

**Experiment Number:** 20116-02  
**Test Type:** 90-DAY  
**Route:** DOSED WATER  
**Species/Strain:** Mouse/B6C3F1

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

**Test Compound:** Aloe vera whole leaf extract (native)

**CAS Number:** ALOEVLEAFEXT

**Date Report Requested:** 10/23/2014

**Time Report Requested:** 13:47:54

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

**Lab:** NCTR

|                             |              |
|-----------------------------|--------------|
| <b>C Number:</b>            | C20116B      |
| <b>Lock Date:</b>           | Not Entered. |
| <b>Cage Range:</b>          | All          |
| <b>Date Range:</b>          | All          |
| <b>Reasons For Removal:</b> | All          |
| <b>Removal Date Range:</b>  | All          |
| <b>Treatment Groups:</b>    | All          |
| <b>Study Gender:</b>        | Both         |
| <b>PWG Approval Date</b>    | NONE         |

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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF ALOE VERA WHOLE LEAF EXTRACT**

**MALE MOUSE**

**Organ**

Intestine Large, Cecum: Goblet Cell

Intestine Large, Colon: Goblet Cell

Intestine Large, Rectum: Goblet Cell

Preputial Gland: Duct

**FEMALE MOUSE**

**Organ**

Intestine Large, Colon: Goblet Cell

Intestine Large, Rectum: Goblet Cell

Ovary

**Morphology**

Hyperplasia

Hyperplasia

Hyperplasia

Dilatation

**Morphology**

Hyperplasia

Hyperplasia

Cyst

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                                     | CONTROL   | MALE     |          |           |  |
|--|-----------|----------|----------|-----------|--|
|  |           | 1% WLN   | 2% WLN   | 3% WLN    |  |
| <b>Adrenal Cortex</b>                    |           |          |          |           |  |
| <b>Accessory Adrenal Cortical Nodule</b> |           |          |          |           |  |
| <b>LESION RATES</b>                      |           |          |          |           |  |
| OVERALL(a)                               | 1/12 (8%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |  |
| POLY-3 RATE (b)                          | 1/12.00   | 0/0.00   | 0/0.00   | 0/12.00   |  |
| POLY-3 PERCENT (g)                       | 8.3%      | 0%       | 0%       | 0%        |  |
| TERMINAL (d)                             | 1/12 (8%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |  |
| FIRST INCIDENCE                          | 100(T)    | ---      | ---      | ---       |  |
| <b>STATISTICAL TESTS</b>                 |           |          |          |           |  |
| POLY 3                                   | (e)       | (e)      | (e)      | P=0.500N  |  |
| POLY 1.5                                 | (e)       | (e)      | (e)      | P=0.500N  |  |
| POLY 6                                   | (e)       | (e)      | (e)      | P=0.500N  |  |
| COCH-ARM / FISHERS                       | P=0.248N  | (e)      | (e)      | P=0.500N  |  |
| MAX-ISO-POLY-3                           | (e)       | (e)      | (e)      | P=0.159N  |  |
| HISTCONT SAME RTE                        |           |          |          |           |  |
| HISTCONT ALL RTES                        |           |          |          |           |  |
| CURR VS HC SAME RTE                      |           |          |          |           |  |
| CURR VS HC ALL RTES                      |           |          |          |           |  |

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 LAST REMOVAL AT 14286 WEEKS**

| DOSE   | CONTROL   | MALE      |            |            |  |
|--|-----------|-----------|------------|------------|--|
|  |           | 1% WLN    | 2% WLN     | 3% WLN     |  |
| <b>Intestine Large, Cecum: Goblet Cell Hyperplasia</b> |           |           |            |            |  |
| <b>LESION RATES</b>                                    |           |           |            |            |  |
| OVERALL(a)   | 0/12 (0%) | 1/12 (8%) | 5/12 (42%) | 9/12 (75%) |  |
| POLY-3 RATE (b)  | 0/12.00   | 1/12.00   | 5/12.00    | 9/12.00    |  |
| POLY-3 PERCENT (g)                                     | 0%        | 8.3%      | 41.7%      | 75%        |  |
| TERMINAL (d)   | 0/12 (0%) | 1/12 (8%) | 5/12 (42%) | 9/12 (75%) |  |
| FIRST INCIDENCE  | ---       | 100(T)    | 100(T)     | 100(T)     |  |
| <b>STATISTICAL TESTS</b>                               |           |           |            |            |  |
| POLY 3   | P=0.000** | P=0.500   | P=0.012*   | P=0.000**  |  |
| POLY 1.5   | P=0.000** | P=0.500   | P=0.012*   | P=0.000**  |  |
| POLY 6   | P=0.000** | P=0.500   | P=0.012*   | P=0.000**  |  |
| COCH-ARM / FISHERS                                     | P=0.000** | P=0.500   | P=0.019*   | P=0.000**  |  |
| MAX-ISO-POLY-3   | P=0.000** | P=0.159   | P=0.003**  | P=0.000**  |  |
| HISTCONT SAME RTE                                      |           |           |            |            |  |
| HISTCONT ALL RTES                                      |           |           |            |            |  |
| CURR VS HC SAME RTE                                    |           |           |            |            |  |
| CURR VS HC ALL RTES                                    |           |           |            |            |  |

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 LAST REMOVAL AT 14286 WEEKS**

| DOSE   | CONTROL   | MALE       |            |             |  |
|--|-----------|------------|------------|-------------|--|
|  |           | 1% WLN     | 2% WLN     | 3% WLN      |  |
| <b>Intestine Large, Colon: Goblet Cell<br/>Hyperplasia</b> |           |            |            |             |  |
| <b>LESION RATES</b>  |           |            |            |             |  |
| OVERALL(a)   | 0/12 (0%) | 3/12 (25%) | 9/12 (75%) | 11/12 (92%) |  |
| POLY-3 RATE (b)  | 0/12.00   | 3/12.00    | 9/12.00    | 11/12.00    |  |
| POLY-3 PERCENT (g)   | 0%        | 25%        | 75%        | 91.7%       |  |
| TERMINAL (d)   | 0/12 (0%) | 3/12 (25%) | 9/12 (75%) | 11/12 (92%) |  |
| FIRST INCIDENCE  | ---       | 100(T)     | 100(T)     | 100(T)      |  |
| <b>STATISTICAL TESTS</b>                                   |           |            |            |             |  |
| POLY 3   | P=0.000** | P=0.101    | P=0.000**  | P=0.000**   |  |
| POLY 1.5   | P=0.000** | P=0.101    | P=0.000**  | P=0.000**   |  |
| POLY 6   | P=0.000** | P=0.101    | P=0.000**  | P=0.000**   |  |
| COCH-ARM / FISHERS   | P=0.000** | P=0.109    | P=0.000**  | P=0.000**   |  |
| MAX-ISO-POLY-3   | P=0.000** | P=0.028*   | P=0.000**  | P=0.000**   |  |
| HISTCONT SAME RTE  |           |            |            |             |  |
| HISTCONT ALL RTES  |           |            |            |             |  |
| CURR VS HC SAME RTE  |           |            |            |             |  |
| CURR VS HC ALL RTES  |           |            |            |             |  |

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 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)**  
**LAST REMOVAL AT 14286 WEEKS**

| DOSE  | CONTROL   | MALE     |          |            |  |
|---|-----------|----------|----------|------------|--|
|   |           | 1% WLN   | 2% WLN   | 3% WLN     |  |
| <b>Intestine Large, Rectum: Goblet Cell</b> |           |          |          |            |  |
| <b>Hyperplasia</b>                          |           |          |          |            |  |
| <b>LESION RATES</b>                         |           |          |          |            |  |
| OVERALL(a)                                  | 0/12 (0%) | 0/0 (0%) | 0/0 (0%) | 4/11 (36%) |  |
| POLY-3 RATE (b)                             | 0/12.00   | 0/0.00   | 0/0.00   | 4/11.00    |  |
| POLY-3 PERCENT (g)                          | 0%        | 0%       | 0%       | 36.4%      |  |
| TERMINAL (d)                                | 0/12 (0%) | 0/0 (0%) | 0/0 (0%) | 4/11 (36%) |  |
| FIRST INCIDENCE                             | ---       | ---      | ---      | 100(T)     |  |
| <b>STATISTICAL TESTS</b>                    |           |          |          |            |  |
| POLY 3                                      | (e)       | (e)      | (e)      | P=0.029*   |  |
| POLY 1.5                                    | (e)       | (e)      | (e)      | P=0.029*   |  |
| POLY 6                                      | (e)       | (e)      | (e)      | P=0.029*   |  |
| COCH-ARM / FISHERS                          | P=0.017*  | (e)      | (e)      | P=0.037*   |  |
| MAX-ISO-POLY-3                              | (e)       | (e)      | (e)      | P=0.007**  |  |
| HISTCONT SAME RTE                           |           |          |          |            |  |
| HISTCONT ALL RTES                           |           |          |          |            |  |
| CURR VS HC SAME RTE                         |           |          |          |            |  |
| CURR VS HC ALL RTES                         |           |          |          |            |  |

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**LAST REMOVAL AT 14286 WEEKS**

| DOSE                                  | CONTROL   | MALE      |           |           |  |
|---------------------------------------|-----------|-----------|-----------|-----------|--|
|                                       |           | 1% WLN    | 2% WLN    | 3% WLN    |  |
| <b>Kidney</b>                         |           |           |           |           |  |
| <b>Infiltration Cellular Lymphoid</b> |           |           |           |           |  |
| <b>LESION RATES</b>                   |           |           |           |           |  |
| OVERALL(a)                            | 0/12 (0%) | 1/12 (8%) | 1/12 (8%) | 0/12 (0%) |  |
| POLY-3 RATE (b)                       | 0/12.00   | 1/12.00   | 1/12.00   | 0/12.00   |  |
| POLY-3 PERCENT (g)                    | 0%        | 8.3%      | 8.3%      | 0%        |  |
| TERMINAL (d)                          | 0/12 (0%) | 1/12 (8%) | 1/12 (8%) | 0/12 (0%) |  |
| FIRST INCIDENCE                       | ---       | 100(T)    | 100(T)    | ---       |  |
| <b>STATISTICAL TESTS</b>              |           |           |           |           |  |
| POLY 3                                | P=0.624   | P=0.500   | P=0.500   | (e)       |  |
| POLY 1.5                              | P=0.624   | P=0.500   | P=0.500   | (e)       |  |
| POLY 6                                | P=0.624   | P=0.500   | P=0.500   | (e)       |  |
| COCH-ARM / FISHERS                    | P=0.627   | P=0.500   | P=0.500   | (e)       |  |
| MAX-ISO-POLY-3                        | P=0.407N  | P=0.159   | P=0.159   | (e)       |  |
| HISTCONT SAME RTE                     |           |           |           |           |  |
| HISTCONT ALL RTES                     |           |           |           |           |  |
| CURR VS HC SAME RTE                   |           |           |           |           |  |
| CURR VS HC ALL RTES                   |           |           |           |           |  |

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 LAST REMOVAL AT 14286 WEEKS**

| DOSE                     | CONTROL   | MALE      |           |           |  |
|--------------------------|-----------|-----------|-----------|-----------|--|
|                          |           | 1% WLN    | 2% WLN    | 3% WLN    |  |
| <b>Liver</b>             |           |           |           |           |  |
| <b>Mixed Cell Focus</b>  |           |           |           |           |  |
| <b>LESION RATES</b>      |           |           |           |           |  |
| OVERALL(a)               | 0/12 (0%) | 0/12 (0%) | 0/12 (0%) | 1/12 (8%) |  |
| POLY-3 RATE (b)          | 0/12.00   | 0/12.00   | 0/12.00   | 1/12.00   |  |
| POLY-3 PERCENT (g)       | 0%        | 0%        | 0%        | 8.3%      |  |
| TERMINAL (d)             | 0/12 (0%) | 0/12 (0%) | 0/12 (0%) | 1/12 (8%) |  |
| FIRST INCIDENCE          | ---       | ---       | ---       | 100(T)    |  |
| <b>STATISTICAL TESTS</b> |           |           |           |           |  |
| POLY 3                   | P=0.186   | (e)       | (e)       | P=0.500   |  |
| POLY 1.5                 | P=0.186   | (e)       | (e)       | P=0.500   |  |
| POLY 6                   | P=0.186   | (e)       | (e)       | P=0.500   |  |
| COCH-ARM / FISHERS       | P=0.183   | (e)       | (e)       | P=0.500   |  |
| MAX-ISO-POLY-3           | P=0.126   | (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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**LAST REMOVAL AT 14286 WEEKS**

| DOSE                     | CONTROL   | MALE      |           |           |  |
|--------------------------|-----------|-----------|-----------|-----------|--|
|                          |           | 1% WLN    | 2% WLN    | 3% WLN    |  |
| <b>Liver</b>             |           |           |           |           |  |
| <b>Tension Lipidosis</b> |           |           |           |           |  |
| <b>LESION RATES</b>      |           |           |           |           |  |
| OVERALL(a)               | 1/12 (8%) | 0/12 (0%) | 1/12 (8%) | 0/12 (0%) |  |
| POLY-3 RATE (b)          | 1/12.00   | 0/12.00   | 1/12.00   | 0/12.00   |  |
| POLY-3 PERCENT (g)       | 8.3%      | 0%        | 8.3%      | 0%        |  |
| TERMINAL (d)             | 1/12 (8%) | 0/12 (0%) | 1/12 (8%) | 0/12 (0%) |  |
| FIRST INCIDENCE          | 100(T)    | ---       | 100(T)    | ---       |  |
| <b>STATISTICAL TESTS</b> |           |           |           |           |  |
| POLY 3                   | P=0.376N  | P=0.500N  | P=0.760   | P=0.500N  |  |
| POLY 1.5                 | P=0.376N  | P=0.500N  | P=0.760   | P=0.500N  |  |
| POLY 6                   | P=0.376N  | P=0.500N  | P=0.760   | P=0.500N  |  |
| COCH-ARM / FISHERS       | P=0.373N  | P=0.500N  | P=0.761N  | P=0.500N  |  |
| MAX-ISO-POLY-3           | P=0.257N  | P=0.159N  | P=1.000   | P=0.159N  |  |
| HISTCONT SAME RTE        |           |           |           |           |  |
| HISTCONT ALL RTES        |           |           |           |           |  |
| CURR VS HC SAME RTE      |           |           |           |           |  |
| CURR VS HC ALL RTES      |           |           |           |           |  |

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 LAST REMOVAL AT 14286 WEEKS**

| DOSE   | CONTROL   | MALE     |          |           |  |
|--|-----------|----------|----------|-----------|--|
|  |           | 1% WLN   | 2% WLN   | 3% WLN    |  |
| <b>Lymph Node, Mandibular<br/>Hyperplasia Lymphoid</b> |           |          |          |           |  |
| <b>LESION RATES</b>                                    |           |          |          |           |  |
| OVERALL(a)   | 0/12 (0%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |  |
| POLY-3 RATE (b)  | 0/12.00   | 0/0.00   | 0/0.00   | 0/12.00   |  |
| POLY-3 PERCENT (g)                                     | 0%        | 0%       | 0%       | 0%        |  |
| TERMINAL (d)   | 0/12 (0%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |  |
| FIRST INCIDENCE  | ---       | ---      | ---      | ---       |  |
| <b>STATISTICAL TESTS</b>                               |           |          |          |           |  |
| POLY 3   | (n)       | (n)      | (n)      | (n)       |  |
| POLY 1.5   | (n)       | (n)      | (n)      | (n)       |  |
| POLY 6   | (n)       | (n)      | (n)      | (n)       |  |
| COCH-ARM / FISHERS                                     | (n)       | (n)      | (n)      | (n)       |  |
| MAX-ISO-POLY-3   | (n)       | (n)      | (n)      | (n)       |  |
| HISTCONT SAME RTE                                      |           |          |          |           |  |
| HISTCONT ALL RTES                                      |           |          |          |           |  |
| CURR VS HC SAME RTE                                    |           |          |          |           |  |
| CURR VS HC ALL RTES                                    |           |          |          |           |  |

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 LAST REMOVAL AT 14286 WEEKS**

| DOSE   | CONTROL    | MALE     |          |            |  |
|--|------------|----------|----------|------------|--|
|  |            | 1% WLN   | 2% WLN   | 3% WLN     |  |
| <b>Lymph Node, Mesenteric<br/>Hyperplasia Lymphoid</b> |            |          |          |            |  |
| <b>LESION RATES</b>                                    |            |          |          |            |  |
| OVERALL(a)   | 4/12 (33%) | 0/0 (0%) | 0/0 (0%) | 7/12 (58%) |  |
| POLY-3 RATE (b)  | 4/12.00    | 0/0.00   | 0/0.00   | 7/12.00    |  |
| POLY-3 PERCENT (g)                                     | 33.3%      | 0%       | 0%       | 58.3%      |  |
| TERMINAL (d)   | 4/12 (33%) | 0/0 (0%) | 0/0 (0%) | 7/12 (58%) |  |
| FIRST INCIDENCE  | 100(T)     | ---      | ---      | 100(T)     |  |
| <b>STATISTICAL TESTS</b>                               |            |          |          |            |  |
| POLY 3   | (e)        | (e)      | (e)      | P=0.209    |  |
| POLY 1.5   | (e)        | (e)      | (e)      | P=0.209    |  |
| POLY 6   | (e)        | (e)      | (e)      | P=0.209    |  |
| COCH-ARM / FISHERS                                     | P=0.137    | (e)      | (e)      | P=0.207    |  |
| MAX-ISO-POLY-3   | (e)        | (e)      | (e)      | P=0.113    |  |
| HISTCONT SAME RTE                                      |            |          |          |            |  |
| HISTCONT ALL RTES                                      |            |          |          |            |  |
| CURR VS HC SAME RTE                                    |            |          |          |            |  |
| CURR VS HC ALL RTES                                    |            |          |          |            |  |

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                                    | CONTROL    | MALE       |            |            |  |
|---|------------|------------|------------|------------|--|
|   |            | 1% WLN     | 2% WLN     | 3% WLN     |  |
| <b>Preputial Gland: Duct Dilatation</b> |            |            |            |            |  |
| <b>LESION RATES</b>                     |            |            |            |            |  |
| OVERALL(a)                              | 7/12 (58%) | 4/4 (100%) | 6/6 (100%) | 0/12 (0%)  |  |
| POLY-3 RATE (b)                         | 7/12.00    | 4/4.00     | 6/6.00     | 0/12.00    |  |
| POLY-3 PERCENT (g)                      | 58.3%      | 100%       | 100%       | 0%         |  |
| TERMINAL (d)                            | 7/12 (58%) | 4/4 (100%) | 6/6 (100%) | 0/12 (0%)  |  |
| FIRST INCIDENCE                         | 100(T)     | 100(T)     | 100(T)     | ---        |  |
| <b>STATISTICAL TESTS</b>                |            |            |            |            |  |
| POLY 3                                  | P=0.000N** | P=0.171    | P=0.086    | P=0.000N** |  |
| POLY 1.5                                | P=0.000N** | P=0.171    | P=0.086    | P=0.000N** |  |
| POLY 6                                  | P=0.000N** | P=0.171    | P=0.086    | P=0.000N** |  |
| COCH-ARM / FISHERS                      | P=0.006N** | P=0.181    | P=0.092    | P=0.002N** |  |
| MAX-ISO-POLY-3                          | P=0.000N** | P=0.099    | P=0.046*   | P=0.000N** |  |
| HISTCONT SAME RTE                       |            |            |            |            |  |
| HISTCONT ALL RTES                       |            |            |            |            |  |
| CURR VS HC SAME RTE                     |            |            |            |            |  |
| CURR VS HC ALL RTES                     |            |            |            |            |  |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Aloe vera whole leaf extract (native)  
 CAS Number: ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                                  | CONTROL   | MALE     |          |           |  |
|---------------------------------------|-----------|----------|----------|-----------|--|
|                                       |           | 1% WLN   | 2% WLN   | 3% WLN    |  |
| <b>Salivary Glands</b>                |           |          |          |           |  |
| <b>Infiltration Cellular Lymphoid</b> |           |          |          |           |  |
| <b>LESION RATES</b>                   |           |          |          |           |  |
| OVERALL(a)                            | 0/12 (0%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |  |
| POLY-3 RATE (b)                       | 0/12.00   | 0/0.00   | 0/0.00   | 0/12.00   |  |
| POLY-3 PERCENT (g)                    | 0%        | 0%       | 0%       | 0%        |  |
| TERMINAL (d)                          | 0/12 (0%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |  |
| FIRST INCIDENCE                       | ---       | ---      | ---      | ---       |  |
| <b>STATISTICAL TESTS</b>              |           |          |          |           |  |
| POLY 3                                | (n)       | (n)      | (n)      | (n)       |  |
| POLY 1.5                              | (n)       | (n)      | (n)      | (n)       |  |
| POLY 6                                | (n)       | (n)      | (n)      | (n)       |  |
| COCH-ARM / FISHERS                    | (n)       | (n)      | (n)      | (n)       |  |
| MAX-ISO-POLY-3                        | (n)       | (n)      | (n)      | (n)       |  |
| HISTCONT SAME RTE                     |           |          |          |           |  |
| HISTCONT ALL RTES                     |           |          |          |           |  |
| CURR VS HC SAME RTE                   |           |          |          |           |  |
| CURR VS HC ALL RTES                   |           |          |          |           |  |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
**Test Compound:** Aloe vera whole leaf extract (native)  
**CAS Number:** ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)**  
**LAST REMOVAL AT 14286 WEEKS**

| DOSE                     | CONTROL   | MALE     |          |           |  |
|--------------------------|-----------|----------|----------|-----------|--|
|                          |           | 1% WLN   | 2% WLN   | 3% WLN    |  |
| <b>Skin: Epidermis</b>   |           |          |          |           |  |
| <b>Inflammation</b>      |           |          |          |           |  |
| <b>LESION RATES</b>      |           |          |          |           |  |
| OVERALL(a)               | 1/12 (8%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |  |
| POLY-3 RATE (b)          | 1/12.00   | 0/0.00   | 0/0.00   | 0/12.00   |  |
| POLY-3 PERCENT (g)       | 8.3%      | 0%       | 0%       | 0%        |  |
| TERMINAL (d)             | 1/12 (8%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |  |
| FIRST INCIDENCE          | 100(T)    | ---      | ---      | ---       |  |
| <b>STATISTICAL TESTS</b> |           |          |          |           |  |
| POLY 3                   | (e)       | (e)      | (e)      | P=0.500N  |  |
| POLY 1.5                 | (e)       | (e)      | (e)      | P=0.500N  |  |
| POLY 6                   | (e)       | (e)      | (e)      | P=0.500N  |  |
| COCH-ARM / FISHERS       | P=0.248N  | (e)      | (e)      | P=0.500N  |  |
| MAX-ISO-POLY-3           | (e)       | (e)      | (e)      | P=0.159N  |  |
| HISTCONT SAME RTE        |           |          |          |           |  |
| HISTCONT ALL RTES        |           |          |          |           |  |
| CURR VS HC SAME RTE      |           |          |          |           |  |
| CURR VS HC ALL RTES      |           |          |          |           |  |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

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

Test Compound: Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 10/23/2014

Time Report Requested: 13:47:54

First Dose M/F: NA / NA

Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                                    | CONTROL    | MALE       |            |            |  |
|---|------------|------------|------------|------------|--|
|   |            | 1% WLN     | 2% WLN     | 3% WLN     |  |
| <b>Spleen</b>                           |            |            |            |            |  |
| <b>Hematopoietic Cell Proliferation</b> |            |            |            |            |  |
| <b>LESION RATES</b>                     |            |            |            |            |  |
| OVERALL(a)                              | 4/12 (33%) | 2/12 (17%) | 2/12 (17%) | 4/12 (33%) |  |
| POLY-3 RATE (b)                         | 4/12.00    | 2/12.00    | 2/12.00    | 4/12.00    |  |
| POLY-3 PERCENT (g)                      | 33.3%      | 16.7%      | 16.7%      | 33.3%      |  |
| TERMINAL (d)                            | 4/12 (33%) | 2/12 (17%) | 2/12 (17%) | 4/12 (33%) |  |
| FIRST INCIDENCE                         | 100(T)     | 100(T)     | 100(T)     | 100(T)     |  |
| <b>STATISTICAL TESTS</b>                |            |            |            |            |  |
| POLY 3                                  | P=0.558    | P=0.323N   | P=0.323N   | P=0.661    |  |
| POLY 1.5                                | P=0.558    | P=0.323N   | P=0.323N   | P=0.661    |  |
| POLY 6                                  | P=0.558    | P=0.323N   | P=0.323N   | P=0.661    |  |
| COCH-ARM / FISHERS                      | P=0.559    | P=0.320N   | P=0.320N   | P=0.667N   |  |
| MAX-ISO-POLY-3                          | P=0.434N   | P=0.179N   | P=0.179N   | P=1.000    |  |
| HISTCONT SAME RTE                       |            |            |            |            |  |
| HISTCONT ALL RTES                       |            |            |            |            |  |
| CURR VS HC SAME RTE                     |            |            |            |            |  |
| CURR VS HC ALL RTES                     |            |            |            |            |  |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
**Test Compound:** Aloe vera whole leaf extract (native)  
**CAS Number:** ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)**  
**LAST REMOVAL AT 14286 WEEKS**

| DOSE                        | CONTROL   | MALE      |           |           |  |
|-----------------------------|-----------|-----------|-----------|-----------|--|
|                             |           | 1% WLN    | 2% WLN    | 3% WLN    |  |
| <b>Spleen</b>               |           |           |           |           |  |
| <b>Hyperplasia Lymphoid</b> |           |           |           |           |  |
| <b>LESION RATES</b>         |           |           |           |           |  |
| OVERALL(a)                  | 0/12 (0%) | 1/12 (8%) | 1/12 (8%) | 0/12 (0%) |  |
| POLY-3 RATE (b)             | 0/12.00   | 1/12.00   | 1/12.00   | 0/12.00   |  |
| POLY-3 PERCENT (g)          | 0%        | 8.3%      | 8.3%      | 0%        |  |
| TERMINAL (d)                | 0/12 (0%) | 1/12 (8%) | 1/12 (8%) | 0/12 (0%) |  |
| FIRST INCIDENCE             | ---       | 100(T)    | 100(T)    | ---       |  |
| <b>STATISTICAL TESTS</b>    |           |           |           |           |  |
| POLY 3                      | P=0.624   | P=0.500   | P=0.500   | (e)       |  |
| POLY 1.5                    | P=0.624   | P=0.500   | P=0.500   | (e)       |  |
| POLY 6                      | P=0.624   | P=0.500   | P=0.500   | (e)       |  |
| COCH-ARM / FISHERS          | P=0.627   | P=0.500   | P=0.500   | (e)       |  |
| MAX-ISO-POLY-3              | P=0.407N  | P=0.159   | P=0.159   | (e)       |  |
| HISTCONT SAME RTE           |           |           |           |           |  |
| HISTCONT ALL RTES           |           |           |           |           |  |
| CURR VS HC SAME RTE         |           |           |           |           |  |
| CURR VS HC ALL RTES         |           |           |           |           |  |



Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Aloe vera whole leaf extract (native)  
 CAS Number: ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                              | CONTROL    | MALE     |          |            |  |
|-----------------------------------|------------|----------|----------|------------|--|
|                                   |            | 1% WLN   | 2% WLN   | 3% WLN     |  |
| <b>Urinary Bladder Dilatation</b> |            |          |          |            |  |
| <b>LESION RATES</b>               |            |          |          |            |  |
| OVERALL(a)                        | 2/12 (17%) | 0/0 (0%) | 0/0 (0%) | 2/12 (17%) |  |
| POLY-3 RATE (b)                   | 2/12.00    | 0/0.00   | 0/0.00   | 2/12.00    |  |
| POLY-3 PERCENT (g)                | 16.7%      | 0%       | 0%       | 16.7%      |  |
| TERMINAL (d)                      | 2/12 (17%) | 0/0 (0%) | 0/0 (0%) | 2/12 (17%) |  |
| FIRST INCIDENCE                   | 100(T)     | ---      | ---      | 100(T)     |  |
| <b>STATISTICAL TESTS</b>          |            |          |          |            |  |
| POLY 3                            | (e)        | (e)      | (e)      | P=0.700    |  |
| POLY 1.5                          | (e)        | (e)      | (e)      | P=0.700    |  |
| POLY 6                            | (e)        | (e)      | (e)      | P=0.700    |  |
| COCH-ARM / FISHERS                | P=0.572    | (e)      | (e)      | P=0.705N   |  |
| MAX-ISO-POLY-3                    | (e)        | (e)      | (e)      | P=1.000    |  |
| HISTCONT SAME RTE                 |            |          |          |            |  |
| HISTCONT ALL RTES                 |            |          |          |            |  |
| CURR VS HC SAME RTE               |            |          |          |            |  |
| CURR VS HC ALL RTES               |            |          |          |            |  |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Aloe vera whole leaf extract (native)  
 CAS Number: ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                                     | FEMALE    |          |          |           |
|--|-----------|----------|----------|-----------|
|  | CONTROL   | 1% WLN   | 2% WLN   | 3% WLN    |
| <b>Adrenal Cortex</b>                    |           |          |          |           |
| <b>Accessory Adrenal Cortical Nodule</b> |           |          |          |           |
| <b>LESION RATES</b>                      |           |          |          |           |
| OVERALL(a)                               | 0/12 (0%) | 0/1 (0%) | 0/0 (0%) | 0/12 (0%) |
| POLY-3 RATE (b)                          | 0/12.00   | 0/1.00   | 0/0.00   | 0/12.00   |
| POLY-3 PERCENT (g)                       | 0%        | 0%       | 0%       | 0%        |
| TERMINAL (d)                             | 0/12 (0%) | 0/1 (0%) | 0/0 (0%) | 0/12 (0%) |
| FIRST INCIDENCE                          | ---       | ---      | ---      | ---       |
| <b>STATISTICAL TESTS</b>                 |           |          |          |           |
| POLY 3                                   | (n)       | (n)      | (n)      | (n)       |
| POLY 1.5                                 | (n)       | (n)      | (n)      | (n)       |
| POLY 6                                   | (n)       | (n)      | (n)      | (n)       |
| COCH-ARM / FISHERS                       | (n)       | (n)      | (n)      | (n)       |
| MAX-ISO-POLY-3                           | (n)       | (n)      | (n)      | (n)       |
| HISTCONT SAME RTE                        |           |          |          |           |
| HISTCONT ALL RTES                        |           |          |          |           |
| CURR VS HC SAME RTE                      |           |          |          |           |
| CURR VS HC ALL RTES                      |           |          |          |           |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
**Test Compound:** Aloe vera whole leaf extract (native)  
**CAS Number:** ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE   | FEMALE    |           |           |           |
|--|-----------|-----------|-----------|-----------|
|  | CONTROL   | 1% WLN    | 2% WLN    | 3% WLN    |
| <b>Intestine Large, Cecum: Goblet Cell<br/>Hyperplasia</b> |           |           |           |           |
| <b>LESION RATES</b>  |           |           |           |           |
| OVERALL(a)   | 0/12 (0%) | 0/12 (0%) | 0/11 (0%) | 1/12 (8%) |
| POLY-3 RATE (b)  | 0/12.00   | 0/12.00   | 0/11.00   | 1/12.00   |
| POLY-3 PERCENT (g)   | 0%        | 0%        | 0%        | 8.3%      |
| TERMINAL (d)   | 0/12 (0%) | 0/12 (0%) | 0/11 (0%) | 1/12 (8%) |
| FIRST INCIDENCE  | ---       | ---       | ---       | 100(T)    |
| <b>STATISTICAL TESTS</b>                                   |           |           |           |           |
| POLY 3   | P=0.185   | (e)       | (e)       | P=0.500   |
| POLY 1.5   | P=0.185   | (e)       | (e)       | P=0.500   |
| POLY 6   | P=0.185   | (e)       | (e)       | P=0.500   |
| COCH-ARM / FISHERS   | P=0.182   | (e)       | (e)       | P=0.500   |
| MAX-ISO-POLY-3   | P=0.130   | (e)       | (e)       | P=0.159   |
| HISTCONT SAME RTE  |           |           |           |           |
| HISTCONT ALL RTES  |           |           |           |           |
| CURR VS HC SAME RTE  |           |           |           |           |
| CURR VS HC ALL RTES  |           |           |           |           |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
**Test Compound:** Aloe vera whole leaf extract (native)  
**CAS Number:** ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE   | FEMALE    |           |            |            |
|--|-----------|-----------|------------|------------|
|  | CONTROL   | 1% WLN    | 2% WLN     | 3% WLN     |
| <b>Intestine Large, Colon: Goblet Cell<br/>Hyperplasia</b> |           |           |            |            |
| <b>LESION RATES</b>  |           |           |            |            |
| OVERALL(a)   | 0/12 (0%) | 0/12 (0%) | 4/11 (36%) | 7/12 (58%) |
| POLY-3 RATE (b)  | 0/12.00   | 0/12.00   | 4/11.00    | 7/12.00    |
| POLY-3 PERCENT (g)   | 0%        | 0%        | 36.4%      | 58.3%      |
| TERMINAL (d)   | 0/12 (0%) | 0/12 (0%) | 4/11 (36%) | 7/12 (58%) |
| FIRST INCIDENCE  | ---       | ---       | 100(T)     | 100(T)     |
| <b>STATISTICAL TESTS</b>                                   |           |           |            |            |
| POLY 3   | P=0.000** | (e)       | P=0.029*   | P=0.000**  |
| POLY 1.5   | P=0.000** | (e)       | P=0.029*   | P=0.000**  |
| POLY 6   | P=0.000** | (e)       | P=0.029*   | P=0.000**  |
| COCH-ARM / FISHERS   | P=0.000** | (e)       | P=0.037*   | P=0.002**  |
| MAX-ISO-POLY-3   | P=0.000** | (e)       | P=0.007**  | P=0.000**  |
| HISTCONT SAME RTE  |           |           |            |            |
| HISTCONT ALL RTES  |           |           |            |            |
| CURR VS HC SAME RTE  |           |           |            |            |
| CURR VS HC ALL RTES  |           |           |            |            |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Aloe vera whole leaf extract (native)  
 CAS Number: ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE  | FEMALE    |          |          |            |
|---|-----------|----------|----------|------------|
|   | CONTROL   | 1% WLN   | 2% WLN   | 3% WLN     |
| <b>Intestine Large, Rectum: Goblet Cell<br/>Hyperplasia</b> |           |          |          |            |
| <b>LESION RATES</b>   |           |          |          |            |
| OVERALL(a)  | 0/12 (0%) | 0/0 (0%) | 0/0 (0%) | 5/11 (45%) |
| POLY-3 RATE (b)   | 0/12.00   | 0/0.00   | 0/0.00   | 5/11.00    |
| POLY-3 PERCENT (g)  | 0%        | 0%       | 0%       | 45.5%      |
| TERMINAL (d)  | 0/12 (0%) | 0/0 (0%) | 0/0 (0%) | 5/11 (45%) |
| FIRST INCIDENCE   | ---       | ---      | ---      | 100(T)     |
| <b>STATISTICAL TESTS</b>                                    |           |          |          |            |
| POLY 3  | (e)       | (e)      | (e)      | P=0.007**  |
| POLY 1.5  | (e)       | (e)      | (e)      | P=0.007**  |
| POLY 6  | (e)       | (e)      | (e)      | P=0.007**  |
| COCH-ARM / FISHERS  | P=0.007** | (e)      | (e)      | P=0.014*   |
| MAX-ISO-POLY-3  | (e)       | (e)      | (e)      | P=0.002**  |
| HISTCONT SAME RTE   |           |          |          |            |
| HISTCONT ALL RTES   |           |          |          |            |
| CURR VS HC SAME RTE   |           |          |          |            |
| CURR VS HC ALL RTES   |           |          |          |            |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Aloe vera whole leaf extract (native)  
 CAS Number: ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                                  | FEMALE    |            |           |           |
|---------------------------------------|-----------|------------|-----------|-----------|
|                                       | CONTROL   | 1% WLN     | 2% WLN    | 3% WLN    |
| <b>Kidney</b>                         |           |            |           |           |
| <b>Infiltration Cellular Lymphoid</b> |           |            |           |           |
| <b>LESION RATES</b>                   |           |            |           |           |
| OVERALL(a)                            | 1/12 (8%) | 2/12 (17%) | 1/11 (9%) | 0/12 (0%) |
| POLY-3 RATE (b)                       | 1/12.00   | 2/12.00    | 1/11.00   | 0/12.00   |
| POLY-3 PERCENT (g)                    | 8.3%      | 16.7%      | 9.1%      | 0%        |
| TERMINAL (d)                          | 1/12 (8%) | 2/12 (17%) | 1/11 (9%) | 0/12 (0%) |
| FIRST INCIDENCE                       | 100(T)    | 100(T)     | 100(T)    | ---       |
| <b>STATISTICAL TESTS</b>              |           |            |           |           |
| POLY 3                                | P=0.254N  | P=0.500    | P=0.741   | P=0.500N  |
| POLY 1.5                              | P=0.254N  | P=0.500    | P=0.741   | P=0.500N  |
| POLY 6                                | P=0.254N  | P=0.500    | P=0.741   | P=0.500N  |
| COCH-ARM / FISHERS                    | P=0.250N  | P=0.500    | P=0.739   | P=0.500N  |
| MAX-ISO-POLY-3                        | P=0.229N  | P=0.276    | P=0.476   | P=0.159N  |
| HISTCONT SAME RTE                     |           |            |           |           |
| HISTCONT ALL RTES                     |           |            |           |           |
| CURR VS HC SAME RTE                   |           |            |           |           |
| CURR VS HC ALL RTES                   |           |            |           |           |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Aloe vera whole leaf extract (native)  
 CAS Number: ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                     | FEMALE    |           |           |           |
|--------------------------|-----------|-----------|-----------|-----------|
|                          | CONTROL   | 1% WLN    | 2% WLN    | 3% WLN    |
| Liver                    |           |           |           |           |
| Mixed Cell Focus         |           |           |           |           |
| <b>LESION RATES</b>      |           |           |           |           |
| OVERALL(a)               | 0/12 (0%) | 0/12 (0%) | 0/11 (0%) | 0/12 (0%) |
| POLY-3 RATE (b)          | 0/12.00   | 0/12.00   | 0/11.00   | 0/12.00   |
| POLY-3 PERCENT (g)       | 0%        | 0%        | 0%        | 0%        |
| TERMINAL (d)             | 0/12 (0%) | 0/12 (0%) | 0/11 (0%) | 0/12 (0%) |
| FIRST INCIDENCE          | ---       | ---       | ---       | ---       |
| <b>STATISTICAL TESTS</b> |           |           |           |           |
| POLY 3                   | (n)       | (n)       | (n)       | (n)       |
| POLY 1.5                 | (n)       | (n)       | (n)       | (n)       |
| POLY 6                   | (n)       | (n)       | (n)       | (n)       |
| COCH-ARM / FISHERS       | (n)       | (n)       | (n)       | (n)       |
| MAX-ISO-POLY-3           | (n)       | (n)       | (n)       | (n)       |
| HISTCONT SAME RTE        |           |           |           |           |
| HISTCONT ALL RTES        |           |           |           |           |
| CURR VS HC SAME RTE      |           |           |           |           |
| CURR VS HC ALL RTES      |           |           |           |           |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Aloe vera whole leaf extract (native)  
 CAS Number: ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                     | FEMALE    |           |           |           |
|--------------------------|-----------|-----------|-----------|-----------|
|                          | CONTROL   | 1% WLN    | 2% WLN    | 3% WLN    |
| <b>Liver</b>             |           |           |           |           |
| <b>Tension Lipidosis</b> |           |           |           |           |
| <b>LESION RATES</b>      |           |           |           |           |
| OVERALL(a)               | 0/12 (0%) | 0/12 (0%) | 1/11 (9%) | 0/12 (0%) |
| POLY-3 RATE (b)          | 0/12.00   | 0/12.00   | 1/11.00   | 0/12.00   |
| POLY-3 PERCENT (g)       | 0%        | 0%        | 9.1%      | 0%        |
| TERMINAL (d)             | 0/12 (0%) | 0/12 (0%) | 1/11 (9%) | 0/12 (0%) |
| FIRST INCIDENCE          | ---       | ---       | 100(T)    | ---       |
| <b>STATISTICAL TESTS</b> |           |           |           |           |
| POLY 3                   | P=0.496   | (e)       | P=0.483   | (e)       |
| POLY 1.5                 | P=0.496   | (e)       | P=0.483   | (e)       |
| POLY 6                   | P=0.496   | (e)       | P=0.483   | (e)       |
| COCH-ARM / FISHERS       | P=0.496   | (e)       | P=0.478   | (e)       |
| MAX-ISO-POLY-3           | P=0.375   | (e)       | P=0.153   | (e)       |
| HISTCONT SAME RTE        |           |           |           |           |
| HISTCONT ALL RTES        |           |           |           |           |
| CURR VS HC SAME RTE      |           |           |           |           |
| CURR VS HC ALL RTES      |           |           |           |           |



Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Aloe vera whole leaf extract (native)  
 CAS Number: ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE   | FEMALE    |          |          |           |
|--|-----------|----------|----------|-----------|
|  | CONTROL   | 1% WLN   | 2% WLN   | 3% WLN    |
| <b>Lymph Node, Mandibular<br/>Hyperplasia Lymphoid</b> |           |          |          |           |
| <b>LESION RATES</b>                                    |           |          |          |           |
| OVERALL(a)   | 1/12 (8%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |
| POLY-3 RATE (b)  | 1/12.00   | 0/0.00   | 0/0.00   | 0/12.00   |
| POLY-3 PERCENT (g)                                     | 8.3%      | 0%       | 0%       | 0%        |
| TERMINAL (d)   | 1/12 (8%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |
| FIRST INCIDENCE  | 100(T)    | ---      | ---      | ---       |
| <b>STATISTICAL TESTS</b>                               |           |          |          |           |
| POLY 3   | (e)       | (e)      | (e)      | P=0.500N  |
| POLY 1.5   | (e)       | (e)      | (e)      | P=0.500N  |
| POLY 6   | (e)       | (e)      | (e)      | P=0.500N  |
| COCH-ARM / FISHERS                                     | P=0.248N  | (e)      | (e)      | P=0.500N  |
| MAX-ISO-POLY-3   | (e)       | (e)      | (e)      | P=0.159N  |
| HISTCONT SAME RTE                                      |           |          |          |           |
| HISTCONT ALL RTES                                      |           |          |          |           |
| CURR VS HC SAME RTE                                    |           |          |          |           |
| CURR VS HC ALL RTES                                    |           |          |          |           |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Aloe vera whole leaf extract (native)  
 CAS Number: ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE   | FEMALE    |          |          |            |
|--|-----------|----------|----------|------------|
|  | CONTROL   | 1% WLN   | 2% WLN   | 3% WLN     |
| <b>Lymph Node, Mesenteric<br/>Hyperplasia Lymphoid</b> |           |          |          |            |
| <b>LESION RATES</b>                                    |           |          |          |            |
| OVERALL(a)   | 0/12 (0%) | 0/0 (0%) | 0/0 (0%) | 2/12 (17%) |
| POLY-3 RATE (b)  | 0/12.00   | 0/0.00   | 0/0.00   | 2/12.00    |
| POLY-3 PERCENT (g)                                     | 0%        | 0%       | 0%       | 16.7%      |
| TERMINAL (d)   | 0/12 (0%) | 0/0 (0%) | 0/0 (0%) | 2/12 (17%) |
| FIRST INCIDENCE  | ---       | ---      | ---      | 100(T)     |
| <b>STATISTICAL TESTS</b>                               |           |          |          |            |
| POLY 3   | (e)       | (e)      | (e)      | P=0.229    |
| POLY 1.5   | (e)       | (e)      | (e)      | P=0.229    |
| POLY 6   | (e)       | (e)      | (e)      | P=0.229    |
| COCH-ARM / FISHERS                                     | P=0.109   | (e)      | (e)      | P=0.239    |
| MAX-ISO-POLY-3   | (e)       | (e)      | (e)      | P=0.069    |
| HISTCONT SAME RTE                                      |           |          |          |            |
| HISTCONT ALL RTEs                                      |           |          |          |            |
| CURR VS HC SAME RTE                                    |           |          |          |            |
| CURR VS HC ALL RTEs                                    |           |          |          |            |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
**Test Compound:** Aloe vera whole leaf extract (native)  
**CAS Number:** ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                     | FEMALE    |          |            |           |
|--------------------------|-----------|----------|------------|-----------|
|                          | CONTROL   | 1% WLN   | 2% WLN     | 3% WLN    |
| Ovary                    |           |          |            |           |
| Cyst                     |           |          |            |           |
| <b>LESION RATES</b>      |           |          |            |           |
| OVERALL(a)               | 0/12 (0%) | 0/0 (0%) | 1/1 (100%) | 0/12 (0%) |
| POLY-3 RATE (b)          | 0/12.00   | 0/0.00   | 1/1.00     | 0/12.00   |
| POLY-3 PERCENT (g)       | 0%        | 0%       | 100%       | 0%        |
| TERMINAL (d)             | 0/12 (0%) | 0/0 (0%) | 1/1 (100%) | 0/12 (0%) |
| FIRST INCIDENCE          | ---       | ---      | 100(T)     | ---       |
| <b>STATISTICAL TESTS</b> |           |          |            |           |
| POLY 3                   | (e)       | (e)      | P=0.077    | (e)       |
| POLY 1.5                 | (e)       | (e)      | P=0.077    | (e)       |
| POLY 6                   | (e)       | (e)      | P=0.077    | (e)       |
| COCH-ARM / FISHERS       | P=0.506   | (e)      | P=0.077    | (e)       |
| MAX-ISO-POLY-3           | (e)       | (e)      | P=0.000**  | (e)       |
| HISTCONT SAME RTE        |           |          |            |           |
| HISTCONT ALL RTES        |           |          |            |           |
| CURR VS HC SAME RTE      |           |          |            |           |
| CURR VS HC ALL RTES      |           |          |            |           |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
**Test Compound:** Aloe vera whole leaf extract (native)  
**CAS Number:** ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                                  | FEMALE    |          |          |           |
|---------------------------------------|-----------|----------|----------|-----------|
|                                       | CONTROL   | 1% WLN   | 2% WLN   | 3% WLN    |
| <b>Salivary Glands</b>                |           |          |          |           |
| <b>Infiltration Cellular Lymphoid</b> |           |          |          |           |
| <b>LESION RATES</b>                   |           |          |          |           |
| OVERALL(a)                            | 1/12 (8%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |
| POLY-3 RATE (b)                       | 1/12.00   | 0/0.00   | 0/0.00   | 0/12.00   |
| POLY-3 PERCENT (g)                    | 8.3%      | 0%       | 0%       | 0%        |
| TERMINAL (d)                          | 1/12 (8%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |
| FIRST INCIDENCE                       | 100(T)    | ---      | ---      | ---       |
| <b>STATISTICAL TESTS</b>              |           |          |          |           |
| POLY 3                                | (e)       | (e)      | (e)      | P=0.500N  |
| POLY 1.5                              | (e)       | (e)      | (e)      | P=0.500N  |
| POLY 6                                | (e)       | (e)      | (e)      | P=0.500N  |
| COCH-ARM / FISHERS                    | P=0.248N  | (e)      | (e)      | P=0.500N  |
| MAX-ISO-POLY-3                        | (e)       | (e)      | (e)      | P=0.159N  |
| HISTCONT SAME RTE                     |           |          |          |           |
| HISTCONT ALL RTES                     |           |          |          |           |
| CURR VS HC SAME RTE                   |           |          |          |           |
| CURR VS HC ALL RTES                   |           |          |          |           |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Aloe vera whole leaf extract (native)  
 CAS Number: ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                     | FEMALE    |          |          |           |
|--------------------------|-----------|----------|----------|-----------|
|                          | CONTROL   | 1% WLN   | 2% WLN   | 3% WLN    |
| <b>Skin: Epidermis</b>   |           |          |          |           |
| <b>Inflammation</b>      |           |          |          |           |
| <b>LESION RATES</b>      |           |          |          |           |
| OVERALL(a)               | 0/12 (0%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |
| POLY-3 RATE (b)          | 0/12.00   | 0/0.00   | 0/0.00   | 0/12.00   |
| POLY-3 PERCENT (g)       | 0%        | 0%       | 0%       | 0%        |
| TERMINAL (d)             | 0/12 (0%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |
| FIRST INCIDENCE          | ---       | ---      | ---      | ---       |
| <b>STATISTICAL TESTS</b> |           |          |          |           |
| POLY 3                   | (n)       | (n)      | (n)      | (n)       |
| POLY 1.5                 | (n)       | (n)      | (n)      | (n)       |
| POLY 6                   | (n)       | (n)      | (n)      | (n)       |
| COCH-ARM / FISHERS       | (n)       | (n)      | (n)      | (n)       |
| MAX-ISO-POLY-3           | (n)       | (n)      | (n)      | (n)       |
| HISTCONT SAME RTE        |           |          |          |           |
| HISTCONT ALL RTES        |           |          |          |           |
| CURR VS HC SAME RTE      |           |          |          |           |
| CURR VS HC ALL RTES      |           |          |          |           |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

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

Test Compound: Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 10/23/2014

Time Report Requested: 13:47:54

First Dose M/F: NA / NA

Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                                    | FEMALE     |            |            |           |
|---|------------|------------|------------|-----------|
|   | CONTROL    | 1% WLN     | 2% WLN     | 3% WLN    |
| <b>Spleen</b>                           |            |            |            |           |
| <b>Hematopoietic Cell Proliferation</b> |            |            |            |           |
| <b>LESION RATES</b>                     |            |            |            |           |
| OVERALL(a)                              | 3/12 (25%) | 3/12 (25%) | 3/11 (27%) | 1/12 (8%) |
| POLY-3 RATE (b)                         | 3/12.00    | 3/12.00    | 3/11.00    | 1/12.00   |
| POLY-3 PERCENT (g)                      | 25%        | 25%        | 27.3%      | 8.3%      |
| TERMINAL (d)                            | 3/12 (25%) | 3/12 (25%) | 3/11 (27%) | 1/12 (8%) |
| FIRST INCIDENCE                         | 100(T)     | 100(T)     | 100(T)     | 100(T)    |
| <b>STATISTICAL TESTS</b>                |            |            |            |           |
| POLY 3                                  | P=0.231N   | P=0.674    | P=0.631    | P=0.295N  |
| POLY 1.5                                | P=0.231N   | P=0.674    | P=0.631    | P=0.295N  |
| POLY 6                                  | P=0.231N   | P=0.674    | P=0.631    | P=0.295N  |
| COCH-ARM / FISHERS                      | P=0.225N   | P=0.680N   | P=0.635    | P=0.295N  |
| MAX-ISO-POLY-3                          | P=0.252N   | P=1.000    | P=0.454    | P=0.142N  |
| HISTCONT SAME RTE                       |            |            |            |           |
| HISTCONT ALL RTES                       |            |            |            |           |
| CURR VS HC SAME RTE                     |            |            |            |           |
| CURR VS HC ALL RTES                     |            |            |            |           |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

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

Test Compound: Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 10/23/2014

Time Report Requested: 13:47:54

First Dose M/F: NA / NA

Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                        | FEMALE     |           |           |           |
|-----------------------------|------------|-----------|-----------|-----------|
|                             | CONTROL    | 1% WLN    | 2% WLN    | 3% WLN    |
| <b>Spleen</b>               |            |           |           |           |
| <b>Hyperplasia Lymphoid</b> |            |           |           |           |
| <b>LESION RATES</b>         |            |           |           |           |
| OVERALL(a)                  | 2/12 (17%) | 1/12 (8%) | 0/11 (0%) | 0/12 (0%) |
| POLY-3 RATE (b)             | 2/12.00    | 1/12.00   | 0/11.00   | 0/12.00   |
| POLY-3 PERCENT (g)          | 16.7%      | 8.3%      | 0%        | 0%        |
| TERMINAL (d)                | 2/12 (17%) | 1/12 (8%) | 0/11 (0%) | 0/12 (0%) |
| FIRST INCIDENCE             | 100(T)     | 100(T)    | ---       | ---       |
| <b>STATISTICAL TESTS</b>    |            |           |           |           |
| POLY 3                      | P=0.059N   | P=0.500N  | P=0.249N  | P=0.229N  |
| POLY 1.5                    | P=0.059N   | P=0.500N  | P=0.249N  | P=0.229N  |
| POLY 6                      | P=0.059N   | P=0.500N  | P=0.249N  | P=0.229N  |
| COCH-ARM / FISHERS          | P=0.058N   | P=0.500N  | P=0.261N  | P=0.239N  |
| MAX-ISO-POLY-3              | P=0.076N   | P=0.276N  | P=0.083N  | P=0.069N  |
| HISTCONT SAME RTE           |            |           |           |           |
| HISTCONT ALL RTES           |            |           |           |           |
| CURR VS HC SAME RTE         |            |           |           |           |
| CURR VS HC ALL RTES         |            |           |           |           |

Experiment Number: 20116-02  
 Test Type: 90-DAY  
 Route: DOSED WATER  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Aloe vera whole leaf extract (native)  
 CAS Number: ALOEVLEAFEXT

Date Report Requested: 10/23/2014  
 Time Report Requested: 13:47:54  
 First Dose M/F: NA / NA  
 Lab: NCTR

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

| DOSE                              | FEMALE    |          |          |           |
|-----------------------------------|-----------|----------|----------|-----------|
|                                   | CONTROL   | 1% WLN   | 2% WLN   | 3% WLN    |
| <b>Urinary Bladder Dilatation</b> |           |          |          |           |
| <b>LESION RATES</b>               |           |          |          |           |
| OVERALL(a)                        | 0/12 (0%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |
| POLY-3 RATE (b)                   | 0/12.00   | 0/0.00   | 0/0.00   | 0/12.00   |
| POLY-3 PERCENT (g)                | 0%        | 0%       | 0%       | 0%        |
| TERMINAL (d)                      | 0/12 (0%) | 0/0 (0%) | 0/0 (0%) | 0/12 (0%) |
| FIRST INCIDENCE                   | ---       | ---      | ---      | ---       |
| <b>STATISTICAL TESTS</b>          |           |          |          |           |
| POLY 3                            | (n)       | (n)      | (n)      | (n)       |
| POLY 1.5                          | (n)       | (n)      | (n)      | (n)       |
| POLY 6                            | (n)       | (n)      | (n)      | (n)       |
| COCH-ARM / FISHERS                | (n)       | (n)      | (n)      | (n)       |
| MAX-ISO-POLY-3                    | (n)       | (n)      | (n)      | (n)       |
| HISTCONT SAME RTE                 |           |          |          |           |
| HISTCONT ALL RTES                 |           |          |          |           |
| CURR VS HC SAME RTE               |           |          |          |           |
| CURR VS HC ALL RTES               |           |          |          |           |



**Experiment Number:** 20116-02  
**Test Type:** 90-DAY  
**Route:** DOSED WATER  
**Species/Strain:** Mouse/B6C3F1

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

**Test Compound:** Aloe vera whole leaf extract (native)

**CAS Number:** ALOEVLEAFEXT

**Date Report Requested:** 10/23/2014  
**Time Report Requested:** 13:47:54  
**First Dose M/F:** NA / NA  
**Lab:** NCTR

**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 \*\***