*Males*

| 001699 | | | Urinalysis | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | |
| No. | Group | Sex | Specific | pH | Leucoc. | Nitrite | Protein | Gluc | Ketones | Urobilino- | Bilirubin | Blood |
| | | | gravity | | | | | | | gen | | |
| | | | | | /µl | | mg/dl | mg/dl | | mg/dl | | Ery/µl |
| | | | | | | | | | | | | |
| 1 | C | m | 1,020 | 6,00 | 10-25 | neg. | 30,00 | norm. | neg. | < 1 | neg. | approx. 250 |
| 2 | C | m | 1,010 | 6,00 | neg. | neg. | neg. | norm. | neg. | < 1 | neg. | neg. |
| 3 | C | m | 1,020 | 6,00 | 10-25 | neg. | neg. | 50,00 | neg. | < 1 | neg. | approx. 50 |
| 4 | C | m | 1,015 | 7,00 | 10-25 | neg. | neg. | 50,00 | neg. | < 1 | neg. | neg. |
| 5 | C | m | 1,015 | 7,00 | 75 | neg. | neg. | 300 | neg. | < 1 | neg. | approx. 10 |
| | | | | | | | | | | | | |
| 13 | HD | m | 1,020 | 6,00 | 10-25 | neg. | 30,00 | norm. | neg. | | neg. | approx. 250 |
| 14 | HD | m | 1,015 | 7,00 | 75 | neg. | 30,00 | norm. | neg. | < 1 | neg. | neg. |
| 15 | HD | m | 1,010 | 6,00 | neg. | neg. | neg. | norm. | neg. | < 1 | neg. | neg. |
| 16 | HD | m | 1,015 | 6,00 | 10-25 | neg. | 30,00 | norm. | neg. | < 1 | neg. | neg. |
| 17 | HD | m | 1,015 | 7,00 | neg. | neg. | neg. | 100,00 | neg. | < 1 | neg. | neg. |
| | | | | | | | | | | | | |
| 25 | MD | m | 1,015 | 6,00 | neg. | neg. | 30,00 | norm. | neg. | < 1 | neg. | neg. |
| 26 | MD | m | 1,015 | 6,00 | neg. | neg. | neg. | norm. | neg. | < 1 | neg. | neg. |
| 27 | MD | m | 1,015 | 7,00 | neg. | neg. | 30,00 | norm. | neg. | < 1 | neg. | neg. |
| 28 | MD | m | 1,015 | 6,00 | neg. | neg. | neg. | norm. | neg. | < 1 | neg. | approx. 5-10 |
| 29 | MD | m | 1,015 | 7,00 | neg. | neg. | 30,00 | norm. | neg. | < 1 | neg. | neg. |
| | | | | | | | | | | | | |
| 37 | LD | m | 1,015 | 6,00 | neg. | neg. | 30,00 | norm. | neg. | < 1 | neg. | neg. |
| 38 | LD | m | 1,020 | 6,00 | 10-25 | neg. | 30,00 | norm. | neg. | < 1 | neg. | approx. 5-10 |
| 39 | LD | m | 1,015 | 6,00 | neg. | neg. | 30,00 | norm. | neg. | < 1 | neg. | neg. |
| 40 | LD | m | 1,010 | 7,00 | neg. | neg. | 30,00 | norm. | neg. | < 1 | neg. | approx. 50 |
| 41 | LD | m | 1,015 | 7,00 | 10-25 | neg. | neg. | 50 | neg. | < 1 | neg. | approx. 250 |

# Organ Weights

*Females*

| **Liver** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 7 | C | f | 5,630 | 181,00 | 3,110 | |
| 8 | C | f | 6,275 | 207,00 | 3,031 | |
| 9 | C | f | 6,223 | 213,00 | 2,922 | |
| 10 | C | f | 6,141 | 210,00 | 2,924 | |
| 11 | C | f | 6,779 | 197,00 | 3,441 | |
| | | Mean value: | **6,210** | **201,60** | **3,086** | |
| | | SD +/-: | 0,366 | 11,62 | 0,191 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 43 | LD | f | 7,070 | 220,00 | 3,214 | |
| 44 | LD | f | 5,608 | 177,00 | 3,168 | |
| 45 | LD | f | 5,427 | 185,00 | 2,934 | |
| 46 | LD | f | 5,874 | 208,00 | 2,824 | |
| 47 | LD | f | 7,018 | 224,00 | 3,133 | |
| | | Mean value: | **6,199** | **202,80** | **3,055** | |
| | | SD +/-: | 0,704 | 18,73 | 0,150 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 31 | MD | f | 6,960 | 188,00 | 3,702 | |
| 32 | MD | f | 7,199 | 191,00 | 3,769 | |
| 33 | MD | f | 5,550 | 164,00 | 3,384 | |
| 34 | MD | f | 6,543 | 188,00 | 3,480 | |
| 35 | MD | f | 7,518 | 206,00 | 3,650 | |
| | | Mean value: | **6,754** | **187,40** | **3,597** | |
| | | SD +/-: | 0,681 | 13,47 | 0,143 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 19 | HD | f | 8,106 | 210,00 | 3,860 | |
| 20 | HD | f | 7,393 | 180,00 | 4,107 | |
| 21 | HD | f | 6,999 | 195,00 | 3,589 | |
| 22 | HD | f | 7,801 | 208,00 | 3,750 | |
| 23 | HD | f | 6,956 | 192,00 | 3,623 | |
| | | Mean value: | **7,451** | **197,00** | **3,786** | |
| | | SD +/-: | 0,448 | 11,03 | 0,187 | |

| **Kidneys** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 7 | C | f | 1,531 | 181,00 | 0,846 | |
| 8 | C | f | 1,963 | 207,00 | 0,948 | |
| 9 | C | f | 1,530 | 213,00 | 0,718 | |
| 10 | C | f | 1,752 | 210,00 | 0,834 | |
| 11 | C | f | 1,720 | 197,00 | 0,873 | |
| | | Mean value: | **1,699** | **201,60** | **0,844** | |
| | | SD +/-: | 0,161 | 11,62 | 0,074 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 43 | LD | f | 1,653 | 220,00 | 0,751 | |
| 44 | LD | f | 1,810 | 177,00 | 1,023 | |
| 45 | LD | f | 1,277 | 185,00 | 0,690 | |
| 46 | LD | f | 1,534 | 208,00 | 0,738 | |
| 47 | LD | f | 1,735 | 224,00 | 0,775 | |
| | | Mean value: | **1,602** | **202,80** | **0,795** | |
| | | SD +/-: | 0,186 | 18,73 | 0,117 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 31 | MD | f | 1,446 | 188,00 | 0,769 | |
| 32 | MD | f | 1,971 | 191,00 | 1,032 | |
| 33 | MD | f | 1,348 | 164,00 | 0,822 | |
| 34 | MD | f | 1,319 | 188,00 | 0,702 | |
| 35 | MD | f | 1,637 | 206,00 | 0,795 | |
| | | Mean value: | **1,544** | **187,40** | **0,824** | |
| | | SD +/-: | 0,241 | 13,47 | 0,111 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 19 | HD | f | 1,514 | 210,00 | 0,721 | |
| 20 | HD | f | 1,516 | 180,00 | 0,842 | |
| 21 | HD | f | 1,445 | 195,00 | 0,741 | |
| 22 | HD | f | 1,876 | 208,00 | 0,902 | |
| 23 | HD | f | 1,906 | 192,00 | 0,993 | |
| | | Mean value: | **1,651** | **197,00** | **0,840** | |
| | | SD +/-: | 0,198 | 11,03 | 0,101 | |

| **Adrenals** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 7 | C | f | 0,097 | 181,00 | 0,054 | |
| 8 | C | f | 0,069 | 207,00 | 0,033 | |
| 9 | C | f | 0,068 | 213,00 | 0,032 | |
| 10 | C | f | 0,067 | 210,00 | 0,032 | |
| 11 | C | f | 0,080 | 197,00 | 0,041 | |
| | | Mean value: | **0,076** | **201,60** | **0,038** | |
| | | SD +/-: | 0,011 | 11,62 | 0,008 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 43 | LD | f | 0,069 | 220,00 | 0,031 | |
| 44 | LD | f | 0,058 | 177,00 | 0,033 | |
| 45 | LD | f | 0,062 | 185,00 | 0,034 | |
| 46 | LD | f | 0,064 | 208,00 | 0,031 | |
| 47 | LD | f | 0,062 | 224,00 | 0,028 | |
| | | Mean value: | **0,063** | **202,80** | **0,031** | |
| | | SD +/-: | 0,004 | 18,73 | 0,002 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 31 | MD | f | 0,065 | 188,00 | 0,035 | |
| 32 | MD | f | 0,070 | 191,00 | 0,037 | |
| 33 | MD | f | 0,068 | 164,00 | 0,041 | |
| 34 | MD | f | 0,060 | 188,00 | 0,032 | |
| 35 | MD | f | 0,065 | 206,00 | 0,032 | |
| | | Mean value: | **0,066** | **187,40** | **0,035** | |
| | | SD +/-: | 0,003 | 13,47 | 0,004 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 19 | HD | f | 0,068 | 210,00 | 0,032 | |
| 20 | HD | f | 0,060 | 180,00 | 0,033 | |
| 21 | HD | f | 0,070 | 195,00 | 0,036 | |
| 22 | HD | f | 0,081 | 208,00 | 0,039 | |
| 23 | HD | f | 0,066 | 192,00 | 0,034 | |
| | | Mean value: | **0,069** | **197,00** | **0,035** | |
| | | SD +/-: | 0,007 | 11,03 | 0,002 | |

| **Thymus** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 7 | C | f | 0,317 | 181,00 | 0,175 | |
| 8 | C | f | 0,382 | 207,00 | 0,185 | |
| 9 | C | f | 0,419 | 213,00 | 0,197 | |
| 10 | C | f | 0,345 | 210,00 | 0,164 | |
| 11 | C | f | 0,417 | 197,00 | 0,212 | |
| | | Mean value: | **0,376** | **201,60** | **0,186** | |
| | | SD +/-: | 0,040 | 11,62 | 0,017 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 43 | LD | f | 0,533 | 220,00 | 0,242 | |
| 44 | LD | f | 0,385 | 177,00 | 0,218 | |
| 45 | LD | f | 0,317 | 185,00 | 0,171 | |
| 46 | LD | f | 0,419 | 208,00 | 0,201 | |
| 47 | LD | f | 0,418 | 224,00 | 0,187 | |
| | | Mean value: | **0,414** | **202,80** | **0,204** | |
| | | SD +/-: | 0,070 | 18,73 | 0,025 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 31 | MD | f | 0,346 | 188,00 | 0,184 | |
| 32 | MD | f | 0,493 | 191,00 | 0,258 | |
| 33 | MD | f | 0,321 | 164,00 | 0,196 | |
| 34 | MD | f | 0,365 | 188,00 | 0,194 | |
| 35 | MD | f | 0,325 | 206,00 | 0,158 | |
| | | Mean value: | **0,370** | **187,40** | **0,198** | |
| | | SD +/-: | 0,063 | 13,47 | 0,033 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 19 | HD | f | 0,322 | 210,00 | 0,153 | |
| 20 | HD | f | 0,299 | 180,00 | 0,166 | |
| 21 | HD | f | 0,386 | 195,00 | 0,198 | |
| 22 | HD | f | 0,387 | 208,00 | 0,186 | |
| 23 | HD | f | 0,364 | 192,00 | 0,190 | |
| | | Mean value: | **0,352** | **197,00** | **0,179** | |
| | | SD +/-: | 0,035 | 11,03 | 0,016 | |

| **Spleen** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 7 | C | f | 0,580 | 181,00 | 0,320 | |
| 8 | C | f | 0,526 | 207,00 | 0,254 | |
| 9 | C | f | 0,519 | 213,00 | 0,244 | |
| 10 | C | f | 0,526 | 210,00 | 0,250 | |
| 11 | C | f | 0,481 | 197,00 | 0,244 | |
| | | Mean value: | **0,526** | **201,60** | **0,263** | |
| | | SD +/-: | 0,032 | 11,62 | 0,029 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 43 | LD | f | 0,426 | 220,00 | 0,194 | |
| 44 | LD | f | 0,504 | 177,00 | 0,285 | |
| 45 | LD | f | 0,562 | 185,00 | 0,304 | |
| 46 | LD | f | 0,476 | 208,00 | 0,229 | |
| 47 | LD | f | 0,544 | 224,00 | 0,243 | |
| | | Mean value: | **0,502** | **202,80** | **0,251** | |
| | | SD +/-: | 0,049 | 18,73 | 0,039 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 31 | MD | f | 0,485 | 188,00 | 0,258 | |
| 32 | MD | f | 0,540 | 191,00 | 0,283 | |
| 33 | MD | f | 0,473 | 164,00 | 0,288 | |
| 34 | MD | f | 0,440 | 188,00 | 0,234 | |
| 35 | MD | f | 0,567 | 206,00 | 0,275 | |
| | | Mean value: | **0,501** | **187,40** | **0,268** | |
| | | SD +/-: | 0,046 | 13,47 | 0,020 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 19 | HD | f | 0,488 | 210,00 | 0,232 | |
| 20 | HD | f | 0,594 | 180,00 | 0,330 | |
| 21 | HD | f | 0,483 | 195,00 | 0,248 | |
| 22 | HD | f | 0,551 | 208,00 | 0,265 | |
| 23 | HD | f | 0,541 | 192,00 | 0,282 | |
| | | Mean value: | **0,531** | **197,00** | **0,271** | |
| | | SD +/-: | 0,042 | 11,03 | 0,034 | |

| **Heart** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 7 | C | f | 0,637 | 181,00 | 0,352 | |
| 8 | C | f | 0,726 | 207,00 | 0,351 | |
| 9 | C | f | 0,650 | 213,00 | 0,305 | |
| 10 | C | f | 0,652 | 210,00 | 0,310 | |
| 11 | C | f | 0,593 | 197,00 | 0,301 | |
| | | Mean value: | **0,652** | **201,60** | **0,324** | |
| | | SD +/-: | 0,043 | 11,62 | 0,023 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 43 | LD | f | 0,650 | 220,00 | 0,295 | |
| 44 | LD | f | 0,619 | 177,00 | 0,350 | |
| 45 | LD | f | 0,561 | 185,00 | 0,303 | |
| 46 | LD | f | 0,634 | 208,00 | 0,305 | |
| 47 | LD | f | 0,662 | 224,00 | 0,296 | |
| | | Mean value: | **0,625** | **202,80** | **0,310** | |
| | | SD +/-: | 0,035 | 18,73 | 0,020 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 31 | MD | f | 0,614 | 188,00 | 0,327 | |
| 32 | MD | f | 0,565 | 191,00 | 0,296 | |
| 33 | MD | f | 0,558 | 164,00 | 0,340 | |
| 34 | MD | f | 0,597 | 188,00 | 0,318 | |
| 35 | MD | f | 0,692 | 206,00 | 0,336 | |
| | | Mean value: | **0,605** | **187,40** | **0,323** | |
| | | SD +/-: | 0,048 | 13,47 | 0,016 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 19 | HD | f | 0,607 | 210,00 | 0,289 | |
| 20 | HD | f | 0,548 | 180,00 | 0,304 | |
| 21 | HD | f | 0,645 | 195,00 | 0,331 | |
| 22 | HD | f | 0,673 | 208,00 | 0,324 | |
| 23 | HD | f | 0,629 | 192,00 | 0,328 | |
| | | Mean value: | **0,620** | **197,00** | **0,315** | |
| | | SD +/-: | 0,042 | 11,03 | 0,016 | |

| **Brain** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 7 | C | f | 1,567 | 181,00 | 0,866 | |
| 8 | C | f | 1,717 | 207,00 | 0,829 | |
| 9 | C | f | 1,683 | 213,00 | 0,790 | |
| 10 | C | f | 1,793 | 210,00 | 0,854 | |
| 11 | C | f | 1,674 | 197,00 | 0,850 | |
| | | Mean value: | **1,687** | **201,60** | **0,838** | |
| | | SD +/-: | 0,073 | 11,62 | 0,027 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 43 | LD | f | 1,761 | 220,00 | 0,800 | |
| 44 | LD | f | 1,775 | 177,00 | 1,003 | |
| 45 | LD | f | 1,696 | 185,00 | 0,917 | |
| 46 | LD | f | 1,847 | 208,00 | 0,888 | |
| 47 | LD | f | 1,832 | 224,00 | 0,818 | |
| | | Mean value: | **1,782** | **202,80** | **0,885** | |
| | | SD +/-: | 0,054 | 18,73 | 0,073 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 31 | MD | f | 1,601 | 188,00 | 0,852 | |
| 32 | MD | f | 1,708 | 191,00 | 0,894 | |
| 33 | MD | f | 1,721 | 164,00 | 1,049 | |
| 34 | MD | f | 1,752 | 188,00 | 0,932 | |
| 35 | MD | f | 1,744 | 206,00 | 0,847 | |
| | | Mean value: | **1,705** | **187,40** | **0,915** | |
| | | SD +/-: | 0,054 | 13,47 | 0,074 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 19 | HD | f | 1,685 | 210,00 | 0,802 | |
| 20 | HD | f | 2,293 | 180,00 | 1,274 | |
| 21 | HD | f | 1,677 | 195,00 | 0,860 | |
| 22 | HD | f | 1,929 | 208,00 | 0,927 | |
| 23 | HD | f | 1,584 | 192,00 | 0,825 | |
| | | Mean value: | **1,834** | **197,00** | **0,938** | |
| | | SD +/-: | 0,257 | 11,03 | 0,173 | |

*Males*

| **Liver** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 1 | C | m | 8,539 | 277,00 | 3,083 | |
| 2 | C | m | 9,078 | 300,00 | 3,026 | |
| 3 | C | m | 9,120 | 290,00 | 3,145 | |
| 4 | C | m | 10,795 | 318,00 | 3,395 | |
| 5 | C | m | 10,445 | 321,00 | 3,254 | |
| | | Mean value: | **9,595** | **301,20** | **3,180** | |
| | | SD +/-: | 0,868 | 16,65 | 0,131 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 37 | LD | m | 10,835 | 320,00 | 3,386 | |
| 38 | LD | m | 9,275 | 283,00 | 3,277 | |
| 39 | LD | m | 8,368 | 256,00 | 3,269 | |
| 40 | LD | m | 8,638 | 281,00 | 3,074 | |
| 41 | LD | m | 9,286 | 280,00 | 3,316 | |
| | | Mean value: | **9,280** | **284,00** | **3,265** | |
| | | SD +/-: | 0,856 | 20,52 | 0,104 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 25 | MD | m | 8,872 | 270,00 | 3,286 | |
| 26 | MD | m | 8,561 | 272,00 | 3,147 | |
| 27 | MD | m | 10,197 | 290,00 | 3,516 | |
| 28 | MD | m | 9,843 | 288,00 | 3,418 | |
| 29 | MD | m | 10,493 | 285,00 | 3,682 | |
| | | Mean value: | **9,593** | **281,00** | **3,410** | |
| | | SD +/-: | 0,751 | 8,34 | 0,184 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 13 | HD | m | 9,672 | 277,00 | 3,492 | |
| 14 | HD | m | 10,487 | 313,00 | 3,350 | |
| 15 | HD | m | 10,587 | 300,00 | 3,529 | |
| 16 | HD | m | 9,550 | 288,00 | 3,316 | |
| 17 | HD | m | 10,488 | 281,00 | 3,732 | |
| | | Mean value: | **10,157** | **291,80** | **3,484** | |
| | | SD +/-: | 0,449 | 13,17 | 0,148 | |

| **Kidneys** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 1 | C | m | 2,059 | 277,00 | 0,743 | |
| 2 | C | m | 2,201 | 300,00 | 0,734 | |
| 3 | C | m | 1,905 | 290,00 | 0,657 | |
| 4 | C | m | 2,250 | 318,00 | 0,708 | |
| 5 | C | m | 2,189 | 321,00 | 0,682 | |
| | | Mean value: | **2,121** | **301,20** | **0,705** | |
| | | SD +/-: | 0,125 | 16,65 | 0,032 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 37 | LD | m | 2,479 | 320,00 | 0,775 | |
| 38 | LD | m | 1,888 | 283,00 | 0,667 | |
| 39 | LD | m | 1,787 | 256,00 | 0,698 | |
| 40 | LD | m | 2,248 | 281,00 | 0,800 | |
| 41 | LD | m | 2,182 | 280,00 | 0,779 | |
| | | Mean value: | **2,117** | **284,00** | **0,744** | |
| | | SD +/-: | 0,251 | 20,52 | 0,052 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 25 | MD | m | 1,923 | 270,00 | 0,712 | |
| 26 | MD | m | 2,006 | 272,00 | 0,738 | |
| 27 | MD | m | 2,133 | 290,00 | 0,736 | |
| 28 | MD | m | 2,248 | 288,00 | 0,781 | |
| 29 | MD | m | 2,369 | 285,00 | 0,831 | |
| | | Mean value: | **2,136** | **281,00** | **0,759** | |
| | | SD +/-: | 0,161 | 8,34 | 0,042 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 13 | HD | m | 2,144 | 277,00 | 0,774 | |
| 14 | HD | m | 2,331 | 313,00 | 0,745 | |
| 15 | HD | m | 2,138 | 300,00 | 0,713 | |
| 16 | HD | m | 2,131 | 288,00 | 0,740 | |
| 17 | HD | m | 2,067 | 281,00 | 0,736 | |
| | | Mean value: | **2,162** | **291,80** | **0,741** | |
| | | SD +/-: | 0,089 | 13,17 | 0,020 | |

| **Adrenals** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 1 | C | m | 0,057 | 277,00 | 0,021 | |
| 2 | C | m | 0,059 | 300,00 | 0,020 | |
| 3 | C | m | 0,047 | 290,00 | 0,016 | |
| 4 | C | m | 0,046 | 318,00 | 0,014 | |
| 5 | C | m | 0,058 | 321,00 | 0,018 | |
| | | Mean value: | **0,053** | **301,20** | **0,018** | |
| | | SD +/-: | 0,006 | 16,65 | 0,002 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 37 | LD | m | 0,075 | 320,00 | 0,023 | |
| 38 | LD | m | 0,050 | 283,00 | 0,018 | |
| 39 | LD | m | 0,042 | 256,00 | 0,016 | |
| 40 | LD | m | 0,054 | 281,00 | 0,019 | |
| 41 | LD | m | 0,056 | 280,00 | 0,020 | |
| | | Mean value: | **0,055** | **284,00** | **0,019** | |
| | | SD +/-: | 0,011 | 20,52 | 0,002 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 25 | MD | m | 0,044 | 270,00 | 0,016 | |
| 26 | MD | m | 0,043 | 272,00 | 0,016 | |
| 27 | MD | m | 0,043 | 290,00 | 0,015 | |
| 28 | MD | m | 0,050 | 288,00 | 0,017 | |
| 29 | MD | m | 0,067 | 285,00 | 0,024 | |
| | | Mean value: | **0,049** | **281,00** | **0,018** | |
| | | SD +/-: | 0,009 | 8,34 | 0,003 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 13 | HD | m | 0,056 | 277,00 | 0,020 | |
| 14 | HD | m | 0,061 | 313,00 | 0,019 | |
| 15 | HD | m | 0,047 | 300,00 | 0,016 | |
| 16 | HD | m | 0,048 | 288,00 | 0,017 | |
| 17 | HD | m | 0,058 | 281,00 | 0,021 | |
| | | Mean value: | **0,054** | **291,80** | **0,019** | |
| | | SD +/-: | 0,006 | 13,17 | 0,002 | |

| **Testes** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 1 | C | m | 3,085 | 277,00 | 1,114 | |
| 2 | C | m | 3,153 | 300,00 | 1,051 | |
| 3 | C | m | 3,231 | 290,00 | 1,114 | |
| 4 | C | m | 3,050 | 318,00 | 0,959 | |
| 5 | C | m | 3,516 | 321,00 | 1,095 | |
| | | Mean value: | **3,207** | **301,20** | **1,067** | |
| | | SD +/-: | 0,166 | 16,65 | 0,058 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 37 | LD | m | 3,193 | 320,00 | 0,998 | |
| 38 | LD | m | 3,062 | 283,00 | 1,082 | |
| 39 | LD | m | 3,100 | 256,00 | 1,211 | |
| 40 | LD | m | 3,373 | 281,00 | 1,200 | |
| 41 | LD | m | 3,434 | 280,00 | 1,226 | |
| | | Mean value: | **3,232** | **284,00** | **1,144** | |
| | | SD +/-: | 0,147 | 20,52 | 0,089 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 25 | MD | m | 3,048 | 270,00 | 1,129 | |
| 26 | MD | m | 2,950 | 272,00 | 1,085 | |
| 27 | MD | m | 3,472 | 290,00 | 1,197 | |
| 28 | MD | m | 3,384 | 288,00 | 1,175 | |
| 29 | MD | m | 3,299 | 285,00 | 1,158 | |
| | | Mean value: | **3,231** | **281,00** | **1,149** | |
| | | SD +/-: | 0,199 | 8,34 | 0,039 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 13 | HD | m | 3,396 | 277,00 | 1,226 | |
| 14 | HD | m | 3,618 | 313,00 | 1,156 | |
| 15 | HD | m | 3,228 | 300,00 | 1,076 | |
| 16 | HD | m | 2,810 | 288,00 | 0,976 | |
| 17 | HD | m | 3,244 | 281,00 | 1,154 | |
| | | Mean value: | **3,259** | **291,80** | **1,118** | |
| | | SD +/-: | 0,265 | 13,17 | 0,085 | |

| **Epididym.** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 1 | C | m | 1,023 | 277,00 | 0,369 | |
| 2 | C | m | 1,036 | 300,00 | 0,345 | |
| 3 | C | m | 1,149 | 290,00 | 0,396 | |
| 4 | C | m | 0,938 | 318,00 | 0,295 | |
| 5 | C | m | 1,153 | 321,00 | 0,359 | |
| | | Mean value: | **1,060** | **301,20** | **0,353** | |
| | | SD +/-: | 0,082 | 16,65 | 0,033 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 37 | LD | m | 1,079 | 320,00 | 0,337 | |
| 38 | LD | m | 1,140 | 283,00 | 0,403 | |
| 39 | LD | m | 0,989 | 256,00 | 0,386 | |
| 40 | LD | m | 1,156 | 281,00 | 0,411 | |
| 41 | LD | m | 1,176 | 280,00 | 0,420 | |
| | | Mean value: | **1,108** | **284,00** | **0,392** | |
| | | SD +/-: | 0,068 | 20,52 | 0,029 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 25 | MD | m | 1,024 | 270,00 | 0,379 | |
| 26 | MD | m | 1,034 | 272,00 | 0,380 | |
| 27 | MD | m | 1,161 | 290,00 | 0,400 | |
| 28 | MD | m | 1,035 | 288,00 | 0,359 | |
| 29 | MD | m | 1,046 | 285,00 | 0,367 | |
| | | Mean value: | **1,060** | **281,00** | **0,377** | |
| | | SD +/-: | 0,051 | 8,34 | 0,014 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 13 | HD | m | 0,998 | 277,00 | 0,360 | |
| 14 | HD | m | 1,081 | 313,00 | 0,345 | |
| 15 | HD | m | 1,087 | 300,00 | 0,362 | |
| 16 | HD | m | 0,987 | 288,00 | 0,343 | |
| 17 | HD | m | 0,994 | 281,00 | 0,354 | |
| | | Mean value: | **1,029** | **291,80** | **0,353** | |
| | | SD +/-: | 0,045 | 13,17 | 0,008 | |

| **Thymus** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 1 | C | m | 0,523 | 277,00 | 0,189 | |
| 2 | C | m | 0,545 | 300,00 | 0,182 | |
| 3 | C | m | 0,465 | 290,00 | 0,160 | |
| 4 | C | m | 0,589 | 318,00 | 0,185 | |
| 5 | C | m | 0,391 | 321,00 | 0,122 | |
| | | Mean value: | **0,503** | **301,20** | **0,168** | |
| | | SD +/-: | 0,069 | 16,65 | 0,025 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 37 | LD | m | 0,526 | 320,00 | 0,164 | |
| 38 | LD | m | 0,339 | 283,00 | 0,120 | |
| 39 | LD | m | 0,458 | 256,00 | 0,179 | |
| 40 | LD | m | 0,492 | 281,00 | 0,175 | |
| 41 | LD | m | 0,524 | 280,00 | 0,187 | |
| | | Mean value: | **0,468** | **284,00** | **0,165** | |
| | | SD +/-: | 0,069 | 20,52 | 0,024 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 25 | MD | m | 0,410 | 270,00 | 0,152 | |
| 26 | MD | m | 0,488 | 272,00 | 0,179 | |
| 27 | MD | m | 0,459 | 290,00 | 0,158 | |
| 28 | MD | m | 0,517 | 288,00 | 0,180 | |
| 29 | MD | m | 0,335 | 285,00 | 0,118 | |
| | | Mean value: | **0,442** | **281,00** | **0,157** | |
| | | SD +/-: | 0,064 | 8,34 | 0,023 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 13 | HD | m | 0,519 | 277,00 | 0,187 | |
| 14 | HD | m | 0,443 | 313,00 | 0,142 | |
| 15 | HD | m | 0,397 | 300,00 | 0,132 | |
| 16 | HD | m | 0,526 | 288,00 | 0,183 | |
| 17 | HD | m | 0,420 | 281,00 | 0,149 | |
| | | Mean value: | **0,461** | **291,80** | **0,159** | |
| | | SD +/-: | 0,052 | 13,17 | 0,022 | |

| **Spleen** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 1 | C | m | 0,539 | 277,00 | 0,195 | |
| 2 | C | m | 0,690 | 300,00 | 0,230 | |
| 3 | C | m | 0,659 | 290,00 | 0,227 | |
| 4 | C | m | 0,775 | 318,00 | 0,244 | |
| 5 | C | m | 0,649 | 321,00 | 0,202 | |
| | | Mean value: | **0,662** | **301,20** | **0,220** | |
| | | SD +/-: | 0,076 | 16,65 | 0,018 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 37 | LD | m | 0,750 | 320,00 | 0,234 | |
| 38 | LD | m | 0,531 | 283,00 | 0,188 | |
| 39 | LD | m | 0,558 | 256,00 | 0,218 | |
| 40 | LD | m | 0,691 | 281,00 | 0,246 | |
| 41 | LD | m | 0,634 | 280,00 | 0,226 | |
| | | Mean value: | **0,633** | **284,00** | **0,222** | |
| | | SD +/-: | 0,081 | 20,52 | 0,020 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 25 | MD | m | 0,511 | 270,00 | 0,189 | |
| 26 | MD | m | 0,503 | 272,00 | 0,185 | |
| 27 | MD | m | 0,553 | 290,00 | 0,191 | |
| 28 | MD | m | 0,572 | 288,00 | 0,199 | |
| 29 | MD | m | 0,607 | 285,00 | 0,213 | |
| | | Mean value: | **0,549** | **281,00** | **0,195** | |
| | | SD +/-: | 0,039 | 8,34 | 0,010 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 13 | HD | m | 0,604 | 277,00 | 0,218 | |
| 14 | HD | m | 0,707 | 313,00 | 0,226 | |
| 15 | HD | m | 0,593 | 300,00 | 0,198 | |
| 16 | HD | m | 0,630 | 288,00 | 0,219 | |
| 17 | HD | m | 0,625 | 281,00 | 0,222 | |
| | | Mean value: | **0,632** | **291,80** | **0,217** | |
| | | SD +/-: | 0,040 | 13,17 | 0,010 | |

| **Heart** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 1 | C | m | 0,864 | 277,00 | 0,312 | |
| 2 | C | m | 0,856 | 300,00 | 0,285 | |
| 3 | C | m | 0,821 | 290,00 | 0,283 | |
| 4 | C | m | 1,083 | 318,00 | 0,341 | |
| 5 | C | m | 0,967 | 321,00 | 0,301 | |
| | | Mean value: | **0,918** | **301,20** | **0,304** | |
| | | SD +/-: | 0,096 | 16,65 | 0,021 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 37 | LD | m | 1,031 | 320,00 | 0,322 | |
| 38 | LD | m | 0,843 | 283,00 | 0,298 | |
| 39 | LD | m | 0,763 | 256,00 | 0,298 | |
| 40 | LD | m | 0,863 | 281,00 | 0,307 | |
| 41 | LD | m | 0,863 | 280,00 | 0,308 | |
| | | Mean value: | **0,873** | **284,00** | **0,307** | |
| | | SD +/-: | 0,087 | 20,52 | 0,009 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 25 | MD | m | 0,778 | 270,00 | 0,288 | |
| 26 | MD | m | 0,804 | 272,00 | 0,296 | |
| 27 | MD | m | 0,816 | 290,00 | 0,281 | |
| 28 | MD | m | 0,822 | 288,00 | 0,285 | |
| 29 | MD | m | 0,890 | 285,00 | 0,312 | |
| | | Mean value: | **0,822** | **281,00** | **0,293** | |
| | | SD +/-: | 0,037 | 8,34 | 0,011 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 13 | HD | m | 0,813 | 277,00 | 0,294 | |
| 14 | HD | m | 0,918 | 313,00 | 0,293 | |
| 15 | HD | m | 0,927 | 300,00 | 0,309 | |
| 16 | HD | m | 0,966 | 288,00 | 0,335 | |
| 17 | HD | m | 0,783 | 281,00 | 0,279 | |
| | | Mean value: | **0,881** | **291,80** | **0,302** | |
| | | SD +/-: | 0,071 | 13,17 | 0,019 | |

| **Brain** | Organ Weight in g | | 001699 | | | |
|---|---|---|---|---|---|---|
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 1 | C | m | 1,891 | 277,00 | 0,683 | |
| 2 | C | m | 1,774 | 300,00 | 0,591 | |
| 3 | C | m | 1,783 | 290,00 | 0,615 | |
| 4 | C | m | 1,916 | 318,00 | 0,603 | |
| 5 | C | m | 1,797 | 321,00 | 0,560 | |
| | | Mean value: | **1,832** | **301,20** | **0,610** | |
| | | SD +/-: | 0,059 | 16,65 | 0,041 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 37 | LD | m | 1,937 | 320,00 | 0,605 | |
| 38 | LD | m | 1,725 | 283,00 | 0,610 | |
| 39 | LD | m | 1,789 | 256,00 | 0,699 | |
| 40 | LD | m | 1,727 | 281,00 | 0,615 | |
| 41 | LD | m | 1,885 | 280,00 | 0,673 | |
| | | Mean value: | **1,813** | **284,00** | **0,640** | |
| | | SD +/-: | 0,085 | 20,52 | 0,038 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 25 | MD | m | 1,832 | 270,00 | 0,679 | |
| 26 | MD | m | 1,745 | 272,00 | 0,642 | |
| 27 | MD | m | 1,770 | 290,00 | 0,610 | |
| 28 | MD | m | 1,864 | 288,00 | 0,647 | |
| 29 | MD | m | 1,852 | 285,00 | 0,650 | |
| | | Mean value: | **1,813** | **281,00** | **0,645** | |
| | | SD +/-: | 0,047 | 8,34 | 0,022 | |
| | | | | | | |
| | | | | Body weight | rel. Organ weight | |
| Animal | Group | Sex | Day 28 | Day 28 | in % | |
| | | | | | | |
| 13 | HD | m | 1,898 | 277,00 | 0,685 | |
| 14 | HD | m | 1,880 | 313,00 | 0,601 | |
| 15 | HD | m | 1,777 | 300,00 | 0,592 | |
| 16 | HD | m | 1,728 | 288,00 | 0,600 | |
| 17 | HD | m | 1,797 | 281,00 | 0,640 | |
| | | Mean value: | **1,816** | **291,80** | **0,624** | |
| | | SD +/-: | 0,064 | 13,17 | 0,035 | |

# Pathology

## *Female Control*

| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
|---|---|---|---|
| | | | |
| Sex: f | Animal No.: 7 | Group: C | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: f | Animal No.: 8 | Group: C | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |

| | | | |
|---|---|---|---|
| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
| | | | |
| Sex: f | Animal No.: 9 | Group: C | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: f | Animal No.: 10 | Group: C | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: f | Animal No.: 11 | Group: C | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |

*Female Low Dose*

| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
|---|---|---|---|
| | | | |
| Sex: f | Animal No.: 43 | Group: LD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: f | Animal No.: 44 | Group: LD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |

| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
|---|---|---|---|
| | | | |
| Sex: f | Animal No.: 45 | Group: LD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: f | Animal No.: 46 | Group: LD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: f | Animal No.: 47 | Group: LD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |

*Female Medium Dose*

| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
|---|---|---|---|
| | | | |
| Sex: f | Animal No.: 31 | Group: MD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: f | Animal No.: 32 | Group: MD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |

| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
|---|---|---|---|
| | | | |
| Sex: f | Animal No.: 33 | Group: MD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: f | Animal No.: 34 | Group: MD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: f | Animal No.: 35 | Group: MD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |

*Female High Dose*

| | | | |
|---|---|---|---|
| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
| | | | |
| Sex: f | Animal No.: 19 | Group: HD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: f | Animal No.: 20 | Group: HD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | abscess-like structure |
| Acc. sex org. | nsf | | under the left axilla |

| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
|---|---|---|---|
| | | | |
| Sex: f | Animal No.: 21 | Group: HD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: f | Animal No.: 22 | Group: HD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: f | Animal No.: 23 | Group: HD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |

*Male Control*

| | | | |
|---|---|---|---|
| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
| | | | |
| Sex: m | Animal No.: 1 | Group: C | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: m | Animal No.: 2 | Group: C | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |

| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
|---|---|---|---|
| | | | |
| Sex: m | Animal No.: 3 | Group: C | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: m | Animal No.: 4 | Group: C | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: m | Animal No.: 5 | Group: C | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |

*Male Low Dose*

| | | | |
|---|---|---|---|
| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
| | | | |
| Sex: m | Animal No.: 37 | Group: LD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: m | Animal No.: 38 | Group: LD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |

| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
|---|---|---|---|
| | | | |
| Sex: m | Animal No.: 39 | Group: LD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: m | Animal No.: 40 | Group: LD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: m | Animal No.: 41 | Group: LD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |

*Male Medium Dose*

| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
|---|---|---|---|
| | | | |
| Sex: m | Animal No.: 25 | Group: MD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: m | Animal No.: 26 | Group: MD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |

| | | | |
|---|---|---|---|
| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
| | | | |
| Sex: m | Animal No.: 27 | Group: MD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: m | Animal No.: 28 | Group: MD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: m | Animal No.: 29 | Group: MD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |

## *Male High Dose*

| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
|---|---|---|---|
| | | | |
| Sex: m | Animal No.: 13 | Group: HD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: m | Animal No.: 14 | Group: HD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |

| | | | |
|---|---|---|---|
| Necropsy protocol Project ID: 001699 | | | nsf: no special findings |
| | | | |
| Sex: m | Animal No.: 15 | Group: HD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: m | Animal No.: 16 | Group: HD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |
| | | | |
| | | | |
| Sex: m | Animal No.: 17 | Group: HD | |
| | | | |
| Organ | Findings | Organ | Findings |
| | | | |
| Surface | nsf | Heart | nsf |
| Orifices | nsf | Lung, Trachea | nsf |
| Posture | nsf | Thymus | nsf |
| Stomach | nsf | Thyroid | nsf |
| Intestines | nsf | Brain | nsf |
| Liver | nsf | Spinal Cord | nsf |
| Spleen | nsf | Lymph Nodes | nsf |
| Kidneys | nsf | Perip. Nerve | nsf |
| Adrenals | nsf | Bonne marrow | nsf |
| Urinary Bladd. | nsf | Saliv. Glands | nsf |
| Gonads | nsf | Gross lesion | nsf |
| Acc. sex org. | nsf | | |

# Behaviour/Functional Observation

*Rears Low Dose*

| | Rears Supp./n.supp. | | | | Project ID | 001699 |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| Sex: m | | | | | | |
| supported rears | | | | nonsupported rears | | |
| | | | | | | |
| Animal No. | before first | week 4 | | Animal No.: | before first | week 4 |
| | dosing | | | | dosing | |
| LD | | | | LD | | |
| 37 | 6 | 2 | | 37 | 0 | 2 |
| 38 | 8 | 4 | | 38 | 0 | 0 |
| 39 | 9 | 5 | | 39 | 0 | 2 |
| 40 | 6 | 2 | | 40 | 0 | 1 |
| 41 | 8 | 9 | | 41 | 1 | 3 |
| mean | 7,4 | 4,4 | | mean | 0,2 | 1,6 |
| Contr | | | | Contr | | |
| 1 | 7 | 1 | | 1 | 2 | 1 |
| 2 | 3 | 6 | | 2 | 0 | 0 |
| 3 | 4 | 4 | | 3 | 0 | 0 |
| 4 | 6 | 3 | | 4 | 0 | 0 |
| 5 | 8 | 3 | | 5 | 1 | 0 |
| mean | 5,6 | 3,4 | | mean | 0,6 | 0,2 |
| | | | | | | |
| | | | | | | |
| Sex: f | | | | | | |
| supported rears | | | | nonsupported rears | | |
| | | | | | | |
| Animal No. | before first | week 4 | | Animal No.: | before first | week 4 |
| | dosing | | | | dosing | |
| LD | | | | LD | | |
| 43 | 3 | 7 | | 43 | 2 | 0 |
| 44 | 6 | 8 | | 44 | 0 | 0 |
| 45 | 7 | 4 | | 45 | 0 | 2 |
| 46 | 6 | 5 | | 46 | 1 | 0 |
| 47 | 10 | 7 | | 47 | 2 | 2 |
| mean | 6,4 | 6,2 | | mean | 1,0 | 0,8 |
| Contr | | | | Contr | | |
| 7 | 8 | 1 | | 7 | 0 | 0 |
| 8 | 5 | 7 | | 8 | 1 | 1 |
| 9 | 7 | 7 | | 9 | 1 | 1 |
| 10 | 4 | 7 | | 10 | 0 | 1 |
| 11 | 6 | 3 | | 11 | 0 | 0 |
| mean | 6 | 5 | | mean | 0,4 | 0,6 |

## Rears Medium Dose

| | Rears Supp./n.supp. | | | | Project ID | 001699 |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| Sex: m | | | | | | |
| supported rears | | | | nonsupported rears | | |
| | | | | | | |
| Animal No. | before first | week 4 | | Animal No.: | before first | week 4 |
| | dosing | | | | dosing | |
| MD | | | | MD | | |
| 25 | 5 | 5 | | 25 | 1 | 1 |
| 26 | 3 | 7 | | 26 | 0 | 1 |
| 27 | 3 | 6 | | 27 | 0 | 3 |
| 28 | 7 | 5 | | 28 | 1 | 3 |
| 29 | 3 | 9 | | 29 | 0 | 3 |
| mean | 4,2 | 6,4 | | mean | 0,4 | 2,2 |
| Contr | | | | Contr | | |
| 1 | 7 | 1 | | 1 | 2 | 1 |
| 2 | 3 | 6 | | 2 | 0 | 0 |
| 3 | 4 | 4 | | 3 | 0 | 0 |
| 4 | 6 | 3 | | 4 | 0 | 0 |
| 5 | 8 | 3 | | 5 | 1 | 0 |
| mean | 5,6 | 3,4 | | mean | 0,6 | 0,2 |
| | | | | | | |
| | | | | | | |
| Sex: f | | | | | | |
| supported rears | | | | nonsupported rears | | |
| | | | | | | |
| Animal No. | before first | week 4 | | Animal No.: | before first | week 4 |
| | dosing | | | | dosing | |
| MD | | | | MD | | |
| 31 | 6 | 5 | | 31 | 0 | 0 |
| 32 | 4 | 6 | | 32 | 0 | 1 |
| 33 | 3 | 9 | | 33 | 0 | 0 |
| 34 | 8 | 7 | | 34 | 0 | 0 |
| 35 | 7 | 1 | | 35 | 0 | 0 |
| mean | 5,6 | 5,6 | | mean | 0,0 | 0,2 |
| Contr | | | | Contr | | |
| 7 | 8 | 1 | | 7 | 0 | 0 |
| 8 | 5 | 7 | | 8 | 1 | 1 |
| 9 | 7 | 7 | | 9 | 1 | 1 |
| 10 | 4 | 7 | | 10 | 0 | 1 |
| 11 | 6 | 3 | | 11 | 0 | 0 |
| mean | 6 | 5 | | mean | 0,4 | 0,6 |

## *Rears High Dose*

| | Rears Supp./n.supp. | | | | Project ID | 001699 |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| Sex: m | | | | | | |
| supported rears | | | | nonsupported rears | | |
| | | | | | | |
| Animal No. | before first | week 4 | | Animal No.: | before first | week 4 |
| | dosing | | | | dosing | |
| HD | | | | HD | | |
| 13 | 9 | 0 | | 13 | 0 | 0 |
| 14 | 6 | 5 | | 14 | 0 | 1 |
| 15 | 9 | 4 | | 15 | 0 | 0 |
| 16 | 6 | 1 | | 16 | 0 | 1 |
| 17 | 12 | 14 | | 17 | 0 | 1 |
| mean | 8,4 | 4,8 | | mean | 0,0 | 0,6 |
| Contr | | | | Contr | | |
| 1 | 7 | 1 | | 1 | 2 | 1 |
| 2 | 3 | 6 | | 2 | 0 | 0 |
| 3 | 4 | 4 | | 3 | 0 | 0 |
| 4 | 6 | 3 | | 4 | 0 | 0 |
| 5 | 8 | 3 | | 5 | 1 | 0 |
| mean | 5,6 | 3,4 | | mean | 0,6 | 0,2 |
| | | | | | | |
| | | | | | | |
| Sex: f | | | | | | |
| supported rears | | | | nonsupported rears | | |
| | | | | | | |
| Animal No. | before first | week 4 | | Animal No.: | before first | week 4 |
| | dosing | | | | dosing | |
| HD | | | | HD | | |
| 19 | 9 | 0 | | 19 | 0 | 0 |
| 20 | 8 | 8 | | 20 | 2 | 0 |
| 21 | 8 | 3 | | 21 | 0 | 0 |
| 22 | 7 | 7 | | 22 | 0 | 1 |
| 23 | 4 | 4 | | 23 | 0 | 0 |
| mean | 7,2 | 4,4 | | mean | 0,4 | 0,2 |
| Contr | | | | Contr | | |
| 7 | 8 | 1 | | 7 | 0 | 0 |
| 8 | 5 | 7 | | 8 | 1 | 1 |
| 9 | 7 | 7 | | 9 | 1 | 1 |
| 10 | 4 | 7 | | 10 | 0 | 1 |
| 11 | 6 | 3 | | 11 | 0 | 0 |
| mean | 6 | 5 | | mean | 0,4 | 0,6 |

## *Urination/Defecation Low Dose*

| | Urination/Defecation | | | Project ID | 001699 | |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | Sex: f | | | | | |
| | Urination | | | Defecation | | |
| | week | | | | week | |
| Animal No.: | before first | week 4 | | Animal No.: | before first | week 4 |
| LD | dosing | | | LD | dosing | |
| | | | | | | |
| 43 | 1 | 0 | | 43 | 2 | 0 |
| 44 | 1 | 0 | | 44 | 0 | 0 |
| 45 | 1 | 0 | | 45 | 2 | 0 |
| 46 | 1 | 0 | | 46 | 0 | 0 |
| 47 | 0 | 0 | | 47 | 0 | 0 |
| | | | | | | |
| Control | | | | Control | | |
| 7 | 0 | 0 | | 7 | 0 | 0 |
| 8 | 1 | 0 | | 8 | 0 | 0 |
| 9 | 1 | 0 | | 9 | 0 | 0 |
| 10 | 0 | 0 | | 10 | 0 | 0 |
| 11 | 1 | 0 | | 11 | 0 | 0 |
| | | | | | | |
| | | | | | | |
| | Sex: m | | | | | |
| | Urination | | | Defecation | | |
| | week | | | | week | |
| Animal No.: | before first | week 4 | | Animal No.: | before first | week 4 |
| LD | dosing | | | LD | dosing | |
| | | | | | | |
| 37 | 0 | 0 | | 37 | 0 | 0 |
| 38 | 1 | 0 | | 38 | 0 | 0 |
| 39 | 0 | 0 | | 39 | 0 | 0 |
| 40 | 0 | 0 | | 40 | 0 | 0 |
| 41 | 0 | 0 | | 41 | 0 | 0 |
| | | | | | | |
| Control | | | | Control | | |
| 1 | 0 | 0 | | 1 | 3 | 0 |
| 2 | 1 | 0 | | 2 | 4 | 0 |
| 3 | 1 | 0 | | 3 | 1 | 0 |
| 4 | 0 | 0 | | 4 | 3 | 0 |
| 5 | 1 | 0 | | 5 | 3 | 0 |

## *Urination/Defecation Medium Dose*

| | Urination/Defecation | | | Project ID | 001699 | |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | Sex: f | | | | | |
| | Urination | | | Defecation | | |
| | week | | | | week | |
| Animal No.: | before first | week 4 | | Animal No.: | before first | week 4 |
| MD | dosing | | | MD | dosing | |
| | | | | | | |
| 31 | 1 | 0 | | 31 | 0 | 0 |
| 32 | 1 | 0 | | 32 | 2 | 0 |
| 33 | 0 | 0 | | 33 | 0 | 0 |
| 34 | 0 | 0 | | 34 | 1 | 0 |
| 35 | 1 | 0 | | 35 | 0 | 0 |
| | | | | | | |
| Control | | | | Control | | |
| 7 | 0 | 0 | | 7 | 0 | 0 |
| 8 | 1 | 0 | | 8 | 0 | 0 |
| 9 | 1 | 0 | | 9 | 0 | 0 |
| 10 | 0 | 0 | | 10 | 0 | 0 |
| 11 | 1 | 0 | | 11 | 0 | 0 |
| | | | | | | |
| | | | | | | |
| | Sex: m | | | | | |
| | Urination | | | Defecation | | |
| | week | | | | week | |
| Animal No.: | before first | week 4 | | Animal No.: | before first | week 4 |
| MD | dosing | | | MD | dosing | |
| | | | | | | |
| 25 | 1 | 0 | | 25 | 0 | 0 |
| 26 | 0 | 0 | | 26 | 0 | 0 |
| 27 | 0 | 0 | | 27 | 0 | 0 |
| 28 | 0 | 0 | | 28 | 0 | 0 |
| 29 | 0 | 0 | | 29 | 0 | 0 |
| | | | | | | |
| Control | | | | Control | | |
| 1 | 0 | 0 | | 1 | 3 | 0 |
| 2 | 1 | 0 | | 2 | 4 | 0 |
| 3 | 1 | 0 | | 3 | 1 | 0 |
| 4 | 0 | 0 | | 4 | 3 | 0 |
| 5 | 1 | 0 | | 5 | 3 | 0 |

## *Urination/Defecation High Dose*

| | Urination/Defecation | | | Project ID | 001699 | |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | Sex: f | | | | | |
| | Urination | | | Defecation | | |
| | week | | | | week | |
| Animal No.: | before first | week 4 | | Animal No.: | before first | week 4 |
| HD | dosing | | | HD | dosing | |
| | | | | | | |
| 19 | 0 | 0 | | 19 | 0 | 0 |
| 20 | 0 | 0 | | 20 | 0 | 0 |
| 21 | 0 | 0 | | 21 | 1 | 0 |
| 22 | 1 | 0 | | 22 | 0 | 0 |
| 23 | 0 | 0 | | 23 | 1 | 0 |
| | | | | | | |
| Control | | | | Control | | |
| 7 | 0 | 0 | | 7 | 0 | 0 |
| 8 | 1 | 0 | | 8 | 0 | 0 |
| 9 | 1 | 0 | | 9 | 0 | 0 |
| 10 | 0 | 0 | | 10 | 0 | 0 |
| 11 | 1 | 0 | | 11 | 0 | 0 |
| | | | | | | |
| | | | | | | |
| | Sex: m | | | | | |
| | Urination | | | Defecation | | |
| | week | | | | week | |
| Animal No.: | before first | week 4 | | Animal No.: | before first | week 4 |
| HD | dosing | | | HD | dosing | |
| | | | | | | |
| 13 | 0 | 1 | | 13 | 1 | 0 |
| 14 | 0 | 0 | | 14 | 0 | 0 |
| 15 | 0 | 0 | | 15 | 0 | 0 |
| 16 | 0 | 1 | | 16 | 2 | 0 |
| 17 | 0 | 0 | | 17 | 2 | 0 |
| | | | | | | |
| Control | | | | Control | | |
| 1 | 0 | 0 | | 1 | 3 | 0 |
| 2 | 1 | 0 | | 2 | 4 | 0 |
| 3 | 1 | 0 | | 3 | 1 | 0 |
| 4 | 0 | 0 | | 4 | 3 | 0 |
| 5 | 1 | 0 | | 5 | 3 | 0 |

## *Body Temperature*

| | Body Temperature | | | Project ID | 001699 | |
|---|---|---|---|---|---|---|
| | °Celsius | | | | | |
| | | | | | | |
| | Sex: f | | | | Sex: m | |
| | week | week 4 | | | week | week 4 |
| Animal No.: | before first | | | Animal No.: | before first | |
| | dosing | | | | dosing | |
| Control | | | | Control | | |
| 7 | 38,1 | 38,1 | | 1 | 38,1 | 37,9 |
| 8 | 38,2 | 38,0 | | 2 | 38,6 | 38,4 |
| 9 | 38,4 | 38,6 | | 3 | 38,7 | 38 |
| 10 | 38,2 | 38,1 | | 4 | 38,3 | 38,2 |
| 11 | 37,9 | 38,5 | | 5 | 38,5 | 38,5 |
| LD | | | | LD | | |
| 43 | 38,2 | 37,8 | | 37 | 38,2 | 37,5 |
| 44 | 38,1 | 39,3 | | 38 | 38,1 | 38 |
| 45 | 38,1 | 38,6 | | 39 | 38,2 | 38,3 |
| 46 | 38,1 | 38,1 | | 40 | 38,2 | 37,6 |
| 47 | 38,2 | 37,8 | | 41 | 38,1 | 37,9 |
| MD | | | | MD | | |
| 31 | 38,2 | 38,2 | | 25 | 38,1 | 37,6 |
| 32 | 37,9 | 37,8 | | 26 | 38,2 | 37,7 |
| 33 | 38,3 | 38,8 | | 27 | 37,9 | 38,2 |
| 34 | 38,1 | 37,8 | | 28 | 38,1 | 37,8 |
| 35 | 38,1 | 37,7 | | 29 | 38,3 | 38 |
| HD | | | | HD | | |
| 19 | 38,6 | 37,2 | | 13 | 38,6 | 37,6 |
| 20 | 38,7 | 37,4 | | 14 | 38,7 | 37,9 |
| 21 | 38,5 | 37,8 | | 15 | 37,8 | 37,8 |
| 22 | 38,1 | 38,1 | | 16 | 37,1 | 37,6 |
| 23 | 37,7 | 37,9 | | 17 | 38 | 38 |

# Histopathological Report

27 pages

CONFIDENTIAL

# 28 days toxicity study with BS 1701

# PROJECT ID: 001699

## FINAL HISTOPATHOLOGY REPORT

Prepared By

J PETER FINN BVSc., MSc., FRCPath., MRCVS

(27 Pages)

FROM:
Precision Histology International Ltd.
One Eyed Lane
Weybread
Diss
Norfolk IP21 5TT
United Kingdom

TO:
BSL BIOSERVICE
Scientific Laboratories GmbH
Behringstrasse 6
D-82152 Planegg
Munich
Germany

28 days toxicity study with BS 1701
001699

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## RESPONSIBLE PERSONNEL

The following members of staff worked on the above study:

Veterinary Histopathologist
J Peter Finn

Histologists
Martyn Carpenter
Rosie Lightfoot
Cathy Peploe
Deborah Spiers
Andrew Whyke

Quality Assurance
Lorraine Finn
Janice Barber

Quality Control Co-ordinator
Lorraine Edwards

Administration
Debbie Riches

Secretariat
Gill Green
Elaine Brown

28 days toxicity study with BS 1701
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## PATHOLOGIST'S SIGNATURE SHEET

I, the undersigned, hereby declare that the following histopathology report for the above study constitutes a true and faithful account of the results obtained in the slide preparation and slide assessment. The procedures were conducted in accordance with current internationally recognised Good Laboratory Practice Regulations.

J. Peter Finn, BVSc., MSc., FRCPath., MRCVS, Study Director

.....

Date.....Feb 2 2007

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## QUALITY ASSURANCE STATEMENT

I hereby confirm on behalf of the Quality Assurance Unit that the histology and histopathology work conducted at Precision Histology International Ltd., in respect of this study was, as far as can be reasonably established, in compliance with the United Kingdom Statutory Instrument No. 1999/3106, the Good Laboratory Practice Regulations 1999 (the GLP Regulations).

Dates of inspections:

| | |
|---|---|
| 19.12.00 | In House Procedures |
| 3.1.01 \| 9.1.01 | Histology |
| | " |
| 10.1.01 | Slide Evaluation |
| | " " |

The dates on which the study findings were reported to Management were as follows:

| | |
|---|---|
| 19.12.00 \| 22.1.01 \| 2.2.01 | In House Procedures |
| 3.1.01 \| 9.1.01 \| 22.1.01 | Histology |
| 2.2.01 | " |
| | " |
| 10.1.01 \| 22.1.01 \| 2.2.01 | Slide Evaluation |
| | " |

Lorraine Ann Finn
Head, Quality Assurance
Date 2 february 2001

Janice Barber
Deputy, Quality Assurance
Date 2 february 2001

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**Materials and Methods**

Formalin fixed tissue samples and appropriate paperwork were received from BSL BIOSERVICE Scientific Laboratories GmbH, Behringstrasse 6, D-82152 Planegg, Munich, Germany at Precision Histology International Ltd., One Eyed Lane, Weybread, Diss, Norfolk, IP21 5TT, United Kingdom on 21 December 2000. The tissues were from a 28 days toxicity study with BS 1701. The study comprised of four groups including a control group as shown below. There were 5 males and 5 females per project group.

| Dose | Animal number | Sex |
|---|---|---|
| Control | 1-5<br>7-11 | Male<br>Female |
| Low Dose<br>(150mg/kg bw) | 37-41<br>43-47 | Male<br>Female |
| Medium Dose<br>(500mg/kg bw) | 25-29<br>31-35 | Male<br>Female |
| High Dose<br>(1000mg/kg bw) | 13-17<br>19-23 | Male<br>Female |

The histology technique was performed at the laboratory of Precision Histology International Ltd. and the slides were evaluated histopathologically by J. Peter Finn. The technique and evaluation were performed initially on the tissues overleaf from all animals in the control and high dose groups. Subsequently, following assessment of the control and high dose groups, it was agreed between J. Peter Finn and the study monitor for BSL Bioservice Scientific Laboratories GmbH to process and evaluate the stomach sections from the low and medium dose groups.

The animal details (supplied by BSL BIOSERVICE Scientific Laboratories GmbH) were entered directly into LABCAT for histopathology computerized system version HP4.33.

Quality Assurance inspections took place during histological slide preparation, slide evaluation and report preparation. The procedures were performed in compliance with current Precision Histotology International Ltd. Standard Operating Procedures.

Adrenals
Brain (Cerebrum, Cerebellum, Mid Brain)
Caecum
Colon
Duodenum
Epididymides
Heart

Ileum
Jejunum
Kidneys
Liver
Lung
Lymph Nodes (Peripheral, Mandibular, Mesenteric)
Ovaries
Peripheral Nerve
Prostate
Rectum
Seminal Vesicles
Spinal Cord
Spleen
Sternum/Bone Marrow
Stomach
Testes
Thymus
Thyroids
Trachea
Urinary Bladder
Uterus
Abnormalities

**Tissue Preparation**

After dehydration in alcohol and embedding in paraffin wax, sections were cut at approximately 5 micron thickness and stained with Haematoxylin and Eosin.

The bone sections were decalcified in 10% formic acid, sectioned and stained with Haematoxylin and Eosin.

**Microscopy**

Slide assessment was performed by J. Peter Finn on the aforementioned tissues and the report was prepared utilising the LABCAT for histopathology computer version HP4.33.

**Archives**

After the final report has been despatched to BSL BIOSERVICE Scientific Laboratories GmbH, Behringstrasse 6, D-82152 Planegg, Munich, Germany the wet tissue, blocks, slides and appropriate paperwork will be returned to the sponsor.

2 February 2001

28 days toxicity study with BS 1701
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**Histopathology Assessment**

**Results**

There are treatment and dosage related changes in the keratinized gastric mucosa in male rats, change being present in all dosage groups – 150, 500 & 1000 mg/kg. In female rats the changes were detected at a lesser frequency and with only a 'minimal' degree, but still within all three dosage levels. The associated changes were of acanthosis and hyperkeratosis.

**Commentary**

The changes in the rats keratinized gastric mucosa were minimal or mild. This change is commonly seen in toxicology studies and is commonly associated with irritation, often with a pH basis. Humans have no keratinized stomach; the oesophagus has a homologous epithelium but is not an acid environment. The two findings are deemed irrelevant in a toxicology trial of a compound potential human exposure.

Other changes observed were those commonly associated with studies in young laboratory rodents and were not treatment related.

**Conclusion**

No histopathological no observable effect level could be detected. As the findings are deemed irrelevant and occur at a dosage of 150 mg/kg only in 2 of 5 males and 1 of 5 females at a minimal degree, a no observed adverse level of 150 mg/kg can be assumed.

J. Peter Finn
February 2 2001

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# REPORT CODE TABLE

| | |
|---|---|
| N | Tissues within normal histological limits |
| A | Autolytic tissue |
| U | Tissues unsuitable for complete evaluation |
| S | Tissues not applicable to animal |
| * | Tissues unavailable for evaluation |
| 1 | minimal |
| 2 | mild |
| 3 | moderate |
| 4 | marked |
| ) | focal |
| ] | locally extensive |
| > | multifocal |
| P | Present |
| B | Neoplasm, Benign |
| M | Neoplasm, Malignant without Metastasis |
| C | Neoplasm, Malignant with Metastasis |
| + | Metastatic Site (+) |
| - | No data entered |
| NAD | No abnormality detected |

28 days toxicity study with BS 1701

## PROJECT SUMMARY

STUDY ID : 001699
FATE: Terminal sacrifice
DAYS ON TEST: ALL

STUDY NUMBER: 001699

SEX: MALE

INCIDENCE OF NON-NEOPLASTIC MICROSCOPIC FINDINGS

| GROUP: | | 1M (1) | 2M (2) | 3M (3) | 4M (4) |
|---|---|---|---|---|---|
| NUMBER OF ANIMALS: | | 5 | 5 | 5 | 5 |
| | | # | # | # | # |
| Adrenal x 2 | # EX | 5 | 0 | 0 | 5 |
| Zona fasciculata vacuolation | | 1 | 0 | 0 | 0 |
| Caecum | # EX | 5 | 0 | 0 | 5 |
| Cerebellum | # EX | 5 | 0 | 0 | 5 |
| Cerebrum | # EX | 5 | 0 | 0 | 5 |
| Colon | # EX | 5 | 0 | 0 | 5 |
| Duodenum | # EX | 5 | 0 | 0 | 5 |
| Epididymis x 2 | # EX | 5 | 0 | 0 | 5 |
| Heart | # EX | 5 | 0 | 0 | 5 |
| Ileum | # EX | 5 | 0 | 0 | 5 |
| Jejunum | # EX | 5 | 0 | 0 | 5 |
| Kidney x 2 | # EX | 5 | 0 | 0 | 5 |
| Basophilic tubules | | 0 | 0 | 0 | 2 |
| Unilateral hydronephrosis | | 0 | 0 | 0 | 2 |
| Bilateral hydronephrosis | | 1 | 0 | 0 | 0 |
| Pelvic tubule dilatation | | 0 | 0 | 0 | 1 |
| Liver x 2 | # EX | 5 | 0 | 0 | 5 |
| Focal lymphocytosis | | 1 | 0 | 0 | 1 |
| Lung x 2 | # EX | 5 | 0 | 0 | 5 |
| Mandibular Lymph Node | # EX | 5 | 0 | 0 | 5 |
| Mesenteric Lymph Node | # EX | 5 | 0 | 0 | 5 |
| Mid Brain | # EX | 5 | 0 | 0 | 5 |

(1) - Control
(2) - 150 mg/kg bw
(3) - 500 mg/kg bw
(4) - 1000 mg/kg bw

28 days toxicity study with BS 1701

## PROJECT SUMMARY

STUDY ID : 001699
FATE: Terminal sacrifice
DAYS ON TEST: ALL

STUDY NUMBER: 001699

SEX: MALE

INCIDENCE OF NON-NEOPLASTIC MICROSCOPIC FINDINGS

| GROUP: | | 1M (1) | 2M (2) | 3M (3) | 4M (4) |
|---|---|---|---|---|---|
| NUMBER OF ANIMALS: | | 5 | 5 | 5 | 5 |
| | | # | # | # | # |
| Peripheral Lymph Node | # EX | 5 | 0 | 0 | 5 |
| Peripheral Nerve | # EX | 5 | 0 | 0 | 5 |
| Prostate | # EX | 5 | 0 | 0 | 5 |
| Rectum | # EX | 5 | 0 | 0 | 5 |
| Seminal Vesicle x 2 | # EX | 5 | 0 | 0 | 5 |
| Spinal Cord | # EX | 5 | 0 | 0 | 5 |
| Spleen | # EX | 5 | 0 | 0 | 5 |
| Sternum/Bone marrow | # EX | 5 | 0 | 0 | 5 |
| Stomach | # EX | 5 | 5 | 5 | 5 |
| Acanthosis | | 0 | 2 | 4 | 5 |
| Hyperkeratosis | | 0 | 2 | 4 | 5 |
| Testis x 2 | # EX | 5 | 0 | 0 | 5 |
| Thymus | # EX | 5 | 0 | 0 | 5 |
| Thyroid x 2 | # EX | 5 | 0 | 0 | 5 |
| Trachea | # EX | 5 | 0 | 0 | 5 |
| Urinary Bladder | # EX | 5 | 0 | 0 | 5 |

(1) - Control
(2) - 150 mg/kg bw
(3) - 500 mg/kg bw
(4) - 1000 mg/kg bw

28 days toxicity study with BS 1701

## PROJECT SUMMARY

STUDY ID : 001699
FATE: Terminal sacrifice
DAYS ON TEST: ALL

STUDY NUMBER: 001699

SEX: FEMALE

INCIDENCE OF NON-NEOPLASTIC MICROSCOPIC FINDINGS

| GROUP: | | 1F (1) | 2F (2) | 3F (3) | 4F (4) |
|---|---|---|---|---|---|
| NUMBER OF ANIMALS: | | 5 | 5 | 5 | 5 |
| | | # | # | # | # |
| Adrenal x 2 | # EX | 5 | 0 | 0 | 5 |
| Caecum | # EX | 5 | 0 | 0 | 5 |
| Cerebellum | # EX | 5 | 0 | 0 | 5 |
| Cerebrum | # EX | 5 | 0 | 0 | 5 |
| Colon | # EX | 5 | 0 | 0 | 5 |
| Duodenum | # EX | 5 | 0 | 0 | 5 |
| Heart | # EX | 5 | 0 | 0 | 5 |
| Ileum | # EX | 5 | 0 | 0 | 5 |
| Jejunum | # EX | 5 | 0 | 0 | 5 |
| Kidney x 2 | # EX | 5 | 0 | 0 | 5 |
| Unilateral hydronephrosis | | 2 | 0 | 0 | 2 |
| Liver x 2 | # EX | 5 | 0 | 0 | 5 |
| Focal lymphocytosis | | 0 | 0 | 0 | 1 |
| Lung x 2 | # EX | 5 | 0 | 0 | 5 |
| Mandibular Lymph Node | # EX | 5 | 0 | 0 | 5 |
| Mesenteric Lymph Node | # EX | 5 | 0 | 0 | 5 |
| Mid Brain | # EX | 5 | 0 | 0 | 5 |
| Ovary x 2 | # EX | 5 | 0 | 0 | 5 |
| Peripheral Lymph Node | # EX | 5 | 0 | 0 | 5 |
| Peripheral Nerve | # EX | 5 | 0 | 0 | 5 |

(1) - Control
(2) - 150 mg/kg bw
(3) - 500 mg/kg bw
(4) - 1000 mg/kg bw

28 days toxicity study with BS 1701

## PROJECT SUMMARY

STUDY NUMBER: 001699

STUDY ID : 001699
FATE: Terminal sacrifice
DAYS ON TEST: ALL

SEX: FEMALE

INCIDENCE OF NON-NEOPLASTIC MICROSCOPIC FINDINGS

| GROUP: | | 1F (1) | 2F (2) | 3F (3) | 4F (4) |
|---|---|---|---|---|---|
| NUMBER OF ANIMALS: | | 5 | 5 | 5 | 5 |
| | | # | # | # | # |
| Rectum | # EX | 5 | 0 | 0 | 5 |
| Spinal Cord | # EX | 5 | 0 | 0 | 5 |
| Spleen | # EX | 5 | 0 | 0 | 5 |
| Sternum/Bone marrow | # EX | 5 | 0 | 0 | 5 |
| Stomach | # EX | 5 | 5 | 5 | 5 |
| Acanthosis | | 0 | 1 | 3 | 1 |
| Hyperkeratosis | | 0 | 1 | 1 | 1 |
| Thymus | # EX | 5 | 0 | 0 | 5 |
| Thyroid x 2 | # EX | 5 | 0 | 0 | 5 |
| Trachea | # EX | 5 | 0 | 0 | 5 |
| Urinary Bladder | # EX | 5 | 0 | 0 | 5 |
| Interstitial lymphocytosis | | 0 | 0 | 0 | 1 |
| Uterus Body | # EX | 5 | 0 | 0 | 5 |
| Physiological dilatation | | 1 | 0 | 0 | 1 |
| Uterus Horn x 2 | # EX | 5 | 0 | 0 | 5 |
| Physiological dilatation | | 1 | 0 | 0 | 1 |
| Axillary Tissue | # EX | 0 | 0 | 0 | 1 |
| Foreign body granuloma | | 0 | 0 | 0 | 1 |

(1) - Control
(2) - 150 mg/kg bw
(3) - 500 mg/kg bw
(4) - 1000 mg/kg bw

28 days toxicity study with BS 1701

## SEVERITY SUMMARY

STUDY ID : 001699
FATE: Terminal sacrifice
DAYS ON TEST: ALL

STUDY NUMBER: 001699

SEX: MALE

| GROUP: | | 1M (1) | 2M (2) | 3M (3) | 4M (4) |
|---|---|---|---|---|---|
| NUMBER OF ANIMALS: | | 5 | 5 | 5 | 5 |
| | | # | # | # | # |
| Stomach | # EX | 5 | 5 | 5 | 5 |
| Acanthosis | | | | | |
| minimal | | 0 | 2 | 3 | 2 |
| mild | | 0 | 0 | 1 | 3 |
| Hyperkeratosis | | | | | |
| minimal | | 0 | 2 | 4 | 0 |
| mild | | 0 | 0 | 0 | 5 |

Severity Calculated by No. of Tissues Scored
(1) - Control
(2) - 150 mg/kg bw
(3) - 500 mg/kg bw
(4) - 1000 mg/kg bw

28 days toxicity study with BS 1701

## SEVERITY SUMMARY

STUDY ID : 001699
FATE: Terminal sacrifice
DAYS ON TEST: ALL

STUDY NUMBER: 001699

SEX: FEMALE

| GROUP: | | 1F (1) | 2F (2) | 3F (3) | 4F (4) |
|---|---|---|---|---|---|
| NUMBER OF ANIMALS: | | 5 | 5 | 5 | 5 |
| | | # | # | # | # |
| Stomach | # EX | 5 | 5 | 5 | 5 |
| Acanthosis | | | | | |
| minimal | | 0 | 1 | 3 | 1 |
| Hyperkeratosis | | | | | |
| minimal | | 0 | 1 | 1 | 1 |

Severity Calculated by No. of Tissues Scored
(1) - Control
(2) - 150 mg/kg bw
(3) - 500 mg/kg bw
(4) - 1000 mg/kg bw

28 days toxicity study with BS 1701

## TABULATED ANIMAL DATA

STUDY ID : 001699
FATE: ALL
DAYS ON TEST: ALL

STUDY NUMBER: 001699
GROUP: 1M: Control
SEX: MALE

| ANIMAL ID: | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| Adrenal x 2 | - | N | N | N | N |
| Zona fasciculata vacuolation | 1 | - | - | - | - |
| Caecum | N | N | N | N | N |
| Cerebellum | N | N | N | N | N |
| Cerebrum | N | N | N | N | N |
| olon | N | N | N | N | N |
| Duodenum | N | N | N | N | N |
| Epididymis x 2 | N | N | N | N | N |
| Heart | N | N | N | N | N |
| Ileum | N | N | N | N | N |
| Jejunum | N | N | N | N | N |
| Kidney x 2 | N | - | N | N | N |
| Bilateral hydronephrosis | - | 2 | - | - | - |
| Liver x 2 | N | - | N | N | N |
| Focal lymphocytosis | - | 1 | - | - | - |
| Lung x 2 | N | N | N | N | N |
| Mandibular Lymph Node | N | N | N | N | N |
| Mesenteric Lymph Node | N | N | N | N | N |
| Mid Brain | N | N | N | N | N |
| Peripheral Lymph Node | N | N | N | N | N |
| Peripheral Nerve | N | N | N | N | N |

See Reports Code Table for Symbol Definitions

28 days toxicity study with BS 1701

## TABULATED ANIMAL DATA

STUDY ID : 001699
FATE: ALL
DAYS ON TEST: ALL

STUDY NUMBER: 001699
GROUP: 1M: Control
SEX: MALE

| ANIMAL ID: | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| Prostate | N | N | N | N | N |
| Rectum | N | N | N | N | N |
| Seminal Vesicle x 2 | N | N | N | N | N |
| Spinal Cord | N | N | N | N | N |
| Spleen | N | N | N | N | N |
| Sternum/Bone marrow | N | N | N | N | N |
| Stomach | N | N | N | N | N |
| Testis x 2 | N | N | N | N | N |
| Thymus | N | N | N | N | N |
| Thyroid x 2 | N | N | N | N | N |
| Trachea | N | N | N | N | N |
| Urinary Bladder | N | N | N | N | N |

See Reports Code Table for Symbol Definitions

28 days toxicity study with BS 1701

## TABULATED ANIMAL DATA

STUDY ID : 001699
FATE: ALL
DAYS ON TEST: ALL

STUDY NUMBER: 001699
GROUP: 2M: 150 mg/kg bw
SEX: MALE

| ANIMAL ID: | 37 | 38 | 39 | 40 | 41 |
|---|---|---|---|---|---|
| Stomach | N | N | - | - | N |
| Acanthosis | - | - | 1 | 1 | - |
| Hyperkeratosis | - | - | 1 | 1 | - |

See Reports Code Table for Symbol Definitions

28 days toxicity study with BS 1701

## TABULATED ANIMAL DATA

STUDY ID : 001699
FATE: ALL
DAYS ON TEST: ALL

STUDY NUMBER: 001699
GROUP: 3M: 500 mg/kg bw
SEX: MALE

| ANIMAL ID: | 25 | 26 | 27 | 28 | 29 |
|---|---|---|---|---|---|
| Stomach | - | - | N | - | - |
| Acanthosis | 2 | 1 | - | 1 | 1 |
| Hyperkeratosis | 1 | 1 | - | 1 | 1 |

See Reports Code Table for Symbol Definitions

28 days toxicity study with BS 1701

## TABULATED ANIMAL DATA

STUDY ID : 001699
FATE: ALL
DAYS ON TEST: ALL

STUDY NUMBER: 001699
GROUP: 4M: 1000 mg/kg bw
SEX: MALE

| ANIMAL ID: | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|
| Adrenal x 2 | N | N | N | N | N |
| Caecum | N | N | N | N | N |
| Cerebellum | N | N | N | N | N |
| Cerebrum | N | N | N | N | N |
| Colon | N | N | N | N | N |
| Duodenum | N | N | N | N | N |
| Epididymis x 2 | N | N | N | N | N |
| Heart | N | N | N | N | N |
| Ileum | N | N | N | N | N |
| Jejunum | N | N | N | N | N |
| Kidney x 2 | - | N | - | - | - |
| Basophilic tubules | - | - | 1 | 1 | - |
| Unilateral hydronephrosis | - | - | - | 2 | 1 |
| Pelvic tubule dilatation | (2) | - | - | - | - |
| Liver x 2 | N | N | N | N | - |
| Focal lymphocytosis | - | - | - | - | 1 |
| ung x 2 | N | N | N | N | N |
| Mandibular Lymph Node | N | N | N | N | N |
| Mesenteric Lymph Node | N | N | N | N | N |
| Mid Brain | N | N | N | N | N |
| Peripheral Lymph Node | N | N | N | N | N |
| Peripheral Nerve | N | N | N | N | N |
| Prostate | N | N | N | N | N |

See Reports Code Table for Symbol Definitions

28 days toxicity study with BS 1701

## TABULATED ANIMAL DATA

STUDY ID : 001699
FATE: ALL
DAYS ON TEST: ALL

STUDY NUMBER: 001699
GROUP: 4M: 1000 mg/kg bw
SEX: MALE

| ANIMAL ID: | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|
| Rectum | N | N | N | N | N |
| Seminal Vesicle x 2 | N | N | N | N | N |
| Spinal Cord | N | N | N | N | N |
| Spleen | N | N | N | N | N |
| Sternum/Bone marrow | N | N | N | N | N |
| Stomach | - | - | - | - | - |
| Acanthosis | 2 | 2 | 1 | 2 | 1 |
| Hyperkeratosis | 2 | 2 | 2 | 2 | 2 |
| Testis x 2 | N | N | N | N | N |
| Thymus | N | N | N | N | N |
| Thyroid x 2 | N | N | N | N | N |
| Trachea | N | N | N | N | N |
| Urinary Bladder | N | N | N | N | N |

See Reports Code Table for Symbol Definitions

28 days toxicity study with BS 1701

## TABULATED ANIMAL DATA

STUDY ID : 001699
FATE: ALL
DAYS ON TEST: ALL

STUDY NUMBER: 001699
GROUP: 1F: Control
SEX: FEMALE

| ANIMAL ID: | 7 | 8 | 9 | 10 | 11 |
|---|---|---|---|---|---|
| Adrenal x 2 | N | N | N | N | N |
| Caecum | N | N | N | N | N |
| Cerebellum | N | N | N | N | N |
| Cerebrum | N | N | N | N | N |
| Colon | N | N | N | N | N |
| Duodenum | N | N | N | N | N |
| Heart | N | N | N | N | N |
| Ileum | N | N | N | N | N |
| Jejunum | N | N | N | N | N |
| Kidney x 2 | - | - | N | N | N |
| Unilateral hydronephrosis | 1 | 3 | - | - | - |
| Liver x 2 | N | N | N | N | N |
| Lung x 2 | N | N | N | N | N |
| Mandibular Lymph Node | N | N | N | N | N |
| Mesenteric Lymph Node | N | N | N | N | N |
| Mid Brain | N | N | N | N | N |
| Ovary x 2 | N | N | N | N | N |
| Peripheral Lymph Node | N | N | N | N | N |
| Peripheral Nerve | N | N | N | N | N |
| Rectum | N | N | N | N | N |
| Spinal Cord | N | N | N | N | N |

See Reports Code Table for Symbol Definitions

28 days toxicity study with BS 1701

## TABULATED ANIMAL DATA

STUDY ID : 001699
FATE: ALL
DAYS ON TEST: ALL

STUDY NUMBER: 001699
GROUP: 1F: Control
SEX: FEMALE

| ANIMAL ID: | 7 | 8 | 9 | 10 | 11 |
|---|---|---|---|---|---|
| Spleen | N | N | N | N | N |
| Sternum/Bone marrow | N | N | N | N | N |
| Stomach | N | N | N | N | N |
| Thymus | N | N | N | N | N |
| Thyroid x 2 | N | N | N | N | N |
| Trachea | N | N | N | N | N |
| Urinary Bladder | N | N | N | N | N |
| Uterus Body | N | N | - | N | N |
| Physiological dilatation | - | - | P | - | - |
| Uterus Horn x 2 | N | N | - | N | N |
| Physiological dilatation | - | - | P | - | - |

See Reports Code Table for Symbol Definitions

28 days toxicity study with BS 1701

## TABULATED ANIMAL DATA

STUDY ID : 001699
FATE: ALL
DAYS ON TEST: ALL

STUDY NUMBER: 001699
GROUP: 2F: 150 mg/kg bw
SEX: FEMALE

| ANIMAL ID: | 43 | 44 | 45 | 46 | 47 |
|---|---|---|---|---|---|
| Stomach | N | N | - | N | N |
| Acanthosis | - | - | 1 | - | - |
| Hyperkeratosis | - | - | 1 | - | - |

See Reports Code Table for Symbol Definitions

28 days toxicity study with BS 1701

## TABULATED ANIMAL DATA

STUDY ID : 001699
FATE: ALL
DAYS ON TEST: ALL

STUDY NUMBER: 001699
GROUP: 3F: 500 mg/kg bw
SEX: FEMALE

| ANIMAL ID: | 31 | 32 | 33 | 34 | 35 |
|---|---|---|---|---|---|
| Stomach | - | - | N | - | N |
| Acanthosis | 1 | 1 | - | 1 | - |
| Hyperkeratosis | - | - | - | 1 | - |

See Reports Code Table for Symbol Definitions

28 days toxicity study with BS 1701

## TABULATED ANIMAL DATA

STUDY ID : 001699
FATE: ALL
DAYS ON TEST: ALL

STUDY NUMBER: 001699
GROUP: 4F: 1000 mg/kg bw
SEX: FEMALE

| ANIMAL ID: | 19 | 20 | 21 | 22 | 23 |
|---|---|---|---|---|---|
| Adrenal x 2 | N | N | N | N | N |
| Caecum | N | N | N | N | N |
| Cerebellum | N | N | N | N | N |
| Cerebrum | N | N | N | N | N |
| Colon | N | N | N | N | N |
| Duodenum | N | N | N | N | N |
| Heart | N | N | N | N | N |
| Ileum | N | N | N | N | N |
| Jejunum | N | N | N | N | N |
| Kidney x 2 | - | N | N | - | N |
| Unilateral hydronephrosis | 3 | - | - | 4 | - |
| Liver x 2 | N | N | - | N | N |
| Focal lymphocytosis | - | - | 2 | - | - |
| Lung x 2 | N | N | N | N | N |
| Mandibular Lymph Node | N | N | N | N | N |
| esenteric Lymph Node | N | N | N | N | N |
| Mid Brain | N | N | N | N | N |
| Ovary x 2 | N | N | N | N | N |
| Peripheral Lymph Node | N | N | N | N | N |
| Peripheral Nerve | N | N | N | N | N |
| Rectum | N | N | N | N | N |
| Spinal Cord | N | N | N | N | N |

See Reports Code Table for Symbol Definitions

28 days toxicity study with BS 1701

## TABULATED ANIMAL DATA

STUDY ID : 001699
FATE: ALL
DAYS ON TEST: ALL

STUDY NUMBER: 001699
GROUP: 4F: 1000 mg/kg bw
SEX: FEMALE

| ANIMAL ID: | 19 | 20 | 21 | 22 | 23 |
|---|---|---|---|---|---|
| Spleen | N | N | N | N | N |
| Sternum/Bone marrow | N | N | N | N | N |
| Stomach | N | N | - | N | N |
| Acanthosis | - | - | 1 | - | - |
| Hyperkeratosis | - | - | 1 | - | - |
| Thymus | N | N | N | N | N |
| Thyroid x 2 | N | N | N | N | N |
| Trachea | N | N | N | N | N |
| Urinary Bladder | - | N | N | N | N |
| Interstitial lymphocytosis | 2 | - | - | - | - |
| Uterus Body | - | N | N | N | N |
| Physiological dilatation | P | - | - | - | - |
| Uterus Horn x 2 | - | N | N | N | N |
| Physiological dilatation | P | - | - | - | - |
| Non-Protocol Tissues: | | | | | |
| Axillary Tissue | - | - | - | - | - |
| Foreign body granuloma | - | 4 | - | - | - |

See Reports Code Table for Symbol Definitions

# Food/Water Quality

*Diet Analyses, microbiology*

3 pages

*Diet Analyses, chemistry*

3 pages

*Water Analyses, microbiology*

2 pages

*Water Analyses, chemistry*

6 pages

GISSEL INSTITUT
FÜR BAKTERIOLOGIE UND HYGIENE
IM AUFTRAG DER GESUNDHEIT

LABORATORIUM FÜR BAKTERIOLOGIE
UND LEBENSMITTELHYGIENE

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EINGANG
31. MAI 2000
Erl.:

Gissel-Institut · Freundallee 25 · 30173 Hannover

Altromin International
Gesellschaft für Tierernährung
Lange Str. 42

32791 Lage

Deutscher Akkreditierungs Rat
DAP-P-02.153-00-98-04

Nach DIN EN 45001 durch die DAP Deutsches Akkreditierungssystem Prüfwesen GmbH akkreditiertes Prüflaboratorium. Die Akkreditierung gilt für die in der Urkunde aufgeführten Prüfverfahren.

Hannover, 24.05.2000

**Untersuchung des Produktes: Futtermittel: altromin Z Ratte/Maus**

Das eingesandte Produkt wurde auftragsgemäß einer Untersuchung unterzogen. Bei diesen Untersuchungen wurden im Prüfbericht folgende Ergebnisse erhalten:

| | |
|---|---|
| **Tagebuchnummer:** | LP004424 |
| **Kunden-Angaben:** | Nr. 95 |
| **Eingangsdatum:** | 19.05.2000 |
| **Verpackung:** | Papiertüte |
| **Anzahl der Proben:** | 1 |
| **Verkehrsbezeichnung:** | Futtermittel: altromin Z Ratte/Maus |

**Prüfauftrag:**

Das Produkt wurde vom Auftraggeber in das Institut eingesandt, um die hygienische Beschaffenheit zu ermitteln.
Dazu wurden folgende Untersuchungen durchgeführt.

| | |
|---|---|
| Untersuchungstag | 19.05.2000 |

**Beschreibung des Produktes**

| | |
|---|---|
| Gewicht (netto) in g | 315,0 g |
| Produkt | rechteckige bräunliche Pellets |
| Geruch/Geschmack | spezifisch |

**Bakteriologische Untersuchung**
Die bakteriologische Untersuchung wird ausschließlich nach standardisierten und validierten Untersuchungsmethoden durchgeführt.
Sachbearbeiterin: Dr. med. vet. Heide Torterotot
Fachtierärztin für Lebensmittelhygiene

| | |
|---|---|
| aerobe Gesamtkeimzahl | $8,6 \times 10^3$ /g |



Die Prüfergebnisse beziehen sich ausschließlich auf die untersuchten Proben.
Eine auszugsweise Veröffentlichung oder Vervielfältigung ist nur mit Genehmigung des Instituts erlaubt.

**Beurteilung als Anlage zum Prüfbericht LP004424**

Das Futter wurde wunschgemäß bakteriologisch untersucht.
Das Erzeugnis ist nach den hier durchgeführten Untersuchungen von einwandfreier hygienischer Qualität.

| | |
|---|---|
| Hefen | < 1,0 x $10^2$ /g |
| Schimmelpilze | < 1,0 x $10^2$ /g |
| sulfitreduz. Clostridien | nicht nachweisbar |
| koagulase-pos. Staphylokokken | < 1,0 x $10^2$ /g |
| Enterokokken | < 1,0 x $10^2$ /g |
| E. coli | < 1,0 x $10^2$ /g |
| Salmonellen in 50g<br>ELISA (Fa. Riedl deHaen) | nicht nachweisbar |

Verantwortlich für den Prüfbericht:



Die Prüfergebnisse beziehen sich ausschließlich auf die untersuchten Proben.
Eine auszugsweise Veröffentlichung oder Vervielfältigung ist nur mit Genehmigung des Instituts erlaubt.

AGRAR- U. UMWELTANALYTIK GMBH

AUA GmbH • Löbstedter Str. 78 • 07749 Jena



# Prüfbericht Nr. AUA 2782-00

| | |
|---|---|
| **Auftraggeber :** | altromin,<br>Lange Straße 42, 32791 Lage |
| **Probenart :** | Futtermittel |
| **Probenumfang :** | 8 Proben |
| **Probenahme :** | Auftraggeber |
| **Probeneingang :** | 28.04.2000 |
| **Prüfzeitraum :** | 28.04.2000 bis 23.05.2000 |

**Untersuchungsergebnisse: siehe ab Seite 2**

**Analysenmethoden :**

| | |
|---|---|
| Aflatoxine : | HPLC - VDLUFA Bd. III, Kap. 16.1.4 (Fremdvergabe) |
| As: | Druckaufschluß mit $HNO_3/HClO_4$, DIN EN ISO 11969 |
| Se: | Druckaufschluß mit $HNO_3/HClO_4$, DIN 38405 D23 |
| Hg: | Druckaufschluß mit $HNO_3/HClO_4$, DIN EN 1483 |
| Pb: | Trockene Veraschung, 480°C, DIN 38406 E 6 - 2 |
| Cd: | Trockene Veraschung, 480°C, DIN EN ISO 5961 |
| antibiotische Aktivität : | Qualitativer Nachweis mittels Keimspektrum (Agardiffussionstest mit Bacillus subtilis) |
| PCB : | analog DFG S19 |
| chlorierte Kohlenwasserstoffe : | analog DFG S19 |
| Phosphorsäureester : | analog DFG S19 |
| Fluorid : | Verfahren DIN 51084 : 1990-07 |

**Bemerkungen :** Die Proben werden, wenn nicht anders vereinbart, 3 Monate im Labor aufbewahrt.
Die Prüfergebnisse beziehen sich nur auf die untersuchten Proben.
Die auszugsweise Vervielfältigung des Prüfberichtes bedarf der schriftlichen Genehmigung durch die AUA GmbH.

Jena, den 08.06.2000

i. A.

Prof. Dr. habil. M. Grün
(Geschäftsführer)

Dr. Karla Jochmann
(Bearbeiter)

Durch die DAP Deutsches Akkreditierungssystem Prüfwesen GmbH akkreditiertes Prüflaboratorium

Die Akkreditierung gilt für die in der Urkunde aufgeführten Prüfverfahren.

Deutscher Akkreditierungs Rat DAP

DAP-P-02.431-00-92-01

Geschäftsstelle: 07749 Jena Löbstedter Str. 78
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GmbH, eingetragen beim Amtsgericht Gera HRB Nr. 2596
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Geschäftsführer: Prof. Dr. habil. Manfred Grün, Dr. Jörg Ruppe
Bankverbindung: Bayerische Vereinsbank Jena (BLZ 830 200 87) Kto.-Nr. 4 181 018
Commerzbank Jena (BLZ 820 400 00) Kto.-Nr. 2 624 500

AGRAR- U. UMWELTANALYTIK GMBH

## report No. AUA 2782.2-00

laboratory number: 2

Declaration of the sample: Nr. 17=altromin Z Standarddiät für Ratte / Maus

Sample received on: 28.04.00
sample packing: paper bag
sample seal: without

### Result of analysis

| PCB | | |
|---|---|---|
| K 28 | mg/kg | < 0,001 |
| K 52 | mg/kg | < 0,001 |
| K 101 | mg/kg | < 0,001 |
| K 153 | mg/kg | < 0,001 |
| K 138 | mg/kg | < 0,001 |
| K 180 | mg/kg | < 0,001 |
| PCB (total) | mg/kg | < 0,001 |

| | | |
|---|---|---|
| Aflatoxin B1 | µg/kg | < 0,3 |
| Aflatoxin B2 | µg/kg | < 0,3 |
| Aflatoxin G1 | µg/kg | < 0,3 |
| Aflatoxin G2 | µg/kg | < 0,3 |

| | | |
|---|---|---|
| Lead (Pb) | mg/kg* | 0,19 |
| Cadmium (Cd) | mg/kg* | 0,068 |
| Mercury (Hg) | mg/kg* | < 0,01 |
| Arsenic (As) | mg/kg* | 0,047 |
| Selenium (Se) | mg/kg* | < 0,050 |
| Fluorine (F) | mg/kg | 7,0 |

*) dry matter

Antibiotic activity non detected (negative)

AGRAR- U. UMWELTANALYTIK GMBH

## report No. AUA 2782.2-00

laboratory number: 2

* Declaration of the sample: Nr. 17=altromin Z Standarddiät für Ratte / Maus

Sample received on: 28.04.00
sample packing: paper bag
sample seal: without

## Result of analysis

**Phosphoric Acid Esters:**

| | | |
|---|---|---|
| Dichlorvos | mg/kg | < 0,010 |
| Chlorthion | mg/kg | < 0,010 |
| Malathione | mg/kg | < 0,010 |
| Parathion (-methyle) | mg/kg | < 0,010 |
| Parathion (-ethyle) | mg/kg | < 0,010 |
| Sulfotep | mg/kg | < 0,010 |
| Fenthione | mg/kg | < 0,010 |
| Diazinone | mg/kg | < 0,010 |
| Dimethoate | mg/kg | < 0,010 |
| Fenithrothione | mg/kg | < 0,010 |
| Bromophos (-ethyle) | mg/kg | < 0,010 |
| Bromophos (-methyle) | mg/kg | < 0,010 |
| Chlorfenvinphos | mg/kg | < 0,010 |
| Chlorpyriphos (-ethyle) | mg/kg | < 0,010 |
| Chlorpyriphos (-methyle) | mg/kg | < 0,010 |
| Pirimiphos (-methyle) | mg/kg | < 0,010 |
| Methidathione | mg/kg | < 0,010 |
| Ethione | mg/kg | < 0,010 |
| Disulfotone | mg/kg | < 0,010 |
| Fenchlorphos | mg/kg | < 0,010 |

*Typ N-1324

AGRAR- U. UMWELTANALYTIK GMBH

**report No. AUA 2782.2-00**

laboratory number: 2

Declaration of the sample: Nr. 17=altromin Z Standarddiät für Ratte / Maus

Sample received on: 28.04.00
sample packing: paper bag
sample seal: without

## Result of analysis

**Chlorinated Hydrocarbons:**

| | | |
|---|---|---|
| HCB (Hexachlorobenzene) | mg/kg | < 0,002 |
| α - HCH | mg/kg | < 0,002 |
| ß - HCH | mg/kg | < 0,002 |
| χ - HCH (Lindan) | mg/kg | < 0,002 |
| δ - HCH | mg/kg | < 0,002 |
| ε - HCH | mg/kg | < 0,002 |
| Heptachlor | mg/kg | < 0,002 |
| cis - Heptachlorepoxide | mg/kg | < 0,002 |
| trans - Heptachlorepoxide | mg/kg | < 0,002 |
| α - Chlordane | mg/kg | < 0,002 |
| χ - Chlordane | mg/kg | < 0,002 |
| oxy - Chlordane | mg/kg | < 0,002 |
| α - Endosulfane | mg/kg | < 0,002 |
| ß - Endosulfane | mg/kg | < 0,002 |
| Endosulfansulfate | mg/kg | < 0,002 |
| Aldrine | mg/kg | < 0,002 |
| Dieldrine | mg/kg | < 0,002 |
| Endrine | mg/kg | < 0,002 |
| o,p - DDE | mg/kg | < 0,002 |
| p,p - DDE | mg/kg | < 0,002 |
| o,p - DDT | mg/kg | < 0,002 |
| o,p - DDD | mg/kg | < 0,002 |
| p,p - DDD | mg/kg | < 0,002 |
| p,p - DDT | mg/kg | < 0,002 |
| Methoxychlor | mg/kg | < 0,002 |
| Tecnazen | mg/kg | < 0,002 |
| Isodrin | mg/kg | < 0,002 |
| Mirex | mg/kg | < 0,002 |

BIOSERVICE
SCIENTIFIC LABORATORIES GmbH

# BERICHT

## TEST intern

16.11.00 hn

Testmaterial — Wasserproben aus „in-vivo“ Bereich: II/2000

| Wasserprobe | Bezeichnung |
|---|---|
| 1 | Raum 2 MS |
| 2 | Raum 4 MS |
| 3 | Raum 5 K |
| 4 | Raum 9 M |
| 5 | Raum 12 M |
| 6 | Raum 13 R |
| 7 | Raum 17 K |

Probenahme: 31.10.00
Probenehmer: Kathrin Huber
Testbeginn: 31.10.00
Testende: 03.11.00
Versuchsleitung: Dipl.-Biol. Kathrin Kraemer
Qualitätssicherung: Dipl.-Biol. Maike Führböter
Archivierung: Eine Ausfertigung des Berichts wird zusammen mit den Rohdaten im Archiv des Auftragnehmers aufbewahrt.

Testmethode: Untersuchung von Wasserproben (TrinkwVo 1990)

Zur Bestimmung der Koloniezahl wird jeweils 1 ml Wasserprobe mit CASO-Agar vergossen (Plattenguß-Verfahren) und 0,1 ml auf CASO-Agar ausspiralisiert. Es werden 2 Gußplatten und 2 Spiralplatten hergestellt. Die Inkubation einer Guß- und Spiralplatte erfolgt jeweils bei 20±2°C und 36±1°C für 48 +/- 4 h.

**BSL BIOSERVICE** Scientific Laboratories GmbH
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Reg.-Gericht: Amtsgericht München, HRB 109 770
Kreisspark. München-Starnberg, BLZ 702 501 50, Kto. 5 003 918
Swift-Code: BYLADEMM ( Bayer. Landesbank München)
Deutsche Bank Planegg, BLZ 700 700 24, Kto. 9 407 750
Swift-Code: DEUTDEDBMUC

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Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Medizinprodukten
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Deutscher Akkreditierungs Rat
ZLG-P-986.96.01

Zum Nachweis von *E. coli* und coliformer Keime werden 100 ml Wasserprobe in doppelt konzentrierte DEV-Laktose-Pepton-Bouillon gegeben und bei 36 +/- 1°C für 48 +/- 4 h inkubiert.

Bei Wachstum und positiver Reaktion (Gas- und Säurebildung) in der DEV-Laktose-Pepton-Bouillon wird eine Subkultur auf Endo-C-Agar angelegt.

Ergebnis

| Wasserprobe | KBE/ml 20±2°C | KBE/ml 36±1°C | E.coli je 100 ml | Coliforme je 100 ml |
|---|---|---|---|---|
| 1 | < 1 | < 1 | n.n. | n.n. |
| 2 | < 1 | < 1 | n.n. | n.n. |
| 3 | < 1 | < 1 | n.n. | n.n. |
| 4 | < 1 | < 1 | n.n. | n.n. |
| 5 | < 1 | < 1 | n.n. | n.n. |
| 6 | < 1 | < 1 | n.n. | n.n. |
| 7 | < 1 | < 1 | n.n. | n.n. |

n.n. = nicht nachweisbar

Dr. Harald Noll
Laborleitung Mikrobiologie

Dipl.-Biol. Kathrin Kraemer
Versuchsleitung Mikrobiologie

- Auszugsweise Wiedergabe dieses Berichtes nur mit schriftlicher Genehmigung der BSL BIOSERVICE Scientific Laboratories GmbH -
- Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände -

Dr. Blasy - Dr. Busse

Umweltlabor zertifiziert durch die AOS-Leitstelle Bayern für Grund- und Abwasser, zugelassen nach § 19 Trinkwasserverordnung, akkreditiert durch das Deutsche Akkreditierungssystem Prüfwesen (DAP) nach DIN EN 45001 (Registrier-Nr.: DAP-PA-01. 432-00-96-00)

Moosstraße 6a · 82279 Eching am Ammersee · Tel. 08143/79-01 · Fax 08143/7214



Auftraggeber: Würmtal-Zweckverband
Entnahmestelle: Hochbehälter 4 (Zu-/Ablaufleitung) OKZ: 1230793400041
Probenbezeichnung: RE 89/0 Probenahme (Datum / Uhrzeit): 13.03.00 / 08,50
Probenehmer: Hr.Reif

# Prüfbericht

## CHEMISCH-TECHNISCHE UND HYGIENISCHE WASSERANALYSE

| Parameter | Befund | zulässiger Höchstwert/Bereich | Gesetz/Richtlinie |
|---|---|---|---|
| Färbung (visuell, vor Ort)<br>Trübung (visuell, vor Ort)<br>Geruch (qualitativ, vor Ort) | farblos<br>klar<br>ohne Besonderheit | | |
| Wassertemperatur(Labor)/(vor Ort=tw)<br>Elektrische Leitfähigkeit bei 25°C | 13,0 / 9,4°C<br>65 µS/m | 25°C<br>200 µS/m | TVO Anl.4 zu § 3<br>TVO Anl.4 zu § 3 |
| pH-Wert(Labor)/(vor Ort)/(berechnet) | 7,38 / 7,51 / 7,40 | 6,5 bis 9,5 | TVO Anl.4 zu § 3 |
| Säurekapazität bis pH 4,3<br>Basekapazität bis pH 8,2 | 6,32 mmol/l<br>0,58 mmol/l | möglichst > 1 mmol/l<br>mögl. < 0,5, nicht > 0,7 mmol | DIN 50930 T.3 u.5<br>DIN 50930 Teil 3 |
| Sauerstoff ($O_2$) | 8,5 mg/l | möglichst > 3, nicht < 2 mg/l | DIN 50930 Teil 2 |
| Summe Erdalkalien | 3,46 mmol/l | | |
| Calcium ($Ca^{2+}$)<br>Magnesium ($Mg^{2+}$)<br>Natrium ($Na^{+}$)<br>Kalium ($K^{+}$)<br>Eisen, gesamt (Fe)<br>Mangan (Mn)<br>Ammonium ($NH_4^{+}$) | 96 mg/l<br>26 mg/l<br>6,3 mg/l<br>2,0 mg/l<br>< 0,005 mg/l<br>< 0,005 mg/l<br>< 0,02 mg/l | 400 mg/l<br>möglichst > 20 mg/l<br>50 mg/l (120 mg/l*)<br>150 mg/l<br>12 mg/l ( 50 mg/l*)<br>0,2 mg/l<br>0,05 mg/l<br>0,5 mg/l (30 mg/l*) | TVO Anl.4 zu § 3<br>DIN 50930 T.2 u.3<br>TVO Anl.4 zu § 3<br>TVO Anl.4 zu § 3<br>TVO Anl.4 zu § 3<br>TVO Anl.4 zu § 3<br>TVO Anl.4 zu § 3<br>TVO Anl.4 zu § 3 |
| Chlorid ($Cl^{-}$)<br>Sulfat ($SO_4^{2-}$)<br>Nitrat ($NO_3^{-}$)<br>Nitrit ($NO_2^{-}$)<br>ortho-Phosphat ($PO_4^{3-}$) | 15 mg/l<br>14 mg/l<br>23 mg/l<br>< 0,02 mg/l<br>< 0,05 mg/l | 250 mg/l<br>240 mg/l (500 mg/l*)<br>50 mg/l<br>0,1 mg/l<br>6,7 mg/l | TVO Anl.4 zu § 3<br>TVO Anl.4 zu § 3<br>TVO Anl.2 zu § 2<br>TVO Anl.2 zu § 2<br>TVO Anl.4 zu § 3 |
| Kieselsäure ($SiO_2$) | 6,4 mg/l | 40 mg/l | TVO Anl.3 zu § 4a |
| DOC<br>Spektr. Absorptionskoeff. 436 nm<br>Spektr. Absorptionskoeff. 254 nm | < 0,5 mg/l<br>0,0 $m^{-1}$<br>0,8 $m^{-1}$ | 0,5 $m^{-1}$ | TVO Anl.4 zu § 3 |
| Aluminium (Al)<br>Arsen (As) | < 0,05 mg/l<br>< 0,001 mg/l | 0,2 mg/l<br>0,01 mg/l | TVO Anl.4 zu § 3<br>TVO Anl.2 zu § 2 |

*) gegen bedingte Überschreitungen bleiben bis zu dem in Klammern gesetzten Höchstwert außer Betracht

Niederlassung der AGRO LAB GmbH

Dr. Blasy - Dr. Busse

Umweltlabor zertifiziert durch die ACS-Leitstelle Bayern für Grund- und Abwasser, zugelassen nach § 19 Trinkwasserverordnung, akkreditiert durch das Deutsche Akkreditierungssystem Prüfwesen (DAP) nach DIN EN 45001 (Registrier-Nr.: DAP-PA-01. 432-00-96-00)

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Seite 2 zu Probe: RE 89/0 / Chemisch-technische und hygienische Wasseranalyse

# Berechnete Daten

| Parameter | Befund | zulässiger Höchstwert/Bereich | Gesetz/Richtlinie |
|---|---|---|---|
| **WASSERHÄRTE, GESAMTMINERALISATION** | | | |
| Gesamthärte | 19,4°dH | | |
| Härtebereich (Waschmittelgesetz) | 3 | | |
| Carbonathärte | 17,6°dH | | |
| Gesamtmineralisation (berechnet) | 574 mg/l | | |
| **BERECHNUNGEN ZUM KALK-KOHLENSÄURE-GLEICHGEWICHT*)** | | | |
| pH-Wert (Labor)/(vor Ort)/(berechnet) | 7,38 / 7,51 / 7,40 | 6,5 bis 9,5 | TVO Anl.4 zu § 3 |
| pH-Wert nach Calciumcarbonat-sättigung, berechnet bei tw ($pH_C$) | 7,25 | | |
| Gleichgewichts-pH-Wert bei tw ($pH_L$) | 7,18 | nicht < -0,2 | TVO Anl.4 zu § 3 |
| Delta-pH-Wert | | | |
| pH(berechnet) - $pH_C$ | 0,15 | | |
| pH(vor Ort) - $pH_C$ | 0,25 | | |
| pH(Labor) - $pH_C$ | 0,12 | | |
| Sättigungsindex (SI) | | | |
| pH(berechnet) - $pH_L$ | 0,22 | | |
| Kohlenstoffdioxid, gelöst ($CO_2$) | 25 mg/l | | |
| Kohlenstoffdioxid, zugehörig ($CO_2$) | 42 mg/l | | |
| Calcit-Lösekapazität bei tw ($D_C$) | -0,19 mmol/l | | |
| Pufferungsintensität bei tw (PI) | 1,34 mmol/l | | |
| **KORROSIONSCHEMISCHE QUOTIENTEN NACH DIN 50930 UND DVGW W 216** | | | |
| Kationenquotient $\frac{1}{2}(c(Na^+)+c(K^+))/(c(Ca^{2+})+c(Mg^{2+}))$ | 0,04 | | DVGW W 216 |
| Muldenkorrosionsquotient $(c(Cl^-)+2c(SO_4^{2-}))/K_{54,3}$ | 0,11 | möglichst < 1, nicht > 3 | DIN 50930 T.2 u.3 |
| Tiefgrubenquotient $(c(Cl^-)+2c(SO_4^{2-}))/c(NO_3^-)$ | 1,92 | möglichst > 2 | DIN 50930 Teil 3 |
| Kupferquotient $c(HCO_3^-)/c(SO_4^{2-})$ | 43,40 | möglichst > 2 | DIN 50930 Teil 5 |

Methoden siehe Methodenliste TW

*) Nach DIN 38404 Teil 10-3 Entwurf (exakte Berechnung unter Berücksichtigung der Ionenpaarbildung)

TVO: Trinkwasser-Verordnung vom 05.12.90; Anlage 2 betrifft gesundheitsschädliche Stoffe, Anlage 3 zugelassene Zusatzstoffe, Anlage 4 unerwünschte Stoffe

DIN 50930: Korrosionsverhalten von metallischen Werkstoffen gegenüber Wasser; Teil 2: Unlegierte und niedrigle gierte Eisenwerkstoffe; Teil 3: Feuerverzinkte Eisenwerkstoffe; Teil 5: Kupfer und Kupferlegierungen

Anmerkung: Das Zeichen < bedeutet, daß der betreffende Stoff bei nebenstehender Nachweisgrenze nicht nachzuweisen ist.

Eching, den 07.04.00

Dr. Timm Busse
staatl. gepr. Lebensmittelchemiker

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Bei Proben unbekannten Ursprungs ist eine Plausibilitätsprüfung nur bedingt möglich. Die auszugsweise Vervielfältigung des Berichts ohne schriftliche Genehmigung ist nicht zulässig.

Niederlassung der AGRO LAB GmbH

**Dr. Blasy - Dr. Busse**

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Moosstraße 6a 82279 Eching am Ammersee · Tel. 08143/79-01 · Fax 08143/7214



Auftraggeber: Würmtal-Zweckverband OKZ: 1230793400041
Entnahmestelle: Hochbehälter 4 (Zu-/Ablaufleitung)
Probenbezeichnung: RE 89/0 Probenahme (Datum / Uhrzeit): 13.03.00 / 08,50
Probenehmer: Hr.Reif

# Prüfbericht

## UNTERSUCHUNGEN NACH ANLAGE 2 NR.1 – 12 UND ANLAGE 3 Nr.1 (THM) DER TRINKWASSER-VERORDNUNG UND BESTIMMUNG DER GESAMTHÄRTE (WASCHMITTELGESETZ)

### A) Feststellungen vor Ort:

| | |
|---|---|
| Färbung (visuell): farblos<br>Trübung (visuell): klar<br>Geruch (qualitativ): ohne Besonderheit | pH-Wert: 7,51<br>Temperatur: 9,4°C<br>Elektrische Leitfähigkeit bei 25°C: 65 mS/m |

### B) Laboruntersuchungen:

| Untersuchungsparameter | Befund in mg/l | Grenzwert gem.TrinkwV in mg/l | berechnet als |
|---|---|---|---|
| 1. Arsen | < 0,001 | 0,01 | As |
| 2. Blei | < 0,002 | 0,04 / 0,01*) | Pb |
| 3. Cadmium | < 0,001 | 0,005 | Cd |
| 4. Chrom | < 0,005 | 0,05 | Cr |
| 5. Cyanid | < 0,01 | 0,05 | CN |
| 6. Fluorid | 0,09 | 1,5 | F |
| 7. Nickel | < 0,02 | 0,05 | Ni |
| 8. Nitrat | 23 | 50 | NO3 |
| 9. Nitrit | < 0,02 | 0,1 | NO2 |
| 10. Quecksilber | < 0,0002 | 0,001 | Hg |
| 11. Polycyclische aromatische Kohlenwasserstoffe | < 0,00005 | 0,0002 | Summe C |
| 12.a Summe Dichlormethan, 1,1,1-Trichlorethan, Trichlorethen, Tetrachlorethen | < 0,0005 | 0,01 | Summe Einzelstoffe |
| 12.b Tetrachlorkohlenstoff | < 0,0001 | 0,003 | CCl4 |
| Summe Trihalogenmethane (THM) | < 0,0008 | 0,01 | Summe THM |

Summe Erdalkalien: 3,47 mmol/l (Gesamthärte: 19,4 °dH) entsprechend Härtebereich 3 des Waschmittelgesetzes

Bestimmungsmethoden: AAS: Nr.1, 10; ICP-AES: 2, 3, 4, 7, Summe Erdalkalien; Photometrie: Nr.5, 9; IC: Nr.8; HPLC/FLD: Nr.11; GC/MS: Nr.12a, b, THM; Elektrometrie: pH-Wert, Leitfähigkeit, Nr.6; Detailangaben siehe Methodenliste

*) 0,01 mg/l = Grenzwert der EU-Richtlinie Qualität von Wasser für den menschlichen Gebrauch

Anmerkung: Das Zeichen < bedeutet, daß der betreffende Stoff bei nebenstehender Nachweisgrenze nicht nachzuweisen ist.

Eching, den 07.04.00

Dr.Timm Busse
staatl.gepr.Lebensmittelchemiker

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Bei Proben unbekannten Ursprungs ist eine Plausibilitätsprüfung nur bedingt möglich. Die auszugsweise Vervielfältigung des Berichts ohne schriftliche Genehmigung ist nicht zulässig.

Niederlassung der AGRO LAB GmbH

Dr. Blasy - Dr. Busse

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Akkreditiert durch das Deutsche Akkreditierungssystem Prüfwesen (DAP) nach DIN EN 45001 (Registrier-Nr.: DAP-PA-01. 432-00-96-00)

Moosstraße 6a · 82279 Eching am Ammersee · Tel. 08143/79-01 · Fax 08143/7214



Auftraggeber: Würmtal-Zweckverband OKZ: 1230793400041
Entnahmestelle: Hochbehälter 4 (Zu-/Ablaufleitung)
Probenbezeichnung: RE 89/0 Probenahme (Datum / Uhrzeit): 13.03.00 / 08,50
Probenehmer: Hr.Reif

# Prüfbericht

## WEITERE PARAMETER

| Parameter | Befund | zulässiger Höchstwert/Bereich | Gesetz/Richtlinie |
|---|---|---|---|
| Chloroform | < 0,0001 mg/l | | |
| Bromdichlormethan | < 0,0002 mg/l | | |
| Dibromchlormethan | < 0,0002 mg/l | | |
| Bromoform | < 0,0003 mg/l | | |
| Σ Trihalogenmethane | < 0,0008 mg/l | 0,01 mg/l | TVO Anl.3 zu § 4a |
| 1,1,1-Trichlorethan | < 0,0001 mg/l | ) | |
| Trichlorethen | < 0,0001 mg/l | ) | |
| Tetrachlorethen | < 0,0001 mg/l | ) 0,01 mg/l | TVO Anl.2 zu § 2 |
| Dichlormethan | < 0,0002 mg/l | ) | |
| Tetrachlorkohlenstoff | < 0,0001 mg/l | 0,003 mg/l | TVO Anl.2 zu § 2 |

Methoden siehe Methodenliste TW

TVO: Trinkwasser-Verordnung vom 05.12.90; Anl.2 betrifft gesundheitsschädliche Stoffe, Anl.3 zugelassene Zusatzstoffe
Anl.4 unerwünschte Stoffe, Anl.7: Richtwerte für Kupfer und Zink in Stagnationswässern

EG-Richtlinie: Qualität von Wasser für den menschlichen Gebrauch

Anmerkungen: Das Zeichen < bedeutet, daß der betreffende Stoff bei nebenstehender Nachweisgrenze nicht nachzuweisen ist.

Eching, den 07.04.00

Dr.Timm Busse
staatl.gepr.Lebensmittelchemiker

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Bei Proben unbekannten Ursprungs ist eine Plausibilitätsprüfung nur bedingt möglich. Die auszugsweise Vervielfältigung des Berichts ohne schriftliche Genehmigung ist nicht zulässig.

Niederlassung der ACRO LAB GmbH

Dr. Blasy - Dr. Busse

Umweltlabor zertifiziert durch die AQS-Leitstelle Bayern für Grund- und Abwasser, zugelassen nach § 19 Trinkwasserverordnung.
Akkreditiert durch das Deutsche Akkreditierungssystem Prüfwesen (DAP) nach DIN EN 45001 (Registrier-Nr.: DAP-PA-01. 432-00-96-00).

Lobosstraße 6a · 82279 Eching am Ammersee · Tel. 08143/79-01 · Fax 08143/7214



Auftraggeber: Würmtal-Zweckverband
Entnahmestelle: Hochbehälter 4 (Zu-/Ablaufleitung) OKZ: 1230793400041
Probenbezeichnung: RE 89/0 Probenahme (Datum / Uhrzeit): 13.03.00 / 08,50
Probenehmer: Hr.Reif

# Prüfbericht

## PHYSIKALISCH-CHEMISCHE UNTERSUCHUNGEN AUF DIE PARAMETER DER ANLAGE 2 NR.13 DER TRINKWASSERVERORDNUNG

(Stoffe zur Pflanzenbehandlung und Schädlingsbekämpfung - PBSM und polychlorierte Biphenyle - PCB)

### A) Feststellungen vor Ort:

| | |
|---|---|
| Färbung (visuell): farblos<br>Trübung (visuell): klar<br>Geruch (qualitativ): ohne Besonderheit | pH-Wert: 7,51<br>Temperatur: 9,4°C<br>Elektrische Leitfähigkeit bei 25°C: 65 mS/m |

### B) Laboruntersuchungen:

| Untersuchungsparameter | Befund in mg/l | zulässiger Höchstwert in mg/l |
|---|---|---|
| Atrazin | < 0,00005 (+) | 0,0001 |
| Bromoxynil | < 0,00001 | 0,0001 |
| Desethylatrazin | 0,00006 | 0,0001 |
| Desethylterbuthylazin | < 0,00001 | 0,0001 |
| Desisopropylatrazin | < 0,00002 | 0,0001 |
| Dichlorprop | < 0,00003 | 0,0001 |
| Isoproturon | < 0,00001 | 0,0001 |
| MCPA | < 0,00003 | 0,0001 |
| Mecoprop | < 0,00003 | 0,0001 |
| Metazachlor | < 0,00001 | 0,0001 |
| Metribuzin | < 0,00001 | 0,0001 |
| Pendimethalin | < 0,00001 | 0,0001 |
| Prosulfocarb | < 0,00001 | 0,0001 |
| Simazin | < 0,00001 | 0,0001 |
| Terbuthylazin | < 0,00001 | 0,0001 |
| Trifluralin | < 0,00001 | 0,0001 |

Niederlassung der AGRO LAB GmbH

Dr. Blasy - Dr. Busse

Umweltlabor zertifiziert durch die AQS-Leitstelle Bayern für Grund- und Abwasser, zugelassen nach § 19 Trinkwasserverordnung, akkreditiert durch das Deutsche Akkreditierungssystem Prüfwesen (DAP) nach DIN EN 45001 (Registrier-Nr.: DAP-PA-01.432-00-96-00)

Moosstraße 8 a · 82279 Eching am Ammersee · Tel. 08143/79-01 · Fax 08143/7214



Seite 2 zu Probe: RE 89/0 / Parameter Anlage 2 Nr.13 Trinkwasserverordnung

Erläuterungen: < 0,00001: Der betreffende Stoff ist bei einer Nachweisgrenze von 0,00001 mg/l nicht nachzuweisen
< 0,00005 (+): Der betreffende Stoff ist im Bereich zwischen Bestimmungsgrenze (0,00005 mg/l) und Nachweisgrenze nur qualitativ nachzuweisen, eine quantitative Aussage in diesem Bereich ist jedoch nicht ohne weiteres möglich.

Methodik: PCB, CHLOR- UND PHOSPHORORGANISCHE PBSM (Aldrin, DDE, DDT, Dieldrin, Endosulfan, HCB, HCH, Lindan, Parathion, Parathion-ethyl und -methyl), FENPROPIMORPH: Flüssig-Flüssigextraktion, GC/MS;
GLUPHOSINAT, GLYPHOSAT, AMPA-SALZ: Vorsäulenderivatisierung, HPLC/Fluoreszenzdetektor;
ANDERE PBSM: Feststoffextraktion, HPLC/Diodenarraydetektor; Verifizierung mit GC/MS bei Konzentrationen über 0,00007 mg/l (sofern möglich).

Eching, den 07.04.00

Dr.Timm Busse
staatl.gepr.Lebensmittelchemiker

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Bei Proben unbekannten Ursprungs ist eine Plausibilitätsprüfung nur bedingt möglich. Die auszugsweise Vervielfältigung des Berichts ohne schriftliche Genehmigung ist nicht zulässig.

# Analytical Chemistry

15 pages

**IBACON**

Institut für
Biologische Analytik und
Consulting IBACON GmbH

# Final Report

# Determination of Wacker BS 1701 in Samples from Repeated Dose Toxicity 28-day Oral Toxicity Study in Rats

(GLP compliant study)

**Study Completion Date: March 09, 2001**
**Author: Dr. Maria Meinerling**

**Sponsor**

Wacker-Chemie GmbH
Werk Burghausen
Johannes-Hess-Straße 24
D-84489 Burghausen
Germany

**Test Facility**

Institut für Biologische Analytik
und Consulting IBACON GmbH
Arheilger Weg 17
D-64380 Rossdorf
Germany

**Project 9546100**

HESSISCHES MINISTERIUM
FÜR UMWELT, LANDWIRTSCHAFT
UND FORSTEN

# GLP-Bescheinigung

**Bescheinigung**

Hiermit wird bestätigt, daß die Prüfeinrichtung
Institut für Biologische Analytik
in 64380 Roßdorf
Industriestraße 1
(Ort, Anschrift)
der IBACON
(Firma)
am 08. und 09 Dezember 1998
(Datum)

von der für die Überwachung zuständigen Behörden über die Einhaltung der Grundsätze der Guten Laborpraxis inspiziert worden ist.

Es wird hiermit bestätigt, daß folgende Prüfungen in dieser Prüfeinrichtung nach den Grundsätzen der Guten Laborpraxis durchgeführt werden:

Prüfungen zur Bestimmung der physikalisch-chemischen Eigenschaften und Gehaltsbestimmungen
Ökotoxikologische Prüfungen zur Bestimmung der Auswirkungen auf aquatische und terrestrische Organismen
Prüfungen zum Verhalten im Boden, im Wasser und in der Luft, Prüfungen zur Bioakkumulation und zur Metabolisierung
Prüfungen zur Bestimmung von Rückständen

**Certificate**

It is hereby certified that the test facility
Insitut für Biologische Analytik
in 64380 Roßdorf
Industriestraße 1
(location, address)
of IBACON
(company name)
on 08. und 09. Dezember 1998
(date)

was inspected by the competent authority regarding compliance with the Principles of Good Laboratory Practice.

It is hereby certified that studies in this test facility are conducted in compliance with the Principles of Good Laboratory Practice:

Physical and chemical properties and determination of content
Environmental toxicity studies on aquatic and terrestrial organisms
Behaviour in water soil and air, Bioaccumulation and metabolism
Residues

Im Auftrag

(Dr. Hecker) Wiesbaden, den 20. August 1999

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## 1. Summary


**Title:** Determination of Wacker BS 1701 in Samples from Repeated Dose Toxicity 28-day Oral Toxicity Study in Rats

**Purpose:** The purpose of the study was the determination of Wacker BS 1701 in samples received from BSL BIOSERVICE, Scientific Laboratories GmbH, Behringstr. 6, D-82152 Planegg after applications of WACKER BS 1701 in a repeated dose toxicity 28-day oral toxicity study in rats. The test item should be determined by measuring the silicon concentration using ICP.

**Summary:** Considering the results of this study, it was not possible to establish a reproducable method to determine the concentrations of Wacker BS 1701 (nominal, stability and homogenity) by either ICP-AES or graphite furnace AAS. There were two main technical reasons responsible:

In the performance of the ICP-AES analysis, there appeared an organic and a water phase in the atomizing chamber after injecting the samples, resulting in significant memory effects. Using alternate solvents like acetone, ethyl acetate, or ethanol, respectively and the technical variation using a cross flow atomizer did not give better results. Typical standard deviation of repeated analysis was 91%.

Varying the analytical method by using the graphite oven AAS did not give reproducable and acceptable results because of the formation of silicon carbide in the graphite tube, resulting in significant memory effects in the course of the measurements. Typical recovery was in the range from 14 to 181%.

## 2. Survey of the Study

### 2.1 General Information

| | |
|---|---|
| **Title:** | Determination of Wacker BS 1701 in Samples from Repeated Dose Toxicity 28-day Oral Toxicity Study in Rats |
| **Sponsor:** | Wacker-Chemie GmbH<br>Werk Burghausen<br>Johannes-Hess-Straße 24<br>D-84489 Burghausen |
| **Monitoring:** | Dr. Axel Bosch |
| **Test Item:** | Wacker BS 1701 |
| **Test Facility:** | Institut für Biologische Analytik<br>und Consulting IBACON GmbH<br>Arheilger Weg 17<br>D-64380 Rossdorf |
| **IBACON-Project:** | 9546100 |
| **Performing Laboratory:** | Arbeitsgemeinschaft<br>GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH<br>Eutinger Str. 24<br>75223 Niefern-Öschelbronn |

**Project Staff:**

| | |
|---|---|
| Test Facility Management: | Dr. Ralf Petto |
| Study Director: | Dr. Maria Meinerling |
| Principal Investigator: | Dr. Kiefer, IFU Umweltanalytik GmbH |
| Head of Quality Assurance Unit: | Dipl. Biol. Christiane Rutschmann-Fröhlich |
| Quality Assurance Managers: | Dipl. Biol. Antje Pfützner<br>Dipl. Biol. Erika Schnellbächer |

**Schedule:**

| | |
|---|---|
| Study Initiation Date: | January 08, 2001 |
| First Study Protocol Amendment: | February 14, 2001 |
| Experimental Starting Date: | January 08, 2001 |
| Experimental Completion Date: | February 01, 2001 |
| Draft Report Date: | February 19, 2001 |
| Study Completion Date: | March 09, 2001 |

## 2.2 Good Laboratory Practice

This study was performed in compliance with:

- The OECD Principles of Good Laboratory Practice (as revised in 1997) and the
- Chemikaliengesetz (*'Chemicals Act'*) der Bundesrepublik Deutschland (ChemG), Anhang 1 (*'Annex 1'*), 1994/97.

Quality Assurance of the study was the responsibility of the test facilities (i.e. IBACON GmbH and IFU Umweltanalytik GmbH) and was carried out in accordance with the GLP regulations and SOPs.
This study and/or procedures were periodically inspected by the Quality Assurance Unit (QAU) of the respective test facility and the dates and phases of the inspections are included into the final report. The data contained with the final report were audited in comparison to the raw data. A quality assurance statement, signed by the Quality Assurance Unit, will be included into the final report.

## 2.3 Archiving

The following data / sample(s) will be archived

for 15 years:
- the study protocol
- the study protocol amendment
- one certified copy of the final report

for at least 2 years:
- one sample of the test item

following the date on which the final report is audited by the Quality Assurance Unit at:

Institut für Biologische Analytik
und Consulting IBACON GmbH
Arheilger Weg 17
D-64380 Rossdorf
Germany

For the period demanded by the principles of GLP, samples of the test item and the reference item and all raw data will be stored in the archives of the performing laboratory Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH.
No raw data or material relating to the study will be discarded without the sponsor's prior consent.

## 2.4 Signatures

**Study Director:** Dr. Maria Meinerling

date: March 09, 2001

**Test Facility Management:** Dr. Ralf Petto

date: March 09, 2001

## 3. Quality Assurance Unit Statement

| | |
|---|---|
| **Test Facility:** | Institut für Biologische Analytik<br>und Consulting IBACON GmbH<br>Arheilger Weg 17<br>64380 Rossdorf<br>Germany |
| IBACON Project: | 9546100 |
| Title of the Study: | Determination of Wacker BS 1701 in Samples from Repeated Dose Toxicity 28-day Oral Toxicity Study in Rats |
| Test Item: | Wacker BS 1701 |
| Study Director: | Dr. Maria Meinerling |

The experimental phase of the analytical part of the study was not inspected but the processes of the laboratory and of the study involved are inspected in regular intervals. The pre-experiments as mentioned in the final report were not inspected.

**Study / Process based Inspections**

| Phases inspected | Dates of QAU Inspections | Dates of Reports to Study Director and to Test Facility Management |
|---|---|---|
| Study Protocol | January 08, 2001 | January 08, 2001 |
| 1st Amendment to Study Protocol | February 12, 2001 | February 14, 2001 |
| Experimental Phase (IBACON GmbH) | January 08, 2001 | January 08, 2001 |
| Experimental Phase (IFU Umweltanalytik GmbH) | September 08, 2000 | October 04, 2000 |
| Draft Report | February 20, 2001 | February 20, 2001 |
| Final Report | March 08, 2001 | March 08, 2001 |

This statement confirms that the final report reflects the raw data.

**Dipl. Biol. Antje Pfützner**

Quality Assurance Unit:

A. Pfützner

date: March 09, 2001

## 4. Statement of Compliance

| | |
|---|---|
| IBACON Project: | 9546100 |
| Title of the Study: | Determination of Wacker BS 1701 in Samples from Repeated Dose Toxicity 28-day Oral Toxicity Study in Rats |
| Test Item: | Wacker BS 1701 |
| Study Director: | Dr. Maria Meinerling |
| GLP-Regulations: | • The OECD Principles of Good Laboratory Practice (as revised in 1997) and the<br>• Chemikaliengesetz (*'Chemicals Act'*) der Bundesrepublik Deutschland (ChemG), Anhang 1 *('Annex 1')*, 1994/97. |
| Integrity of the Study: | This study (excluding pre-tests), performed in the test facility of GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, was conducted in compliance with the Good Laboratory Practice regulations. There were no circumstances that may have affected the quality or integrity of the study. |

Study Director: Dr. Maria Meinerling

Meinerling

date: March 09, 2001

## 5. Objectives of the Study

**5.1 Title**

Determination of Wacker BS 1701 in Samples from Repeated Dose Toxicity 28-day Oral Toxicity Study in Rats

**5.2 Purpose**

The purpose of the study was the determination of Wacker BS 1701 in samples received from BSL BIOSERVICE, Scientific Laboratories GmbH, Behringstr. 6, D-82152 Planegg after applications of WACKER BS 1701 in a repeated dose toxicity 28-day oral toxicity study in rats. The test item should be determined by measuring the silicon concentration using ICP.

## 6. Material and Methods

### 6.1 Test Item

The test item was applied in 28-day oral toxicity study in rats. The information concerning the test item were provided by the sponsor:

| | |
|---|---|
| Name: | Wacker BS 1701 |
| Batch No.: | KH 02343 |
| Active Ingredient(s) / Purity: | alkylalkoxysilane / 98.53 %, (GC) |
| Certificate of Analysis Ref. Code / Date: | 20.07.2000 |
| Aggregate State at RT: | liquid |
| Colour: | colourless |
| Density (at 25 °C): | 0.86 g/cm$^3$ |
| Solubility: | in water: insoluble |
| Stability: | pure: see expiry date<br>in water: stable in aqueous solution for at least 24 h |
| Expiry Date: | November 2001 |
| Storage: | in original container, at room temperature, in the dark |

### 6.2 Reference Item

The analytical standards and the information concerning the analytical standards were provided by the supplier:

| | |
|---|---|
| IUPAC Name: | Ammoniumhexafluorosilikat |
| Charge: | 80301644 |
| Product No.: | 1.12310.0100 |
| Purity: | 1000 mg/L |
| Expiry Date: | July 2001 |

### 6.3 Test System

The specimen from 28-day oral toxicity study in rats after application of Wacker BS 1701 should be examined for the concentration of the test item in the samples. The specimen and the information concerning the specimen were provided by BSL BIOSERVICE:

Test System:

| Specimen | Description |
|---|---|
| 1 | 001699 Konz 0 23.11.00 |
| 2 | 001699 Konz 30 mg/mL 23.11.00 |
| 3 | 001699 Konz 100 mg/mL 23.11.00 |
| 4 | 001699 Konz 200 mg/mL 23.11.00 |
| 5 | 001699 Konz 0 30.11.00 |
| 6 | 001699 Konz 30 mg/mL 30.11.00 |
| 7 | 001699 Konz 100 mg/mL 30.11.00 |
| 8 | 001699 Konz 200 mg/mL 30.11.00 |
| 9 | 001699 Konz 0 07.12.00 |
| 10 | 001699 Konz 30 mg/mL 07.12.00 |
| 11 | 001699 Konz 100 mg/mL 07.12.00 |
| 12 | 001699 Konz 200 mg/mL 07.12.00 |
| 13 | 001699 Konz 0 19.12.00 |
| 14 | 001699 Konz 30 mg/mL 19.12.00 |
| 15 | 001699 Konz 100 mg/mL 19.12.00 |
| 16 | 001699 Konz 200 mg/mL 19.12.00 |
| 17 | Stabilität 200 mg/mL 12.12.00 0h |
| 18 | Stabilität 200 mg/mL 12.12.00 8h |
| 19 | Stabilität 30 mg/mL 12.12.00 0h |
| 20 | Stabilität 30 mg/mL 12.12.00 8h |
| 21 | Homogenität 200 mg/mL 12.12.00 |
| 22 | Homogenität 200 mg/mL 12.12.00 |
| 23 | Homogenität 200 mg/mL 12.12.00 |
| 24 | Homogenität 30 mg/mL 12.12.00 |
| 25 | Homogenität 30 mg/mL 12.12.00 |
| 26 | Homogenität 30 mg/mL 12.12.00 |

Origin: The samples were received from BSL Bioservice Scientific Laboratories GmbH, Behringstr. 6, D-82152 Planegg. The samples were obtained from supervised study by applying Wacker BS 1701 (BSL BIOSERVICE Number of Study 001699). Collecting, processing, storage and transportation of the specimen to IBACON were at the responsibility of BSL BIOSERVICE.

Storage: All specimen were stored deep frozen and will be kept stored until 3 months following the date on which the final report is audited by the Quality Assurance Unit. The sponsor will be informed prior discarding the specimens.

### 6.4 Analytical Methods

The analytical method was provided by the sponsor and was modified to suit the purpose and the instrumentation available at the performing laboratory.

| | |
|---|---|
| Analytical Methods: | According to information of the sponsor ICP analysis was used to quantify the test item concentration. |

### 6.5 Fortification

| | |
|---|---|
| Fortification (ICP-AES): | To determine the repeatability and the recovery of the analytical method, stock solutions were prepared by weighting 100 mg test item into a 100 mL flask and mixing with N,N-Dimethylformamide and deionized water. |
| Fortification (Graphite Furnace AAS): | To determine the repeatability and the recovery of the analytical method, solutions at two concentration levels were prepared by weighing 103.4 and 203.67 mg test item, respectively, into a 100 mL flask and mixing with ethanol and deionized water. |

### 6.6 Standard Solutions

| | |
|---|---|
| Standard Solutions (ICP-AES): | Standard solutions were prepared by dilution of stock solutions of the reference item with deionized water. The nominal concentrations were 2, 4, 8 and 16 mg/L, respectively. |
| Standard Solutions (Graphite Furnace AAS): | Standard solutions were prepared by dilution of stock solutions of the reference item with deionized water. The nominal concentrations were 100, 200, 300, 400 and 500 µg/L, respectively. |

### 6.7 Analytical-Equipment

| | |
|---|---|
| ICP-System: | ICP Spectroflame D, Spectro Analytical Systems |
| AAS-System: | Perkin Elmer AAS 4100 with HGA 700 |

### 6.8 Result Evaluation

Quantitation:

Injected samples should be quantified by the measured Si-concentration with reference to the calibration curve. The latter was obtained by correlation of the measured Si-concentration of the test item in standard solutions to their corresponding concentration in mg/L. The correlation was performed using a linear regression function given by equation 1:

$y = a * x + b$ (1)

where

y = measured concentration Si in the injected samples [mg/L]

| | |
|---|---|
| | x = concentration of the test item in the injected samples [mg /L]<br>a = slope<br>b = y-axis intercept |
| Test Item Concentration: | The concentration of the test item in the treatment samples and in the control samples were calculated by equation 2:<br>$x = (y - b) / a$ (2)<br>where<br>x = test item concentration [mg/L]<br>y = Si concentration [mg/L]<br>a = slope of calibration curve<br>b = y-axis intercept of calibration curve |
| Recovery: | The recovery of the test item in a sample was calculated by equation 3:<br>$R = (c/c_{nom}) * 100\ \%$ (3)<br>where<br>R = % of nominal<br>c = concentration of the test item in sample found by equation 2 [mg/L]<br>$c_{nom}$ = nominal concentration of the test item given by the study director [mg/L] |

## 6.9 Deviations to the Study Protocol

| | |
|---|---|
| Concerning: | Analytical method |
| According to Study Protocol: | ICP analysis |
| Deviation to the Study Protocol: | The determination of silicon was alternatively tested by graphite furnace AAS. |
| Reason for the Deviation: | It was not possible to quantify the contents of the the test item by determination of silicon by ICP-AES. |
| Presumed Effect on the Study: | None |

| | |
|---|---|
| Concerning: | Result evaluation |
| According to Study Protocol: | The concentration of the test item in the treatment samples and in the control samples were calculated by equation 1 and 2: |
| Deviation to the Study Protocol: | The determination of the test item concentration was not possible. |
| Reason for the Deviation: | It was not possible to quantify the contents of the the test item by determination of silicon by ICP-AES. |
| Presumed Effect on the Study: | No verification of the test item concentration was performed. |

## 7. Results and Discussion

**ICP-AES Analysis:**

At the beginning of the measuring sequence, a calibration curve was prepared. Five concentrations (blank, 2.0 mg/L, 4.0 mg/L, 8.0 mg/L and 16 mg/L) of the reference item covering the concentration range of the test item solutions were injected.

The analysis of the test item solutions to determine the repeatability and the recovery of the analytical method, respectively, did not give reproducable and acceptable results. Typical standard deviation of repeated analysis was 91%.

The reason for this observation was the appearing phase separation of the emulsion. In the atomizing chamber of the ICP-AES, there appeared an organic and a water phase, resulting in memory effects in the course of the measurements.

The alternate sample preparation by dissolving the test item in acetone, ethyl acetate, or ethanol, respectively, and the technical equipment variation using a cross flow atomizer did not give better results.

**Graphite Furnace AAS-Analysis:**

At the beginning of the measuring sequence, a calibration curve was prepared. Six concentrations of the reference item (blank, 100 µg/L, 200 µg/L, 300 µg/L, 400 µg/L and 500 µg/L) covering the concentration range of the test item solutions were injected.

The analysis of the test item solutions to determine the repeatability and the recovery of the analytical method, respectively, did not give reproducable and acceptable results. Typical recovery was in the range from 14 to 181%.

The reason for this observation was the formation of silicon carbide in the graphite tube, resulting in memory effects in the course of the measurements.

**Conclusion:**

Considering the results of this study, it was not possible to establish a reproducable method to determine the concentrations of Wacker BS 1701 (nominal, stability and homogenity) by either ICP-AES or graphite furnace AAS.

According to RCC project 797424 the water solubility of the test item was determined to be < 0.25 mg/L. In the study no additional formation of the hydrolysis product ethanol was determined and the test item is stated to be stable in water.

However, no suitable quantification method for the test item from aqueous solution was available. Only a hyrolysis product was determined. A hydrolysis study could not be performed due to the special properties of the test item.

## 8. References

1. Chemikaliengesetz der Bundesrepublik Deutschland (ChemG), Anhang 1, in der Fassung der Bekanntmachung vom 25. Juli 1994 (BGBl. I S. 1703) mit Änderungen vom 27. September 1994 (BGBl. I S. 2705) und 14. Mai 1997 (BGBl I S. 1060)

2. The OECD Principles of Good Laboratory Practice, adopted by Council on 26th November 1997 [C(97)186/Final], Environment Directorate, Organisation for Economic Co-operation and Development, Paris 1998)

3. RCC Study Number 797242; Report Determination of the Water Solubility of WACKER BS 1701

4. RCC Study Number 797275; Draft Report Hydrolysis of WACKER BS 1701 at different pH values

## 9. Distribution of the Final Report

| | |
|---|---|
| Sponsor: | the original final report |
| IBACON: | one certified copy of the final report |