

TDMS No. 20301 - 04
Test Type: 90-DAY
Route: DOSED FEED
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

p-Toluenesulfonamide
CAS Number: 70-55-3

Date Report Requested: 05/19/2011
Time Report Requested: 12:47:52
First Dose M/F: 10/19/06 / 10/20/06
Lab: MBA

F1_M3

C Number:	C20301		
Lock Date:	12/23/2009		
Cage Range:	ALL		
Date Range:	ALL		
Reasons For Removal:	25022 ACCK	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 008 0 ppm	Include 009 625 ppm	Include 010 1250 ppm
	Include 011 2500 ppm	Include 012 5000 ppm	Include 013 10000 ppm
Study Gender:	Both		
TDMSE Version:	2.4.0.0_003		
PWG Approval Date:	NONE		

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Lab: MBA

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Males

DOSE	0 ppm	10000 ppm
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**Adrenal Cortex: Subcapsular
Hyperplasia**

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

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Males

DOSE	0 ppm	10000 ppm
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Eye: Retina
Dysplasia

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)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Males

DOSE	0 ppm	10000 ppm
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Eye: Retrobulbar
Inflammation

LESION RATES

OVERALL (a)	3/10 (30%)	5/10 (50%)
POLY-3 RATE (b)	3/10.00	5/10.00
POLY-3 PERCENT (g)	30%	50%
TERMINAL (d)	3/10 (30%)	5/10 (50%)
FIRST INCIDENCE	92 (T)	92 (T)

STATISTICAL TESTS

POLY 3	P=0.329
POLY 1.5	P=0.329
POLY 6	P=0.329
COCH-ARM / FISHERS	P=0.325
MAX-ISO-POLY-3	P=0.188

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Males

DOSE	0 ppm	10000 ppm
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**Harderian Gland
Inflammation**

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

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Males

DOSE	0 ppm	10000 ppm
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Harderian Gland
Inflammation Chronic

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)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Males

DOSE	0 ppm	10000 ppm
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**Kidney
Inflammation Chronic**

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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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Males

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

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Males

DOSE	0 ppm	10000 ppm
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Liver
Inflammation Chronic

LESION RATES

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

STATISTICAL TESTS

POLY 3	P=0.678
POLY 1.5	P=0.678
POLY 6	P=0.678
COCH-ARM / FISHERS	P=0.686N
MAX-ISO-POLY-3	P=1.000

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Males

DOSE	0 ppm	10000 ppm
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Liver
Necrosis

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)

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TERMINAL SACRIFICE AT 14 WEEKS**

Males		
DOSE	0 ppm	10000 ppm
<hr/>		
Lung Hemorrhage		
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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	---	---
<hr/>		
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

DOSE	0 ppm	10000 ppm
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Lung: Arteriole
Inflammation Acute 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	---	---

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

DOSE	0 ppm	10000 ppm
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Thyroid Gland
Cyst

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

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Males

DOSE	0 ppm	10000 ppm
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Urinary Bladder
Inflammation Chronic

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)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 ppm	10000 ppm
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**Adrenal Cortex: Subcapsular
Hyperplasia**

LESION RATES

OVERALL (a)	5/10 (50%)	6/10 (60%)
POLY-3 RATE (b)	5/10.00	6/9.03
POLY-3 PERCENT (g)	50%	66.4%
TERMINAL (d)	5/10 (50%)	6/9 (67%)
FIRST INCIDENCE	92 (T)	92 (T)

STATISTICAL TESTS

POLY 3	P=0.401
POLY 1.5	P=0.417
POLY 6	P=0.398
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.253

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TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 ppm	10000 ppm
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Eye: Retina
Dysplasia

LESION RATES

OVERALL (a)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	1/9.03
POLY-3 PERCENT (g)	0%	11.1%
TERMINAL (d)	0/10 (0%)	1/9 (11%)
FIRST INCIDENCE	---	92 (T)

STATISTICAL TESTS

POLY 3	P=0.480
POLY 1.5	P=0.483
POLY 6	P=0.479
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.157

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TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 ppm	10000 ppm
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Eye: Retrobulbar
Inflammation

LESION RATES

OVERALL (a)	1/10 (10%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	1/9.03
POLY-3 PERCENT (g)	10%	11.1%
TERMINAL (d)	1/10 (10%)	1/9 (11%)
FIRST INCIDENCE	92 (T)	92 (T)

STATISTICAL TESTS

POLY 3	P=0.738
POLY 1.5	P=0.741
POLY 6	P=0.737
COCH-ARM / FISHERS	P=0.763N
MAX-ISO-POLY-3	P=0.470

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TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 ppm	10000 ppm
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Harderian Gland
Inflammation

LESION RATES

OVERALL (a)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	1/9.03
POLY-3 PERCENT (g)	0%	11.1%
TERMINAL (d)	0/10 (0%)	1/9 (11%)
FIRST INCIDENCE	---	92 (T)

STATISTICAL TESTS

POLY 3	P=0.480
POLY 1.5	P=0.483
POLY 6	P=0.479
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.157

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TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 ppm	10000 ppm
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Harderian Gland
Inflammation Chronic

LESION RATES

OVERALL (a)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	1/9.03
POLY-3 PERCENT (g)	0%	11.1%
TERMINAL (d)	0/10 (0%)	1/9 (11%)
FIRST INCIDENCE	---	92 (T)

STATISTICAL TESTS

POLY 3	P=0.480
POLY 1.5	P=0.483
POLY 6	P=0.479
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.157

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 ppm	10000 ppm
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**Kidney
Inflammation Chronic**

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/9.03
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/9 (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 - 04
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 ppm	10000 ppm
------	-------	-----------

Kidney
Nephropathy

LESION RATES

OVERALL (a)	2/10 (20%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/9.03
POLY-3 PERCENT (g)	20%	0%
TERMINAL (d)	2/10 (20%)	0/9 (0%)
FIRST INCIDENCE	92 (T)	---

STATISTICAL TESTS

POLY 3	P=0.251N
POLY 1.5	P=0.247N
POLY 6	P=0.252N
COCH-ARM / FISHERS	P=0.237N
MAX-ISO-POLY-3	P=0.088N

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Species/Strain: MICE/B6C3F1

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

Date Report Requested: 05/19/2011
Time Report Requested: 12:47:52
First Dose M/F: 10/19/06 / 10/20/06
Lab: MBA

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 ppm	10000 ppm
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Liver
Inflammation Chronic

LESION RATES

OVERALL (a)	2/10 (20%)	4/9 (44%)
POLY-3 RATE (b)	2/10.00	4/9.00
POLY-3 PERCENT (g)	20%	44.4%
TERMINAL (d)	2/10 (20%)	4/9 (44%)
FIRST INCIDENCE	92 (T)	92 (T)

STATISTICAL TESTS

POLY 3	P=0.262
POLY 1.5	P=0.262
POLY 6	P=0.262
COCH-ARM / FISHERS	P=0.259
MAX-ISO-POLY-3	P=0.136

TDMS No. 20301 - 04
Test Type: 90-DAY
Route: DOSED FEED
Species/Strain: MICE/B6C3F1

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Lab: MBA

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 ppm	10000 ppm
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Liver
Necrosis

LESION RATES

OVERALL (a)	1/10 (10%)	0/9 (0%)
POLY-3 RATE (b)	1/10.00	0/9.00
POLY-3 PERCENT (g)	10%	0%
TERMINAL (d)	1/10 (10%)	0/9 (0%)
FIRST INCIDENCE	92 (T)	---

STATISTICAL TESTS

POLY 3	P=0.521N
POLY 1.5	P=0.521N
POLY 6	P=0.521N
COCH-ARM / FISHERS	P=0.526N
MAX-ISO-POLY-3	P=0.178N

TDMS No. 20301 - 04
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 ppm	10000 ppm
------	-------	-----------

Lung
Hemorrhage

LESION RATES

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/9.03
POLY-3 PERCENT (g)	10%	0%
TERMINAL (d)	1/10 (10%)	0/9 (0%)
FIRST INCIDENCE	92 (T)	---

STATISTICAL TESTS

POLY 3	P=0.520N
POLY 1.5	P=0.517N
POLY 6	P=0.521N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.183N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 ppm	10000 ppm
------	-------	-----------

Lung: Arteriole
Inflammation Acute Focal

LESION RATES

OVERALL (a)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	1/9.03
POLY-3 PERCENT (g)	0%	11.1%
TERMINAL (d)	0/10 (0%)	1/9 (11%)
FIRST INCIDENCE	---	92 (T)

STATISTICAL TESTS

POLY 3	P=0.480
POLY 1.5	P=0.483
POLY 6	P=0.479
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.157

TDMS No. 20301 - 04
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 ppm	10000 ppm
------	-------	-----------

Ovary
Inflammation Focal Granulomatous

LESION RATES

OVERALL (a)	0/10 (0%)	1/9 (11%)
POLY-3 RATE (b)	0/10.00	1/9.00
POLY-3 PERCENT (g)	0%	11.1%
TERMINAL (d)	0/10 (0%)	1/9 (11%)
FIRST INCIDENCE	---	92 (T)

STATISTICAL TESTS

POLY 3	P=0.479
POLY 1.5	P=0.479
POLY 6	P=0.479
COCH-ARM / FISHERS	P=0.474
MAX-ISO-POLY-3	P=0.150

TDMS No. 20301 - 04
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 ppm	10000 ppm
------	-------	-----------

Thyroid Gland
Cyst

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/9.03
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/9 (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 - 04
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TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 ppm	10000 ppm
------	-------	-----------

Urinary Bladder
Inflammation Chronic

LESION RATES

OVERALL (a)	0/10 (0%)	1/9 (11%)
POLY-3 RATE (b)	0/10.00	1/9.00
POLY-3 PERCENT (g)	0%	11.1%
TERMINAL (d)	0/10 (0%)	1/9 (11%)
FIRST INCIDENCE	---	92 (T)

STATISTICAL TESTS

POLY 3	P=0.479
POLY 1.5	P=0.479
POLY 6	P=0.479
COCH-ARM / FISHERS	P=0.474
MAX-ISO-POLY-3	P=0.150

TDMS No. 20301 - 04
Test Type: 90-DAY
Route: DOSED FEED
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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 ***