

**TDMS No.** 99032 - 03  
**Test Type:** CHRONIC  
**Route:** SKIN APPLICATION  
**Species/Strain:** RATS/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Pyrogallol  
**CAS Number:** 87-66-1

**Date Report Requested:** 12/17/2009  
**Time Report Requested:** 08:48:44  
**First Dose M/F:** 09/15/04 / 09/16/04  
**Lab:** BAT

F1\_R2

**C Number:** C99032  
**Lock Date:** 09/07/2007  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.2.0

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**HISTORICAL CONTROL STUDIES**  
From May 2009 report

**SAME ROUTE**

99028-05 -- bis(2-Chloroethoxy)methane (SKIN ETHANOL)  
97003-07 -- 1,2-Dibromo-2,4-dicyanobutane (SKIN ETHANOL)  
93020-07 -- Diisopropylcarbodiimide (SKIN ETHANOL)

**ALL ROUTES**

99024-07 -- Androstenedione (GAVAGE METHYLCELLULOSE)  
99028-05 -- bis(2-Chloroethoxy)methane (SKIN ETHANOL)  
20011-05 -- 1-Bromopropane (INHALATION AIR)  
99027-03 -- Chromium picolinate monohydrate (ORAL FEED)  
05174-05 -- Cresols (ORAL FEED)  
96011-05 -- Cumene (INHALATION AIR)  
97003-07 -- 1,2-Dibromo-2,4-dicyanobutane (SKIN ETHANOL)  
99017-05 -- Diethylamine (INHALATION AIR)  
93020-07 -- Diisopropylcarbodiimide (SKIN ETHANOL)  
88123-05 -- Formamide (GAVAGE WATER)  
20005-05 -- Ginseng (GAVAGE WATER)  
99007-05 -- Goldenseal root powder (ORAL FEED)  
95011-07 -- 5-(Hydroxymethyl)-2-furfural (GAVAGE WATER)  
88105-03 -- Isoeugenol (GAVAGE CORN OIL)  
20007-05 -- Kava kava extract (GAVAGE CORN OIL)  
97006-01 -- Methyl isobutyl ketone (INHALATION AIR)  
91005-07 -- Methylene blue trihydrate (GAVAGE METHYLCELLULOSE)  
92013-05 -- 4-Methylimidazole (ORAL FEED)  
88006-03 -- alpha-Methylstyrene (INHALATION AIR)  
20008-03 -- Milk thistle extract (ORAL FEED)  
99023-03 -- beta-Myrcene (GAVAGE CORN OIL)  
97008-05 -- Propargyl alcohol (INHALATION AIR)  
99020-05 -- Pulegone (GAVAGE CORN OIL)  
20114-07 -- Sodium dichromate dihydrate (VI) (ORAL WATER)

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**HISTORICAL CONTROL STUDIES**  
**From May 2009 report**

93025-07 -- Tetralin (INHALATION AIR)  
96019-05 -- Water disinfection byproducts (Bromochloroacetic acid) (ORAL WATER)  
96017-05 -- Water disinfection byproducts (Dibromoacetic acid) (ORAL WATER)  
96015-05 -- Water disinfection byproducts (Dibromoacetonitrile) (ORAL WATER)

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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 Medulla  
Clitoral/Preputial Gland  
Heart  
Islets, Pancreatic  
Liver  
Lung  
Pituitary Gland  
Testes  
Thyroid Gland

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

### MALE RATS

#### Organ

Lung

Pituitary Gland: Pars Distalis or Unspecified Site

Skin

Testes

All Organs

#### Morphology

Alveolar/Bronchiolar Carcinoma

Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma

Adenoma

Carcinoma or Adenoma

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

Squamous Cell Papilloma

Adenoma

Benign Tumors

Malignant Tumors

### FEMALE RATS

#### Organ

Clitoral/Preputial Gland

Mammary Gland

Mesentery

All Organs

#### Morphology

Adenoma

Fibroadenoma

Fibroma, Fibroadenoma or Adenoma

Fibroma, Fibroadenoma, Carcinoma, or Adenoma

Schwannoma Malignant

Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated

Benign Tumors

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Adrenal Medulla</b>				
<b>Pheochromocytoma Benign</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	4/50 (8%)	6/50 (12%)	7/50 (14%)	3/50 (6%)
POLY-3 RATE (b)	4/38.86	6/41.06	7/42.42	3/43.38
POLY-3 PERCENT (g)	10.3%	14.6%	16.5%	6.9%
TERMINAL (d)	3/23 (13%)	5/28 (18%)	6/28 (21%)	1/28 (4%)
FIRST INCIDENCE	694	599	647	681
HC TUMORS SAME ROUTE	11/150 (7%)			
HC TUMORS ALL ROUTES	197/1395 (14%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.210N	P=0.403	P=0.311	P=0.440N
POLY 1.5	P=0.234N	P=0.391	P=0.294	P=0.464N
POLY 6	P=0.180N	P=0.428	P=0.335	P=0.405N
COCH-ARM / FISHERS	P=0.270N	P=0.370	P=0.262	P=0.500N
MAX-ISO-POLY-3	P=0.293N	P=0.286	P=0.217	P=0.303N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Adrenal Medulla</b>				
<b>Pheochromocytoma: Benign, Complex, Malignant, NOS</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	5/50 (10%)	6/50 (12%)	7/50 (14%)	4/50 (8%)
POLY-3 RATE (b)	5/39.47	6/41.06	7/42.42	4/43.38
POLY-3 PERCENT (g)	12.7%	14.6%	16.5%	9.2%
TERMINAL (d)	3/23 (13%)	5/28 (18%)	6/28 (21%)	2/28 (7%)
FIRST INCIDENCE	532	599	647	681
HC TUMORS SAME ROUTE	14/150 (9%)			
HC TUMORS ALL ROUTES	227/1395 (16%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.286N	P=0.528	P=0.430	P=0.441N
POLY 1.5	P=0.310N	P=0.519	P=0.414	P=0.464N
POLY 6	P=0.254N	P=0.549	P=0.452	P=0.406N
COCH-ARM / FISHERS	P=0.345N	P=0.500	P=0.380	P=0.500N
MAX-ISO-POLY-3	P=0.397N	P=0.400	P=0.318	P=0.316N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Clitoral/Preputial Gland Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/38.73	0/40.62	0/42.13	0/43.08
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/23 (0%)	0/28 (0%)	0/28 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	5/150 (3%)			
HC TUMORS ALL ROUTES	53/1396 (4%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Clitoral/Preputial Gland Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/38.73	0/40.62	0/42.13	0/43.08
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/23 (0%)	0/28 (0%)	0/28 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	1/150 (1%)			
HC TUMORS ALL ROUTES	20/1396 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Clitoral/Preputial Gland Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/38.73	0/40.62	0/42.13	0/43.08
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/23 (0%)	0/28 (0%)	0/28 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	6/150 (4%)			
HC TUMORS ALL ROUTES	71/1396 (5%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Heart</b>				
<b>Schwannoma Malignant</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/39.51	1/40.62	1/42.32	0/43.08
POLY-3 PERCENT (g)	5.1%	2.5%	2.4%	0%
TERMINAL (d)	1/23 (4%)	1/28 (4%)	0/28 (0%)	0/28 (0%)
FIRST INCIDENCE	440	727 (T)	678	---
HC TUMORS SAME ROUTE	1/150 (1%)			
HC TUMORS ALL ROUTES	4/1398 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.200N	P=0.490N	P=0.476N	P=0.218N
POLY 1.5	P=0.205N	P=0.493N	P=0.484N	P=0.226N
POLY 6	P=0.194N	P=0.481N	P=0.464N	P=0.207N
COCH-ARM / FISHERS	P=0.210N	P=0.500N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.125N	P=0.274N	P=0.267N	P=0.075N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Islets, Pancreatic Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	3/50 (6%)	5/50 (10%)	4/50 (8%)	5/50 (10%)
POLY-3 RATE (b)	3/38.91	5/40.62	4/42.38	5/43.90
POLY-3 PERCENT (g)	7.7%	12.3%	9.4%	11.4%
TERMINAL (d)	2/23 (9%)	5/28 (18%)	2/28 (7%)	3/28 (11%)
FIRST INCIDENCE	681	727 (T)	673	552
HC TUMORS SAME ROUTE	14/150 (9%)			
HC TUMORS ALL ROUTES	90/1394 (7%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.480	P=0.379	P=0.547	P=0.424
POLY 1.5	P=0.450	P=0.372	P=0.531	P=0.397
POLY 6	P=0.522	P=0.395	P=0.568	P=0.463
COCH-ARM / FISHERS	P=0.407	P=0.357	P=0.500	P=0.357
MAX-ISO-POLY-3	P=0.485	P=0.253	P=0.393	P=0.298
HISTCONT SAME RTE	P=0.600	P=0.340	P=0.525	P=0.401
HISTCONT ALL RTEs	P=0.364	P=0.258	P=0.459	P=0.296

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Liver</b>				
<b>Hepatocellular Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/39.17	0/40.62	2/42.13	1/43.08
POLY-3 PERCENT (g)	2.6%	0%	4.8%	2.3%
TERMINAL (d)	0/23 (0%)	0/28 (0%)	2/28 (7%)	1/28 (4%)
FIRST INCIDENCE	598	---	727 (T)	727 (T)
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	16/1398 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.616	P=0.493N	P=0.525	P=0.739N
POLY 1.5	P=0.603	P=0.495N	P=0.518	P=0.748N
POLY 6	P=0.632	P=0.488N	P=0.535	P=0.728N
COCH-ARM / FISHERS	P=0.584	P=0.500N	P=0.500	P=0.753N
MAX-ISO-POLY-3	P=0.425	P=0.158N	P=0.307	P=0.473N
HISTCONT SAME RTE	P=0.175	(e)	P=0.070	P=0.145
HISTCONT ALL RTEs	P=0.362	(e)	P=0.115	P=0.433

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Liver</b>				
<b>Hepatocellular Carcinoma or Hepatocellular Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/39.17	1/40.99	2/42.13	1/43.08
POLY-3 PERCENT (g)	2.6%	2.4%	4.8%	2.3%
TERMINAL (d)	0/23 (0%)	0/28 (0%)	2/28 (7%)	1/28 (4%)
FIRST INCIDENCE	598	622	727 (T)	727 (T)
HC TUMORS SAME ROUTE	1/150 (1%)			
HC TUMORS ALL ROUTES	21/1398 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.607N	P=0.751N	P=0.525	P=0.739N
POLY 1.5	P=0.617N	P=0.754N	P=0.518	P=0.748N
POLY 6	P=0.593N	P=0.744N	P=0.535	P=0.728N
COCH-ARM / FISHERS	P=0.634N	P=0.753N	P=0.500	P=0.753N
MAX-ISO-POLY-3	P=0.621	P=0.487N	P=0.307	P=0.473N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Liver</b>				
<b>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/39.17	1/40.99	2/42.13	1/43.08
POLY-3 PERCENT (g)	2.6%	2.4%	4.8%	2.3%
TERMINAL (d)	0/23 (0%)	0/28 (0%)	2/28 (7%)	1/28 (4%)
FIRST INCIDENCE	598	622	727 (T)	727 (T)
HC TUMORS SAME ROUTE	1/150 (1%)			
HC TUMORS ALL ROUTES	21/1398 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.607N	P=0.751N	P=0.525	P=0.739N
POLY 1.5	P=0.617N	P=0.754N	P=0.518	P=0.748N
POLY 6	P=0.593N	P=0.744N	P=0.535	P=0.728N
COCH-ARM / FISHERS	P=0.634N	P=0.753N	P=0.500	P=0.753N
MAX-ISO-POLY-3	P=0.621	P=0.487N	P=0.307	P=0.473N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Lung</b>				
<b>Alveolar/Bronchiolar Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	3/50 (6%)	2/50 (4%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	3/38.83	2/41.00	2/42.13	0/43.08
POLY-3 PERCENT (g)	7.7%	4.9%	4.8%	0%
TERMINAL (d)	2/23 (9%)	1/28 (4%)	2/28 (7%)	0/28 (0%)
FIRST INCIDENCE	702	619	727 (T)	---
HC TUMORS SAME ROUTE	2/150 (1%)			
HC TUMORS ALL ROUTES	14/1398 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.092N	P=0.475N	P=0.463N	P=0.101N
POLY 1.5	P=0.097N	P=0.484N	P=0.475N	P=0.108N
POLY 6	P=0.086N	P=0.457N	P=0.447N	P=0.091N
COCH-ARM / FISHERS	P=0.104N	P=0.500N	P=0.500N	P=0.121N
MAX-ISO-POLY-3	P=0.082N	P=0.305N	P=0.298N	P=0.037N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Lung</b>				
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	4/50 (8%)	3/50 (6%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	4/38.83	3/41.00	2/42.13	0/43.08
POLY-3 PERCENT (g)	10.3%	7.3%	4.8%	0%
TERMINAL (d)	3/23 (13%)	2/28 (7%)	2/28 (7%)	0/28 (0%)
FIRST INCIDENCE	702	619	727 (T)	---
HC TUMORS SAME ROUTE	8/150 (5%)			
HC TUMORS ALL ROUTES	45/1398 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.043N*	P=0.470N	P=0.299N	P=0.047N*
POLY 1.5	P=0.046N*	P=0.481N	P=0.312N	P=0.052N
POLY 6	P=0.039N*	P=0.449N	P=0.283N	P=0.041N*
COCH-ARM / FISHERS	P=0.051N	P=0.500N	P=0.339N	P=0.059N
MAX-ISO-POLY-3	P=0.042N*	P=0.323N	P=0.180N	P=0.019N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Mammary Gland Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/38.73	0/40.62	0/42.13	0/43.08
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/23 (0%)	0/28 (0%)	0/28 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	4/1398 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Mammary Gland Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/38.94	0/40.62	0/42.13	0/43.08
POLY-3 PERCENT (g)	2.6%	0%	0%	0%
TERMINAL (d)	0/23 (0%)	0/28 (0%)	0/28 (0%)	0/28 (0%)
FIRST INCIDENCE	673	---	---	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	7/1398 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.542N	P=0.492N	P=0.484N	P=0.480N
POLY 1.5	P=0.540N	P=0.494N	P=0.489N	P=0.488N
POLY 6	P=0.547N	P=0.486N	P=0.478N	P=0.469N
COCH-ARM / FISHERS	P=0.534N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.128N	P=0.158N	P=0.158N	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Mammary Gland Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/38.94	0/40.62	0/42.13	0/43.08
POLY-3 PERCENT (g)	2.6%	0%	0%	0%
TERMINAL (d)	0/23 (0%)	0/28 (0%)	0/28 (0%)	0/28 (0%)
FIRST INCIDENCE	673	---	---	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	11/1398 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.542N	P=0.492N	P=0.484N	P=0.480N
POLY 1.5	P=0.540N	P=0.494N	P=0.489N	P=0.488N
POLY 6	P=0.547N	P=0.486N	P=0.478N	P=0.469N
COCH-ARM / FISHERS	P=0.534N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.128N	P=0.158N	P=0.158N	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Mammary Gland Fibroadenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/38.73	2/40.62	1/42.13	1/43.08
POLY-3 PERCENT (g)	0%	4.9%	2.4%	2.3%
TERMINAL (d)	0/23 (0%)	2/28 (7%)	1/28 (4%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	727 (T)	727 (T)
HC TUMORS SAME ROUTE	4/150 (3%)			
HC TUMORS ALL ROUTES	48/1398 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.682N	P=0.247	P=0.517	P=0.521
POLY 1.5	P=0.670	P=0.244	P=0.511	P=0.513
POLY 6	P=0.665N	P=0.255	P=0.524	P=0.533
COCH-ARM / FISHERS	P=0.649	P=0.247	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.310	P=0.086	P=0.179	P=0.184
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Mammary Gland</b>				
<b>Fibroma, Fibroadenoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/38.73	2/40.62	1/42.13	1/43.08
POLY-3 PERCENT (g)	0%	4.9%	2.4%	2.3%
TERMINAL (d)	0/23 (0%)	2/28 (7%)	1/28 (4%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	727 (T)	727 (T)
HC TUMORS SAME ROUTE	4/150 (3%)			
HC TUMORS ALL ROUTES	54/1398 (4%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.682N	P=0.247	P=0.517	P=0.521
POLY 1.5	P=0.670	P=0.244	P=0.511	P=0.513
POLY 6	P=0.665N	P=0.255	P=0.524	P=0.533
COCH-ARM / FISHERS	P=0.649	P=0.247	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.310	P=0.086	P=0.179	P=0.184
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Mammary Gland</b>				
<b>Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/38.94	2/40.62	1/42.13	1/43.08
POLY-3 PERCENT (g)	2.6%	4.9%	2.4%	2.3%
TERMINAL (d)	0/23 (0%)	2/28 (7%)	1/28 (4%)	1/28 (4%)
FIRST INCIDENCE	673	727 (T)	727 (T)	727 (T)
HC TUMORS SAME ROUTE	4/150 (3%)			
HC TUMORS ALL ROUTES	60/1398 (4%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.519N	P=0.515	P=0.743N	P=0.738N
POLY 1.5	P=0.530N	P=0.510	P=0.749N	P=0.747N
POLY 6	P=0.505N	P=0.525	P=0.736N	P=0.725N
COCH-ARM / FISHERS	P=0.545N	P=0.500	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.567N	P=0.296	P=0.477N	P=0.471N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Mesentery</b>				
<b>Schwannoma Malignant</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/38.73	0/40.62	0/42.13	0/43.08
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/23 (0%)	0/28 (0%)	0/28 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	0/1398 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Pituitary Gland: Pars Distalis or Unspecified Site Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	33/50 (66%)	33/49 (67%)	34/50 (68%)	27/50 (54%)
POLY-3 RATE (b)	33/45.22	33/46.30	34/47.41	27/46.47
POLY-3 PERCENT (g)	73%	71.3%	71.7%	58.1%
TERMINAL (d)	14/23 (61%)	17/27 (63%)	18/28 (64%)	14/28 (50%)
FIRST INCIDENCE	527	449	466	496
HC TUMORS SAME ROUTE	96/149 (64%)			
HC TUMORS ALL ROUTES	641/1393 (46%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.051N	P=0.521N	P=0.540N	P=0.093N
POLY 1.5	P=0.058N	P=0.546N	P=0.567N	P=0.107N
POLY 6	P=0.045N*	P=0.502N	P=0.519N	P=0.082N
COCH-ARM / FISHERS	P=0.076N	P=0.528	P=0.500	P=0.154N
MAX-ISO-POLY-3	P=0.084N	P=0.425N	P=0.444N	P=0.063N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	33/50 (66%)	33/49 (67%)	34/50 (68%)	27/50 (54%)
POLY-3 RATE (b)	33/45.22	33/46.30	34/47.41	27/46.47
POLY-3 PERCENT (g)	73%	71.3%	71.7%	58.1%
TERMINAL (d)	14/23 (61%)	17/27 (63%)	18/28 (64%)	14/28 (50%)
FIRST INCIDENCE	527	449	466	496
HC TUMORS SAME ROUTE	101/149 (68%)			
HC TUMORS ALL ROUTES	647/1393 (46%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.051N	P=0.521N	P=0.540N	P=0.093N
POLY 1.5	P=0.058N	P=0.546N	P=0.567N	P=0.107N
POLY 6	P=0.045N*	P=0.502N	P=0.519N	P=0.082N
COCH-ARM / FISHERS	P=0.076N	P=0.528	P=0.500	P=0.154N
MAX-ISO-POLY-3	P=0.084N	P=0.425N	P=0.444N	P=0.063N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	2/50 (4%)	6/50 (12%)
POLY-3 RATE (b)	3/39.54	1/40.62	2/42.61	6/43.20
POLY-3 PERCENT (g)	7.6%	2.5%	4.7%	13.9%
TERMINAL (d)	1/23 (4%)	1/28 (4%)	1/28 (4%)	5/28 (18%)
FIRST INCIDENCE	608	727 (T)	583	696
HC TUMORS SAME ROUTE	8/150 (5%)			
HC TUMORS ALL ROUTES	116/1398 (8%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.055	P=0.295N	P=0.466N	P=0.286
POLY 1.5	P=0.051	P=0.297N	P=0.476N	P=0.269
POLY 6	P=0.059	P=0.288N	P=0.453N	P=0.310
COCH-ARM / FISHERS	P=0.047*	P=0.309N	P=0.500N	P=0.243
MAX-ISO-POLY-3	P=0.089	P=0.149N	P=0.300N	P=0.189
HISTCONT SAME RTE	P=0.103	P=1.000	P=1.000	P=0.102
HISTCONT ALL RTEs	P=0.102	P=1.000	P=1.000	P=0.228

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Fibroma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/39.01	2/40.72	2/42.13	1/43.55
POLY-3 PERCENT (g)	2.6%	4.9%	4.8%	2.3%
TERMINAL (d)	0/23 (0%)	1/28 (4%)	2/28 (7%)	0/28 (0%)
FIRST INCIDENCE	652	702	727 (T)	589
HC TUMORS SAME ROUTE	13/150 (9%)			
HC TUMORS ALL ROUTES	125/1398 (9%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.475N	P=0.515	P=0.527	P=0.736N
POLY 1.5	P=0.491N	P=0.510	P=0.518	P=0.746N
POLY 6	P=0.454N	P=0.525	P=0.538	P=0.722N
COCH-ARM / FISHERS	P=0.514N	P=0.500	P=0.500	P=0.753N
MAX-ISO-POLY-3	P=0.539N	P=0.296	P=0.309	P=0.469N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	3/50 (6%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	1/39.01	3/40.72	4/42.13	1/43.55
POLY-3 PERCENT (g)	2.6%	7.4%	9.5%	2.3%
TERMINAL (d)	0/23 (0%)	2/28 (7%)	4/28 (14%)	0/28 (0%)
FIRST INCIDENCE	652	702	727 (T)	589
HC TUMORS SAME ROUTE	16/150 (11%)			
HC TUMORS ALL ROUTES	154/1398 (11%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.323N	P=0.320	P=0.202	P=0.736N
POLY 1.5	P=0.344N	P=0.315	P=0.195	P=0.746N
POLY 6	P=0.295N	P=0.330	P=0.211	P=0.722N
COCH-ARM / FISHERS	P=0.376N	P=0.309	P=0.181	P=0.753N
MAX-ISO-POLY-3	P=0.342N	P=0.169	P=0.105	P=0.469N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/38.73	1/40.62	2/42.13	0/43.08
POLY-3 PERCENT (g)	0%	2.5%	4.8%	0%
TERMINAL (d)	0/23 (0%)	1/28 (4%)	2/28 (7%)	0/28 (0%)
FIRST INCIDENCE	---	727 (T)	727 (T)	---
HC TUMORS SAME ROUTE	3/150 (2%)			
HC TUMORS ALL ROUTES	30/1398 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.445N	P=0.510	P=0.256	(e)
POLY 1.5	P=0.459N	P=0.506	P=0.250	(e)
POLY 6	P=0.425N	P=0.516	P=0.264	(e)
COCH-ARM / FISHERS	P=0.481N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.352N	P=0.170	P=0.094	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTEs	(h)	(h)	(h)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Keratoacanthoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	2/39.14	1/40.62	2/42.61	2/43.08
POLY-3 PERCENT (g)	5.1%	2.5%	4.7%	4.6%
TERMINAL (d)	1/23 (4%)	1/28 (4%)	1/28 (4%)	2/28 (7%)
FIRST INCIDENCE	608	727 (T)	583	727 (T)
HC TUMORS SAME ROUTE	5/150 (3%)			
HC TUMORS ALL ROUTES	66/1398 (5%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.572	P=0.487N	P=0.664N	P=0.659N
POLY 1.5	P=0.558	P=0.491N	P=0.673N	P=0.673N
POLY 6	P=0.589	P=0.478N	P=0.650N	P=0.640N
COCH-ARM / FISHERS	P=0.539	P=0.500N	P=0.691N	P=0.691N
MAX-ISO-POLY-3	P=0.627N	P=0.272N	P=0.466N	P=0.462N
HISTCONT SAME RTE	P=0.712	P=1.000	P=0.565	P=0.570
HISTCONT ALL RTEs	P=0.766	P=1.000	P=1.000	P=1.000

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/38.73	1/41.03	3/43.26	0/43.08
POLY-3 PERCENT (g)	0%	2.4%	6.9%	0%
TERMINAL (d)	0/23 (0%)	0/28 (0%)	0/28 (0%)	0/28 (0%)
FIRST INCIDENCE	---	609	580	---
HC TUMORS SAME ROUTE	5/150 (3%)			
HC TUMORS ALL ROUTES	12/1398 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.406N	P=0.512	P=0.139	(e)
POLY 1.5	P=0.423N	P=0.507	P=0.132	(e)
POLY 6	P=0.383N	P=0.520	P=0.151	(e)
COCH-ARM / FISHERS	P=0.449N	P=0.500	P=0.121	(e)
MAX-ISO-POLY-3	P=0.272	P=0.173	P=0.055	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTEs	(h)	(h)	(h)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Schwannoma Malignant</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/38.73	1/41.03	3/43.26	0/43.08
POLY-3 PERCENT (g)	0%	2.4%	6.9%	0%
TERMINAL (d)	0/23 (0%)	0/28 (0%)	0/28 (0%)	0/28 (0%)
FIRST INCIDENCE	---	609	580	---
HC TUMORS SAME ROUTE	4/150 (3%)			
HC TUMORS ALL ROUTES	11/1398 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.406N	P=0.512	P=0.139	(e)
POLY 1.5	P=0.423N	P=0.507	P=0.132	(e)
POLY 6	P=0.383N	P=0.520	P=0.151	(e)
COCH-ARM / FISHERS	P=0.449N	P=0.500	P=0.121	(e)
MAX-ISO-POLY-3	P=0.272	P=0.173	P=0.055	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTEs	(h)	(h)	(h)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Squamous Cell Papilloma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	1/39.12	0/40.62	0/42.13	3/43.08
POLY-3 PERCENT (g)	2.6%	0%	0%	7%
TERMINAL (d)	0/23 (0%)	0/28 (0%)	0/28 (0%)	3/28 (11%)
FIRST INCIDENCE	615	---	---	727 (T)
HC TUMORS SAME ROUTE	1/150 (1%)			
HC TUMORS ALL ROUTES	15/1398 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.052	P=0.493N	P=0.485N	P=0.340
POLY 1.5	P=0.050*	P=0.495N	P=0.490N	P=0.327
POLY 6	P=0.055	P=0.487N	P=0.479N	P=0.359
COCH-ARM / FISHERS	P=0.049*	P=0.500N	P=0.500N	P=0.309
MAX-ISO-POLY-3	P=0.068	P=0.158N	P=0.158N	P=0.189
HISTCONT SAME RTE	P=0.070	(e)	(e)	P=0.072
HISTCONT ALL RTEs	P=0.064	(e)	(e)	P=0.051

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	2/50 (4%)	5/50 (10%)
POLY-3 RATE (b)	3/39.54	1/40.62	2/42.61	5/43.08
POLY-3 PERCENT (g)	7.6%	2.5%	4.7%	11.6%
TERMINAL (d)	1/23 (4%)	1/28 (4%)	1/28 (4%)	5/28 (18%)
FIRST INCIDENCE	608	727 (T)	583	727 (T)
HC TUMORS SAME ROUTE	7/150 (5%)			
HC TUMORS ALL ROUTES	89/1398 (6%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.126	P=0.295N	P=0.466N	P=0.404
POLY 1.5	P=0.119	P=0.297N	P=0.476N	P=0.386
POLY 6	P=0.134	P=0.288N	P=0.453N	P=0.428
COCH-ARM / FISHERS	P=0.111	P=0.309N	P=0.500N	P=0.357
MAX-ISO-POLY-3	P=0.196	P=0.149N	P=0.300N	P=0.278
HISTCONT SAME RTE	P=0.170	P=1.000	P=1.000	P=0.159
HISTCONT ALL RTEs	P=0.227	P=1.000	P=1.000	P=0.347

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Squamous Cell Papilloma, Papilloma, or Keratoacanthoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	2/50 (4%)	5/50 (10%)
POLY-3 RATE (b)	3/39.54	1/40.62	2/42.61	5/43.08
POLY-3 PERCENT (g)	7.6%	2.5%	4.7%	11.6%
TERMINAL (d)	1/23 (4%)	1/28 (4%)	1/28 (4%)	5/28 (18%)
FIRST INCIDENCE	608	727 (T)	583	727 (T)
HC TUMORS SAME ROUTE	6/150 (4%)			
HC TUMORS ALL ROUTES	81/1398 (6%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.126	P=0.295N	P=0.466N	P=0.404
POLY 1.5	P=0.119	P=0.297N	P=0.476N	P=0.386
POLY 6	P=0.134	P=0.288N	P=0.453N	P=0.428
COCH-ARM / FISHERS	P=0.111	P=0.309N	P=0.500N	P=0.357
MAX-ISO-POLY-3	P=0.196	P=0.149N	P=0.300N	P=0.278
HISTCONT SAME RTE	P=0.178	P=1.000	P=1.000	P=0.182
HISTCONT ALL RTEs	P=0.227	P=1.000	P=1.000	P=0.329

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Testes</b>				
<b>Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	37/50 (74%)	31/50 (62%)	42/50 (84%)	37/50 (74%)
POLY-3 RATE (b)	37/43.74	31/43.55	42/47.20	37/45.88
POLY-3 PERCENT (g)	84.6%	71.2%	89%	80.6%
TERMINAL (d)	22/23 (96%)	22/28 (79%)	26/28 (93%)	25/28 (89%)
FIRST INCIDENCE	507	469	491	589
HC TUMORS SAME ROUTE	103/150 (69%)			
HC TUMORS ALL ROUTES	1160/1398 (83%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.537	P=0.079N	P=0.359	P=0.406N
POLY 1.5	P=0.450	P=0.092N	P=0.279	P=0.479N
POLY 6	P=0.507N	P=0.062N	P=0.517	P=0.285N
COCH-ARM / FISHERS	P=0.358	P=0.142N	P=0.163	P=0.590N
MAX-ISO-POLY-3	P=0.288	P=0.044N*	P=0.244	P=0.296N
HISTCONT SAME RTE	P=0.321	P=1.000	P=0.144	P=0.410
HISTCONT ALL RTEs	P=0.334	P=1.000	P=0.298	P=1.000

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Thyroid Gland: C-Cell Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	9/50 (18%)	9/50 (18%)	7/50 (14%)	6/50 (12%)
POLY-3 RATE (b)	9/40.06	9/42.13	7/42.60	6/43.59
POLY-3 PERCENT (g)	22.5%	21.4%	16.4%	13.8%
TERMINAL (d)	4/23 (17%)	5/28 (18%)	6/28 (21%)	3/28 (11%)
FIRST INCIDENCE	603	559	589	654
HC TUMORS SAME ROUTE	25/150 (17%)			
HC TUMORS ALL ROUTES	175/1391 (13%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.186N	P=0.558N	P=0.338N	P=0.225N
POLY 1.5	P=0.204N	P=0.573N	P=0.354N	P=0.248N
POLY 6	P=0.165N	P=0.530N	P=0.324N	P=0.197N
COCH-ARM / FISHERS	P=0.230N	P=0.602N	P=0.393N	P=0.288N
MAX-ISO-POLY-3	P=0.266N	P=0.451N	P=0.250N	P=0.159N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Thyroid Gland: C-Cell Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	9/50 (18%)	10/50 (20%)	7/50 (14%)	7/50 (14%)
POLY-3 RATE (b)	9/40.06	10/42.51	7/42.60	7/43.59
POLY-3 PERCENT (g)	22.5%	23.5%	16.4%	16.1%
TERMINAL (d)	4/23 (17%)	5/28 (18%)	6/28 (21%)	4/28 (14%)
FIRST INCIDENCE	603	559	589	654
HC TUMORS SAME ROUTE	33/150 (22%)			
HC TUMORS ALL ROUTES	214/1391 (15%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.249N	P=0.559	P=0.338N	P=0.320N
POLY 1.5	P=0.269N	P=0.538	P=0.354N	P=0.347N
POLY 6	P=0.226N	P=0.596	P=0.324N	P=0.285N
COCH-ARM / FISHERS	P=0.299N	P=0.500	P=0.393N	P=0.393N
MAX-ISO-POLY-3	P=0.361N	P=0.454	P=0.250N	P=0.237N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Thyroid Gland: Follicular Cell Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/38.73	0/40.62	2/42.26	1/43.08
POLY-3 PERCENT (g)	0%	0%	4.7%	2.3%
TERMINAL (d)	0/23 (0%)	0/28 (0%)	1/28 (4%)	1/28 (4%)
FIRST INCIDENCE	---	---	694	727 (T)
HC TUMORS SAME ROUTE	2/150 (1%)			
HC TUMORS ALL ROUTES	26/1391 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.445	(e)	P=0.257	P=0.521
POLY 1.5	P=0.428	(e)	P=0.250	P=0.513
POLY 6	P=0.466	(e)	P=0.266	P=0.533
COCH-ARM / FISHERS	P=0.404	(e)	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.215	(e)	P=0.094	P=0.184
HISTCONT SAME RTE	P=0.271	(e)	P=0.123	P=0.246
HISTCONT ALL RTEs	P=0.248	(e)	P=0.108	P=0.221

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>All Organs</b>				
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	11/50 (22%)	12/50 (24%)	11/50 (22%)	10/50 (20%)
POLY-3 RATE (b)	11/41.06	12/43.39	11/44.60	10/45.40
POLY-3 PERCENT (g)	26.8%	27.7%	24.7%	22%
TERMINAL (d)	4/23 (17%)	5/28 (18%)	4/28 (14%)	1/28 (4%)
FIRST INCIDENCE	507	469	580	451
HC TUMORS SAME ROUTE	47/150 (31%)			
HC TUMORS ALL ROUTES	536/1398 (38%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.319N	P=0.562	P=0.509N	P=0.396N
POLY 1.5	P=0.352N	P=0.541	P=0.538N	P=0.435N
POLY 6	P=0.282N	P=0.596	P=0.472N	P=0.347N
COCH-ARM / FISHERS	P=0.404N	P=0.500	P=0.595N	P=0.500N
MAX-ISO-POLY-3	P=0.479N	P=0.464	P=0.412N	P=0.312N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>All Organs</b>				
<b>Mesothelioma: Benign, Malignant, NOS</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	5/50 (10%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	2/39.09	5/40.62	1/42.13	4/43.20
POLY-3 PERCENT (g)	5.1%	12.3%	2.4%	9.3%
TERMINAL (d)	1/23 (4%)	5/28 (18%)	1/28 (4%)	3/28 (11%)
FIRST INCIDENCE	626	727 (T)	727 (T)	696
HC TUMORS SAME ROUTE	4/150 (3%)			
HC TUMORS ALL ROUTES	36/1398 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.475	P=0.230	P=0.474N	P=0.384
POLY 1.5	P=0.457	P=0.226	P=0.482N	P=0.365
POLY 6	P=0.500	P=0.239	P=0.464N	P=0.410
COCH-ARM / FISHERS	P=0.431	P=0.218	P=0.500N	P=0.339
MAX-ISO-POLY-3	P=0.399	P=0.132	P=0.266N	P=0.247
HISTCONT SAME RTE	P=0.256	P=0.071	P=1.000	P=0.074
HISTCONT ALL RTEs	P=0.082	P=0.018*	P=1.000	P=0.055

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>All Organs</b>				
<b>Mesothelioma: Malignant</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	5/50 (10%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	2/39.09	5/40.62	1/42.13	4/43.20
POLY-3 PERCENT (g)	5.1%	12.3%	2.4%	9.3%
TERMINAL (d)	1/23 (4%)	5/28 (18%)	1/28 (4%)	3/28 (11%)
FIRST INCIDENCE	626	727 (T)	727 (T)	696
HC TUMORS SAME ROUTE	3/150 (2%)			
HC TUMORS ALL ROUTES	35/1398 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.475	P=0.230	P=0.474N	P=0.384
POLY 1.5	P=0.457	P=0.226	P=0.482N	P=0.365
POLY 6	P=0.500	P=0.239	P=0.464N	P=0.410
COCH-ARM / FISHERS	P=0.431	P=0.218	P=0.500N	P=0.339
MAX-ISO-POLY-3	P=0.399	P=0.132	P=0.266N	P=0.247
HISTCONT SAME RTE	P=0.242	P=0.081	P=1.000	P=0.094
HISTCONT ALL RTEs	P=0.082	P=0.019*	P=1.000	P=0.057

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>All Organs</b>				
<b>Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	47/50 (94%)	49/50 (98%)	50/50 (100%)	45/50 (90%)
POLY-3 RATE (b)	47/47.70	49/49.52	50/50.00	45/47.92
POLY-3 PERCENT (g)	98.5%	99%	100%	93.9%
TERMINAL (d)	23/23 (100%)	28/28 (100%)	28/28 (100%)	27/28 (96%)
FIRST INCIDENCE	507	449	466	496
HC TUMORS SAME ROUTE	142/150 (95%)			
HC TUMORS ALL ROUTES	1350/1398 (97%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.035N*	P=0.854	P=0.701	P=0.228N
POLY 1.5	P=0.037N*	P=0.681	P=0.410	P=0.235N
POLY 6	P=0.029N*	P=0.996	P=0.999	P=0.216N
COCH-ARM / FISHERS	P=0.072N	P=0.309	P=0.121	P=0.357N
MAX-ISO-POLY-3	P=0.029N*	P=0.391	P=0.093	P=0.086N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>All Organs</b>				
<b>Malignant Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	22/50 (44%)	24/50 (48%)	22/50 (44%)	16/50 (32%)
POLY-3 RATE (b)	22/44.82	24/45.17	22/46.66	16/45.84
POLY-3 PERCENT (g)	49.1%	53.1%	47.2%	34.9%
TERMINAL (d)	7/23 (30%)	12/28 (43%)	9/28 (32%)	5/28 (18%)
FIRST INCIDENCE	440	469	491	451
HC TUMORS SAME ROUTE	83/150 (55%)			
HC TUMORS ALL ROUTES	784/1398 (56%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.048N*	P=0.430	P=0.510N	P=0.120N
POLY 1.5	P=0.053N	P=0.433	P=0.527N	P=0.128N
POLY 6	P=0.043N*	P=0.449	P=0.484N	P=0.109N
COCH-ARM / FISHERS	P=0.066N	P=0.421	P=0.580N	P=0.151N
MAX-ISO-POLY-3	P=0.078N	P=0.348	P=0.425N	P=0.084N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>All Organs</b>				
<b>Malignant and Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	49/50 (98%)	50/50 (100%)	50/50 (100%)	48/50 (96%)
POLY-3 RATE (b)	49/49.00	50/50.00	50/50.00	48/48.76
POLY-3 PERCENT (g)	100%	100%	100%	98.4%
TERMINAL (d)	23/23 (100%)	28/28 (100%)	28/28 (100%)	28/28 (100%)
FIRST INCIDENCE	440	449	466	451
HC TUMORS SAME ROUTE	149/150 (99%)			
HC TUMORS ALL ROUTES	1388/1398 (99%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.303N	P=1.000	P=1.000	P=0.633N
POLY 1.5	P=0.148N	P=1.000	P=1.000	P=0.460N
POLY 6	P=0.580N	P=0.500	P=0.500	P=0.853N
COCH-ARM / FISHERS	P=0.177N	P=0.500	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.100N	P=0.161	P=0.161	P=0.138N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Adrenal Medulla</b>				
<b>Pheochromocytoma Benign</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/42.58	1/44.11	2/41.13	2/42.96
POLY-3 PERCENT (g)	2.4%	2.3%	4.9%	4.7%
TERMINAL (d)	0/29 (0%)	0/33 (0%)	2/26 (8%)	1/31 (3%)
FIRST INCIDENCE	230	695	728 (T)	695
HC TUMORS SAME ROUTE	2/149 (1%)			
HC TUMORS ALL ROUTES	37/1338 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.401	P=0.753N	P=0.488	P=0.503
POLY 1.5	P=0.401	P=0.756N	P=0.494	P=0.500
POLY 6	P=0.404	P=0.746N	P=0.482	P=0.511
COCH-ARM / FISHERS	P=0.404	P=0.753N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.438	P=0.489N	P=0.273	P=0.284
HISTCONT SAME RTE	P=0.173	P=0.443	P=0.120	P=0.119
HISTCONT ALL RTEs	P=0.512	P=1.000	P=0.340	P=0.354

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Adrenal Medulla</b>				
<b>Pheochromocytoma: Benign, Complex, Malignant, NOS</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/42.58	1/44.11	2/41.13	2/42.96
POLY-3 PERCENT (g)	2.4%	2.3%	4.9%	4.7%
TERMINAL (d)	0/29 (0%)	0/33 (0%)	2/26 (8%)	1/31 (3%)
FIRST INCIDENCE	230	695	728 (T)	695
HC TUMORS SAME ROUTE	2/149 (1%)			
HC TUMORS ALL ROUTES	49/1338 (4%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.401	P=0.753N	P=0.488	P=0.503
POLY 1.5	P=0.401	P=0.756N	P=0.494	P=0.500
POLY 6	P=0.404	P=0.746N	P=0.482	P=0.511
COCH-ARM / FISHERS	P=0.404	P=0.753N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.438	P=0.489N	P=0.273	P=0.284
HISTCONT SAME RTE	P=0.173	P=0.443	P=0.120	P=0.119
HISTCONT ALL RTEs	P=0.512	P=1.000	P=0.340	P=0.354

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Clitoral/Preputial Gland Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	3/50 (6%)	0/50 (0%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	3/41.61	0/43.98	3/41.95	0/42.83
POLY-3 PERCENT (g)	7.2%	0%	7.2%	0%
TERMINAL (d)	3/29 (10%)	0/33 (0%)	1/26 (4%)	0/31 (0%)
FIRST INCIDENCE	728 (T)	---	590	---
HC TUMORS SAME ROUTE	10/150 (7%)			
HC TUMORS ALL ROUTES	125/1347 (9%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.196N	P=0.109N	P=0.659N	P=0.113N
POLY 1.5	P=0.194N	P=0.112N	P=0.658N	P=0.115N
POLY 6	P=0.197N	P=0.103N	P=0.659N	P=0.109N
COCH-ARM / FISHERS	P=0.192N	P=0.121N	P=0.661N	P=0.121N
MAX-ISO-POLY-3	P=0.062N	P=0.038N*	P=0.495N	P=0.038N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Clitoral/Preputial Gland Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	1/50 (2%)	3/50 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/41.61	3/44.63	0/41.13	1/42.83
POLY-3 PERCENT (g)	2.4%	6.7%	0%	2.3%
TERMINAL (d)	1/29 (3%)	1/33 (3%)	0/26 (0%)	1/31 (3%)
FIRST INCIDENCE	728 (T)	572	---	728 (T)
HC TUMORS SAME ROUTE	2/150 (1%)			
HC TUMORS ALL ROUTES	37/1347 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.442N	P=0.331	P=0.502N	P=0.754N
POLY 1.5	P=0.448N	P=0.321	P=0.500N	P=0.757N
POLY 6	P=0.434N	P=0.346	P=0.505N	P=0.750N
COCH-ARM / FISHERS	P=0.455N	P=0.309	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.292N	P=0.180	P=0.161N	P=0.491N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Clitoral/Preputial Gland Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	4/50 (8%)	3/50 (6%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	4/41.61	3/44.63	3/41.95	1/42.83
POLY-3 PERCENT (g)	9.6%	6.7%	7.2%	2.3%
TERMINAL (d)	4/29 (14%)	1/33 (3%)	1/26 (4%)	1/31 (3%)
FIRST INCIDENCE	728 (T)	572	590	728 (T)
HC TUMORS SAME ROUTE	12/150 (8%)			
HC TUMORS ALL ROUTES	162/1347 (12%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.157N	P=0.462N	P=0.496N	P=0.169N
POLY 1.5	P=0.157N	P=0.476N	P=0.494N	P=0.173N
POLY 6	P=0.156N	P=0.439N	P=0.495N	P=0.162N
COCH-ARM / FISHERS	P=0.155N	P=0.500N	P=0.500N	P=0.181N
MAX-ISO-POLY-3	P=0.150N	P=0.319N	P=0.343N	P=0.081N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Heart</b>				
<b>Schwannoma Malignant</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/41.61	0/43.98	0/41.13	0/42.83
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/29 (0%)	0/33 (0%)	0/26 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	1/150 (1%)			
HC TUMORS ALL ROUTES	4/1350 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Islets, Pancreatic Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/42.44	0/43.98	0/41.13	1/43.22
POLY-3 PERCENT (g)	4.7%	0%	0%	2.3%
TERMINAL (d)	0/29 (0%)	0/33 (0%)	0/26 (0%)	0/31 (0%)
FIRST INCIDENCE	608	---	---	617
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	23/1340 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.701	P=0.229N	P=0.244N	P=0.494N
POLY 1.5	P=0.702	P=0.231N	P=0.239N	P=0.496N
POLY 6	P=0.701	P=0.225N	P=0.250N	P=0.489N
COCH-ARM / FISHERS	P=0.704	P=0.247N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.138N	P=0.076N	P=0.082N	P=0.277N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Liver</b>				
<b>Hepatocellular Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/41.61	1/43.98	0/41.13	0/42.83
POLY-3 PERCENT (g)	4.8%	2.3%	0%	0%
TERMINAL (d)	2/29 (7%)	1/33 (3%)	0/26 (0%)	0/31 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	---	---
HC TUMORS SAME ROUTE	6/150 (4%)			
HC TUMORS ALL ROUTES	17/1350 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.204N	P=0.481N	P=0.239N	P=0.230N
POLY 1.5	P=0.204N	P=0.487N	P=0.237N	P=0.233N
POLY 6	P=0.203N	P=0.470N	P=0.242N	P=0.226N
COCH-ARM / FISHERS	P=0.203N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.081N	P=0.269N	P=0.078N	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Liver</b>				
<b>Hepatocellular Carcinoma or Hepatocellular Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	2/50 (4%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/41.61	2/43.98	0/41.13	1/42.83
POLY-3 PERCENT (g)	4.8%	4.6%	0%	2.3%
TERMINAL (d)	2/29 (7%)	2/33 (6%)	0/26 (0%)	1/31 (3%)
FIRST INCIDENCE	728 (T)	728 (T)	---	728 (T)
HC TUMORS SAME ROUTE	6/150 (4%)			
HC TUMORS ALL ROUTES	18/1350 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.421N	P=0.674N	P=0.239N	P=0.490N
POLY 1.5	P=0.423N	P=0.681N	P=0.237N	P=0.494N
POLY 6	P=0.417N	P=0.663N	P=0.242N	P=0.482N
COCH-ARM / FISHERS	P=0.425N	P=0.691N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.274N	P=0.477N	P=0.078N	P=0.274N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Liver</b>				
<b>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	2/50 (4%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/41.61	2/43.98	0/41.13	1/42.83
POLY-3 PERCENT (g)	4.8%	4.6%	0%	2.3%
TERMINAL (d)	2/29 (7%)	2/33 (6%)	0/26 (0%)	1/31 (3%)
FIRST INCIDENCE	728 (T)	728 (T)	---	728 (T)
HC TUMORS SAME ROUTE	6/150 (4%)			
HC TUMORS ALL ROUTES	18/1350 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.421N	P=0.674N	P=0.239N	P=0.490N
POLY 1.5	P=0.423N	P=0.681N	P=0.237N	P=0.494N
POLY 6	P=0.417N	P=0.663N	P=0.242N	P=0.482N
COCH-ARM / FISHERS	P=0.425N	P=0.691N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.274N	P=0.477N	P=0.078N	P=0.274N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Lung</b>				
<b>Alveolar/Bronchiolar Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/41.61	1/43.98	0/41.13	1/42.83
POLY-3 PERCENT (g)	0%	2.3%	0%	2.3%
TERMINAL (d)	0/29 (0%)	1/33 (3%)	0/26 (0%)	1/31 (3%)
FIRST INCIDENCE	---	728 (T)	---	728 (T)
HC TUMORS SAME ROUTE	1/150 (1%)			
HC TUMORS ALL ROUTES	7/1350 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.484	P=0.511	(e)	P=0.506
POLY 1.5	P=0.481	P=0.507	(e)	P=0.504
POLY 6	P=0.489	P=0.517	(e)	P=0.510
COCH-ARM / FISHERS	P=0.476	P=0.500	(e)	P=0.500
MAX-ISO-POLY-3	P=0.270	P=0.172	(e)	P=0.166
HISTCONT SAME RTE	P=0.341	P=0.230	(e)	P=0.221
HISTCONT ALL RTEs	P=0.235	P=0.143	(e)	P=0.141

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Lung</b>				
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/41.61	2/43.98	0/41.13	1/42.83
POLY-3 PERCENT (g)	0%	4.6%	0%	2.3%
TERMINAL (d)	0/29 (0%)	2/33 (6%)	0/26 (0%)	1/31 (3%)
FIRST INCIDENCE	---	728 (T)	---	728 (T)
HC TUMORS SAME ROUTE	4/150 (3%)			
HC TUMORS ALL ROUTES	30/1350 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.645	P=0.250	(e)	P=0.506
POLY 1.5	P=0.641	P=0.245	(e)	P=0.504
POLY 6	P=0.653	P=0.257	(e)	P=0.510
COCH-ARM / FISHERS	P=0.634	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.344	P=0.088	(e)	P=0.166
HISTCONT SAME RTE	P=0.432	P=0.114	(e)	P=0.221
HISTCONT ALL RTEs	P=0.399	P=0.100	(e)	P=0.197

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Mammary Gland Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/42.16	0/43.98	1/41.48	0/42.83
POLY-3 PERCENT (g)	4.7%	0%	2.4%	0%
TERMINAL (d)	0/29 (0%)	0/33 (0%)	0/26 (0%)	0/31 (0%)
FIRST INCIDENCE	608	---	632	---
HC TUMORS SAME ROUTE	1/150 (1%)			
HC TUMORS ALL ROUTES	20/1350 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.301N	P=0.228N	P=0.506N	P=0.233N
POLY 1.5	P=0.300N	P=0.231N	P=0.501N	P=0.235N
POLY 6	P=0.303N	P=0.223N	P=0.512N	P=0.231N
COCH-ARM / FISHERS	P=0.296N	P=0.247N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.081N	P=0.076N	P=0.287N	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Mammary Gland Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/41.85	1/43.98	0/41.13	2/43.34
POLY-3 PERCENT (g)	2.4%	2.3%	0%	4.6%
TERMINAL (d)	0/29 (0%)	1/33 (3%)	0/26 (0%)	1/31 (3%)
FIRST INCIDENCE	664	728 (T)	---	574
HC TUMORS SAME ROUTE	7/150 (5%)			
HC TUMORS ALL ROUTES	74/1350 (6%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.326	P=0.750N	P=0.503N	P=0.512
POLY 1.5	P=0.323	P=0.753N	P=0.500N	P=0.507
POLY 6	P=0.330	P=0.744N	P=0.507N	P=0.520
COCH-ARM / FISHERS	P=0.321	P=0.753N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.298	P=0.485N	P=0.163N	P=0.294
HISTCONT SAME RTE	P=0.376	P=1.000	(e)	P=0.395
HISTCONT ALL RTEs	P=0.347	P=1.000	(e)	P=0.367

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Mammary Gland Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	3/42.40	1/43.98	1/41.48	2/43.34
POLY-3 PERCENT (g)	7.1%	2.3%	2.4%	4.6%
TERMINAL (d)	0/29 (0%)	1/33 (3%)	0/26 (0%)	1/31 (3%)
FIRST INCIDENCE	608	728 (T)	632	574
HC TUMORS SAME ROUTE	8/150 (5%)			
HC TUMORS ALL ROUTES	94/1350 (7%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.638N	P=0.292N	P=0.313N	P=0.490N
POLY 1.5	P=0.637	P=0.296N	P=0.307N	P=0.493N
POLY 6	P=0.636N	P=0.286N	P=0.320N	P=0.484N
COCH-ARM / FISHERS	P=0.639	P=0.309N	P=0.309N	P=0.500N
MAX-ISO-POLY-3	P=0.294N	P=0.149N	P=0.162N	P=0.316N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Mammary Gland Fibroadenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	24/50 (48%)	15/50 (30%)	21/50 (42%)	13/50 (26%)
POLY-3 RATE (b)	24/42.85	15/44.54	21/43.02	13/44.51
POLY-3 PERCENT (g)	56%	33.7%	48.8%	29.2%
TERMINAL (d)	19/29 (66%)	11/33 (33%)	14/26 (54%)	6/31 (19%)
FIRST INCIDENCE	633	661	590	590
HC TUMORS SAME ROUTE	42/150 (28%)			
HC TUMORS ALL ROUTES	701/1350 (52%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.034N*	P=0.025N*	P=0.321N	P=0.008N**
POLY 1.5	P=0.041N*	P=0.032N*	P=0.319N	P=0.011N*
POLY 6	P=0.025N*	P=0.018N*	P=0.319N	P=0.005N**
COCH-ARM / FISHERS	P=0.053N	P=0.050N*	P=0.344N	P=0.019N*
MAX-ISO-POLY-3	P=0.008N**	P=0.016N*	P=0.246N	P=0.004N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Mammary Gland</b>				
<b>Fibroma, Fibroadenoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	25/50 (50%)	15/50 (30%)	21/50 (42%)	13/50 (26%)
POLY-3 RATE (b)	25/43.27	15/44.54	21/43.02	13/44.51
POLY-3 PERCENT (g)	57.8%	33.7%	48.8%	29.2%
TERMINAL (d)	19/29 (66%)	11/33 (33%)	14/26 (54%)	6/31 (19%)
FIRST INCIDENCE	608	661	590	590
HC TUMORS SAME ROUTE	43/150 (29%)			
HC TUMORS ALL ROUTES	711/1350 (53%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.026N*	P=0.016N*	P=0.261N	P=0.004N**
POLY 1.5	P=0.031N*	P=0.020N*	P=0.255N	P=0.006N**
POLY 6	P=0.020N*	P=0.012N*	P=0.269N	P=0.003N**
COCH-ARM / FISHERS	P=0.042N*	P=0.033N*	P=0.274N	P=0.011N*
MAX-ISO-POLY-3	P=0.005N**	P=0.010N**	P=0.195N	P=0.002N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Mammary Gland</b>				
<b>Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	26/50 (52%)	16/50 (32%)	21/50 (42%)	15/50 (30%)
POLY-3 RATE (b)	26/43.51	16/44.54	21/43.02	15/45.02
POLY-3 PERCENT (g)	59.8%	35.9%	48.8%	33.3%
TERMINAL (d)	19/29 (66%)	12/33 (36%)	14/26 (54%)	7/31 (23%)
FIRST INCIDENCE	608	661	590	574
HC TUMORS SAME ROUTE	48/150 (32%)			
HC TUMORS ALL ROUTES	748/1350 (55%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.046N*	P=0.017N*	P=0.202N	P=0.009N**
POLY 1.5	P=0.056N	P=0.021N*	P=0.194N	P=0.012N*
POLY 6	P=0.034N*	P=0.014N*	P=0.214N	P=0.006N**
COCH-ARM / FISHERS	P=0.074N	P=0.034N*	P=0.212N	P=0.021N*
MAX-ISO-POLY-3	P=0.009N**	P=0.010N**	P=0.146N	P=0.005N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Mesentery</b>				
<b>Schwannoma Malignant</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/42.06	0/43.98	0/41.13	0/42.83
POLY-3 PERCENT (g)	4.8%	0%	0%	0%
TERMINAL (d)	0/29 (0%)	0/33 (0%)	0/26 (0%)	0/31 (0%)
FIRST INCIDENCE	664	---	---	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	0/1350 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.300N	P=0.227N	P=0.242N	P=0.233N
POLY 1.5	P=0.299N	P=0.230N	P=0.238N	P=0.234N
POLY 6	P=0.302N	P=0.222N	P=0.247N	P=0.230N
COCH-ARM / FISHERS	P=0.296N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.035N*	P=0.076N	P=0.080N	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Pituitary Gland: Pars Distalis or Unspecified Site Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	25/50 (50%)	29/50 (58%)	28/50 (56%)	27/50 (54%)
POLY-3 RATE (b)	25/46.25	29/48.05	28/45.17	27/44.19
POLY-3 PERCENT (g)	54.1%	60.4%	62%	61.1%
TERMINAL (d)	11/29 (38%)	17/33 (52%)	18/26 (69%)	20/31 (65%)
FIRST INCIDENCE	530	439	414	594
HC TUMORS SAME ROUTE	90/150 (60%)			
HC TUMORS ALL ROUTES	744/1344 (55%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.384	P=0.340	P=0.285	P=0.318
POLY 1.5	P=0.450	P=0.324	P=0.331	P=0.367
POLY 6	P=0.305	P=0.357	P=0.218	P=0.260
COCH-ARM / FISHERS	P=0.543	P=0.274	P=0.344	P=0.421
MAX-ISO-POLY-3	P=0.386	P=0.271	P=0.220	P=0.251
HISTCONT SAME RTE	P=0.484	P=0.366	P=0.295	P=0.337
HISTCONT ALL RTEs	P=0.451	P=0.338	P=0.270	P=0.310

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	25/50 (50%)	29/50 (58%)	29/50 (58%)	27/50 (54%)
POLY-3 RATE (b)	25/46.25	29/48.05	29/45.20	27/44.19
POLY-3 PERCENT (g)	54.1%	60.4%	64.2%	61.1%
TERMINAL (d)	11/29 (38%)	17/33 (52%)	18/26 (69%)	20/31 (65%)
FIRST INCIDENCE	530	439	414	594
HC TUMORS SAME ROUTE	93/150 (62%)			
HC TUMORS ALL ROUTES	758/1344 (56%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.390	P=0.340	P=0.216	P=0.318
POLY 1.5	P=0.459	P=0.324	P=0.258	P=0.367
POLY 6	P=0.310	P=0.357	P=0.157	P=0.260
COCH-ARM / FISHERS	P=0.552N	P=0.274	P=0.274	P=0.421
MAX-ISO-POLY-3	P=0.335	P=0.271	P=0.160	P=0.251
HISTCONT SAME RTE	P=0.421	P=0.366	P=0.214	P=0.337
HISTCONT ALL RTEs	P=0.390	P=0.338	P=0.191	P=0.310

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/41.70	0/43.98	0/41.13	1/42.83
POLY-3 PERCENT (g)	2.4%	0%	0%	2.3%
TERMINAL (d)	0/29 (0%)	0/33 (0%)	0/26 (0%)	1/31 (3%)
FIRST INCIDENCE	705	---	---	728 (T)
HC TUMORS SAME ROUTE	2/150 (1%)			
HC TUMORS ALL ROUTES	24/1350 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.519	P=0.489N	P=0.503N	P=0.755N
POLY 1.5	P=0.521	P=0.493N	P=0.500N	P=0.757N
POLY 6	P=0.518	P=0.484N	P=0.506N	P=0.751N
COCH-ARM / FISHERS	P=0.524	P=0.500N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.405N	P=0.158N	P=0.162N	P=0.492N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Fibroma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/41.61	0/43.98	0/41.13	0/42.83
POLY-3 PERCENT (g)	2.4%	0%	0%	0%
TERMINAL (d)	1/29 (3%)	0/33 (0%)	0/26 (0%)	0/31 (0%)
FIRST INCIDENCE	728 (T)	---	---	---
HC TUMORS SAME ROUTE	2/150 (1%)			
HC TUMORS ALL ROUTES	25/1350 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.539N	P=0.489N	P=0.502N	P=0.494N
POLY 1.5	P=0.538N	P=0.493N	P=0.500N	P=0.496N
POLY 6	P=0.542N	P=0.483N	P=0.505N	P=0.490N
COCH-ARM / FISHERS	P=0.534N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.128N	P=0.158N	P=0.161N	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/41.61	0/43.98	1/41.60	0/42.83
POLY-3 PERCENT (g)	2.4%	0%	2.4%	0%
TERMINAL (d)	1/29 (3%)	0/33 (0%)	0/26 (0%)	0/31 (0%)
FIRST INCIDENCE	728 (T)	---	590	---
HC TUMORS SAME ROUTE	2/150 (1%)			
HC TUMORS ALL ROUTES	32/1350 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.481N	P=0.489N	P=0.761	P=0.494N
POLY 1.5	P=0.480N	P=0.493N	P=0.759N	P=0.496N
POLY 6	P=0.483N	P=0.483N	P=0.760	P=0.490N
COCH-ARM / FISHERS	P=0.476N	P=0.500N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.259N	P=0.158N	P=0.499	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/41.61	0/43.98	1/41.60	0/42.83
POLY-3 PERCENT (g)	0%	0%	2.4%	0%
TERMINAL (d)	0/29 (0%)	0/33 (0%)	0/26 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	590	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	8/1350 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.775N	(e)	P=0.500	(e)
POLY 1.5	P=0.775N	(e)	P=0.501	(e)
POLY 6	P=0.774N	(e)	P=0.499	(e)
COCH-ARM / FISHERS	P=0.776N	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.394	(e)	P=0.158	(e)
HISTCONT SAME RTE	(h)	(e)	(h)	(e)
HISTCONT ALL RTEs	(h)	(e)	(h)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Keratoacanthoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/41.61	0/43.98	0/41.13	1/42.83
POLY-3 PERCENT (g)	0%	0%	0%	2.3%
TERMINAL (d)	0/29 (0%)	0/33 (0%)	0/26 (0%)	1/31 (3%)
FIRST INCIDENCE	---	---	---	728 (T)
HC TUMORS SAME ROUTE	1/150 (1%)			
HC TUMORS ALL ROUTES	8/1350 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.225	(e)	(e)	P=0.506
POLY 1.5	P=0.225	(e)	(e)	P=0.504
POLY 6	P=0.226	(e)	(e)	P=0.510
COCH-ARM / FISHERS	P=0.224	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.138	(e)	(e)	P=0.166
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/41.61	0/43.98	0/41.13	2/42.83
POLY-3 PERCENT (g)	2.4%	0%	0%	4.7%
TERMINAL (d)	1/29 (3%)	0/33 (0%)	0/26 (0%)	2/31 (7%)
FIRST INCIDENCE	728 (T)	---	---	728 (T)
HC TUMORS SAME ROUTE	2/150 (1%)			
HC TUMORS ALL ROUTES	3/1350 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.175	P=0.489N	P=0.502N	P=0.510
POLY 1.5	P=0.175	P=0.493N	P=0.500N	P=0.506
POLY 6	P=0.174	P=0.483N	P=0.505N	P=0.518
COCH-ARM / FISHERS	P=0.177	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.150	P=0.158N	P=0.161N	P=0.291
HISTCONT SAME RTE	P=0.189	(e)	(e)	P=0.230
HISTCONT ALL RTEs	P=0.009**	(e)	(e)	P=0.009**

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Schwannoma Malignant</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/41.61	0/43.98	0/41.13	1/42.83
POLY-3 PERCENT (g)	2.4%	0%	0%	2.3%
TERMINAL (d)	1/29 (3%)	0/33 (0%)	0/26 (0%)	1/31 (3%)
FIRST INCIDENCE	728 (T)	---	---	728 (T)
HC TUMORS SAME ROUTE	2/150 (1%)			
HC TUMORS ALL ROUTES	3/1350 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.519	P=0.489N	P=0.502N	P=0.754N
POLY 1.5	P=0.521	P=0.493N	P=0.500N	P=0.757N
POLY 6	P=0.518	P=0.483N	P=0.505N	P=0.750N
COCH-ARM / FISHERS	P=0.524	P=0.500N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.405N	P=0.158N	P=0.161N	P=0.491N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Squamous Cell Papilloma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/41.61	0/43.98	0/41.13	0/42.83
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/29 (0%)	0/33 (0%)	0/26 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	5/1350 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/41.61	0/43.98	0/41.13	1/42.83
POLY-3 PERCENT (g)	0%	0%	0%	2.3%
TERMINAL (d)	0/29 (0%)	0/33 (0%)	0/26 (0%)	1/31 (3%)
FIRST INCIDENCE	---	---	---	728 (T)
HC TUMORS SAME ROUTE	2/150 (1%)			
HC TUMORS ALL ROUTES	16/1350 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.225	(e)	(e)	P=0.506
POLY 1.5	P=0.225	(e)	(e)	P=0.504
POLY 6	P=0.226	(e)	(e)	P=0.510
COCH-ARM / FISHERS	P=0.224	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.138	(e)	(e)	P=0.166
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Skin</b>				
<b>Squamous Cell Papilloma, Papilloma, or Keratoacanthoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/41.61	0/43.98	0/41.13	1/42.83
POLY-3 PERCENT (g)	0%	0%	0%	2.3%
TERMINAL (d)	0/29 (0%)	0/33 (0%)	0/26 (0%)	1/31 (3%)
FIRST INCIDENCE	---	---	---	728 (T)
HC TUMORS SAME ROUTE	1/150 (1%)			
HC TUMORS ALL ROUTES	13/1350 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.225	(e)	(e)	P=0.506
POLY 1.5	P=0.225	(e)	(e)	P=0.504
POLY 6	P=0.226	(e)	(e)	P=0.510
COCH-ARM / FISHERS	P=0.224	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.138	(e)	(e)	P=0.166
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Thyroid Gland: C-Cell Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	7/50 (14%)	6/50 (12%)	6/50 (12%)	7/50 (14%)
POLY-3 RATE (b)	7/41.81	6/43.98	6/41.68	7/42.90
POLY-3 PERCENT (g)	16.7%	13.6%	14.4%	16.3%
TERMINAL (d)	6/29 (21%)	6/33 (18%)	3/26 (12%)	6/31 (19%)
FIRST INCIDENCE	674	728 (T)	617	712
HC TUMORS SAME ROUTE	17/150 (11%)			
HC TUMORS ALL ROUTES	141/1338 (11%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.510	P=0.461N	P=0.502N	P=0.595N
POLY 1.5	P=0.507	P=0.474N	P=0.496N	P=0.602N
POLY 6	P=0.515	P=0.440N	P=0.508N	P=0.581N
COCH-ARM / FISHERS	P=0.507	P=0.500N	P=0.500N	P=0.613N
MAX-ISO-POLY-3	P=0.627N	P=0.348N	P=0.383N	P=0.478N
HISTCONT SAME RTE	P=0.594	P=1.000	P=0.596	P=0.446
HISTCONT ALL RTEs	P=0.441	P=0.520	P=0.478	P=0.355

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Thyroid Gland: C-Cell Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	7/50 (14%)	6/50 (12%)	6/50 (12%)	7/50 (14%)
POLY-3 RATE (b)	7/41.81	6/43.98	6/41.68	7/42.90
POLY-3 PERCENT (g)	16.7%	13.6%	14.4%	16.3%
TERMINAL (d)	6/29 (21%)	6/33 (18%)	3/26 (12%)	6/31 (19%)
FIRST INCIDENCE	674	728 (T)	617	712
HC TUMORS SAME ROUTE	19/150 (13%)			
HC TUMORS ALL ROUTES	157/1338 (12%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.510	P=0.461N	P=0.502N	P=0.595N
POLY 1.5	P=0.507	P=0.474N	P=0.496N	P=0.602N
POLY 6	P=0.515	P=0.440N	P=0.508N	P=0.581N
COCH-ARM / FISHERS	P=0.507	P=0.500N	P=0.500N	P=0.613N
MAX-ISO-POLY-3	P=0.627N	P=0.348N	P=0.383N	P=0.478N
HISTCONT SAME RTE	P=0.594	P=1.000	P=1.000	P=0.501
HISTCONT ALL RTEs	P=0.634	P=0.610	P=0.565	P=0.443

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Thyroid Gland: Follicular Cell Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/41.61	1/44.05	0/41.13	1/42.83
POLY-3 PERCENT (g)	2.4%	2.3%	0%	2.3%
TERMINAL (d)	1/29 (3%)	0/33 (0%)	0/26 (0%)	1/31 (3%)
FIRST INCIDENCE	728 (T)	712	---	728 (T)
HC TUMORS SAME ROUTE	3/150 (2%)			
HC TUMORS ALL ROUTES	12/1338 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.671	P=0.748N	P=0.502N	P=0.754N
POLY 1.5	P=0.670	P=0.752N	P=0.500N	P=0.757N
POLY 6	P=0.673	P=0.741N	P=0.505N	P=0.750N
COCH-ARM / FISHERS	P=0.670	P=0.753N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.539N	P=0.484N	P=0.161N	P=0.491N
HISTCONT SAME RTE	P=0.748	P=1.000	(e)	P=1.000
HISTCONT ALL RTEs	P=0.531	P=0.362	(e)	P=0.356

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Uterus</b>				
<b>Polyp Stromal</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	7/50 (14%)	7/50 (14%)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	7/41.61	7/43.98	5/42.39	3/42.86
POLY-3 PERCENT (g)	16.8%	15.9%	11.8%	7%
TERMINAL (d)	7/29 (24%)	7/33 (21%)	2/26 (8%)	2/31 (7%)
FIRST INCIDENCE	728 (T)	728 (T)	574	721
HC TUMORS SAME ROUTE	17/150 (11%)			
HC TUMORS ALL ROUTES	241/1350 (18%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.104N	P=0.571N	P=0.365N	P=0.143N
POLY 1.5	P=0.107N	P=0.586N	P=0.367N	P=0.149N
POLY 6	P=0.100N	P=0.546N	P=0.357N	P=0.133N
COCH-ARM / FISHERS	P=0.109N	P=0.613N	P=0.380N	P=0.159N
MAX-ISO-POLY-3	P=0.152N	P=0.455N	P=0.258N	P=0.083N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>Uterus</b>				
<b>Sarcoma Stromal or Polyp Stromal</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	7/50 (14%)	7/50 (14%)	6/50 (12%)	3/50 (6%)
POLY-3 RATE (b)	7/41.61	7/43.98	6/42.86	3/42.86
POLY-3 PERCENT (g)	16.8%	15.9%	14%	7%
TERMINAL (d)	7/29 (24%)	7/33 (21%)	2/26 (8%)	2/31 (7%)
FIRST INCIDENCE	728 (T)	728 (T)	574	721
HC TUMORS SAME ROUTE	19/150 (13%)			
HC TUMORS ALL ROUTES	250/1350 (19%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.102N	P=0.571N	P=0.477N	P=0.143N
POLY 1.5	P=0.105N	P=0.586N	P=0.483N	P=0.149N
POLY 6	P=0.098N	P=0.546N	P=0.464N	P=0.133N
COCH-ARM / FISHERS	P=0.106N	P=0.613N	P=0.500N	P=0.159N
MAX-ISO-POLY-3	P=0.159N	P=0.455N	P=0.361N	P=0.083N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>All Organs</b>				
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	8/50 (16%)	9/50 (18%)	17/50 (34%)	11/50 (22%)
POLY-3 RATE (b)	8/42.05	9/44.30	17/44.50	11/44.99
POLY-3 PERCENT (g)	19%	20.3%	38.2%	24.5%
TERMINAL (d)	6/29 (21%)	7/33 (21%)	7/26 (27%)	6/31 (19%)
FIRST INCIDENCE	646	661	495	449
HC TUMORS SAME ROUTE	31/150 (21%)			
HC TUMORS ALL ROUTES	288/1350 (21%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.430	P=0.548	P=0.038*	P=0.362
POLY 1.5	P=0.405	P=0.531	P=0.036*	P=0.340
POLY 6	P=0.463	P=0.574	P=0.044*	P=0.395
COCH-ARM / FISHERS	P=0.372	P=0.500	P=0.032*	P=0.306
MAX-ISO-POLY-3	P=0.165	P=0.440	P=0.025*	P=0.277
HISTCONT SAME RTE	P=0.208	P=0.580	P=0.030*	P=0.373
HISTCONT ALL RTEs	P=0.189	P=0.557	P=0.025*	P=0.345

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>All Organs</b>				
<b>Mesothelioma: Benign, Malignant, NOS</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/41.61	0/43.98	0/41.13	0/42.83
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/29 (0%)	0/33 (0%)	0/26 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	5/1350 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>All Organs</b>				
<b>Mesothelioma: Malignant</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/41.61	0/43.98	0/41.13	0/42.83
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/29 (0%)	0/33 (0%)	0/26 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	4/1350 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>All Organs</b>				
<b>Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	43/50 (86%)	40/50 (80%)	42/50 (84%)	34/50 (68%)
POLY-3 RATE (b)	43/47.97	40/48.12	42/47.52	34/45.31
POLY-3 PERCENT (g)	89.6%	83.1%	88.4%	75%
TERMINAL (d)	26/29 (90%)	27/33 (82%)	24/26 (92%)	24/31 (77%)
FIRST INCIDENCE	230	439	414	590
HC TUMORS SAME ROUTE	127/150 (85%)			
HC TUMORS ALL ROUTES	1176/1350 (87%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.042N*	P=0.256N	P=0.555N	P=0.046N*
POLY 1.5	P=0.029N*	P=0.260N	P=0.507N	P=0.034N*
POLY 6	P=0.063N	P=0.253N	P=0.625N	P=0.064N
COCH-ARM / FISHERS	P=0.018N*	P=0.298N	P=0.500N	P=0.028N*
MAX-ISO-POLY-3	P=0.039N*	P=0.169N	P=0.415N	P=0.027N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>All Organs</b>				
<b>Malignant Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	12/50 (24%)	17/50 (34%)	20/50 (40%)	18/50 (36%)
POLY-3 RATE (b)	12/42.88	17/44.94	20/45.39	18/45.71
POLY-3 PERCENT (g)	28%	37.8%	44.1%	39.4%
TERMINAL (d)	6/29 (21%)	13/33 (39%)	7/26 (27%)	11/31 (36%)
FIRST INCIDENCE	646	572	495	449
HC TUMORS SAME ROUTE	56/150 (37%)			
HC TUMORS ALL ROUTES	491/1350 (36%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.310	P=0.224	P=0.085	P=0.180
POLY 1.5	P=0.286	P=0.213	P=0.079	P=0.163
POLY 6	P=0.340	P=0.240	P=0.096	P=0.203
COCH-ARM / FISHERS	P=0.253	P=0.189	P=0.066	P=0.138
MAX-ISO-POLY-3	P=0.158	P=0.167	P=0.060	P=0.134
HISTCONT SAME RTE	P=0.200	P=0.223	P=0.076	P=0.178
HISTCONT ALL RTEs	P=0.182	P=0.199	P=0.066	P=0.158

TDMS No. 99032 - 03  
 Test Type: CHRONIC  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pyrogallol  
 CAS Number: 87-66-1

Date Report Requested: 12/17/2009  
 Time Report Requested: 08:48:44  
 First Dose M/F: 09/15/04 / 09/16/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>All Organs</b>				
<b>Malignant and Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	45/50 (90%)	42/50 (84%)	47/50 (94%)	44/50 (88%)
POLY-3 RATE (b)	45/48.35	42/48.63	47/49.18	44/47.98
POLY-3 PERCENT (g)	93.1%	86.4%	95.6%	91.7%
TERMINAL (d)	26/29 (90%)	28/33 (85%)	24/26 (92%)	28/31 (90%)
FIRST INCIDENCE	230	439	414	449
HC TUMORS SAME ROUTE	140/150 (93%)			
HC TUMORS ALL ROUTES	1271/1350 (94%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.504	P=0.221N	P=0.461	P=0.555N
POLY 1.5	P=0.522	P=0.225N	P=0.442	P=0.537N
POLY 6	P=0.491	P=0.227N	P=0.477	P=0.573N
COCH-ARM / FISHERS	P=0.583N	P=0.277N	P=0.357	P=0.500N
MAX-ISO-POLY-3	P=0.384	P=0.134N	P=0.294	P=0.397N
HISTCONT SAME RTE	P=0.482	P=1.000	P=0.396	P=1.000
HISTCONT ALL RTEs	P=0.447	P=1.000	P=0.368	P=1.000

TDMS No. 99032 - 03  
Test Type: CHRONIC  
Route: SKIN APPLICATION  
Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
Pyrogallol  
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## LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.  
(b) Number of tumor-bearing animals/Poly-3 number  
(d) Observed incidence at terminal kill.  
(e) Value of Statistic cannot be computed.  
(f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.  
(g) Poly-3 adjusted lifetime tumor incidence.  
(h) Value of Historical Controls statistic is only calculated when Poly-3 trend is positive and when there is more than one tumor in the treatment groups.  
(I) Interim sacrifice  
(T) Terminal sacrifice  
# Tumor rates based on numbers of animals necropsied.  
\* To the right of any statistical result, indicates significance at ( $P \leq 0.05$ ).  
\*\* To the right of any statistical result, indicates significance at ( $P \leq 0.01$ ).  
N Indicates a negative trend for all tests  
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

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