

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

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

TEF evaluation (PCB 118)

**CAS Number:** 31508-00-6

**Date Report Requested:** 06/24/2008

**Time Report Requested:** 13:37:02

**First Dose M/F:** NA / 03/26/04

**Lab:** BAT

14 Wk\_SSAC\_R8

**C Number:** C20304

**Lock Date:** 10/12/2006

**Cage Range:** ALL

**Date Range:** ALL

**Reasons For Removal:** 25017 SSAC

**Removal Date Range:** 30-Jun-2004 - 30-Jun-2004

**Treatment Groups:** Include 001 0 UG/KG

Include 002 10 UG/KG

Include 003 30 UG/KG

Include 004 100 UG/KG

Include 005 220 UG/KG

Include 006 460 UG/KG

Include 007 1000 UG/KG

Include 008 4600 UG/KG

**Study Gender:** Female

**TDMSE Version:** 2.0.0

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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF TEF evaluation (PCB 118)**

**FEMALE RATS**

**Organ**

Liver

Liver: Hepatocyte

Spleen

Thyroid Gland: Follicular Cell

**Morphology**

Fatty Change Diffuse

Inflammation

Necrosis

Pigmentation

Toxic Hepatopathy

Hypertrophy

Multinucleated

Hematopoietic Cell Proliferation

Hypertrophy

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
 LAST REMOVAL AT 14 WEEKS**

DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

**Adrenal Cortex  
 Hypertrophy**

**LESION RATES**

OVERALL (a)	0/10 (0%)	2/10 (20%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	2/10.00	0/10.00	0/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	20%	0%	0%	10%	0%
INT SACRIFICE 1	0/10 (0%)	2/10 (20%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	97 (I)	---	---	97 (I)	---

**STATISTICAL TESTS**

POLY 3	P=0.440N	P=0.227	(e)	(e)	P=0.500	(e)
POLY 1.5	P=0.440N	P=0.227	(e)	(e)	P=0.500	(e)
POLY 6	P=0.440N	P=0.227	(e)	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.442N	P=0.237	(e)	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.225N	P=0.068	(e)	(e)	P=0.158	(e)

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
LAST REMOVAL AT 14 WEEKS

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Females

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DOSE	1000 UG/KG	4600 UG/KG
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Adrenal Cortex  
Hypertrophy

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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%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

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STATISTICAL TESTS

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

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 LAST REMOVAL AT 14 WEEKS**

DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

Liver  
 Fatty Change Diffuse

**LESION RATES**

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%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---	---

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	(e)	(e)	(e)	(e)
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	(e)
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
LAST REMOVAL AT 14 WEEKS

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Females

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DOSE	1000 UG/KG	4600 UG/KG
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Liver  
Fatty Change Diffuse

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LESION RATES

OVERALL (a)	0/10 (0%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	10/10.00
POLY-3 PERCENT (g)	0%	100%
INT SACRIFICE 1	0/10 (0%)	10/10 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	97 (I)

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STATISTICAL TESTS

POLY 3	(e)	P<0.001**
POLY 1.5	(e)	P<0.001**
POLY 6	(e)	P<0.001**
COCH-ARM / FISHERS	(e)	P<0.001**
MAX-ISO-POLY-3	(e)	P<0.001**

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 LAST REMOVAL AT 14 WEEKS**

DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

Liver  
 Hepatodiaphragmatic Nodule

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	2/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	20%	0%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	97 (l)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.580N	(e)	(e)	P=0.227	(e)	(e)
POLY 1.5	P=0.580N	(e)	(e)	P=0.227	(e)	(e)
POLY 6	P=0.580N	(e)	(e)	P=0.227	(e)	(e)
COCH-ARM / FISHERS	P=0.576N	(e)	(e)	P=0.237	(e)	(e)
MAX-ISO-POLY-3	P=0.446N	(e)	(e)	P=0.068	(e)	(e)

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
LAST REMOVAL AT 14 WEEKS

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Females

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DOSE	1000 UG/KG	4600 UG/KG
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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%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

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STATISTICAL TESTS

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

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 LAST REMOVAL AT 14 WEEKS**

DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

**Liver  
 Inflammation**

**LESION RATES**

OVERALL (a)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	9/10.00	10/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	90%	100%	100%	100%	100%	100%
INT SACRIFICE 1	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	97 (I)	97 (I)	97 (I)	97 (I)	97 (I)	97 (I)

**STATISTICAL TESTS**

POLY 3	P=0.751	P=0.500	P=0.500	P=0.500	P=0.500	P=0.500
POLY 1.5	P=0.751	P=0.500	P=0.500	P=0.500	P=0.500	P=0.500
POLY 6	P=0.751	P=0.500	P=0.500	P=0.500	P=0.500	P=0.500
COCH-ARM / FISHERS	P=0.753	P=0.500	P=0.500	P=0.500	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.043*	P=0.158	P=0.158	P=0.158	P=0.158	P=0.158

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LAST REMOVAL AT 14 WEEKS

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Females

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DOSE	1000 UG/KG	4600 UG/KG
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Liver  
Inflammation

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LESION RATES

OVERALL (a)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	10/10.00	10/10.00
POLY-3 PERCENT (g)	100%	100%
INT SACRIFICE 1	10/10 (100%)	10/10 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	97 (I)	97 (I)

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STATISTICAL TESTS

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

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 LAST REMOVAL AT 14 WEEKS**

DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

Liver  
 Necrosis

**LESION RATES**

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%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---	---

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	(e)	(e)	(e)	(e)
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	(e)
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
LAST REMOVAL AT 14 WEEKS

---

Females

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DOSE	1000 UG/KG	4600 UG/KG
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Liver  
Necrosis

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LESION RATES

OVERALL (a)	3/10 (30%)	9/10 (90%)
POLY-3 RATE (b)	3/10.00	9/10.00
POLY-3 PERCENT (g)	30%	90%
INT SACRIFICE 1	3/10 (30%)	9/10 (90%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	97 (I)	97 (I)

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STATISTICAL TESTS

POLY 3	P=0.095	P<0.001**
POLY 1.5	P=0.095	P<0.001**
POLY 6	P=0.095	P<0.001**
COCH-ARM / FISHERS	P=0.105	P<0.001**
MAX-ISO-POLY-3	P=0.025*	P<0.001**

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 LAST REMOVAL AT 14 WEEKS**

DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

**Liver  
 Pigmentation**

**LESION RATES**

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%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---	---

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	(e)	(e)	(e)	(e)
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	(e)
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

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LAST REMOVAL AT 14 WEEKS

---

Females

---

DOSE	1000 UG/KG	4600 UG/KG
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Liver  
Pigmentation

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LESION RATES

OVERALL (a)	5/10 (50%)	8/10 (80%)
POLY-3 RATE (b)	5/10.00	8/10.00
POLY-3 PERCENT (g)	50%	80%
INT SACRIFICE 1	5/10 (50%)	8/10 (80%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	97 (I)	97 (I)

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STATISTICAL TESTS

POLY 3	P=0.008**	P<0.001**
POLY 1.5	P=0.008**	P<0.001**
POLY 6	P=0.008**	P<0.001**
COCH-ARM / FISHERS	P=0.016*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**

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DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

Liver  
 Toxic Hepatopathy

**LESION RATES**

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%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---	---

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	(e)	(e)	(e)	(e)
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	(e)
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

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First Dose M/F: NA / 03/26/04  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
LAST REMOVAL AT 14 WEEKS

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Females

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DOSE	1000 UG/KG	4600 UG/KG
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Liver  
Toxic Hepatopathy

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LESION RATES

OVERALL (a)	0/10 (0%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	10/10.00
POLY-3 PERCENT (g)	0%	100%
INT SACRIFICE 1	0/10 (0%)	10/10 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	97 (I)

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STATISTICAL TESTS

POLY 3	(e)	P<0.001**
POLY 1.5	(e)	P<0.001**
POLY 6	(e)	P<0.001**
COCH-ARM / FISHERS	(e)	P<0.001**
MAX-ISO-POLY-3	(e)	P<0.001**

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 TEF evaluation (PCB 118)  
 CAS Number: 31508-00-6

Date Report Requested: 06/24/2008  
 Time Report Requested: 13:37:02  
 First Dose M/F: NA / 03/26/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
 LAST REMOVAL AT 14 WEEKS**

DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
<b>Liver: Hepatocyte Hypertrophy</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)	5/10 (50%)	6/10 (60%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	1/10.00	5/10.00	6/10.00
POLY-3 PERCENT (g)	0%	0%	10%	10%	50%	60%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)	5/10 (50%)	6/10 (60%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	97 (I)	97 (I)	97 (I)	97 (I)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	P=0.500	P=0.500	P=0.008**	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.500	P=0.500	P=0.008**	P<0.001**
POLY 6	P<0.001**	(e)	P=0.500	P=0.500	P=0.008**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	P=0.500	P=0.016*	P=0.005**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.158	P=0.158	P<0.001**	P<0.001**

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

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
LAST REMOVAL AT 14 WEEKS

---

Females

---

DOSE	1000 UG/KG	4600 UG/KG
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Liver: Hepatocyte  
Hypertrophy

---

LESION RATES

OVERALL (a)	9/10 (90%)	10/10 (100%)
POLY-3 RATE (b)	9/10.00	10/10.00
POLY-3 PERCENT (g)	90%	100%
INT SACRIFICE 1	9/10 (90%)	10/10 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	97 (I)	97 (I)

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STATISTICAL TESTS

POLY 3	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**

---

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
 LAST REMOVAL AT 14 WEEKS

DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

Liver: Hepatocyte  
 Multinucleated

LESION RATES

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%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---	---

STATISTICAL TESTS

POLY 3	P<0.001**	(e)	(e)	(e)	(e)	(e)
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	(e)
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

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

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
LAST REMOVAL AT 14 WEEKS

---

Females

---

DOSE	1000 UG/KG	4600 UG/KG
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Liver: Hepatocyte  
Multinucleated

---

LESION RATES

OVERALL (a)	0/10 (0%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	10/10.00
POLY-3 PERCENT (g)	0%	100%
INT SACRIFICE 1	0/10 (0%)	10/10 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	97 (I)

---

STATISTICAL TESTS

POLY 3	(e)	P<0.001**
POLY 1.5	(e)	P<0.001**
POLY 6	(e)	P<0.001**
COCH-ARM / FISHERS	(e)	P<0.001**
MAX-ISO-POLY-3	(e)	P<0.001**

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TDMS No. 20304 - 01  
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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
 LAST REMOVAL AT 14 WEEKS**

DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

**Spleen  
 Hematopoietic Cell Proliferation**

**LESION RATES**

OVERALL (a)	6/10 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	6/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	60%	0%	0%	0%	0%	0%
INT SACRIFICE 1	6/10 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	97 (l)	---	---	---	---	---

**STATISTICAL TESTS**

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	P=0.005N**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
LAST REMOVAL AT 14 WEEKS

---

Females

---

DOSE	1000 UG/KG	4600 UG/KG
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Spleen  
Hematopoietic Cell Proliferation

---

LESION RATES

OVERALL (a)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
INT SACRIFICE 1	0/0 (0%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

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STATISTICAL TESTS

POLY 3	(e)	P<0.001N**
POLY 1.5	(e)	P<0.001N**
POLY 6	(e)	P<0.001N**
COCH-ARM / FISHERS	(e)	P=0.005N**
MAX-ISO-POLY-3	(e)	P<0.001N**

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TDMS No. 20304 - 01  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
 LAST REMOVAL AT 14 WEEKS**

DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

**Spleen  
 Pigmentation**

**LESION RATES**

OVERALL (a)	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	10/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	100%	0%	0%	0%	0%	0%
INT SACRIFICE 1	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	97 (l)	---	---	---	---	---

**STATISTICAL TESTS**

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. 20304 - 01  
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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
LAST REMOVAL AT 14 WEEKS

---

Females

---

DOSE	1000 UG/KG	4600 UG/KG
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Spleen  
Pigmentation

---

LESION RATES

OVERALL (a)	0/0 (0%)	10/10 (100%)
POLY-3 RATE (b)	0/0.00	10/10.00
POLY-3 PERCENT (g)	0%	100%
INT SACRIFICE 1	0/0 (0%)	10/10 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	97 (I)

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STATISTICAL TESTS

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

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 LAST REMOVAL AT 14 WEEKS**

DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

**Thyroid Gland: Follicular Cell Hypertrophy**

**LESION RATES**

OVERALL (a)	1/10 (10%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	1/10 (10%)	2/10 (20%)
POLY-3 RATE (b)	1/10.00	0/10.00	1/10.00	0/10.00	1/10.00	2/10.00
POLY-3 PERCENT (g)	10%	0%	10%	0%	10%	20%
INT SACRIFICE 1	1/10 (10%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	1/10 (10%)	2/10 (20%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	97 (I)	---	97 (I)	---	97 (I)	97 (I)

**STATISTICAL TESTS**

POLY 3	P=0.007**	P=0.500N	P=0.760	P=0.500N	P=0.760	P=0.500
POLY 1.5	P=0.007**	P=0.500N	P=0.760	P=0.500N	P=0.760	P=0.500
POLY 6	P=0.007**	P=0.500N	P=0.760	P=0.500N	P=0.760	P=0.500
COCH-ARM / FISHERS	P=0.008**	P=0.500N	P=0.763N	P=0.500N	P=0.763N	P=0.500
MAX-ISO-POLY-3	P=0.013*	P=0.158N	P=1.000	P=0.158N	P=1.000	P=0.274

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

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
LAST REMOVAL AT 14 WEEKS

---

Females

---

DOSE	1000 UG/KG	4600 UG/KG
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Thyroid Gland: Follicular Cell  
Hypertrophy

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LESION RATES

OVERALL (a)	2/10 (20%)	4/10 (40%)
POLY-3 RATE (b)	2/10.00	4/10.00
POLY-3 PERCENT (g)	20%	40%
INT SACRIFICE 1	2/10 (20%)	4/10 (40%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	97 (I)	97 (I)

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STATISTICAL TESTS

POLY 3	P=0.500	P=0.148
POLY 1.5	P=0.500	P=0.148
POLY 6	P=0.500	P=0.148
COCH-ARM / FISHERS	P=0.500	P=0.152
MAX-ISO-POLY-3	P=0.274	P=0.060

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

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

## **LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (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. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death.
  - (e) Value of Statistic cannot be computed.
  - (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
- Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors.  
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

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