

**TDMS No.** 20306 - 02  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** RATS/SD

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

PCN 66/67 comparison study  
**CAS Number:** PCNCOMPARISN

**Date Report Requested:** 07/21/2008  
**Time Report Requested:** 16:15:19  
**First Dose M/F:** NA / 10/06/03  
**Lab:** BAT

PCN67

<b>C Number:</b>	C20306		
<b>Lock Date:</b>	10/07/2004		
<b>Cage Range:</b>	ALL		
<b>Date Range:</b>	ALL		
<b>Reasons For Removal:</b>	ALL		
<b>Removal Date Range:</b>	ALL		
<b>Treatment Groups:</b>	Include 001 0 NG/KG	Include 007 1000 NG/KG 67	Include 008 10,000 NG/KG 67
	Include 009 50,000 NG/KG 67	Include 010 100,000 NG/KG 67	Include 011 200,000 NG/KG 67
<b>Study Gender:</b>	Female		
<b>TDMSE Version:</b>	2.0.0		

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**SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF PCN 66/67 comparison study**

**FEMALE RATS**

**Organ**

Liver

Liver: Hepatocyte

Thyroid Gland: Follicular Cell

**Morphology**

Fatty Change

Hepatocyte, Multinucleate

Inflammation

Necrosis Focal

Toxic Hepatopathy

Hypertrophy

Hypertrophy

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 67	10,000 NG/KG 67	50,000 NG/KG 67	100,000 NG/KG 67	200,000 NG/KG 67

**Adrenal Cortex Hypertrophy**

**LESION RATES**

OVERALL (a)	0/10 (0%)	2/10 (20%)	1/10 (10%)	1/10 (10%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	2/10.00	1/10.00	1/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	20%	10%	10%	10%	0%
TERMINAL (d)	0/10 (0%)	2/10 (20%)	1/10 (10%)	1/10 (10%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	94 (T)	94 (T)	94 (T)	94 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.286N	P=0.227	P=0.500	P=0.500	P=0.500	(e)
POLY 1.5	P=0.286N	P=0.227	P=0.500	P=0.500	P=0.500	(e)
POLY 6	P=0.286N	P=0.227	P=0.500	P=0.500	P=0.500	(e)
COCH-ARM / FISHERS	P=0.282N	P=0.237	P=0.500	P=0.500	P=0.500	(e)
MAX-ISO-POLY-3	P=0.396	P=0.067	P=0.158	P=0.158	P=0.158	(e)

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 67	10,000 NG/KG 67	50,000 NG/KG 67	100,000 NG/KG 67	200,000 NG/KG 67

**Clitoral Gland  
 Inflammation Chronic**

**LESION RATES**

OVERALL (a)	6/10 (60%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	6/10 (60%)
POLY-3 RATE (b)	6/10.00	0/0.00	0/1.00	0/0.00	0/0.00	6/10.00
POLY-3 PERCENT (g)	60%	0%	0%	0%	0%	60%
TERMINAL (d)	6/10 (60%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	6/10 (60%)
FIRST INCIDENCE	94 (T)	---	---	---	---	94 (T)

**STATISTICAL TESTS**

POLY 3	(e)	(e)	P=0.463N	(e)	(e)	P=0.667
POLY 1.5	(e)	(e)	P=0.463N	(e)	(e)	P=0.667
POLY 6	(e)	(e)	P=0.463N	(e)	(e)	P=0.667
COCH-ARM / FISHERS	P=0.497	(e)	P=0.455N	(e)	(e)	P=0.675N
MAX-ISO-POLY-3	(e)	(e)	P=0.204N	(e)	(e)	P=1.000

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 67	10,000 NG/KG 67	50,000 NG/KG 67	100,000 NG/KG 67	200,000 NG/KG 67

**Kidney  
 Mineralization**

**LESION RATES**

OVERALL (a)	4/10 (40%)	5/10 (50%)	4/10 (40%)	6/10 (60%)	5/10 (50%)	5/10 (50%)
POLY-3 RATE (b)	4/10.00	5/10.00	4/10.00	6/10.00	5/10.00	5/10.00
POLY-3 PERCENT (g)	40%	50%	40%	60%	50%	50%
TERMINAL (d)	4/10 (40%)	5/10 (50%)	4/10 (40%)	6/10 (60%)	5/10 (50%)	5/10 (50%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)

**STATISTICAL TESTS**

POLY 3	P=0.431	P=0.500	P=0.667	P=0.333	P=0.500	P=0.500
POLY 1.5	P=0.431	P=0.500	P=0.667	P=0.333	P=0.500	P=0.500
POLY 6	P=0.431	P=0.500	P=0.667	P=0.333	P=0.500	P=0.500
COCH-ARM / FISHERS	P=0.428	P=0.500	P=0.675N	P=0.328	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.521	P=0.334	P=1.000	P=0.192	P=0.334	P=0.334

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 67	10,000 NG/KG 67	50,000 NG/KG 67	100,000 NG/KG 67	200,000 NG/KG 67

**Kidney  
 Nephropathy**

**LESION RATES**

OVERALL (a)	6/10 (60%)	6/10 (60%)	3/10 (30%)	6/10 (60%)	7/10 (70%)	5/10 (50%)
POLY-3 RATE (b)	6/10.00	6/10.00	3/10.00	6/10.00	7/10.00	5/10.00
POLY-3 PERCENT (g)	60%	60%	30%	60%	70%	50%
TERMINAL (d)	6/10 (60%)	6/10 (60%)	3/10 (30%)	6/10 (60%)	7/10 (70%)	5/10 (50%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)

**STATISTICAL TESTS**

POLY 3	P=0.499	P=0.667	P=0.186N	P=0.667	P=0.500	P=0.500N
POLY 1.5	P=0.499	P=0.667	P=0.186N	P=0.667	P=0.500	P=0.500N
POLY 6	P=0.499	P=0.667	P=0.186N	P=0.667	P=0.500	P=0.500N
COCH-ARM / FISHERS	P=0.499	P=0.675N	P=0.185N	P=0.675N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.597	P=1.000	P=0.090N	P=1.000	P=0.327	P=0.334N

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 67	10,000 NG/KG 67	50,000 NG/KG 67	100,000 NG/KG 67	200,000 NG/KG 67

Liver  
 Fatty Change

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)

**STATISTICAL TESTS**

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

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**TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1000 NG/KG 67	10,000 NG/KG 67	50,000 NG/KG 67	100,000 NG/KG 67	200,000 NG/KG 67

Liver  
 Hepatocyte, Multinucleate

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)

**STATISTICAL TESTS**

POLY 3	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
POLY 6	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.011*	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	P=0.008**	(e)	(e)	(e)	(e)	P=0.067



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**TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1000 NG/KG 67	10,000 NG/KG 67	50,000 NG/KG 67	100,000 NG/KG 67	200,000 NG/KG 67

**Liver Inflammation**

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	2/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	20%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	---	94 (T)	94 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	(e)	(e)	P=0.227	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	(e)	P=0.227	P<0.001**
POLY 6	P<0.001**	(e)	(e)	(e)	P=0.227	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P=0.237	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	P=0.067	P<0.001**

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**TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1000 NG/KG 67	10,000 NG/KG 67	50,000 NG/KG 67	100,000 NG/KG 67	200,000 NG/KG 67

**Liver  
 Inflammation Chronic**

**LESION RATES**

OVERALL (a)	8/10 (80%)	9/10 (90%)	8/10 (80%)	9/10 (90%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	8/10.00	9/10.00	8/10.00	9/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	80%	90%	80%	90%	100%	100%
TERMINAL (d)	8/10 (80%)	9/10 (90%)	8/10 (80%)	9/10 (90%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)

**STATISTICAL TESTS**

POLY 3	P=0.078	P=0.500	P=0.702	P=0.500	P=0.227	P=0.227
POLY 1.5	P=0.078	P=0.500	P=0.702	P=0.500	P=0.227	P=0.227
POLY 6	P=0.078	P=0.500	P=0.702	P=0.500	P=0.227	P=0.227
COCH-ARM / FISHERS	P=0.075	P=0.500	P=0.709N	P=0.500	P=0.237	P=0.237
MAX-ISO-POLY-3	P=0.130	P=0.274	P=1.000	P=0.274	P=0.067	P=0.067

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 67	10,000 NG/KG 67	50,000 NG/KG 67	100,000 NG/KG 67	200,000 NG/KG 67

Liver  
 Necrosis Focal

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	6/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	60%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)

**STATISTICAL TESTS**

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

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 67	10,000 NG/KG 67	50,000 NG/KG 67	100,000 NG/KG 67	200,000 NG/KG 67

**Liver  
 Pigmentation**

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	2/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	20%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	94 (T)	94 (T)

**STATISTICAL TESTS**

POLY 3	P=0.078	(e)	(e)	(e)	P=0.227	P=0.500
POLY 1.5	P=0.078	(e)	(e)	(e)	P=0.227	P=0.500
POLY 6	P=0.078	(e)	(e)	(e)	P=0.227	P=0.500
COCH-ARM / FISHERS	P=0.081	(e)	(e)	(e)	P=0.237	P=0.500
MAX-ISO-POLY-3	P=0.110	(e)	(e)	(e)	P=0.067	P=0.158

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**TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1000 NG/KG 67	10,000 NG/KG 67	50,000 NG/KG 67	100,000 NG/KG 67	200,000 NG/KG 67

Liver  
 Toxic Hepatopathy

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)

**STATISTICAL TESTS**

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

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**TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1000 NG/KG 67	10,000 NG/KG 67	50,000 NG/KG 67	100,000 NG/KG 67	200,000 NG/KG 67

Liver: Hepatocyte Hypertrophy

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)	3/10 (30%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	1/10.00	3/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	10%	10%	30%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)	3/10 (30%)	10/10 (100%)
FIRST INCIDENCE	---	---	94 (T)	94 (T)	94 (T)	94 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	P=0.500	P=0.500	P=0.095	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.500	P=0.500	P=0.095	P<0.001**
POLY 6	P<0.001**	(e)	P=0.500	P=0.500	P=0.095	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	P=0.500	P=0.105	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.158	P=0.158	P=0.024*	P<0.001**

TDMS No. 20306 - 02  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 PCN 66/67 comparison study  
 CAS Number: PCNCOMPARISN

Date Report Requested: 07/21/2008  
 Time Report Requested: 16:15:19  
 First Dose M/F: NA / 10/06/03  
 Lab: BAT

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 67	10,000 NG/KG 67	50,000 NG/KG 67	100,000 NG/KG 67	200,000 NG/KG 67

**Nose: Respiratory Epithelium Inflammation**

**LESION RATES**

OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	0%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	94 (T)	---	---	---	---	---

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227N
COCH-ARM / FISHERS	P=0.132N	(e)	(e)	(e)	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.067N

TDMS No. 20306 - 02  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 PCN 66/67 comparison study  
 CAS Number: PCNCOMPARISN

Date Report Requested: 07/21/2008  
 Time Report Requested: 16:15:19  
 First Dose M/F: NA / 10/06/03  
 Lab: BAT

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 67	10,000 NG/KG 67	50,000 NG/KG 67	100,000 NG/KG 67	200,000 NG/KG 67

**Spleen  
 Pigmentation Hemosiderin**

**LESION RATES**

OVERALL (a)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	9/10 (90%)
POLY-3 RATE (b)	10/10.00	10/10.00	10/10.00	10/10.00	10/10.00	9/10.00
POLY-3 PERCENT (g)	100%	100%	100%	100%	100%	90%
TERMINAL (d)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	9/10 (90%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)

**STATISTICAL TESTS**

POLY 3	P=0.105N	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	P=0.105N	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	P=0.105N	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.103N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	P=0.076N	(e)	(e)	(e)	(e)	P=0.158N



TDMS No. 20306 - 02  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 PCN 66/67 comparison study  
 CAS Number: PCNCOMPARISN

Date Report Requested: 07/21/2008  
 Time Report Requested: 16:15:19  
 First Dose M/F: NA / 10/06/03  
 Lab: BAT

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 67	10,000 NG/KG 67	50,000 NG/KG 67	100,000 NG/KG 67	200,000 NG/KG 67

**Thyroid Gland: Follicular Cell Hypertrophy**

**LESION RATES**

OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	7/10 (70%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00	0/10.00	7/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	70%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	7/10 (70%)
FIRST INCIDENCE	94 (T)	---	---	---	---	94 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.003**
POLY 1.5	P<0.001**	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.003**
POLY 6	P<0.001**	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.003**
COCH-ARM / FISHERS	P<0.001**	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.010**
MAX-ISO-POLY-3	P<0.001**	P=0.158N	P=0.158N	P=0.158N	P=0.158N	P<0.001**

**TDMS No.** 20306 - 02  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
PCN 66/67 comparison study  
**CAS Number:** PCNCOMPARISN

**Date Report Requested:** 07/21/2008  
**Time Report Requested:** 16:15:19  
**First Dose M/F:** NA / 10/06/03  
**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 \*\*\*