

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 004 100 UG/KG
Include 007 1000 UG/KG
Study Gender: Female
TDMSE Version: 2.0.0

Include 002 10 UG/KG

Include 005 220 UG/KG

Include 008 4600 UG/KG

Include 003 30 UG/KG

Include 006 460 UG/KG

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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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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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Adrenal Cortex
Hypertrophy

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	---	---

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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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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Lab: BAT

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
Fatty Change Diffuse

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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 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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LAST REMOVAL AT 14 WEEKS

Females

DOSE	1000 UG/KG	4600 UG/KG
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Liver
Hepatodiaphragmatic Nodule

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	---	---

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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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

Females

DOSE	1000 UG/KG	4600 UG/KG
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Liver
Inflammation

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)

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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LAST REMOVAL AT 14 WEEKS

Females

DOSE	1000 UG/KG	4600 UG/KG
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Liver
Necrosis

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)

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

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)

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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LAST REMOVAL AT 14 WEEKS

Females

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

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**

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
Liver: Hepatocyte Hypertrophy						
LESION RATES						
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)

STATISTICAL TESTS

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
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/SD

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Lab: BAT

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)

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**

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

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
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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**

TDMS No. 20304 - 01
 Test Type: CHRONIC
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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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First Dose M/F: NA / 03/26/04
Lab: BAT

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	---	---

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**

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
 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)

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)

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

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

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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

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)

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

TDMS No. 20304 - 01
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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 ***