

**TDMS No.** 20301 - 03  
**Test Type:** 90-DAY  
**Route:** DOSED FEED  
**Species/Strain:** RATS/F344/N Tac

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

p-Toluenesulfonamide  
**CAS Number:** 70-55-3

**Date Report Requested:** 05/19/2011  
**Time Report Requested:** 12:43:46  
**First Dose M/F:** 10/17/06 / 10/18/06  
**Lab:** MBA

F1\_RD

**C Number:** C20301

**Lock Date:** 12/23/2009

**Cage Range:** ALL

**Date Range:** ALL

**Reasons For Removal:** 25021 TSAC

**Removal Date Range:** ALL

**Treatment Groups:** Include 001 0 PPM

Include 002 625 PPM

Include 003 1250 PPM

Include 004 2500 PPM

Include 005 5000 PPM

Include 006 10000 PPM

Include 007 0 PPM

Include 008 625 PPM

Include 009 1250 PPM

Include 010 2500 PPM

Include 011 5000 PPM

Include 012 10000 PPM

**Study Gender:** Both

**TDMSE Version:** 2.4.0.0\_003

**PWG Approval Date:** NONE

TDMS No. 20301 - 03  
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First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Males**

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DOSE	0 PPM	10000 PPM
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Harderian Gland  
Inflammation Chronic

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**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

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Lab: MBA

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

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**Males**

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DOSE	0 PPM	10000 PPM
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Heart  
Cardiomyopathy

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**LESION RATES**

OVERALL (a)	4/10 (40%)	4/10 (40%)
POLY-3 RATE (b)	4/10.00	4/10.00
POLY-3 PERCENT (g)	40%	40%
TERMINAL (d)	4/10 (40%)	4/10 (40%)
FIRST INCIDENCE	92 (T)	92 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.667
POLY 1.5	P=0.667
POLY 6	P=0.667
COCH-ARM / FISHERS	P=0.675N
MAX-ISO-POLY-3	P=1.000

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First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Males**

---

DOSE	0 PPM	10000 PPM
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---

Heart  
Infiltration Cellular Focal Histiocyte

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**LESION RATES**

OVERALL (a)	2/10 (20%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	1/10.00
POLY-3 PERCENT (g)	20%	10%
TERMINAL (d)	2/10 (20%)	1/10 (10%)
FIRST INCIDENCE	92 (T)	92 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.500N
POLY 1.5	P=0.500N
POLY 6	P=0.500N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.274N

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

**Males**

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DOSE	0 PPM	10000 PPM
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Kidney  
Inflammation

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**LESION RATES**

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---

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**STATISTICAL TESTS**

POLY 3	P=0.500N
POLY 1.5	P=0.500N
POLY 6	P=0.500N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.158N

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TDMS No. 20301 - 03  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

**Males**

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DOSE	0 PPM	10000 PPM
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Kidney  
Nephropathy

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**LESION RATES**

OVERALL (a)	4/10 (40%)	4/10 (40%)
POLY-3 RATE (b)	4/10.00	4/10.00
POLY-3 PERCENT (g)	40%	40%
TERMINAL (d)	4/10 (40%)	4/10 (40%)
FIRST INCIDENCE	92 (T)	92 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.667
POLY 1.5	P=0.667
POLY 6	P=0.667
COCH-ARM / FISHERS	P=0.675N
MAX-ISO-POLY-3	P=1.000

---

TDMS No. 20301 - 03  
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Lab: MBA

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

**Males**

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DOSE	0 PPM	10000 PPM
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Kidney: Pelvis  
Dilatation Focal

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**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

---

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TERMINAL SACRIFICE AT 14 WEEKS**

---

**Males**

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DOSE	0 PPM	10000 PPM
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Liver  
Hepatodiaphragmatic Nodule

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**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

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Lab: MBA

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

**Males**

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DOSE	0 PPM	10000 PPM
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Liver  
Inflammation Chronic

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**LESION RATES**

OVERALL (a)	9/10 (90%)	9/10 (90%)
POLY-3 RATE (b)	9/10.00	9/10.00
POLY-3 PERCENT (g)	90%	90%
TERMINAL (d)	9/10 (90%)	9/10 (90%)
FIRST INCIDENCE	92 (T)	92 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.760
POLY 1.5	P=0.760
POLY 6	P=0.760
COCH-ARM / FISHERS	P=0.763N
MAX-ISO-POLY-3	P=1.000

---

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First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Males**

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DOSE	0 PPM	10000 PPM
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Lung  
Hemorrhage

**LESION RATES**

OVERALL (a)	1/10 (10%)	2/10 (20%)
POLY-3 RATE (b)	1/10.00	2/10.00
POLY-3 PERCENT (g)	10%	20%
TERMINAL (d)	1/10 (10%)	2/10 (20%)
FIRST INCIDENCE	92 (T)	92 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.500
POLY 1.5	P=0.500
POLY 6	P=0.500
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.274

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First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Males**

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DOSE	0 PPM	10000 PPM
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Lung  
Infiltration Cellular Histiocyte

**LESION RATES**

OVERALL (a)	1/10 (10%)	2/10 (20%)
POLY-3 RATE (b)	1/10.00	2/10.00
POLY-3 PERCENT (g)	10%	20%
TERMINAL (d)	1/10 (10%)	2/10 (20%)
FIRST INCIDENCE	92 (T)	92 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.500
POLY 1.5	P=0.500
POLY 6	P=0.500
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.274

---

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Lab: MBA

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

**Males**

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DOSE	0 PPM	10000 PPM
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Lung  
Inflammation Chronic

**LESION RATES**

OVERALL (a)	2/10 (20%)	3/10 (30%)
POLY-3 RATE (b)	2/10.00	3/10.00
POLY-3 PERCENT (g)	20%	30%
TERMINAL (d)	2/10 (20%)	3/10 (30%)
FIRST INCIDENCE	92 (T)	92 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.500
POLY 1.5	P=0.500
POLY 6	P=0.500
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.310

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TDMS No. 20301 - 03  
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Species/Strain: RATS/F344/N Tac

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

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Lab: MBA

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

**Males**

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DOSE	0 PPM	10000 PPM
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Lymph Node, Mesenteric  
Infiltration Cellular Histiocyte

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**LESION RATES**

OVERALL (a)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	10%
TERMINAL (d)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	92 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.500
POLY 1.5	P=0.500
POLY 6	P=0.500
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.158

---

TDMS No. 20301 - 03  
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**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**

**Males**

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DOSE	0 PPM	10000 PPM
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Pancreas  
Inflammation Chronic

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**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

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TDMS No. 20301 - 03  
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TERMINAL SACRIFICE AT 14 WEEKS**

**Males**

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DOSE	0 PPM	10000 PPM
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Pancreas: Acinus  
Atrophy

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**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

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

**Males**

---

DOSE	0 PPM	10000 PPM
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Preputial Gland  
Inflammation Chronic

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**LESION RATES**

OVERALL (a)	2/9 (22%)	0/10 (0%)
POLY-3 RATE (b)	2/9.00	0/10.00
POLY-3 PERCENT (g)	22.2%	0%
TERMINAL (d)	2/9 (22%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---

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**STATISTICAL TESTS**

POLY 3	P=0.201N
POLY 1.5	P=0.201N
POLY 6	P=0.201N
COCH-ARM / FISHERS	P=0.211N
MAX-ISO-POLY-3	P=0.059N

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TERMINAL SACRIFICE AT 14 WEEKS**

**Males**

---

DOSE	0 PPM	10000 PPM
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Spleen  
Ectopic Tissue

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**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

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

**Males**

---

DOSE	0 PPM	10000 PPM
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Stomach, Glandular  
Hyperplasia Basal Cell

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**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

---

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

---

**Males**

---

DOSE	0 PPM	10000 PPM
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Stomach, Glandular: Glands  
Ectasia Focal

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**LESION RATES**

OVERALL (a)	1/10 (10%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	1/10.00
POLY-3 PERCENT (g)	10%	10%
TERMINAL (d)	1/10 (10%)	1/10 (10%)
FIRST INCIDENCE	92 (T)	92 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.760
POLY 1.5	P=0.760
POLY 6	P=0.760
COCH-ARM / FISHERS	P=0.763N
MAX-ISO-POLY-3	P=1.000

---

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

---

**Males**

---

DOSE	0 PPM	10000 PPM
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Testes  
Atrophy

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**LESION RATES**

OVERALL (a)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	10%
TERMINAL (d)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	92 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.500
POLY 1.5	P=0.500
POLY 6	P=0.500
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.158

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
p-Toluenesulfonamide  
CAS Number: 70-55-3

Date Report Requested: 05/19/2011  
Time Report Requested: 12:43:46  
First Dose M/F: 10/17/06 / 10/18/06  
Lab: MBA

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

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**Males**

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DOSE	0 PPM	10000 PPM
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Testes  
Metaplasia Cartilagenous Focal

---

**LESION RATES**

OVERALL (a)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	10%
TERMINAL (d)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	92 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.500
POLY 1.5	P=0.500
POLY 6	P=0.500
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.158

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

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

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

---

DOSE	0 PPM	10000 PPM
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---

Clitoral Gland  
Inflammation Chronic

---

**LESION RATES**

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---

---

**STATISTICAL TESTS**

POLY 3	P=0.500N
POLY 1.5	P=0.500N
POLY 6	P=0.500N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.158N

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
p-Toluenesulfonamide  
CAS Number: 70-55-3

Date Report Requested: 05/19/2011  
Time Report Requested: 12:43:46  
First Dose M/F: 10/17/06 / 10/18/06  
Lab: MBA

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

**Females**

---

DOSE	0 PPM	10000 PPM
------	-------	-----------

---

Harderian Gland  
Inflammation Chronic

---

**LESION RATES**

OVERALL (a)	1/10 (10%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	1/10.00
POLY-3 PERCENT (g)	10%	10%
TERMINAL (d)	1/10 (10%)	1/10 (10%)
FIRST INCIDENCE	92 (T)	92 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.760
POLY 1.5	P=0.760
POLY 6	P=0.760
COCH-ARM / FISHERS	P=0.763N
MAX-ISO-POLY-3	P=1.000

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
p-Toluenesulfonamide  
CAS Number: 70-55-3

Date Report Requested: 05/19/2011  
Time Report Requested: 12:43:46  
First Dose M/F: 10/17/06 / 10/18/06  
Lab: MBA

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

**Females**

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DOSE	0 PPM	10000 PPM
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Heart  
Cardiomyopathy

---

**LESION RATES**

OVERALL (a)	2/10 (20%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	1/10.00
POLY-3 PERCENT (g)	20%	10%
TERMINAL (d)	2/10 (20%)	1/10 (10%)
FIRST INCIDENCE	92 (T)	92 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.500N
POLY 1.5	P=0.500N
POLY 6	P=0.500N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.274N

---



TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

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

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

---

DOSE	0 PPM	10000 PPM
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---

Heart  
Infiltration Cellular Focal Histiocyte

---

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

---

**STATISTICAL TESTS**

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

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

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

---

DOSE	0 PPM	10000 PPM
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---

Kidney  
Inflammation

---

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

---

**STATISTICAL TESTS**

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

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DOSE	0 PPM	10000 PPM
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---

Kidney  
Nephropathy

---

**LESION RATES**

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---

---

**STATISTICAL TESTS**

POLY 3	P=0.500N
POLY 1.5	P=0.500N
POLY 6	P=0.500N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.158N

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

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

p-Toluenesulfonamide  
CAS Number: 70-55-3

Date Report Requested: 05/19/2011  
Time Report Requested: 12:43:46  
First Dose M/F: 10/17/06 / 10/18/06  
Lab: MBA

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

---

**Females**

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<b>DOSE</b>	<b>0 PPM</b>	<b>10000 PPM</b>
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**Kidney: Pelvis  
Dilatation Focal**

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**LESION RATES**

<b>OVERALL (a)</b>	1/10 (10%)	0/10 (0%)
<b>POLY-3 RATE (b)</b>	1/10.00	0/10.00
<b>POLY-3 PERCENT (g)</b>	10%	0%
<b>TERMINAL (d)</b>	1/10 (10%)	0/10 (0%)
<b>FIRST INCIDENCE</b>	92 (T)	---

---

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.500N
<b>POLY 1.5</b>	P=0.500N
<b>POLY 6</b>	P=0.500N
<b>COCH-ARM / FISHERS</b>	P=0.500N
<b>MAX-ISO-POLY-3</b>	P=0.158N

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

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

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

---

DOSE	0 PPM	10000 PPM
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Liver  
Hepatodiaphragmatic Nodule

**LESION RATES**

OVERALL (a)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	10%
TERMINAL (d)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	92 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.500
POLY 1.5	P=0.500
POLY 6	P=0.500
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.158

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

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

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

---

DOSE	0 PPM	10000 PPM
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---

Liver  
Inflammation Chronic

---

**LESION RATES**

OVERALL (a)	10/10 (100%)	9/10 (90%)
POLY-3 RATE (b)	10/10.00	9/10.00
POLY-3 PERCENT (g)	100%	90%
TERMINAL (d)	10/10 (100%)	9/10 (90%)
FIRST INCIDENCE	92 (T)	92 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.500N
POLY 1.5	P=0.500N
POLY 6	P=0.500N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.158N

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

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

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

---

<b>DOSE</b>	<b>0 PPM</b>	<b>10000 PPM</b>
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---

Lung  
Hemorrhage

**LESION RATES**

<b>OVERALL (a)</b>	0/10 (0%)	0/10 (0%)
<b>POLY-3 RATE (b)</b>	0/10.00	0/10.00
<b>POLY-3 PERCENT (g)</b>	0%	0%
<b>TERMINAL (d)</b>	0/10 (0%)	0/10 (0%)
<b>FIRST INCIDENCE</b>	---	---

---

**STATISTICAL TESTS**

<b>POLY 3</b>	(n)
<b>POLY 1.5</b>	(n)
<b>POLY 6</b>	(n)
<b>COCH-ARM / FISHERS</b>	(n)
<b>MAX-ISO-POLY-3</b>	(n)

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

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

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

---

DOSE	0 PPM	10000 PPM
------	-------	-----------

---

Lung  
Infiltration Cellular Histiocyte

---

**LESION RATES**

OVERALL (a)	1/10 (10%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	1/10.00
POLY-3 PERCENT (g)	10%	10%
TERMINAL (d)	1/10 (10%)	1/10 (10%)
FIRST INCIDENCE	92 (T)	92 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.760
POLY 1.5	P=0.760
POLY 6	P=0.760
COCH-ARM / FISHERS	P=0.763N
MAX-ISO-POLY-3	P=1.000

---



TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

---

DOSE	0 PPM	10000 PPM
------	-------	-----------

---

Lung  
Inflammation Chronic

---

**LESION RATES**

OVERALL (a)	1/10 (10%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	1/10.00
POLY-3 PERCENT (g)	10%	10%
TERMINAL (d)	1/10 (10%)	1/10 (10%)
FIRST INCIDENCE	92 (T)	92 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.760
POLY 1.5	P=0.760
POLY 6	P=0.760
COCH-ARM / FISHERS	P=0.763N
MAX-ISO-POLY-3	P=1.000

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

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

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

---

DOSE	0 PPM	10000 PPM
------	-------	-----------

---

Lymph Node, Mesenteric  
Infiltration Cellular Histiocyte

---

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

---

**STATISTICAL TESTS**

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

---

DOSE	0 PPM	10000 PPM
------	-------	-----------

---

Ovary  
Cyst Focal

---

**LESION RATES**

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---

---

**STATISTICAL TESTS**

POLY 3	P=0.500N
POLY 1.5	P=0.500N
POLY 6	P=0.500N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.158N

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

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

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

---

DOSE	0 PPM	10000 PPM
------	-------	-----------

---

Pancreas  
Inflammation Chronic

---

**LESION RATES**

OVERALL (a)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	10%
TERMINAL (d)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	92 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.500
POLY 1.5	P=0.500
POLY 6	P=0.500
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.158

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

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

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

---

<b>DOSE</b>	<b>0 PPM</b>	<b>10000 PPM</b>
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---

**Pancreas: Acinus  
Atrophy**

---

**LESION RATES**

<b>OVERALL (a)</b>	1/10 (10%)	1/10 (10%)
<b>POLY-3 RATE (b)</b>	1/10.00	1/10.00
<b>POLY-3 PERCENT (g)</b>	10%	10%
<b>TERMINAL (d)</b>	1/10 (10%)	1/10 (10%)
<b>FIRST INCIDENCE</b>	92 (T)	92 (T)

---

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.760
<b>POLY 1.5</b>	P=0.760
<b>POLY 6</b>	P=0.760
<b>COCH-ARM / FISHERS</b>	P=0.763N
<b>MAX-ISO-POLY-3</b>	P=1.000

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

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

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

---

DOSE	0 PPM	10000 PPM
------	-------	-----------

---

Spleen  
Ectopic Tissue

---

**LESION RATES**

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---

---

**STATISTICAL TESTS**

POLY 3	P=0.500N
POLY 1.5	P=0.500N
POLY 6	P=0.500N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.158N

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
p-Toluenesulfonamide  
CAS Number: 70-55-3

Date Report Requested: 05/19/2011  
Time Report Requested: 12:43:46  
First Dose M/F: 10/17/06 / 10/18/06  
Lab: MBA

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

**Females**

---

DOSE	0 PPM	10000 PPM
------	-------	-----------

---

Stomach, Glandular  
Hyperplasia Basal Cell

---

**LESION RATES**

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---

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**STATISTICAL TESTS**

POLY 3	P=0.500N
POLY 1.5	P=0.500N
POLY 6	P=0.500N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.158N

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

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

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

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DOSE	0 PPM	10000 PPM
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Stomach, Glandular: Glands  
Ectasia Focal

---

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

---



TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
p-Toluenesulfonamide  
CAS Number: 70-55-3

Date Report Requested: 05/19/2011  
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First Dose M/F: 10/17/06 / 10/18/06  
Lab: MBA

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

**Females**

---

DOSE	0 PPM	10000 PPM
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---

Uterus  
Hydrometra

---

**LESION RATES**

OVERALL (a)	2/10 (20%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/10.00
POLY-3 PERCENT (g)	20%	0%
TERMINAL (d)	2/10 (20%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---

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**STATISTICAL TESTS**

POLY 3	P=0.227N
POLY 1.5	P=0.227N
POLY 6	P=0.227N
COCH-ARM / FISHERS	P=0.237N
MAX-ISO-POLY-3	P=0.066N

---

TDMS No. 20301 - 03  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

p-Toluenesulfonamide

CAS Number: 70-55-3

Date Report Requested: 05/19/2011

Time Report Requested: 12:43:46

First Dose M/F: 10/17/06 / 10/18/06

Lab: MBA

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

**Females**

---

DOSE	0 PPM	10000 PPM
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---

Uterus: Bilateral  
Hydrometra

---

**LESION RATES**

OVERALL (a)	2/10 (20%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/10.00
POLY-3 PERCENT (g)	20%	0%
TERMINAL (d)	2/10 (20%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---

---

**STATISTICAL TESTS**

POLY 3	P=0.227N
POLY 1.5	P=0.227N
POLY 6	P=0.227N
COCH-ARM / FISHERS	P=0.237N
MAX-ISO-POLY-3	P=0.066N

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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.
  - (n) No statistics are calculated if all dose groups have fewer than two tumors.
  - (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 \*\*\*