

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
Pathologist: VASCONCELOS, D.

Date Report Reqsted: 12/13/2005
Time Report Reqsted: 13:07:55
First Dose M/F: NA / 10/06/03
Lab: BAT

SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) 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

Nose: Respiratory Epithelium

Pancreas: Acinus

Stomach, Forestomach: Epithelium

Thymus

Thyroid Gland: Follicular Cell

Morphology

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

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

Females

DOSE 0 NG/KG

Clitoral Gland
Inflammation Chronic

LESION RATES

OVERALL (a)	7/20 (35%)
POLY-3 RATE (b)	7/20.00
POLY-3 PERCENT (g)	35%
TERMINAL (d)	7/20 (35%)
FIRST INCIDENCE	94 (T)

STATISTICAL TESTS

LIFE TABLE
POLY 3
POLY 1.5
POLY 6
LOGISTIC REGRESSION
COCH-ARM / FISHERS
ORDER RESTRICTED

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Females

DOSE 0 NG/KG

Harderian Gland
Hyperplasia

LESION RATES

OVERALL (a)	3/20 (15%)
POLY-3 RATE (b)	3/20.00
POLY-3 PERCENT (g)	15%
TERMINAL (d)	3/20 (15%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Harderian Gland
Infiltration Cellular Mononuclear Cell

LESION RATES

OVERALL (a)	4/20 (20%)
POLY-3 RATE (b)	4/20.00
POLY-3 PERCENT (g)	20%
TERMINAL (d)	4/20 (20%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Kidney
Mineralization

LESION RATES

OVERALL (a)	36/60 (60%)
POLY-3 RATE (b)	36/60.00
POLY-3 PERCENT (g)	60%
TERMINAL (d)	36/60 (60%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Kidney
Nephropathy

LESION RATES

OVERALL (a)	43/60 (72%)
POLY-3 RATE (b)	43/60.00
POLY-3 PERCENT (g)	71.7%
TERMINAL (d)	43/60 (72%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Liver
Fatty Change

LESION RATES

OVERALL (a)	20/60 (33%)
POLY-3 RATE (b)	20/60.00
POLY-3 PERCENT (g)	33.3%
TERMINAL (d)	20/60 (33%)
FIRST INCIDENCE	94 (T)

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

Females

DOSE 0 NG/KG

Liver
Hepatocyte, Multinucleate

LESION RATES

OVERALL (a)	13/60 (22%)
POLY-3 RATE (b)	13/60.00
POLY-3 PERCENT (g)	21.7%
TERMINAL (d)	13/60 (22%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Liver
Inflammation

LESION RATES

OVERALL (a)	20/60 (33%)
POLY-3 RATE (b)	20/60.00
POLY-3 PERCENT (g)	33.3%
TERMINAL (d)	20/60 (33%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Liver
Inflammation Chronic

LESION RATES

OVERALL (a)	57/60 (95%)
POLY-3 RATE (b)	57/60.00
POLY-3 PERCENT (g)	95%
TERMINAL (d)	57/60 (95%)
FIRST INCIDENCE	94 (T)

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

Females

DOSE 0 NG/KG

Liver
Necrosis Focal

LESION RATES

OVERALL (a)	5/60 (8%)
POLY-3 RATE (b)	5/60.00
POLY-3 PERCENT (g)	8.3%
TERMINAL (d)	5/60 (8%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Liver
Pigmentation

LESION RATES

OVERALL (a)	12/60 (20%)
POLY-3 RATE (b)	12/60.00
POLY-3 PERCENT (g)	20%
TERMINAL (d)	12/60 (20%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Liver
Toxic Hepatopathy

LESION RATES

OVERALL (a)	21/60 (35%)
POLY-3 RATE (b)	21/60.00
POLY-3 PERCENT (g)	35%
TERMINAL (d)	21/60 (35%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Liver: Hepatocyte
Hypertrophy

LESION RATES

OVERALL (a)	40/60 (67%)
POLY-3 RATE (b)	40/60.00
POLY-3 PERCENT (g)	66.7%
TERMINAL (d)	40/60 (67%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Liver: Oval Cell
Hyperplasia

LESION RATES

OVERALL (a)	3/60 (5%)
POLY-3 RATE (b)	3/60.00
POLY-3 PERCENT (g)	5%
TERMINAL (d)	3/60 (5%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Lung: Alveolar Epithelium
Metaplasia Bronchiolar

LESION RATES

OVERALL (a)	2/60 (3%)
POLY-3 RATE (b)	2/60.00
POLY-3 PERCENT (g)	3.3%
TERMINAL (d)	2/60 (3%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Nose: Respiratory Epithelium
Inflammation

LESION RATES

OVERALL (a)	2/20 (10%)
POLY-3 RATE (b)	2/20.00
POLY-3 PERCENT (g)	10%
TERMINAL (d)	2/20 (10%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Pancreas: Acinus
Atrophy Diffuse

LESION RATES

OVERALL (a)	3/60 (5%)
POLY-3 RATE (b)	3/60.00
POLY-3 PERCENT (g)	5%
TERMINAL (d)	3/60 (5%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Pancreas: Acinus
Atrophy Focal

LESION RATES

OVERALL (a)	3/60 (5%)
POLY-3 RATE (b)	3/60.00
POLY-3 PERCENT (g)	5%
TERMINAL (d)	3/60 (5%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Pancreas: Acinus
Vacuolization Cytoplasmic

LESION RATES

OVERALL (a)	5/60 (8%)
POLY-3 RATE (b)	5/60.00
POLY-3 PERCENT (g)	8.3%
TERMINAL (d)	5/60 (8%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Spleen
Pigmentation Hemosiderin

LESION RATES

OVERALL (a)	60/60 (100%)
POLY-3 RATE (b)	60/60.00
POLY-3 PERCENT (g)	100%
TERMINAL (d)	60/60 (100%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Stomach, Forestomach: Epithelium
Hyperkeratosis

LESION RATES

OVERALL (a)	3/60 (5%)
POLY-3 RATE (b)	3/60.00
POLY-3 PERCENT (g)	5%
TERMINAL (d)	3/60 (5%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Thymus
Atrophy

LESION RATES

OVERALL (a)	15/60 (25%)
POLY-3 RATE (b)	15/60.00
POLY-3 PERCENT (g)	25%
TERMINAL (d)	15/60 (25%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Thyroid Gland: Follicular Cell
Hypertrophy

LESION RATES

OVERALL (a)	18/60 (30%)
POLY-3 RATE (b)	18/60.00
POLY-3 PERCENT (g)	30%
TERMINAL (d)	18/60 (30%)
FIRST INCIDENCE	94 (T)

STATISTICAL TESTS

LIFE TABLE
POLY 3
POLY 1.5
POLY 6
LOGISTIC REGRESSION
COCH-ARM / FISHERS
ORDER RESTRICTED

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
Pathologist: VASCONCELOS, D.

Date Report Reqsted: 12/13/2005
Time Report Reqsted: 13:07:55
First Dose M/F: NA / 10/06/03
Lab: BAT

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

Females

DOSE 0 NG/KG

Tooth: Gingiva
Inflammation

LESION RATES

OVERALL (a)	5/5 (100%)
POLY-3 RATE (b)	5/5.00
POLY-3 PERCENT (g)	100%
TERMINAL (d)	5/5 (100%)
FIRST INCIDENCE	94 (T)

STATISTICAL TESTS

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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 ***