.580N	P=0.512	(e)	(e)
POLY 3	P=0.576N	P=0.491	(e)	(e)
POLY 1.5	P=0.575N	P=0.492	(e)	(e)
POLY 6	P=0.576N	P=0.494	(e)	(e)
LOGISTIC REGRESSION	(e)	P=0.512	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
ORDER RESTRICTED	P=0.396N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.420N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Clitoral/Preputial Gland
 Adenoma**

TUMOR RATES

OVERALL (a)	3/48 (6%)	3/50 (6%)	4/49 (8%)	5/50 (10%)
POLY-3 RATE (b)	3/42.8	3/42.9	4/43.23	5/39.46
POLY-3 PERCENT (g)	7%	7%	9.3%	12.7%
TERMINAL (d)	3/31 (10%)	3/35 (9%)	4/34 (12%)	5/31 (16%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	730 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.224	P=0.607N	P=0.551	P=0.354
POLY 3	P=0.209	P=0.662N	P=0.506	P=0.312
POLY 1.5	P=0.220	P=0.661N	P=0.508	P=0.324
POLY 6	P=0.198	P=0.655N	P=0.507	P=0.301
LOGISTIC REGRESSION	P=0.224	P=0.607N	P=0.551	P=0.354
COCH-ARM / FISHERS	P=0.262	P=0.641N	P=0.512	P=0.381
ORDER RESTRICTED	P=0.297	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.321	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Requested: 09/28/2006
 Time Report Requested: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Clitoral/Preputial Gland
 Carcinoma**

TUMOR RATES

OVERALL (a)	2/48 (4%)	2/50 (4%)	0/49 (0%)	2/50 (4%)
POLY-3 RATE (b)	2/42.87	2/42.9	0/43.23	2/39.46
POLY-3 PERCENT (g)	4.7%	4.7%	0%	5.1%
TERMINAL (d)	1/31 (3%)	2/35 (6%)	0/34 (0%)	2/31 (7%)
FIRST INCIDENCE	713	730 (T)	---	730 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.574N	P=0.661N	P=0.230N	P=0.683
POLY 3	P=0.559N	P=0.694N	P=0.235N	P=0.664
POLY 1.5	P=0.556N	P=0.693N	P=0.234N	P=0.673
POLY 6	P=0.562N	P=0.689N	P=0.235N	P=0.656
LOGISTIC REGRESSION	P=0.594N	P=0.674N	P=0.232N	P=0.664
COCH-ARM / FISHERS	P=0.545N	P=0.676N	P=0.242N	P=0.676N
ORDER RESTRICTED	P=0.465N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.483N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Clitoral/Preputial Gland
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	5/48 (10%)	5/50 (10%)	4/49 (8%)	7/50 (14%)
POLY-3 RATE (b)	5/42.87	5/42.9	4/43.23	7/39.46
POLY-3 PERCENT (g)	11.7%	11.7%	9.3%	17.7%
TERMINAL (d)	4/31 (13%)	5/35 (14%)	4/34 (12%)	7/31 (23%)
FIRST INCIDENCE	713	730 (T)	730 (T)	730 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.276	P=0.561N	P=0.448N	P=0.370
POLY 3	P=0.262	P=0.630N	P=0.495N	P=0.320
POLY 1.5	P=0.275	P=0.629N	P=0.492N	P=0.337
POLY 6	P=0.248	P=0.622N	P=0.494N	P=0.305
LOGISTIC REGRESSION	P=0.250	P=0.581N	P=0.464N	P=0.328
COCH-ARM / FISHERS	P=0.325	P=0.603N	P=0.487N	P=0.409
ORDER RESTRICTED	P=0.279	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.303	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Islets, Pancreatic
 Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)	1/47 (2%)	0/49 (0%)
POLY-3 RATE (b)	0/44.8	0/42.55	1/41.82	0/39.46
POLY-3 PERCENT (g)	0%	0%	2.4%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	---	---	730 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.687	(e)	P=0.506	(e)
POLY 3	P=0.644	(e)	P=0.486	(e)
POLY 1.5	P=0.656	(e)	P=0.487	(e)
POLY 6	P=0.631	(e)	P=0.487	(e)
LOGISTIC REGRESSION	(e)	(e)	P=0.506	(e)
COCH-ARM / FISHERS	P=0.691	(e)	P=0.485	(e)
ORDER RESTRICTED	P=0.369	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.396	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
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 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Liver				
Hepatocellular Adenoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (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. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
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 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Lung				
Alveolar/Bronchiolar Adenoma				
TUMOR RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	1/44.8	2/42.9	1/43.84	4/39.46
POLY-3 PERCENT (g)	2.2%	4.7%	2.3%	10.1%
TERMINAL (d)	1/33 (3%)	2/35 (6%)	1/34 (3%)	4/31 (13%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	730 (T)
STATISTICAL TESTS				
LIFE TABLE	P=0.090	P=0.521	P=0.755N	P=0.159
POLY 3	P=0.091	P=0.485	P=0.756	P=0.142
POLY 1.5	P=0.095	P=0.486	P=0.758	P=0.149
POLY 6	P=0.087	P=0.489	P=0.755	P=0.136
LOGISTIC REGRESSION	P=0.090	P=0.521	P=0.755N	P=0.159
COCH-ARM / FISHERS	P=0.111	P=0.500	P=0.753N	P=0.181
ORDER RESTRICTED	P=0.066	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.086	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Lung
 Alveolar/Bronchiolar Carcinoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (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. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 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)	1/50 (2%)	2/50 (4%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	1/44.8	2/42.9	1/43.84	4/39.46
POLY-3 PERCENT (g)	2.2%	4.7%	2.3%	10.1%
TERMINAL (d)	1/33 (3%)	2/35 (6%)	1/34 (3%)	4/31 (13%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	730 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.090	P=0.521	P=0.755N	P=0.159
POLY 3	P=0.091	P=0.485	P=0.756	P=0.142
POLY 1.5	P=0.095	P=0.486	P=0.758	P=0.149
POLY 6	P=0.087	P=0.489	P=0.755	P=0.136
LOGISTIC REGRESSION	P=0.090	P=0.521	P=0.755N	P=0.159
COCH-ARM / FISHERS	P=0.111	P=0.500	P=0.753N	P=0.181
ORDER RESTRICTED	P=0.066	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.086	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
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 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Mammary Gland Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	4/50 (8%)	1/50 (2%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	4/45.16	1/42.9	2/43.84	4/39.84
POLY-3 PERCENT (g)	8.9%	2.3%	4.6%	10%
TERMINAL (d)	3/33 (9%)	1/35 (3%)	2/34 (6%)	3/31 (10%)
FIRST INCIDENCE	627	730 (T)	730 (T)	623
STATISTICAL TESTS				
LIFE TABLE	P=0.386	P=0.170N	P=0.333N	P=0.587
POLY 3	P=0.400	P=0.194N	P=0.351N	P=0.573
POLY 1.5	P=0.409	P=0.193N	P=0.345N	P=0.587
POLY 6	P=0.390	P=0.192N	P=0.356N	P=0.561
LOGISTIC REGRESSION	P=0.376	P=0.191N	P=0.347N	P=0.581
COCH-ARM / FISHERS	P=0.438	P=0.181N	P=0.339N	P=0.643N
ORDER RESTRICTED	P=0.299	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.328	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Mammary Gland Fibroadenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	26/50 (52%)	28/50 (56%)	19/50 (38%)	18/50 (36%)
POLY-3 RATE (b)	26/46.18	28/43.71	19/44.79	18/41.25
POLY-3 PERCENT (g)	56.3%	64.1%	42.4%	43.6%
TERMINAL (d)	20/33 (61%)	24/35 (69%)	15/34 (44%)	13/31 (42%)
FIRST INCIDENCE	617	660	529	606
STATISTICAL TESTS				
LIFE TABLE	P=0.073N	P=0.526	P=0.108N	P=0.175N
POLY 3	P=0.053N	P=0.292	P=0.127N	P=0.162N
POLY 1.5	P=0.048N*	P=0.314	P=0.119N	P=0.147N
POLY 6	P=0.058N	P=0.294	P=0.137N	P=0.172N
LOGISTIC REGRESSION	P=0.083N	P=0.336	P=0.133N	P=0.198N
COCH-ARM / FISHERS	P=0.026N*	P=0.421	P=0.114N	P=0.079N
ORDER RESTRICTED	P=0.076N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.083N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Mammary Gland
 Fibroma, Fibroadenoma, Carcinoma, or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	28/50 (56%)	29/50 (58%)	21/50 (42%)	22/50 (44%)
POLY-3 RATE (b)	28/46.54	29/43.71	21/44.79	22/41.63
POLY-3 PERCENT (g)	60.2%	66.3%	46.9%	52.9%
TERMINAL (d)	21/33 (64%)	25/35 (71%)	17/34 (50%)	16/31 (52%)
FIRST INCIDENCE	617	660	529	606

STATISTICAL TESTS

LIFE TABLE	P=0.185N	P=0.550N	P=0.111N	P=0.318N
POLY 3	P=0.148N	P=0.345	P=0.138N	P=0.314N
POLY 1.5	P=0.135N	P=0.376	P=0.125N	P=0.286N
POLY 6	P=0.163N	P=0.336	P=0.157N	P=0.334N
LOGISTIC REGRESSION	P=0.216N	P=0.401	P=0.136N	P=0.358N
COCH-ARM / FISHERS	P=0.076N	P=0.500	P=0.115N	P=0.159N
ORDER RESTRICTED	P=0.149N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.173N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)
 Squamous Cell Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.9	1/44.1	0/39.46
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	660	---

STATISTICAL TESTS

LIFE TABLE	P=0.671	(e)	P=0.505	(e)
POLY 3	P=0.641	(e)	P=0.497	(e)
POLY 1.5	P=0.652	(e)	P=0.498	(e)
POLY 6	P=0.628	(e)	P=0.497	(e)
LOGISTIC REGRESSION	P=0.705	(e)	P=0.507	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
ORDER RESTRICTED	P=0.380	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.404	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)
 Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	1/42.9	1/44.1	0/39.46
POLY-3 PERCENT (g)	0%	2.3%	2.3%	0%
TERMINAL (d)	0/33 (0%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	730 (T)	660	---

STATISTICAL TESTS

LIFE TABLE	P=0.629N	P=0.512	P=0.505	(e)
POLY 3	P=0.627N	P=0.491	P=0.497	(e)
POLY 1.5	P=0.621N	P=0.492	P=0.498	(e)
POLY 6	P=0.633N	P=0.494	P=0.497	(e)
LOGISTIC REGRESSION	P=0.610N	P=0.512	P=0.507	(e)
COCH-ARM / FISHERS	P=0.595N	P=0.500	P=0.500	(e)
ORDER RESTRICTED	P=0.402	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.426	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
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 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Oral Mucosa
 Squamous Cell Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (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. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Pancreas
 Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)	0/48 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.55	0/42.3	0/39.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (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. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Pancreas
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)	0/48 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.55	0/42.3	0/39.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (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. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 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)	25/50 (50%)	20/48 (42%)	20/49 (41%)	20/49 (41%)
POLY-3 RATE (b)	25/47.56	20/43.29	20/45.52	20/42.56
POLY-3 PERCENT (g)	52.6%	46.2%	43.9%	47%
TERMINAL (d)	16/33 (49%)	15/35 (43%)	14/34 (41%)	12/31 (39%)
FIRST INCIDENCE	559	389	529	496

STATISTICAL TESTS

LIFE TABLE	P=0.401N	P=0.195N	P=0.234N	P=0.389N
POLY 3	P=0.343N	P=0.345N	P=0.264N	P=0.374N
POLY 1.5	P=0.320N	P=0.331N	P=0.251N	P=0.346N
POLY 6	P=0.367N	P=0.348N	P=0.281N	P=0.398N
LOGISTIC REGRESSION	P=0.310N	P=0.301N	P=0.238N	P=0.316N
COCH-ARM / FISHERS	P=0.239N	P=0.266N	P=0.237N	P=0.237N
ORDER RESTRICTED	P=0.392N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.413N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Skin
 Basal Cell Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (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. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

Skin
 Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (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. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

Skin
 Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/44.8	0/42.9	1/43.84	1/39.93
POLY-3 PERCENT (g)	0%	0%	2.3%	2.5%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	---	---	730 (T)	590

STATISTICAL TESTS

LIFE TABLE	P=0.220	(e)	P=0.506	P=0.478
POLY 3	P=0.208	(e)	P=0.496	P=0.477
POLY 1.5	P=0.213	(e)	P=0.497	P=0.481
POLY 6	P=0.203	(e)	P=0.494	P=0.474
LOGISTIC REGRESSION	P=0.243	(e)	P=0.506	P=0.555
COCH-ARM / FISHERS	P=0.236	(e)	P=0.500	P=0.500
ORDER RESTRICTED	P=0.229	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.256	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Skin Fibroma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	1/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/33 (0%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	730 (T)	---	---
STATISTICAL TESTS				
LIFE TABLE	P=0.580N	P=0.512	(e)	(e)
POLY 3	P=0.576N	P=0.491	(e)	(e)
POLY 1.5	P=0.575N	P=0.492	(e)	(e)
POLY 6	P=0.576N	P=0.494	(e)	(e)
LOGISTIC REGRESSION	(e)	P=0.512	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
ORDER RESTRICTED	P=0.396N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.420N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 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)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	1/42.9	1/44.1	0/39.46
POLY-3 PERCENT (g)	0%	2.3%	2.3%	0%
TERMINAL (d)	0/33 (0%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	730 (T)	660	---

STATISTICAL TESTS

LIFE TABLE	P=0.629N	P=0.512	P=0.505	(e)
POLY 3	P=0.627N	P=0.491	P=0.497	(e)
POLY 1.5	P=0.621N	P=0.492	P=0.498	(e)
POLY 6	P=0.633N	P=0.494	P=0.497	(e)
LOGISTIC REGRESSION	P=0.610N	P=0.512	P=0.507	(e)
COCH-ARM / FISHERS	P=0.595N	P=0.500	P=0.500	(e)
ORDER RESTRICTED	P=0.402	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.426	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 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)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.9	1/44.1	0/39.46
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	660	---

STATISTICAL TESTS

LIFE TABLE	P=0.671	(e)	P=0.505	(e)
POLY 3	P=0.641	(e)	P=0.497	(e)
POLY 1.5	P=0.652	(e)	P=0.498	(e)
POLY 6	P=0.628	(e)	P=0.497	(e)
LOGISTIC REGRESSION	P=0.705	(e)	P=0.507	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
ORDER RESTRICTED	P=0.380	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.404	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Skin				
Hemangiosarcoma				
TUMOR RATES				
	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (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. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
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 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Skin				
Keratoacanthoma				
TUMOR RATES				
	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (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. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Skin				
Lipoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	1/43.06	1/44.02	0/39.46
POLY-3 PERCENT (g)	0%	2.3%	2.3%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	688	683	---
STATISTICAL TESTS				
LIFE TABLE	P=0.629N	P=0.511	P=0.495	(e)
POLY 3	P=0.627N	P=0.492	P=0.496	(e)
POLY 1.5	P=0.621N	P=0.492	P=0.498	(e)
POLY 6	P=0.633N	P=0.495	P=0.496	(e)
LOGISTIC REGRESSION	P=0.603N	P=0.499	P=0.504	(e)
COCH-ARM / FISHERS	P=0.595N	P=0.500	P=0.500	(e)
ORDER RESTRICTED	P=0.402	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.426	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

Skin
 Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.8	0/42.9	0/43.84	1/39.93
POLY-3 PERCENT (g)	0%	0%	0%	2.5%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	590

STATISTICAL TESTS

LIFE TABLE	P=0.189	(e)	(e)	P=0.478
POLY 3	P=0.186	(e)	(e)	P=0.477
POLY 1.5	P=0.189	(e)	(e)	P=0.481
POLY 6	P=0.184	(e)	(e)	P=0.474
LOGISTIC REGRESSION	P=0.230	(e)	(e)	P=0.555
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
ORDER RESTRICTED	P=0.102	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.124	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Skin
 Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/44.8	0/42.9	1/43.84	1/39.93
POLY-3 PERCENT (g)	0%	0%	2.3%	2.5%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	---	---	730 (T)	590

STATISTICAL TESTS

LIFE TABLE	P=0.220	(e)	P=0.506	P=0.478
POLY 3	P=0.208	(e)	P=0.496	P=0.477
POLY 1.5	P=0.213	(e)	P=0.497	P=0.481
POLY 6	P=0.203	(e)	P=0.494	P=0.474
LOGISTIC REGRESSION	P=0.243	(e)	P=0.506	P=0.555
COCH-ARM / FISHERS	P=0.236	(e)	P=0.500	P=0.500
ORDER RESTRICTED	P=0.229	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.256	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
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 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Skin
 Squamous Cell Papilloma, Papilloma, or Keratoacanthoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.9	1/43.84	0/39.46
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	---	---	730 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.687	(e)	P=0.506	(e)
POLY 3	P=0.642	(e)	P=0.496	(e)
POLY 1.5	P=0.653	(e)	P=0.497	(e)
POLY 6	P=0.630	(e)	P=0.494	(e)
LOGISTIC REGRESSION	(e)	(e)	P=0.506	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
ORDER RESTRICTED	P=0.379	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.403	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

Thymus
 Thymoma: Benign, Malignant, NOS

TUMOR RATES

OVERALL (a)	0/47 (0%)	0/47 (0%)	0/46 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/42.5	0/39.9	0/40.08	0/39.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/32 (0%)	0/32 (0%)	0/32 (0%)	0/31 (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. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Thyroid Gland: C-Cell
 Adenoma**

TUMOR RATES

OVERALL (a)	7/50 (14%)	8/46 (17%)	7/46 (15%)	6/48 (13%)
POLY-3 RATE (b)	7/45.1	8/40.86	7/41.26	6/39.53
POLY-3 PERCENT (g)	15.5%	19.6%	17%	15.2%
TERMINAL (d)	6/33 (18%)	8/35 (23%)	6/34 (18%)	4/31 (13%)
FIRST INCIDENCE	647	730 (T)	660	547

STATISTICAL TESTS

LIFE TABLE	P=0.467N	P=0.547	P=0.594N	P=0.565N
POLY 3	P=0.487N	P=0.417	P=0.544	P=0.601N
POLY 1.5	P=0.472N	P=0.417	P=0.544	P=0.588N
POLY 6	P=0.499N	P=0.430	P=0.549	P=0.611N
LOGISTIC REGRESSION	P=0.512N	P=0.470	P=0.552	P=0.606N
COCH-ARM / FISHERS	P=0.412N	P=0.429	P=0.547	P=0.532N
ORDER RESTRICTED	P=0.607N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.619N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Thyroid Gland: C-Cell
 Carcinoma**

TUMOR RATES

OVERALL (a)	3/50 (6%)	2/46 (4%)	2/46 (4%)	2/48 (4%)
POLY-3 RATE (b)	3/44.8	2/41.12	2/41	2/38.82
POLY-3 PERCENT (g)	6.7%	4.9%	4.9%	5.2%
TERMINAL (d)	3/33 (9%)	1/35 (3%)	2/34 (6%)	2/31 (7%)
FIRST INCIDENCE	730 (T)	660	730 (T)	730 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.474N	P=0.474N	P=0.486N	P=0.529N
POLY 3	P=0.480N	P=0.539N	P=0.540N	P=0.565N
POLY 1.5	P=0.471N	P=0.542N	P=0.540N	P=0.555N
POLY 6	P=0.489N	P=0.527N	P=0.537N	P=0.573N
LOGISTIC REGRESSION	P=0.501N	P=0.537N	P=0.486N	P=0.529N
COCH-ARM / FISHERS	P=0.443N	P=0.540N	P=0.540N	P=0.520N
ORDER RESTRICTED	P=0.571N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.586N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Thyroid Gland: C-Cell
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	9/50 (18%)	10/46 (22%)	9/46 (20%)	8/48 (17%)
POLY-3 RATE (b)	9/45.1	10/41.12	9/41.26	8/39.53
POLY-3 PERCENT (g)	20%	24.3%	21.8%	20.2%
TERMINAL (d)	8/33 (24%)	9/35 (26%)	8/34 (24%)	6/31 (19%)
FIRST INCIDENCE	647	660	660	547

STATISTICAL TESTS

LIFE TABLE	P=0.492N	P=0.554	P=0.580N	P=0.572N
POLY 3	P=0.515N	P=0.410	P=0.521	P=0.594
POLY 1.5	P=0.496N	P=0.407	P=0.522	P=0.603N
POLY 6	P=0.531N	P=0.430	P=0.527	P=0.584
LOGISTIC REGRESSION	P=0.546N	P=0.445	P=0.537	P=0.576
COCH-ARM / FISHERS	P=0.425N	P=0.419	P=0.525	P=0.537N
ORDER RESTRICTED	P=0.626	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.636	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Thyroid Gland: Follicular Cell
 Carcinoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	0/46 (0%)	1/46 (2%)	0/48 (0%)
POLY-3 RATE (b)	1/44.8	0/40.86	1/41	0/38.82
POLY-3 PERCENT (g)	2.2%	0%	2.4%	0%
TERMINAL (d)	1/33 (3%)	0/35 (0%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	730 (T)	---	730 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.420N	P=0.488N	P=0.755N	P=0.512N
POLY 3	P=0.426N	P=0.518N	P=0.741	P=0.529N
POLY 1.5	P=0.422N	P=0.519N	P=0.741	P=0.524N
POLY 6	P=0.431N	P=0.514N	P=0.743	P=0.532N
LOGISTIC REGRESSION	P=0.420N	(e)	P=0.755N	(e)
COCH-ARM / FISHERS	P=0.411N	P=0.521N	P=0.731	P=0.510N
ORDER RESTRICTED	P=0.281N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.314N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Thyroid Gland: Follicular Cell
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	1/46 (2%)	1/46 (2%)	0/48 (0%)
POLY-3 RATE (b)	1/44.8	1/41.21	1/41	0/38.82
POLY-3 PERCENT (g)	2.2%	2.4%	2.4%	0%
TERMINAL (d)	1/33 (3%)	0/35 (0%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	730 (T)	632	730 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.340N	P=0.756N	P=0.755N	P=0.512N
POLY 3	P=0.342N	P=0.742	P=0.741	P=0.529N
POLY 1.5	P=0.337N	P=0.740	P=0.741	P=0.524N
POLY 6	P=0.347N	P=0.749	P=0.743	P=0.532N
LOGISTIC REGRESSION	P=0.329N	P=0.751	P=0.755N	(e)
COCH-ARM / FISHERS	P=0.319N	P=0.731	P=0.731	P=0.510N
ORDER RESTRICTED	P=0.335N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.367N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Uterus				
Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	8/50 (16%)	16/50 (32%)	6/50 (12%)	5/50 (10%)
POLY-3 RATE (b)	8/45.27	16/45.99	6/44.35	5/39.81
POLY-3 PERCENT (g)	17.7%	34.8%	13.5%	12.6%
TERMINAL (d)	5/33 (15%)	10/35 (29%)	5/34 (15%)	4/31 (13%)
FIRST INCIDENCE	673	389	573	632
STATISTICAL TESTS				
LIFE TABLE	P=0.101N	P=0.073	P=0.381N	P=0.349N
POLY 3	P=0.104N	P=0.050*	P=0.402N	P=0.363N
POLY 1.5	P=0.092N	P=0.046*	P=0.395N	P=0.345N
POLY 6	P=0.117N	P=0.059	P=0.409N	P=0.382N
LOGISTIC REGRESSION	P=0.073N	P=0.054	P=0.403N	P=0.372N
COCH-ARM / FISHERS	P=0.062N	P=0.050*	P=0.387N	P=0.277N
ORDER RESTRICTED	P=0.086N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.107N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 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)	8/50 (16%)	16/50 (32%)	7/50 (14%)	5/50 (10%)
POLY-3 RATE (b)	8/45.27	16/45.99	7/44.97	5/39.81
POLY-3 PERCENT (g)	17.7%	34.8%	15.6%	12.6%
TERMINAL (d)	5/33 (15%)	10/35 (29%)	5/34 (15%)	4/31 (13%)
FIRST INCIDENCE	673	389	529	632

STATISTICAL TESTS

LIFE TABLE	P=0.111N	P=0.073	P=0.492N	P=0.349N
POLY 3	P=0.115N	P=0.050*	P=0.506N	P=0.363N
POLY 1.5	P=0.103N	P=0.046*	P=0.503N	P=0.345N
POLY 6	P=0.129N	P=0.059	P=0.508N	P=0.382N
LOGISTIC REGRESSION	P=0.074N	P=0.054	P=0.503N	P=0.372N
COCH-ARM / FISHERS	P=0.068N	P=0.050*	P=0.500N	P=0.277N
ORDER RESTRICTED	P=0.089N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.111N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Zymbal's Gland
 Carcinoma**

TUMOR RATES

	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.8	1/43.63	0/43.84	1/39.75
POLY-3 PERCENT (g)	0%	2.3%	0%	2.5%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	469	---	651

STATISTICAL TESTS

LIFE TABLE	P=0.377	P=0.487	(e)	P=0.457
POLY 3	P=0.374	P=0.495	(e)	P=0.476
POLY 1.5	P=0.380	P=0.494	(e)	P=0.480
POLY 6	P=0.370	P=0.498	(e)	P=0.473
LOGISTIC REGRESSION	P=0.499	P=0.654	(e)	P=0.512
COCH-ARM / FISHERS	P=0.405	P=0.500	(e)	P=0.500
ORDER RESTRICTED	P=0.228	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.256	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**All Organs
 Hemangiosarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (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. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

All Organs
 Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated

TUMOR RATES	#	#	#	#
OVERALL (a)	8/50 (16%)	5/50 (10%)	12/50 (24%)	8/50 (16%)
POLY-3 RATE (b)	8/46	5/43.12	12/46.5	8/39.81
POLY-3 PERCENT (g)	17.4%	11.6%	25.8%	20.1%
TERMINAL (d)	3/33 (9%)	4/35 (11%)	6/34 (18%)	7/31 (23%)
FIRST INCIDENCE	617	671	499	632

STATISTICAL TESTS

LIFE TABLE	P=0.289	P=0.273N	P=0.238	P=0.504
POLY 3	P=0.268	P=0.318N	P=0.232	P=0.483
POLY 1.5	P=0.294	P=0.310N	P=0.231	P=0.512
POLY 6	P=0.237	P=0.321N	P=0.235	P=0.450
LOGISTIC REGRESSION	P=0.340	P=0.294N	P=0.252	P=0.511
COCH-ARM / FISHERS	P=0.386	P=0.277N	P=0.227	P=0.607N
ORDER RESTRICTED	P=0.250	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.281	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

All Organs
 Mesothelioma: Benign, Malignant, NOS

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (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. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**All Organs
 Mesothelioma: Malignant**

TUMOR RATES

	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	0/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/34 (0%)	0/31 (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. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
 Time Report Reqsted: 17:49:41
 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**All Organs
 Osteosarcoma**

TUMOR RATES

	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	1/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/33 (0%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	730 (T)	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.580N	P=0.512	(e)	(e)
POLY 3	P=0.576N	P=0.491	(e)	(e)
POLY 1.5	P=0.575N	P=0.492	(e)	(e)
POLY 6	P=0.576N	P=0.494	(e)	(e)
LOGISTIC REGRESSION	(e)	P=0.512	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
ORDER RESTRICTED	P=0.396N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.420N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
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 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**All Organs
 Osteosarcoma or Osteoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.8	1/42.9	0/43.84	0/39.46
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/33 (0%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	730 (T)	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.580N	P=0.512	(e)	(e)
POLY 3	P=0.576N	P=0.491	(e)	(e)
POLY 1.5	P=0.575N	P=0.492	(e)	(e)
POLY 6	P=0.576N	P=0.494	(e)	(e)
LOGISTIC REGRESSION	(e)	P=0.512	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
ORDER RESTRICTED	P=0.396N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.420N	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 ISOEUGENOL
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**All Organs
 Benign Tumors**

TUMOR RATES

	#	#	#	#
OVERALL (a)	41/50 (82%)	45/50 (90%)	36/50 (72%)	40/50 (80%)
POLY-3 RATE (b)	41/48.89	45/47.59	36/47.08	40/43.86
POLY-3 PERCENT (g)	83.9%	94.6%	76.5%	91.2%
TERMINAL (d)	28/33 (85%)	33/35 (94%)	27/34 (79%)	29/31 (94%)
FIRST INCIDENCE	400	389	529	496

STATISTICAL TESTS

LIFE TABLE	P=0.449	P=0.399	P=0.218N	P=0.366
POLY 3	P=0.397	P=0.075	P=0.248N	P=0.213
POLY 1.5	P=0.490	P=0.085	P=0.213N	P=0.290
POLY 6	P=0.318	P=0.082	P=0.294N	P=0.163
LOGISTIC REGRESSION	P=0.526	P=0.098	P=0.188N	P=0.287
COCH-ARM / FISHERS	P=0.251N	P=0.194	P=0.171N	P=0.500N
ORDER RESTRICTED	P=0.211	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.237	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
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 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**All Organs
 Malignant Tumors**

TUMOR RATES	#	#	#	#
OVERALL (a)	18/50 (36%)	12/50 (24%)	21/50 (42%)	20/50 (40%)
POLY-3 RATE (b)	18/46.77	12/44.36	21/47.64	20/42.56
POLY-3 PERCENT (g)	38.5%	27.1%	44.1%	47%
TERMINAL (d)	10/33 (30%)	8/35 (23%)	12/34 (35%)	13/31 (42%)
FIRST INCIDENCE	617	469	499	541

STATISTICAL TESTS

LIFE TABLE	P=0.113	P=0.142N	P=0.365	P=0.282
POLY 3	P=0.115	P=0.173N	P=0.365	P=0.274
POLY 1.5	P=0.123	P=0.168N	P=0.357	P=0.292
POLY 6	P=0.107	P=0.172N	P=0.376	P=0.259
LOGISTIC REGRESSION	P=0.151	P=0.153N	P=0.362	P=0.308
COCH-ARM / FISHERS	P=0.191	P=0.138N	P=0.341	P=0.418
ORDER RESTRICTED	P=0.133	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.153	(e)	(e)	(e)

TDMS No. 88105-03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

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

Date Report Reqsted: 09/28/2006
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 First Dose M/F: 04/22/02 / 04/23/02
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 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)	46/50 (92%)	46/50 (92%)	46/50 (92%)	43/50 (86%)
POLY-3 RATE (b)	46/50	46/47.59	46/50	43/44.93
POLY-3 PERCENT (g)	92%	96.7%	92%	95.7%
TERMINAL (d)	29/33 (88%)	34/35 (97%)	30/34 (88%)	30/31 (97%)
FIRST INCIDENCE	400	389	499	496

STATISTICAL TESTS

LIFE TABLE	P=0.413	P=0.463N	P=0.547N	P=0.466
POLY 3	P=0.388	P=0.285	P=0.642	P=0.370
POLY 1.5	P=0.485	P=0.360	P=0.642	P=0.485
POLY 6	P=0.311	P=0.230	P=0.642	P=0.280
LOGISTIC REGRESSION	P=0.533N	P=0.457	(e)	P=0.564
COCH-ARM / FISHERS	P=0.174N	P=0.643N	P=0.643N	P=0.262N
ORDER RESTRICTED	P=0.346	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.370	(e)	(e)	(e)

TDMS No. 88105-03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344

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

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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 ***