

**Experiment Number:** 93027-27  
**Test Type:** 90-DAY  
**Route:** DOSED FEED  
**Species/Strain:** HAMSTERS/SYRIAN

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

**Test Compound:** Peroxisome project (Gemfibrozil)

**CAS Number:** 25812-30-0

**Date Report Requested:** 10/15/2014

**Time Report Requested:** 17:32:49

**First Dose M/F:** NA / NA

**Lab:** BAT

**C Number:** C93027B  
**Lock Date:** 06/12/1996  
**Cage Range:** All  
**Date Range:** All  
**Reasons For Removal:** All  
**Removal Date Range:** All  
**Treatment Groups:** All  
**Study Gender:** Male  
**PWG Approval Date:** NONE

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

**MALE HAMSTERS**

**Organ**

Epididymis  
Kidney

Liver  
Pancreas  
Prostate  
Seminal Vesicle  
Testes

**Morphology**

Degeneration  
Mineralization  
Nephropathy  
Depletion Glycogen  
Inflammation Chronic  
Atrophy  
Atrophy  
Atrophy

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 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                     | MALE      |          |          |          |            |            |
|--------------------------|-----------|----------|----------|----------|------------|------------|
|                          | 0 PPM     | 100 PPM  | 1000 PPM | 6000 PPM | 12,000 PPM | 24,000 PPM |
| <b>Epididymis</b>        |           |          |          |          |            |            |
| <b>Degeneration</b>      |           |          |          |          |            |            |
| <b>LESION RATES</b>      |           |          |          |          |            |            |
| OVERALL(a)               | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 1/1 (100%) | 0/10 (0%)  |
| POLY-3 RATE (b)          | 0/10.00   | 0/0.00   | 0/0.00   | 0/0.00   | 1/1.00     | 0/10.00    |
| POLY-3 PERCENT (g)       | 0%        | 0%       | 0%       | 0%       | 100%       | 0%         |
| TERMINAL (d)             | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 1/1 (100%) | 0/10 (0%)  |
| FIRST INCIDENCE          | ---       | ---      | ---      | ---      | 92(T)      | ---        |
| <b>STATISTICAL TESTS</b> |           |          |          |          |            |            |
| POLY 3                   | (e)       | (e)      | (e)      | (e)      | P=0.091    | (e)        |
| POLY 1.5                 | (e)       | (e)      | (e)      | (e)      | P=0.091    | (e)        |
| POLY 6                   | (e)       | (e)      | (e)      | (e)      | P=0.091    | (e)        |
| COCH-ARM / FISHERS       | P=0.700   | (e)      | (e)      | (e)      | P=0.091    | (e)        |
| MAX-ISO-POLY-3           | (e)       | (e)      | (e)      | (e)      | P=0.000**  | (e)        |
| HISTCONT SAME RTE        |           |          |          |          |            |            |
| HISTCONT ALL RTES        |           |          |          |          |            |            |
| CURR VS HC SAME RTE      |           |          |          |          |            |            |
| CURR VS HC ALL RTES      |           |          |          |          |            |            |

Experiment Number: 93027-27  
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**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
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 CAS Number: 25812-30-0

Date Report Requested: 10/15/2014  
 Time Report Requested: 17:32:49  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                                    | MALE       |          |          |          |            |            |
|---|------------|----------|----------|----------|------------|------------|
|   | 0 PPM      | 100 PPM  | 1000 PPM | 6000 PPM | 12,000 PPM | 24,000 PPM |
| <b>Gallbladder</b>                      |            |          |          |          |            |            |
| <b>Infiltration Cellular Mixed Cell</b> |            |          |          |          |            |            |
| <b>LESION RATES</b>                     |            |          |          |          |            |            |
| OVERALL(a)                              | 6/10 (60%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%)   | 9/10 (90%) |
| POLY-3 RATE (b)                         | 6/10.00    | 0/0.00   | 0/0.00   | 0/0.00   | 0/0.00     | 9/10.00    |
| POLY-3 PERCENT (g)                      | 60%        | 0%       | 0%       | 0%       | 0%         | 90%        |
| TERMINAL (d)                            | 6/10 (60%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%)   | 9/10 (90%) |
| FIRST INCIDENCE                         | 92(T)      | ---      | ---      | ---      | ---        | 92(T)      |
| <b>STATISTICAL TESTS</b>                |            |          |          |          |            |            |
| POLY 3                                  | (e)        | (e)      | (e)      | (e)      | (e)        | P=0.148    |
| POLY 1.5                                | (e)        | (e)      | (e)      | (e)      | (e)        | P=0.148    |
| POLY 6                                  | (e)        | (e)      | (e)      | (e)      | (e)        | P=0.148    |
| COCH-ARM / FISHERS                      | P=0.098    | (e)      | (e)      | (e)      | (e)        | P=0.152    |
| MAX-ISO-POLY-3                          | (e)        | (e)      | (e)      | (e)      | (e)        | P=0.059    |
| HISTCONT SAME RTE                       |            |          |          |          |            |            |
| HISTCONT ALL RTES                       |            |          |          |          |            |            |
| CURR VS HC SAME RTE                     |            |          |          |          |            |            |
| CURR VS HC ALL RTES                     |            |          |          |          |            |            |

Experiment Number: 93027-27  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: HAMSTERS/SYRIAN

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Peroxisome project (Gemfibrozil)  
 CAS Number: 25812-30-0

Date Report Requested: 10/15/2014  
 Time Report Requested: 17:32:49  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                     | MALE       |           |          |            |            |            |
|--------------------------|------------|-----------|----------|------------|------------|------------|
|                          | 0 PPM      | 100 PPM   | 1000 PPM | 6000 PPM   | 12,000 PPM | 24,000 PPM |
| <b>Kidney</b>            |            |           |          |            |            |            |
| <b>Mineralization</b>    |            |           |          |            |            |            |
| <b>LESION RATES</b>      |            |           |          |            |            |            |
| OVERALL(a)               | 1/10 (10%) | 1/9 (11%) | 0/8 (0%) | 1/10 (10%) | 1/10 (10%) | 8/10 (80%) |
| POLY-3 RATE (b)          | 1/10.00    | 1/9.00    | 0/8.00   | 1/10.00    | 1/10.00    | 8/10.00    |
| POLY-3 PERCENT (g)       | 10%        | 11.1%     | 0%       | 10%        | 10%        | 80%        |
| TERMINAL (d)             | 1/10 (10%) | 1/9 (11%) | 0/8 (0%) | 1/10 (10%) | 1/10 (10%) | 8/10 (80%) |
| FIRST INCIDENCE          | 92(T)      | 92(T)     | ---      | 92(T)      | 92(T)      | 92(T)      |
| <b>STATISTICAL TESTS</b> |            |           |          |            |            |            |
| POLY 3                   | P=0.000**  | P=0.737   | P=0.544N | P=0.760    | P=0.760    | P=0.000**  |
| POLY 1.5                 | P=0.000**  | P=0.737   | P=0.544N | P=0.760    | P=0.760    | P=0.000**  |
| POLY 6                   | P=0.000**  | P=0.737   | P=0.544N | P=0.760    | P=0.760    | P=0.000**  |
| COCH-ARM / FISHERS       | P=0.000**  | P=0.737   | P=0.556N | P=0.763N   | P=0.763N   | P=0.003**  |
| MAX-ISO-POLY-3           | P=0.000**  | P=0.471   | P=0.200N | P=1.000    | P=1.000    | P=0.000**  |
| HISTCONT SAME RTE        |            |           |          |            |            |            |
| HISTCONT ALL RTES        |            |           |          |            |            |            |
| CURR VS HC SAME RTE      |            |           |          |            |            |            |
| CURR VS HC ALL RTES      |            |           |          |            |            |            |

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 Species/Strain: HAMSTERS/SYRIAN

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Peroxisome project (Gemfibrozil)  
 CAS Number: 25812-30-0

Date Report Requested: 10/15/2014  
 Time Report Requested: 17:32:49  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                     | MALE       |           |           |            |            |              |
|--------------------------|------------|-----------|-----------|------------|------------|--------------|
|                          | 0 PPM      | 100 PPM   | 1000 PPM  | 6000 PPM   | 12,000 PPM | 24,000 PPM   |
| <b>Kidney</b>            |            |           |           |            |            |              |
| <b>Nephropathy</b>       |            |           |           |            |            |              |
| <b>LESION RATES</b>      |            |           |           |            |            |              |
| OVERALL(a)               | 3/10 (30%) | 1/9 (11%) | 4/8 (50%) | 6/10 (60%) | 4/10 (40%) | 10/10 (100%) |
| POLY-3 RATE (b)          | 3/10.00    | 1/9.00    | 4/8.00    | 6/10.00    | 4/10.00    | 10/10.00     |
| POLY-3 PERCENT (g)       | 30%        | 11.1%     | 50%       | 60%        | 40%        | 100%         |
| TERMINAL (d)             | 3/10 (30%) | 1/9 (11%) | 4/8 (50%) | 6/10 (60%) | 4/10 (40%) | 10/10 (100%) |
| FIRST INCIDENCE          | 92(T)      | 92(T)     | 92(T)     | 92(T)      | 92(T)      | 92(T)        |
| <b>STATISTICAL TESTS</b> |            |           |           |            |            |              |
| POLY 3                   | P=0.000**  | P=0.333N  | P=0.358   | P=0.186    | P=0.500    | P=0.000**    |
| POLY 1.5                 | P=0.000**  | P=0.333N  | P=0.358   | P=0.186    | P=0.500    | P=0.000**    |
| POLY 6                   | P=0.000**  | P=0.333N  | P=0.358   | P=0.186    | P=0.500    | P=0.000**    |
| COCH-ARM / FISHERS       | P=0.000**  | P=0.333N  | P=0.352   | P=0.185    | P=0.500    | P=0.002**    |
| MAX-ISO-POLY-3           | P=0.000**  | P=0.170N  | P=0.215   | P=0.090    | P=0.327    | P=0.000**    |
| HISTCONT SAME RTE        |            |           |           |            |            |              |
| HISTCONT ALL RTES        |            |           |           |            |            |              |
| CURR VS HC SAME RTE      |            |           |           |            |            |              |
| CURR VS HC ALL RTES      |            |           |           |            |            |              |

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**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Peroxisome project (Gemfibrozil)  
 CAS Number: 25812-30-0

Date Report Requested: 10/15/2014  
 Time Report Requested: 17:32:49  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                      | MALE      |           |            |            |            |              |
|---------------------------|-----------|-----------|------------|------------|------------|--------------|
|                           | 0 PPM     | 100 PPM   | 1000 PPM   | 6000 PPM   | 12,000 PPM | 24,000 PPM   |
| <b>Liver</b>              |           |           |            |            |            |              |
| <b>Depletion Glycogen</b> |           |           |            |            |            |              |
| <b>LESION RATES</b>       |           |           |            |            |            |              |
| OVERALL(a)                | 0/10 (0%) | 5/9 (56%) | 4/10 (40%) | 8/10 (80%) | 9/10 (90%) | 10/10 (100%) |
| POLY-3 RATE (b)           | 0/10.00   | 5/9.00    | 4/10.00    | 8/10.00    | 9/10.00    | 10/10.00     |
| POLY-3 PERCENT (g)        | 0%        | 55.6%     | 40%        | 80%        | 90%        | 100%         |
| TERMINAL (d)              | 0/10 (0%) | 5/9 (56%) | 4/10 (40%) | 8/10 (80%) | 9/10 (90%) | 10/10 (100%) |
| FIRST INCIDENCE           | ---       | 92(T)     | 92(T)      | 92(T)      | 92(T)      | 92(T)        |
| <b>STATISTICAL TESTS</b>  |           |           |            |            |            |              |
| POLY 3                    | P=0.000** | P=0.003** | P=0.033*   | P=0.000**  | P=0.000**  | P=NA         |
| POLY 1.5                  | P=0.000** | P=0.003** | P=0.033*   | P=0.000**  | P=0.000**  | P=NA         |
| POLY 6                    | P=0.000** | P=0.003** | P=0.033*   | P=0.000**  | P=0.000**  | P=NA         |
| COCH-ARM / FISHERS        | P=0.000** | P=0.011*  | P=0.043*   | P=0.000**  | P=0.000**  | P=0.000**    |
| MAX-ISO-POLY-3            | P=0.000** | P<0.001** | P=0.007**  | P=0.000**  | P=0.000**  | (e)          |
| HISTCONT SAME RTE         |           |           |            |            |            |              |
| HISTCONT ALL RTES         |           |           |            |            |            |              |
| CURR VS HC SAME RTE       |           |           |            |            |            |              |
| CURR VS HC ALL RTES       |           |           |            |            |            |              |

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Test Compound: Peroxisome project (Gemfibrozil)  
 CAS Number: 25812-30-0

Date Report Requested: 10/15/2014  
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 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                                    | MALE       |            |            |            |              |              |
|---|------------|------------|------------|------------|--------------|--------------|
|   | 0 PPM      | 100 PPM    | 1000 PPM   | 6000 PPM   | 12,000 PPM   | 24,000 PPM   |
| <b>Liver</b>                            |            |            |            |            |              |              |
| <b>Infiltration Cellular Mixed Cell</b> |            |            |            |            |              |              |
| <b>LESION RATES</b>                     |            |            |            |            |              |              |
| OVERALL(a)                              | 9/10 (90%) | 9/9 (100%) | 9/10 (90%) | 9/10 (90%) | 10/10 (100%) | 10/10 (100%) |
| POLY-3 RATE (b)                         | 9/10.00    | 9/9.00     | 9/10.00    | 9/10.00    | 10/10.00     | 10/10.00     |
| POLY-3 PERCENT (g)                      | 90%        | 100%       | 90%        | 90%        | 100%         | 100%         |
| TERMINAL (d)                            | 9/10 (90%) | 9/9 (100%) | 9/10 (90%) | 9/10 (90%) | 10/10 (100%) | 10/10 (100%) |
| FIRST INCIDENCE                         | 92(T)      | 92(T)      | 92(T)      | 92(T)      | 92(T)        | 92(T)        |
| <b>STATISTICAL TESTS</b>                |            |            |            |            |              |              |
| POLY 3                                  | P=0.276    | P=0.521    | P=0.760    | P=0.760    | P=0.500      | P=0.500      |
| POLY 1.5                                | P=0.276    | P=0.521    | P=0.760    | P=0.760    | P=0.500      | P=0.500      |
| POLY 6                                  | P=0.276    | P=0.521    | P=0.760    | P=0.760    | P=0.500      | P=0.500      |
| COCH-ARM / FISHERS                      | P=0.271    | P=0.526    | P=0.763N   | P=0.763N   | P=0.500      | P=0.500      |
| MAX-ISO-POLY-3                          | P=0.299    | P=0.179    | P=1.000    | P=1.000    | P=0.159      | P=0.159      |
| HISTCONT SAME RTE                       |            |            |            |            |              |              |
| HISTCONT ALL RTES                       |            |            |            |            |              |              |
| CURR VS HC SAME RTE                     |            |            |            |            |              |              |
| CURR VS HC ALL RTES                     |            |            |            |            |              |              |



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**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Peroxisome project (Gemfibrozil)  
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Date Report Requested: 10/15/2014  
 Time Report Requested: 17:32:49  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                        | MALE      |          |           |           |            |            |
|-----------------------------|-----------|----------|-----------|-----------|------------|------------|
|                             | 0 PPM     | 100 PPM  | 1000 PPM  | 6000 PPM  | 12,000 PPM | 24,000 PPM |
| <b>Liver</b>                |           |          |           |           |            |            |
| <b>Inflammation Chronic</b> |           |          |           |           |            |            |
| <b>LESION RATES</b>         |           |          |           |           |            |            |
| OVERALL(a)                  | 0/10 (0%) | 0/9 (0%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%)  | 1/10 (10%) |
| POLY-3 RATE (b)             | 0/10.00   | 0/9.00   | 0/10.00   | 0/10.00   | 0/10.00    | 1/10.00    |
| POLY-3 PERCENT (g)          | 0%        | 0%       | 0%        | 0%        | 0%         | 10%        |
| TERMINAL (d)                | 0/10 (0%) | 0/9 (0%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%)  | 1/10 (10%) |
| FIRST INCIDENCE             | ---       | ---      | ---       | ---       | ---        | 92(T)      |
| <b>STATISTICAL TESTS</b>    |           |          |           |           |            |            |
| POLY 3                      | P=0.109   | (e)      | (e)       | (e)       | (e)        | P=0.500    |
| POLY 1.5                    | P=0.109   | (e)      | (e)       | (e)       | (e)        | P=0.500    |
| POLY 6                      | P=0.109   | (e)      | (e)       | (e)       | (e)        | P=0.500    |
| COCH-ARM / FISHERS          | P=0.106   | (e)      | (e)       | (e)       | (e)        | P=0.500    |
| MAX-ISO-POLY-3              | P=0.079   | (e)      | (e)       | (e)       | (e)        | P=0.159    |
| HISTCONT SAME RTE           |           |          |           |           |            |            |
| HISTCONT ALL RTES           |           |          |           |           |            |            |
| CURR VS HC SAME RTE         |           |          |           |           |            |            |
| CURR VS HC ALL RTES         |           |          |           |           |            |            |

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Date Report Requested: 10/15/2014  
 Time Report Requested: 17:32:49  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                     | MALE      |          |           |           |            |            |
|--------------------------|-----------|----------|-----------|-----------|------------|------------|
|                          | 0 PPM     | 100 PPM  | 1000 PPM  | 6000 PPM  | 12,000 PPM | 24,000 PPM |
| <b>Liver</b>             |           |          |           |           |            |            |
| <b>Necrosis</b>          |           |          |           |           |            |            |
| <b>LESION RATES</b>      |           |          |           |           |            |            |
| OVERALL(a)               | 0/10 (0%) | 0/9 (0%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%)  | 1/10 (10%) |
| POLY-3 RATE (b)          | 0/10.00   | 0/9.00   | 0/10.00   | 0/10.00   | 0/10.00    | 1/10.00    |
| POLY-3 PERCENT (g)       | 0%        | 0%       | 0%        | 0%        | 0%         | 10%        |
| TERMINAL (d)             | 0/10 (0%) | 0/9 (0%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%)  | 1/10 (10%) |
| FIRST INCIDENCE          | ---       | ---      | ---       | ---       | ---        | 92(T)      |
| <b>STATISTICAL TESTS</b> |           |          |           |           |            |            |
| POLY 3                   | P=0.109   | (e)      | (e)       | (e)       | (e)        | P=0.500    |
| POLY 1.5                 | P=0.109   | (e)      | (e)       | (e)       | (e)        | P=0.500    |
| POLY 6                   | P=0.109   | (e)      | (e)       | (e)       | (e)        | P=0.500    |
| COCH-ARM / FISHERS       | P=0.106   | (e)      | (e)       | (e)       | (e)        | P=0.500    |
| MAX-ISO-POLY-3           | P=0.079   | (e)      | (e)       | (e)       | (e)        | P=0.159    |
| HISTCONT SAME RTE        |           |          |           |           |            |            |
| HISTCONT ALL RTES        |           |          |           |           |            |            |
| CURR VS HC SAME RTE      |           |          |           |           |            |            |
| CURR VS HC ALL RTES      |           |          |           |           |            |            |

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 Route: DOSED FEED  
 Species/Strain: HAMSTERS/SYRIAN

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Peroxisome project (Gemfibrozil)  
 CAS Number: 25812-30-0

Date Report Requested: 10/15/2014  
 Time Report Requested: 17:32:49  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                     | MALE       |          |          |          |            |            |
|--------------------------|------------|----------|----------|----------|------------|------------|
|                          | 0 PPM      | 100 PPM  | 1000 PPM | 6000 PPM | 12,000 PPM | 24,000 PPM |
| <b>Lung</b>              |            |          |          |          |            |            |
| <b>Hemorrhage</b>        |            |          |          |          |            |            |
| <b>LESION RATES</b>      |            |          |          |          |            |            |
| OVERALL(a)               | 5/10 (50%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%)   | 4/10 (40%) |
| POLY-3 RATE (b)          | 5/10.00    | 0/0.00   | 0/0.00   | 0/0.00   | 0/0.00     | 4/10.00    |
| POLY-3 PERCENT (g)       | 50%        | 0%       | 0%       | 0%       | 0%         | 40%        |
| TERMINAL (d)             | 5/10 (50%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%)   | 4/10 (40%) |
| FIRST INCIDENCE          | 92(T)      | ---      | ---      | ---      | ---        | 92(T)      |
| <b>STATISTICAL TESTS</b> |            |          |          |          |            |            |
| POLY 3                   | (e)        | (e)      | (e)      | (e)      | (e)        | P=0.500N   |
| POLY 1.5                 | (e)        | (e)      | (e)      | (e)      | (e)        | P=0.500N   |
| POLY 6                   | (e)        | (e)      | (e)      | (e)      | (e)        | P=0.500N   |
| COCH-ARM / FISHERS       | P=0.411N   | (e)      | (e)      | (e)      | (e)        | P=0.500N   |
| MAX-ISO-POLY-3           | (e)        | (e)      | (e)      | (e)      | (e)        | P=0.334N   |
| HISTCONT SAME RTE        |            |          |          |          |            |            |
| HISTCONT ALL RTES        |            |          |          |          |            |            |
| CURR VS HC SAME RTE      |            |          |          |          |            |            |
| CURR VS HC ALL RTES      |            |          |          |          |            |            |

Experiment Number: 93027-27  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: HAMSTERS/SYRIAN

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Peroxisome project (Gemfibrozil)  
 CAS Number: 25812-30-0

Date Report Requested: 10/15/2014  
 Time Report Requested: 17:32:49  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                        | MALE       |            |            |            |            |              |
|-----------------------------|------------|------------|------------|------------|------------|--------------|
|                             | 0 PPM      | 100 PPM    | 1000 PPM   | 6000 PPM   | 12,000 PPM | 24,000 PPM   |
| <b>Pancreas</b>             |            |            |            |            |            |              |
| <b>Inflammation Chronic</b> |            |            |            |            |            |              |
| <b>LESION RATES</b>         |            |            |            |            |            |              |
| OVERALL(a)                  | 6/10 (60%) | 6/10 (60%) | 6/10 (60%) | 7/10 (70%) | 7/9 (78%)  | 10/10 (100%) |
| POLY-3 RATE (b)             | 6/10.00    | 6/10.00    | 6/10.00    | 7/10.00    | 7/9.00     | 10/10.00     |
| POLY-3 PERCENT (g)          | 60%        | 60%        | 60%        | 70%        | 77.8%      | 100%         |
| TERMINAL (d)                | 6/10 (60%) | 6/10 (60%) | 6/10 (60%) | 7/10 (70%) | 7/9 (78%)  | 10/10 (100%) |
| FIRST INCIDENCE             | 92(T)      | 92(T)      | 92(T)      | 92(T)      | 92(T)      | 92(T)        |
| <b>STATISTICAL TESTS</b>    |            |            |            |            |            |              |
| POLY 3                      | P=0.012*   | P=0.667    | P=0.667    | P=0.500    | P=0.372    | P=0.033*     |
| POLY 1.5                    | P=0.012*   | P=0.667    | P=0.667    | P=0.500    | P=0.372    | P=0.033*     |
| POLY 6                      | P=0.012*   | P=0.667    | P=0.667    | P=0.500    | P=0.372    | P=0.033*     |
| COCH-ARM / FISHERS          | P=0.012*   | P=0.675N   | P=0.675N   | P=0.500    | P=0.370    | P=0.043*     |
| MAX-ISO-POLY-3              | P=0.021*   | P=1.000    | P=1.000    | P=0.327    | P=0.217    | P=0.007**    |
| HISTCONT SAME RTE           |            |            |            |            |            |              |
| HISTCONT ALL RTES           |            |            |            |            |            |              |
| CURR VS HC SAME RTE         |            |            |            |            |            |              |
| CURR VS HC ALL RTES         |            |            |            |            |            |              |

Experiment Number: 93027-27  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: HAMSTERS/SYRIAN

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Peroxisome project (Gemfibrozil)

CAS Number: 25812-30-0

Date Report Requested: 10/15/2014

Time Report Requested: 17:32:49

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                     | MALE      |            |            |            |            |            |
|--------------------------|-----------|------------|------------|------------|------------|------------|
|                          | 0 PPM     | 100 PPM    | 1000 PPM   | 6000 PPM   | 12,000 PPM | 24,000 PPM |
| <b>Prostate Atrophy</b>  |           |            |            |            |            |            |
| <b>LESION RATES</b>      |           |            |            |            |            |            |
| OVERALL(a)               | 0/10 (0%) | 1/10 (10%) | 3/10 (30%) | 5/10 (50%) | 2/9 (22%)  | 5/10 (50%) |
| POLY-3 RATE (b)          | 0/10.00   | 1/10.00    | 3/10.00    | 5/10.00    | 2/9.00     | 5/10.00    |
| POLY-3 PERCENT (g)       | 0%        | 10%        | 30%        | 50%        | 22.2%      | 50%        |
| TERMINAL (d)             | 0/10 (0%) | 1/10 (10%) | 3/10 (30%) | 5/10 (50%) | 2/9 (22%)  | 5/10 (50%) |
| FIRST INCIDENCE          | ---       | 92(T)      | 92(T)      | 92(T)      | 92(T)      | 92(T)      |
| <b>STATISTICAL TESTS</b> |           |            |            |            |            |            |
| POLY 3                   | P=0.021*  | P=0.500    | P=0.095    | P=0.008**  | P=0.201    | P=0.008**  |
| POLY 1.5                 | P=0.021*  | P=0.500    | P=0.095    | P=0.008**  | P=0.201    | P=0.008**  |
| POLY 6                   | P=0.021*  | P=0.500    | P=0.095    | P=0.008**  | P=0.201    | P=0.008**  |
| COCH-ARM / FISHERS       | P=0.026*  | P=0.500    | P=0.105    | P=0.016*   | P=0.211    | P=0.016*   |
| MAX-ISO-POLY-3           | P=0.008** | P=0.159    | P=0.025*   | P<0.001**  | P=0.060    | P<0.001**  |
| HISTCONT SAME RTE        |           |            |            |            |            |            |
| HISTCONT ALL RTES        |           |            |            |            |            |            |
| CURR VS HC SAME RTE      |           |            |            |            |            |            |
| CURR VS HC ALL RTES      |           |            |            |            |            |            |

Experiment Number: 93027-27  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: HAMSTERS/SYRIAN

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Peroxisome project (Gemfibrozil)  
 CAS Number: 25812-30-0

Date Report Requested: 10/15/2014  
 Time Report Requested: 17:32:49  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                     | MALE      |            |            |            |            |            |
|--------------------------|-----------|------------|------------|------------|------------|------------|
|                          | 0 PPM     | 100 PPM    | 1000 PPM   | 6000 PPM   | 12,000 PPM | 24,000 PPM |
| <b>Seminal Vesicle</b>   |           |            |            |            |            |            |
| <b>Atrophy</b>           |           |            |            |            |            |            |
| <b>LESION RATES</b>      |           |            |            |            |            |            |
| OVERALL(a)               | 0/10 (0%) | 1/10 (10%) | 3/10 (30%) | 5/10 (50%) | 2/9 (22%)  | 5/10 (50%) |
| POLY-3 RATE (b)          | 0/10.00   | 1/10.00    | 3/10.00    | 5/10.00    | 2/9.00     | 5/10.00    |
| POLY-3 PERCENT (g)       | 0%        | 10%        | 30%        | 50%        | 22.2%      | 50%        |
| TERMINAL (d)             | 0/10 (0%) | 1/10 (10%) | 3/10 (30%) | 5/10 (50%) | 2/9 (22%)  | 5/10 (50%) |
| FIRST INCIDENCE          | ---       | 92(T)      | 92(T)      | 92(T)      | 92(T)      | 92(T)      |
| <b>STATISTICAL TESTS</b> |           |            |            |            |            |            |
| POLY 3                   | P=0.021*  | P=0.500    | P=0.095    | P=0.008**  | P=0.201    | P=0.008**  |
| POLY 1.5                 | P=0.021*  | P=0.500    | P=0.095    | P=0.008**  | P=0.201    | P=0.008**  |
| POLY 6                   | P=0.021*  | P=0.500    | P=0.095    | P=0.008**  | P=0.201    | P=0.008**  |
| COCH-ARM / FISHERS       | P=0.026*  | P=0.500    | P=0.105    | P=0.016*   | P=0.211    | P=0.016*   |
| MAX-ISO-POLY-3           | P=0.008** | P=0.159    | P=0.025*   | P<0.001**  | P=0.060    | P<0.001**  |
| HISTCONT SAME RTE        |           |            |            |            |            |            |
| HISTCONT ALL RTES        |           |            |            |            |            |            |
| CURR VS HC SAME RTE      |           |            |            |            |            |            |
| CURR VS HC ALL RTES      |           |            |            |            |            |            |

Experiment Number: 93027-27  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: HAMSTERS/SYRIAN

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Peroxisome project (Gemfibrozil)  
 CAS Number: 25812-30-0

Date Report Requested: 10/15/2014  
 Time Report Requested: 17:32:49  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                     | MALE       |            |            |            |            |            |
|--------------------------|------------|------------|------------|------------|------------|------------|
|                          | 0 PPM      | 100 PPM    | 1000 PPM   | 6000 PPM   | 12,000 PPM | 24,000 PPM |
| <b>Testes</b>            |            |            |            |            |            |            |
| <b>Atrophy</b>           |            |            |            |            |            |            |
| <b>LESION RATES</b>      |            |            |            |            |            |            |
| OVERALL(a)               | 1/10 (10%) | 2/10 (20%) | 3/10 (30%) | 5/10 (50%) | 4/10 (40%) | 5/10 (50%) |
| POLY-3 RATE (b)          | 1/10.00    | 2/10.00    | 3/10.00    | 5/10.00    | 4/10.00    | 5/10.00    |
| POLY-3 PERCENT (g)       | 10%        | 20%        | 30%        | 50%        | 40%        | 50%        |
| TERMINAL (d)             | 1/10 (10%) | 2/10 (20%) | 3/10 (30%) | 5/10 (50%) | 4/10 (40%) | 5/10 (50%) |
| FIRST INCIDENCE          | 92(T)      | 92(T)      | 92(T)      | 92(T)      | 92(T)      | 92(T)      |
| <b>STATISTICAL TESTS</b> |            |            |            |            |            |            |
| POLY 3                   | P=0.051    | P=0.500    | P=0.292    | P=0.061    | P=0.148    | P=0.061    |
| POLY 1.5                 | P=0.051    | P=0.500    | P=0.292    | P=0.061    | P=0.148    | P=0.061    |
| POLY 6                   | P=0.051    | P=0.500    | P=0.292    | P=0.061    | P=0.148    | P=0.061    |
| COCH-ARM / FISHERS       | P=0.051    | P=0.500    | P=0.291    | P=0.070    | P=0.152    | P=0.070    |
| MAX-ISO-POLY-3           | P=0.053    | P=0.274    | P=0.138    | P=0.020*   | P=0.059    | P=0.020*   |
| HISTCONT SAME RTE        |            |            |            |            |            |            |
| HISTCONT ALL RTES        |            |            |            |            |            |            |
| CURR VS HC SAME RTE      |            |            |            |            |            |            |
| CURR VS HC ALL RTES      |            |            |            |            |            |            |

Experiment Number: 93027-27  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: HAMSTERS/SYRIAN

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Peroxisome project (Gemfibrozil)  
 CAS Number: 25812-30-0

Date Report Requested: 10/15/2014  
 Time Report Requested: 17:32:49  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                                  | MALE       |          |          |          |            |            |
|---------------------------------------|------------|----------|----------|----------|------------|------------|
|                                       | 0 PPM      | 100 PPM  | 1000 PPM | 6000 PPM | 12,000 PPM | 24,000 PPM |
| <b>Urinary Bladder Mineralization</b> |            |          |          |          |            |            |
| <b>LESION RATES</b>                   |            |          |          |          |            |            |
| OVERALL(a)                            | 2/10 (20%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%)   | 3/10 (30%) |
| POLY-3 RATE (b)                       | 2/10.00    | 0/0.00   | 0/0.00   | 0/0.00   | 0/0.00     | 3/10.00    |
| POLY-3 PERCENT (g)                    | 20%        | 0%       | 0%       | 0%       | 0%         | 30%        |
| TERMINAL (d)                          | 2/10 (20%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%)   | 3/10 (30%) |
| FIRST INCIDENCE                       | 92(T)      | ---      | ---      | ---      | ---        | 92(T)      |
| <b>STATISTICAL TESTS</b>              |            |          |          |          |            |            |
| POLY 3                                | (e)        | (e)      | (e)      | (e)      | (e)        | P=0.500    |
| POLY 1.5                              | (e)        | (e)      | (e)      | (e)      | (e)        | P=0.500    |
| POLY 6                                | (e)        | (e)      | (e)      | (e)      | (e)        | P=0.500    |
| COCH-ARM / FISHERS                    | P=0.398    | (e)      | (e)      | (e)      | (e)        | P=0.500    |
| MAX-ISO-POLY-3                        | (e)        | (e)      | (e)      | (e)      | (e)        | P=0.311    |
| HISTCONT SAME RTE                     |            |          |          |          |            |            |
| HISTCONT ALL RTES                     |            |          |          |          |            |            |
| CURR VS HC SAME RTE                   |            |          |          |          |            |            |
| CURR VS HC ALL RTES                   |            |          |          |          |            |            |



**Experiment Number:** 93027-27  
**Test Type:** 90-DAY  
**Route:** DOSED FEED  
**Species/Strain:** HAMSTERS/SYRIAN

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

**Test Compound:** Peroxisome project (Gemfibrozil)  
**CAS Number:** 25812-30-0

**Date Report Requested:** 10/15/2014  
**Time Report Requested:** 17:32:49  
**First Dose M/F:** NA / NA  
**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 \*\***