

TDMS No. 20306-03
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 COMPARISON STUDY
CAS Number: PCNCOMPARISN
Pathologist: VASCONCELOS, D.
Final1 grps17891011

Date Report Reqsted: 12/13/2005
Time Report Reqsted: 9:08:56
First Dose M/F: NA / 10/13/03
Lab: BAT

C Number:	C20306		
Lock Date:	10/07/2004		
Cage Range:	1 - 9999		
Date Range:	1-JAN-1940 to 17-SEP-2040		
Reasons For Removal:	ALL		
Removal Date Range:	JAN /1 /1940 - SEP /17 /2040		
Treatment Groups:	Include 1 0 NG/KG	Include 7 1000 NG/KG 67	Include 8 10,000 NG/KG 67
	Include 9 50,000 NG/KG 67	Include 10 100,000 NG/KG 67	Include 11 200,000 NG/KG 67

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

FEMALE RATS

Organ

Kidney
Liver

Liver: Hepatocyte
Lymph Node, Mesenteric
Pancreas
Spleen
Thymus

Morphology

Mineralization
Fatty Change
Hepatocyte, Multinucleate
Inflammation Chronic
Toxic Hepatopathy
Hypertrophy
Infiltration Cellular Histiocyte
Infiltration Cellular Mononuclear Cell
Hematopoietic Cell Proliferation
Atrophy

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

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

**Heart
 Cardiomyopathy**

LESION RATES

OVERALL (a)	9/15 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	8/10 (80%)
POLY-3 RATE (b)	9/15.00	0/0.00	0/0.00	0/0.00	0/0.00	8/10.00
POLY-3 PERCENT (g)	60%	0%	0%	0%	0%	80%
TERMINAL (d)	9/15 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	8/10 (80%)
FIRST INCIDENCE	94 (T)	---	---	---	---	94 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.208	P=1.000	P=1.000	P=1.000	P=1.000	P=0.274
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.274
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.274
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.274
LOGISTIC REGRESSION	P=0.208	(e)	(e)	(e)	(e)	P=0.274
COCH-ARM / FISHERS	P=0.203	P=1.000	P=1.000	P=1.000	P=1.000	P=0.274
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)

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

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

**Kidney
 Mineralization**

LESION RATES

OVERALL (a)	15/15 (100%)	10/10 (100%)	9/10 (90%)	10/10 (100%)	6/10 (60%)	7/10 (70%)
POLY-3 RATE (b)	15/15.00	10/10.00	9/10.00	10/10.00	6/10.00	7/10.00
POLY-3 PERCENT (g)	100%	100%	90%	100%	60%	70%
TERMINAL (d)	15/15 (100%)	10/10 (100%)	9/10 (90%)	10/10 (100%)	6/10 (60%)	7/10 (70%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.003N**	(e)	P=0.419N	(e)	P=0.019N*	P=0.055N
POLY 3	P<0.001N**	(e)	P=0.418N	(e)	P=0.008N**	P=0.040N*
POLY 1.5	P<0.001N**	(e)	P=0.418N	(e)	P=0.008N**	P=0.040N*
POLY 6	P<0.001N**	(e)	P=0.418N	(e)	P=0.008N**	P=0.040N*
LOGISTIC REGRESSION	P=0.003N**	(e)	P=0.419N	(e)	P=0.019N*	P=0.055N
COCH-ARM / FISHERS	P=0.003N**	(e)	P=0.400N	(e)	P=0.017N*	P=0.052N
ORDER RESTRICTED	P=0.003N**	(e)	(e)	(e)	(e)	(e)

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

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

**Kidney
 Nephropathy**

LESION RATES

OVERALL (a)	2/15 (13%)	1/10 (10%)	4/10 (40%)	2/10 (20%)	3/10 (30%)	3/10 (30%)
POLY-3 RATE (b)	2/15.00	1/10.00	4/10.00	2/10.00	3/10.00	3/10.00
POLY-3 PERCENT (g)	13.3%	10%	40%	20%	30%	30%
TERMINAL (d)	2/15 (13%)	1/10 (10%)	4/10 (40%)	2/10 (20%)	3/10 (30%)	3/10 (30%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.257	P=0.644N	P=0.151	P=0.543	P=0.309	P=0.309
POLY 3	P=0.259	P=0.641N	P=0.145	P=0.543	P=0.309	P=0.309
POLY 1.5	P=0.259	P=0.641N	P=0.145	P=0.543	P=0.309	P=0.309
POLY 6	P=0.259	P=0.641N	P=0.145	P=0.543	P=0.309	P=0.309
LOGISTIC REGRESSION	P=0.257	P=0.644N	P=0.151	P=0.543	P=0.309	P=0.309
COCH-ARM / FISHERS	P=0.256	P=0.654N	P=0.147	P=0.532	P=0.301	P=0.301
ORDER RESTRICTED	P=0.252	(e)	(e)	(e)	(e)	(e)

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 Lab: BAT

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

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

Liver
 Fatty Change

LESION RATES

OVERALL (a)	0/15 (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

LIFE TABLE	P=0.008**	(e)	(e)	(e)	(e)	P=0.151
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
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.151
COCH-ARM / FISHERS	P=0.008**	(e)	(e)	(e)	(e)	P=0.150
ORDER RESTRICTED	P=0.002**	(e)	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 14 WEEKS**

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

Liver
 Hepatocyte, Multinucleate

LESION RATES

OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	9/10 (90%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	1/10.00	0/10.00	9/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	0%	90%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	9/10 (90%)
FIRST INCIDENCE	---	---	---	94 (T)	---	94 (T)

STATISTICAL TESTS

LIFE TABLE	P<0.001**	(e)	(e)	P=0.419	(e)	P<0.001**
POLY 3	P<0.001**	(e)	(e)	P=0.418	(e)	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	P=0.418	(e)	P<0.001**
POLY 6	P<0.001**	(e)	(e)	P=0.418	(e)	P<0.001**
LOGISTIC REGRESSION	(e)	(e)	(e)	P=0.419	(e)	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.400	(e)	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 14 WEEKS**

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

Liver
 Hepatodiaphragmatic Nodule

LESION RATES

OVERALL (a)	1/15 (7%)	1/10 (10%)	2/10 (20%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/15.00	1/10.00	2/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	6.7%	10%	20%	0%	0%	10%
TERMINAL (d)	1/15 (7%)	1/10 (10%)	2/10 (20%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	---	---	94 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.483N	P=0.671	P=0.356	P=0.581N	P=0.581N	P=0.671
POLY 3	P=0.483N	P=0.668	P=0.356	P=0.580N	P=0.580N	P=0.668
POLY 1.5	P=0.483N	P=0.668	P=0.356	P=0.580N	P=0.580N	P=0.668
POLY 6	P=0.483N	P=0.668	P=0.356	P=0.580N	P=0.580N	P=0.668
LOGISTIC REGRESSION	P=0.483N	P=0.671	P=0.356	(e)	(e)	P=0.671
COCH-ARM / FISHERS	P=0.482N	P=0.650	P=0.346	P=0.600N	P=0.600N	P=0.650
ORDER RESTRICTED	P=0.409N	(e)	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 14 WEEKS**

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

Liver
 Inflammation Chronic

LESION RATES

OVERALL (a)	7/15 (47%)	9/10 (90%)	9/10 (90%)	7/10 (70%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	7/15.00	9/10.00	9/10.00	7/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	46.7%	90%	90%	70%	100%	100%
TERMINAL (d)	7/15 (47%)	9/10 (90%)	9/10 (90%)	7/10 (70%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.013*	P=0.040*	P=0.040*	P=0.234	P=0.010**	P=0.010**
POLY 3	P=0.006**	P=0.028*	P=0.028*	P=0.233	P=0.003**	P=0.003**
POLY 1.5	P=0.006**	P=0.028*	P=0.028*	P=0.233	P=0.003**	P=0.003**
POLY 6	P=0.006**	P=0.028*	P=0.028*	P=0.233	P=0.003**	P=0.003**
LOGISTIC REGRESSION	P=0.013*	P=0.040*	P=0.040*	P=0.234	P=0.010**	P=0.010**
COCH-ARM / FISHERS	P=0.013*	P=0.034*	P=0.034*	P=0.231	P=0.006**	P=0.006**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)

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

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

Liver
 Toxic Hepatopathy

LESION RATES

OVERALL (a)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	9/10 (90%)
POLY-3 RATE (b)	0/15.00	0/10.00	0/10.00	0/10.00	0/10.00	9/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	90%
TERMINAL (d)	0/15 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	9/10 (90%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)

STATISTICAL TESTS

LIFE TABLE	P<0.001**	(e)	(e)	(e)	(e)	P<0.001**
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**
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 14 WEEKS**

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

Liver: Hepatocyte
 Hypertrophy

LESION RATES

OVERALL (a)	1/15 (7%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	10/10 (100%)
POLY-3 RATE (b)	1/15.00	0/10.00	0/10.00	0/10.00	1/10.00	10/10.00
POLY-3 PERCENT (g)	6.7%	0%	0%	0%	10%	100%
TERMINAL (d)	1/15 (7%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	10/10 (100%)
FIRST INCIDENCE	94 (T)	---	---	---	94 (T)	94 (T)

STATISTICAL TESTS

LIFE TABLE	P<0.001**	P=0.581N	P=0.581N	P=0.581N	P=0.671	P<0.001**
POLY 3	P<0.001**	P=0.580N	P=0.580N	P=0.580N	P=0.668	P<0.001**
POLY 1.5	P<0.001**	P=0.580N	P=0.580N	P=0.580N	P=0.668	P<0.001**
POLY 6	P<0.001**	P=0.580N	P=0.580N	P=0.580N	P=0.668	P<0.001**
LOGISTIC REGRESSION	P<0.001**	(e)	(e)	(e)	P=0.671	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.600N	P=0.600N	P=0.600N	P=0.650	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)

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

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

Lung: Alveolus
 Infiltration Cellular Histiocyte

LESION RATES

OVERALL (a)	3/15 (20%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	2/10 (20%)	2/10 (20%)
POLY-3 RATE (b)	3/15.00	1/10.00	1/10.00	0/10.00	2/10.00	2/10.00
POLY-3 PERCENT (g)	20%	10%	10%	0%	20%	20%
TERMINAL (d)	3/15 (20%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	2/10 (20%)	2/10 (20%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	---	94 (T)	94 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.379	P=0.457N	P=0.457N	P=0.194N	P=0.691	P=0.691
POLY 3	P=0.381	P=0.457N	P=0.457N	P=0.188N	P=0.688	P=0.688
POLY 1.5	P=0.381	P=0.457N	P=0.457N	P=0.188N	P=0.688	P=0.688
POLY 6	P=0.381	P=0.457N	P=0.457N	P=0.188N	P=0.688	P=0.688
LOGISTIC REGRESSION	P=0.379	P=0.457N	P=0.457N	(e)	P=0.691	P=0.691
COCH-ARM / FISHERS	P=0.378	P=0.468N	P=0.468N	P=0.198N	P=0.687	P=0.687
ORDER RESTRICTED	P=0.478	(e)	(e)	(e)	(e)	(e)

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 Route: GAVAGE
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 PCN 66/67 COMPARISON STUDY
 CAS Number: PCNCOMPARISN
 Pathologist: VASCONCELOS, D.

Date Report Reqsted: 12/13/2005
 Time Report Reqsted: 9:08:56
 First Dose M/F: NA / 10/13/03
 Lab: BAT

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

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

**Lymph Node, Mesenteric
 Atrophy**

LESION RATES

OVERALL (a)	1/15 (7%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	2/10 (20%)	1/10 (10%)
POLY-3 RATE (b)	1/15.00	0/0.00	0/0.00	0/10.00	2/10.00	1/10.00
POLY-3 PERCENT (g)	6.7%	0%	0%	0%	20%	10%
TERMINAL (d)	1/15 (7%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	2/10 (20%)	1/10 (10%)
FIRST INCIDENCE	94 (T)	---	---	---	94 (T)	94 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.394	P=1.000	P=1.000N	P=0.581N	P=0.356	P=0.671
POLY 3	(e)	(e)	(e)	P=0.580N	P=0.356	P=0.668
POLY 1.5	(e)	(e)	(e)	P=0.580N	P=0.356	P=0.668
POLY 6	(e)	(e)	(e)	P=0.580N	P=0.356	P=0.668
LOGISTIC REGRESSION	P=0.394	(e)	(e)	(e)	P=0.356	P=0.671
COCH-ARM / FISHERS	P=0.393	P=1.000	P=1.000	P=0.600N	P=0.346	P=0.650
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)

TDMS No. 20306-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 PCN 66/67 COMPARISON STUDY
 CAS Number: PCNCOMPARISN
 Pathologist: VASCONCELOS, D.

Date Report Reqsted: 12/13/2005
 Time Report Reqsted: 9:08:56
 First Dose M/F: NA / 10/13/03
 Lab: BAT

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

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

Lymph Node, Mesenteric
 Infiltration Cellular Histiocyte

LESION RATES

OVERALL (a)	6/15 (40%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)
POLY-3 RATE (b)	6/15.00	0/0.00	0/0.00	0/10.00	0/10.00	6/10.00
POLY-3 PERCENT (g)	40%	0%	0%	0%	0%	60%
TERMINAL (d)	6/15 (40%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)
FIRST INCIDENCE	94 (T)	---	---	---	---	94 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.168	P=1.000	P=1.000N	P=0.038N*	P=0.038N*	P=0.288
POLY 3	(e)	(e)	(e)	P=0.025N*	P=0.025N*	P=0.288
POLY 1.5	(e)	(e)	(e)	P=0.025N*	P=0.025N*	P=0.288
POLY 6	(e)	(e)	(e)	P=0.025N*	P=0.025N*	P=0.288
LOGISTIC REGRESSION	P=0.168	(e)	(e)	(e)	(e)	P=0.288
COCH-ARM / FISHERS	P=0.165	P=1.000	P=1.000	P=0.028N*	P=0.028N*	P=0.284
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)

TDMS No. 20306-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 PCN 66/67 COMPARISON STUDY
 CAS Number: PCNCOMPARISN
 Pathologist: VASCONCELOS, D.

Date Report Reqsted: 12/13/2005
 Time Report Reqsted: 9:08:56
 First Dose M/F: NA / 10/13/03
 Lab: BAT

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

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

**Pancreas
 Infiltration Cellular Mononuclear Cell**

LESION RATES

OVERALL (a)	7/15 (47%)	3/10 (30%)	6/10 (60%)	5/10 (50%)	9/10 (90%)	4/10 (40%)
POLY-3 RATE (b)	7/15.00	3/10.00	6/10.00	5/10.00	9/10.00	4/10.00
POLY-3 PERCENT (g)	46.7%	30%	60%	50%	90%	40%
TERMINAL (d)	7/15 (47%)	3/10 (30%)	6/10 (60%)	5/10 (50%)	9/10 (90%)	4/10 (40%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.397	P=0.342N	P=0.405	P=0.595	P=0.040*	P=0.532N
POLY 3	P=0.394	P=0.343N	P=0.406	P=0.593	P=0.028*	P=0.532N
POLY 1.5	P=0.394	P=0.343N	P=0.406	P=0.593	P=0.028*	P=0.532N
POLY 6	P=0.394	P=0.343N	P=0.406	P=0.593	P=0.028*	P=0.532N
LOGISTIC REGRESSION	P=0.397	P=0.342N	P=0.405	P=0.595	P=0.040*	P=0.532N
COCH-ARM / FISHERS	P=0.397	P=0.341N	P=0.404	P=0.596	P=0.034*	P=0.534N
ORDER RESTRICTED	P=0.171	(e)	(e)	(e)	(e)	(e)

TDMS No. 20306-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 PCN 66/67 COMPARISON STUDY
 CAS Number: PCNCOMPARISN
 Pathologist: VASCONCELOS, D.

Date Report Reqsted: 12/13/2005
 Time Report Reqsted: 9:08:56
 First Dose M/F: NA / 10/13/03
 Lab: BAT

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

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

**Spleen
 Hematopoietic Cell Proliferation**

LESION RATES

OVERALL (a)	0/15 (0%)	10/10 (100%)	9/10 (90%)	5/10 (50%)	6/10 (60%)	0/10 (0%)
POLY-3 RATE (b)	0/15.00	10/10.00	9/10.00	5/10.00	6/10.00	0/10.00
POLY-3 PERCENT (g)	0%	100%	90%	50%	60%	0%
TERMINAL (d)	0/15 (0%)	10/10 (100%)	9/10 (90%)	5/10 (50%)	6/10 (60%)	0/10 (0%)
FIRST INCIDENCE	---	94 (T)	94 (T)	94 (T)	94 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.010N**	P<0.001**	P<0.001**	P=0.006**	P=0.002**	(e)
POLY 3	P<0.001N**	P<0.001N**	P<0.001**	P<0.001**	P<0.001**	(e)
POLY 1.5	P<0.001N**	P<0.001N**	P<0.001**	P<0.001**	P<0.001**	(e)
POLY 6	P<0.001N**	P<0.001N**	P<0.001**	P<0.001**	P<0.001**	(e)
LOGISTIC REGRESSION	(e)	P<0.001**	P<0.001**	P=0.006**	P=0.002**	(e)
COCH-ARM / FISHERS	P=0.010N**	P<0.001**	P<0.001**	P=0.005**	P<0.001**	(e)
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)

TDMS No. 20306-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 PCN 66/67 COMPARISON STUDY
 CAS Number: PCNCOMPARISN
 Pathologist: VASCONCELOS, D.

Date Report Reqsted: 12/13/2005
 Time Report Reqsted: 9:08:56
 First Dose M/F: NA / 10/13/03
 Lab: BAT

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

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

**Spleen
 Pigmentation Hemosiderin**

LESION RATES

OVERALL (a)	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

LIFE TABLE	(e)	(e)	(e)	(e)	(e)	(e)
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)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)

TDMS No. 20306-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 PCN 66/67 COMPARISON STUDY
 CAS Number: PCNCOMPARISN
 Pathologist: VASCONCELOS, D.

Date Report Reqsted: 12/13/2005
 Time Report Reqsted: 9:08:56
 First Dose M/F: NA / 10/13/03
 Lab: BAT

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

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

**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%)	0/10 (0%)
POLY-3 RATE (b)	4/15.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	26.7%	0%	0%	0%	0%	0%
TERMINAL (d)	4/15 (27%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	94 (T)	---	---	---	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.070N	P=1.000	P=1.000N	P=1.000	P=1.000N	P=0.115N
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.104N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.104N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.104N
LOGISTIC REGRESSION	P=0.070N	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.066N	P=1.000	P=1.000	P=1.000	P=1.000	P=0.108N
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)

TDMS No. 20306-03
 Test Type: 90-DAY
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 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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 First Dose M/F: NA / 10/13/03
 Lab: BAT

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

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

**Thymus
 Atrophy**

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

LIFE TABLE	P<0.001**	(e)	(e)	(e)	(e)	P=0.055
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*
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.055
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	P=0.052
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)

TDMS No. 20306-03
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
PCN 66/67 COMPARISON STUDY
CAS Number: PCNCOMPARISN
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LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
 - (b) Number of tumor-bearing animals/Poly-3 number
 - (d) Observed incidence at terminal kill.
 - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death.
 - (e) Value of Statistic cannot be computed.
 - (g) Poly-3 adjusted lifetime tumor incidence.
 - (I) Interim sacrifice
 - (T) Terminal sacrifice
 - # Tumor rates based on numbers of animals necropsied.
 - * To the right of any statistical result, indicates significance at ($P \leq 0.05$).
 - ** To the right of any statistical result, indicates significance at ($P \leq 0.01$).
 - N Indicates a negative trend for all tests
- Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors.
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***