

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.
F1 PCN 67

Date Report Requested: 12/13/2005
Time Report Requested: 13:07:43
First Dose M/F: NA / 10/06/03
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

Adrenal Cortex
Clitoral Gland
Kidney

Liver

Liver: Hepatocyte
Nose: Respiratory Epithelium
Spleen
Thyroid Gland: Follicular Cell

Morphology

Hypertrophy
Inflammation Chronic
Mineralization
Nephropathy
Fatty Change
Hepatocyte, Multinucleate
Inflammation
Inflammation Chronic
Necrosis Focal
Pigmentation
Toxic Hepatopathy
Hypertrophy
Inflammation
Pigmentation Hemosiderin
Hypertrophy

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

Females

DOSE 0 NG/KG

Adrenal Cortex
Hypertrophy

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)

STATISTICAL TESTS

LIFE TABLE
POLY 3
POLY 1.5
POLY 6
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COCH-ARM / FISHERS
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Females

DOSE 0 NG/KG

Clitoral Gland
Inflammation Chronic

LESION RATES

OVERALL (a)	12/21 (57%)
POLY-3 RATE (b)	12/21.00
POLY-3 PERCENT (g)	57.1%
TERMINAL (d)	12/21 (57%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Kidney
Mineralization

LESION RATES

OVERALL (a)	29/60 (48%)
POLY-3 RATE (b)	29/60.00
POLY-3 PERCENT (g)	48.3%
TERMINAL (d)	29/60 (48%)
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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Kidney
Nephropathy

LESION RATES

OVERALL (a)	33/60 (55%)
POLY-3 RATE (b)	33/60.00
POLY-3 PERCENT (g)	55%
TERMINAL (d)	33/60 (55%)
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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Liver
Fatty Change

LESION RATES

OVERALL (a)	10/60 (17%)
POLY-3 RATE (b)	10/60.00
POLY-3 PERCENT (g)	16.7%
TERMINAL (d)	10/60 (17%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Liver
Hepatocyte, Multinucleate

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

Liver
Inflammation

LESION RATES

OVERALL (a)	12/60 (20%)
POLY-3 RATE (b)	12/60.00
POLY-3 PERCENT (g)	20%
TERMINAL (d)	12/60 (20%)
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)
TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE 0 NG/KG

Liver
Inflammation Chronic

LESION RATES

OVERALL (a)	54/60 (90%)
POLY-3 RATE (b)	54/60.00
POLY-3 PERCENT (g)	90%
TERMINAL (d)	54/60 (90%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Liver
Necrosis Focal

LESION RATES

OVERALL (a)	6/60 (10%)
POLY-3 RATE (b)	6/60.00
POLY-3 PERCENT (g)	10%
TERMINAL (d)	6/60 (10%)
FIRST INCIDENCE	94 (T)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE 0 NG/KG

Liver
Pigmentation

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

Liver
Toxic Hepatopathy

LESION RATES

OVERALL (a)	10/60 (17%)
POLY-3 RATE (b)	10/60.00
POLY-3 PERCENT (g)	16.7%
TERMINAL (d)	10/60 (17%)
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)	15/60 (25%)
POLY-3 RATE (b)	15/60.00
POLY-3 PERCENT (g)	25%
TERMINAL (d)	15/60 (25%)
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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

Spleen
Pigmentation Hemosiderin

LESION RATES

OVERALL (a)	59/60 (98%)
POLY-3 RATE (b)	59/60.00
POLY-3 PERCENT (g)	98.3%
TERMINAL (d)	59/60 (98%)
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)	8/60 (13%)
POLY-3 RATE (b)	8/60.00
POLY-3 PERCENT (g)	13.3%
TERMINAL (d)	8/60 (13%)
FIRST INCIDENCE	94 (T)

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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 ***