

**Experiment Number:** 20614 - 02  
**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:** 06/14/2018  
**Time Report Requested:** 19:58:50  
**First Dose M/F:** 07/27/09 / NA  
**Lab:** BAT

SSAC Males 300-0, 300-20, 300-40, 300-80

**NTP Study Number:** C20614B  
**Lock Date:** 01/10/2012  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** 25017 SSAC  
**Removal Date Range:** ALL  
**Treatment Groups:** Include 002 300/0 ppm  
Include 008 300/80 ppm  
**Study Gender:** Male  
**TDMSE Version:** 2.5.0.0\_sfh  
**PWG Approval Date:** NONE

Include 004 300/20 ppm

Include 006 300/40 ppm

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

**MALE RATS**

**Organ**

Liver

Liver: Hepatocyte

**Morphology**

Necrosis

Pigment

Cytoplasmic Alteration

Hypertrophy

Single Cell Death

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

| DOSE                      | Males     |            |            |            |
|---------------------------|-----------|------------|------------|------------|
|                           | 300/0 ppm | 300/20 ppm | 300/40 ppm | 300/80 ppm |
| Liver<br>Basophilic Focus |           |            |            |            |
| <b>LESION RATES</b>       |           |            |            |            |
| OVERALL (a)               | 0/10 (0%) | 1/10 (10%) | 0/10 (0%)  | 0/10 (0%)  |
| POLY-3 RATE (b)           | 0/10.00   | 1/10.00    | 0/10.00    | 0/10.00    |
| POLY-3 PERCENT (g)        | 0%        | 10%        | 0%         | 0%         |
| INT SACRIFICE 1           | 0/10 (0%) | 1/10 (10%) | 0/10 (0%)  | 0/10 (0%)  |
| TERMINAL (d)              | 0/0 (0%)  | 0/0 (0%)   | 0/0 (0%)   | 0/0 (0%)   |
| FIRST INCIDENCE           | ---       | 108 (l)    | ---        | ---        |
| <b>STATISTICAL TESTS</b>  |           |            |            |            |
| POLY 3                    | P=0.567N  | P=0.500    | (e)        | (e)        |
| POLY 1.5                  | P=0.567N  | P=0.500    | (e)        | (e)        |
| POLY 6                    | P=0.567N  | P=0.500    | (e)        | (e)        |
| COCH-ARM / FISHERS        | P=0.568N  | P=0.500    | (e)        | (e)        |
| MAX-ISO-POLY-3            | P=0.388N  | P=0.159    | (e)        | (e)        |

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LAST REMOVAL AT 16 WEEKS**

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| DOSE                     | Males      |            |            |            |
|--------------------------|------------|------------|------------|------------|
|                          | 300/0 ppm  | 300/20 ppm | 300/40 ppm | 300/80 ppm |
| <hr/>                    |            |            |            |            |
| Liver                    |            |            |            |            |
| Clear Cell Focus         |            |            |            |            |
| <hr/>                    |            |            |            |            |
| <b>LESION RATES</b>      |            |            |            |            |
| OVERALL (a)              | 1/10 (10%) | 2/10 (20%) | 0/10 (0%)  | 2/10 (20%) |
| POLY-3 RATE (b)          | 1/10.00    | 2/10.00    | 0/10.00    | 2/10.00    |
| POLY-3 PERCENT (g)       | 10%        | 20%        | 0%         | 20%        |
| INT SACRIFICE 1          | 1/10 (10%) | 2/10 (20%) | 0/10 (0%)  | 2/10 (20%) |
| TERMINAL (d)             | 0/0 (0%)   | 0/0 (0%)   | 0/0 (0%)   | 0/0 (0%)   |
| FIRST INCIDENCE          | 108 (I)    | 108 (I)    | ---        | 108 (I)    |
| <hr/>                    |            |            |            |            |
| <b>STATISTICAL TESTS</b> |            |            |            |            |
| POLY 3                   | P=0.468    | P=0.500    | P=0.500N   | P=0.500    |
| POLY 1.5                 | P=0.468    | P=0.500    | P=0.500N   | P=0.500    |
| POLY 6                   | P=0.468    | P=0.500    | P=0.500N   | P=0.500    |
| COCH-ARM / FISHERS       | P=0.468    | P=0.500    | P=0.500N   | P=0.500    |
| MAX-ISO-POLY-3           | P=0.409    | P=0.275    | P=0.159N   | P=0.275    |

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LAST REMOVAL AT 16 WEEKS

| DOSE                      | Males      |            |            |            |
|---------------------------|------------|------------|------------|------------|
|                           | 300/0 ppm  | 300/20 ppm | 300/40 ppm | 300/80 ppm |
| <b>Liver</b>              |            |            |            |            |
| <b>Inflammation Focal</b> |            |            |            |            |
| <b>LESION RATES</b>       |            |            |            |            |
| OVERALL (a)               | 7/10 (70%) | 9/10 (90%) | 7/10 (70%) | 8/10 (80%) |
| POLY-3 RATE (b)           | 7/10.00    | 9/10.00    | 7/10.00    | 8/10.00    |
| POLY-3 PERCENT (g)        | 70%        | 90%        | 70%        | 80%        |
| INT SACRIFICE 1           | 7/10 (70%) | 9/10 (90%) | 7/10 (70%) | 8/10 (80%) |
| TERMINAL (d)              | 0/0 (0%)   | 0/0 (0%)   | 0/0 (0%)   | 0/0 (0%)   |
| FIRST INCIDENCE           | 108 (I)    | 108 (I)    | 108 (I)    | 108 (I)    |
| <b>STATISTICAL TESTS</b>  |            |            |            |            |
| POLY 3                    | P=0.525    | P=0.292    | P=0.678    | P=0.500    |
| POLY 1.5                  | P=0.525    | P=0.292    | P=0.678    | P=0.500    |
| POLY 6                    | P=0.525    | P=0.292    | P=0.678    | P=0.500    |
| COCH-ARM / FISHERS        | P=0.526    | P=0.291    | P=0.686N   | P=0.500    |
| MAX-ISO-POLY-3            | P=0.483    | P=0.136    | P=1.000    | P=0.311    |

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Lab: BAT

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

| DOSE                     | Males     |            |            |            |
|--------------------------|-----------|------------|------------|------------|
|                          | 300/0 ppm | 300/20 ppm | 300/40 ppm | 300/80 ppm |
| Liver<br>Necrosis        |           |            |            |            |
| <b>LESION RATES</b>      |           |            |            |            |
| OVERALL (a)              | 0/10 (0%) | 2/10 (20%) | 3/10 (30%) | 1/10 (10%) |
| POLY-3 RATE (b)          | 0/10.00   | 2/10.00    | 3/10.00    | 1/10.00    |
| POLY-3 PERCENT (g)       | 0%        | 20%        | 30%        | 10%        |
| INT SACRIFICE 1          | 0/10 (0%) | 2/10 (20%) | 3/10 (30%) | 1/10 (10%) |
| TERMINAL (d)             | 0/0 (0%)  | 0/0 (0%)   | 0/0 (0%)   | 0/0 (0%)   |
| FIRST INCIDENCE          | ---       | 108 (I)    | 108 (I)    | 108 (I)    |
| <b>STATISTICAL TESTS</b> |           |            |            |            |
| POLY 3                   | P=0.441   | P=0.227    | P=0.095    | P=0.500    |
| POLY 1.5                 | P=0.441   | P=0.227    | P=0.095    | P=0.500    |
| POLY 6                   | P=0.441   | P=0.227    | P=0.095    | P=0.500    |
| COCH-ARM / FISHERS       | P=0.441   | P=0.237    | P=0.105    | P=0.500    |
| MAX-ISO-POLY-3           | P=0.167   | P=0.067    | P=0.025*   | P=0.159    |

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

| DOSE                     | Males     |            |            |              |
|--------------------------|-----------|------------|------------|--------------|
|                          | 300/0 ppm | 300/20 ppm | 300/40 ppm | 300/80 ppm   |
| Liver<br>Pigment         |           |            |            |              |
| <b>LESION RATES</b>      |           |            |            |              |
| OVERALL (a)              | 0/10 (0%) | 3/10 (30%) | 7/10 (70%) | 10/10 (100%) |
| POLY-3 RATE (b)          | 0/10.00   | 3/10.00    | 7/10.00    | 10/10.00     |
| POLY-3 PERCENT (g)       | 0%        | 30%        | 70%        | 100%         |
| INT SACRIFICE 1          | 0/10 (0%) | 3/10 (30%) | 7/10 (70%) | 10/10 (100%) |
| TERMINAL (d)             | 0/0 (0%)  | 0/0 (0%)   | 0/0 (0%)   | 0/0 (0%)     |
| FIRST INCIDENCE          | ---       | 108 (l)    | 108 (l)    | 108 (l)      |
| <b>STATISTICAL TESTS</b> |           |            |            |              |
| POLY 3                   | P<0.001** | P=0.095    | P<0.001**  | P<0.001**    |
| POLY 1.5                 | P<0.001** | P=0.095    | P<0.001**  | P<0.001**    |
| POLY 6                   | P<0.001** | P=0.095    | P<0.001**  | P<0.001**    |
| COCH-ARM / FISHERS       | P<0.001** | P=0.105    | P=0.002**  | P<0.001**    |
| MAX-ISO-POLY-3           | P<0.001** | P=0.025*   | P<0.001**  | (e)          |

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LAST REMOVAL AT 16 WEEKS**

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| DOSE                     | Males     |            |              |              |
|--------------------------|-----------|------------|--------------|--------------|
|                          | 300/0 ppm | 300/20 ppm | 300/40 ppm   | 300/80 ppm   |
| <hr/>                    |           |            |              |              |
| Liver: Hepatocyte        |           |            |              |              |
| Cytoplasmic Alteration   |           |            |              |              |
| <hr/>                    |           |            |              |              |
| <b>LESION RATES</b>      |           |            |              |              |
| OVERALL (a)              | 0/10 (0%) | 9/10 (90%) | 10/10 (100%) | 10/10 (100%) |
| POLY-3 RATE (b)          | 0/10.00   | 9/10.00    | 10/10.00     | 10/10.00     |
| POLY-3 PERCENT (g)       | 0%        | 90%        | 100%         | 100%         |
| INT SACRIFICE 1          | 0/10 (0%) | 9/10 (90%) | 10/10 (100%) | 10/10 (100%) |
| TERMINAL (d)             | 0/0 (0%)  | 0/0 (0%)   | 0/0 (0%)     | 0/0 (0%)     |
| FIRST INCIDENCE          | ---       | 108 (l)    | 108 (l)      | 108 (l)      |
| <hr/>                    |           |            |              |              |
| <b>STATISTICAL TESTS</b> |           |            |              |              |
| POLY 3                   | P<0.001** | P<0.001**  | P<0.001**    | P<0.001**    |
| POLY 1.5                 | P<0.001** | P<0.001**  | P<0.001**    | P<0.001**    |
| POLY 6                   | P<0.001** | P<0.001**  | P<0.001**    | P<0.001**    |
| COCH-ARM / FISHERS       | P<0.001** | P<0.001**  | P<0.001**    | P<0.001**    |
| MAX-ISO-POLY-3           | P<0.001** | P<0.001**  | (e)          | (e)          |

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Lab: BAT

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LAST REMOVAL AT 16 WEEKS**

| DOSE                                 | Males     |            |              |              |
|--------------------------------------|-----------|------------|--------------|--------------|
|                                      | 300/0 ppm | 300/20 ppm | 300/40 ppm   | 300/80 ppm   |
| <b>Liver: Hepatocyte Hypertrophy</b> |           |            |              |              |
| <b>LESION RATES</b>                  |           |            |              |              |
| OVERALL (a)                          | 0/10 (0%) | 9/10 (90%) | 10/10 (100%) | 10/10 (100%) |
| POLY-3 RATE (b)                      | 0/10.00   | 9/10.00    | 10/10.00     | 10/10.00     |
| POLY-3 PERCENT (g)                   | 0%        | 90%        | 100%         | 100%         |
| INT SACRIFICE 1                      | 0/10 (0%) | 9/10 (90%) | 10/10 (100%) | 10/10 (100%) |
| TERMINAL (d)                         | 0/0 (0%)  | 0/0 (0%)   | 0/0 (0%)     | 0/0 (0%)     |
| FIRST INCIDENCE                      | ---       | 108 (l)    | 108 (l)      | 108 (l)      |
| <b>STATISTICAL TESTS</b>             |           |            |              |              |
| POLY 3                               | P<0.001** | P<0.001**  | P<0.001**    | P<0.001**    |
| POLY 1.5                             | P<0.001** | P<0.001**  | P<0.001**    | P<0.001**    |
| POLY 6                               | P<0.001** | P<0.001**  | P<0.001**    | P<0.001**    |
| COCH-ARM / FISHERS                   | P<0.001** | P<0.001**  | P<0.001**    | P<0.001**    |
| MAX-ISO-POLY-3                       | P<0.001** | P<0.001**  | (e)          | (e)          |

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LAST REMOVAL AT 16 WEEKS

| DOSE   | Males     |            |            |              |
|--|-----------|------------|------------|--------------|
|  | 300/0 ppm | 300/20 ppm | 300/40 ppm | 300/80 ppm   |
| <b>Liver: Hepatocyte<br/>Single Cell Death</b> |           |            |            |              |
| <b>LESION RATES</b>                            |           |            |            |              |
| OVERALL (a)                                    | 0/10 (0%) | 5/10 (50%) | 8/10 (80%) | 10/10 (100%) |
| POLY-3 RATE (b)                                | 0/10.00   | 5/10.00    | 8/10.00    | 10/10.00     |
| POLY-3 PERCENT (g)                             | 0%        | 50%        | 80%        | 100%         |
| INT SACRIFICE 1                                | 0/10 (0%) | 5/10 (50%) | 8/10 (80%) | 10/10 (100%) |
| TERMINAL (d)                                   | 0/0 (0%)  | 0/0 (0%)   | 0/0 (0%)   | 0/0 (0%)     |
| FIRST INCIDENCE                                | ---       | 108 (l)    | 108 (l)    | 108 (l)      |
| <b>STATISTICAL TESTS</b>                       |           |            |            |              |
| POLY 3   | P<0.001** | P=0.008**  | P<0.001**  | P<0.001**    |
| POLY 1.5                                       | P<0.001** | P=0.008**  | P<0.001**  | P<0.001**    |
| POLY 6   | P<0.001** | P=0.008**  | P<0.001**  | P<0.001**    |
| COCH-ARM / FISHERS                             | P<0.001** | P=0.016*   | P<0.001**  | P<0.001**    |
| MAX-ISO-POLY-3                                 | P<0.001** | P<0.001**  | P<0.001**  | (e)          |

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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.
  - (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 \*\*\*