

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: 09:31:49
First Dose M/F: NA / 10/13/03
Lab: BAT

F1_Rev.1_PCN66

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 002 1000 NG/KG 66 Include 003 10,000 NG/KG 66
Include 004 50,000 NG/KG 66 Include 005 100,000 NG/KG 66 Include 006 200,000 NG/KG 66

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

Blood Vessel: Aorta
Harderian Gland
Heart
Heart: Myocardium
Heart: Ventricle
Kidney

Liver

Liver: Bile Duct
Liver: Hepatocyte

Liver: Oval Cell
Liver: Portal Vein
Lung: Alveolus
Lymph Node, Mesenteric

Ovary
Thymus
Uterus

Morphology

Thrombus
Infiltration Cellular Mononuclear Cell
Cardiomyopathy
Inflammation
Thrombus
Mineralization
Nephropathy
Fatty Change
Hepatocyte, Multinucleate
Inflammation
Inflammation Chronic
Inflammation Granulomatous
Pigmentation
Toxic Hepatopathy
Hyperplasia
Degeneration
Glandular Structures
Hyperplasia
Hypertrophy
Hyperplasia
Fibrosis Focal
Infiltration Cellular Histiocyte
Atrophy
Infiltration Cellular Histiocyte
Atrophy
Atrophy
Atrophy

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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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Adrenal Cortex						
Infiltration Cellular Mixed Cell						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/9 (0%)
POLY-3 RATE (b)	0/15.00	0/10.00	1/10.00	0/10.00	0/10.00	0/8.79
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%)	0/8 (0%)
FIRST INCIDENCE	---	---	94 (T)	---	---	---
STATISTICAL TESTS						
POLY 3	P=0.535N	(e)	P=0.418	(e)	(e)	(e)
POLY 1.5	P=0.537N	(e)	P=0.418	(e)	(e)	(e)
POLY 6	P=0.532N	(e)	P=0.418	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.539N	(e)	P=0.400	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.576N	(e)	P=0.128	(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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Adrenal Cortex						
Inflammation Histiocytic						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/9 (0%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	1/10.00	0/8.79
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%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	94 (T)	---
STATISTICAL TESTS						
POLY 3	P=0.504	(e)	(e)	(e)	P=0.418	(e)
POLY 1.5	P=0.511	(e)	(e)	(e)	P=0.418	(e)
POLY 6	P=0.491	(e)	(e)	(e)	P=0.418	(e)
COCH-ARM / FISHERS	P=0.519	(e)	(e)	(e)	P=0.400	(e)
MAX-ISO-POLY-3	P=0.349	(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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Adrenal Cortex: Zona Fasciculata						
Vacuolization Cytoplasmic						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/9 (0%)
POLY-3 RATE (b)	0/15.00	0/10.00	1/10.00	0/10.00	0/10.00	0/8.79
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%)	0/8 (0%)
FIRST INCIDENCE	---	---	94 (T)	---	---	---
STATISTICAL TESTS						
POLY 3	P=0.535N	(e)	P=0.418	(e)	(e)	(e)
POLY 1.5	P=0.537N	(e)	P=0.418	(e)	(e)	(e)
POLY 6	P=0.532N	(e)	P=0.418	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.539N	(e)	P=0.400	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.576N	(e)	P=0.128	(e)	(e)	(e)

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Route: GAVAGE

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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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Blood Vessel: Aorta Thrombus						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/15.00	0/0.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	30%
TERMINAL (d)	0/15 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/8 (13%)
FIRST INCIDENCE	---	---	---	---	---	82
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.040*
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.040*
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.040*
COCH-ARM / FISHERS	P=0.026*	(e)	(e)	(e)	(e)	P=0.052
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.013*

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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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Blood Vessel: Pulmonary Artery Thrombus						
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	1/9.66
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10.4%
TERMINAL (d)	0/15 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	87
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.412
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.415
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.407
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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 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Harderian Gland Infiltration Cellular Mononuclear Cell						
LESION RATES						
OVERALL (a)	0/15 (0%)	1/10 (10%)	0/10 (0%)	2/10 (20%)	1/10 (10%)	8/10 (80%)
POLY-3 RATE (b)	0/15.00	1/10.00	0/10.00	2/10.00	1/10.00	8/9.66
POLY-3 PERCENT (g)	0%	10%	0%	20%	10%	82.8%
TERMINAL (d)	0/15 (0%)	1/10 (10%)	0/10 (0%)	2/10 (20%)	1/10 (10%)	7/8 (88%)
FIRST INCIDENCE	---	94 (T)	---	94 (T)	94 (T)	87
STATISTICAL TESTS						
POLY 3	P<0.001**	P=0.418	(e)	P=0.139	P=0.418	P<0.001**
POLY 1.5	P<0.001**	P=0.418	(e)	P=0.139	P=0.418	P<0.001**
POLY 6	P<0.001**	P=0.418	(e)	P=0.139	P=0.418	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.400	(e)	P=0.150	P=0.400	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.128	(e)	P=0.045*	P=0.128	P<0.001**

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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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Harderian Gland: Duct Metaplasia						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	1/9.46
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10.6%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/8 (13%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.086	(e)	(e)	(e)	(e)	P=0.407
POLY 1.5	P=0.088	(e)	(e)	(e)	(e)	P=0.412
POLY 6	P=0.083	(e)	(e)	(e)	(e)	P=0.399
COCH-ARM / FISHERS	P=0.089	(e)	(e)	(e)	(e)	P=0.400
MAX-ISO-POLY-3	P=0.064	(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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Heart						
Cardiomyopathy						
LESION RATES						
OVERALL (a)	9/15 (60%)	8/10 (80%)	7/10 (70%)	7/10 (70%)	4/10 (40%)	4/10 (40%)
POLY-3 RATE (b)	9/15.00	8/10.00	7/10.00	7/10.00	4/10.00	4/9.46
POLY-3 PERCENT (g)	60%	80%	70%	70%	40%	42.3%
TERMINAL (d)	9/15 (60%)	8/10 (80%)	7/10 (70%)	7/10 (70%)	4/10 (40%)	4/8 (50%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.054N	P=0.274	P=0.467	P=0.467	P=0.288N	P=0.334N
POLY 1.5	P=0.047N*	P=0.274	P=0.467	P=0.467	P=0.288N	P=0.312N
POLY 6	P=0.066N	P=0.274	P=0.467	P=0.467	P=0.288N	P=0.372N
COCH-ARM / FISHERS	P=0.040N*	P=0.274	P=0.470	P=0.470	P=0.284N	P=0.284N
MAX-ISO-POLY-3	P=0.099N	P=0.173	P=0.326	P=0.326	P=0.189N	P=0.227N

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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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Heart: Myocardium Inflammation						
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%)	1/8 (13%)
FIRST INCIDENCE	---	---	---	---	---	82
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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Heart: Valve Thrombus						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	1/9.46
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10.6%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/8 (13%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.086	(e)	(e)	(e)	(e)	P=0.407
POLY 1.5	P=0.088	(e)	(e)	(e)	(e)	P=0.412
POLY 6	P=0.083	(e)	(e)	(e)	(e)	P=0.399
COCH-ARM / FISHERS	P=0.089	(e)	(e)	(e)	(e)	P=0.400
MAX-ISO-POLY-3	P=0.064	(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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Heart: Ventricle Thrombus						
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	2/9.79
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20.4%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/8 (13%)
FIRST INCIDENCE	---	---	---	---	---	82
STATISTICAL TESTS						
POLY 3	P=0.005**	(e)	(e)	(e)	(e)	P=0.135
POLY 1.5	P=0.005**	(e)	(e)	(e)	(e)	P=0.137
POLY 6	P=0.005**	(e)	(e)	(e)	(e)	P=0.132
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*

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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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Intestine Large, Colon: Serosa Cyst						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/15.00	0/0.00	0/0.00	1/1.00	0/0.00	0/9.46
POLY-3 PERCENT (g)	0%	0%	0%	100%	0%	0%
TERMINAL (d)	0/15 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	94 (T)	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	P=0.062	(e)	(e)
POLY 1.5	(e)	(e)	(e)	P=0.062	(e)	(e)
POLY 6	(e)	(e)	(e)	P=0.062	(e)	(e)
COCH-ARM / FISHERS	P=0.589N	(e)	(e)	P=0.062	(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: 09:31:49
 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Kidney Mineralization						
LESION RATES						
OVERALL (a)	15/15 (100%)	7/10 (70%)	10/10 (100%)	7/10 (70%)	5/10 (50%)	7/9 (78%)
POLY-3 RATE (b)	15/15.00	7/10.00	10/10.00	7/10.00	5/10.00	7/9.00
POLY-3 PERCENT (g)	100%	70%	100%	70%	50%	77.8%
TERMINAL (d)	15/15 (100%)	7/10 (70%)	10/10 (100%)	7/10 (70%)	5/10 (50%)	6/8 (75%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	87
STATISTICAL TESTS						
POLY 3	P=0.068N	P=0.040N*	(e)	P=0.040N*	P<0.001N**	P=0.117N
POLY 1.5	P=0.068N	P=0.040N*	(e)	P=0.040N*	P<0.001N**	P=0.117N
POLY 6	P=0.068N	P=0.040N*	(e)	P=0.040N*	P<0.001N**	P=0.117N
COCH-ARM / FISHERS	P=0.081N	P=0.052N	(e)	P=0.052N	P=0.005N**	P=0.130N
MAX-ISO-POLY-3	P=0.034N*	P=0.013N*	(e)	P=0.013N*	P<0.001N**	P=0.038N*

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: 09:31:49
 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Kidney						
Nephropathy						
LESION RATES						
OVERALL (a)	2/15 (13%)	1/10 (10%)	1/10 (10%)	3/10 (30%)	4/10 (40%)	4/9 (44%)
POLY-3 RATE (b)	2/15.00	1/10.00	1/10.00	3/10.00	4/10.00	4/8.79
POLY-3 PERCENT (g)	13.3%	10%	10%	30%	40%	45.5%
TERMINAL (d)	2/15 (13%)	1/10 (10%)	1/10 (10%)	3/10 (30%)	4/10 (40%)	4/8 (50%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.012*	P=0.641N	P=0.641N	P=0.309	P=0.145	P=0.100
POLY 1.5	P=0.013*	P=0.641N	P=0.641N	P=0.309	P=0.145	P=0.103
POLY 6	P=0.011*	P=0.641N	P=0.641N	P=0.309	P=0.145	P=0.094
COCH-ARM / FISHERS	P=0.014*	P=0.654N	P=0.654N	P=0.301	P=0.147	P=0.113
MAX-ISO-POLY-3	P=0.022*	P=0.413N	P=0.413N	P=0.180	P=0.079	P=0.057

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver						
Clear Cell Focus						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/9 (0%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	1/10.00	0/8.79
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%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	94 (T)	---
STATISTICAL TESTS						
POLY 3	P=0.504	(e)	(e)	(e)	P=0.418	(e)
POLY 1.5	P=0.511	(e)	(e)	(e)	P=0.418	(e)
POLY 6	P=0.491	(e)	(e)	(e)	P=0.418	(e)
COCH-ARM / FISHERS	P=0.519	(e)	(e)	(e)	P=0.400	(e)
MAX-ISO-POLY-3	P=0.349	(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: 09:31:49
 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver						
Fatty Change						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	7/10 (70%)	9/9 (100%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	1/10.00	7/10.00	9/9.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	70%	100%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	7/10 (70%)	8/8 (100%)
FIRST INCIDENCE	---	---	---	94 (T)	94 (T)	87
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<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.128	P<0.001**	(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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver						
Hematopoietic Cell Proliferation						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/9 (11%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	1/8.79
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	11.4%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/8 (13%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.077	(e)	(e)	(e)	(e)	P=0.392
POLY 1.5	P=0.078	(e)	(e)	(e)	(e)	P=0.394
POLY 6	P=0.076	(e)	(e)	(e)	(e)	P=0.388
COCH-ARM / FISHERS	P=0.079	(e)	(e)	(e)	(e)	P=0.375
MAX-ISO-POLY-3	P=0.052	(e)	(e)	(e)	(e)	P=0.120

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver						
Hepatocyte, Multinucleate						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	10/10 (100%)	9/9 (100%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	10/10.00	9/9.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	100%	100%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	10/10 (100%)	8/8 (100%)
FIRST INCIDENCE	---	---	---	---	94 (T)	87
STATISTICAL TESTS						
POLY 3	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P<0.001**	(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: 09:31:49
 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver						
Hepatodiaphragmatic Nodule						
LESION RATES						
OVERALL (a)	1/15 (7%)	2/10 (20%)	3/10 (30%)	1/10 (10%)	1/10 (10%)	2/9 (22%)
POLY-3 RATE (b)	1/15.00	2/10.00	3/10.00	1/10.00	1/10.00	2/8.79
POLY-3 PERCENT (g)	6.7%	20%	30%	10%	10%	22.8%
TERMINAL (d)	1/15 (7%)	2/10 (20%)	3/10 (30%)	1/10 (10%)	1/10 (10%)	2/8 (25%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.493	P=0.356	P=0.156	P=0.668	P=0.668	P=0.311
POLY 1.5	P=0.497	P=0.356	P=0.156	P=0.668	P=0.668	P=0.315
POLY 6	P=0.486	P=0.356	P=0.156	P=0.668	P=0.668	P=0.305
COCH-ARM / FISHERS	P=0.502	P=0.346	P=0.159	P=0.650	P=0.650	P=0.308
MAX-ISO-POLY-3	P=0.342	P=0.184	P=0.075	P=0.395	P=0.395	P=0.160

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver Inflammation						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/9 (33%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	3/8.79
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	34.1%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/8 (38%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
STATISTICAL TESTS						
POLY 3	P<0.001**	(e)	(e)	(e)	(e)	P=0.025*
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	P=0.026*
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	P=0.024*
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	P=0.042*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	P=0.009**

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: 09:31:49
 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver						
Inflammation Chronic						
LESION RATES						
OVERALL (a)	7/15 (47%)	6/10 (60%)	8/10 (80%)	9/10 (90%)	9/10 (90%)	8/9 (89%)
POLY-3 RATE (b)	7/15.00	6/10.00	8/10.00	9/10.00	9/10.00	8/8.79
POLY-3 PERCENT (g)	46.7%	60%	80%	90%	90%	91%
TERMINAL (d)	7/15 (47%)	6/10 (60%)	8/10 (80%)	9/10 (90%)	9/10 (90%)	8/8 (100%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.014*	P=0.406	P=0.102	P=0.028*	P=0.028*	P=0.033*
POLY 1.5	P=0.016*	P=0.406	P=0.102	P=0.028*	P=0.028*	P=0.037*
POLY 6	P=0.010**	P=0.406	P=0.102	P=0.028*	P=0.028*	P=0.026*
COCH-ARM / FISHERS	P=0.024*	P=0.404	P=0.105	P=0.034*	P=0.034*	P=0.048*
MAX-ISO-POLY-3	P=0.025*	P=0.282	P=0.061	P=0.015*	P=0.015*	P=0.020*

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: 09:31:49
 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver						
Inflammation Granulomatous						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	8/10 (80%)	0/9 (0%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	8/10.00	0/8.79
POLY-3 PERCENT (g)	0%	0%	0%	0%	80%	0%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	8/10 (80%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	94 (T)	---
STATISTICAL TESTS						
POLY 3	P<0.001**	(e)	(e)	(e)	P<0.001**	(e)
POLY 1.5	P<0.001**	(e)	(e)	(e)	P<0.001**	(e)
POLY 6	P<0.001**	(e)	(e)	(e)	P<0.001**	(e)
COCH-ARM / FISHERS	P=0.038*	(e)	(e)	(e)	P<0.001**	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	P<0.001**	(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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver						
Necrosis Focal						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/9 (0%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	1/10.00	0/8.79
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%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	94 (T)	---
STATISTICAL TESTS						
POLY 3	P=0.504	(e)	(e)	(e)	P=0.418	(e)
POLY 1.5	P=0.511	(e)	(e)	(e)	P=0.418	(e)
POLY 6	P=0.491	(e)	(e)	(e)	P=0.418	(e)
COCH-ARM / FISHERS	P=0.519	(e)	(e)	(e)	P=0.400	(e)
MAX-ISO-POLY-3	P=0.349	(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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver Pigmentation						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	4/9 (44%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	1/10.00	0/10.00	4/8.79
POLY-3 PERCENT (g)	0%	0%	0%	10%	0%	45.5%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	4/8 (50%)
FIRST INCIDENCE	---	---	---	94 (T)	---	94 (T)
STATISTICAL TESTS						
POLY 3	P<0.001**	(e)	(e)	P=0.418	(e)	P=0.003**
POLY 1.5	P<0.001**	(e)	(e)	P=0.418	(e)	P=0.004**
POLY 6	P<0.001**	(e)	(e)	P=0.418	(e)	P=0.003**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.400	(e)	P=0.012*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.128	(e)	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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver						
Toxic Hepatopathy						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	8/10 (80%)	9/9 (100%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	8/10.00	9/9.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	80%	100%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	8/10 (80%)	8/8 (100%)
FIRST INCIDENCE	---	---	---	---	94 (T)	87
STATISTICAL TESTS						
POLY 3	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	P<0.001**	(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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver: Bile Duct Cyst						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/9 (11%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	1/8.79
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	11.4%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/8 (13%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.077	(e)	(e)	(e)	(e)	P=0.392
POLY 1.5	P=0.078	(e)	(e)	(e)	(e)	P=0.394
POLY 6	P=0.076	(e)	(e)	(e)	(e)	P=0.388
COCH-ARM / FISHERS	P=0.079	(e)	(e)	(e)	(e)	P=0.375
MAX-ISO-POLY-3	P=0.052	(e)	(e)	(e)	(e)	P=0.120

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver: Bile Duct Hyperplasia						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/9 (67%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	6/8.79
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	68.2%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/8 (75%)
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**

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver: Hepatocyte Degeneration						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	4/9 (44%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	4/8.79
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	45.5%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	4/8 (50%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
STATISTICAL TESTS						
POLY 3	P<0.001**	(e)	(e)	(e)	(e)	P=0.003**
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	P=0.004**
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	P=0.003**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	P=0.012*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver: Hepatocyte Glandular Structures						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	5/9 (56%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	5/8.79
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	56.9%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	5/8 (63%)
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=0.003**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver: Hepatocyte Hyperplasia						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/9 (67%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	6/8.79
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	68.2%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/8 (75%)
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**

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver: Hepatocyte Hypertrophy						
LESION RATES						
OVERALL (a)	1/15 (7%)	0/10 (0%)	0/10 (0%)	4/10 (40%)	10/10 (100%)	9/9 (100%)
POLY-3 RATE (b)	1/15.00	0/10.00	0/10.00	4/10.00	10/10.00	9/9.00
POLY-3 PERCENT (g)	6.7%	0%	0%	40%	100%	100%
TERMINAL (d)	1/15 (7%)	0/10 (0%)	0/10 (0%)	4/10 (40%)	10/10 (100%)	8/8 (100%)
FIRST INCIDENCE	94 (T)	---	---	94 (T)	94 (T)	87
STATISTICAL TESTS						
POLY 3	P<0.001**	P=0.580N	P=0.580N	P=0.054	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.580N	P=0.580N	P=0.054	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.580N	P=0.580N	P=0.054	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.600N	P=0.600N	P=0.064	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.229N	P=0.229N	P=0.025*	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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver: Oval Cell Hyperplasia						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	8/9 (89%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	8/9.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	88.9%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	7/8 (88%)
FIRST INCIDENCE	---	---	---	---	---	87
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**

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: 09:31:49
 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Liver: Portal Vein						
Fibrosis Focal						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/9 (22%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	2/8.79
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	22.8%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/8 (25%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.003**	(e)	(e)	(e)	(e)	P=0.113
POLY 1.5	P=0.003**	(e)	(e)	(e)	(e)	P=0.115
POLY 6	P=0.003**	(e)	(e)	(e)	(e)	P=0.110
COCH-ARM / FISHERS	P=0.006**	(e)	(e)	(e)	(e)	P=0.130
MAX-ISO-POLY-3	P=0.004**	(e)	(e)	(e)	(e)	P=0.038*

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Lung						
Inflammation Chronic						
LESION RATES						
OVERALL (a)	0/15 (0%)	1/10 (10%)	1/10 (10%)	1/10 (10%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/15.00	1/10.00	1/10.00	1/10.00	1/10.00	0/9.46
POLY-3 PERCENT (g)	0%	10%	10%	10%	10%	0%
TERMINAL (d)	0/15 (0%)	1/10 (10%)	1/10 (10%)	1/10 (10%)	1/10 (10%)	0/8 (0%)
FIRST INCIDENCE	---	94 (T)	94 (T)	94 (T)	94 (T)	---
STATISTICAL TESTS						
POLY 3	P=0.484N	P=0.418	P=0.418	P=0.418	P=0.418	(e)
POLY 1.5	P=0.477N	P=0.418	P=0.418	P=0.418	P=0.418	(e)
POLY 6	P=0.494N	P=0.418	P=0.418	P=0.418	P=0.418	(e)
COCH-ARM / FISHERS	P=0.468N	P=0.400	P=0.400	P=0.400	P=0.400	(e)
MAX-ISO-POLY-3	P=0.451	P=0.128	P=0.128	P=0.128	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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Lung Metaplasia						
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	0/9.46
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%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	94 (T)	---
STATISTICAL TESTS						
POLY 3	P=0.495	(e)	(e)	(e)	P=0.418	(e)
POLY 1.5	P=0.512	(e)	(e)	(e)	P=0.418	(e)
POLY 6	P=0.467	(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=0.352	(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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Lung: Alveolar Epithelium Hyperplasia						
LESION RATES						
OVERALL (a)	1/15 (7%)	2/10 (20%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/15.00	2/10.00	1/10.00	1/10.00	0/10.00	0/9.46
POLY-3 PERCENT (g)	6.7%	20%	10%	10%	0%	0%
TERMINAL (d)	1/15 (7%)	2/10 (20%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	0/8 (0%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	---	---
STATISTICAL TESTS						
POLY 3	P=0.145N	P=0.356	P=0.668	P=0.668	P=0.580N	P=0.591N
POLY 1.5	P=0.144N	P=0.356	P=0.668	P=0.668	P=0.580N	P=0.586N
POLY 6	P=0.147N	P=0.356	P=0.668	P=0.668	P=0.580N	P=0.598N
COCH-ARM / FISHERS	P=0.138N	P=0.346	P=0.650	P=0.650	P=0.600N	P=0.600N
MAX-ISO-POLY-3	P=0.269N	P=0.184	P=0.395	P=0.395	P=0.229N	P=0.241N

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: 09:31:49
 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Lung: Alveolus Infiltration Cellular Histiocyte						
LESION RATES						
OVERALL (a)	3/15 (20%)	2/10 (20%)	2/10 (20%)	3/10 (30%)	6/10 (60%)	6/10 (60%)
POLY-3 RATE (b)	3/15.00	2/10.00	2/10.00	3/10.00	6/10.00	6/9.46
POLY-3 PERCENT (g)	20%	20%	20%	30%	60%	63.5%
TERMINAL (d)	3/15 (20%)	2/10 (20%)	2/10 (20%)	3/10 (30%)	6/10 (60%)	6/8 (75%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.002**	P=0.688	P=0.688	P=0.463	P=0.045*	P=0.032*
POLY 1.5	P=0.003**	P=0.688	P=0.688	P=0.463	P=0.045*	P=0.038*
POLY 6	P=0.002**	P=0.688	P=0.688	P=0.463	P=0.045*	P=0.025*
COCH-ARM / FISHERS	P=0.005**	P=0.687	P=0.687	P=0.455	P=0.053	P=0.053
MAX-ISO-POLY-3	P=0.004**	P=1.000	P=1.000	P=0.306	P=0.025*	P=0.019*

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: 09:31:49
 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Lung: Interstitium Inflammation Granulomatous						
LESION RATES						
OVERALL (a)	1/15 (7%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/15.00	0/10.00	0/10.00	0/10.00	1/10.00	0/9.46
POLY-3 PERCENT (g)	6.7%	0%	0%	0%	10%	0%
TERMINAL (d)	1/15 (7%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/8 (0%)
FIRST INCIDENCE	94 (T)	---	---	---	94 (T)	---
STATISTICAL TESTS						
POLY 3	P=0.659N	P=0.580N	P=0.580N	P=0.580N	P=0.668	P=0.591N
POLY 1.5	P=0.655N	P=0.580N	P=0.580N	P=0.580N	P=0.668	P=0.586N
POLY 6	P=0.664N	P=0.580N	P=0.580N	P=0.580N	P=0.668	P=0.598N
COCH-ARM / FISHERS	P=0.654N	P=0.600N	P=0.600N	P=0.600N	P=0.650	P=0.600N
MAX-ISO-POLY-3	P=0.393N	P=0.229N	P=0.229N	P=0.229N	P=0.395	P=0.241N

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: 09:31:49
 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Lymph Node, Mesenteric Atrophy						
LESION RATES						
OVERALL (a)	1/15 (7%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	4/9 (44%)
POLY-3 RATE (b)	1/15.00	0/10.00	0/10.00	1/10.00	0/10.00	4/8.79
POLY-3 PERCENT (g)	6.7%	0%	0%	10%	0%	45.5%
TERMINAL (d)	1/15 (7%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	4/8 (50%)
FIRST INCIDENCE	94 (T)	---	---	94 (T)	---	94 (T)
STATISTICAL TESTS						
POLY 3	P<0.001**	P=0.580N	P=0.580N	P=0.668	P=0.580N	P=0.032*
POLY 1.5	P<0.001**	P=0.580N	P=0.580N	P=0.668	P=0.580N	P=0.034*
POLY 6	P<0.001**	P=0.580N	P=0.580N	P=0.668	P=0.580N	P=0.030*
COCH-ARM / FISHERS	P<0.001**	P=0.600N	P=0.600N	P=0.650	P=0.600N	P=0.047*
MAX-ISO-POLY-3	P<0.001**	P=0.229N	P=0.229N	P=0.395	P=0.229N	P=0.016*

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Lymph Node, Mesenteric Hyperplasia Lymphoid						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/9 (0%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	1/10.00	0/8.79
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%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	94 (T)	---
STATISTICAL TESTS						
POLY 3	P=0.504	(e)	(e)	(e)	P=0.418	(e)
POLY 1.5	P=0.511	(e)	(e)	(e)	P=0.418	(e)
POLY 6	P=0.491	(e)	(e)	(e)	P=0.418	(e)
COCH-ARM / FISHERS	P=0.519	(e)	(e)	(e)	P=0.400	(e)
MAX-ISO-POLY-3	P=0.349	(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: 09:31:49
 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Lymph Node, Mesenteric Infiltration Cellular Histiocyte						
LESION RATES						
OVERALL (a)	6/15 (40%)	6/10 (60%)	6/10 (60%)	5/10 (50%)	9/10 (90%)	3/9 (33%)
POLY-3 RATE (b)	6/15.00	6/10.00	6/10.00	5/10.00	9/10.00	3/8.79
POLY-3 PERCENT (g)	40%	60%	60%	50%	90%	34.1%
TERMINAL (d)	6/15 (40%)	6/10 (60%)	6/10 (60%)	5/10 (50%)	9/10 (90%)	3/8 (38%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.534N	P=0.288	P=0.288	P=0.468	P=0.011*	P=0.558N
POLY 1.5	P=0.519N	P=0.288	P=0.288	P=0.468	P=0.011*	P=0.550N
POLY 6	P=0.559N	P=0.288	P=0.288	P=0.468	P=0.011*	P=0.571N
COCH-ARM / FISHERS	P=0.502N	P=0.284	P=0.284	P=0.466	P=0.016*	P=0.547N
MAX-ISO-POLY-3	P=0.283N	P=0.189	P=0.189	P=0.332	P=0.006**	P=0.404N

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Lymph Node, Mesenteric Infiltration Cellular Plasma Cell						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/9 (11%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	1/8.79
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	11.4%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/8 (13%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.077	(e)	(e)	(e)	(e)	P=0.392
POLY 1.5	P=0.078	(e)	(e)	(e)	(e)	P=0.394
POLY 6	P=0.076	(e)	(e)	(e)	(e)	P=0.388
COCH-ARM / FISHERS	P=0.079	(e)	(e)	(e)	(e)	P=0.375
MAX-ISO-POLY-3	P=0.052	(e)	(e)	(e)	(e)	P=0.120

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: 09:31:49
 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Mesentery: Fat Necrosis						
LESION RATES						
OVERALL (a)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	0/0.00	1/1.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	100%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Ovary Atrophy						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	9/9 (100%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	9/9.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	100%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	8/8 (100%)
FIRST INCIDENCE	---	---	---	---	---	87
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	(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: 09:31:49
 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Ovary: Periovarian Tissue Cyst						
LESION RATES						
OVERALL (a)	1/15 (7%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)
POLY-3 RATE (b)	1/15.00	0/10.00	0/10.00	0/10.00	0/10.00	0/8.79
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%)	0/8 (0%)
FIRST INCIDENCE	94 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	P=0.477N	P=0.580N	P=0.580N	P=0.580N	P=0.580N	P=0.605N
POLY 1.5	P=0.479N	P=0.580N	P=0.580N	P=0.580N	P=0.580N	P=0.603N
POLY 6	P=0.473N	P=0.580N	P=0.580N	P=0.580N	P=0.580N	P=0.609N
COCH-ARM / FISHERS	P=0.481N	P=0.600N	P=0.600N	P=0.600N	P=0.600N	P=0.625N
MAX-ISO-POLY-3	P=0.255N	P=0.229N	P=0.229N	P=0.229N	P=0.229N	P=0.250N

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: 09:31:49
 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Pancreas						
Infiltration Cellular Mononuclear Cell						
LESION RATES						
OVERALL (a)	7/15 (47%)	5/10 (50%)	4/10 (40%)	6/10 (60%)	3/10 (30%)	6/9 (67%)
POLY-3 RATE (b)	7/15.00	5/10.00	4/10.00	6/10.00	3/10.00	6/8.79
POLY-3 PERCENT (g)	46.7%	50%	40%	60%	30%	68.2%
TERMINAL (d)	7/15 (47%)	5/10 (50%)	4/10 (40%)	6/10 (60%)	3/10 (30%)	6/8 (75%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.289	P=0.593	P=0.532N	P=0.406	P=0.343N	P=0.280
POLY 1.5	P=0.297	P=0.593	P=0.532N	P=0.406	P=0.343N	P=0.291
POLY 6	P=0.276	P=0.593	P=0.532N	P=0.406	P=0.343N	P=0.263
COCH-ARM / FISHERS	P=0.302	P=0.596	P=0.534N	P=0.404	P=0.341N	P=0.300
MAX-ISO-POLY-3	P=0.328	P=0.442	P=0.386N	P=0.282	P=0.229N	P=0.187

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Pancreas: Acinus						
Atrophy Focal						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/9 (0%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	1/10.00	0/8.79
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%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	94 (T)	---
STATISTICAL TESTS						
POLY 3	P=0.504	(e)	(e)	(e)	P=0.418	(e)
POLY 1.5	P=0.511	(e)	(e)	(e)	P=0.418	(e)
POLY 6	P=0.491	(e)	(e)	(e)	P=0.418	(e)
COCH-ARM / FISHERS	P=0.519	(e)	(e)	(e)	P=0.400	(e)
MAX-ISO-POLY-3	P=0.349	(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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Pancreas: Acinus						
Vacuolization Cytoplasmic						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/9 (11%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	1/8.79
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	11.4%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/8 (13%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.077	(e)	(e)	(e)	(e)	P=0.392
POLY 1.5	P=0.078	(e)	(e)	(e)	(e)	P=0.394
POLY 6	P=0.076	(e)	(e)	(e)	(e)	P=0.388
COCH-ARM / FISHERS	P=0.079	(e)	(e)	(e)	(e)	P=0.375
MAX-ISO-POLY-3	P=0.052	(e)	(e)	(e)	(e)	P=0.120

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Pituitary Gland 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	0/9.46
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%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	94 (T)	---
STATISTICAL TESTS						
POLY 3	P=0.495	(e)	(e)	(e)	P=0.418	(e)
POLY 1.5	P=0.512	(e)	(e)	(e)	P=0.418	(e)
POLY 6	P=0.467	(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=0.352	(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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Spleen						
Hematopoietic Cell Proliferation						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/9 (0%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	1/10.00	0/10.00	0/8.79
POLY-3 PERCENT (g)	0%	0%	0%	10%	0%	0%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	94 (T)	---	---
STATISTICAL TESTS						
POLY 3	P=0.751N	(e)	(e)	P=0.418	(e)	(e)
POLY 1.5	P=0.752N	(e)	(e)	P=0.418	(e)	(e)
POLY 6	P=0.751N	(e)	(e)	P=0.418	(e)	(e)
COCH-ARM / FISHERS	P=0.753N	(e)	(e)	P=0.400	(e)	(e)
MAX-ISO-POLY-3	P=0.517	(e)	(e)	P=0.128	(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: 09:31:49
 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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Spleen Pigmentation Hemosiderin						
LESION RATES						
OVERALL (a)	15/15 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	8/9 (89%)
POLY-3 RATE (b)	15/15.00	10/10.00	10/10.00	10/10.00	10/10.00	8/9.00
POLY-3 PERCENT (g)	100%	100%	100%	100%	100%	88.9%
TERMINAL (d)	15/15 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	7/8 (88%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	87
STATISTICAL TESTS						
POLY 3	P=0.078N	(e)	(e)	(e)	(e)	P=0.397N
POLY 1.5	P=0.078N	(e)	(e)	(e)	(e)	P=0.397N
POLY 6	P=0.078N	(e)	(e)	(e)	(e)	P=0.397N
COCH-ARM / FISHERS	P=0.079N	(e)	(e)	(e)	(e)	P=0.375N
MAX-ISO-POLY-3	P=0.052N	(e)	(e)	(e)	(e)	P=0.120N

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
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%)	0/9 (0%)
POLY-3 RATE (b)	1/15.00	0/10.00	0/10.00	0/10.00	0/10.00	0/8.79
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%)	0/8 (0%)
FIRST INCIDENCE	94 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	P=0.477N	P=0.580N	P=0.580N	P=0.580N	P=0.580N	P=0.605N
POLY 1.5	P=0.479N	P=0.580N	P=0.580N	P=0.580N	P=0.580N	P=0.603N
POLY 6	P=0.473N	P=0.580N	P=0.580N	P=0.580N	P=0.580N	P=0.609N
COCH-ARM / FISHERS	P=0.481N	P=0.600N	P=0.600N	P=0.600N	P=0.600N	P=0.625N
MAX-ISO-POLY-3	P=0.255N	P=0.229N	P=0.229N	P=0.229N	P=0.229N	P=0.250N

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Stomach, Forestomach: Epithelium Hyperplasia						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/9 (11%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	1/8.79
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	11.4%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/8 (13%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
STATISTICAL TESTS						
POLY 3	P=0.077	(e)	(e)	(e)	(e)	P=0.392
POLY 1.5	P=0.078	(e)	(e)	(e)	(e)	P=0.394
POLY 6	P=0.076	(e)	(e)	(e)	(e)	P=0.388
COCH-ARM / FISHERS	P=0.079	(e)	(e)	(e)	(e)	P=0.375
MAX-ISO-POLY-3	P=0.052	(e)	(e)	(e)	(e)	P=0.120

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
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%)	2/9 (22%)
POLY-3 RATE (b)	4/15.00	0/0.00	0/0.00	0/0.00	0/0.00	2/9.00
POLY-3 PERCENT (g)	26.7%	0%	0%	0%	0%	22.2%
TERMINAL (d)	4/15 (27%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/8 (13%)
FIRST INCIDENCE	94 (T)	---	---	---	---	87
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.592N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.592N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.592N
COCH-ARM / FISHERS	P=0.500N	(e)	(e)	(e)	(e)	P=0.603N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.417N

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Stomach, Glandular: Glands Ectasia						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/9 (11%)
POLY-3 RATE (b)	0/15.00	0/0.00	0/0.00	0/0.00	0/0.00	1/8.79
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	11.4%
TERMINAL (d)	0/15 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/8 (13%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.392
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.394
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.388
COCH-ARM / FISHERS	P=0.214	(e)	(e)	(e)	(e)	P=0.375
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.120

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Thymus Atrophy						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	2/10 (20%)	10/10 (100%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	1/10.00	2/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	20%	100%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	2/10 (20%)	8/8 (100%)
FIRST INCIDENCE	---	---	---	94 (T)	94 (T)	82
STATISTICAL TESTS						
POLY 3	P<0.001**	(e)	(e)	P=0.418	P=0.139	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	P=0.418	P=0.139	P<0.001**
POLY 6	P<0.001**	(e)	(e)	P=0.418	P=0.139	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.400	P=0.150	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.128	P=0.045*	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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Urinary Bladder						
Infiltration Cellular Lymphocyte						
LESION RATES						
OVERALL (a)	1/15 (7%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/9 (0%)
POLY-3 RATE (b)	1/15.00	0/0.00	0/0.00	0/0.00	0/0.00	0/8.79
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%)	0/8 (0%)
FIRST INCIDENCE	94 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.605N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.603N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.609N
COCH-ARM / FISHERS	P=0.396N	(e)	(e)	(e)	(e)	P=0.625N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.250N

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: 09:31:49

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	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66
Uterus Atrophy						
LESION RATES						
OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	9/9 (100%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	9/9.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	100%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	8/8 (100%)
FIRST INCIDENCE	---	---	---	---	---	87
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	(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

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Time Report Requested: 09:31:49

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 ***