

**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

**C Number:** C20304  
**Lock Date:** 10/12/2006  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** 25022 ACCK                      25021 TSAC                      25020 NATD  
                                25019 MSAC  
**Removal Date Range:** ALL  
**Treatment Groups:** Include 008 4600 UG/KG                      Include 009 4600 UG/KG STOP  
**Study Gender:** Female  
**TDMSE Version:** 2.0.0

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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  
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

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

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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%)	

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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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Females

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DOSE	4600 UG/KG	4600 UG/KG STOP
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Adrenal Medulla  
Pheochromocytoma Benign

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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%)	

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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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Females

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DOSE	4600 UG/KG	4600 UG/KG STOP
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Liver  
Cholangiocarcinoma

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**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%)	

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**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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Lab: BAT

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

**Females**

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<b>DOSE</b>	<b>4600 UG/KG</b>	<b>4600 UG/KG STOP</b>
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Liver  
Hepatocellular Adenoma

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**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%)	

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**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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 TERMINAL SACRIFICE AT 105 WEEKS

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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 TERMINAL SACRIFICE AT 105 WEEKS**

**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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 TERMINAL SACRIFICE AT 105 WEEKS**

**Females**

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

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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TERMINAL SACRIFICE AT 105 WEEKS

Females

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DOSE	4600 UG/KG	4600 UG/KG STOP
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Mammary Gland  
Carcinoma

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TUMOR RATES	#	#
OVERALL (a)	2/52 (4%)	2/50 (4%)
POLY-3 RATE (b)	2/40.64	2/40.85
POLY-3 PERCENT (g)	4.9%	4.9%
TERMINAL (d)	1/25 (4%)	0/25 (0%)
FIRST INCIDENCE	484	545
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

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STATISTICAL TESTS

POLY 3	P=0.693N
POLY 1.5	P=0.691N
POLY 6	P=0.695N
COCH-ARM / FISHERS	P=0.676
MAX-ISO-POLY-3	P=0.497N
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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**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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**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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**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**

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

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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**

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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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TERMINAL SACRIFICE AT 105 WEEKS**

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**Females**

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<b>DOSE</b>	<b>4600 UG/KG</b>	<b>4600 UG/KG STOP</b>
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**Oral Mucosa  
Squamous Cell Carcinoma**

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<b>TUMOR RATES</b>	<b>#</b>	<b>#</b>
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%)	

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**STATISTICAL TESTS**

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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
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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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 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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**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)

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

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

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Females

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

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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%)	

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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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TDMS No. 20304 - 01  
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STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(SD)  
TERMINAL SACRIFICE AT 105 WEEKS

Females

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DOSE	4600 UG/KG	4600 UG/KG STOP
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Stomach, Forestomach  
Squamous Cell Carcinoma or Papilloma Squamous

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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%)	

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STATISTICAL TESTS

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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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TDMS No. 20304 - 01  
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P08: STATISTICAL ANALYSIS OF PRIMARY 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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**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)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(SD)  
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**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  
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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

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Females

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

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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%)	

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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)

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TDMS No. 20304 - 01  
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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**

**Uterus  
 Schwannoma Malignant**

<b>TUMOR RATES</b>	<b>#</b>	<b>#</b>
OVERALL (a)	1/52 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/39.99	2/40.51
POLY-3 PERCENT (g)	2.5%	4.9%
TERMINAL (d)	0/25 (0%)	0/25 (0%)
FIRST INCIDENCE	718	567
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

**STATISTICAL TESTS**

POLY 3	P=0.504
POLY 1.5	P=0.505
POLY 6	P=0.504
COCH-ARM / FISHERS	P=0.485
MAX-ISO-POLY-3	P=0.286
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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Lab: BAT

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

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**Females**

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

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<b>TUMOR RATES</b>	<b>#</b>	<b>#</b>
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%)	

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**STATISTICAL TESTS**

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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)

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TDMS No. 20304 - 01  
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**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 TEF evaluation (PCB 118)  
 CAS Number: 31508-00-6

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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  
 Benign Tumors

TUMOR RATES	#	#
OVERALL (a)	36/52 (69%)	30/50 (60%)
POLY-3 RATE (b)	36/43.7	30/43.98
POLY-3 PERCENT (g)	82.4%	68.2%
TERMINAL (d)	23/25 (92%)	19/25 (76%)
FIRST INCIDENCE	433	302
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.082N
POLY 1.5	P=0.087N
POLY 6	P=0.082N
COCH-ARM / FISHERS	P=0.221N
MAX-ISO-POLY-3	P=0.050N*
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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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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**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)

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

**Females**

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

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<b>TUMOR RATES</b>	<b>#</b>	<b>#</b>
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**

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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)

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## **LEGEND**

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

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