

**TDMS No.** 20203 - 01  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract  
**CAS Number:** GREENTEAEXTR

**Date Report Requested:** 04/15/2009  
**Time Report Requested:** 08:55:05  
**First Dose M/F:** 04/17/06 / 04/18/06  
**Lab:** BAT

F\_RD

**C Number:** C20203  
**Lock Date:** 11/14/2006  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.1.0

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**SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF GREEN TEA EXTRACT**

**MALE RATS**

**Organ**

Adrenal Cortex

Liver

Lung

Lymph Node, Mandibular

Lymph Node, Mesenteric

Nose: Lamina Propria

Nose: Nasopharyngeal Duct

Nose: Nerve

Nose: Olfactory Epithelium

Nose: Olfactory Epithelium, Glands

Nose: Respiratory Epithelium

Testes: Seminiferous Tubule

Thymus

**FEMALE RATS**

**Organ**

Liver

Liver: Bile Duct

Liver: Oval Cell

Liver: Periportal

Lymph Node, Mandibular

Lymph Node, Mesenteric

Nose

Nose: Lamina Propria

Nose: Nerve

**Morphology**

Vacuolization Cytoplasmic

Infiltration Cellular Mononuclear Cell

Hemorrhage

Hyperplasia

Hyperplasia Lymphoid

Infiltration Cellular Histiocyte

Pigmentation Histiocyte

Degeneration

Inflammation

Atrophy

Atrophy

Metaplasia

Necrosis

Pigmentation

Hyperplasia

Hyperplasia

Degeneration

Atrophy

**Morphology**

Mitosis

Pigmentation

Hyperplasia

Hyperplasia

Hypertrophy

Hyperplasia

Hyperplasia Lymphoid

Infiltration Cellular Histiocyte

Inflammation

Pigmentation Histiocyte

Atrophy

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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF GREEN TEA EXTRACT**

Nose: Olfactory Epithelium

Atrophy

Metaplasia

Pigmentation

Nose: Olfactory Epithelium, Glands

Hyperplasia

Thymus

Atrophy

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Adrenal Cortex</b>						
<b>Vacuolization Cytoplasmic</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
<b>POLY-3 RATE (b)</b>	3/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
<b>POLY-3 PERCENT (g)</b>	30%	0%	0%	0%	0%	0%
<b>TERMINAL (d)</b>	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
<b>FIRST INCIDENCE</b>	93 (T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	(e)	(e)	(e)	(e)	(e)	P=0.095N
<b>POLY 1.5</b>	(e)	(e)	(e)	(e)	(e)	P=0.095N
<b>POLY 6</b>	(e)	(e)	(e)	(e)	(e)	P=0.095N
<b>COCH-ARM / FISHERS</b>	P=0.059N	(e)	(e)	(e)	(e)	P=0.105N
<b>MAX-ISO-POLY-3</b>	(e)	(e)	(e)	(e)	(e)	P=0.025N*

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Heart</b>						
<b>Cardiomyopathy</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	9/10 (90%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	8/10 (80%)
<b>POLY-3 RATE (b)</b>	9/10.00	0/0.00	0/0.00	0/0.00	0/0.00	8/10.00
<b>POLY-3 PERCENT (g)</b>	90%	0%	0%	0%	0%	80%
<b>TERMINAL (d)</b>	9/10 (90%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	8/10 (80%)
<b>FIRST INCIDENCE</b>	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	(e)	(e)	(e)	(e)	(e)	P=0.500N
<b>POLY 1.5</b>	(e)	(e)	(e)	(e)	(e)	P=0.500N
<b>POLY 6</b>	(e)	(e)	(e)	(e)	(e)	P=0.500N
<b>COCH-ARM / FISHERS</b>	P=0.377N	(e)	(e)	(e)	(e)	P=0.500N
<b>MAX-ISO-POLY-3</b>	(e)	(e)	(e)	(e)	(e)	P=0.274N

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Kidney Mineralization</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.132	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.066

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Kidney</b>						
<b>Nephropathy</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	8/10 (80%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/10 (50%)
<b>POLY-3 RATE (b)</b>	8/10.00	0/0.00	0/0.00	0/0.00	0/0.00	5/10.00
<b>POLY-3 PERCENT (g)</b>	80%	0%	0%	0%	0%	50%
<b>TERMINAL (d)</b>	8/10 (80%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/10 (50%)
<b>FIRST INCIDENCE</b>	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	(e)	(e)	(e)	(e)	(e)	P=0.174N
<b>POLY 1.5</b>	(e)	(e)	(e)	(e)	(e)	P=0.174N
<b>POLY 6</b>	(e)	(e)	(e)	(e)	(e)	P=0.174N
<b>COCH-ARM / FISHERS</b>	P=0.121N	(e)	(e)	(e)	(e)	P=0.175N
<b>MAX-ISO-POLY-3</b>	(e)	(e)	(e)	(e)	(e)	P=0.079N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Liver</b>						
<b>Hepatodiaphragmatic Nodule</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	1/10 (10%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	2/10 (20%)
<b>POLY-3 RATE (b)</b>	1/10.00	1/10.00	0/10.00	0/10.00	1/10.00	2/10.00
<b>POLY-3 PERCENT (g)</b>	10%	10%	0%	0%	10%	20%
<b>TERMINAL (d)</b>	1/10 (10%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	2/10 (20%)
<b>FIRST INCIDENCE</b>	93 (T)	93 (T)	---	---	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.176	P=0.760	P=0.500N	P=0.500N	P=0.760	P=0.500
<b>POLY 1.5</b>	P=0.176	P=0.760	P=0.500N	P=0.500N	P=0.760	P=0.500
<b>POLY 6</b>	P=0.176	P=0.760	P=0.500N	P=0.500N	P=0.760	P=0.500
<b>COCH-ARM / FISHERS</b>	P=0.171	P=0.763N	P=0.500N	P=0.500N	P=0.763N	P=0.500
<b>MAX-ISO-POLY-3</b>	P=0.116	P=1.000	P=0.158N	P=0.158N	P=1.000	P=0.274



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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Liver</b>						
<b>Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	7/10 (70%)	9/10 (90%)	7/10 (70%)	5/10 (50%)	8/10 (80%)	4/10 (40%)
<b>POLY-3 RATE (b)</b>	7/10.00	9/10.00	7/10.00	5/10.00	8/10.00	4/10.00
<b>POLY-3 PERCENT (g)</b>	70%	90%	70%	50%	80%	40%
<b>TERMINAL (d)</b>	7/10 (70%)	9/10 (90%)	7/10 (70%)	5/10 (50%)	8/10 (80%)	4/10 (40%)
<b>FIRST INCIDENCE</b>	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.054N	P=0.292	P=0.678	P=0.329N	P=0.500	P=0.186N
<b>POLY 1.5</b>	P=0.054N	P=0.292	P=0.678	P=0.329N	P=0.500	P=0.186N
<b>POLY 6</b>	P=0.054N	P=0.292	P=0.678	P=0.329N	P=0.500	P=0.186N
<b>COCH-ARM / FISHERS</b>	P=0.057N	P=0.291	P=0.686N	P=0.325N	P=0.500	P=0.185N
<b>MAX-ISO-POLY-3</b>	P=0.027N*	P=0.136	P=1.000	P=0.188N	P=0.310	P=0.089N

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TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Liver						
Mitosis						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Liver Pigmentation						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Liver: Bile Duct Hyperplasia</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	10%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	93 (T)	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.488N	P=0.500	(e)	(e)	(e)	(e)
POLY 1.5	P=0.488N	P=0.500	(e)	(e)	(e)	(e)
POLY 6	P=0.488N	P=0.500	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.488N	P=0.500	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.193N	P=0.158	(e)	(e)	(e)	(e)

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TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Liver: Oval Cell Hyperplasia						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Liver: Periportal Hypertrophy</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Lung Hemorrhage</b>						
<b>LESION RATES</b>						
OVERALL (a)	6/10 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	6/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	60%	0%	0%	0%	0%	0%
TERMINAL (d)	6/10 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P<0.001N**
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P<0.001N**
POLY 6	(e)	(e)	(e)	(e)	(e)	P<0.001N**
COCH-ARM / FISHERS	P=0.004N**	(e)	(e)	(e)	(e)	P=0.005N**
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P<0.001N**

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Lung Inflammation</b>						
<b>LESION RATES</b>						
OVERALL (a)	9/10 (90%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	7/10 (70%)
POLY-3 RATE (b)	9/10.00	0/0.00	0/0.00	0/0.00	0/0.00	7/10.00
POLY-3 PERCENT (g)	90%	0%	0%	0%	0%	70%
TERMINAL (d)	9/10 (90%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	7/10 (70%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.292N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.292N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.292N
COCH-ARM / FISHERS	P=0.201N	(e)	(e)	(e)	(e)	P=0.291N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.136N



TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Lymph Node, Mandibular Hyperplasia</b>						
<b>LESION RATES</b>						
OVERALL (a)	5/10 (50%)	10/10 (100%)	7/10 (70%)	9/10 (90%)	8/10 (80%)	8/10 (80%)
POLY-3 RATE (b)	5/10.00	10/10.00	7/10.00	9/10.00	8/10.00	8/10.00
POLY-3 PERCENT (g)	50%	100%	70%	90%	80%	80%
TERMINAL (d)	5/10 (50%)	10/10 (100%)	7/10 (70%)	9/10 (90%)	8/10 (80%)	8/10 (80%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.381	P=0.008**	P=0.329	P=0.061	P=0.174	P=0.174
POLY 1.5	P=0.381	P=0.008**	P=0.329	P=0.061	P=0.174	P=0.174
POLY 6	P=0.381	P=0.008**	P=0.329	P=0.061	P=0.174	P=0.174
COCH-ARM / FISHERS	P=0.384	P=0.016*	P=0.325	P=0.070	P=0.175	P=0.175
MAX-ISO-POLY-3	P=0.029*	P<0.001**	P=0.188	P=0.020*	P=0.079	P=0.079

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Lymph Node, Mandibular Hyperplasia Lymphoid</b>						
<b>LESION RATES</b>						
OVERALL (a)	3/10 (30%)	0/10 (0%)	2/10 (20%)	0/10 (0%)	1/10 (10%)	2/10 (20%)
POLY-3 RATE (b)	3/10.00	0/10.00	2/10.00	0/10.00	1/10.00	2/10.00
POLY-3 PERCENT (g)	30%	0%	20%	0%	10%	20%
TERMINAL (d)	3/10 (30%)	0/10 (0%)	2/10 (20%)	0/10 (0%)	1/10 (10%)	2/10 (20%)
FIRST INCIDENCE	93 (T)	---	93 (T)	---	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.537	P=0.095N	P=0.500N	P=0.095N	P=0.292N	P=0.500N
POLY 1.5	P=0.537	P=0.095N	P=0.500N	P=0.095N	P=0.292N	P=0.500N
POLY 6	P=0.537	P=0.095N	P=0.500N	P=0.095N	P=0.292N	P=0.500N
COCH-ARM / FISHERS	P=0.537	P=0.105N	P=0.500N	P=0.105N	P=0.291N	P=0.500N
MAX-ISO-POLY-3	P=0.092N	P=0.025N*	P=0.310N	P=0.025N*	P=0.136N	P=0.310N

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Lymph Node, Mesenteric Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	2/10 (20%)	6/10 (60%)	7/10 (70%)	7/10 (70%)	7/10 (70%)
POLY-3 RATE (b)	0/10.00	2/10.00	6/10.00	7/10.00	7/10.00	7/10.00
POLY-3 PERCENT (g)	0%	20%	60%	70%	70%	70%
TERMINAL (d)	0/10 (0%)	2/10 (20%)	6/10 (60%)	7/10 (70%)	7/10 (70%)	7/10 (70%)
FIRST INCIDENCE	---	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	P=0.227	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.227	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.227	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P=0.004**	P=0.237	P=0.005**	P=0.002**	P=0.002**	P=0.002**
MAX-ISO-POLY-3	P<0.001**	P=0.066	P<0.001**	P<0.001**	P<0.001**	P<0.001**

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose Inflammation</b>						
<b>LESION RATES</b>						
OVERALL (a)	2/10 (20%)	3/10 (30%)	1/10 (10%)	2/10 (20%)	3/10 (30%)	5/10 (50%)
POLY-3 RATE (b)	2/10.00	3/10.00	1/10.00	2/10.00	3/10.00	5/10.00
POLY-3 PERCENT (g)	20%	30%	10%	20%	30%	50%
TERMINAL (d)	2/10 (20%)	3/10 (30%)	1/10 (10%)	2/10 (20%)	3/10 (30%)	5/10 (50%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.055	P=0.500	P=0.500N	P=0.702	P=0.500	P=0.174
POLY 1.5	P=0.055	P=0.500	P=0.500N	P=0.702	P=0.500	P=0.174
POLY 6	P=0.055	P=0.500	P=0.500N	P=0.702	P=0.500	P=0.174
COCH-ARM / FISHERS	P=0.053	P=0.500	P=0.500N	P=0.709N	P=0.500	P=0.175
MAX-ISO-POLY-3	P=0.055	P=0.310	P=0.274N	P=1.000	P=0.310	P=0.079

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Lamina Propria Pigmentation Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
POLY 6	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.010**	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	P=0.005**	(e)	(e)	(e)	(e)	P=0.066

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Nasopharyngeal Duct Degeneration</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	3/10.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	30%	30%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)	3/10 (30%)
FIRST INCIDENCE	---	---	---	---	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	(e)	(e)	P=0.095	P=0.095
POLY 1.5	P<0.001**	(e)	(e)	(e)	P=0.095	P=0.095
POLY 6	P<0.001**	(e)	(e)	(e)	P=0.095	P=0.095
COCH-ARM / FISHERS	P=0.002**	(e)	(e)	(e)	P=0.105	P=0.105
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	P=0.025*	P=0.025*

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Nasopharyngeal Duct Inflammation</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	2/10.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	20%	30%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	3/10 (30%)
FIRST INCIDENCE	---	---	---	---	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	(e)	(e)	P=0.227	P=0.095
POLY 1.5	P<0.001**	(e)	(e)	(e)	P=0.227	P=0.095
POLY 6	P<0.001**	(e)	(e)	(e)	P=0.227	P=0.095
COCH-ARM / FISHERS	P=0.002**	(e)	(e)	(e)	P=0.237	P=0.105
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	P=0.066	P=0.025*

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Nerve Atrophy</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	5/10 (50%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	5/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	50%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	5/10 (50%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	---	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	(e)	(e)	P=0.008**	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	(e)	P=0.008**	P<0.001**
POLY 6	P<0.001**	(e)	(e)	(e)	P=0.008**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P=0.016*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	P<0.001**	(e)



**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Olfactory Epithelium Atrophy</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	2/10 (20%)	1/10 (10%)	3/10 (30%)	9/10 (90%)
POLY-3 RATE (b)	0/10.00	0/10.00	2/10.00	1/10.00	3/10.00	9/10.00
POLY-3 PERCENT (g)	0%	0%	20%	10%	30%	90%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	2/10 (20%)	1/10 (10%)	3/10 (30%)	9/10 (90%)
FIRST INCIDENCE	---	---	93 (T)	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	P=0.227	P=0.500	P=0.095	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.227	P=0.500	P=0.095	P<0.001**
POLY 6	P<0.001**	(e)	P=0.227	P=0.500	P=0.095	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.237	P=0.500	P=0.105	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.066	P=0.158	P=0.025*	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Olfactory Epithelium Metaplasia</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	6/10 (60%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	0/10.00	6/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	10%	0%	60%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	6/10 (60%)	10/10 (100%)
FIRST INCIDENCE	---	---	93 (T)	---	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	P=0.500	(e)	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.500	(e)	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	P=0.500	(e)	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	(e)	P=0.005**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.158	(e)	P<0.001**	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Olfactory Epithelium</b>						
<b>Necrosis</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	3/10 (30%)
<b>POLY-3 RATE (b)</b>	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00	3/10.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	0%	0%	10%	30%
<b>TERMINAL (d)</b>	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	3/10 (30%)
<b>FIRST INCIDENCE</b>	---	---	---	---	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P<0.001**	(e)	(e)	(e)	P=0.500	P=0.095
<b>POLY 1.5</b>	P<0.001**	(e)	(e)	(e)	P=0.500	P=0.095
<b>POLY 6</b>	P<0.001**	(e)	(e)	(e)	P=0.500	P=0.095
<b>COCH-ARM / FISHERS</b>	P=0.002**	(e)	(e)	(e)	P=0.500	P=0.105
<b>MAX-ISO-POLY-3</b>	P<0.001**	(e)	(e)	(e)	P=0.158	P=0.025*

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Olfactory Epithelium Pigmentation</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	4/10 (40%)	5/10 (50%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	4/10.00	5/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	40%	50%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	4/10 (40%)	5/10 (50%)
FIRST INCIDENCE	---	---	---	---	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	(e)	(e)	P=0.033*	P=0.008**
POLY 1.5	P<0.001**	(e)	(e)	(e)	P=0.033*	P=0.008**
POLY 6	P<0.001**	(e)	(e)	(e)	P=0.033*	P=0.008**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P=0.043*	P=0.016*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	P=0.007**	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Olfactory Epithelium, Glands Hyperplasia</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)	7/10 (70%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	3/10.00	7/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	30%	70%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)	7/10 (70%)
FIRST INCIDENCE	---	---	---	---	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	(e)	(e)	P=0.095	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	(e)	P=0.095	P<0.001**
POLY 6	P<0.001**	(e)	(e)	(e)	P=0.095	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P=0.105	P=0.002**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	P=0.025*	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Respiratory Epithelium Hyperplasia</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	4/10 (40%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00	2/10.00	4/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	20%	40%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	4/10 (40%)
FIRST INCIDENCE	93 (T)	---	---	---	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	P=0.500N	P=0.500N	P=0.500N	P=0.500	P=0.148
POLY 1.5	P<0.001**	P=0.500N	P=0.500N	P=0.500N	P=0.500	P=0.148
POLY 6	P<0.001**	P=0.500N	P=0.500N	P=0.500N	P=0.500	P=0.148
COCH-ARM / FISHERS	P=0.002**	P=0.500N	P=0.500N	P=0.500N	P=0.500	P=0.152
MAX-ISO-POLY-3	P<0.001**	P=0.158N	P=0.158N	P=0.158N	P=0.274	P=0.058

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Preputial Gland Inflammation</b>						
<b>LESION RATES</b>						
OVERALL (a)	9/10 (90%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	9/10 (90%)
POLY-3 RATE (b)	9/10.00	0/0.00	0/0.00	0/0.00	0/0.00	9/10.00
POLY-3 PERCENT (g)	90%	0%	0%	0%	0%	90%
TERMINAL (d)	9/10 (90%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	9/10 (90%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.760
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.760
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.760
COCH-ARM / FISHERS	P=0.645	(e)	(e)	(e)	(e)	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=1.000

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Testes: Seminiferous Tubule Degeneration</b>						
<b>LESION RATES</b>						
OVERALL (a)	3/10 (30%)	1/10 (10%)	2/10 (20%)	3/10 (30%)	3/10 (30%)	7/10 (70%)
POLY-3 RATE (b)	3/10.00	1/10.00	2/10.00	3/10.00	3/10.00	7/10.00
POLY-3 PERCENT (g)	30%	10%	20%	30%	30%	70%
TERMINAL (d)	3/10 (30%)	1/10 (10%)	2/10 (20%)	3/10 (30%)	3/10 (30%)	7/10 (70%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.004**	P=0.292N	P=0.500N	P=0.678	P=0.678	P=0.082
POLY 1.5	P=0.004**	P=0.292N	P=0.500N	P=0.678	P=0.678	P=0.082
POLY 6	P=0.004**	P=0.292N	P=0.500N	P=0.678	P=0.678	P=0.082
COCH-ARM / FISHERS	P=0.005**	P=0.291N	P=0.500N	P=0.686N	P=0.686N	P=0.089
MAX-ISO-POLY-3	P=0.004**	P=0.136N	P=0.310N	P=1.000	P=1.000	P=0.032*



**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Thymus Atrophy</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	5/8 (63%)
<b>POLY-3 RATE (b)</b>	0/10.00	0/10.00	0/10.00	1/10.00	0/10.00	5/8.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	0%	10%	0%	62.5%
<b>TERMINAL (d)</b>	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	5/8 (63%)
<b>FIRST INCIDENCE</b>	---	---	---	93 (T)	---	93 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P<0.001**	(e)	(e)	P=0.500	(e)	P<0.001**
<b>POLY 1.5</b>	P<0.001**	(e)	(e)	P=0.500	(e)	P<0.001**
<b>POLY 6</b>	P<0.001**	(e)	(e)	P=0.500	(e)	P<0.001**
<b>COCH-ARM / FISHERS</b>	P<0.001**	(e)	(e)	P=0.500	(e)	P=0.007**
<b>MAX-ISO-POLY-3</b>	P<0.001**	(e)	(e)	P=0.158	(e)	P<0.001**

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Adrenal Cortex</b>						
<b>Vacuolization Cytoplasmic</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
<b>POLY-3 RATE (b)</b>	0/10.00	0/0.00	0/0.11	0/0.00	0/0.00	1/10.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	0%	0%	0%	10%
<b>TERMINAL (d)</b>	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
<b>FIRST INCIDENCE</b>	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	(e)	(e)	(e)	(e)	(e)	P=0.500
<b>POLY 1.5</b>	(e)	(e)	(e)	(e)	(e)	P=0.500
<b>POLY 6</b>	(e)	(e)	(e)	(e)	(e)	P=0.500
<b>COCH-ARM / FISHERS</b>	P=0.289	(e)	(e)	(e)	(e)	P=0.500
<b>MAX-ISO-POLY-3</b>	(e)	(e)	(e)	(e)	(e)	P=0.158

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Clitoral Gland Inflammation</b>						
<b>LESION RATES</b>						
OVERALL (a)	5/10 (50%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	5/10.00	0/0.00	1/1.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	50%	0%	100%	0%	0%	20%
TERMINAL (d)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	93 (T)	---	45	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	P=0.536	(e)	(e)	P=0.174N
POLY 1.5	(e)	(e)	P=0.536	(e)	(e)	P=0.174N
POLY 6	(e)	(e)	P=0.536	(e)	(e)	P=0.174N
COCH-ARM / FISHERS	P=0.089N	(e)	P=0.545	(e)	(e)	P=0.175N
MAX-ISO-POLY-3	(e)	(e)	P=0.251	(e)	(e)	P=0.079N

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Heart</b>						
<b>Cardiomyopathy</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	9/10 (90%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	6/10 (60%)
<b>POLY-3 RATE (b)</b>	9/10.00	0/0.00	1/1.00	0/0.00	0/0.00	6/10.00
<b>POLY-3 PERCENT (g)</b>	90%	0%	100%	0%	0%	60%
<b>TERMINAL (d)</b>	9/10 (90%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	6/10 (60%)
<b>FIRST INCIDENCE</b>	93 (T)	---	45	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	(e)	(e)	P=0.913	(e)	(e)	P=0.148N
<b>POLY 1.5</b>	(e)	(e)	P=0.913	(e)	(e)	P=0.148N
<b>POLY 6</b>	(e)	(e)	P=0.913	(e)	(e)	P=0.148N
<b>COCH-ARM / FISHERS</b>	P=0.083N	(e)	P=0.909	(e)	(e)	P=0.152N
<b>MAX-ISO-POLY-3</b>	(e)	(e)	P=0.409	(e)	(e)	P=0.058N

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Kidney Mineralization</b>						
<b>LESION RATES</b>						
OVERALL (a)	5/10 (50%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	5/10 (50%)
POLY-3 RATE (b)	5/10.00	0/0.00	0/0.11	0/0.00	0/0.00	5/10.00
POLY-3 PERCENT (g)	50%	0%	0%	0%	0%	50%
TERMINAL (d)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/10 (50%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	P=0.803N	(e)	(e)	P=0.664
POLY 1.5	(e)	(e)	P=0.745N	(e)	(e)	P=0.664
POLY 6	(e)	(e)	P=0.826N	(e)	(e)	P=0.664
COCH-ARM / FISHERS	P=0.525	(e)	P=0.545N	(e)	(e)	P=0.672N
MAX-ISO-POLY-3	(e)	(e)	P=0.468N	(e)	(e)	P=1.000

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Kidney</b>						
<b>Nephropathy</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
<b>POLY-3 RATE (b)</b>	0/10.00	0/0.00	0/0.11	0/0.00	0/0.00	1/10.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	0%	0%	0%	10%
<b>TERMINAL (d)</b>	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
<b>FIRST INCIDENCE</b>	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	(e)	(e)	(e)	(e)	(e)	P=0.500
<b>POLY 1.5</b>	(e)	(e)	(e)	(e)	(e)	P=0.500
<b>POLY 6</b>	(e)	(e)	(e)	(e)	(e)	P=0.500
<b>COCH-ARM / FISHERS</b>	P=0.289	(e)	(e)	(e)	(e)	P=0.500
<b>MAX-ISO-POLY-3</b>	(e)	(e)	(e)	(e)	(e)	P=0.158

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Liver</b>						
<b>Hepatodiaphragmatic Nodule</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	1/10 (10%)	0/10 (0%)	1/10 (10%)	2/10 (20%)	1/10 (10%)	2/10 (20%)
<b>POLY-3 RATE (b)</b>	1/10.00	0/10.00	1/9.11	2/10.00	1/10.00	2/10.00
<b>POLY-3 PERCENT (g)</b>	10%	0%	11%	20%	10%	20%
<b>TERMINAL (d)</b>	1/10 (10%)	0/10 (0%)	1/9 (11%)	2/10 (20%)	1/10 (10%)	2/10 (20%)
<b>FIRST INCIDENCE</b>	93 (T)	---	93 (T)	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.249	P=0.500N	P=0.740	P=0.500	P=0.760	P=0.500
<b>POLY 1.5</b>	P=0.247	P=0.500N	P=0.745	P=0.500	P=0.760	P=0.500
<b>POLY 6</b>	P=0.250	P=0.500N	P=0.737	P=0.500	P=0.760	P=0.500
<b>COCH-ARM / FISHERS</b>	P=0.236	P=0.500N	P=0.763N	P=0.500	P=0.763N	P=0.500
<b>MAX-ISO-POLY-3</b>	P=0.154	P=0.158N	P=0.473	P=0.274	P=1.000	P=0.274

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Liver</b>						
<b>Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	9/10 (90%)	8/10 (80%)	6/10 (60%)	7/10 (70%)	8/10 (80%)	7/10 (70%)
<b>POLY-3 RATE (b)</b>	9/10.00	8/10.00	6/10.00	7/10.00	8/10.00	7/10.00
<b>POLY-3 PERCENT (g)</b>	90%	80%	60%	70%	80%	70%
<b>TERMINAL (d)</b>	9/10 (90%)	8/10 (80%)	5/9 (56%)	7/10 (70%)	8/10 (80%)	7/10 (70%)
<b>FIRST INCIDENCE</b>	93 (T)	93 (T)	45	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.406N	P=0.500N	P=0.148N	P=0.292N	P=0.500N	P=0.292N
<b>POLY 1.5</b>	P=0.406N	P=0.500N	P=0.148N	P=0.292N	P=0.500N	P=0.292N
<b>POLY 6</b>	P=0.406N	P=0.500N	P=0.148N	P=0.292N	P=0.500N	P=0.292N
<b>COCH-ARM / FISHERS</b>	P=0.403N	P=0.500N	P=0.152N	P=0.291N	P=0.500N	P=0.291N
<b>MAX-ISO-POLY-3</b>	P=0.157N	P=0.274N	P=0.058N	P=0.136N	P=0.274N	P=0.136N



**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Liver</b>						
<b>Mitosis</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.11	0/10.00	0/10.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
POLY 6	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.010**	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	P=0.005**	(e)	(e)	(e)	(e)	P=0.066

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Liver Pigmentation</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.11	0/10.00	0/10.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
POLY 6	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.010**	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	P=0.005**	(e)	(e)	(e)	(e)	P=0.066

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Liver: Bile Duct Hyperplasia</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.11	0/10.00	0/10.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	30%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	(e)	(e)	(e)	P=0.095
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	P=0.095
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	P=0.095
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	P=0.105
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	P=0.025*

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Liver: Oval Cell Hyperplasia</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.11	0/10.00	0/10.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	30%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	(e)	(e)	(e)	P=0.095
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	P=0.095
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	P=0.095
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	P=0.105
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	P=0.025*

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Liver: Periportal Hypertrophy</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.11	0/10.00	0/10.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
POLY 6	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.010**	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	P=0.005**	(e)	(e)	(e)	(e)	P=0.066

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Lung Hemorrhage</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.11	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	20%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	P=0.941N	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	P=0.936N	(e)	(e)	P=0.500
POLY 6	(e)	(e)	P=0.943N	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.351	(e)	P=0.909N	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	P=0.488N	(e)	(e)	P=0.274

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Lung Inflammation</b>						
<b>LESION RATES</b>						
OVERALL (a)	8/10 (80%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	9/10 (90%)
POLY-3 RATE (b)	8/10.00	0/0.00	1/1.00	0/0.00	0/0.00	9/10.00
POLY-3 PERCENT (g)	80%	0%	100%	0%	0%	90%
TERMINAL (d)	8/10 (80%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	9/10 (90%)
FIRST INCIDENCE	93 (T)	---	45	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	P=0.786	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	P=0.786	(e)	(e)	P=0.500
POLY 6	(e)	(e)	P=0.786	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.402	(e)	P=0.818	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	P=0.366	(e)	(e)	P=0.274

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Lymph Node, Mandibular Hyperplasia</b>						
<b>LESION RATES</b>						
OVERALL (a)	4/10 (40%)	5/10 (50%)	7/10 (70%)	7/10 (70%)	7/10 (70%)	8/10 (80%)
POLY-3 RATE (b)	4/10.00	5/10.00	7/10.00	7/10.00	7/10.00	8/10.00
POLY-3 PERCENT (g)	40%	50%	70%	70%	70%	80%
TERMINAL (d)	4/10 (40%)	5/10 (50%)	6/9 (67%)	7/10 (70%)	7/10 (70%)	8/10 (80%)
FIRST INCIDENCE	93 (T)	93 (T)	45	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.069	P=0.500	P=0.186	P=0.186	P=0.186	P=0.077
POLY 1.5	P=0.069	P=0.500	P=0.186	P=0.186	P=0.186	P=0.077
POLY 6	P=0.069	P=0.500	P=0.186	P=0.186	P=0.186	P=0.077
COCH-ARM / FISHERS	P=0.067	P=0.500	P=0.185	P=0.185	P=0.185	P=0.085
MAX-ISO-POLY-3	P=0.033*	P=0.332	P=0.089	P=0.089	P=0.089	P=0.029*



TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Lymph Node, Mandibular Hyperplasia Lymphoid</b>						
<b>LESION RATES</b>						
OVERALL (a)	3/10 (30%)	4/10 (40%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	3/10.00	4/10.00	1/9.11	1/10.00	0/10.00	2/10.00
POLY-3 PERCENT (g)	30%	40%	11%	10%	0%	20%
TERMINAL (d)	3/10 (30%)	4/10 (40%)	1/9 (11%)	1/10 (10%)	0/10 (0%)	2/10 (20%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.237N	P=0.500	P=0.328N	P=0.292N	P=0.095N	P=0.500N
POLY 1.5	P=0.241N	P=0.500	P=0.318N	P=0.292N	P=0.095N	P=0.500N
POLY 6	P=0.236N	P=0.500	P=0.332N	P=0.292N	P=0.095N	P=0.500N
COCH-ARM / FISHERS	P=0.255N	P=0.500	P=0.291N	P=0.291N	P=0.105N	P=0.500N
MAX-ISO-POLY-3	P=0.071N	P=0.325	P=0.171N	P=0.136N	P=0.025N*	P=0.310N

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Lymph Node, Mesenteric Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL (a)	8/10 (80%)	10/10 (100%)	9/10 (90%)	7/10 (70%)	7/10 (70%)	6/10 (60%)
POLY-3 RATE (b)	8/10.00	10/10.00	9/10.00	7/10.00	7/10.00	6/10.00
POLY-3 PERCENT (g)	80%	100%	90%	70%	70%	60%
TERMINAL (d)	8/10 (80%)	10/10 (100%)	8/9 (89%)	7/10 (70%)	7/10 (70%)	6/10 (60%)
FIRST INCIDENCE	93 (T)	93 (T)	45	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.039N*	P=0.227	P=0.500	P=0.500N	P=0.500N	P=0.318N
POLY 1.5	P=0.039N*	P=0.227	P=0.500	P=0.500N	P=0.500N	P=0.318N
POLY 6	P=0.039N*	P=0.227	P=0.500	P=0.500N	P=0.500N	P=0.318N
COCH-ARM / FISHERS	P=0.039N*	P=0.237	P=0.500	P=0.500N	P=0.500N	P=0.314N
MAX-ISO-POLY-3	P=0.039N*	P=0.066	P=0.274	P=0.310N	P=0.310N	P=0.172N

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose Inflammation</b>						
<b>LESION RATES</b>						
OVERALL (a)	2/10 (20%)	1/10 (10%)	1/10 (10%)	4/10 (40%)	10/10 (100%)	8/10 (80%)
POLY-3 RATE (b)	2/10.00	1/10.00	1/9.11	4/10.00	10/10.00	8/10.00
POLY-3 PERCENT (g)	20%	10%	11%	40%	100%	80%
TERMINAL (d)	2/10 (20%)	1/10 (10%)	1/9 (11%)	4/10 (40%)	10/10 (100%)	8/10 (80%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	P=0.500N	P=0.533N	P=0.318	P<0.001**	P=0.004**
POLY 1.5	P<0.001**	P=0.500N	P=0.525N	P=0.318	P<0.001**	P=0.004**
POLY 6	P<0.001**	P=0.500N	P=0.537N	P=0.318	P<0.001**	P=0.004**
COCH-ARM / FISHERS	P<0.001**	P=0.500N	P=0.500N	P=0.314	P<0.001**	P=0.012*
MAX-ISO-POLY-3	P<0.001**	P=0.274N	P=0.309N	P=0.172	P<0.001**	P<0.001**

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Lamina Propria Pigmentation Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.11	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.109	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	P=0.108	(e)	(e)	(e)	(e)	P=0.500
POLY 6	P=0.109	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.105	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.041*	(e)	(e)	(e)	(e)	P=0.158

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Nasopharyngeal Duct Degeneration</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.11	0/10.00	2/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	20%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	2/10 (20%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	93 (T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.419	(e)	(e)	(e)	P=0.227	(e)
POLY 1.5	P=0.417	(e)	(e)	(e)	P=0.227	(e)
POLY 6	P=0.420	(e)	(e)	(e)	P=0.227	(e)
COCH-ARM / FISHERS	P=0.414	(e)	(e)	(e)	P=0.237	(e)
MAX-ISO-POLY-3	P=0.096	(e)	(e)	(e)	P=0.066	(e)

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Nasopharyngeal Duct Inflammation</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.11	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:05

First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Nerve Atrophy</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	4/10 (40%)	5/10 (50%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.11	1/10.00	4/10.00	5/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	40%	50%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	1/10 (10%)	4/10 (40%)	5/10 (50%)
FIRST INCIDENCE	---	---	---	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	(e)	P=0.500	P=0.033*	P=0.008**
POLY 1.5	P<0.001**	(e)	(e)	P=0.500	P=0.033*	P=0.008**
POLY 6	P<0.001**	(e)	(e)	P=0.500	P=0.033*	P=0.008**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.500	P=0.043*	P=0.016*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.158	P=0.007**	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Olfactory Epithelium Atrophy</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	7/10 (70%)
POLY-3 RATE (b)	0/10.00	1/10.00	1/9.11	0/10.00	0/10.00	7/10.00
POLY-3 PERCENT (g)	0%	10%	11%	0%	0%	70%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	1/9 (11%)	0/10 (0%)	0/10 (0%)	7/10 (70%)
FIRST INCIDENCE	---	93 (T)	93 (T)	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	P=0.500	P=0.481	(e)	(e)	P<0.001**
POLY 1.5	P<0.001**	P=0.500	P=0.486	(e)	(e)	P<0.001**
POLY 6	P<0.001**	P=0.500	P=0.479	(e)	(e)	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.500	(e)	(e)	P=0.002**
MAX-ISO-POLY-3	P<0.001**	P=0.158	P=0.157	(e)	(e)	P<0.001**



**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Olfactory Epithelium Metaplasia</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	5/10 (50%)	4/10 (40%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.11	0/10.00	5/10.00	4/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	50%	40%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	5/10 (50%)	4/10 (40%)
FIRST INCIDENCE	---	---	---	---	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	(e)	(e)	P=0.008**	P=0.033*
POLY 1.5	P<0.001**	(e)	(e)	(e)	P=0.008**	P=0.033*
POLY 6	P<0.001**	(e)	(e)	(e)	P=0.008**	P=0.033*
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P=0.016*	P=0.043*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	P<0.001**	P=0.007**

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Olfactory Epithelium</b>						
<b>Necrosis</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.11	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

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First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Olfactory Epithelium Pigmentation</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	3/10 (30%)	5/10 (50%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.11	2/10.00	3/10.00	5/10.00
POLY-3 PERCENT (g)	0%	0%	0%	20%	30%	50%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	2/10 (20%)	3/10 (30%)	5/10 (50%)
FIRST INCIDENCE	---	---	---	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	(e)	P=0.227	P=0.095	P=0.008**
POLY 1.5	P<0.001**	(e)	(e)	P=0.227	P=0.095	P=0.008**
POLY 6	P<0.001**	(e)	(e)	P=0.227	P=0.095	P=0.008**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.237	P=0.105	P=0.016*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.066	P=0.025*	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Olfactory Epithelium, Glands Hyperplasia</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	1/10 (10%)	4/10 (40%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.11	2/10.00	1/10.00	4/10.00
POLY-3 PERCENT (g)	0%	0%	0%	20%	10%	40%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	2/10 (20%)	1/10 (10%)	4/10 (40%)
FIRST INCIDENCE	---	---	---	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	(e)	P=0.227	P=0.500	P=0.033*
POLY 1.5	P<0.001**	(e)	(e)	P=0.227	P=0.500	P=0.033*
POLY 6	P<0.001**	(e)	(e)	P=0.227	P=0.500	P=0.033*
COCH-ARM / FISHERS	P=0.002**	(e)	(e)	P=0.237	P=0.500	P=0.043*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.066	P=0.158	P=0.007**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Nose: Respiratory Epithelium Hyperplasia</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.11	1/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	10%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	1/10 (10%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	93 (T)	93 (T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.628	(e)	(e)	P=0.500	P=0.500	(e)
POLY 1.5	P=0.625	(e)	(e)	P=0.500	P=0.500	(e)
POLY 6	P=0.629	(e)	(e)	P=0.500	P=0.500	(e)
COCH-ARM / FISHERS	P=0.620	(e)	(e)	P=0.500	P=0.500	(e)
MAX-ISO-POLY-3	P=0.206	(e)	(e)	P=0.158	P=0.158	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Thymus Atrophy</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.11	0/10.00	0/10.00	6/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	60%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	(e)	(e)	(e)	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	P<0.001**
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	P=0.005**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	P<0.001**

TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

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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.
  - (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 \*\*\*