

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

PCN 66/67 comparison study
CAS Number: PCNCOMPARISN

Date Report Requested: 07/21/2008
Time Report Requested: 16:07:54
First Dose M/F: NA / 10/06/03
Lab: BAT

PCN66

C 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: 2.0.0

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

FEMALE RATS

Organ

Clitoral Gland
Harderian Gland
Kidney

Liver

Liver: Hepatocyte
Liver: Oval Cell
Lung: Alveolar Epithelium
Pancreas: Acinus

Thymus
Thyroid Gland: Follicular Cell

Morphology

Inflammation Chronic
Hyperplasia
Mineralization
Nephropathy
Fatty Change
Hepatocyte, Multinucleate
Inflammation
Inflammation Chronic
Necrosis Focal
Pigmentation
Toxic Hepatopathy
Hypertrophy
Hyperplasia
Metaplasia Bronchiolar
Atrophy Diffuse
Vacuolization Cytoplasmic
Atrophy
Hypertrophy

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66

**Clitoral Gland
 Inflammation Chronic**

LESION RATES

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

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.018N*
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.018N*
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.018N*
COCH-ARM / FISHERS	P=0.017N*	(e)	(e)	(e)	(e)	P=0.029N*
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.005N**

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66

**Harderian Gland
 Hyperplasia**

LESION RATES

OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	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)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.095
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.095
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.095
COCH-ARM / FISHERS	P=0.059	(e)	(e)	(e)	(e)	P=0.105
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.024*

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 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)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	30%
TERMINAL (d)	1/10 (10%)	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=0.292
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.292
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.292
COCH-ARM / FISHERS	P=0.201	(e)	(e)	(e)	(e)	P=0.291
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.135

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 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)	4/10 (40%)	6/10 (60%)	6/10 (60%)	7/10 (70%)	5/10 (50%)	8/10 (80%)
POLY-3 RATE (b)	4/10.00	6/10.00	6/10.00	7/10.00	5/10.00	8/10.00
POLY-3 PERCENT (g)	40%	60%	60%	70%	50%	80%
TERMINAL (d)	4/10 (40%)	6/10 (60%)	6/10 (60%)	7/10 (70%)	5/10 (50%)	8/10 (80%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)

STATISTICAL TESTS

POLY 3	P=0.139	P=0.333	P=0.333	P=0.186	P=0.500	P=0.077
POLY 1.5	P=0.139	P=0.333	P=0.333	P=0.186	P=0.500	P=0.077
POLY 6	P=0.139	P=0.333	P=0.333	P=0.186	P=0.500	P=0.077
COCH-ARM / FISHERS	P=0.135	P=0.328	P=0.328	P=0.185	P=0.500	P=0.085
MAX-ISO-POLY-3	P=0.066	P=0.192	P=0.192	P=0.090	P=0.334	P=0.029*

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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)	6/10 (60%)	7/10 (70%)	8/10 (80%)	6/10 (60%)	6/10 (60%)	10/10 (100%)
POLY-3 RATE (b)	6/10.00	7/10.00	8/10.00	6/10.00	6/10.00	10/10.00
POLY-3 PERCENT (g)	60%	70%	80%	60%	60%	100%
TERMINAL (d)	6/10 (60%)	7/10 (70%)	8/10 (80%)	6/10 (60%)	6/10 (60%)	10/10 (100%)
FIRST INCIDENCE	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)

STATISTICAL TESTS

POLY 3	P=0.081	P=0.500	P=0.318	P=0.667	P=0.667	P=0.033*
POLY 1.5	P=0.081	P=0.500	P=0.318	P=0.667	P=0.667	P=0.033*
POLY 6	P=0.081	P=0.500	P=0.318	P=0.667	P=0.667	P=0.033*
COCH-ARM / FISHERS	P=0.081	P=0.500	P=0.314	P=0.675N	P=0.675N	P=0.043*
MAX-ISO-POLY-3	P=0.042*	P=0.327	P=0.171	P=1.000	P=1.000	P=0.007**

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

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**	P<0.001**

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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)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	4/10 (40%)	9/10 (90%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	4/10.00	9/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	40%	90%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	4/10 (40%)	9/10 (90%)
FIRST INCIDENCE	---	---	---	---	94 (T)	94 (T)

STATISTICAL TESTS

POLY 3	P<0.001**	(e)	(e)	(e)	P=0.033*	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	(e)	P=0.033*	P<0.001**
POLY 6	P<0.001**	(e)	(e)	(e)	P=0.033*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P=0.043*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	P=0.007**	P<0.001**

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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)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	9/10 (90%)	9/10 (90%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	2/10.00	9/10.00	9/10.00
POLY-3 PERCENT (g)	0%	0%	0%	20%	90%	90%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	9/10 (90%)	9/10 (90%)
FIRST INCIDENCE	---	---	---	94 (T)	94 (T)	94 (T)

STATISTICAL TESTS

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

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 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)	8/10 (80%)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	8/10.00	9/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	80%	90%	100%	100%	100%	100%
TERMINAL (d)	8/10 (80%)	9/10 (90%)	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	P=0.139	P=0.500	P=0.227	P=0.227	P=0.227	P=0.227
POLY 1.5	P=0.139	P=0.500	P=0.227	P=0.227	P=0.227	P=0.227
POLY 6	P=0.139	P=0.500	P=0.227	P=0.227	P=0.227	P=0.227
COCH-ARM / FISHERS	P=0.142	P=0.500	P=0.237	P=0.237	P=0.237	P=0.237
MAX-ISO-POLY-3	P=0.034*	P=0.274	P=0.067	P=0.067	P=0.067	P=0.067

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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)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	4/10 (40%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00	4/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	40%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	4/10 (40%)
FIRST INCIDENCE	---	---	---	---	94 (T)	94 (T)

STATISTICAL TESTS

POLY 3	P<0.001**	(e)	(e)	(e)	P=0.500	P=0.033*
POLY 1.5	P<0.001**	(e)	(e)	(e)	P=0.500	P=0.033*
POLY 6	P<0.001**	(e)	(e)	(e)	P=0.500	P=0.033*
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P=0.500	P=0.043*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	P=0.158	P=0.007**

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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)	0/10 (0%)	0/10 (0%)	0/10 (0%)	4/10 (40%)	3/10 (30%)	5/10 (50%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	4/10.00	3/10.00	5/10.00
POLY-3 PERCENT (g)	0%	0%	0%	40%	30%	50%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	4/10 (40%)	3/10 (30%)	5/10 (50%)
FIRST INCIDENCE	---	---	---	94 (T)	94 (T)	94 (T)

STATISTICAL TESTS

POLY 3	P<0.001**	(e)	(e)	P=0.033*	P=0.095	P=0.008**
POLY 1.5	P<0.001**	(e)	(e)	P=0.033*	P=0.095	P=0.008**
POLY 6	P<0.001**	(e)	(e)	P=0.033*	P=0.095	P=0.008**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.043*	P=0.105	P=0.016*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.007**	P=0.024*	P=0.002**

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

STATISTICAL TESTS

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

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

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

Date Report Requested: 07/21/2008
 Time Report Requested: 16:07:54
 First Dose M/F: NA / 10/06/03
 Lab: BAT

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 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)	0/10 (0%)	4/10 (40%)	6/10 (60%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	4/10.00	6/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	40%	60%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	4/10 (40%)	6/10 (60%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	94 (T)	94 (T)	94 (T)	94 (T)	94 (T)

STATISTICAL TESTS

POLY 3	P<0.001**	P=0.033*	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.033*	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.033*	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.043*	P=0.005**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.007**	P<0.001**	P<0.001**	P<0.001**	P<0.001**

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

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

Date Report Requested: 07/21/2008
 Time Report Requested: 16:07:54
 First Dose M/F: NA / 10/06/03
 Lab: BAT

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 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)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	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)	0/10 (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=0.095
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	P=0.095
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	P=0.095
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	P=0.105
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	P=0.024*

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

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

Date Report Requested: 07/21/2008
 Time Report Requested: 16:07:54
 First Dose M/F: NA / 10/06/03
 Lab: BAT

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66

**Lung: Alveolar Epithelium
 Metaplasia Bronchiolar**

LESION RATES

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

STATISTICAL TESTS

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

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

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

Date Report Requested: 07/21/2008
 Time Report Requested: 16:07:54
 First Dose M/F: NA / 10/06/03
 Lab: BAT

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66

Nose: Respiratory Epithelium Inflammation

LESION RATES

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

STATISTICAL TESTS

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

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

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

Date Report Requested: 07/21/2008
 Time Report Requested: 16:07:54
 First Dose M/F: NA / 10/06/03
 Lab: BAT

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66

Pancreas: Acinus
 Atrophy Diffuse

LESION RATES

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

STATISTICAL TESTS

POLY 3	P=0.012*	(e)	(e)	(e)	P=0.500	P=0.227
POLY 1.5	P=0.012*	(e)	(e)	(e)	P=0.500	P=0.227
POLY 6	P=0.012*	(e)	(e)	(e)	P=0.500	P=0.227
COCH-ARM / FISHERS	P=0.013*	(e)	(e)	(e)	P=0.500	P=0.237
MAX-ISO-POLY-3	P=0.022*	(e)	(e)	(e)	P=0.158	P=0.067

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

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

Date Report Requested: 07/21/2008
 Time Report Requested: 16:07:54
 First Dose M/F: NA / 10/06/03
 Lab: BAT

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 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)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	2/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	20%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	94 (T)	94 (T)

STATISTICAL TESTS

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

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

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

Date Report Requested: 07/21/2008
 Time Report Requested: 16:07:54
 First Dose M/F: NA / 10/06/03
 Lab: BAT

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 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)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	5/10 (50%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	5/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	50%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	5/10 (50%)
FIRST INCIDENCE	---	---	---	---	---	94 (T)

STATISTICAL TESTS

POLY 3	P<0.001**	(e)	(e)	(e)	(e)	P=0.008**
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	P=0.008**
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	P=0.008**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	P=0.016*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	P=0.002**

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

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

Date Report Requested: 07/21/2008
 Time Report Requested: 16:07:54
 First Dose M/F: NA / 10/06/03
 Lab: BAT

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 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)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	10/10.00	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)	10/10 (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)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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Date Report Requested: 07/21/2008
 Time Report Requested: 16:07:54
 First Dose M/F: NA / 10/06/03
 Lab: BAT

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66

**Stomach, Forestomach: Epithelium
 Hyperkeratosis**

LESION RATES

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

STATISTICAL TESTS

POLY 3	P=0.078	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.500
POLY 1.5	P=0.078	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.500
POLY 6	P=0.078	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.500
COCH-ARM / FISHERS	P=0.081	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.056	P=0.158N	P=0.158N	P=0.158N	P=0.158N	P=0.274

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

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

Date Report Requested: 07/21/2008
 Time Report Requested: 16:07:54
 First Dose M/F: NA / 10/06/03
 Lab: BAT

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 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)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	5/10 (50%)	9/10 (90%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	0/10.00	5/10.00	9/10.00
POLY-3 PERCENT (g)	0%	0%	10%	0%	50%	90%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	5/10 (50%)	9/10 (90%)
FIRST INCIDENCE	---	---	94 (T)	---	94 (T)	94 (T)

STATISTICAL TESTS

POLY 3	P<0.001**	(e)	P=0.500	(e)	P=0.008**	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.500	(e)	P=0.008**	P<0.001**
POLY 6	P<0.001**	(e)	P=0.500	(e)	P=0.008**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	(e)	P=0.016*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.158	(e)	P=0.002**	P<0.001**

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

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

Date Report Requested: 07/21/2008
 Time Report Requested: 16:07:54
 First Dose M/F: NA / 10/06/03
 Lab: BAT

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66

Thyroid Gland: Follicular Cell Hypertrophy

LESION RATES

OVERALL (a)	1/10 (10%)	0/10 (0%)	2/10 (20%)	3/10 (30%)	6/10 (60%)	6/10 (60%)
POLY-3 RATE (b)	1/10.00	0/10.00	2/10.00	3/10.00	6/10.00	6/10.00
POLY-3 PERCENT (g)	10%	0%	20%	30%	60%	60%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	2/10 (20%)	3/10 (30%)	6/10 (60%)	6/10 (60%)
FIRST INCIDENCE	94 (T)	---	94 (T)	94 (T)	94 (T)	94 (T)

STATISTICAL TESTS

POLY 3	P<0.001**	P=0.500N	P=0.500	P=0.292	P=0.018*	P=0.018*
POLY 1.5	P<0.001**	P=0.500N	P=0.500	P=0.292	P=0.018*	P=0.018*
POLY 6	P<0.001**	P=0.500N	P=0.500	P=0.292	P=0.018*	P=0.018*
COCH-ARM / FISHERS	P<0.001**	P=0.500N	P=0.500	P=0.291	P=0.029*	P=0.029*
MAX-ISO-POLY-3	P<0.001**	P=0.158N	P=0.274	P=0.135	P=0.005**	P=0.005**

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

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

Date Report Requested: 07/21/2008
 Time Report Requested: 16:07:54
 First Dose M/F: NA / 10/06/03
 Lab: BAT

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

DOSE	Females					
	0 NG/KG	1000 NG/KG 66	10,000 NG/KG 66	50,000 NG/KG 66	100,000 NG/KG 66	200,000 NG/KG 66

Tooth: Gingiva
 Inflammation

LESION RATES

OVERALL (a)	1/1 (100%)	0/0 (0%)	1/1 (100%)	3/3 (100%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	1/1.00	0/0.00	1/1.00	3/3.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	100%	0%	100%	100%	0%	0%
TERMINAL (d)	1/1 (100%)	0/0 (0%)	1/1 (100%)	3/3 (100%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	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)

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

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

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

LEGEND

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

*** END OF REPORT ***