

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Perfluorooctanoic Acid

CAS Number: 335-67-1

Date Report Requested: 09/16/2018

Time Report Requested: 18:26:39

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

Lab: BAT

Uterine section report with litter -- 0-1000, 300-1000

NTP Study Number: C20614

Lock Date: 01/10/2012

Cage Range: ALL

Date Range: ALL

Reasons For Removal: 25021 TSAC 25020 NATD 25019 MSAC
25016 Aborted

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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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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**Uterus (Standard Evaluation)
Carcinoma**

TUMOR RATES

	#	#
OVERALL (a)	4/50 (8%)	1/50 (2%)
LITTERS (b)	4/31 (13%)	1/30 (3%)
POLY-3 RATE (c)	4/37.30	1/37.22
POLY-3 PERCENT (g)	10.7%	2.7%
TERMINAL (d)	1/23 (4%)	1/23 (4%)
FIRST INCIDENCE	652	744 (T)

STATISTICAL TESTS

POLY 3	P=0.177N
POLY 1.5	P=0.171N
POLY 6	P=0.193N
RAO-SCOTT	P=0.193N
LITTER C-A/FISHERS	P=0.187N

Experiment Number: 20614 - 01

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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Uterus (Longitudinal Evaluation)

Carcinoma

TUMOR RATES

	#	#
OVERALL (a)	8/50 (16%)	5/50 (10%)
LITTERS (b)	7/31 (23%)	5/30 (17%)
POLY-3 RATE (c)	8/37.58	5/38.13
POLY-3 PERCENT (g)	21.3%	13.1%
TERMINAL (d)	4/23 (17%)	3/23 (13%)
FIRST INCIDENCE	652	574

STATISTICAL TESTS

POLY 3	P=0.261N
POLY 1.5	P=0.252N
POLY 6	P=0.288N
RAO-SCOTT	P=0.269N
LITTER C-A/FISHERS	P=0.399N

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

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TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Uterus (Standard or Longitudinal Evaluation)

Carcinoma

TUMOR RATES

	#	#
OVERALL (a)	8/50 (16%)	5/50 (10%)
LITTERS (b)	7/31 (23%)	5/30 (17%)
POLY-3 RATE (c)	8/37.58	5/38.13
POLY-3 PERCENT (g)	21.3%	13.1%
TERMINAL (d)	4/23 (17%)	3/23 (13%)
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Experiment Number: 20614 - 01
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Route: DOSED FEED
Species/Strain: RATS/HSD

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Uterus (Standard Evaluation)
Carcinoma or Adenoma

TUMOR RATES

	#	#
OVERALL (a)	4/50 (8%)	1/50 (2%)
LITTERS (b)	4/31 (13%)	1/30 (3%)
POLY-3 RATE (c)	4/37.30	1/37.22
POLY-3 PERCENT (g)	10.7%	2.7%
TERMINAL (d)	1/23 (4%)	1/23 (4%)
FIRST INCIDENCE	652	744 (T)

STATISTICAL TESTS

POLY 3	P=0.177N
POLY 1.5	P=0.171N
POLY 6	P=0.193N
RAO-SCOTT	P=0.193N
LITTER C-A/FISHERS	P=0.187N

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TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Uterus (Longitudinal Evaluation)
Carcinoma or Adenoma

TUMOR RATES	#	#
OVERALL (a)	8/50 (16%)	5/50 (10%)
LITTERS (b)	7/31 (23%)	5/30 (17%)
POLY-3 RATE (c)	8/37.58	5/38.13
POLY-3 PERCENT (g)	21.3%	13.1%
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Females

DOSE	0/1000 ppm	300/1000 ppm
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**Uterus (Standard or Longitudinal Evaluation)
Carcinoma or Adenoma**

TUMOR RATES

	#	#
OVERALL (a)	8/50 (16%)	5/50 (10%)
LITTERS (b)	7/31 (23%)	5/30 (17%)
POLY-3 RATE (c)	8/37.58	5/38.13
POLY-3 PERCENT (g)	21.3%	13.1%
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Females

DOSE	0/1000 ppm	300/1000 ppm
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Uterus (Standard Evaluation)

Polyp, Stromal

TUMOR RATES

	#	#
OVERALL (a)	5/50 (10%)	3/50 (6%)
LITTERS (b)	5/31 (16%)	3/30 (10%)
POLY-3 RATE (c)	5/37.09	3/37.63
POLY-3 PERCENT (g)	13.5%	8%
TERMINAL (d)	3/23 (13%)	2/23 (9%)
FIRST INCIDENCE	695	624

STATISTICAL TESTS

POLY 3	P=0.346N
POLY 1.5	P=0.338N
POLY 6	P=0.369N
RAO-SCOTT	P=0.318N
LITTER C-A/FISHERS	P=0.372N

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

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Uterus (Longitudinal Evaluation)
Polyp, Stromal

TUMOR RATES	#	#
OVERALL (a)	13/50 (26%)	17/50 (34%)
LITTERS (b)	12/31 (39%)	14/30 (47%)
POLY-3 RATE (c)	13/37.80	17/40.45
POLY-3 PERCENT (g)	34.4%	42%
TERMINAL (d)	9/23 (39%)	9/23 (39%)
FIRST INCIDENCE	540	491

STATISTICAL TESTS

POLY 3	P=0.319
POLY 1.5	P=0.314
POLY 6	P=0.309
RAO-SCOTT	P=0.312
LITTER C-A/FISHERS	P=0.356

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Perfluorooctanoic Acid

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Time Report Requested: 18:26:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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**Uterus (Standard or Longitudinal Evaluation)
Polyp, Stromal**

TUMOR RATES	#	#
OVERALL (a)	13/50 (26%)	17/50 (34%)
LITTERS (b)	12/31 (39%)	14/30 (47%)
POLY-3 RATE (c)	13/37.80	17/40.45
POLY-3 PERCENT (g)	34.4%	42%
TERMINAL (d)	9/23 (39%)	9/23 (39%)
FIRST INCIDENCE	540	491

STATISTICAL TESTS

POLY 3	P=0.319
POLY 1.5	P=0.314
POLY 6	P=0.309
RAO-SCOTT	P=0.312
LITTER C-A/FISHERS	P=0.356

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Uterus (Standard Evaluation)
Sarcoma Stromal

TUMOR RATES	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)
LITTERS (b)	1/31 (3%)	0/30 (0%)
POLY-3 RATE (c)	1/37.15	0/37.22
POLY-3 PERCENT (g)	2.7%	0%
TERMINAL (d)	0/23 (0%)	0/23 (0%)
FIRST INCIDENCE	669	---

STATISTICAL TESTS

POLY 3	P=0.500N
POLY 1.5	P=0.495N
POLY 6	P=0.510N
RAO-SCOTT	P=0.535N
LITTER C-A/FISHERS	P=0.508N

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Species/Strain: RATS/HSD

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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

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

Uterus (Longitudinal Evaluation)
Sarcoma Stromal

TUMOR RATES	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)
LITTERS (b)	2/31 (6%)	0/30 (0%)
POLY-3 RATE (c)	2/37.15	0/37.22
POLY-3 PERCENT (g)	5.4%	0%
TERMINAL (d)	1/23 (4%)	0/23 (0%)
FIRST INCIDENCE	669	---

STATISTICAL TESTS

POLY 3	P=0.236N
POLY 1.5	P=0.231N
POLY 6	P=0.247N
RAO-SCOTT	P=0.298N
LITTER C-A/FISHERS	P=0.254N

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Uterus (Standard or Longitudinal Evaluation)

Sarcoma Stromal

TUMOR RATES

	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)
LITTERS (b)	2/31 (6%)	0/30 (0%)
POLY-3 RATE (c)	2/37.15	0/37.22
POLY-3 PERCENT (g)	5.4%	0%
TERMINAL (d)	1/23 (4%)	0/23 (0%)
FIRST INCIDENCE	669	---

STATISTICAL TESTS

POLY 3	P=0.236N
POLY 1.5	P=0.231N
POLY 6	P=0.247N
RAO-SCOTT	P=0.298N
LITTER C-A/FISHERS	P=0.254N

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Uterus (Standard Evaluation)
Sarcoma Stromal or Polyp Stromal

TUMOR RATES	#	#
OVERALL (a)	6/50 (12%)	3/50 (6%)
LITTERS (b)	5/31 (16%)	3/30 (10%)
POLY-3 RATE (c)	6/37.36	3/37.63
POLY-3 PERCENT (g)	16.1%	8%
TERMINAL (d)	3/23 (13%)	2/23 (9%)
FIRST INCIDENCE	669	624

STATISTICAL TESTS

POLY 3	P=0.234N
POLY 1.5	P=0.226N
POLY 6	P=0.257N
RAO-SCOTT	P=0.257N
LITTER C-A/FISHERS	P=0.372N

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Uterus (Longitudinal Evaluation)
Sarcoma Stromal or Polyp Stromal

TUMOR RATES	#	#
OVERALL (a)	15/50 (30%)	17/50 (34%)
LITTERS (b)	13/31 (42%)	14/30 (47%)
POLY-3 RATE (c)	15/38.07	17/40.45
POLY-3 PERCENT (g)	39.4%	42%
TERMINAL (d)	10/23 (44%)	9/23 (39%)
FIRST INCIDENCE	540	491

STATISTICAL TESTS

POLY 3	P=0.497
POLY 1.5	P=0.491
POLY 6	P=0.481
RAO-SCOTT	P=0.482
LITTER C-A/FISHERS	P=0.455

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Uterus (Standard or Longitudinal Evaluation)
Sarcoma Stromal or Polyp Stromal

TUMOR RATES	#	#
OVERALL (a)	15/50 (30%)	17/50 (34%)
LITTERS (b)	13/31 (42%)	14/30 (47%)
POLY-3 RATE (c)	15/38.07	17/40.45
POLY-3 PERCENT (g)	39.4%	42%
TERMINAL (d)	10/23 (44%)	9/23 (39%)
FIRST INCIDENCE	540	491

STATISTICAL TESTS

POLY 3	P=0.497
POLY 1.5	P=0.491
POLY 6	P=0.481
RAO-SCOTT	P=0.482
LITTER C-A/FISHERS	P=0.455

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Vagina (Longitudinal Evaluation)
Granular Cell Tumor

TUMOR RATES	#	#
OVERALL (a)	4/50 (8%)	0/50 (0%)
LITTERS (b)	4/31 (13%)	0/30 (0%)
POLY-3 RATE (c)	4/37.67	0/37.22
POLY-3 PERCENT (g)	10.6%	0%
TERMINAL (d)	2/23 (9%)	0/23 (0%)
FIRST INCIDENCE	505	---

STATISTICAL TESTS

POLY 3	P=0.060N
POLY 1.5	P=0.057N
POLY 6	P=0.067N
RAO-SCOTT	P=0.103N
LITTER C-A/FISHERS	P=0.060N

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Vagina (Standard or Longitudinal Evaluation)

Granular Cell Tumor

TUMOR RATES

	#	#
OVERALL (a)	4/50 (8%)	0/50 (0%)
LITTERS (b)	4/31 (13%)	0/30 (0%)
POLY-3 RATE (c)	4/37.67	0/37.22
POLY-3 PERCENT (g)	10.6%	0%
TERMINAL (d)	2/23 (9%)	0/23 (0%)
FIRST INCIDENCE	505	---

STATISTICAL TESTS

POLY 3	P=0.060N
POLY 1.5	P=0.057N
POLY 6	P=0.067N
RAO-SCOTT	P=0.103N
LITTER C-A/FISHERS	P=0.060N

Experiment Number: 20614 - 01
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Vagina (Standard Evaluation)
Squamous Cell Carcinoma

TUMOR RATES

	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)
LITTERS (b)	1/31 (3%)	0/30 (0%)
POLY-3 RATE (c)	1/37.15	0/37.22
POLY-3 PERCENT (g)	2.7%	0%
TERMINAL (d)	0/23 (0%)	0/23 (0%)
FIRST INCIDENCE	669	---

STATISTICAL TESTS

POLY 3	P=0.500N
POLY 1.5	P=0.495N
POLY 6	P=0.510N
RAO-SCOTT	P=0.535N
LITTER C-A/FISHERS	P=0.508N

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Perfluorooctanoic Acid

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TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Vagina (Standard or Longitudinal Evaluation)

Squamous Cell Carcinoma

TUMOR RATES

	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)
LITTERS (b)	1/31 (3%)	0/30 (0%)
POLY-3 RATE (c)	1/37.15	0/37.22
POLY-3 PERCENT (g)	2.7%	0%
TERMINAL (d)	0/23 (0%)	0/23 (0%)
FIRST INCIDENCE	669	---

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POLY 3	P=0.500N
POLY 1.5	P=0.495N
POLY 6	P=0.510N
RAO-SCOTT	P=0.535N
LITTER C-A/FISHERS	P=0.508N

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Perfluorooctanoic Acid
CAS Number: 335-67-1

Date Report Requested: 09/16/2018
Time Report Requested: 18:26:39
First Dose M/F: 10/27/08 / 10/28/08
Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

DOSE	0/1000 ppm	300/1000 ppm
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Vagina (Longitudinal Evaluation)
Squamous Cell Papilloma

TUMOR RATES	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)
LITTERS (b)	1/31 (3%)	0/30 (0%)
POLY-3 RATE (c)	1/36.88	0/37.22
POLY-3 PERCENT (g)	2.7%	0%
TERMINAL (d)	1/23 (4%)	0/23 (0%)
FIRST INCIDENCE	744 (T)	---

STATISTICAL TESTS

POLY 3	P=0.498N
POLY 1.5	P=0.494N
POLY 6	P=0.507N
RAO-SCOTT	P=0.543N
LITTER C-A/FISHERS	P=0.508N

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Perfluorooctanoic Acid

CAS Number: 335-67-1

Date Report Requested: 09/16/2018

Time Report Requested: 18:26:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Females

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

Vagina (Standard or Longitudinal Evaluation)

Squamous Cell Papilloma

TUMOR RATES

	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)
LITTERS (b)	1/31 (3%)	0/30 (0%)
POLY-3 RATE (c)	1/36.88	0/37.22
POLY-3 PERCENT (g)	2.7%	0%
TERMINAL (d)	1/23 (4%)	0/23 (0%)
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STATISTICAL TESTS

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Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Perfluorooctanoic Acid

CAS Number: 335-67-1

Date Report Requested: 09/16/2018

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

Lab: BAT

LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
- (b) Number of litters with tumor-bearing animals/number of litters examined at site
- (c) 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.
- (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 Rao-Scott statistic performs the Poly-3 test with an adjustment for within-litter correlation.
The Litter C-A/Fishers statistic compares directly the litter incidence rates.

*** END OF REPORT ***