

TDMS No. 20304 - 01
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/SD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
TEF evaluation (PCB 118)
CAS Number: 31508-00-6

Date Report Requested: 07/08/2008
Time Report Requested: 12:16:00
First Dose M/F: NA / 03/26/04
Lab: BAT

**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
Kidney
Liver
Lung
Ovary
Pancreas
Parathyroid Gland
Pituitary Gland
Thyroid Gland

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SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF TEF evaluation (PCB 118)

FEMALE RATS

Organ

Liver

Lung

Mammary Gland

Pituitary Gland: Pars Distalis or Unspecified Site

Uterus

All Organs

Morphology

Cholangiocarcinoma

Hepatocellular Adenoma

Hepatocellular Carcinoma or Hepatocellular Adenoma

Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

Hepatocholangioma

Cystic Keratinizing Epithelioma

Fibroadenoma

Fibroma, Fibroadenoma, Carcinoma, or Adenoma

Adenoma

Carcinoma or Adenoma

Carcinoma

Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or

Undifferentiated Cell Type

Benign Tumors

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

Females

DOSE	4600 UG/KG	4600 UG/KG STOP
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Adrenal Cortex
Adenoma

TUMOR RATES

OVERALL (a)	4/49 (8%)	1/49 (2%)
POLY-3 RATE (b)	4/39.54	1/39.96
POLY-3 PERCENT (g)	10.1%	2.5%
TERMINAL (d)	2/25 (8%)	0/25 (0%)
FIRST INCIDENCE	673	671
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.174N
POLY 1.5	P=0.171N
POLY 6	P=0.179N
COCH-ARM / FISHERS	P=0.181N
MAX-ISO-POLY-3	P=0.081N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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**Adrenal Medulla
Pheochromocytoma Benign**

TUMOR RATES

OVERALL (a)	0/49 (0%)	2/49 (4%)
POLY-3 RATE (b)	0/39.16	2/39.73
POLY-3 PERCENT (g)	0%	5%
TERMINAL (d)	0/25 (0%)	2/25 (8%)
FIRST INCIDENCE	---	733 (T)
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.240
POLY 1.5	P=0.243
POLY 6	P=0.236
COCH-ARM / FISHERS	P=0.247
MAX-ISO-POLY-3	P=0.078
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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Liver
Cholangiocarcinoma

TUMOR RATES

OVERALL (a)	36/49 (73%)	29/49 (59%)
POLY-3 RATE (b)	36/42.58	29/42.62
POLY-3 PERCENT (g)	84.6%	68.1%
TERMINAL (d)	22/25 (88%)	17/25 (68%)
FIRST INCIDENCE	433	567
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.048N*
POLY 1.5	P=0.047N*
POLY 6	P=0.055N
COCH-ARM / FISHERS	P=0.100N
MAX-ISO-POLY-3	P=0.026N*
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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Liver
Hepatocellular Adenoma

TUMOR RATES

OVERALL (a)	24/49 (49%)	1/49 (2%)
POLY-3 RATE (b)	24/40.49	1/39.73
POLY-3 PERCENT (g)	59.3%	2.5%
TERMINAL (d)	17/25 (68%)	1/25 (4%)
FIRST INCIDENCE	617	733 (T)
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P<0.001N**
POLY 1.5	P<0.001N**
POLY 6	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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Females

DOSE	4600 UG/KG	4600 UG/KG STOP
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**Liver
Hepatocellular Carcinoma or Hepatocellular Adenoma**

TUMOR RATES

OVERALL (a)	24/49 (49%)	1/49 (2%)
POLY-3 RATE (b)	24/40.49	1/39.73
POLY-3 PERCENT (g)	59.3%	2.5%
TERMINAL (d)	17/25 (68%)	1/25 (4%)
FIRST INCIDENCE	617	733 (T)
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P<0.001N**
POLY 1.5	P<0.001N**
POLY 6	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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Females

DOSE	4600 UG/KG	4600 UG/KG STOP
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Liver
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

TUMOR RATES

OVERALL (a)	24/49 (49%)	1/49 (2%)
POLY-3 RATE (b)	24/40.49	1/39.73
POLY-3 PERCENT (g)	59.3%	2.5%
TERMINAL (d)	17/25 (68%)	1/25 (4%)
FIRST INCIDENCE	617	733 (T)
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P<0.001N**
POLY 1.5	P<0.001N**
POLY 6	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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Females

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Liver
 Hepatocholangioma

TUMOR RATES

OVERALL (a)	4/49 (8%)	0/49 (0%)
POLY-3 RATE (b)	4/39.43	0/39.73
POLY-3 PERCENT (g)	10.1%	0%
TERMINAL (d)	3/25 (12%)	0/25 (0%)
FIRST INCIDENCE	687	---
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.058N
POLY 1.5	P=0.057N
POLY 6	P=0.060N
COCH-ARM / FISHERS	P=0.059N
MAX-ISO-POLY-3	P=0.018N*
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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DOSE	4600 UG/KG	4600 UG/KG STOP
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Lung
 Cystic Keratinizing Epithelioma

TUMOR RATES

OVERALL (a)	20/50 (40%)	0/50 (0%)
POLY-3 RATE (b)	20/40.61	0/39.74
POLY-3 PERCENT (g)	49.2%	0%
TERMINAL (d)	12/25 (48%)	0/25 (0%)
FIRST INCIDENCE	617	---
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P<0.001N**
POLY 1.5	P<0.001N**
POLY 6	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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**Mammary Gland
 Fibroadenoma**

TUMOR RATES	#	#
OVERALL (a)	8/52 (15%)	17/50 (34%)
POLY-3 RATE (b)	8/41.18	17/43.27
POLY-3 PERCENT (g)	19.4%	39.3%
TERMINAL (d)	5/25 (20%)	9/25 (36%)
FIRST INCIDENCE	433	302
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.036*
POLY 1.5	P=0.035*
POLY 6	P=0.036*
COCH-ARM / FISHERS	P=0.025*
MAX-ISO-POLY-3	P=0.024*
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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Females

DOSE	4600 UG/KG	4600 UG/KG STOP
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**Mammary Gland
Fibroma, Fibroadenoma, Carcinoma, or Adenoma**

TUMOR RATES	#	#
OVERALL (a)	10/52 (19%)	18/50 (36%)
POLY-3 RATE (b)	10/41.89	18/43.86
POLY-3 PERCENT (g)	23.9%	41%
TERMINAL (d)	6/25 (24%)	9/25 (36%)
FIRST INCIDENCE	433	302
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.068
POLY 1.5	P=0.067
POLY 6	P=0.069
COCH-ARM / FISHERS	P=0.047*
MAX-ISO-POLY-3	P=0.047*
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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Females

DOSE	4600 UG/KG	4600 UG/KG STOP
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**Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)
 Squamous Cell Carcinoma**

TUMOR RATES	#	#
OVERALL (a)	2/52 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/40.71	0/39.74
POLY-3 PERCENT (g)	4.9%	0%
TERMINAL (d)	0/25 (0%)	0/25 (0%)
FIRST INCIDENCE	620	---
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.242N
POLY 1.5	P=0.238N
POLY 6	P=0.248N
COCH-ARM / FISHERS	P=0.257N
MAX-ISO-POLY-3	P=0.078N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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Females

DOSE **4600 UG/KG** **4600 UG/KG
STOP**

**Oral Mucosa
Squamous Cell Carcinoma**

TUMOR RATES	#	#
OVERALL (a)	2/52 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/40.71	0/39.74
POLY-3 PERCENT (g)	4.9%	0%
TERMINAL (d)	0/25 (0%)	0/25 (0%)
FIRST INCIDENCE	620	---
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.242N
POLY 1.5	P=0.238N
POLY 6	P=0.248N
COCH-ARM / FISHERS	P=0.257N
MAX-ISO-POLY-3	P=0.078N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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**Pancreas
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	2/47 (4%)	0/49 (0%)
POLY-3 RATE (b)	2/37.63	0/39.73
POLY-3 PERCENT (g)	5.3%	0%
TERMINAL (d)	2/25 (8%)	0/25 (0%)
FIRST INCIDENCE	733 (T)	---
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.224N
POLY 1.5	P=0.222N
POLY 6	P=0.229N
COCH-ARM / FISHERS	P=0.237N
MAX-ISO-POLY-3	P=0.073N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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Females

DOSE	4600 UG/KG	4600 UG/KG STOP
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**Pituitary Gland: Pars Distalis or Unspecified Site
 Adenoma**

TUMOR RATES

OVERALL (a)	4/52 (8%)	12/50 (24%)
POLY-3 RATE (b)	4/39.93	12/40.05
POLY-3 PERCENT (g)	10%	30%
TERMINAL (d)	4/25 (16%)	10/25 (40%)
FIRST INCIDENCE	733 (T)	672
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.023*
POLY 1.5	P=0.025*
POLY 6	P=0.020*
COCH-ARM / FISHERS	P=0.022*
MAX-ISO-POLY-3	P=0.012*
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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

TUMOR RATES

OVERALL (a)	4/52 (8%)	13/50 (26%)
POLY-3 RATE (b)	4/39.93	13/40.05
POLY-3 PERCENT (g)	10%	32.5%
TERMINAL (d)	4/25 (16%)	11/25 (44%)
FIRST INCIDENCE	733 (T)	672
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTEs	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.012*
POLY 1.5	P=0.014*
POLY 6	P=0.010**
COCH-ARM / FISHERS	P=0.013*
MAX-ISO-POLY-3	P=0.006**
HISTCONT SAME RTE	(e)
HISTCONT ALL RTEs	(e)

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**Stomach, Forestomach
Squamous Cell Carcinoma or Papilloma Squamous**

TUMOR RATES	#	#
OVERALL (a)	0/52 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/39.93	2/39.74
POLY-3 PERCENT (g)	0%	5%
TERMINAL (d)	0/25 (0%)	2/25 (8%)
FIRST INCIDENCE	---	733 (T)
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.236
POLY 1.5	P=0.238
POLY 6	P=0.232
COCH-ARM / FISHERS	P=0.238
MAX-ISO-POLY-3	P=0.076
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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**Thyroid Gland: C-Cell
 Adenoma**

TUMOR RATES

OVERALL (a)	6/49 (12%)	5/50 (10%)
POLY-3 RATE (b)	6/39.64	5/40.22
POLY-3 PERCENT (g)	15.1%	12.4%
TERMINAL (d)	4/25 (16%)	4/25 (16%)
FIRST INCIDENCE	620	589
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTEs	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.490N
POLY 1.5	P=0.481N
POLY 6	P=0.503N
COCH-ARM / FISHERS	P=0.486N
MAX-ISO-POLY-3	P=0.361N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTEs	(h)

TDMS No. 20304 - 01
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/SD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 TEF evaluation (PCB 118)
 CAS Number: 31508-00-6

Date Report Requested: 07/08/2008
 Time Report Requested: 12:16:00
 First Dose M/F: NA / 03/26/04
 Lab: BAT

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

Females

DOSE	4600 UG/KG	4600 UG/KG STOP
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**Uterus
 Carcinoma**

TUMOR RATES	#	#
OVERALL (a)	3/52 (6%)	11/50 (22%)
POLY-3 RATE (b)	3/40.16	11/40.86
POLY-3 PERCENT (g)	7.5%	26.9%
TERMINAL (d)	2/25 (8%)	6/25 (24%)
FIRST INCIDENCE	672	642
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.019*
POLY 1.5	P=0.020*
POLY 6	P=0.019*
COCH-ARM / FISHERS	P=0.017*
MAX-ISO-POLY-3	P=0.010**
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

TDMS No. 20304 - 01
 Test Type: CHRONIC
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 Species/Strain: RATS/SD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 TEF evaluation (PCB 118)
 CAS Number: 31508-00-6

Date Report Requested: 07/08/2008
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 First Dose M/F: NA / 03/26/04
 Lab: BAT

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

Females

DOSE	4600 UG/KG	4600 UG/KG STOP
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**Uterus
 Polyp Stromal**

TUMOR RATES	#	#
OVERALL (a)	6/52 (12%)	4/50 (8%)
POLY-3 RATE (b)	6/40.56	4/39.74
POLY-3 PERCENT (g)	14.8%	10.1%
TERMINAL (d)	4/25 (16%)	4/25 (16%)
FIRST INCIDENCE	617	733 (T)
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.381N
POLY 1.5	P=0.370N
POLY 6	P=0.397N
COCH-ARM / FISHERS	P=0.396N
MAX-ISO-POLY-3	P=0.261N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

TDMS No. 20304 - 01
Test Type: CHRONIC
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Species/Strain: RATS/SD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
TEF evaluation (PCB 118)
CAS Number: 31508-00-6

Date Report Requested: 07/08/2008
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First Dose M/F: NA / 03/26/04
Lab: BAT

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

Females

DOSE	4600 UG/KG	4600 UG/KG STOP
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All Organs
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type

TUMOR RATES	#	#
OVERALL (a)	3/52 (6%)	0/50 (0%)
POLY-3 RATE (b)	3/40.29	0/39.74
POLY-3 PERCENT (g)	7.5%	0%
TERMINAL (d)	1/25 (4%)	0/25 (0%)
FIRST INCIDENCE	673	---
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.120N
POLY 1.5	P=0.118N
POLY 6	P=0.124N
COCH-ARM / FISHERS	P=0.129N
MAX-ISO-POLY-3	P=0.039N*
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

TDMS No. 20304 - 01
 Test Type: CHRONIC
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 Species/Strain: RATS/SD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
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 First Dose M/F: NA / 03/26/04
 Lab: BAT

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

Females

DOSE	4600 UG/KG	4600 UG/KG STOP
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**All Organs
 Malignant Tumors**

TUMOR RATES	#	#
OVERALL (a)	39/52 (75%)	37/50 (74%)
POLY-3 RATE (b)	39/44.9	37/44.7
POLY-3 PERCENT (g)	86.9%	82.8%
TERMINAL (d)	22/25 (88%)	20/25 (80%)
FIRST INCIDENCE	433	545
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.397N
POLY 1.5	P=0.376N
POLY 6	P=0.405N
COCH-ARM / FISHERS	P=0.544N
MAX-ISO-POLY-3	P=0.284N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

TDMS No. 20304 - 01
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/SD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
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 Lab: BAT

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

Females

DOSE	4600 UG/KG	4600 UG/KG STOP
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**All Organs
 Malignant and Benign Tumors**

TUMOR RATES	#	#
OVERALL (a)	45/52 (87%)	44/50 (88%)
POLY-3 RATE (b)	45/46.15	44/46.95
POLY-3 PERCENT (g)	97.5%	93.7%
TERMINAL (d)	25/25 (100%)	23/25 (92%)
FIRST INCIDENCE	433	302
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.331N
POLY 1.5	P=0.337N
POLY 6	P=0.315N
COCH-ARM / FISHERS	P=0.531
MAX-ISO-POLY-3	P=0.159N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

TDMS No. 20304 - 01
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/SD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
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First Dose M/F: NA / 03/26/04
Lab: BAT

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 ***