

Table 5-2 Urinalysis - Summary

B131138

Day(s) Relative to Start Date

| Sex: Male |      | Urinalysis          |                    |                    |                    |                    |
|-----------|------|---------------------|--------------------|--------------------|--------------------|--------------------|
|           |      | Specific Gravity    | Urine Volume (mL)  | Na (mmol)          | K (mmol)           | Cl (mmol)          |
|           |      | 28                  | 28                 | 28                 | 28                 | 28                 |
| 0 mg/kg   | Mean | 1.0628 <sup>1</sup> | 10.47 <sup>1</sup> | 1.359 <sup>1</sup> | 3.346 <sup>1</sup> | 2.218 <sup>1</sup> |
|           | SD   | 0.0147              | 5.46               | 0.429              | 1.011              | 0.829              |
|           | N    | 6                   | 6                  | 6                  | 6                  | 6                  |
| 1 mg/kg   | Mean | 1.0557              | 10.90              | 1.699              | 3.504              | 2.513              |
|           | SD   | 0.0101              | 2.29               | 0.403              | 0.663              | 0.560              |
|           | N    | 6                   | 6                  | 6                  | 6                  | 6                  |
| 10 mg/kg  | Mean | 1.0557              | 11.27              | 1.489              | 3.561              | 2.253              |
|           | SD   | 0.0035              | 2.04               | 0.791              | 0.694              | 0.834              |
|           | N    | 3                   | 3                  | 3                  | 3                  | 3                  |
| 25 mg/kg  | Mean | 1.0565              | 10.95              | 1.808              | 3.413              | 2.597              |
|           | SD   | 0.0094              | 1.93               | 0.130              | 0.713              | 0.380              |
|           | N    | 4                   | 4                  | 4                  | 4                  | 4                  |

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1 [I - Automatic Transformation: Identity]

Table 5-2 Urinalysis - Summary

B131138

Day(s) Relative to Start Date

| Sex: Female |      | Urinalysis          |                   |                    |                    |                    |
|-------------|------|---------------------|-------------------|--------------------|--------------------|--------------------|
|             |      | Specific Gravity    | Urine Volume (mL) | Na (mmol)          | K (mmol)           | Cl (mmol)          |
|             |      | 28                  | 28                | 28                 | 28                 | 28                 |
| 0 mg/kg     | Mean | 1.0663 <sup>1</sup> | 7.50 <sup>1</sup> | 1.046 <sup>1</sup> | 2.714 <sup>1</sup> | 1.771 <sup>1</sup> |
|             | SD   | 0.0118              | 1.92              | 0.229              | 0.208              | 0.127              |
|             | N    | 6                   | 6                 | 6                  | 6                  | 6                  |
| 1 mg/kg     | Mean | 1.0633              | 8.57              | 1.038              | 2.780              | 1.740              |
|             | SD   | 0.0167              | 3.11              | 0.175              | 0.405              | 0.326              |
|             | N    | 6                   | 6                 | 6                  | 6                  | 6                  |
| 10 mg/kg    | Mean | 1.0555              | 11.73             | 1.328              | 3.092              | 2.025              |
|             | SD   | 0.0221              | 6.17              | 0.361              | 0.632              | 0.533              |
|             | N    | 6                   | 6                 | 6                  | 6                  | 6                  |

1 [I - Automatic Transformation: Identity]

Table 6 Hematology - Summary

B131138

Day(s) Relative to Start Date

| Sex: Male |      | Hematology                                 |                         |                      |                      |                      |                      |                                      |                      |                     |                      |  |                       |
|-----------|------|--|-------------------------|----------------------|----------------------|----------------------|----------------------|--------------------------------------|----------------------|---------------------|----------------------|--|-----------------------|
|           |      | Red Blood Cell Count (10 <sup>6</sup> /μL) | Hemoglobin conc. (g/dL) | Hematocrit (%)       | MCV (fL)             | MCH (pg)             | MCHC (g/dL)          | Platelet Count (10 <sup>3</sup> /μL) | Reticulocyte (%)     | PT (sec)            | APTT (sec)           | White Blood Cell Count (10 <sup>3</sup> /μL) | Lymphocyte (%)        |
|           |      | 29   | 29                      | 29                   | 29                   | 29                   | 29                   | 29                                   | 29                   | 29                  | 29                   | 29   | 29                    |
| 0 mg/kg   | Mean | 8.243 R <sup>1</sup>                       | 15.65 R <sup>1</sup>    | 43.98 R <sup>1</sup> | 53.38 I <sup>3</sup> | 18.98 I <sup>3</sup> | 35.58 R <sup>1</sup> | 1095.0 R <sup>1</sup>                | 3.517 R <sup>1</sup> | 9.32 I <sup>3</sup> | 15.25 I <sup>3</sup> | 9.768 I <sup>3</sup>                         | 79.58 I <sup>3</sup>  |
|           | SD   | 0.390                                      | 0.71                    | 1.56                 | 1.51                 | 0.38                 | 0.51                 | 47.3                                 | 0.693                | 0.36                | 0.75                 | 2.355  | 7.67                  |
|           | N    | 6  | 6                       | 6                    | 6                    | 6                    | 6                    | 6                                    | 6                    | 6                   | 6                    | 6  | 6                     |
| 1 mg/kg   | Mean | 7.947                                      | 15.05                   | 42.57                | 53.58                | 18.93                | 35.37                | 1139.5                               | 4.227                | 8.98                | 14.13                | 13.228                                       | 81.20                 |
|           | SD   | 0.521                                      | 0.99                    | 2.56                 | 1.61                 | 0.43                 | 0.56                 | 147.9                                | 0.917                | 0.28                | 0.58                 | 4.244  | 4.48                  |
|           | N    | 6  | 6                       | 6                    | 6                    | 6                    | 6                    | 6                                    | 6                    | 6                   | 6                    | 6  | 6                     |
| 10 mg/kg  | Mean | 5.185                                      | 9.75 d <sup>2</sup>     | 29.30                | 59.50                | 18.80                | 31.90                | 1223.5                               | 14.380               | 8.70                | 15.95                | 17.045                                       | 54.25 dd <sup>5</sup> |
|           | SD   | 3.543                                      | 6.72                    | 16.55                | 8.77                 | 0.14                 | 4.95                 | 644.2                                | 15.259               | 0.28                | 0.21                 | 9.553  | 17.75                 |
|           | N    | 2  | 2                       | 2                    | 2                    | 2                    | 2                    | 2                                    | 2                    | 2                   | 2                    | 2  | 2                     |
| 25 mg/kg  | Mean | 6.995 d <sup>2</sup>                       | 12.85 d <sup>2</sup>    | 36.70 d <sup>2</sup> | 52.45                | 18.35                | 35.05                | 1927.5                               | 7.000                | 8.55 d <sup>4</sup> | 14.65                | 18.390                                       | 42.85 dd <sup>5</sup> |
|           | SD   | 0.219                                      | 0.07                    | 0.71                 | 0.64                 | 0.49                 | 0.49                 | 539.5                                | 3.833                | 0.07                | 2.62                 | 7.439  | 10.11                 |
|           | N    | 2  | 2                       | 2                    | 2                    | 2                    | 2                    | 2                                    | 2                    | 2                   | 2                    | 2  | 2                     |

1 [R - Automatic Transformation: Rank]  
 3 [I - Automatic Transformation: Identity]  
 5 [dd - Test: Dunnett 2 Sided p < 0.01]

2 [d - Test: Dunnett Non-Parametric 2 Sided p < 0.05]  
 4 [d - Test: Dunnett 2 Sided p < 0.05]

Table 6 Hematology - Summary

B131138

Day(s) Relative to Start Date

| Sex: Male |      | Hematology            |                      |                     |                     |                       |                        |                       |                       |                       |  |
|-----------|------|-----------------------|----------------------|---------------------|---------------------|-----------------------|------------------------|-----------------------|-----------------------|-----------------------|--|
|           |      | Neutrophil            | Eosinophil           | Basophil            | Monocyte            | Lymphocyte            | Neutrophil             | Eosinophil            | Basophil              | Monocyte              |  |
|           |      | (%)                   | (%)                  | (%)                 | (%)                 | (10 <sup>3</sup> /μL) | (10 <sup>3</sup> /μL)  | (10 <sup>3</sup> /μL) | (10 <sup>3</sup> /μL) | (10 <sup>3</sup> /μL) |  |
|           |      | 29                    | 29                   | 29                  | 29                  | 29                    | 29                     | 29                    | 29                    | 29                    |  |
| 0 mg/kg   | Mean | 15.92 I <sup>1</sup>  | 2.08 I <sup>1</sup>  | 0.02 I <sup>1</sup> | 2.40 I <sup>1</sup> | 7.782 I <sup>1</sup>  | 1.552 L <sup>4</sup>   | 0.208 I <sup>1</sup>  | 0.002 I <sup>1</sup>  | 0.225 I <sup>1</sup>  |  |
|           | SD   | 7.25                  | 0.32                 | 0.04                | 0.77                | 2.019                 | 0.894                  | 0.070                 | 0.004                 | 0.073                 |  |
|           | N    | 6                     | 6                    | 6                   | 6                   | 6                     | 6                      | 6                     | 6                     | 6                     |  |
| 1 mg/kg   | Mean | 14.70                 | 1.23 dd <sup>2</sup> | 0.00                | 2.87                | 10.702                | 1.985                  | 0.158                 | 0.002                 | 0.382                 |  |
|           | SD   | 4.62                  | 0.21                 | 0.00                | 0.50                | 3.352                 | 0.947                  | 0.032                 | 0.004                 | 0.178                 |  |
|           | N    | 6                     | 6                    | 6                   | 6                   | 6                     | 6                      | 6                     | 6                     | 6                     |  |
| 10 mg/kg  | Mean | 42.10 dd <sup>2</sup> | 1.10 d <sup>3</sup>  | 0.00                | 2.55                | 8.395                 | 8.100 d <sup>3</sup>   | 0.155                 | 0.000                 | 0.395                 |  |
|           | SD   | 19.37                 | 0.85                 | 0.00                | 0.78                | 2.157                 | 7.326                  | 0.035                 | 0.000                 | 0.106                 |  |
|           | N    | 2                     | 2                    | 2                   | 2                   | 2                     | 2                      | 2                     | 2                     | 2                     |  |
| 25 mg/kg  | Mean | 55.10 dd <sup>2</sup> | 0.65 dd <sup>2</sup> | 0.00                | 1.40                | 7.500                 | 10.545 dd <sup>2</sup> | 0.115                 | 0.000                 | 0.230                 |  |
|           | SD   | 10.89                 | 0.21                 | 0.00                | 0.57                | 1.329                 | 6.088                  | 0.021                 | 0.000                 | 0.000                 |  |
|           | N    | 2                     | 2                    | 2                   | 2                   | 2                     | 2                      | 2                     | 2                     | 2                     |  |

1 [I - Automatic Transformation: Identity]  
 3 [d - Test: Dunnett 2 Sided p < 0.05]

2 [dd - Test: Dunnett 2 Sided p < 0.01]  
 4 [L - Automatic Transformation: Log]

Table 6 Hematology - Summary

B131138

Day(s) Relative to Start Date

| Sex: Female |      | Hematology                                 |                         |                      |                      |                      |                      |                                      |                      |                     |                      |  |                      |
|-------------|------|--|-------------------------|----------------------|----------------------|----------------------|----------------------|--------------------------------------|----------------------|---------------------|----------------------|--|----------------------|
|             |      | Red Blood Cell Count (10 <sup>6</sup> /μL) | Hemoglobin conc. (g/dL) | Hematocrit (%)       | MCV (fL)             | MCH (pg)             | MCHC (g/dL)          | Platelet Count (10 <sup>3</sup> /μL) | Reticulocyte (%)     | PT (sec)            | APTT (sec)           | White Blood Cell Count (10 <sup>3</sup> /μL) | Lymphocyte (%)       |
|             |      | 29   | 29                      | 29                   | 29                   | 29                   | 29                   | 29                                   | 29                   | 29                  | 29                   | 29   | 29                   |
| 0 mg/kg     | Mean | 7.602 R <sup>1</sup>                       | 14.92 R <sup>1</sup>    | 41.42 R <sup>1</sup> | 54.52 R <sup>1</sup> | 19.63 I <sup>3</sup> | 36.03 R <sup>1</sup> | 1028.0 I <sup>3</sup>                | 3.202 R <sup>1</sup> | 8.38 I <sup>3</sup> | 13.85 I <sup>3</sup> | 8.448 I <sup>3</sup>                         | 84.83 I <sup>3</sup> |
|             | SD   | 0.421                                      | 0.76                    | 2.13                 | 1.30                 | 0.33                 | 0.44                 | 489.0                                | 0.559                | 0.41                | 1.49                 | 2.911  | 3.23                 |
|             | N    | 6  | 6                       | 6                    | 6                    | 6                    | 6                    | 6                                    | 6                    | 6                   | 6                    | 6  | 6                    |
| 1 mg/kg     | Mean | 7.228                                      | 13.90                   | 38.87 d <sup>2</sup> | 53.78                | 19.23                | 35.75                | 1341.7                               | 3.888                | 8.47                | 14.43                | 9.517  | 76.38                |
|             | SD   | 0.236                                      | 0.54                    | 0.86                 | 1.43                 | 0.51                 | 0.70                 | 126.9                                | 1.372                | 0.27                | 1.23                 | 2.483  | 10.17                |
|             | N    | 6  | 6                       | 6                    | 6                    | 6                    | 6                    | 6                                    | 6                    | 6                   | 6                    | 6  | 6                    |
| 10 mg/kg    | Mean | 6.597                                      | 12.68                   | 36.10 d <sup>2</sup> | 57.25                | 19.42                | 34.50                | 1184.7                               | 10.408               | 8.37                | 14.93                | 11635  | 72.10                |
|             | SD   | 1.956                                      | 3.51                    | 7.52                 | 10.59                | 0.93                 | 3.96                 | 340.4                                | 17.075               | 0.24                | 0.82                 | 2.657  | 16.53                |
|             | N    | 6  | 6                       | 6                    | 6                    | 6                    | 6                    | 6                                    | 6                    | 6                   | 6                    | 6  | 6                    |

1 [R - Automatic Transformation: Rank]  
 3 [I - Automatic Transformation: Identity]

2 [d - Test: Dunnett Non-Parametric 2 Sided p < 0.05]

Table 6 Hematology - Summary

B131138

Day(s) Relative to Start Date

| Sex: Female |      | Hematology          |                     |                     |                     |                                     |                                     |                                     |                                   |                                   |
|-------------|------|---------------------|---------------------|---------------------|---------------------|-------------------------------------|-------------------------------------|-------------------------------------|-----------------------------------|-----------------------------------|
|             |      | Neutrophil<br>(%)   | Eosinophil<br>(%)   | Basophil<br>(%)     | Monocyte<br>(%)     | Lymphocyte<br>(10 <sup>3</sup> /μL) | Neutrophil<br>(10 <sup>3</sup> /μL) | Eosinophil<br>(10 <sup>3</sup> /μL) | Basophil<br>(10 <sup>3</sup> /μL) | Monocyte<br>(10 <sup>3</sup> /μL) |
|             |      | 29                  | 29                  | 29                  | 29                  | 29                                  | 29                                  | 29                                  | 29                                | 29                                |
| 0 mg/kg     | Mean | 1118 L <sup>1</sup> | 1.40 I <sup>2</sup> | 0.00 R <sup>3</sup> | 2.58 I <sup>2</sup> | 7.200 I <sup>2</sup>                | 0.912 L <sup>1</sup>                | 0.120 I <sup>2</sup>                | 0.000 R <sup>3</sup>              | 0.217 I <sup>2</sup>              |
|             | SD   | 3.09                | 0.24                | 0.00                | 0.80                | 2.609                               | 0.302                               | 0.052                               | 0.000                             | 0.105                             |
|             | N    | 6                   | 6                   | 6                   | 6                   | 6                                   | 6                                   | 6                                   | 6                                 | 6                                 |
| 1 mg/kg     | Mean | 19.47               | 1.70                | 0.00 n <sup>4</sup> | 2.45                | 7.090                               | 2.032                               | 0.158                               | 0.000 n <sup>4</sup>              | 0.237                             |
|             | SD   | 10.03               | 0.37                | 0.00                | 0.69                | 1.075                               | 1.541                               | 0.038                               | 0.000                             | 0.110                             |
|             | N    | 6                   | 6                   | 6                   | 6                   | 6                                   | 6                                   | 6                                   | 6                                 | 6                                 |
| 10 mg/kg    | Mean | 24.12               | 1.32                | 0.00 n <sup>4</sup> | 2.47                | 8.047                               | 3.137                               | 0.140                               | 0.000 n <sup>4</sup>              | 0.312                             |
|             | SD   | 16.49               | 0.94                | 0.00                | 1.33                | 0.946                               | 2.733                               | 0.097                               | 0.000                             | 0.214                             |
|             | N    | 6                   | 6                   | 6                   | 6                   | 6                                   | 6                                   | 6                                   | 6                                 | 6                                 |

1 [L - Automatic Transformation: Log]  
3 [R - Automatic Transformation: Rank]

2 [I - Automatic Transformation: Identity]  
4 [n - Data not appropriate for statistical analysis]

Table 7 Blood Chemistry - Summary

B131138

Day(s) Relative to Start Date

| Sex: Male |      | Blood Chemistry      |                     |                      |                    |                       |                             |                               |                             |                       |                      |                                 |                         |
|-----------|------|----------------------|---------------------|----------------------|--------------------|-----------------------|-----------------------------|-------------------------------|-----------------------------|-----------------------|----------------------|---------------------------------|-------------------------|
|           |      | ASAT<br>(U/L)        | ALAT<br>(U/L)       | LDH<br>(U/L)         | Gamma GT<br>(U/L)  | ALP<br>(U/L)          | Creatine<br>Kinase<br>(U/L) | Total<br>Bilirubin<br>(mg/dL) | Urea<br>Nitrogen<br>(mg/dL) | Creatinine<br>(mg/dL) | Glucose<br>(mg/dL)   | Total<br>Cholesterol<br>(mg/dL) | Phospholipid<br>(mg/dL) |
|           |      | 29                   | 29                  | 29                   | 29                 | 29                    | 29                          | 29                            | 29                          | 29                    | 29                   | 29                              | 29                      |
| 0 mg/kg   | Mean | 104.3 R <sup>1</sup> | 31.7 I <sup>2</sup> | 164.8 I <sup>2</sup> | 0.8 I <sup>2</sup> | 411.0 I <sup>2</sup>  | 2518 L <sup>5</sup>         | 0.07 I <sup>2</sup>           | 16.13 I <sup>2</sup>        | 0.20 I <sup>2</sup>   | 120.5 I <sup>2</sup> | 57.7 I <sup>2</sup>             | 86.2 I <sup>2</sup>     |
|           | SD   | 19.7                 | 8.4                 | 40.2                 | 0.4                | 58.1                  | 59.5                        | 0.05                          | 1.69                        | 0.00                  | 9.1                  | 9.0                             | 10.9                    |
|           | N    | 6                    | 6                   | 6                    | 6                  | 6                     | 6                           | 6                             | 6                           | 6                     | 6                    | 6                               | 6                       |
| 1 mg/kg   | Mean | 103.2                | 29.3                | 159.8                | 0.8                | 461.2                 | 205.0                       | 0.08                          | 14.32                       | 0.20                  | 120.2                | 65.3                            | 94.3                    |
|           | SD   | 12.0                 | 4.5                 | 31.6                 | 0.4                | 37.7                  | 55.1                        | 0.04                          | 2.03                        | 0.00                  | 11.5                 | 8.6                             | 10.4                    |
|           | N    | 6                    | 6                   | 6                    | 6                  | 6                     | 6                           | 6                             | 6                           | 6                     | 6                    | 6                               | 6                       |
| 10 mg/kg  | Mean | 250.0                | 47.5                | 303.5 d <sup>3</sup> | 1.5                | 572.0 dd <sup>4</sup> | 847.0 d <sup>3</sup>        | 0.20                          | 22.55 d <sup>3</sup>        | 0.25 d <sup>3</sup>   | 103.5                | 54.0                            | 85.0                    |
|           | SD   | 230.5                | 23.3                | 169.0                | 0.7                | 38.2                  | 722.7                       | 0.14                          | 4.60                        | 0.07                  | 16.3                 | 8.5                             | 5.7                     |
|           | N    | 2                    | 2                   | 2                    | 2                  | 2                     | 2                           | 2                             | 2                           | 2                     | 2                    | 2                               | 2                       |
| 25 mg/kg  | Mean | 136.0                | 28.5                | 180.0                | 2.5 d <sup>3</sup> | 502.0                 | 182.5                       | 0.15                          | 20.80                       | 0.30 dd <sup>4</sup>  | 105.5                | 44.5                            | 72.0                    |
|           | SD   | 39.6                 | 4.9                 | 46.7                 | 2.1                | 9.9                   | 40.3                        | 0.07                          | 6.36                        | 0.00                  | 10.6                 | 0.7                             | 4.2                     |
|           | N    | 2                    | 2                   | 2                    | 2                  | 2                     | 2                           | 2                             | 2                           | 2                     | 2                    | 2                               | 2                       |

1 [R - Automatic Transformation: Rank]  
 3 [d - Test: Dunnett 2 Sided p < 0.05]  
 5 [L - Automatic Transformation: Log]

2 [I - Automatic Transformation: Identity]  
 4 [dd - Test: Dunnett 2 Sided p < 0.01]

Table 7 Blood Chemistry - Summary

B131138

Day(s) Relative to Start Date

| Sex: Male |      | Blood Chemistry         |                         |                      |                       |                           |                           |                         |                          |                      |                              |                              |                            |
|-----------|------|-------------------------|-------------------------|----------------------|-----------------------|---------------------------|---------------------------|-------------------------|--------------------------|----------------------|------------------------------|------------------------------|----------------------------|
|           |      | Triglyceride<br>(mg/dL) | Total Protein<br>(g/dL) | A/G Ratio            | Albumin<br>(%)        | Alpha1<br>Globulin<br>(%) | Alpha2<br>Globulin<br>(%) | Beta<br>Globulin<br>(%) | Gamma<br>Globulin<br>(%) | Albumin<br>(g/dL)    | Alpha1<br>Globulin<br>(g/dL) | Alpha2<br>Globulin<br>(g/dL) | Beta<br>Globulin<br>(g/dL) |
|           |      | 29                      | 29                      | 29                   | 29                    | 29                        | 29                        | 29                      | 29                       | 29                   | 29                           | 29                           | 29                         |
| 0 mg/kg   | Mean | 15.8 I <sup>1</sup>     | 5.97 I <sup>1</sup>     | 0.977 I <sup>1</sup> | 48.93 I <sup>1</sup>  | 18.92 I <sup>1</sup>      | 8.62 I <sup>1</sup>       | 17.22 I <sup>1</sup>    | 6.32 I <sup>1</sup>      | 2.91 I <sup>1</sup>  | 1.13 I <sup>1</sup>          | 0.51 I <sup>1</sup>          | 1.03 I <sup>1</sup>        |
|           | SD   | 7.9                     | 0.27                    | 0.224                | 4.99                  | 3.78                      | 1.08                      | 1.24                    | 2.40                     | 0.21                 | 0.24                         | 0.07                         | 0.12                       |
|           | N    | 6                       | 6                       | 6                    | 6                     | 6                         | 6                         | 6                       | 6                        | 6                    | 6                            | 6                            | 6                          |
| 1 mg/kg   | Mean | 14.5                    | 6.15                    | 0.997                | 49.68                 | 18.72                     | 8.73                      | 16.95                   | 5.92                     | 3.05                 | 1.15                         | 0.54                         | 1.04                       |
|           | SD   | 1.9                     | 0.18                    | 0.140                | 3.50                  | 1.28                      | 1.47                      | 1.93                    | 1.59                     | 0.22                 | 0.07                         | 0.10                         | 0.14                       |
|           | N    | 6                       | 6                       | 6                    | 6                     | 6                         | 6                         | 6                       | 6                        | 6                    | 6                            | 6                            | 6                          |
| 10 mg/kg  | Mean | 23.0                    | 5.85                    | 0.525 d <sup>2</sup> | 34.35 dd <sup>3</sup> | 25.20 d <sup>2</sup>      | 14.80 dd <sup>3</sup>     | 22.25 dd <sup>3</sup>   | 3.40                     | 2.02 dd <sup>3</sup> | 1.48                         | 0.85 dd <sup>3</sup>         | 1.29                       |
|           | SD   | 5.7                     | 0.64                    | 0.049                | 2.05                  | 2.12                      | 4.10                      | 2.47                    | 2.40                     | 0.34                 | 0.28                         | 0.15                         | 0.00                       |
|           | N    | 2                       | 2                       | 2                    | 2                     | 2                         | 2                         | 2                       | 2                        | 2                    | 2                            | 2                            | 2                          |
| 25 mg/kg  | Mean | 11.5                    | 6.00                    | 0.540 d <sup>2</sup> | 34.90 dd <sup>3</sup> | 23.10                     | 14.25 dd <sup>3</sup>     | 23.25 dd <sup>3</sup>   | 4.50                     | 2.08 dd <sup>3</sup> | 1.39                         | 0.86 dd <sup>3</sup>         | 1.39 dd <sup>3</sup>       |
|           | SD   | 3.5                     | 0.42                    | 0.113                | 4.53                  | 1.27                      | 0.92                      | 0.07                    | 2.40                     | 0.12                 | 0.17                         | 0.12                         | 0.09                       |
|           | N    | 2                       | 2                       | 2                    | 2                     | 2                         | 2                         | 2                       | 2                        | 2                    | 2                            | 2                            | 2                          |

1 [I - Automatic Transformation: Identity]  
3 [dd - Test: Dunnett 2 Sided p < 0.01]

2 [d - Test: Dunnett 2 Sided p < 0.05]

Table 7 Blood Chemistry - Summary

B131138

Day(s) Relative to Start Date

| Sex: Male |      | Blood Chemistry       |                    |                              |                     |                    |                      |
|-----------|------|-----------------------|--------------------|------------------------------|---------------------|--------------------|----------------------|
|           |      | Gamma Globulin (g/dL) | Ca (mg/dL)         | Inorganic Phosphorus (mg/dL) | Na (mmol/L)         | K (mmol/L)         | Cl (mmol/L)          |
|           |      | 29                    | 29                 | 29                           | 29                  | 29                 | 29                   |
| 0 mg/kg   | Mean | 0.38 <sup>1</sup>     | 9.70 <sup>1</sup>  | 8.73 <sup>1</sup>            | 145.5 <sup>1</sup>  | 4.23 <sup>1</sup>  | 105.2 <sup>1</sup>   |
|           | SD   | 0.16                  | 0.15               | 0.54                         | 0.5                 | 0.12               | 0.8                  |
|           | N    | 6                     | 6                  | 6                            | 6                   | 6                  | 6                    |
| 1 mg/kg   | Mean | 0.36                  | 9.93 <sup>d2</sup> | 8.33                         | 145.0               | 4.33               | 105.2                |
|           | SD   | 0.09                  | 0.15               | 0.44                         | 0.6                 | 0.15               | 0.4                  |
|           | N    | 6                     | 6                  | 6                            | 6                   | 6                  | 6                    |
| 10 mg/kg  | Mean | 0.21                  | 9.50               | 8.70                         | 145.5               | 4.35               | 106.0                |
|           | SD   | 0.16                  | 0.14               | 0.14                         | 0.7                 | 0.35               | 1.4                  |
|           | N    | 2                     | 2                  | 2                            | 2                   | 2                  | 2                    |
| 25 mg/kg  | Mean | 0.28                  | 9.95               | 9.05                         | 147.0 <sup>d2</sup> | 4.75 <sup>d2</sup> | 102.5 <sup>dd3</sup> |
|           | SD   | 0.16                  | 0.07               | 0.21                         | 0.0                 | 0.49               | 0.7                  |
|           | N    | 2                     | 2                  | 2                            | 2                   | 2                  | 2                    |

1 [I - Automatic Transformation: Identity]  
 3 [dd - Test: Dunnett 2 Sided p < 0.01]

2 [d - Test: Dunnett 2 Sided p < 0.05]

Table 7 Blood Chemistry - Summary

B131138

Day(s) Relative to Start Date

| Sex: Female |      | Blood Chemistry     |                     |                     |                    |                      |                             |                               |                             |                       |                      |                                 |                         |
|-------------|------|---------------------|---------------------|---------------------|--------------------|----------------------|-----------------------------|-------------------------------|-----------------------------|-----------------------|----------------------|---------------------------------|-------------------------|
|             |      | ASAT<br>(U/L)       | ALAT<br>(U/L)       | LDH<br>(U/L)        | Gamma GT<br>(U/L)  | ALP<br>(U/L)         | Creatine<br>Kinase<br>(U/L) | Total<br>Bilirubin<br>(mg/dL) | Urea<br>Nitrogen<br>(mg/dL) | Creatinine<br>(mg/dL) | Glucose<br>(mg/dL)   | Total<br>Cholesterol<br>(mg/dL) | Phospholipid<br>(mg/dL) |
|             |      | 29                  | 29                  | 29                  | 29                 | 29                   | 29                          | 29                            | 29                          | 29                    | 29                   | 29                              | 29                      |
| 0 mg/kg     | Mean | 90.8 L <sup>1</sup> | 27.0 I <sup>2</sup> | 87.2 L <sup>1</sup> | 1.0 I <sup>2</sup> | 220.0 I <sup>2</sup> | 104.2 I <sup>2</sup>        | 0.03 L <sup>1</sup>           | 18.57 I <sup>2</sup>        | 0.28 I <sup>2</sup>   | 123.2 I <sup>2</sup> | 71.8 I <sup>2</sup>             | 119.0 I <sup>2</sup>    |
|             | SD   | 21.5                | 9.6                 | 39.3                | 0.0                | 67.9                 | 29.8                        | 0.05                          | 2.15                        | 0.04                  | 3.7                  | 10.5                            | 14.1                    |
|             | N    | 6                   | 6                   | 6                   | 6                  | 6                    | 6                           | 6                             | 6                           | 6                     | 6                    | 6                               | 6                       |
| 1 mg/kg     | Mean | 104.7               | 28.2                | 84.8                | 1.0                | 271.5                | 108.5                       | 0.03                          | 18.25                       | 0.27                  | 108.5 d <sup>3</sup> | 64.0                            | 112.3                   |
|             | SD   | 11.0                | 4.3                 | 14.3                | 0.0                | 76.2                 | 19.5                        | 0.05                          | 3.49                        | 0.05                  | 8.5                  | 7.9                             | 14.5                    |
|             | N    | 6                   | 6                   | 6                   | 6                  | 6                    | 6                           | 6                             | 6                           | 6                     | 6                    | 6                               | 6                       |
| 10 mg/kg    | Mean | 135.3               | 28.3                | 222.8               | 1.5                | 303.0                | 125.7                       | 0.12                          | 19.60                       | 0.27                  | 119.0                | 61.0                            | 109.7                   |
|             | SD   | 71.0                | 8.7                 | 256.2               | 1.8                | 145.2                | 15.6                        | 0.19                          | 3.45                        | 0.05                  | 12.4                 | 18.9                            | 28.6                    |
|             | N    | 6                   | 6                   | 6                   | 6                  | 6                    | 6                           | 6                             | 6                           | 6                     | 6                    | 6                               | 6                       |

1 [L - Automatic Transformation: Log]  
3 [d - Test: Dunnett 2 Sided p < 0.05]

2 [I - Automatic Transformation: Identity]

Table 7 Blood Chemistry - Summary

B131138

Day(s) Relative to Start Date

| Sex: Female |      | Blood Chemistry         |                         |                      |                      |                           |                           |                         |                          |                     |                              |                              |                            |
|-------------|------|-------------------------|-------------------------|----------------------|----------------------|---------------------------|---------------------------|-------------------------|--------------------------|---------------------|------------------------------|------------------------------|----------------------------|
|             |      | Triglyceride<br>(mg/dL) | Total Protein<br>(g/dL) | A/G Ratio            | Albumin<br>(%)       | Alpha1<br>Globulin<br>(%) | Alpha2<br>Globulin<br>(%) | Beta<br>Globulin<br>(%) | Gamma<br>Globulin<br>(%) | Albumin<br>(g/dL)   | Alpha1<br>Globulin<br>(g/dL) | Alpha2<br>Globulin<br>(g/dL) | Beta<br>Globulin<br>(g/dL) |
|             |      | 29                      | 29                      | 29                   | 29                   | 29                        | 29                        | 29                      | 29                       | 29                  | 29                           | 29                           | 29                         |
| 0 mg/kg     | Mean | 16.7 I <sup>1</sup>     | 6.50 I <sup>1</sup>     | 1.258 I <sup>1</sup> | 55.55 I <sup>1</sup> | 12.08 I <sup>1</sup>      | 9.27 R <sup>3</sup>       | 15.13 I <sup>1</sup>    | 7.97 I <sup>1</sup>      | 3.60 R <sup>3</sup> | 0.78 I <sup>1</sup>          | 0.60 I <sup>1</sup>          | 0.99 I <sup>1</sup>        |
|             | SD   | 8.5                     | 0.34                    | 0.151                | 3.21                 | 1.03                      | 1.13                      | 1.12                    | 1.67                     | 0.17                | 0.05                         | 0.10                         | 0.12                       |
|             | N    | 6                       | 6                       | 6                    | 6                    | 6                         | 6                         | 6                       | 6                        | 6                   | 6                            | 6                            | 6                          |
| 1 mg/kg     | Mean | 14.8                    | 6.50                    | 1.020                | 49.95                | 15.65 d <sup>2</sup>      | 9.72                      | 17.72                   | 6.97                     | 3.23 d <sup>4</sup> | 1.02                         | 0.63                         | 1.16                       |
|             | SD   | 4.0                     | 0.39                    | 0.219                | 5.71                 | 2.60                      | 0.60                      | 2.48                    | 1.41                     | 0.21                | 0.23                         | 0.05                         | 0.23                       |
|             | N    | 6                       | 6                       | 6                    | 6                    | 6                         | 6                         | 6                       | 6                        | 6                   | 6                            | 6                            | 6                          |
| 10 mg/kg    | Mean | 18.5                    | 6.42                    | 1.022                | 49.03                | 14.97                     | 11.22                     | 18.47                   | 6.32                     | 3.15                | 0.96                         | 0.72                         | 1.19                       |
|             | SD   | 5.0                     | 0.29                    | 0.369                | 9.75                 | 3.22                      | 3.88                      | 3.21                    | 1.50                     | 0.64                | 0.22                         | 0.23                         | 0.21                       |
|             | N    | 6                       | 6                       | 6                    | 6                    | 6                         | 6                         | 6                       | 6                        | 6                   | 6                            | 6                            | 6                          |

1 [I - Automatic Transformation: Identity]  
3 [R - Automatic Transformation: Rank]

2 [d - Test: Dunnett 2 Sided p < 0.05]  
4 [d - Test: Dunnett Non-Parametric 2 Sided p < 0.05]

Table 7 Blood Chemistry - Summary

B131138

Day(s) Relative to Start Date

| Sex: Female |      | Blood Chemistry       |                   |                              |                    |                    |                    |
|-------------|------|-----------------------|-------------------|------------------------------|--------------------|--------------------|--------------------|
|             |      | Gamma Globulin (g/dL) | Ca (mg/dL)        | Inorganic Phosphorus (mg/dL) | Na (mmol/L)        | K (mmol/L)         | Cl (mmol/L)        |
|             |      | 29                    | 29                | 29                           | 29                 | 29                 | 29                 |
| 0 mg/kg     | Mean | 0.52 <sup>1</sup>     | 9.85 <sup>1</sup> | 7.42 <sup>1</sup>            | 146.2 <sup>1</sup> | 3.82 <sup>1</sup>  | 106.8 <sup>1</sup> |
|             | SD   | 0.14                  | 0.43              | 0.69                         | 1.2                | 0.21               | 1.2                |
|             | N    | 6                     | 6                 | 6                            | 6                  | 6                  | 6                  |
| 1 mg/kg     | Mean | 0.46                  | 9.73              | 7.68                         | 143.3              | 4.12 <sup>d2</sup> | 106.0              |
|             | SD   | 0.12                  | 0.31              | 0.53                         | 3.7                | 0.23               | 2.5                |
|             | N    | 6                     | 6                 | 6                            | 6                  | 6                  | 6                  |
| 10 mg/kg    | Mean | 0.41                  | 9.98              | 7.57                         | 145.8              | 4.00               | 107.0              |
|             | SD   | 0.11                  | 0.12              | 0.35                         | 1.9                | 0.14               | 2.3                |
|             | N    | 6                     | 6                 | 6                            | 6                  | 6                  | 6                  |

1 [I - Automatic Transformation: Identity]

2 [d - Test: Dunnett 2 Sided p < 0.05]

Table 8 Organ Weight - Summary

B131138

Day(s) Relative to Start Date

| Sex: Male |      | Organ Weight (Rat)    |                    |                    |                    |  |                    |                                       |                    |                                     |                    |                       |                    |
|-----------|------|-----------------------|--------------------|--------------------|--------------------|--|--------------------|---------------------------------------|--------------------|-------------------------------------|--------------------|-----------------------|--------------------|
|           |      | Final Body Weight (g) | Brain (g)          | Brain Ratio (%)    | Pituitary (mg)     | Pituitary Ratio ( $\times 10^{-3}\%$ ) | Thyroids (mg)      | Thyroids Ratio ( $\times 10^{-3}\%$ ) | Thymus (mg)        | Thymus Ratio ( $\times 10^{-3}\%$ ) | Submand GLs (g)    | Submand GLs Ratio (%) | Lungs (g)          |
|           |      | 29                    | 29                 | 29                 | 29                 | 29                                     | 29                 | 29                                    | 29                 | 29                                  | 29                 | 29                    | 29                 |
| 0 mg/kg   | Mean | 416.13 <sup>1</sup>   | 2.118 <sup>1</sup> | 0.511 <sup>1</sup> | 15.50 <sup>1</sup> | 3.73 <sup>1</sup>                      | 20.85 <sup>1</sup> | 5.04 <sup>1</sup>                     | 423.3 <sup>1</sup> | 102.04 <sup>1</sup>                 | 0.760 <sup>1</sup> | 0.182 <sup>1</sup>    | 1.603 <sup>1</sup> |
|           | SD   | 32.08                 | 0.090              | 0.030              | 1.32               | 0.19                                   | 2.02               | 0.69                                  | 126.5              | 3158                                | 0.139              | 0.024                 | 0.152              |
|           | N    | 6                     | 6                  | 6                  | 6                  | 6                                      | 6                  | 6                                     | 6                  | 6                                   | 6                  | 6                     | 6                  |
| 1 mg/kg   | Mean | 409.73                | 2.097              | 0.512              | 15.27              | 3.72                                   | 26.28              | 6.36                                  | 344.8              | 83.77                               | 0.733              | 0.179                 | 1.540              |
|           | SD   | 32.76                 | 0.147              | 0.020              | 1.59               | 0.20                                   | 6.89               | 1.25                                  | 85.9               | 17.09                               | 0.111              | 0.019                 | 0.068              |
|           | N    | 6                     | 6                  | 6                  | 6                  | 6                                      | 6                  | 6                                     | 6                  | 6                                   | 6                  | 6                     | 6                  |
| 10 mg/kg  | Mean | 391.03                | 2.143              | 0.551              | 15.40              | 3.96                                   | 21.73              | 5.61                                  | 245.0              | 61.87                               | 0.690              | 0.177                 | 1.630              |
|           | SD   | 41.26                 | 0.090              | 0.039              | 1.15               | 0.36                                   | 0.93               | 0.83                                  | 99.4               | 19.95                               | 0.061              | 0.012                 | 0.062              |
|           | N    | 3                     | 3                  | 3                  | 3                  | 3                                      | 3                  | 3                                     | 3                  | 3                                   | 3                  | 3                     | 3                  |
| 25 mg/kg  | Mean | 387.55                | 2.130              | 0.550              | 15.45              | 3.98                                   | 20.80              | 5.39                                  | 242.0              | 62.32                               | 0.770              | 0.199                 | 1.780              |
|           | SD   | 9.97                  | 0.042              | 0.025              | 0.92               | 0.13                                   | 6.36               | 1.78                                  | 43.8               | 9.71                                | 0.057              | 0.009                 | 0.184              |
|           | N    | 2                     | 2                  | 2                  | 2                  | 2                                      | 2                  | 2                                     | 2                  | 2                                   | 2                  | 2                     | 2                  |

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1 [I - Automatic Transformation: Identity]

Table 8 Organ Weight - Summary

B131138

Day(s) Relative to Start Date

| Sex: Male |      | Organ Weight (Rat)  |                    |                    |                    |                    |                     |                     |                     |                      |                    |                                      |                    |
|-----------|------|---------------------|--------------------|--------------------|--------------------|--------------------|---------------------|---------------------|---------------------|----------------------|--------------------|--------------------------------------|--------------------|
|           |      | Lungs Ratio (%)     | Heart (g)          | Heart Ratio (%)    | Liver (g)          | Liver Ratio (%)    | Spleen (g)          | Spleen Ratio (%)    | Kidneys (g)         | Kidneys Ratio (%)    | Adrenals (mg)      | Adrenals Ratio (x10 <sup>-3</sup> %) | Testes (g)         |
|           |      | 29                  | 29                 | 29                 | 29                 | 29                 | 29                  | 29                  | 29                  | 29                   | 29                 | 29                                   | 29                 |
| 0 mg/kg   | Mean | 0.385 <sup>1</sup>  | 1.338 <sup>1</sup> | 0.323 <sup>1</sup> | 9.607 <sup>1</sup> | 2.313 <sup>1</sup> | 0.803 <sup>1</sup>  | 0.192 <sup>1</sup>  | 2.867 <sup>1</sup>  | 0.688 <sup>1</sup>   | 69.53 <sup>1</sup> | 16.66 <sup>1</sup>                   | 3.205 <sup>1</sup> |
|           | SD   | 0.017               | 0.067              | 0.022              | 0.622              | 0.133              | 0.162               | 0.028               | 0.312               | 0.049                | 13.02              | 2.56                                 | 0.207              |
|           | N    | 6                   | 6                  | 6                  | 6                  | 6                  | 6                   | 6                   | 6                   | 6                    | 6                  | 6                                    | 6                  |
| 1 mg/kg   | Mean | 0.378               | 1.272              | 0.311              | 9.412              | 2.301              | 0.835               | 0.204               | 2.710               | 0.663                | 69.27              | 16.81                                | 3.302              |
|           | SD   | 0.034               | 0.117              | 0.030              | 0.647              | 0.107              | 0.168               | 0.040               | 0.166               | 0.032                | 12.19              | 1.98                                 | 0.131              |
|           | N    | 6                   | 6                  | 6                  | 6                  | 6                  | 6                   | 6                   | 6                   | 6                    | 6                  | 6                                    | 6                  |
| 10 mg/kg  | Mean | 0.419               | 1.313              | 0.338              | 10.010             | 2.576              | 1.270 <sup>d2</sup> | 0.335 <sup>d2</sup> | 2.930               | 0.754                | 70.93              | 18.34                                | 3.003              |
|           | SD   | 0.029               | 0.081              | 0.031              | 0.669              | 0.272              | 0.427               | 0.144               | 0.187               | 0.076                | 13.23              | 4.16                                 | 0.335              |
|           | N    | 3                   | 3                  | 3                  | 3                  | 3                  | 3                   | 3                   | 3                   | 3                    | 3                  | 3                                    | 3                  |
| 25 mg/kg  | Mean | 0.459 <sup>d2</sup> | 1.275              | 0.329              | 9.725              | 2.509              | 0.940               | 0.243               | 3.460 <sup>d2</sup> | 0.894 <sup>dd3</sup> | 77.90              | 20.09                                | 3.000              |
|           | SD   | 0.036               | 0.049              | 0.004              | 0.233              | 0.004              | 0.198               | 0.057               | 0.141               | 0.059                | 4.24               | 0.58                                 | 0.042              |
|           | N    | 2                   | 2                  | 2                  | 2                  | 2                  | 2                   | 2                   | 2                   | 2                    | 2                  | 2                                    | 2                  |

1 [I - Automatic Transformation: Identity]

2 [d - Test: Dunnett 2 Sided p < 0.05]

3 [dd - Test: Dunnett 2 Sided p < 0.01]

Table 8

Organ Weight - Summary

B131138

Day(s) Relative to Start Date

| Sex: Male |      | Organ Weight (Rat)   |                      |                      |
|-----------|------|----------------------|----------------------|----------------------|
|           |      | Testes Ratio (%)     | Prostate (g)         | Prostate Ratio (%)   |
|           |      | 29                   | 29                   | 29                   |
| 0 mg/kg   | Mean | 0.774 I <sup>1</sup> | 0.620 I <sup>1</sup> | 0.150 I <sup>1</sup> |
|           | SD   | 0.075                | 0.082                | 0.023                |
|           | N    | 6                    | 6                    | 6                    |
| 1 mg/kg   | Mean | 0.809                | 0.735                | 0.178                |
|           | SD   | 0.056                | 0.209                | 0.041                |
|           | N    | 6                    | 6                    | 6                    |
| 10 mg/kg  | Mean | 0.780                | 0.477                | 0.121                |
|           | SD   | 0.170                | 0.105                | 0.014                |
|           | N    | 3                    | 3                    | 3                    |
| 25 mg/kg  | Mean | 0.774                | 0.585                | 0.151                |
|           | SD   | 0.009                | 0.078                | 0.016                |
|           | N    | 2                    | 2                    | 2                    |

1 [I - Automatic Transformation: Identity]

Table 8 Organ Weight - Summary

B131138

Day(s) Relative to Start Date

| Sex: Female |      | Organ Weight (Rat)    |                    |                    |                    |  |                    |                                       |                     |                                     |                    |                        |                    |                    |
|-------------|------|-----------------------|--------------------|--------------------|--------------------|--|--------------------|---------------------------------------|---------------------|-------------------------------------|--------------------|------------------------|--------------------|--------------------|
|             |      | Final Body Weight (g) | Brain (g)          | Brain Ratio (%)    | Pituitary (mg)     | Pituitary Ratio (×10 <sup>^</sup> -3%) | Thyroids (mg)      | Thyroids Ratio (×10 <sup>^</sup> -3%) | Thymus (mg)         | Thymus Ratio (×10 <sup>^</sup> -3%) | Submand. GLs (g)   | Submand. GLs Ratio (%) | Lungs (g)          | Lungs Ratio (%)    |
|             |      | 29                    | 29                 | 29                 | 29                 | 29                                     | 29                 | 29                                    | 29                  | 29                                  | 29                 | 29                     | 29                 | 29                 |
| 0 mg/kg     | Mean | 252.03 <sup>1</sup>   | 1.878 <sup>1</sup> | 0.747 <sup>1</sup> | 20.38 <sup>1</sup> | 8.12 <sup>1</sup>                      | 23.33 <sup>1</sup> | 9.27 <sup>1</sup>                     | 388.3 <sup>1</sup>  | 153.53 <sup>1</sup>                 | 0.478 <sup>1</sup> | 0.190 <sup>1</sup>     | 1.202 <sup>1</sup> | 0.477 <sup>1</sup> |
|             | SD   | 16.30                 | 0.066              | 0.035              | 1.78               | 0.95                                   | 3.01               | 1.13                                  | 69.6                | 20.81                               | 0.039              | 0.017                  | 0.106              | 0.024              |
|             | N    | 6                     | 6                  | 6                  | 6                  | 6                                      | 6                  | 6                                     | 6                   | 6                                   | 6                  | 6                      | 6                  | 6                  |
| 1 mg/kg     | Mean | 243.97                | 1.905              | 0.783              | 22.02              | 9.02                                   | 23.70              | 9.70                                  | 282.0 <sup>d2</sup> | 115.61 <sup>d2</sup>                | 0.463              | 0.190                  | 1.173              | 0.481              |
|             | SD   | 9.90                  | 0.079              | 0.062              | 2.06               | 0.77                                   | 4.21               | 1.54                                  | 67.0                | 27.11                               | 0.049              | 0.020                  | 0.080              | 0.028              |
|             | N    | 6                     | 6                  | 6                  | 6                  | 6                                      | 6                  | 6                                     | 6                   | 6                                   | 6                  | 6                      | 6                  | 6                  |
| 10 mg/kg    | Mean | 245.07                | 1.910              | 0.783              | 22.62              | 9.27                                   | 23.15              | 9.46                                  | 317.3               | 128.25                              | 0.438              | 0.179                  | 1.248              | 0.511              |
|             | SD   | 17.93                 | 0.067              | 0.066              | 2.02               | 1.09                                   | 3.16               | 1.25                                  | 82.8                | 25.09                               | 0.061              | 0.027                  | 0.048              | 0.036              |
|             | N    | 6                     | 6                  | 6                  | 6                  | 6                                      | 6                  | 6                                     | 6                   | 6                                   | 6                  | 6                      | 6                  | 6                  |

1 [I - Automatic Transformation: Identity]

2 [d - Test: Dunnett 2 Sided p < 0.05]

Table 8 Organ Weight - Summary

B131138

Day(s) Relative to Start Date

| Sex: Female |      | Organ Weight (Rat)   |                       |                      |                       |                      |                        |                      |                         |                      |   |                      |  |
|-------------|------|----------------------|-----------------------|----------------------|-----------------------|----------------------|------------------------|----------------------|-------------------------|----------------------|---|----------------------|--|
|             |      | Heart<br>(g)         | Heart<br>Ratio<br>(%) | Liver<br>(g)         | Liver<br>Ratio<br>(%) | Spleen<br>(g)        | Spleen<br>Ratio<br>(%) | Kidneys<br>(g)       | Kidneys<br>Ratio<br>(%) | Adrenals<br>(mg)     | Adrenals<br>Ratio<br>( $\times 10^{-3}\%$ ) | Ovaries<br>(mg)      | Ovaries<br>Ratio<br>( $\times 10^{-3}\%$ ) |
|             |      | 29                   | 29                    | 29                   | 29                    | 29                   | 29                     | 29                   | 29                      | 29                   | 29  | 29                   | 29   |
| 0 mg/kg     | Mean | 0.842 I <sup>1</sup> | 0.335 I <sup>1</sup>  | 6.670 I <sup>1</sup> | 2.649 I <sup>1</sup>  | 0.553 R <sup>2</sup> | 0.220 R <sup>2</sup>   | 1.653 I <sup>1</sup> | 0.656 I <sup>1</sup>    | 73.05 I <sup>1</sup> | 28.98 I <sup>1</sup>                        | 92.38 I <sup>1</sup> | 36.65 I <sup>1</sup>                       |
|             | SD   | 0.058                | 0.025                 | 0.431                | 0.138                 | 0.031                | 0.020                  | 0.139                | 0.023                   | 8.94                 | 2.86  | 12.62                | 4.55                                       |
|             | N    | 6                    | 6                     | 6                    | 6                     | 6                    | 6                      | 6                    | 6                       | 6                    | 6   | 6                    | 6  |
| 1 mg/kg     | Mean | 0.820                | 0.336                 | 6.282                | 2.574                 | 0.592                | 0.243                  | 1.670                | 0.685                   | 69.18                | 28.33                                       | 86.20                | 35.28                                      |
|             | SD   | 0.028                | 0.010                 | 0.469                | 0.152                 | 0.068                | 0.026                  | 0.114                | 0.041                   | 8.02                 | 2.74  | 8.92                 | 2.69                                       |
|             | N    | 6                    | 6                     | 6                    | 6                     | 6                    | 6                      | 6                    | 6                       | 6                    | 6   | 6                    | 6  |
| 10 mg/kg    | Mean | 0.908                | 0.372                 | 6.672                | 2.726                 | 0.822                | 0.343                  | 1.797                | 0.735 d <sup>3</sup>    | 75.18                | 30.79                                       | 88.05                | 35.96                                      |
|             | SD   | 0.092                | 0.039                 | 0.601                | 0.221                 | 0.596                | 0.269                  | 0.150                | 0.074                   | 16.72                | 7.36  | 9.54                 | 3.40                                       |
|             | N    | 6                    | 6                     | 6                    | 6                     | 6                    | 6                      | 6                    | 6                       | 6                    | 6   | 6                    | 6  |

1 [I - Automatic Transformation: Identity]  
3 [d - Test: Dunnett 2 Sided p < 0.05]

2 [R - Automatic Transformation: Rank]

Table 9 Necropsy - Summary

B131138

| Removal Reason: Scheduled sacrifice | Male    |         |          |          | Female  |         |          |
|-------------------------------------|---------|---------|----------|----------|---------|---------|----------|
|                                     | 0 mg/kg | 1 mg/kg | 10 mg/kg | 25 mg/kg | 0 mg/kg | 1 mg/kg | 10 mg/kg |
| Number of Animals:                  | 6       | 6       | 3        | 2        | 6       | 6       | 6        |
| <b>Necropsy Findings</b>            |         |         |          |          |         |         |          |
| Present                             | 0       | 1       | 3        | 2        | 0       | 3       | 5        |
| Absent                              | 6       | 5       | 0        | 0        | 6       | 3       | 1        |
| <b>Spleen</b>                       |         |         |          |          |         |         |          |
| Enlargement                         | .       | .       | .        | .        | .       | .       | 1        |
| <b>Administered Site</b>            |         |         |          |          |         |         |          |
| Nodule                              | .       | 0       | 1        | 2        | .       | 3       | 4        |
| Whitish patch                       | .       | 1       | 0        | 0        | .       | 0       | 0        |
| Hematoma                            | .       | 0       | 2        | 0        | .       | 0       | 1        |
| <b>Abdominal Cavity</b>             |         |         |          |          |         |         |          |
| Adhesion; multiple organs, nodule   | .       | .       | .        | 1        | .       | .       | .        |
| <b>Whole Body</b>                   |         |         |          |          |         |         |          |
| Anemia                              | .       | .       | 1        | .        | .       | .       | .        |

Table 9 Necropsy - Summary

B131138

| Removal Reason: Death          | Male     |          |          | Female   |          |
|--------------------------------|----------|----------|----------|----------|----------|
|                                | 10 mg/kg | 25 mg/kg | 10 mg/kg | 25 mg/kg | 25 mg/kg |
| Number of Animals:             | 3        | 4        | 1        | 6        | 1        |
| <b>Necropsy Findings</b>       |          |          |          |          |          |
| Present                        | 3        | 4        | 1        | 6        | 1        |
| <b>Stomach</b>                 |          |          |          |          |          |
| Abnormal contents; dark red    | .        | .        | .        | 1        | .        |
| <b>Duodenum</b>                |          |          |          |          |          |
| Abnormal contents; dark red    | .        | .        | .        | 1        | .        |
| <b>Jejunum</b>                 |          |          |          |          |          |
| Abnormal contents; dark red    | .        | 1        | .        | 1        | .        |
| <b>Ileum</b>                   |          |          |          |          |          |
| Abnormal contents; dark red    | .        | 1        | .        | 1        | .        |
| <b>Lungs (And Bronchus)</b>    |          |          |          |          |          |
| Edema                          | 1        | 1        | .        | 2        | .        |
| <b>Kidney</b>                  |          |          |          |          |          |
| Dilatation; pelvis, unilateral | .        | 0        | .        | 1        | .        |
| Enlargement; unilateral        | .        | 1        | .        | 0        | .        |
| <b>Urinary Bladder</b>         |          |          |          |          |          |
| Abnormal urine; dark red       | .        | .        | .        | 1        | .        |
| <b>Prostate</b>                |          |          |          |          |          |
| Dark reddish change            | .        | 1        | .        | .        | .        |
| <b>Adrenal</b>                 |          |          |          |          |          |
| Enlargement; bilateral         | .        | .        | .        | 2        | .        |
| <b>Skin</b>                    |          |          |          |          |          |
| Edema; subcutis                | 1        | .        | .        | .        | .        |

Table 9 Necropsy - Summary

B131138

| Removal Reason: Death               | Male     |          |          | Female   |          |
|-------------------------------------|----------|----------|----------|----------|----------|
|                                     | 10 mg/kg | 25 mg/kg | 10 mg/kg | 25 mg/kg | 25 mg/kg |
| Number of Animals:                  | 3        | 4        | 1        | 6        | 1        |
| <b>Administered Site</b>            |          |          |          |          |          |
| Nodule                              | 0        | 1        | 0        | 1        | 1        |
| Hematoma                            | 3        | 3        | 1        | 5        | 0        |
| <b>Thoracic Cavity</b>              |          |          |          |          |          |
| Increase; pleural fluid             | 1        | 2        | .        | .        | .        |
| <b>Abdominal Cavity</b>             |          |          |          |          |          |
| Increase; abdominal fluid           | 3        | 3        | 1        | 3        | 1        |
| Adhesion; multiple organs, nodule   | 0        | 1        | 0        | 1        | 1        |
| Adhesion; multiple organs, hematoma | 2        | 1        | 1        | 2        | 0        |