

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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P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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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
Adrenal Cortex						
Infiltration Cellular Lymphocyte						
LESION RATES						
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)	---	---	---	---
STATISTICAL TESTS						
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
Adrenal Cortex						
Infiltration Cellular Mononuclear Cell						
LESION RATES						
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)	---
STATISTICAL TESTS						
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
Bone Marrow Inflammation Histiocytic						
LESION RATES						
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)
STATISTICAL TESTS						
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
Harderian Gland Infiltration Cellular Mononuclear Cell						
LESION RATES						
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)
STATISTICAL TESTS						
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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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
Heart						
Cardiomyopathy						
LESION RATES						
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)
STATISTICAL TESTS						
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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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
Intestine Small, Jejunum Inflammation Chronic						
LESION RATES						
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)
STATISTICAL TESTS						
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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 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
Kidney Mineralization						
LESION RATES						
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)
STATISTICAL TESTS						
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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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
Kidney Nephropathy						
LESION RATES						
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)
STATISTICAL TESTS						
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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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
Kidney: Cortex Cyst						
LESION RATES						
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)	---
STATISTICAL TESTS						
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
Liver						
Hepatocyte, Multinucleate						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	30%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
STATISTICAL TESTS						
POLY 3	P<0.001**	(e)	(e)	(e)	(e)	P=0.040*
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	P=0.040*
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	P=0.040*
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	P=0.052
MAX-ISO-POLY-3	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						
LESION RATES						
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)
STATISTICAL TESTS						
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
Liver						
Inflammation Chronic						
LESION RATES						
OVERALL (a)	7/15 (47%)	7/10 (70%)	8/10 (80%)	10/10 (100%)	9/10 (90%)	10/10 (100%)
POLY-3 RATE (b)	7/15.00	7/10.00	8/10.00	10/10.00	9/10.00	10/10.00
POLY-3 PERCENT (g)	46.7%	70%	80%	100%	90%	100%
TERMINAL (d)	7/15 (47%)	7/10 (70%)	8/10 (80%)	10/10 (100%)	9/10 (90%)	10/10 (100%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.002**	P=0.233	P=0.102	P=0.003**	P=0.028*	P=0.003**
POLY 1.5	P=0.002**	P=0.233	P=0.102	P=0.003**	P=0.028*	P=0.003**
POLY 6	P=0.002**	P=0.233	P=0.102	P=0.003**	P=0.028*	P=0.003**
COCH-ARM / FISHERS	P=0.005**	P=0.231	P=0.105	P=0.006**	P=0.034*	P=0.006**
MAX-ISO-POLY-3	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
Liver						
Inflammation Granulomatous						
LESION RATES						
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)
STATISTICAL TESTS						
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						
LESION RATES						
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)
STATISTICAL TESTS						
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
Liver						
Toxic Hepatopathy						
LESION RATES						
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)
STATISTICAL TESTS						
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
Liver: Hepatocyte Hypertrophy						
LESION RATES						
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)
STATISTICAL TESTS						
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
Lung						
Inflammation Chronic						
LESION RATES						
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)	---	---	---
STATISTICAL TESTS						
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
Lung						
Pigmentation Hemosiderin						
LESION RATES						
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)	---
STATISTICAL TESTS						
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
Lung: Alveolar Epithelium Hyperplasia						
LESION RATES						
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)
STATISTICAL TESTS						
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
Lung: Alveolus Infiltration Cellular Histiocyte						
LESION RATES						
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)
STATISTICAL TESTS						
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
Lung: Interstitium Inflammation Granulomatous						
LESION RATES						
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)
STATISTICAL TESTS						
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
Lymph Node, Mesenteric Atrophy						
LESION RATES						
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)	---	---	---	---	---
STATISTICAL TESTS						
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
Lymph Node, Mesenteric Infiltration Cellular Histiocyte						
LESION RATES						
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)
STATISTICAL TESTS						
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
Mesentery: Fat Necrosis						
LESION RATES						
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)
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)

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
Nose: Nerve Inflammation Chronic						
LESION RATES						
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)
STATISTICAL TESTS						
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
Nose: Respiratory Epithelium Inflammation						
LESION RATES						
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)
STATISTICAL TESTS						
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
Ovary: Periovarian Tissue Cyst						
LESION RATES						
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)	---	---
STATISTICAL TESTS						
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
Pancreas						
Infiltration Cellular Mononuclear Cell						
LESION RATES						
OVERALL (a)	7/15 (47%)	5/10 (50%)	0/10 (0%)	5/10 (50%)	4/10 (40%)	5/10 (50%)
POLY-3 RATE (b)	7/15.00	5/10.00	0/10.00	5/10.00	4/10.00	5/10.00
POLY-3 PERCENT (g)	46.7%	50%	0%	50%	40%	50%
TERMINAL (d)	7/15 (47%)	5/10 (50%)	0/10 (0%)	5/10 (50%)	4/10 (40%)	5/10 (50%)
FIRST INCIDENCE	94 (T)	94 (T)	---	94 (T)	94 (T)	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.279	P=0.593	P=0.010N**	P=0.593	P=0.532N	P=0.593
POLY 1.5	P=0.279	P=0.593	P=0.010N**	P=0.593	P=0.532N	P=0.593
POLY 6	P=0.279	P=0.593	P=0.010N**	P=0.593	P=0.532N	P=0.593
COCH-ARM / FISHERS	P=0.282	P=0.596	P=0.013N*	P=0.596	P=0.534N	P=0.596
MAX-ISO-POLY-3	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
Pancreas: Acinus						
Atrophy Focal						
LESION RATES						
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)	---	---	---	---
STATISTICAL TESTS						
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
Spleen						
Hematopoietic Cell Proliferation						
LESION RATES						
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)
STATISTICAL TESTS						
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
Spleen						
Pigmentation Hemosiderin						
LESION RATES						
OVERALL (a)	15/15 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	15/15.00	10/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	100%	100%	100%	100%	100%	100%
TERMINAL (d)	15/15 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)
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)

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
Spleen: Capsule Inflammation Chronic						
LESION RATES						
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)	---	---	---
STATISTICAL TESTS						
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
Stomach, Forestomach Infiltration Cellular Mononuclear Cell						
LESION RATES						
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)	---	---	---	---	---
STATISTICAL TESTS						
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
Stomach, Glandular Infiltration Cellular Mononuclear Cell						
LESION RATES						
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)
STATISTICAL TESTS						
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						
LESION RATES						
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)
STATISTICAL TESTS						
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
Thyroid Gland Cyst						
LESION RATES						
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)
STATISTICAL TESTS						
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
Urinary Bladder						
Infiltration Cellular Lymphocyte						
LESION RATES						
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)	---	---	---	---	---
STATISTICAL TESTS						
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 ***