

Experiment Number: 20614 - 01
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Perfluorooctanoic Acid
CAS Number: 335-67-1

Date Report Requested: 07/26/2018
Time Report Requested: 20:23:06
First Dose M/F: 10/27/08 / 10/28/08
Lab: BAT

Female SSACs 0-1000, 300-1000

NTP Study Number: C20614
Lock Date: 01/10/2012
Cage Range: ALL
Date Range: ALL
Reasons For Removal: 25017 SSAC
Removal Date Range: ALL
Treatment Groups: Include 008 0/1000 ppm Include 010 300/1000 ppm
Study Gender: Both
TDMSE Version: 2.5.0.0_sfh
PWG Approval Date: 07/25/2018

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF PERFLUOROOCCTANOIC ACID

FEMALE RATS

Organ

Liver

Lymph Node, Mesenteric

Morphology

Pigment

Atrophy Lymphocyte

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LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Brain: Cerebrum
Necrosis Chronic

LESION RATES

OVERALL (a)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	10%
INT SACRIFICE 1	0/10 (0%)	1/10 (10%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	109 (l)

STATISTICAL TESTS

POLY 3	P=0.500
POLY 1.5	P=0.500
POLY 6	P=0.500
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.158

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DOSE	0/1000 ppm	300/1000 ppm
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Kidney
Nephropathy Chronic Progressive

LESION RATES

OVERALL (a)	6/10 (60%)	4/10 (40%)
POLY-3 RATE (b)	6/10.00	4/10.00
POLY-3 PERCENT (g)	60%	40%
INT SACRIFICE 1	6/10 (60%)	4/10 (40%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	109 (I)

STATISTICAL TESTS

POLY 3	P=0.333N
POLY 1.5	P=0.333N
POLY 6	P=0.333N
COCH-ARM / FISHERS	P=0.328N
MAX-ISO-POLY-3	P=0.193N

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Females

DOSE	0/1000 ppm	300/1000 ppm
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**Kidney: Papilla, Urothelium
Hyperplasia**

LESION RATES

OVERALL (a)	4/10 (40%)	4/10 (40%)
POLY-3 RATE (b)	4/10.00	4/10.00
POLY-3 PERCENT (g)	40%	40%
INT SACRIFICE 1	4/10 (40%)	4/10 (40%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	109 (I)

STATISTICAL TESTS

POLY 3	P=0.667
POLY 1.5	P=0.667
POLY 6	P=0.667
COCH-ARM / FISHERS	P=0.675N
MAX-ISO-POLY-3	P=1.000

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Females

DOSE	0/1000 ppm	300/1000 ppm
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**Kidney: Pelvis
Inflammation Chronic**

LESION RATES

OVERALL (a)	1/10 (10%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	1/10.00
POLY-3 PERCENT (g)	10%	10%
INT SACRIFICE 1	1/10 (10%)	1/10 (10%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	109 (I)

STATISTICAL TESTS

POLY 3	P=0.760
POLY 1.5	P=0.760
POLY 6	P=0.760
COCH-ARM / FISHERS	P=0.763N
MAX-ISO-POLY-3	P=1.000

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LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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**Kidney: Renal Tubule
Mineral**

LESION RATES

OVERALL (a)	7/10 (70%)	5/10 (50%)
POLY-3 RATE (b)	7/10.00	5/10.00
POLY-3 PERCENT (g)	70%	50%
INT SACRIFICE 1	7/10 (70%)	5/10 (50%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	109 (I)

STATISTICAL TESTS

POLY 3	P=0.329N
POLY 1.5	P=0.329N
POLY 6	P=0.329N
COCH-ARM / FISHERS	P=0.325N
MAX-ISO-POLY-3	P=0.188N

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LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Liver
Extramedullary Hematopoiesis

LESION RATES

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%
INT SACRIFICE 1	1/10 (10%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	---

STATISTICAL TESTS

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

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Species/Strain: RATS/HSD

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LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
-------------	-------------------	---------------------

Liver
Inflammation Focal

LESION RATES

OVERALL (a)	8/10 (80%)	6/10 (60%)
POLY-3 RATE (b)	8/10.00	6/10.00
POLY-3 PERCENT (g)	80%	60%
INT SACRIFICE 1	8/10 (80%)	6/10 (60%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	109 (I)

STATISTICAL TESTS

POLY 3	P=0.318N
POLY 1.5	P=0.318N
POLY 6	P=0.318N
COCH-ARM / FISHERS	P=0.314N
MAX-ISO-POLY-3	P=0.172N

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LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Liver
Necrosis

LESION RATES

OVERALL (a)	2/10 (20%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/10.00
POLY-3 PERCENT (g)	20%	0%
INT SACRIFICE 1	2/10 (20%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	---

STATISTICAL TESTS

POLY 3	P=0.227N
POLY 1.5	P=0.227N
POLY 6	P=0.227N
COCH-ARM / FISHERS	P=0.237N
MAX-ISO-POLY-3	P=0.066N

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Lab: BAT

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LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Liver
Pigment

LESION RATES

OVERALL (a)	2/10 (20%)	6/10 (60%)
POLY-3 RATE (b)	2/10.00	6/10.00
POLY-3 PERCENT (g)	20%	60%
INT SACRIFICE 1	2/10 (20%)	6/10 (60%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	109 (I)

STATISTICAL TESTS

POLY 3	P=0.077
POLY 1.5	P=0.077
POLY 6	P=0.077
COCH-ARM / FISHERS	P=0.085
MAX-ISO-POLY-3	P=0.029*

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LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Liver: Bile Duct
Hyperplasia

LESION RATES

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%
INT SACRIFICE 1	1/10 (10%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	---

STATISTICAL TESTS

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

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LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
-------------	-------------------	---------------------

Liver: Hepatocyte
Cytoplasmic Alteration

LESION RATES

OVERALL (a)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	10/10.00	10/10.00
POLY-3 PERCENT (g)	100%	100%
INT SACRIFICE 1	10/10 (100%	10/10 (100%
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	109 (I)

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)

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LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
-------------	-------------------	---------------------

Liver: Hepatocyte
Hypertrophy

LESION RATES

OVERALL (a)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	10/10.00	10/10.00
POLY-3 PERCENT (g)	100%	100%
INT SACRIFICE 1	10/10 (100%)	10/10 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	109 (I)

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)

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LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
------	------------	--------------

Liver: Hepatocyte
Single Cell Death

LESION RATES

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%
INT SACRIFICE 1	1/10 (10%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	---

STATISTICAL TESTS

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

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Females

DOSE	0/1000 ppm	300/1000 ppm
-------------	-------------------	---------------------

**Lung: Alveolus
Infiltration Cellular Histiocyte**

LESION RATES

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%
INT SACRIFICE 1	1/10 (10%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	---

STATISTICAL TESTS

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

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Females

DOSE	0/1000 ppm	300/1000 ppm
------	------------	--------------

Lymph Node, Mandibular
Atrophy

LESION RATES

OVERALL (a)	1/10 (10%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	1/10.00
POLY-3 PERCENT (g)	10%	10%
INT SACRIFICE 1	1/10 (10%)	1/10 (10%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	109 (I)

STATISTICAL TESTS

POLY 3	P=0.760
POLY 1.5	P=0.760
POLY 6	P=0.760
COCH-ARM / FISHERS	P=0.763N
MAX-ISO-POLY-3	P=1.000

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Females

DOSE	0/1000 ppm	300/1000 ppm
-------------	-------------------	---------------------

**Lymph Node, Mandibular
Atrophy Lymphocyte**

LESION RATES

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%
INT SACRIFICE 1	1/10 (10%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	---

STATISTICAL TESTS

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

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LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
------	------------	--------------

Lymph Node, Mandibular
Atrophy Lymphoid

LESION RATES

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%
INT SACRIFICE 1	1/10 (10%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	---

STATISTICAL TESTS

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

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LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
------	------------	--------------

Lymph Node, Mesenteric
Atrophy Lymphocyte

LESION RATES

OVERALL (a)	0/9 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/9.00	3/10.00
POLY-3 PERCENT (g)	0%	30%
INT SACRIFICE 1	0/9 (0%)	3/10 (30%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	109 (I)

STATISTICAL TESTS

POLY 3	P=0.114
POLY 1.5	P=0.114
POLY 6	P=0.114
COCH-ARM / FISHERS	P=0.124
MAX-ISO-POLY-3	P=0.035*

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LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
-------------	-------------------	---------------------

**Lymph Node: Bronchial
Hemorrhage**

LESION RATES

OVERALL (a)	1/2 (50%)	0/0 (0%)
POLY-3 RATE (b)	1/2.00	0/0.00
POLY-3 PERCENT (g)	50%	0%
INT SACRIFICE 1	1/2 (50%)	0/0 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	---

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Perfluorooctanoic Acid

CAS Number: 335-67-1

Date Report Requested: 07/26/2018

Time Report Requested: 20:23:06

First Dose M/F: 10/27/08 / 10/28/08

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Ovary
Cyst

LESION RATES

OVERALL (a)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	10%
INT SACRIFICE 1	0/10 (0%)	1/10 (10%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	109 (I)

STATISTICAL TESTS

POLY 3	P=0.500
POLY 1.5	P=0.500
POLY 6	P=0.500
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.158

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

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LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Spleen
Extramedullary Hematopoiesis

LESION RATES

OVERALL (a)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	10%
INT SACRIFICE 1	0/10 (0%)	1/10 (10%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	109 (I)

STATISTICAL TESTS

POLY 3	P=0.500
POLY 1.5	P=0.500
POLY 6	P=0.500
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.158

Experiment Number: 20614 - 01

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LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Spleen
Pigment

LESION RATES

OVERALL (a)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	10/10.00	10/10.00
POLY-3 PERCENT (g)	100%	100%
INT SACRIFICE 1	10/10 (100%)	10/10 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	109 (I)

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)

Experiment Number: 20614 - 01
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Thyroid Gland
Ectopic Thymus

LESION RATES

OVERALL (a)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	10%
INT SACRIFICE 1	0/10 (0%)	1/10 (10%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	109 (l)

STATISTICAL TESTS

POLY 3	P=0.500
POLY 1.5	P=0.500
POLY 6	P=0.500
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.158

Experiment Number: 20614 - 01
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Thyroid Gland: Follicular Cell
Hypertrophy

LESION RATES

OVERALL (a)	1/10 (10%)	4/10 (40%)
POLY-3 RATE (b)	1/10.00	4/10.00
POLY-3 PERCENT (g)	10%	40%
INT SACRIFICE 1	1/10 (10%)	4/10 (40%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	109 (I)	109 (I)

STATISTICAL TESTS

POLY 3	P=0.148
POLY 1.5	P=0.148
POLY 6	P=0.148
COCH-ARM / FISHERS	P=0.152
MAX-ISO-POLY-3	P=0.058

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
LAST REMOVAL AT 16 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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**Urinary Bladder
Inflammation**

LESION RATES

OVERALL (a)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	10%
INT SACRIFICE 1	0/10 (0%)	1/10 (10%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	109 (I)

STATISTICAL TESTS

POLY 3	P=0.500
POLY 1.5	P=0.500
POLY 6	P=0.500
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.158

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

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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 ***