

**Experiment Number:** 20306 - 03  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** RATS/F 344/N

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

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

**Date Report Requested:** 08/27/2015  
**Time Report Requested:** 10:28:05  
**First Dose M/F:** NA / 10/13/03  
**Lab:** BAT

F1\_Rev. 1\_TCDD

**NTP Study Number:** C20306

**Lock Date:** 10/07/2004

**Cage Range:** ALL

**Date Range:** ALL

**Reasons For Removal:** ALL

**Removal Date Range:** ALL

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

Include 012 1 NG/KG

Include 013 10 NG/KG

Include 014 50 NG/KG

Include 015 100 NG/KG

Include 016 200 NG/KG

**Study Gender:** Female

**TDMSE Version:** 3.0.2.2\_002

**PWG Approval Date:** NONE

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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF PCN 66/67 COMPARISON STUDY**

**FEMALE RATS**

**Organ**

Harderian Gland

Kidney

Liver

Liver: Hepatocyte

Pancreas

Pancreas: Acinus

Spleen

Thymus

Thyroid Gland

**Morphology**

Infiltration Cellular Mononuclear Cell

Mineralization

Nephropathy

Hepatocyte, Multinucleate

Inflammation Chronic

Inflammation Granulomatous

Pigmentation

Toxic Hepatopathy

Hypertrophy

Infiltration Cellular Mononuclear Cell

Atrophy Focal

Hematopoietic Cell Proliferation

Atrophy

Cyst

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Adrenal Cortex</b>						
<b>Infiltration Cellular Lymphocyte</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/15.00	1/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	10%	0%	0%	0%	0%
TERMINAL (d)	0/15 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	94 (T)	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.474N	P=0.418	(e)	(e)	(e)	(e)
POLY 1.5	P=0.474N	P=0.418	(e)	(e)	(e)	(e)
POLY 6	P=0.474N	P=0.418	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.474N	P=0.400	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.433N	P=0.128	(e)	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Adrenal Cortex</b>						
<b>Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	0%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	94 (T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.531	(e)	(e)	(e)	P=0.418	(e)
POLY 1.5	P=0.531	(e)	(e)	(e)	P=0.418	(e)
POLY 6	P=0.531	(e)	(e)	(e)	P=0.418	(e)
COCH-ARM / FISHERS	P=0.531	(e)	(e)	(e)	P=0.400	(e)
MAX-ISO-POLY-3	P=0.339	(e)	(e)	(e)	P=0.128	(e)

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Bone Marrow Inflammation Histiocytic</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/15.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/15 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.418
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.418
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.418
COCH-ARM / FISHERS	P=0.233	(e)	(e)	(e)	(e)	P=0.400
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.128

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Harderian Gland</b>						
<b>Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/15.00	0/0.00	0/0.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/15 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.139
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.139
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.139
COCH-ARM / FISHERS	P=0.076	(e)	(e)	(e)	(e)	P=0.150
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.045*

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Heart</b>						
<b>Cardiomyopathy</b>						
<b>LESION RATES</b>						
OVERALL (a)	9/15 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	9/10 (90%)
POLY-3 RATE (b)	9/15.00	0/0.00	0/0.00	0/0.00	0/0.00	9/10.00
POLY-3 PERCENT (g)	60%	0%	0%	0%	0%	90%
TERMINAL (d)	9/15 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	9/10 (90%)
FIRST INCIDENCE	94 (T)	---	---	---	---	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.115
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.115
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.115
COCH-ARM / FISHERS	P=0.079	(e)	(e)	(e)	(e)	P=0.118
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.064

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Intestine Small, Jejunum Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/15.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/15 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.418
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.418
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.418
COCH-ARM / FISHERS	P=0.233	(e)	(e)	(e)	(e)	P=0.400
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.128



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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Kidney Mineralization</b>						
<b>LESION RATES</b>						
OVERALL (a)	15/15 (100%)	9/10 (90%)	9/10 (90%)	9/10 (90%)	8/10 (80%)	4/10 (40%)
POLY-3 RATE (b)	15/15.00	9/10.00	9/10.00	9/10.00	8/10.00	4/10.00
POLY-3 PERCENT (g)	100%	90%	90%	90%	80%	40%
TERMINAL (d)	15/15 (100%)	9/10 (90%)	9/10 (90%)	9/10 (90%)	8/10 (80%)	4/10 (40%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001N**	P=0.418N	P=0.418N	P=0.418N	P=0.139N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.418N	P=0.418N	P=0.418N	P=0.139N	P<0.001N**
POLY 6	P<0.001N**	P=0.418N	P=0.418N	P=0.418N	P=0.139N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.400N	P=0.400N	P=0.400N	P=0.150N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.128N	P=0.128N	P=0.128N	P=0.045N*	P<0.001N**

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Kidney</b>						
<b>Nephropathy</b>						
<b>LESION RATES</b>						
OVERALL (a)	2/15 (13%)	1/10 (10%)	0/10 (0%)	2/10 (20%)	7/10 (70%)	3/10 (30%)
POLY-3 RATE (b)	2/15.00	1/10.00	0/10.00	2/10.00	7/10.00	3/10.00
POLY-3 PERCENT (g)	13.3%	10%	0%	20%	70%	30%
TERMINAL (d)	2/15 (13%)	1/10 (10%)	0/10 (0%)	2/10 (20%)	7/10 (70%)	3/10 (30%)
FIRST INCIDENCE	94 (T)	94 (T)	---	94 (T)	94 (T)	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.008**	P=0.641N	P=0.328N	P=0.543	P=0.002**	P=0.309
POLY 1.5	P=0.008**	P=0.641N	P=0.328N	P=0.543	P=0.002**	P=0.309
POLY 6	P=0.008**	P=0.641N	P=0.328N	P=0.543	P=0.002**	P=0.309
COCH-ARM / FISHERS	P=0.016*	P=0.654N	P=0.350N	P=0.532	P=0.007**	P=0.301
MAX-ISO-POLY-3	P=0.013*	P=0.413N	P=0.137N	P=0.347	P<0.001**	P=0.180

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Species/Strain: RATS/F 344/N

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Kidney: Cortex Cyst</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	0%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	94 (T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.531	(e)	(e)	(e)	P=0.418	(e)
POLY 1.5	P=0.531	(e)	(e)	(e)	P=0.418	(e)
POLY 6	P=0.531	(e)	(e)	(e)	P=0.418	(e)
COCH-ARM / FISHERS	P=0.531	(e)	(e)	(e)	P=0.400	(e)
MAX-ISO-POLY-3	P=0.339	(e)	(e)	(e)	P=0.128	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Liver</b>						
<b>Hepatocyte, Multinucleate</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
<b>POLY-3 RATE (b)</b>	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	3/10.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	0%	0%	0%	30%
<b>TERMINAL (d)</b>	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
<b>FIRST INCIDENCE</b>	---	---	---	---	---	94 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P<0.001**	(e)	(e)	(e)	(e)	P=0.040*
<b>POLY 1.5</b>	P<0.001**	(e)	(e)	(e)	(e)	P=0.040*
<b>POLY 6</b>	P<0.001**	(e)	(e)	(e)	(e)	P=0.040*
<b>COCH-ARM / FISHERS</b>	P<0.001**	(e)	(e)	(e)	(e)	P=0.052
<b>MAX-ISO-POLY-3</b>	P<0.001**	(e)	(e)	(e)	(e)	P=0.013*

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
Liver						
Hepatodiaphragmatic Nodule						
<b>LESION RATES</b>						
OVERALL (a)	1/15 (7%)	1/10 (10%)	1/10 (10%)	3/10 (30%)	2/10 (20%)	1/10 (10%)
POLY-3 RATE (b)	1/15.00	1/10.00	1/10.00	3/10.00	2/10.00	1/10.00
POLY-3 PERCENT (g)	6.7%	10%	10%	30%	20%	10%
TERMINAL (d)	1/15 (7%)	1/10 (10%)	1/10 (10%)	3/10 (30%)	2/10 (20%)	1/10 (10%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.478	P=0.668	P=0.668	P=0.156	P=0.356	P=0.668
POLY 1.5	P=0.478	P=0.668	P=0.668	P=0.156	P=0.356	P=0.668
POLY 6	P=0.478	P=0.668	P=0.668	P=0.156	P=0.356	P=0.668
COCH-ARM / FISHERS	P=0.477	P=0.650	P=0.650	P=0.159	P=0.346	P=0.650
MAX-ISO-POLY-3	P=0.369	P=0.395	P=0.395	P=0.075	P=0.184	P=0.395

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Liver</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	7/15 (47%)	7/10 (70%)	8/10 (80%)	10/10 (100%)	9/10 (90%)	10/10 (100%)
<b>POLY-3 RATE (b)</b>	7/15.00	7/10.00	8/10.00	10/10.00	9/10.00	10/10.00
<b>POLY-3 PERCENT (g)</b>	46.7%	70%	80%	100%	90%	100%
<b>TERMINAL (d)</b>	7/15 (47%)	7/10 (70%)	8/10 (80%)	10/10 (100%)	9/10 (90%)	10/10 (100%)
<b>FIRST INCIDENCE</b>	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.002**	P=0.233	P=0.102	P=0.003**	P=0.028*	P=0.003**
<b>POLY 1.5</b>	P=0.002**	P=0.233	P=0.102	P=0.003**	P=0.028*	P=0.003**
<b>POLY 6</b>	P=0.002**	P=0.233	P=0.102	P=0.003**	P=0.028*	P=0.003**
<b>COCH-ARM / FISHERS</b>	P=0.005**	P=0.231	P=0.105	P=0.006**	P=0.034*	P=0.006**
<b>MAX-ISO-POLY-3</b>	P=0.002**	P=0.149	P=0.061	P=0.002**	P=0.015*	P=0.002**

Experiment Number: 20306 - 03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

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

Date Report Requested: 08/27/2015  
 Time Report Requested: 10:28:05  
 First Dose M/F: NA / 10/13/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Liver</b>						
<b>Inflammation Granulomatous</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	0/10 (0%)	2/10 (20%)	0/10 (0%)	4/10 (40%)	4/10 (40%)
POLY-3 RATE (b)	0/15.00	0/10.00	2/10.00	0/10.00	4/10.00	4/10.00
POLY-3 PERCENT (g)	0%	0%	20%	0%	40%	40%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	2/10 (20%)	0/10 (0%)	4/10 (40%)	4/10 (40%)
FIRST INCIDENCE	---	---	94 (T)	---	94 (T)	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	P=0.139	(e)	P=0.008**	P=0.008**
POLY 1.5	P<0.001**	(e)	P=0.139	(e)	P=0.008**	P=0.008**
POLY 6	P<0.001**	(e)	P=0.139	(e)	P=0.008**	P=0.008**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.150	(e)	P=0.017*	P=0.017*
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.045*	(e)	P=0.003**	P=0.003**

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
Liver Pigmentation						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	2/10 (20%)	4/10 (40%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	1/10.00	2/10.00	4/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	20%	40%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	2/10 (20%)	4/10 (40%)
FIRST INCIDENCE	---	---	---	94 (T)	94 (T)	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	(e)	P=0.418	P=0.139	P=0.008**
POLY 1.5	P<0.001**	(e)	(e)	P=0.418	P=0.139	P=0.008**
POLY 6	P<0.001**	(e)	(e)	P=0.418	P=0.139	P=0.008**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.400	P=0.150	P=0.017*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.128	P=0.045*	P=0.003**



Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Liver</b>						
<b>Toxic Hepatopathy</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/15.00	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)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.005**	(e)	(e)	(e)	(e)	P=0.139
POLY 1.5	P=0.005**	(e)	(e)	(e)	(e)	P=0.139
POLY 6	P=0.005**	(e)	(e)	(e)	(e)	P=0.139
COCH-ARM / FISHERS	P=0.008**	(e)	(e)	(e)	(e)	P=0.150
MAX-ISO-POLY-3	P=0.006**	(e)	(e)	(e)	(e)	P=0.045*

Experiment Number: 20306 - 03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

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

Date Report Requested: 08/27/2015  
 Time Report Requested: 10:28:05  
 First Dose M/F: NA / 10/13/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Liver: Hepatocyte Hypertrophy</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/15 (7%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	4/10 (40%)	8/10 (80%)
POLY-3 RATE (b)	1/15.00	0/10.00	0/10.00	0/10.00	4/10.00	8/10.00
POLY-3 PERCENT (g)	6.7%	0%	0%	0%	40%	80%
TERMINAL (d)	1/15 (7%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	4/10 (40%)	8/10 (80%)
FIRST INCIDENCE	94 (T)	---	---	---	94 (T)	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	P=0.580N	P=0.580N	P=0.580N	P=0.054	P<0.001**
POLY 1.5	P<0.001**	P=0.580N	P=0.580N	P=0.580N	P=0.054	P<0.001**
POLY 6	P<0.001**	P=0.580N	P=0.580N	P=0.580N	P=0.054	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.600N	P=0.600N	P=0.600N	P=0.064	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.229N	P=0.229N	P=0.229N	P=0.025*	P<0.001**

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Lung</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/15.00	0/10.00	1/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	10%	0%	0%	0%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	94 (T)	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.525N	(e)	P=0.418	(e)	(e)	(e)
POLY 1.5	P=0.525N	(e)	P=0.418	(e)	(e)	(e)
POLY 6	P=0.525N	(e)	P=0.418	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.525N	(e)	P=0.400	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.552N	(e)	P=0.128	(e)	(e)	(e)

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Lung</b>						
<b>Pigmentation Hemosiderin</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	0%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	94 (T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.531	(e)	(e)	(e)	P=0.418	(e)
POLY 1.5	P=0.531	(e)	(e)	(e)	P=0.418	(e)
POLY 6	P=0.531	(e)	(e)	(e)	P=0.418	(e)
COCH-ARM / FISHERS	P=0.531	(e)	(e)	(e)	P=0.400	(e)
MAX-ISO-POLY-3	P=0.339	(e)	(e)	(e)	P=0.128	(e)

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Lung: Alveolar Epithelium Hyperplasia</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/15 (7%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/15.00	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	6.7%	0%	0%	0%	0%	10%
TERMINAL (d)	1/15 (7%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	94 (T)	---	---	---	---	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.349	P=0.580N	P=0.580N	P=0.580N	P=0.580N	P=0.668
POLY 1.5	P=0.349	P=0.580N	P=0.580N	P=0.580N	P=0.580N	P=0.668
POLY 6	P=0.349	P=0.580N	P=0.580N	P=0.580N	P=0.580N	P=0.668
COCH-ARM / FISHERS	P=0.346	P=0.600N	P=0.600N	P=0.600N	P=0.600N	P=0.650
MAX-ISO-POLY-3	P=0.277	P=0.229N	P=0.229N	P=0.229N	P=0.229N	P=0.395

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Lung: Alveolus Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL (a)	3/15 (20%)	0/10 (0%)	3/10 (30%)	0/10 (0%)	3/10 (30%)	4/10 (40%)
POLY-3 RATE (b)	3/15.00	0/10.00	3/10.00	0/10.00	3/10.00	4/10.00
POLY-3 PERCENT (g)	20%	0%	30%	0%	30%	40%
TERMINAL (d)	3/15 (20%)	0/10 (0%)	3/10 (30%)	0/10 (0%)	3/10 (30%)	4/10 (40%)
FIRST INCIDENCE	94 (T)	---	94 (T)	---	94 (T)	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.054	P=0.188N	P=0.463	P=0.188N	P=0.463	P=0.266
POLY 1.5	P=0.054	P=0.188N	P=0.463	P=0.188N	P=0.463	P=0.266
POLY 6	P=0.054	P=0.188N	P=0.463	P=0.188N	P=0.463	P=0.266
COCH-ARM / FISHERS	P=0.058	P=0.198N	P=0.455	P=0.198N	P=0.455	P=0.261
MAX-ISO-POLY-3	P=0.099	P=0.083N	P=0.306	P=0.083N	P=0.306	P=0.163

Experiment Number: 20306 - 03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

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

Date Report Requested: 08/27/2015  
 Time Report Requested: 10:28:05  
 First Dose M/F: NA / 10/13/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)**  
**TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Lung: Interstitium Inflammation Granulomatous</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/15 (7%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/15.00	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	6.7%	0%	0%	0%	0%	10%
TERMINAL (d)	1/15 (7%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	94 (T)	---	---	---	---	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.349	P=0.580N	P=0.580N	P=0.580N	P=0.580N	P=0.668
POLY 1.5	P=0.349	P=0.580N	P=0.580N	P=0.580N	P=0.580N	P=0.668
POLY 6	P=0.349	P=0.580N	P=0.580N	P=0.580N	P=0.580N	P=0.668
COCH-ARM / FISHERS	P=0.346	P=0.600N	P=0.600N	P=0.600N	P=0.600N	P=0.650
MAX-ISO-POLY-3	P=0.277	P=0.229N	P=0.229N	P=0.229N	P=0.229N	P=0.395

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Lymph Node, Mesenteric Atrophy</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/15 (7%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/15.00	0/0.00	0/0.00	0/0.00	0/1.00	0/10.00
POLY-3 PERCENT (g)	6.7%	0%	0%	0%	0%	0%
TERMINAL (d)	1/15 (7%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
FIRST INCIDENCE	94 (T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.960N	P=0.580N
POLY 1.5	(e)	(e)	(e)	(e)	P=0.960N	P=0.580N
POLY 6	(e)	(e)	(e)	(e)	P=0.960N	P=0.580N
COCH-ARM / FISHERS	P=0.372N	(e)	(e)	(e)	P=0.937N	P=0.600N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.427N	P=0.229N



Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Lymph Node, Mesenteric Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL (a)	6/15 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	7/10 (70%)
POLY-3 RATE (b)	6/15.00	0/0.00	0/0.00	0/0.00	1/1.00	7/10.00
POLY-3 PERCENT (g)	40%	0%	0%	0%	100%	70%
TERMINAL (d)	6/15 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	7/10 (70%)
FIRST INCIDENCE	94 (T)	---	---	---	94 (T)	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.449	P=0.143
POLY 1.5	(e)	(e)	(e)	(e)	P=0.449	P=0.143
POLY 6	(e)	(e)	(e)	(e)	P=0.449	P=0.143
COCH-ARM / FISHERS	P=0.096	(e)	(e)	(e)	P=0.438	P=0.144
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.200	P=0.089

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Mesentery: Fat Necrosis</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)
POLY-3 RATE (b)	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	1/1.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	100%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
<b>STATISTICAL TESTS</b>						
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)

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Nose: Nerve Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/15.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/15 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.418
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.418
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.418
COCH-ARM / FISHERS	P=0.233	(e)	(e)	(e)	(e)	P=0.400
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.128

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

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

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Nose: Respiratory Epithelium Inflammation</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/15.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/15 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.418
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.418
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.418
COCH-ARM / FISHERS	P=0.233	(e)	(e)	(e)	(e)	P=0.400
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.128

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

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

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Ovary: Periovarian Tissue Cyst</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/15 (7%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/15.00	0/10.00	0/10.00	1/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	6.7%	0%	0%	10%	0%	0%
TERMINAL (d)	1/15 (7%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	94 (T)	---	---	94 (T)	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.456N	P=0.580N	P=0.580N	P=0.668	P=0.580N	P=0.580N
POLY 1.5	P=0.456N	P=0.580N	P=0.580N	P=0.668	P=0.580N	P=0.580N
POLY 6	P=0.456N	P=0.580N	P=0.580N	P=0.668	P=0.580N	P=0.580N
COCH-ARM / FISHERS	P=0.455N	P=0.600N	P=0.600N	P=0.650	P=0.600N	P=0.600N
MAX-ISO-POLY-3	P=0.369N	P=0.229N	P=0.229N	P=0.395	P=0.229N	P=0.229N

Experiment Number: 20306 - 03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

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

Date Report Requested: 08/27/2015  
 Time Report Requested: 10:28:05  
 First Dose M/F: NA / 10/13/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Pancreas</b>						
<b>Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	7/15 (47%)	5/10 (50%)	0/10 (0%)	5/10 (50%)	4/10 (40%)	5/10 (50%)
<b>POLY-3 RATE (b)</b>	7/15.00	5/10.00	0/10.00	5/10.00	4/10.00	5/10.00
<b>POLY-3 PERCENT (g)</b>	46.7%	50%	0%	50%	40%	50%
<b>TERMINAL (d)</b>	7/15 (47%)	5/10 (50%)	0/10 (0%)	5/10 (50%)	4/10 (40%)	5/10 (50%)
<b>FIRST INCIDENCE</b>	94 (T)	94 (T)	---	94 (T)	94 (T)	94 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.279	P=0.593	P=0.010N**	P=0.593	P=0.532N	P=0.593
<b>POLY 1.5</b>	P=0.279	P=0.593	P=0.010N**	P=0.593	P=0.532N	P=0.593
<b>POLY 6</b>	P=0.279	P=0.593	P=0.010N**	P=0.593	P=0.532N	P=0.593
<b>COCH-ARM / FISHERS</b>	P=0.282	P=0.596	P=0.013N*	P=0.596	P=0.534N	P=0.596
<b>MAX-ISO-POLY-3</b>	P=0.430	P=0.442	P=0.005N**	P=0.442	P=0.386N	P=0.442

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Pancreas: Acinus</b>						
<b>Atrophy Focal</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/15.00	2/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	20%	0%	0%	0%	0%
TERMINAL (d)	0/15 (0%)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	94 (T)	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.265N	P=0.139	(e)	(e)	(e)	(e)
POLY 1.5	P=0.265N	P=0.139	(e)	(e)	(e)	(e)
POLY 6	P=0.265N	P=0.139	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.274N	P=0.150	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.256N	P=0.045*	(e)	(e)	(e)	(e)

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Spleen</b>						
<b>Hematopoietic Cell Proliferation</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	1/10 (10%)	2/10 (20%)	1/10 (10%)	1/10 (10%)	1/10 (10%)
POLY-3 RATE (b)	0/15.00	1/10.00	2/10.00	1/10.00	1/10.00	1/10.00
POLY-3 PERCENT (g)	0%	10%	20%	10%	10%	10%
TERMINAL (d)	0/15 (0%)	1/10 (10%)	2/10 (20%)	1/10 (10%)	1/10 (10%)	1/10 (10%)
FIRST INCIDENCE	---	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.529	P=0.418	P=0.139	P=0.418	P=0.418	P=0.418
POLY 1.5	P=0.529	P=0.418	P=0.139	P=0.418	P=0.418	P=0.418
POLY 6	P=0.529	P=0.418	P=0.139	P=0.418	P=0.418	P=0.418
COCH-ARM / FISHERS	P=0.530	P=0.400	P=0.150	P=0.400	P=0.400	P=0.400
MAX-ISO-POLY-3	P=0.321	P=0.128	P=0.045*	P=0.128	P=0.128	P=0.128



Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

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

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Spleen</b>						
<b>Pigmentation Hemosiderin</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	15/15 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
<b>POLY-3 RATE (b)</b>	15/15.00	10/10.00	10/10.00	10/10.00	10/10.00	10/10.00
<b>POLY-3 PERCENT (g)</b>	100%	100%	100%	100%	100%	100%
<b>TERMINAL (d)</b>	15/15 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
<b>FIRST INCIDENCE</b>	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	(e)	(e)	(e)	(e)	(e)	(e)
<b>POLY 1.5</b>	(e)	(e)	(e)	(e)	(e)	(e)
<b>POLY 6</b>	(e)	(e)	(e)	(e)	(e)	(e)
<b>COCH-ARM / FISHERS</b>	(e)	(e)	(e)	(e)	(e)	(e)
<b>MAX-ISO-POLY-3</b>	(e)	(e)	(e)	(e)	(e)	(e)

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Spleen: Capsule Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/15.00	0/10.00	1/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	10%	0%	0%	0%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	94 (T)	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.525N	(e)	P=0.418	(e)	(e)	(e)
POLY 1.5	P=0.525N	(e)	P=0.418	(e)	(e)	(e)
POLY 6	P=0.525N	(e)	P=0.418	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.525N	(e)	P=0.400	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.552N	(e)	P=0.128	(e)	(e)	(e)

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Stomach, Forestomach Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/15 (7%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/15.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	6.7%	0%	0%	0%	0%	0%
TERMINAL (d)	1/15 (7%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	94 (T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.469N	P=0.580N	P=0.580N	P=0.580N	P=0.580N	P=0.580N
POLY 1.5	P=0.469N	P=0.580N	P=0.580N	P=0.580N	P=0.580N	P=0.580N
POLY 6	P=0.469N	P=0.580N	P=0.580N	P=0.580N	P=0.580N	P=0.580N
COCH-ARM / FISHERS	P=0.469N	P=0.600N	P=0.600N	P=0.600N	P=0.600N	P=0.600N
MAX-ISO-POLY-3	P=0.218N	P=0.229N	P=0.229N	P=0.229N	P=0.229N	P=0.229N

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Stomach, Glandular Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	4/15 (27%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	4/15.00	0/0.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	26.7%	0%	0%	0%	0%	30%
TERMINAL (d)	4/15 (27%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	94 (T)	---	---	---	---	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.603
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.603
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.603
COCH-ARM / FISHERS	P=0.518	(e)	(e)	(e)	(e)	P=0.601
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.436

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
Thymus Atrophy						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	5/10 (50%)	9/10 (90%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	1/10.00	5/10.00	9/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	50%	90%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	5/10 (50%)	9/10 (90%)
FIRST INCIDENCE	---	---	---	94 (T)	94 (T)	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	(e)	(e)	P=0.418	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	P=0.418	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	(e)	P=0.418	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.400	P=0.005**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.128	P<0.001**	P<0.001**

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Thyroid Gland Cyst</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/15 (0%)	1/10 (10%)	0/10 (0%)	3/10 (30%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/15.00	1/10.00	0/10.00	3/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	10%	0%	30%	0%	10%
TERMINAL (d)	0/15 (0%)	1/10 (10%)	0/10 (0%)	3/10 (30%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	94 (T)	---	94 (T)	---	94 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.437	P=0.418	(e)	P=0.040*	(e)	P=0.418
POLY 1.5	P=0.437	P=0.418	(e)	P=0.040*	(e)	P=0.418
POLY 6	P=0.437	P=0.418	(e)	P=0.040*	(e)	P=0.418
COCH-ARM / FISHERS	P=0.439	P=0.400	(e)	P=0.052	(e)	P=0.400
MAX-ISO-POLY-3	P=0.228	P=0.128	(e)	P=0.013*	(e)	P=0.128

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 NG/KG	1 NG/KG	10 NG/KG	50 NG/KG	100 NG/KG	200 NG/KG
<b>Urinary Bladder</b>						
<b>Infiltration Cellular Lymphocyte</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/15 (7%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/15.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	6.7%	0%	0%	0%	0%	0%
TERMINAL (d)	1/15 (7%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	94 (T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.580N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.580N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.580N
COCH-ARM / FISHERS	P=0.377N	(e)	(e)	(e)	(e)	P=0.600N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.229N

Experiment Number: 20306 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

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

PCN 66/67 comparison study

CAS Number: PCNCOMPARISN

Date Report Requested: 08/27/2015

Time Report Requested: 10:28:05

First Dose M/F: NA / 10/13/03

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.
  - (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 \*\*\*