

**TDMS No.** 99024 - 07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** RATS/F 344

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Androstenedione  
**CAS Number:** 63-05-8

**Date Report Requested:** 07/18/2008  
**Time Report Requested:** 13:49:10  
**First Dose M/F:** 02/03/03 / 02/03/03  
**Lab:** SRI

F1\_R2

**C Number:** C99024C  
**Lock Date:** 06/29/2006  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.0.0

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## HISTORICAL CONTROL STUDIES From October 2007 Report

### SAME ROUTE

91005-07 -- Methylene blue trihydrate (GAVAGE METHYLCELLULOSE)

### ALL ROUTES

88138-03 -- Benzophenone (ORAL FEED)  
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)  
93020-07 -- Diisopropylcarbodiimide (SKIN ETHANOL)  
88004-05 -- Divinylbenzene (INHALATION AIR)  
88123-05 -- Formamide (GAVAGE WATER)  
95011-07 -- 5-(Hydroxymethyl)-2-furfural (GAVAGE WATER)  
88105-03 -- Isoeugenol (GAVAGE CORN OIL)  
97006-01 -- Methyl isobutyl ketone (INHALATION AIR)  
91005-07 -- Methylene blue trihydrate (GAVAGE METHYLCELLULOSE)  
92012-05 -- 2-Methylimidazole (ORAL FEED)  
92013-05 -- 4-Methylimidazole (ORAL FEED)  
88006-03 -- alpha-Methylstyrene (INHALATION AIR)  
99023-03 -- beta-Myrcene (GAVAGE CORN OIL)  
97008-05 -- Propargyl alcohol (INHALATION AIR)  
20114-07 -- Sodium dichromate dihydrate (VI) (ORAL WATER)  
96001-05 -- Stoddard solvent (type IIC) (INHALATION AIR)  
96019-05 -- Water disinfection byproducts (Bromochloroacetic acid) (ORAL WATER)  
96018-03 -- Water disinfection byproducts (Bromodichloromethane) (ORAL WATER)  
96017-05 -- Water disinfection byproducts (Dibromoacetic acid) (ORAL WATER)  
96015-05 -- Water disinfection byproducts (Dibromoacetonitrile) (ORAL WATER)  
96010-03 -- Water disinfection byproducts (Sodium chlorate) (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 Cortex  
Adrenal Medulla  
Brain  
Clitoral/Preputial Gland  
Islets, Pancreatic  
Kidney  
Liver  
Lung  
Ovary  
Pancreas  
Pituitary Gland  
Salivary Glands  
Spleen  
Testes  
Thymus  
Thyroid Gland

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

### MALE RATS

<u>Organ</u>	<u>Morphology</u>
Adrenal Cortex	Adenoma
Clitoral/Preputial Gland	Adenoma
Lung	Alveolar/Bronchiolar Adenoma
	Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma
Mammary Gland	Fibroma, Fibroadenoma or Adenoma
	Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Pancreas	Adenoma
Testes	Adenoma
Thyroid Gland: Follicular Cell	Adenoma
All Organs	Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated

### FEMALE RATS

<u>Organ</u>	<u>Morphology</u>
Clitoral/Preputial Gland	Carcinoma
Mammary Gland	Carcinoma or Adenoma
	Fibroadenoma
	Fibroma, Fibroadenoma or Adenoma
	Fibroma, Fibroadenoma, Carcinoma, or Adenoma
All Organs	Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated
	Benign Tumors
	Malignant Tumors
	Malignant and Benign Tumors

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Adrenal Cortex  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	3/50 (6%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/39.49	0/44.49	0/42.72	1/43.06
POLY-3 PERCENT (g)	7.6%	0%	0%	2.3%
TERMINAL (d)	1/21 (5%)	0/33 (0%)	0/29 (0%)	1/27 (4%)
FIRST INCIDENCE	688	---	---	729 (T)
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	6/1197 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.365N	P=0.098N	P=0.105N	P=0.274N
POLY 1.5	P=0.353N	P=0.107N	P=0.111N	P=0.286N
POLY 6	P=0.381N	P=0.088N	P=0.097N	P=0.264N
COCH-ARM / FISHERS	P=0.343N	P=0.121N	P=0.121N	P=0.309N
MAX-ISO-POLY-3	P=0.040N*	P=0.037N*	P=0.037N*	P=0.143N
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)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Adrenal Medulla  
 Pheochromocytoma Benign**

**TUMOR RATES**

OVERALL (a)	7/50 (14%)	12/50 (24%)	4/50 (8%)	5/50 (10%)
POLY-3 RATE (b)	7/40.01	12/44.58	4/42.78	5/43.22
POLY-3 PERCENT (g)	17.5%	26.9%	9.4%	11.6%
TERMINAL (d)	3/21 (14%)	11/33 (33%)	3/29 (10%)	4/27 (15%)
FIRST INCIDENCE	612	708	712	687
HC TUMORS SAME RTE	9/50 (18%)			
HC TUMORS ALL RTES	181/1196 (15%)			

**STATISTICAL TESTS**

POLY 3	P=0.117N	P=0.218	P=0.221N	P=0.324N
POLY 1.5	P=0.127N	P=0.187	P=0.238N	P=0.344N
POLY 6	P=0.111N	P=0.261	P=0.201N	P=0.308N
COCH-ARM / FISHERS	P=0.150N	P=0.154	P=0.262N	P=0.380N
MAX-ISO-POLY-3	P=0.122N	P=0.161	P=0.144N	P=0.230N
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)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

**TUMOR RATES**

OVERALL (a)	8/50 (16%)	12/50 (24%)	5/50 (10%)	5/50 (10%)
POLY-3 RATE (b)	8/40.57	12/44.58	5/42.78	5/43.22
POLY-3 PERCENT (g)	19.7%	26.9%	11.7%	11.6%
TERMINAL (d)	3/21 (14%)	11/33 (33%)	4/29 (14%)	4/27 (15%)
FIRST INCIDENCE	554	708	712	687
HC TUMORS SAME RTE	11/50 (22%)			
HC TUMORS ALL RTES	209/1196 (18%)			

**STATISTICAL TESTS**

POLY 3	P=0.089N	P=0.298	P=0.239N	P=0.232N
POLY 1.5	P=0.095N	P=0.264	P=0.254N	P=0.248N
POLY 6	P=0.086N	P=0.343	P=0.221N	P=0.222N
COCH-ARM / FISHERS	P=0.112N	P=0.227	P=0.277N	P=0.277N
MAX-ISO-POLY-3	P=0.129N	P=0.226	P=0.162N	P=0.158N
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)  
 TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

Clitoral/Preputial Gland  
 Adenoma

TUMOR RATES

OVERALL (a)	3/50 (6%)	2/50 (4%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	3/39.64	2/44.49	0/42.72	4/43.48
POLY-3 PERCENT (g)	7.6%	4.5%	0%	9.2%
TERMINAL (d)	2/21 (10%)	2/33 (6%)	0/29 (0%)	2/27 (7%)
FIRST INCIDENCE	592	729 (T)	---	666
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	43/1193 (4%)			

STATISTICAL TESTS

POLY 3	P=0.331	P=0.448N	P=0.105N	P=0.550
POLY 1.5	P=0.331	P=0.471N	P=0.111N	P=0.531
POLY 6	P=0.328	P=0.417N	P=0.098N	P=0.571
COCH-ARM / FISHERS	P=0.324	P=0.500N	P=0.121N	P=0.500
MAX-ISO-POLY-3	P=0.251	P=0.289N	P=0.037N*	P=0.397
HISTCONT SAME RTE	P=0.243	P=0.450	(e)	P=0.155
HISTCONT ALL RTES	P=0.290	P=0.596	(e)	P=0.218

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Clitoral/Preputial Gland  
 Carcinoma**

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/39.18	0/44.49	1/43.29	1/43.3
POLY-3 PERCENT (g)	0%	0%	2.3%	2.3%
TERMINAL (d)	0/21 (0%)	0/33 (0%)	0/29 (0%)	0/27 (0%)
FIRST INCIDENCE	---	---	547	666
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	16/1193 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.301	(e)	P=0.520	P=0.520
POLY 1.5	P=0.296	(e)	P=0.511	P=0.512
POLY 6	P=0.304	(e)	P=0.532	P=0.528
COCH-ARM / FISHERS	P=0.284	(e)	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.294	(e)	P=0.183	P=0.183
HISTCONT SAME RTE	P=0.255	(e)	P=0.201	P=0.201
HISTCONT ALL RTES	P=0.343	(e)	P=0.219	P=0.219

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Clitoral/Preputial Gland  
 Carcinoma or Adenoma**

**TUMOR RATES**

OVERALL (a)	3/50 (6%)	2/50 (4%)	1/50 (2%)	5/50 (10%)
POLY-3 RATE (b)	3/39.64	2/44.49	1/43.29	5/43.72
POLY-3 PERCENT (g)	7.6%	4.5%	2.3%	11.4%
TERMINAL (d)	2/21 (10%)	2/33 (6%)	0/29 (0%)	2/27 (7%)
FIRST INCIDENCE	592	729 (T)	547	666
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	57/1193 (5%)			

**STATISTICAL TESTS**

POLY 3	P=0.190	P=0.448N	P=0.274N	P=0.411
POLY 1.5	P=0.188	P=0.471N	P=0.287N	P=0.389
POLY 6	P=0.189	P=0.417N	P=0.256N	P=0.435
COCH-ARM / FISHERS	P=0.181	P=0.500N	P=0.309N	P=0.357
MAX-ISO-POLY-3	P=0.191	P=0.289N	P=0.143N	P=0.285
HISTCONT SAME RTE	P=0.126	P=0.450	P=0.666	P=0.134
HISTCONT ALL RTES	P=0.220	P=1.000	P=1.000	P=0.179

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

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DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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**Islets, Pancreatic  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	4/50 (8%)	3/50 (6%)	9/50 (18%)	1/50 (2%)
POLY-3 RATE (b)	4/39.51	3/44.78	9/42.93	1/43.11
POLY-3 PERCENT (g)	10.1%	6.7%	21%	2.3%
TERMINAL (d)	2/21 (10%)	2/33 (6%)	8/29 (28%)	0/27 (0%)
FIRST INCIDENCE	686	652	674	717
HC TUMORS SAME RTE	4/50 (8%)			
HC TUMORS ALL RTES	73/1194 (6%)			

**STATISTICAL TESTS**

POLY 3	P=0.160N	P=0.432N	P=0.146	P=0.152N
POLY 1.5	P=0.167N	P=0.463N	P=0.132	P=0.162N
POLY 6	P=0.161N	P=0.392N	P=0.166	P=0.143N
COCH-ARM / FISHERS	P=0.189N	P=0.500N	P=0.117	P=0.181N
MAX-ISO-POLY-3	P=0.106N	P=0.298N	P=0.096	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Islets, Pancreatic  
 Carcinoma or Adenoma**

**TUMOR RATES**

OVERALL (a)	4/50 (8%)	4/50 (8%)	9/50 (18%)	2/50 (4%)
POLY-3 RATE (b)	4/39.51	4/44.99	9/42.93	2/43.24
POLY-3 PERCENT (g)	10.1%	8.9%	21%	4.6%
TERMINAL (d)	2/21 (10%)	2/33 (6%)	8/29 (28%)	0/27 (0%)
FIRST INCIDENCE	686	652	674	697
HC TUMORS SAME RTE	4/50 (8%)			
HC TUMORS ALL RTES	100/1194 (8%)			

**STATISTICAL TESTS**

POLY 3	P=0.244N	P=0.570N	P=0.146	P=0.296N
POLY 1.5	P=0.253N	P=0.604N	P=0.132	P=0.311N
POLY 6	P=0.243N	P=0.525N	P=0.166	P=0.280N
COCH-ARM / FISHERS	P=0.281N	P=0.643N	P=0.117	P=0.339N
MAX-ISO-POLY-3	P=0.183N	P=0.427N	P=0.096	P=0.179N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Kidney: Renal Tubule  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/38.5	0/44.49	2/42.72	1/43.3
POLY-3 PERCENT (g)	0%	0%	4.7%	2.3%
TERMINAL (d)	0/21 (0%)	0/33 (0%)	2/29 (7%)	0/27 (0%)
FIRST INCIDENCE	---	---	729 (T)	666
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	5/1190 (0%)			

**STATISTICAL TESTS**

POLY 3	P=0.346	(e)	P=0.261	P=0.523
POLY 1.5	P=0.339	(e)	P=0.252	P=0.516
POLY 6	P=0.348	(e)	P=0.272	P=0.531
COCH-ARM / FISHERS	P=0.324	(e)	P=0.253	P=0.505
MAX-ISO-POLY-3	P=0.213	(e)	P=0.097	P=0.186
HISTCONT SAME RTE	P=0.294	(e)	P=0.163	P=0.200
HISTCONT ALL RTES	P=0.064	(e)	P=0.009**	P=0.114

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 TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

Liver  
 Hepatocellular Adenoma

TUMOR RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	2/39.29	0/44.49	1/42.72	3/43.11
POLY-3 PERCENT (g)	5.1%	0%	2.3%	7%
TERMINAL (d)	1/21 (5%)	0/33 (0%)	1/29 (3%)	2/27 (7%)
FIRST INCIDENCE	701	---	729 (T)	717
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	10/1199 (1%)			

STATISTICAL TESTS

POLY 3	P=0.217	P=0.210N	P=0.471N	P=0.542
POLY 1.5	P=0.220	P=0.222N	P=0.484N	P=0.526
POLY 6	P=0.208	P=0.195N	P=0.454N	P=0.559
COCH-ARM / FISHERS	P=0.219	P=0.247N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.233	P=0.075N	P=0.264N	P=0.367
HISTCONT SAME RTE	P=0.173	(e)	P=0.660	P=0.141
HISTCONT ALL RTES	P=0.008**	(e)	P=0.350	P=0.017*

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Liver  
 Hepatocellular Carcinoma or Hepatocellular Adenoma**

**TUMOR RATES**

OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	2/39.29	1/44.49	1/42.72	4/43.31
POLY-3 PERCENT (g)	5.1%	2.3%	2.3%	9.2%
TERMINAL (d)	1/21 (5%)	1/33 (3%)	1/29 (3%)	2/27 (7%)
FIRST INCIDENCE	701	729 (T)	729 (T)	676
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	12/1199 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.149	P=0.457N	P=0.471N	P=0.383
POLY 1.5	P=0.149	P=0.476N	P=0.484N	P=0.365
POLY 6	P=0.146	P=0.431N	P=0.454N	P=0.402
COCH-ARM / FISHERS	P=0.144	P=0.500N	P=0.500N	P=0.339
MAX-ISO-POLY-3	P=0.177	P=0.257N	P=0.264N	P=0.246
HISTCONT SAME RTE	P=0.138	P=1.000	P=0.660	P=0.138
HISTCONT ALL RTES	P<0.001**	P=0.395	P=0.386	P=0.005**

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

Liver  
 Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

**TUMOR RATES**

OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	2/39.29	1/44.49	1/42.72	4/43.31
POLY-3 PERCENT (g)	5.1%	2.3%	2.3%	9.2%
TERMINAL (d)	1/21 (5%)	1/33 (3%)	1/29 (3%)	2/27 (7%)
FIRST INCIDENCE	701	729 (T)	729 (T)	676
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	12/1199 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.149	P=0.457N	P=0.471N	P=0.383
POLY 1.5	P=0.149	P=0.476N	P=0.484N	P=0.365
POLY 6	P=0.146	P=0.431N	P=0.454N	P=0.402
COCH-ARM / FISHERS	P=0.144	P=0.500N	P=0.500N	P=0.339
MAX-ISO-POLY-3	P=0.177	P=0.257N	P=0.264N	P=0.246
HISTCONT SAME RTE	P=0.138	P=1.000	P=0.660	P=0.138
HISTCONT ALL RTES	P<0.001**	P=0.395	P=0.386	P=0.005**

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

---

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

---

**Lung  
 Alveolar/Bronchiolar Adenoma**

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	0/39.18	0/44.49	5/43.27	2/43.06
POLY-3 PERCENT (g)	0%	0%	11.6%	4.6%
TERMINAL (d)	0/21 (0%)	0/33 (0%)	2/29 (7%)	2/27 (7%)
FIRST INCIDENCE	---	---	631	729 (T)
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	31/1199 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.195	(e)	P=0.039*	P=0.258
POLY 1.5	P=0.189	(e)	P=0.035*	P=0.250
POLY 6	P=0.196	(e)	P=0.046*	P=0.267
COCH-ARM / FISHERS	P=0.177	(e)	P=0.028*	P=0.247
MAX-ISO-POLY-3	P=0.060	(e)	P=0.017*	P=0.096
HISTCONT SAME RTE	P=0.102	(e)	P=0.031*	P=0.162
HISTCONT ALL RTES	P=0.068	(e)	P=0.017*	P=0.110

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TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

---

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

---

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

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	0/39.18	0/44.49	5/43.27	3/43.22
POLY-3 PERCENT (g)	0%	0%	11.6%	6.9%
TERMINAL (d)	0/21 (0%)	0/33 (0%)	2/29 (7%)	2/27 (7%)
FIRST INCIDENCE	---	---	631	687
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	46/1199 (4%)			

**STATISTICAL TESTS**

POLY 3	P=0.083	(e)	P=0.039*	P=0.137
POLY 1.5	P=0.079	(e)	P=0.035*	P=0.130
POLY 6	P=0.084	(e)	P=0.046*	P=0.145
COCH-ARM / FISHERS	P=0.074	(e)	P=0.028*	P=0.121
MAX-ISO-POLY-3	P=0.046*	(e)	P=0.017*	P=0.053
HISTCONT SAME RTE	P=0.078	(e)	P=0.031*	P=0.093
HISTCONT ALL RTES	P=0.052	(e)	P=0.017*	P=0.058

---

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Mammary Gland  
 Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/39.18	1/44.49	0/42.72	0/43.06
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/21 (0%)	1/33 (3%)	0/29 (0%)	0/27 (0%)
FIRST INCIDENCE	---	729 (T)	---	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	8/1199 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.585N	P=0.525	(e)	(e)
POLY 1.5	P=0.594N	P=0.514	(e)	(e)
POLY 6	P=0.574N	P=0.541	(e)	(e)
COCH-ARM / FISHERS	P=0.606N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.409N	P=0.189	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Mammary Gland  
 Carcinoma or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/39.18	1/44.49	0/42.72	0/43.06
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/21 (0%)	1/33 (3%)	0/29 (0%)	0/27 (0%)
FIRST INCIDENCE	---	729 (T)	---	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	13/1199 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.585N	P=0.525	(e)	(e)
POLY 1.5	P=0.594N	P=0.514	(e)	(e)
POLY 6	P=0.574N	P=0.541	(e)	(e)
COCH-ARM / FISHERS	P=0.606N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.409N	P=0.189	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Mammary Gland Fibroadenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	5/50 (10%)	0/50 (0%)	6/50 (12%)
POLY-3 RATE (b)	2/39.34	5/44.64	0/42.72	6/43.06
POLY-3 PERCENT (g)	5.1%	11.2%	0%	13.9%
TERMINAL (d)	1/21 (5%)	3/33 (9%)	0/29 (0%)	6/27 (22%)
FIRST INCIDENCE	688	708	---	729 (T)
HC TUMORS SAME RTE	2/50 (4%)			
HC TUMORS ALL RTES	43/1199 (4%)			

**STATISTICAL TESTS**

POLY 3	P=0.139	P=0.270	P=0.219N	P=0.162
POLY 1.5	P=0.133	P=0.245	P=0.227N	P=0.151
POLY 6	P=0.141	P=0.306	P=0.209N	P=0.173
COCH-ARM / FISHERS	P=0.125	P=0.218	P=0.247N	P=0.134
MAX-ISO-POLY-3	P=0.119	P=0.172	P=0.075N	P=0.096
HISTCONT SAME RTE	P=0.190	P=0.185	(e)	P=0.162
HISTCONT ALL RTES	P=0.040*	P=0.079	(e)	P=0.034*

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Mammary Gland  
 Fibroma, Fibroadenoma or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	6/50 (12%)	0/50 (0%)	6/50 (12%)
POLY-3 RATE (b)	3/39.49	6/44.64	0/42.72	6/43.06
POLY-3 PERCENT (g)	7.6%	13.4%	0%	13.9%
TERMINAL (d)	1/21 (5%)	4/33 (12%)	0/29 (0%)	6/27 (22%)
FIRST INCIDENCE	688	708	---	729 (T)
HC TUMORS SAME RTE	2/50 (4%)			
HC TUMORS ALL RTES	49/1199 (4%)			

**STATISTICAL TESTS**

POLY 3	P=0.283	P=0.305	P=0.105N	P=0.285
POLY 1.5	P=0.275	P=0.276	P=0.111N	P=0.269
POLY 6	P=0.286	P=0.346	P=0.097N	P=0.299
COCH-ARM / FISHERS	P=0.259	P=0.243	P=0.121N	P=0.243
MAX-ISO-POLY-3	P=0.238	P=0.208	P=0.037N*	P=0.188
HISTCONT SAME RTE	P=0.316	P=0.144	(e)	P=0.144
HISTCONT ALL RTES	P=0.063	P=0.047*	(e)	P=0.045*

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	6/50 (12%)	0/50 (0%)	6/50 (12%)
POLY-3 RATE (b)	3/39.49	6/44.64	0/42.72	6/43.06
POLY-3 PERCENT (g)	7.6%	13.4%	0%	13.9%
TERMINAL (d)	1/21 (5%)	4/33 (12%)	0/29 (0%)	6/27 (22%)
FIRST INCIDENCE	688	708	---	729 (T)
HC TUMORS SAME RTE	2/50 (4%)			
HC TUMORS ALL RTES	55/1199 (5%)			

**STATISTICAL TESTS**

POLY 3	P=0.283	P=0.305	P=0.105N	P=0.285
POLY 1.5	P=0.275	P=0.276	P=0.111N	P=0.269
POLY 6	P=0.286	P=0.346	P=0.097N	P=0.299
COCH-ARM / FISHERS	P=0.259	P=0.243	P=0.121N	P=0.243
MAX-ISO-POLY-3	P=0.238	P=0.208	P=0.037N*	P=0.188
HISTCONT SAME RTE	P=0.316	P=0.144	(e)	P=0.144
HISTCONT ALL RTES	P=0.098	P=0.063	(e)	P=0.060

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

---

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

---

**Pancreas  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	3/50 (6%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	3/39.18	0/44.49	2/42.72	0/43.06
POLY-3 PERCENT (g)	7.7%	0%	4.7%	0%
TERMINAL (d)	3/21 (14%)	0/33 (0%)	2/29 (7%)	0/27 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	21/1191 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.141N	P=0.097N	P=0.461N	P=0.102N
POLY 1.5	P=0.138N	P=0.107N	P=0.478N	P=0.108N
POLY 6	P=0.149N	P=0.086N	P=0.436N	P=0.096N
COCH-ARM / FISHERS	P=0.138N	P=0.121N	P=0.500N	P=0.121N
MAX-ISO-POLY-3	P=0.040N*	P=0.037N*	P=0.296N	P=0.037N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

---

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Pituitary Gland: Pars Distalis or Unspecified Site  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	19/50 (38%)	21/50 (42%)	15/49 (31%)	24/50 (48%)
POLY-3 RATE (b)	19/41.78	21/46.75	15/44.36	24/45.86
POLY-3 PERCENT (g)	45.5%	44.9%	33.8%	52.3%
TERMINAL (d)	10/21 (48%)	13/33 (39%)	9/29 (31%)	14/27 (52%)
FIRST INCIDENCE	547	551	547	563
HC TUMORS SAME RTE	25/50 (50%)			
HC TUMORS ALL RTES	541/1192 (45%)			

**STATISTICAL TESTS**

POLY 3	P=0.241	P=0.565N	P=0.184N	P=0.331
POLY 1.5	P=0.224	P=0.521	P=0.226N	P=0.280
POLY 6	P=0.247	P=0.457N	P=0.137N	P=0.389
COCH-ARM / FISHERS	P=0.187	P=0.419	P=0.287N	P=0.210
MAX-ISO-POLY-3	P=0.259	P=0.479N	P=0.138N	P=0.265
HISTCONT SAME RTE	P=0.379	P=1.000	P=1.000	P=0.401
HISTCONT ALL RTES	P=0.300	P=1.000	P=1.000	P=0.327

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Skin</b>				
<b>Basal Cell Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	1/39.3	2/44.71	4/42.72	0/43.06
POLY-3 PERCENT (g)	2.5%	4.5%	9.4%	0%
TERMINAL (d)	0/21 (0%)	1/33 (3%)	4/29 (14%)	0/27 (0%)
FIRST INCIDENCE	699	672	729 (T)	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	6/1199 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.272N	P=0.545	P=0.204	P=0.482N
POLY 1.5	P=0.282N	P=0.524	P=0.193	P=0.489N
POLY 6	P=0.267N	P=0.572	P=0.220	P=0.475N
COCH-ARM / FISHERS	P=0.304N	P=0.500	P=0.181	P=0.500N
MAX-ISO-POLY-3	P=0.186N	P=0.329	P=0.107	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	5/50 (10%)	7/50 (14%)	7/50 (14%)	2/50 (4%)
POLY-3 RATE (b)	5/40.36	7/44.79	7/42.78	2/43.53
POLY-3 PERCENT (g)	12.4%	15.6%	16.4%	4.6%
TERMINAL (d)	1/21 (5%)	5/33 (15%)	6/29 (21%)	1/27 (4%)
FIRST INCIDENCE	589	672	712	589
HC TUMORS SAME RTE	7/50 (14%)			
HC TUMORS ALL RTES	112/1199 (9%)			

**STATISTICAL TESTS**

POLY 3	P=0.098N	P=0.454	P=0.420	P=0.185N
POLY 1.5	P=0.104N	P=0.420	P=0.403	P=0.196N
POLY 6	P=0.096N	P=0.497	P=0.441	P=0.176N
COCH-ARM / FISHERS	P=0.121N	P=0.380	P=0.380	P=0.218N
MAX-ISO-POLY-3	P=0.135N	P=0.342	P=0.308	P=0.106N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Skin</b>				
<b>Fibroma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	5/50 (10%)	7/50 (14%)	9/50 (18%)	5/50 (10%)
POLY-3 RATE (b)	5/40.03	7/44.88	9/43.27	5/43.76
POLY-3 PERCENT (g)	12.5%	15.6%	20.8%	11.4%
TERMINAL (d)	2/21 (10%)	5/33 (15%)	8/29 (28%)	2/27 (7%)
FIRST INCIDENCE	612	641	558	610
HC TUMORS SAME RTE	6/50 (12%)			
HC TUMORS ALL RTEs	121/1199 (10%)			

**STATISTICAL TESTS**

POLY 3	P=0.424N	P=0.461	P=0.235	P=0.574N
POLY 1.5	P=0.440N	P=0.424	P=0.217	P=0.595N
POLY 6	P=0.416N	P=0.510	P=0.259	P=0.553N
COCH-ARM / FISHERS	P=0.478N	P=0.380	P=0.194	P=0.630N
MAX-ISO-POLY-3	P=0.442N	P=0.348	P=0.164	P=0.441N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	6/50 (12%)	8/50 (16%)	9/50 (18%)	8/50 (16%)
POLY-3 RATE (b)	6/40.03	8/44.88	9/43.27	8/44.23
POLY-3 PERCENT (g)	15%	17.8%	20.8%	18.1%
TERMINAL (d)	3/21 (14%)	6/33 (18%)	8/29 (28%)	4/27 (15%)
FIRST INCIDENCE	612	641	558	589
HC TUMORS SAME RTE	8/50 (16%)			
HC TUMORS ALL RTES	146/1199 (12%)			

**STATISTICAL TESTS**

POLY 3	P=0.462	P=0.477	P=0.343	P=0.465
POLY 1.5	P=0.441	P=0.436	P=0.319	P=0.435
POLY 6	P=0.476	P=0.530	P=0.374	P=0.497
COCH-ARM / FISHERS	P=0.397	P=0.387	P=0.288	P=0.387
MAX-ISO-POLY-3	P=0.494	P=0.369	P=0.253	P=0.357
HISTCONT SAME RTE	P=0.643	P=0.530	P=0.385	P=0.516
HISTCONT ALL RTES	P=0.219	P=0.351	P=0.204	P=0.339

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Skin</b>				
<b>Fibrosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/39.18	0/44.49	0/42.72	2/43.06
POLY-3 PERCENT (g)	2.6%	0%	0%	4.6%
TERMINAL (d)	1/21 (5%)	0/33 (0%)	0/29 (0%)	2/27 (7%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)
HC TUMORS SAME RTE	3/50 (6%)			
HC TUMORS ALL RTES	14/1199 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.215	P=0.475N	P=0.483N	P=0.533
POLY 1.5	P=0.218	P=0.486N	P=0.490N	P=0.520
POLY 6	P=0.209	P=0.459N	P=0.472N	P=0.546
COCH-ARM / FISHERS	P=0.218	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.170	P=0.158N	P=0.158N	P=0.316
HISTCONT SAME RTE	P=0.263	(e)	(e)	P=0.464
HISTCONT ALL RTES	P=0.164	(e)	(e)	P=0.115

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Skin</b>				
<b>Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	1/39.18	1/44.49	0/42.72	3/43.53
POLY-3 PERCENT (g)	2.6%	2.3%	0%	6.9%
TERMINAL (d)	1/21 (5%)	1/33 (3%)	0/29 (0%)	2/27 (7%)
FIRST INCIDENCE	729 (T)	729 (T)	---	589
HC TUMORS SAME RTE	3/50 (6%)			
HC TUMORS ALL RTES	26/1199 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.145	P=0.732N	P=0.483N	P=0.344
POLY 1.5	P=0.143	P=0.745N	P=0.490N	P=0.328
POLY 6	P=0.144	P=0.713N	P=0.472N	P=0.360
COCH-ARM / FISHERS	P=0.138	P=0.753N	P=0.500N	P=0.309
MAX-ISO-POLY-3	P=0.144	P=0.465N	P=0.158N	P=0.192
HISTCONT SAME RTE	P=0.225	P=1.000	(e)	P=0.304
HISTCONT ALL RTES	P=0.108	P=1.000	(e)	P=0.074

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Skin</b>				
<b>Keratoacanthoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	4/50 (8%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	3/40.08	4/44.58	3/42.78	1/43.06
POLY-3 PERCENT (g)	7.5%	9%	7%	2.3%
TERMINAL (d)	1/21 (5%)	3/33 (9%)	2/29 (7%)	1/27 (4%)
FIRST INCIDENCE	589	708	712	729 (T)
HC TUMORS SAME RTE	3/50 (6%)			
HC TUMORS ALL RTES	71/1199 (6%)			

**STATISTICAL TESTS**

POLY 3	P=0.165N	P=0.558	P=0.633N	P=0.279N
POLY 1.5	P=0.169N	P=0.532	P=0.645N	P=0.289N
POLY 6	P=0.164N	P=0.591	P=0.615N	P=0.272N
COCH-ARM / FISHERS	P=0.181N	P=0.500	P=0.661N	P=0.309N
MAX-ISO-POLY-3	P=0.237N	P=0.405	P=0.467N	P=0.144N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Skin</b>				
<b>Schwannoma Malignant</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/39.18	2/44.49	0/42.72	1/43.49
POLY-3 PERCENT (g)	0%	4.5%	0%	2.3%
TERMINAL (d)	0/21 (0%)	2/33 (6%)	0/29 (0%)	0/27 (0%)
FIRST INCIDENCE	---	729 (T)	---	605
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	7/1199 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.602	P=0.266	(e)	P=0.521
POLY 1.5	P=0.586	P=0.253	(e)	P=0.513
POLY 6	P=0.619	P=0.285	(e)	P=0.530
COCH-ARM / FISHERS	P=0.562	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.370	P=0.103	(e)	P=0.184
HISTCONT SAME RTE	P=0.485	P=0.173	(e)	P=0.201
HISTCONT ALL RTES	P=0.397	P=0.029*	(e)	P=0.221

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	1/39.3	2/44.71	4/42.72	0/43.06
POLY-3 PERCENT (g)	2.5%	4.5%	9.4%	0%
TERMINAL (d)	0/21 (0%)	1/33 (3%)	4/29 (14%)	0/27 (0%)
FIRST INCIDENCE	699	672	729 (T)	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	9/1199 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.272N	P=0.545	P=0.204	P=0.482N
POLY 1.5	P=0.282N	P=0.524	P=0.193	P=0.489N
POLY 6	P=0.267N	P=0.572	P=0.220	P=0.475N
COCH-ARM / FISHERS	P=0.304N	P=0.500	P=0.181	P=0.500N
MAX-ISO-POLY-3	P=0.186N	P=0.329	P=0.107	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Skin</b>				
<b>Squamous Cell Papilloma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/39.34	1/44.49	1/42.72	2/43.53
POLY-3 PERCENT (g)	2.5%	2.3%	2.3%	4.6%
TERMINAL (d)	0/21 (0%)	1/33 (3%)	1/29 (3%)	1/27 (4%)
FIRST INCIDENCE	688	729 (T)	729 (T)	589
HC TUMORS SAME RTE	4/50 (8%)			
HC TUMORS ALL RTES	16/1199 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.378	P=0.733N	P=0.742N	P=0.535
POLY 1.5	P=0.372	P=0.746N	P=0.750N	P=0.522
POLY 6	P=0.380	P=0.715N	P=0.731N	P=0.549
COCH-ARM / FISHERS	P=0.358	P=0.753N	P=0.753N	P=0.500
MAX-ISO-POLY-3	P=0.463	P=0.466N	P=0.476N	P=0.319
HISTCONT SAME RTE	P=0.612	P=1.000	P=1.000	P=0.468
HISTCONT ALL RTES	P=0.266	P=0.520	P=0.511	P=0.215

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	4/50 (8%)	5/50 (10%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	4/40.24	5/44.58	4/42.78	2/43.53
POLY-3 PERCENT (g)	9.9%	11.2%	9.4%	4.6%
TERMINAL (d)	1/21 (5%)	4/33 (12%)	3/29 (10%)	1/27 (4%)
FIRST INCIDENCE	589	708	712	589
HC TUMORS SAME RTE	7/50 (14%)			
HC TUMORS ALL RTES	91/1199 (8%)			

**STATISTICAL TESTS**

POLY 3	P=0.191N	P=0.564	P=0.610N	P=0.301N
POLY 1.5	P=0.199N	P=0.535	P=0.624N	P=0.314N
POLY 6	P=0.189N	P=0.600	P=0.592N	P=0.290N
COCH-ARM / FISHERS	P=0.215N	P=0.500	P=0.643N	P=0.339N
MAX-ISO-POLY-3	P=0.287N	P=0.427	P=0.464N	P=0.182N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	4/50 (8%)	5/50 (10%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	4/40.24	5/44.58	4/42.78	2/43.53
POLY-3 PERCENT (g)	9.9%	11.2%	9.4%	4.6%
TERMINAL (d)	1/21 (5%)	4/33 (12%)	3/29 (10%)	1/27 (4%)
FIRST INCIDENCE	589	708	712	589
HC TUMORS SAME RTE	7/50 (14%)			
HC TUMORS ALL RTES	87/1199 (7%)			

**STATISTICAL TESTS**

POLY 3	P=0.191N	P=0.564	P=0.610N	P=0.301N
POLY 1.5	P=0.199N	P=0.535	P=0.624N	P=0.314N
POLY 6	P=0.189N	P=0.600	P=0.592N	P=0.290N
COCH-ARM / FISHERS	P=0.215N	P=0.500	P=0.643N	P=0.339N
MAX-ISO-POLY-3	P=0.287N	P=0.427	P=0.464N	P=0.182N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Skin: Sebaceous Gland  
 Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/39.18	0/44.49	2/43.1	0/43.06
POLY-3 PERCENT (g)	0%	0%	4.6%	0%
TERMINAL (d)	0/21 (0%)	0/33 (0%)	1/29 (3%)	0/27 (0%)
FIRST INCIDENCE	---	---	621	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	8/1199 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.702N	(e)	P=0.259	(e)
POLY 1.5	P=0.706N	(e)	P=0.249	(e)
POLY 6	P=0.702N	(e)	P=0.273	(e)
COCH-ARM / FISHERS	P=0.716	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.289	(e)	P=0.096	(e)
HISTCONT SAME RTE	(h)	(e)	(h)	(e)
HISTCONT ALL RTES	(h)	(e)	(h)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Skin: Sebaceous Gland  
 Carcinoma or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/39.18	0/44.49	2/43.1	1/43.48
POLY-3 PERCENT (g)	0%	0%	4.6%	2.3%
TERMINAL (d)	0/21 (0%)	0/33 (0%)	1/29 (3%)	0/27 (0%)
FIRST INCIDENCE	---	---	621	607
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	9/1199 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.345	(e)	P=0.259	P=0.521
POLY 1.5	P=0.337	(e)	P=0.249	P=0.513
POLY 6	P=0.350	(e)	P=0.273	P=0.530
COCH-ARM / FISHERS	P=0.320	(e)	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.212	(e)	P=0.096	P=0.184
HISTCONT SAME RTE	P=0.294	(e)	P=0.162	P=0.201
HISTCONT ALL RTES	P=0.243	(e)	P=0.066	P=0.221

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

Testes  
 Adenoma

TUMOR RATES

OVERALL (a)	42/50 (84%)	39/50 (78%)	36/50 (72%)	26/50 (52%)
POLY-3 RATE (b)	42/46.12	39/46.53	36/45.48	26/44.74
POLY-3 PERCENT (g)	91.1%	83.8%	79.2%	58.1%
TERMINAL (d)	20/21 (95%)	30/33 (91%)	24/29 (83%)	19/27 (70%)
FIRST INCIDENCE	464	540	558	607
HC TUMORS SAME RTE	41/50 (82%)			
HC TUMORS ALL RTES	1035/1199 (86%)			

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.203N	P=0.070N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.249N	P=0.083N	P<0.001N**
POLY 6	P<0.001N**	P=0.175N	P=0.066N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.306N	P=0.114N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.119N	P=0.036N*	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Thyroid Gland: C-Cell  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	3/50 (6%)	3/50 (6%)	4/50 (8%)	4/50 (8%)
POLY-3 RATE (b)	3/39.37	3/44.58	4/43.31	4/43.38
POLY-3 PERCENT (g)	7.6%	6.7%	9.2%	9.2%
TERMINAL (d)	1/21 (5%)	2/33 (6%)	2/29 (7%)	2/27 (7%)
FIRST INCIDENCE	699	708	605	666
HC TUMORS SAME RTE	6/50 (12%)			
HC TUMORS ALL RTES	151/1185 (13%)			

**STATISTICAL TESTS**

POLY 3	P=0.445	P=0.604N	P=0.552	P=0.553
POLY 1.5	P=0.435	P=0.631N	P=0.529	P=0.532
POLY 6	P=0.448	P=0.568N	P=0.584	P=0.574
COCH-ARM / FISHERS	P=0.412	P=0.661N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.587	P=0.440N	P=0.399	P=0.400
HISTCONT SAME RTE	P=0.735	P=1.000	P=0.565	P=0.566
HISTCONT ALL RTES	P=0.691	P=1.000	P=0.507	P=0.508

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

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DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

---

**Thyroid Gland: C-Cell  
 Carcinoma**

**TUMOR RATES**

OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/39.18	2/44.49	2/42.72	2/43.24
POLY-3 PERCENT (g)	2.6%	4.5%	4.7%	4.6%
TERMINAL (d)	1/21 (5%)	2/33 (6%)	2/29 (7%)	1/27 (4%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	684
HC TUMORS SAME RTE	2/50 (4%)			
HC TUMORS ALL RTES	38/1185 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.492	P=0.544	P=0.530	P=0.534
POLY 1.5	P=0.481	P=0.524	P=0.517	P=0.521
POLY 6	P=0.500	P=0.571	P=0.548	P=0.549
COCH-ARM / FISHERS	P=0.459	P=0.500	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.521	P=0.328	P=0.313	P=0.317
HISTCONT SAME RTE	P=0.670	P=0.479	P=0.461	P=0.466
HISTCONT ALL RTES	P=0.611	P=0.412	P=0.392	P=0.398

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TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

**TUMOR RATES**

OVERALL (a)	4/50 (8%)	4/50 (8%)	6/50 (12%)	6/50 (12%)
POLY-3 RATE (b)	4/39.37	4/44.58	6/43.31	6/43.55
POLY-3 PERCENT (g)	10.2%	9%	13.9%	13.8%
TERMINAL (d)	2/21 (10%)	3/33 (9%)	4/29 (14%)	3/27 (11%)
FIRST INCIDENCE	699	708	605	666
HC TUMORS SAME RTE	8/50 (16%)			
HC TUMORS ALL RTES	188/1185 (16%)			

**STATISTICAL TESTS**

POLY 3	P=0.322	P=0.574N	P=0.430	P=0.434
POLY 1.5	P=0.311	P=0.606N	P=0.403	P=0.408
POLY 6	P=0.327	P=0.531N	P=0.468	P=0.462
COCH-ARM / FISHERS	P=0.285	P=0.643N	P=0.370	P=0.370
MAX-ISO-POLY-3	P=0.458	P=0.430N	P=0.312	P=0.316
HISTCONT SAME RTE	P=0.607	P=1.000	P=0.460	P=0.464
HISTCONT ALL RTES	P=0.537	P=1.000	P=0.391	P=0.396

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Thyroid Gland: Follicular Cell  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/39.4	0/44.49	1/42.72	0/43.06
POLY-3 PERCENT (g)	7.6%	0%	2.3%	0%
TERMINAL (d)	1/21 (5%)	0/33 (0%)	1/29 (3%)	0/27 (0%)
FIRST INCIDENCE	689	---	729 (T)	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	15/1185 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.119N	P=0.098N	P=0.276N	P=0.103N
POLY 1.5	P=0.114N	P=0.107N	P=0.289N	P=0.109N
POLY 6	P=0.127N	P=0.087N	P=0.260N	P=0.097N
COCH-ARM / FISHERS	P=0.112N	P=0.121N	P=0.309N	P=0.121N
MAX-ISO-POLY-3	P=0.023N*	P=0.037N*	P=0.143N	P=0.037N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

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DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

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TUMOR RATES	#	#	#	#
OVERALL (a)	26/50 (52%)	22/50 (44%)	18/50 (36%)	18/50 (36%)
POLY-3 RATE (b)	26/44.06	22/46.05	18/45.06	18/45.92
POLY-3 PERCENT (g)	59%	47.8%	39.9%	39.2%
TERMINAL (d)	9/21 (43%)	14/33 (42%)	8/29 (28%)	7/27 (26%)
FIRST INCIDENCE	526	629	558	563
HC TUMORS SAME RTE	23/50 (46%)			
HC TUMORS ALL RTES	465/1199 (39%)			

**STATISTICAL TESTS**

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POLY 3	P=0.052N	P=0.191N	P=0.050N*	P=0.042N*
POLY 1.5	P=0.058N	P=0.225N	P=0.060N	P=0.052N
POLY 6	P=0.052N	P=0.160N	P=0.043N*	P=0.038N*
COCH-ARM / FISHERS	P=0.078N	P=0.274N	P=0.079N	P=0.079N
MAX-ISO-POLY-3	P=0.046N*	P=0.143N	P=0.033N*	P=0.028N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**All Organs  
 Mesothelioma: Benign, Malignant, NOS**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	1/39.18	2/45.1	3/43.91	2/43.24
POLY-3 PERCENT (g)	2.6%	4.4%	6.8%	4.6%
TERMINAL (d)	1/21 (5%)	0/33 (0%)	0/29 (0%)	1/27 (4%)
FIRST INCIDENCE	729 (T)	641	442	684
HC TUMORS SAME RTE	3/50 (6%)			
HC TUMORS ALL RTES	35/1199 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.496	P=0.549	P=0.347	P=0.534
POLY 1.5	P=0.485	P=0.526	P=0.329	P=0.521
POLY 6	P=0.502	P=0.579	P=0.372	P=0.549
COCH-ARM / FISHERS	P=0.462	P=0.500	P=0.309	P=0.500
MAX-ISO-POLY-3	P=0.423	P=0.333	P=0.196	P=0.317
HISTCONT SAME RTE	P=0.571	P=0.485	P=0.309	P=0.466
HISTCONT ALL RTES	P=0.435	P=0.418	P=0.192	P=0.398

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**All Organs  
 Mesothelioma: Malignant**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/39.18	1/44.81	2/43.14	2/43.24
POLY-3 PERCENT (g)	2.6%	2.2%	4.6%	4.6%
TERMINAL (d)	1/21 (5%)	0/33 (0%)	0/29 (0%)	1/27 (4%)
FIRST INCIDENCE	729 (T)	641	631	684
HC TUMORS SAME RTE	3/50 (6%)			
HC TUMORS ALL RTES	34/1199 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.391	P=0.730N	P=0.534	P=0.534
POLY 1.5	P=0.386	P=0.744N	P=0.519	P=0.521
POLY 6	P=0.393	P=0.710N	P=0.555	P=0.549
COCH-ARM / FISHERS	P=0.370	P=0.753N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.485	P=0.463N	P=0.317	P=0.317
HISTCONT SAME RTE	P=0.635	P=1.000	P=0.465	P=0.466
HISTCONT ALL RTES	P=0.568	P=1.000	P=0.397	P=0.398

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>All Organs</b>				
<b>Osteosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/39.74	0/44.49	2/43.57	0/43.06
POLY-3 PERCENT (g)	2.5%	0%	4.6%	0%
TERMINAL (d)	0/21 (0%)	0/33 (0%)	1/29 (3%)	0/27 (0%)
FIRST INCIDENCE	554	---	387	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	11/1199 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.435N	P=0.477N	P=0.532	P=0.484N
POLY 1.5	P=0.434N	P=0.488N	P=0.519	P=0.490N
POLY 6	P=0.441N	P=0.464N	P=0.549	P=0.478N
COCH-ARM / FISHERS	P=0.438N	P=0.500N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.332N	P=0.158N	P=0.315	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**All Organs  
 Osteosarcoma or Osteoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/39.74	0/44.49	2/43.57	0/43.06
POLY-3 PERCENT (g)	2.5%	0%	4.6%	0%
TERMINAL (d)	0/21 (0%)	0/33 (0%)	1/29 (3%)	0/27 (0%)
FIRST INCIDENCE	554	---	387	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	13/1199 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.435N	P=0.477N	P=0.532	P=0.484N
POLY 1.5	P=0.434N	P=0.488N	P=0.519	P=0.490N
POLY 6	P=0.441N	P=0.464N	P=0.549	P=0.478N
COCH-ARM / FISHERS	P=0.438N	P=0.500N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.332N	P=0.158N	P=0.315	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**All Organs  
 Benign Tumors**

TUMOR RATES	#	#	#	#
OVERALL (a)	47/50 (94%)	47/50 (94%)	46/50 (92%)	46/50 (92%)
POLY-3 RATE (b)	47/47.83	47/48.18	46/48.31	46/48.23
POLY-3 PERCENT (g)	98.3%	97.6%	95.2%	95.4%
TERMINAL (d)	21/21 (100%)	33/33 (100%)	28/29 (97%)	27/27 (100%)
FIRST INCIDENCE	464	540	442	563
HC TUMORS SAME RTE	47/50 (94%)			
HC TUMORS ALL RTES	1166/1199 (97%)			

**STATISTICAL TESTS**

POLY 3	P=0.270N	P=0.746N	P=0.373N	P=0.379N
POLY 1.5	P=0.294N	P=0.728N	P=0.427N	P=0.408N
POLY 6	P=0.335N	P=0.854N	P=0.339N	P=0.482N
COCH-ARM / FISHERS	P=0.412N	P=0.661N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.256N	P=0.363N	P=0.154N	P=0.136N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>All Organs</b>				
<b>Malignant Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	34/50 (68%)	29/50 (58%)	28/50 (56%)	29/50 (58%)
POLY-3 RATE (b)	34/47.12	29/46.26	28/47.16	29/48.2
POLY-3 PERCENT (g)	72.2%	62.7%	59.4%	60.2%
TERMINAL (d)	10/21 (48%)	20/33 (61%)	13/29 (45%)	11/27 (41%)
FIRST INCIDENCE	456	629	387	563
HC TUMORS SAME RTE	30/50 (60%)			
HC TUMORS ALL RTES	686/1199 (57%)			

**STATISTICAL TESTS**

POLY 3	P=0.182N	P=0.220N	P=0.132N	P=0.150N
POLY 1.5	P=0.202N	P=0.213N	P=0.135N	P=0.163N
POLY 6	P=0.172N	P=0.242N	P=0.139N	P=0.149N
COCH-ARM / FISHERS	P=0.256N	P=0.204N	P=0.151N	P=0.204N
MAX-ISO-POLY-3	P=0.162N	P=0.161N	P=0.091N	P=0.106N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Males			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**All Organs  
 Malignant and Benign Tumors**

TUMOR RATES	#	#	#	#
OVERALL (a)	49/50 (98%)	48/50 (96%)	48/50 (96%)	49/50 (98%)
POLY-3 RATE (b)	49/49.15	48/48.5	48/49.37	49/49.42
POLY-3 PERCENT (g)	99.7%	99%	97.2%	99.2%
TERMINAL (d)	21/21 (100%)	33/33 (100%)	28/29 (97%)	27/27 (100%)
FIRST INCIDENCE	456	540	387	563
HC TUMORS SAME RTE	49/50 (98%)			
HC TUMORS ALL RTES	1195/1199 (100%)			

**STATISTICAL TESTS**

POLY 3	P=0.678N	P=0.900N	P=0.422N	P=0.950N
POLY 1.5	P=0.663N	P=0.739N	P=0.431N	P=0.837N
POLY 6	P=0.741N	P=1.000N	P=0.457N	P=1.000N
COCH-ARM / FISHERS	P=0.544	P=0.500N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.327N	P=0.241N	P=0.130N	P=0.278N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
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 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Adrenal Cortex  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/46.64	1/46.01	1/43.47	1/44.14
POLY-3 PERCENT (g)	0%	2.2%	2.3%	2.3%
TERMINAL (d)	0/38 (0%)	1/37 (3%)	0/33 (0%)	1/37 (3%)
FIRST INCIDENCE	---	729 (T)	640	729 (T)
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	17/1098 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.417	P=0.497	P=0.486	P=0.489
POLY 1.5	P=0.426	P=0.498	P=0.492	P=0.493
POLY 6	P=0.408	P=0.497	P=0.479	P=0.484
COCH-ARM / FISHERS	P=0.438	P=0.500	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.332	P=0.159	P=0.158	P=0.158
HISTCONT SAME RTE	P=0.468	P=0.255	P=0.255	P=0.255
HISTCONT ALL RTES	P=0.385	P=0.189	P=0.189	P=0.189

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Adrenal Medulla  
 Pheochromocytoma Benign**

**TUMOR RATES**

OVERALL (a)	3/50 (6%)	1/50 (2%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	3/46.75	1/46.11	3/43.61	1/44.14
POLY-3 PERCENT (g)	6.4%	2.2%	6.9%	2.3%
TERMINAL (d)	2/38 (5%)	0/37 (0%)	2/33 (6%)	1/37 (3%)
FIRST INCIDENCE	703	704	592	729 (T)
HC TUMORS SAME RTE	2/50 (4%)			
HC TUMORS ALL RTEs	27/1091 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.336N	P=0.310N	P=0.630	P=0.326N
POLY 1.5	P=0.327N	P=0.310N	P=0.643	P=0.318N
POLY 6	P=0.346N	P=0.310N	P=0.614	P=0.335N
COCH-ARM / FISHERS	P=0.315N	P=0.309N	P=0.661N	P=0.309N
MAX-ISO-POLY-3	P=0.282N	P=0.159N	P=0.466	P=0.176N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
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 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

**TUMOR RATES**

OVERALL (a)	4/50 (8%)	1/50 (2%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	4/46.75	1/46.11	3/43.61	2/44.14
POLY-3 PERCENT (g)	8.6%	2.2%	6.9%	4.5%
TERMINAL (d)	3/38 (8%)	0/37 (0%)	2/33 (6%)	2/37 (5%)
FIRST INCIDENCE	703	704	592	729 (T)
HC TUMORS SAME RTE	2/50 (4%)			
HC TUMORS ALL RTES	36/1091 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.419N	P=0.183N	P=0.538N	P=0.364N
POLY 1.5	P=0.410N	P=0.182N	P=0.522N	P=0.353N
POLY 6	P=0.431N	P=0.182N	P=0.556N	P=0.376N
COCH-ARM / FISHERS	P=0.397N	P=0.181N	P=0.500N	P=0.339N
MAX-ISO-POLY-3	P=0.331N	P=0.088N	P=0.386N	P=0.228N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
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 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Clitoral/Preputial Gland  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	12/50 (24%)	11/50 (22%)	12/50 (24%)	9/50 (18%)
POLY-3 RATE (b)	12/47.23	11/46.65	12/43.76	9/44.57
POLY-3 PERCENT (g)	25.4%	23.6%	27.4%	20.2%
TERMINAL (d)	9/38 (24%)	9/37 (24%)	9/33 (27%)	8/37 (22%)
FIRST INCIDENCE	619	610	652	605
HC TUMORS SAME RTE	7/50 (14%)			
HC TUMORS ALL RTES	104/1096 (10%)			

**STATISTICAL TESTS**

POLY 3	P=0.333N	P=0.514N	P=0.508	P=0.365N
POLY 1.5	P=0.308N	P=0.511N	P=0.543	P=0.343N
POLY 6	P=0.363N	P=0.513N	P=0.467	P=0.390N
COCH-ARM / FISHERS	P=0.277N	P=0.500N	P=0.592N	P=0.312N
MAX-ISO-POLY-3	P=0.456N	P=0.417N	P=0.415	P=0.282N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
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 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Clitoral/Preputial Gland  
 Carcinoma**

**TUMOR RATES**

OVERALL (a)	1/50 (2%)	2/50 (4%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	1/46.8	2/46.27	5/43.74	2/44.14
POLY-3 PERCENT (g)	2.1%	4.3%	11.4%	4.5%
TERMINAL (d)	0/38 (0%)	1/37 (3%)	3/33 (9%)	2/37 (5%)
FIRST INCIDENCE	689	659	547	729 (T)
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	29/1096 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.424	P=0.496	P=0.086	P=0.480
POLY 1.5	P=0.442	P=0.497	P=0.093	P=0.488
POLY 6	P=0.405	P=0.497	P=0.079	P=0.471
COCH-ARM / FISHERS	P=0.465	P=0.500	P=0.102	P=0.500
MAX-ISO-POLY-3	P=0.188	P=0.278	P=0.041*	P=0.269
HISTCONT SAME RTE	P=0.287	P=0.229	P=0.073	P=0.223
HISTCONT ALL RTES	P=0.218	P=0.348	P=0.044*	P=0.335

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
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 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Clitoral/Preputial Gland  
 Carcinoma or Adenoma**

**TUMOR RATES**

OVERALL (a)	13/50 (26%)	13/50 (26%)	17/50 (34%)	11/50 (22%)
POLY-3 RATE (b)	13/47.39	13/46.91	17/44.34	11/44.57
POLY-3 PERCENT (g)	27.4%	27.7%	38.3%	24.7%
TERMINAL (d)	9/38 (24%)	10/37 (27%)	12/33 (36%)	10/37 (27%)
FIRST INCIDENCE	619	610	547	605
HC TUMORS SAME RTE	8/50 (16%)			
HC TUMORS ALL RTES	133/1096 (12%)			

**STATISTICAL TESTS**

POLY 3	P=0.432N	P=0.579	P=0.185	P=0.475N
POLY 1.5	P=0.396N	P=0.580	P=0.214	P=0.447N
POLY 6	P=0.478N	P=0.582	P=0.155	P=0.508N
COCH-ARM / FISHERS	P=0.351N	P=0.590N	P=0.257	P=0.408N
MAX-ISO-POLY-3	P=0.415N	P=0.487	P=0.139	P=0.384N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

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 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Islets, Pancreatic  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/46.64	2/46.01	1/43.15	1/44.14
POLY-3 PERCENT (g)	2.1%	4.4%	2.3%	2.3%
TERMINAL (d)	1/38 (3%)	2/37 (5%)	1/33 (3%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	2/49 (4%)			
HC TUMORS ALL RTES	21/1092 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.565N	P=0.495	P=0.743	P=0.748
POLY 1.5	P=0.558N	P=0.496	P=0.750	P=0.753
POLY 6	P=0.573N	P=0.495	P=0.734	P=0.743
COCH-ARM / FISHERS	P=0.548N	P=0.500	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.612N	P=0.278	P=0.478	P=0.484
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
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 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Islets, Pancreatic  
 Carcinoma or Adenoma**

**TUMOR RATES**

OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/47.03	2/46.01	1/43.15	1/44.14
POLY-3 PERCENT (g)	4.3%	4.4%	2.3%	2.3%
TERMINAL (d)	1/38 (3%)	2/37 (5%)	1/33 (3%)	1/37 (3%)
FIRST INCIDENCE	619	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	2/49 (4%)			
HC TUMORS ALL RTES	25/1092 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.388N	P=0.686	P=0.530N	P=0.522N
POLY 1.5	P=0.381N	P=0.688	P=0.517N	P=0.513N
POLY 6	P=0.397N	P=0.684	P=0.545N	P=0.532N
COCH-ARM / FISHERS	P=0.370N	P=0.691N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.481N	P=0.490	P=0.313N	P=0.305N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Kidney: Renal Tubule  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/45.33	0/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	0/33 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	1/1093 (0%)			

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
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 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

Liver  
 Hepatocellular Adenoma

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/46.01	0/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	0/33 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	14/1099 (1%)			

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

---

Liver  
 Hepatocellular Carcinoma or Hepatocellular Adenoma

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/46.01	0/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	0/33 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	14/1099 (1%)			

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

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TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
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 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

Liver  
 Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/46.01	0/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	0/33 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	14/1099 (1%)			

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Lung  
 Alveolar/Bronchiolar Adenoma**

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/46.64	0/46.01	2/43.46	1/44.14
POLY-3 PERCENT (g)	0%	0%	4.6%	2.3%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	1/33 (3%)	1/37 (3%)
FIRST INCIDENCE	---	---	643	729 (T)
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	24/1099 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.299	(e)	P=0.222	P=0.489
POLY 1.5	P=0.308	(e)	P=0.228	P=0.493
POLY 6	P=0.290	(e)	P=0.215	P=0.484
COCH-ARM / FISHERS	P=0.320	(e)	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.170	(e)	P=0.076	P=0.158
HISTCONT SAME RTE	P=0.262	(e)	P=0.130	P=0.211
HISTCONT ALL RTES	P=0.196	(e)	P=0.086	P=0.189

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/46.64	0/46.01	2/43.46	1/44.14
POLY-3 PERCENT (g)	0%	0%	4.6%	2.3%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	1/33 (3%)	1/37 (3%)
FIRST INCIDENCE	---	---	643	729 (T)
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	29/1099 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.299	(e)	P=0.222	P=0.489
POLY 1.5	P=0.308	(e)	P=0.228	P=0.493
POLY 6	P=0.290	(e)	P=0.215	P=0.484
COCH-ARM / FISHERS	P=0.320	(e)	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.170	(e)	P=0.076	P=0.158
HISTCONT SAME RTE	P=0.262	(e)	P=0.130	P=0.211
HISTCONT ALL RTES	P=0.196	(e)	P=0.086	P=0.189

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
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 Androstenedione  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Mammary Gland Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/46.88	1/46.01	0/43.15	0/44.14
POLY-3 PERCENT (g)	4.3%	2.2%	0%	0%
TERMINAL (d)	0/38 (0%)	1/37 (3%)	0/33 (0%)	0/37 (0%)
FIRST INCIDENCE	689	729 (T)	---	---
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	60/1100 (6%)			

**STATISTICAL TESTS**

POLY 3	P=0.141N	P=0.507N	P=0.256N	P=0.251N
POLY 1.5	P=0.140N	P=0.505N	P=0.248N	P=0.245N
POLY 6	P=0.143N	P=0.508N	P=0.266N	P=0.257N
COCH-ARM / FISHERS	P=0.138N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.095N	P=0.288N	P=0.094N	P=0.089N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
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 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Mammary Gland Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/47.26	1/46.01	0/43.15	0/44.14
POLY-3 PERCENT (g)	6.4%	2.2%	0%	0%
TERMINAL (d)	0/38 (0%)	1/37 (3%)	0/33 (0%)	0/37 (0%)
FIRST INCIDENCE	621	729 (T)	---	---
HC TUMORS SAME RTE	2/50 (4%)			
HC TUMORS ALL RTES	75/1100 (7%)			

**STATISTICAL TESTS**

POLY 3	P=0.069N	P=0.315N	P=0.136N	P=0.131N
POLY 1.5	P=0.068N	P=0.312N	P=0.129N	P=0.126N
POLY 6	P=0.070N	P=0.319N	P=0.146N	P=0.138N
COCH-ARM / FISHERS	P=0.069N	P=0.309N	P=0.121N	P=0.121N
MAX-ISO-POLY-3	P=0.034N*	P=0.164N	P=0.053N	P=0.049N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
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 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Mammary Gland Fibroadenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	35/50 (70%)	31/50 (62%)	22/50 (44%)	12/50 (24%)
POLY-3 RATE (b)	35/48.39	31/46.94	22/46.23	12/44.56
POLY-3 PERCENT (g)	72.3%	66.1%	47.6%	26.9%
TERMINAL (d)	28/38 (74%)	26/37 (70%)	13/33 (39%)	11/37 (30%)
FIRST INCIDENCE	619	652	547	610
HC TUMORS SAME RTE	28/50 (56%)			
HC TUMORS ALL RTEs	574/1100 (52%)			

**STATISTICAL TESTS**

POLY 3	P<0.001N**	P=0.326N	P=0.009N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.305N	P=0.008N**	P<0.001N**
POLY 6	P<0.001N**	P=0.351N	P=0.012N*	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.263N	P=0.007N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.253N	P=0.006N**	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
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 Route: GAVAGE  
 Species/Strain: RATS/F 344

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 Androstenedione  
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 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Mammary Gland Fibroma, Fibroadenoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	36/50 (72%)	31/50 (62%)	22/50 (44%)	12/50 (24%)
POLY-3 RATE (b)	36/48.77	31/46.94	22/46.23	12/44.56
POLY-3 PERCENT (g)	73.8%	66.1%	47.6%	26.9%
TERMINAL (d)	28/38 (74%)	26/37 (70%)	13/33 (39%)	11/37 (30%)
FIRST INCIDENCE	619	652	547	610
HC TUMORS SAME RTE	29/50 (58%)			
HC TUMORS ALL RTEs	583/1100 (53%)			

**STATISTICAL TESTS**

POLY 3	P<0.001N**	P=0.269N	P=0.006N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.241N	P=0.004N**	P<0.001N**
POLY 6	P<0.001N**	P=0.305N	P=0.008N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.198N	P=0.004N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.205N	P=0.004N**	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

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 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	37/50 (74%)	32/50 (64%)	22/50 (44%)	12/50 (24%)
POLY-3 RATE (b)	37/48.86	32/46.94	22/46.23	12/44.56
POLY-3 PERCENT (g)	75.7%	68.2%	47.6%	26.9%
TERMINAL (d)	28/38 (74%)	27/37 (73%)	13/33 (39%)	11/37 (30%)
FIRST INCIDENCE	619	652	547	610
HC TUMORS SAME RTE	30/50 (60%)			
HC TUMORS ALL RTEs	619/1100 (56%)			

**STATISTICAL TESTS**

POLY 3	P<0.001N**	P=0.272N	P=0.003N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.241N	P=0.002N**	P<0.001N**
POLY 6	P<0.001N**	P=0.315N	P=0.005N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.194N	P=0.002N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.206N	P=0.002N**	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Pancreas  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/46.64	0/46.01	0/43.15	1/44.14
POLY-3 PERCENT (g)	0%	0%	0%	2.3%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	0/33 (0%)	1/37 (3%)
FIRST INCIDENCE	---	---	---	729 (T)
HC TUMORS SAME RTE	1/49 (2%)			
HC TUMORS ALL RTES	3/1093 (0%)			

**STATISTICAL TESTS**

POLY 3	P=0.204	(e)	(e)	P=0.489
POLY 1.5	P=0.207	(e)	(e)	P=0.493
POLY 6	P=0.201	(e)	(e)	P=0.484
COCH-ARM / FISHERS	P=0.211	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.124	(e)	(e)	P=0.158
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
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 Species/Strain: RATS/F 344

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Pituitary Gland: Pars Distalis or Unspecified Site  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	19/50 (38%)	19/50 (38%)	17/49 (35%)	12/50 (24%)
POLY-3 RATE (b)	19/47.72	19/47.08	17/44.35	12/45.27
POLY-3 PERCENT (g)	39.8%	40.4%	38.3%	26.5%
TERMINAL (d)	13/38 (34%)	13/37 (35%)	12/33 (36%)	10/37 (27%)
FIRST INCIDENCE	621	610	552	547
HC TUMORS SAME RTE	36/50 (72%)			
HC TUMORS ALL RTES	613/1093 (56%)			

**STATISTICAL TESTS**

POLY 3	P=0.081N	P=0.562	P=0.527N	P=0.125N
POLY 1.5	P=0.070N	P=0.565	P=0.494N	P=0.112N
POLY 6	P=0.098N	P=0.562	P=0.565N	P=0.144N
COCH-ARM / FISHERS	P=0.059N	P=0.582N	P=0.447N	P=0.097N
MAX-ISO-POLY-3	P=0.128N	P=0.478	P=0.442N	P=0.091N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
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 Species/Strain: RATS/F 344

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 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Skin</b>				
<b>Basal Cell Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/46.01	0/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	0/33 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	3/1100 (0%)			

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

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 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/46.01	1/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	1/33 (3%)	0/37 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
HC TUMORS SAME RTE	3/50 (6%)			
HC TUMORS ALL RTES	24/1100 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.773	(e)	P=0.484	(e)
POLY 1.5	P=0.780	(e)	P=0.491	(e)
POLY 6	P=0.766	(e)	P=0.477	(e)
COCH-ARM / FISHERS	P=0.789	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.384	(e)	P=0.158	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
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 Species/Strain: RATS/F 344

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 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Skin</b>				
<b>Fibroma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/46.64	2/46.58	1/43.15	1/44.14
POLY-3 PERCENT (g)	6.4%	4.3%	2.3%	2.3%
TERMINAL (d)	3/38 (8%)	0/37 (0%)	1/33 (3%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	610	729 (T)	729 (T)
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTEs	19/1100 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.250N	P=0.501N	P=0.334N	P=0.325N
POLY 1.5	P=0.244N	P=0.502N	P=0.322N	P=0.317N
POLY 6	P=0.258N	P=0.496N	P=0.348N	P=0.334N
COCH-ARM / FISHERS	P=0.236N	P=0.500N	P=0.309N	P=0.309N
MAX-ISO-POLY-3	P=0.256N	P=0.324N	P=0.183N	P=0.175N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

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 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	3/50 (6%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	3/46.64	3/46.9	3/43.54	1/44.14
POLY-3 PERCENT (g)	6.4%	6.4%	6.9%	2.3%
TERMINAL (d)	3/38 (8%)	0/37 (0%)	2/33 (6%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	610	619	729 (T)
HC TUMORS SAME RTE	2/50 (4%)			
HC TUMORS ALL RTEs	25/1100 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.241N	P=0.660N	P=0.630	P=0.325N
POLY 1.5	P=0.232N	P=0.662	P=0.643	P=0.317N
POLY 6	P=0.253N	P=0.653N	P=0.615	P=0.334N
COCH-ARM / FISHERS	P=0.218N	P=0.661N	P=0.661N	P=0.309N
MAX-ISO-POLY-3	P=0.311N	P=0.496N	P=0.466	P=0.175N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Skin</b>				
<b>Fibrosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/46.01	2/43.54	0/44.14
POLY-3 PERCENT (g)	0%	0%	4.6%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	1/33 (3%)	0/37 (0%)
FIRST INCIDENCE	---	---	619	---
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	5/1100 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.694	(e)	P=0.222	(e)
POLY 1.5	P=0.703	(e)	P=0.228	(e)
POLY 6	P=0.684	(e)	P=0.215	(e)
COCH-ARM / FISHERS	P=0.716	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.249	(e)	P=0.076	(e)
HISTCONT SAME RTE	P=0.366	(e)	P=0.130	(e)
HISTCONT ALL RTES	P=0.276	(e)	P=0.011*	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Skin</b>				
<b>Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	2/46.49	2/43.54	0/44.14
POLY-3 PERCENT (g)	0%	4.3%	4.6%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	1/33 (3%)	0/37 (0%)
FIRST INCIDENCE	---	639	619	---
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	6/1100 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.471N	P=0.236	P=0.222	(e)
POLY 1.5	P=0.461N	P=0.236	P=0.228	(e)
POLY 6	P=0.482N	P=0.238	P=0.215	(e)
COCH-ARM / FISHERS	P=0.446N	P=0.247	P=0.247	(e)
MAX-ISO-POLY-3	P=0.279	P=0.076	P=0.076	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTES	(h)	(h)	(h)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Skin</b>				
<b>Keratoacanthoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/46.01	0/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	0/33 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	8/1100 (1%)			

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Skin</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)	0/46.64	0/46.01	0/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	0/33 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	3/1100 (0%)			

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/46.01	0/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	0/33 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	4/1100 (0%)			

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Skin</b>				
<b>Squamous Cell Papilloma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/46.01	1/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	1/33 (3%)	0/37 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	3/1100 (0%)			

**STATISTICAL TESTS**

POLY 3	P=0.773	(e)	P=0.484	(e)
POLY 1.5	P=0.780	(e)	P=0.491	(e)
POLY 6	P=0.766	(e)	P=0.477	(e)
COCH-ARM / FISHERS	P=0.789	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.384	(e)	P=0.158	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/46.01	1/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	1/33 (3%)	0/37 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	12/1100 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.773	(e)	P=0.484	(e)
POLY 1.5	P=0.780	(e)	P=0.491	(e)
POLY 6	P=0.766	(e)	P=0.477	(e)
COCH-ARM / FISHERS	P=0.789	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.384	(e)	P=0.158	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/46.01	1/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	1/33 (3%)	0/37 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	11/1100 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.773	(e)	P=0.484	(e)
POLY 1.5	P=0.780	(e)	P=0.491	(e)
POLY 6	P=0.766	(e)	P=0.477	(e)
COCH-ARM / FISHERS	P=0.789	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.384	(e)	P=0.158	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Skin: Sebaceous 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)	0/46.64	0/46.01	0/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	0/33 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	1/1100 (0%)			

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Skin: Sebaceous Gland  
 Carcinoma or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/46.01	1/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	1/33 (3%)	0/37 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	1/1100 (0%)			

**STATISTICAL TESTS**

POLY 3	P=0.773	(e)	P=0.484	(e)
POLY 1.5	P=0.780	(e)	P=0.491	(e)
POLY 6	P=0.766	(e)	P=0.477	(e)
COCH-ARM / FISHERS	P=0.789	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.384	(e)	P=0.158	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Thyroid Gland: C-Cell  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	4/50 (8%)	4/50 (8%)	5/50 (10%)	5/50 (10%)
POLY-3 RATE (b)	4/47.03	4/46.45	5/43.73	5/44.14
POLY-3 PERCENT (g)	8.5%	8.6%	11.4%	11.3%
TERMINAL (d)	3/38 (8%)	2/37 (5%)	4/33 (12%)	5/37 (14%)
FIRST INCIDENCE	619	652	547	729 (T)
HC TUMORS SAME RTE	7/50 (14%)			
HC TUMORS ALL RTES	124/1086 (11%)			

**STATISTICAL TESTS**

POLY 3	P=0.378	P=0.636	P=0.454	P=0.460
POLY 1.5	P=0.397	P=0.637	P=0.474	P=0.477
POLY 6	P=0.356	P=0.638	P=0.431	P=0.443
COCH-ARM / FISHERS	P=0.421	P=0.643N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.523	P=0.492	P=0.327	P=0.331
HISTCONT SAME RTE	P=0.672	P=0.661	P=0.478	P=0.483
HISTCONT ALL RTES	P=0.614	P=0.622	P=0.412	P=0.418

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Thyroid Gland: C-Cell  
 Carcinoma**

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/46.01	1/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	1/33 (3%)	0/37 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	18/1086 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.773	(e)	P=0.484	(e)
POLY 1.5	P=0.780	(e)	P=0.491	(e)
POLY 6	P=0.766	(e)	P=0.477	(e)
COCH-ARM / FISHERS	P=0.789	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.384	(e)	P=0.158	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

**TUMOR RATES**

OVERALL (a)	4/50 (8%)	4/50 (8%)	6/50 (12%)	5/50 (10%)
POLY-3 RATE (b)	4/47.03	4/46.45	6/43.73	5/44.14
POLY-3 PERCENT (g)	8.5%	8.6%	13.7%	11.3%
TERMINAL (d)	3/38 (8%)	2/37 (5%)	5/33 (15%)	5/37 (14%)
FIRST INCIDENCE	619	652	547	729 (T)
HC TUMORS SAME RTE	7/50 (14%)			
HC TUMORS ALL RTES	141/1086 (13%)			

**STATISTICAL TESTS**

POLY 3	P=0.376	P=0.636	P=0.324	P=0.460
POLY 1.5	P=0.397	P=0.637	P=0.343	P=0.477
POLY 6	P=0.353	P=0.638	P=0.302	P=0.443
COCH-ARM / FISHERS	P=0.423	P=0.643N	P=0.370	P=0.500
MAX-ISO-POLY-3	P=0.438	P=0.492	P=0.223	P=0.331
HISTCONT SAME RTE	P=0.587	P=0.661	P=0.346	P=0.483
HISTCONT ALL RTES	P=0.514	P=0.622	P=0.274	P=0.418

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**Thyroid Gland: Follicular Cell  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/46.64	1/46.01	0/43.15	1/44.35
POLY-3 PERCENT (g)	0%	2.2%	0%	2.3%
TERMINAL (d)	0/38 (0%)	1/37 (3%)	0/33 (0%)	0/37 (0%)
FIRST INCIDENCE	---	729 (T)	---	674
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	5/1086 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.411	P=0.497	(e)	P=0.490
POLY 1.5	P=0.417	P=0.498	(e)	P=0.494
POLY 6	P=0.406	P=0.497	(e)	P=0.486
COCH-ARM / FISHERS	P=0.425	P=0.500	(e)	P=0.500
MAX-ISO-POLY-3	P=0.255	P=0.159	(e)	P=0.158
HISTCONT SAME RTE	P=0.254	P=0.215	(e)	P=0.210
HISTCONT ALL RTES	P=0.285	P=0.183	(e)	P=0.181

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Uterus</b>				
<b>Polyp Stromal</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	9/50 (18%)	12/50 (24%)	10/50 (20%)	5/50 (10%)
POLY-3 RATE (b)	9/46.64	12/46.76	10/44.05	5/44.75
POLY-3 PERCENT (g)	19.3%	25.7%	22.7%	11.2%
TERMINAL (d)	9/38 (24%)	9/37 (24%)	8/33 (24%)	4/37 (11%)
FIRST INCIDENCE	729 (T)	610	547	534
HC TUMORS SAME RTE	13/50 (26%)			
HC TUMORS ALL RTES	203/1100 (19%)			

**STATISTICAL TESTS**

POLY 3	P=0.110N	P=0.313	P=0.444	P=0.216N
POLY 1.5	P=0.102N	P=0.309	P=0.467	P=0.207N
POLY 6	P=0.119N	P=0.322	P=0.419	P=0.224N
COCH-ARM / FISHERS	P=0.092N	P=0.312	P=0.500	P=0.194N
MAX-ISO-POLY-3	P=0.141N	P=0.232	P=0.348	P=0.145N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	5/50 (10%)	11/50 (22%)	18/50 (36%)	15/50 (30%)
POLY-3 RATE (b)	5/47.95	11/47.23	18/46.93	15/49.45
POLY-3 PERCENT (g)	10.4%	23.3%	38.4%	30.3%
TERMINAL (d)	1/38 (3%)	5/37 (14%)	8/33 (24%)	3/37 (8%)
FIRST INCIDENCE	512	610	442	510
HC TUMORS SAME RTE	12/50 (24%)			
HC TUMORS ALL RTES	265/1100 (24%)			

**STATISTICAL TESTS**

POLY 3	P=0.029*	P=0.079	P<0.001**	P=0.013*
POLY 1.5	P=0.026*	P=0.080	P<0.001**	P=0.012*
POLY 6	P=0.036*	P=0.079	P<0.001**	P=0.015*
COCH-ARM / FISHERS	P=0.024*	P=0.086	P=0.002**	P=0.011*
MAX-ISO-POLY-3	P=0.005**	P=0.046*	P<0.001**	P=0.007**
HISTCONT SAME RTE	P=0.009**	P=0.081	P<0.001**	P=0.014*
HISTCONT ALL RTES	P=0.005**	P=0.050*	P<0.001**	P=0.007**

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
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 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**All Organs  
 Mesothelioma: Benign, Malignant, NOS**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/46.01	0/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	0/33 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	4/1100 (0%)			

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**All Organs  
 Mesothelioma: Malignant**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	0/46.01	0/43.15	0/44.14
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	0/33 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/50 (0%)			
HC TUMORS ALL RTES	3/1100 (0%)			

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
 Time Report Requested: 13:49:10  
 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>All Organs</b>				
<b>Osteosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	1/46.71	1/43.15	0/44.14
POLY-3 PERCENT (g)	0%	2.1%	2.3%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	1/33 (3%)	0/37 (0%)
FIRST INCIDENCE	---	485	729 (T)	---
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	5/1100 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.590N	P=0.500	P=0.484	(e)
POLY 1.5	P=0.584N	P=0.500	P=0.491	(e)
POLY 6	P=0.597N	P=0.501	P=0.477	(e)
COCH-ARM / FISHERS	P=0.575N	P=0.500	P=0.500	(e)
MAX-ISO-POLY-3	P=0.411	P=0.159	P=0.158	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTES	(h)	(h)	(h)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
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 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**All Organs  
 Osteosarcoma or Osteoma**

**TUMOR RATES**

	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/46.64	1/46.71	1/43.15	0/44.14
POLY-3 PERCENT (g)	0%	2.1%	2.3%	0%
TERMINAL (d)	0/38 (0%)	0/37 (0%)	1/33 (3%)	0/37 (0%)
FIRST INCIDENCE	---	485	729 (T)	---
HC TUMORS SAME RTE	1/50 (2%)			
HC TUMORS ALL RTES	5/1100 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.590N	P=0.500	P=0.484	(e)
POLY 1.5	P=0.584N	P=0.500	P=0.491	(e)
POLY 6	P=0.597N	P=0.501	P=0.477	(e)
COCH-ARM / FISHERS	P=0.575N	P=0.500	P=0.500	(e)
MAX-ISO-POLY-3	P=0.411	P=0.159	P=0.158	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTES	(h)	(h)	(h)	(e)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
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 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>All Organs</b>				
<b>Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	44/50 (88%)	44/50 (88%)	40/50 (80%)	32/50 (64%)
POLY-3 RATE (b)	44/49.35	44/48.13	40/48.33	32/46.93
POLY-3 PERCENT (g)	89.2%	91.4%	82.8%	68.2%
TERMINAL (d)	33/38 (87%)	34/37 (92%)	26/33 (79%)	26/37 (70%)
FIRST INCIDENCE	619	610	547	534
HC TUMORS SAME RTE	47/50 (94%)			
HC TUMORS ALL RTES	966/1100 (88%)			

**STATISTICAL TESTS**

POLY 3	P<0.001N**	P=0.487	P=0.263N	P=0.008N**
POLY 1.5	P<0.001N**	P=0.530	P=0.238N	P=0.005N**
POLY 6	P=0.002N**	P=0.451	P=0.299N	P=0.015N*
COCH-ARM / FISHERS	P<0.001N**	P=0.620N	P=0.207N	P=0.005N**
MAX-ISO-POLY-3	P<0.001N**	P=0.351	P=0.178N	P=0.004N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
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 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>All Organs</b>				
<b>Malignant Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	10/50 (20%)	16/50 (32%)	25/50 (50%)	19/50 (38%)
POLY-3 RATE (b)	10/48.73	16/48.68	25/47.83	19/49.45
POLY-3 PERCENT (g)	20.5%	32.9%	52.3%	38.4%
TERMINAL (d)	2/38 (5%)	6/37 (16%)	13/33 (39%)	7/37 (19%)
FIRST INCIDENCE	512	485	442	510
HC TUMORS SAME RTE	19/50 (38%)			
HC TUMORS ALL RTES	428/1100 (39%)			

**STATISTICAL TESTS**

POLY 3	P=0.065	P=0.125	P<0.001**	P=0.041*
POLY 1.5	P=0.062	P=0.124	P<0.001**	P=0.039*
POLY 6	P=0.071	P=0.129	P<0.001**	P=0.044*
COCH-ARM / FISHERS	P=0.061	P=0.127	P=0.002**	P=0.038*
MAX-ISO-POLY-3	P=0.007**	P=0.084	P<0.001**	P=0.025*
HISTCONT SAME RTE	P=0.013*	P=0.143	P<0.001**	P=0.046*
HISTCONT ALL RTES	P=0.008**	P=0.096	P<0.001**	P=0.026*

TDMS No. 99024 - 07  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Androstenedione  
 CAS Number: 63-05-8

Date Report Requested: 07/18/2008  
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 First Dose M/F: 02/03/03 / 02/03/03  
 Lab: SRI

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

DOSE	Females			
	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG

**All Organs  
 Malignant and Benign Tumors**

**TUMOR RATES**

	#	#	#	#
OVERALL (a)	46/50 (92%)	46/50 (92%)	46/50 (92%)	40/50 (80%)
POLY-3 RATE (b)	46/50	46/49.1	46/50	40/50
POLY-3 PERCENT (g)	92%	93.7%	92%	80%
TERMINAL (d)	34/38 (90%)	34/37 (92%)	29/33 (88%)	27/37 (73%)
FIRST INCIDENCE	512	485	442	510
HC TUMORS SAME RTE	50/50 (100%)			
HC TUMORS ALL RTES	1039/1100 (95%)			

**STATISTICAL TESTS**

POLY 3	P=0.016N*	P=0.525	P=0.642	P=0.074N
POLY 1.5	P=0.017N*	P=0.556	P=0.642	P=0.074N
POLY 6	P=0.016N*	P=0.512	P=0.642	P=0.074N
COCH-ARM / FISHERS	P=0.023N*	P=0.643N	P=0.643N	P=0.074N
MAX-ISO-POLY-3	P=0.024N*	P=0.372	P=1.000	P=0.041N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99024 - 07  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
Androstenedione  
CAS Number: 63-05-8

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Lab: SRI

## 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 \*\*\*