

1 - クロロ - 2,4 - ジニトロベンゼンのラット及びマウスを用いた
経口投与によるがん原性試験（混餌試験）報告書

APPENDIX

(F1～K4)

がん原性試験 NO. 0095 ; 0096

APPENDIXES (CONTINUED)

| | | |
|----------|-----|---|
| APPENDIX | F 1 | CHEMICAL INTAKE CHANGES : SUMMARY, RAT: MALE (2 - YEAR STUDY) |
| APPENDIX | F 2 | CHEMICAL INTAKE CHANGES: SUMMARY, RAT: FEMALE (2 - YEAR STUDY) |
| APPENDIX | F 3 | CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: MALE (2 - YEAR STUDY) |
| APPENDIX | F 4 | CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: FEMALE (2 - YEAR STUDY) |
| APPENDIX | G 1 | HEMATOLOGY: SUMMARY, RAT: MALE (2 - YEAR STUDY) |
| APPENDIX | G 2 | HEMATOLOGY: SUMMARY, RAT: FEMALE (2 - YEAR STUDY) |
| APPENDIX | G 3 | HEMATOLOGY: SUMMARY, MOUSE: MALE (2 - YEAR STUDY) |
| APPENDIX | G 4 | HEMATOLOGY: SUMMARY, MOUSE: FEMALE (2 - YEAR STUDY) |
| APPENDIX | H 1 | BIOCHEMISTRY: SUMMARY, RAT: MALE (2 - YEAR STUDY) |
| APPENDIX | H 2 | BIOCHEMISTRY: SUMMARY, RAT: FEMALE (2 - YEAR STUDY) |
| APPENDIX | H 3 | BIOCHEMISTRY: SUMMARY, MOUSE: MALE (2 - YEAR STUDY) |
| APPENDIX | H 4 | BIOCHEMISTRY: SUMMARY, MOUSE: FEMALE (2 - YEAR STUDY) |
| APPENDIX | I 1 | URINALYSIS: SUMMARY, RAT: MALE (2 - YEAR STUDY) |
| APPENDIX | I 2 | URINALYSIS: SUMMARY, RAT: FEMALE (2 - YEAR STUDY) |
| APPENDIX | I 3 | URINALYSIS: SUMMARY, MOUSE: MALE (2 - YEAR STUDY) |
| APPENDIX | I 4 | URINALYSIS: SUMMARY, MOUSE: FEMALE (2 - YEAR STUDY) |
| APPENDIX | J 1 | GROSS FINDINGS: SUMMARY, RAT: MALE: DEAD AND MORIBUND ANIMALS (2 - YEAR STUDY) |
| APPENDIX | J 2 | GROSS FINDINGS: SUMMARY, RAT: FEMALE: DEAD AND MORIBUND ANIMALS (2 - YEAR STUDY) |
| APPENDIX | J 3 | GROSS FINDINGS: SUMMARY, RAT: MALE: SACRIFICED ANIMALS (2 - YEAR STUDY) |

APPENDIXES (CONTINUED)

| | | |
|----------|-----|--|
| APPENDIX | J 4 | GROSS FINDINGS: SUMMARY, RAT: FEMALE: SACRIFICED ANIMALS (2 - YEAR STUDY) |
| APPENDIX | J 5 | GROSS FINDINGS: SUMMARY, MOUSE: MALE: DEAD AND MORIBUND ANIMALS (2 - YEAR STUDY) |
| APPENDIX | J 6 | GROSS FINDINGS: SUMMARY, MOUSE: FEMALE: DEAD AND MORIBUND ANIMALS (2 - YEAR STUDY) |
| APPENDIX | J 7 | GROSS FINDINGS: SUMMARY, MOUSE: MALE: SACRIFICED ANIMALS (2 - YEAR STUDY) |
| APPENDIX | J 8 | GROSS FINDINGS: SUMMARY, MOUSE: FEMALE: SACRIFICED ANIMALS (2 - YEAR STUDY) |
| APPENDIX | K 1 | ORGAN WEIGHT: ABSOLUTE: SUMMARY, RAT: MALE (2 - YEAR STUDY) |
| APPENDIX | K 2 | ORGAN WEIGHT: ABSOLUTE: SUMMARY, RAT: FEMALE (2 - YEAR STUDY) |
| APPENDIX | K 3 | ORGAN WEIGHT: ABSOLUTE: SUMMARY, MOUSE: MALE (2 - YEAR STUDY) |
| APPENDIX | K 4 | ORGAN WEIGHT: ABSOLUTE: SUMMARY, MOUSE: FEMALE (2 - YEAR STUDY) |
| APPENDIX | L 1 | ORGAN WEIGHT: RELATIVE: SUMMARY, RAT: MALE (2 - YEAR STUDY) |
| APPENDIX | L 2 | ORGAN WEIGHT: RELATIVE: SUMMARY, RAT: FEMALE (2 - YEAR STUDY) |
| APPENDIX | L 3 | ORGAN WEIGHT: RELATIVE: SUMMARY, MOUSE: MALE (2 - YEAR STUDY) |
| APPENDIX | L 4 | ORGAN WEIGHT: RELATIVE: SUMMARY, MOUSE: FEMALE (2 - YEAR STUDY) |

APPENDIX F 1

CHEMICAL INTAKE CHANGES: SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0095
ANIMAL : RAT F344
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

| Group Name | Administration (weeks) | | | | | | |
|------------|------------------------|----------------|----------------|----------------|----------------|----------------|----------------|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 26.362± 0.731 | 24.176± 0.692 | 21.953± 0.749 | 20.060± 0.717 | 18.839± 0.680 | 17.633± 0.785 | 17.038± 0.827 |
| 800 ppm | 64.930± 1.776 | 60.725± 2.174 | 55.124± 1.915 | 50.715± 1.860 | 47.425± 1.643 | 43.857± 1.566 | 41.801± 1.619 |
| 2000 ppm | 143.115± 11.549 | 150.913± 5.133 | 137.904± 4.280 | 126.094± 4.056 | 118.229± 4.309 | 110.936± 3.774 | 107.897± 4.099 |

(HAN300)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
UNIT : mg/kg/d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

| Group Name | Administration (weeks) | | | | | | | | | |
|------------|------------------------|---------------|---------------|---------------|---------------|---------------|---------------|--------------|--|--|
| | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | | |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | | |
| 320 ppm | 16.248± 0.809 | 15.458± 0.811 | 15.013± 0.789 | 14.435± 0.830 | 14.122± 0.671 | 13.573± 0.642 | 13.134± 0.637 | | | |
| 800 ppm | 39.960± 1.598 | 38.910± 1.529 | 36.779± 1.647 | 35.654± 2.057 | 34.805± 1.810 | 33.879± 1.876 | 32.830± 1.674 | | | |
| 2000 ppm | 99.338± 3.551 | 96.627± 3.673 | 93.685± 3.871 | 91.640± 4.279 | 87.627± 4.457 | 86.237± 4.091 | 84.283± 4.089 | | | |

(HAN300)

BAIS 2

STUDY NO. : 0095
 ANIMAL : RAT F344
 UNIT : mg/kg/day
 REPORT TYPE : A1 104
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

| Group Name | Administration (weeks) | | | | | | |
|------------|------------------------|---------------|---------------|---------------|---------------|---------------|---------------|
| | 16 | 18 | 20 | 22 | 24 | 26 | 28 |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 12.815± 0.567 | 12.736± 0.565 | 12.578± 0.567 | 12.284± 0.581 | 12.318± 0.555 | 12.455± 0.592 | 12.026± 0.575 |
| 800 ppm | 32.650± 1.976 | 32.076± 1.479 | 31.420± 1.528 | 30.995± 1.713 | 31.297± 1.613 | 31.371± 1.594 | 30.449± 1.846 |
| 2000 ppm | 82.026± 3.999 | 80.354± 4.083 | 79.824± 3.605 | 78.017± 4.210 | 79.154± 5.063 | 80.000± 4.690 | 76.815± 5.748 |

(HAN300)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 4

| Group Name | Administration (weeks) | | | | | | | | | |
|------------|------------------------|---------------|---------------|---------------|---------------|---------------|---------------|--------------|--|--|
| | 30 | 32 | 34 | 36 | 38 | 40 | 42 | | | |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | | |
| 320 ppm | 11.779± 0.524 | 11.561± 0.778 | 11.803± 0.604 | 11.684± 0.811 | 11.471± 0.656 | 11.438± 0.630 | 11.291± 0.559 | | | |
| 800 ppm | 29.610± 1.610 | 28.946± 1.333 | 29.833± 1.403 | 29.162± 1.476 | 29.094± 1.651 | 28.536± 1.578 | 28.216± 1.479 | | | |
| 2000 ppm | 76.547± 5.008 | 74.739± 4.454 | 76.860± 4.624 | 76.623± 3.947 | 74.957± 3.886 | 72.593± 6.648 | 73.497± 4.370 | | | |

(HAN300)

BAIS 2

STUDY NO. : 0095
 ANIMAL : RAT F344
 UNIT : mg/kg/day
 REPORT TYPE : A1 104
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

| Group Name | Administration (weeks) | | | | | | | | | |
|------------|------------------------|---------------|---------------|---------------|---------------|---------------|---------------|--------------|--|--|
| | 44 | 46 | 48 | 52 | 54 | 56 | 58 | | | |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | | |
| 320 ppm | 11.219± 0.781 | 11.181± 0.638 | 11.128± 0.649 | 10.682± 0.621 | 10.772± 0.696 | 10.830± 0.639 | 10.804± 0.625 | | | |
| 800 ppm | 28.120± 1.413 | 27.814± 1.479 | 27.770± 1.390 | 26.615± 1.858 | 26.941± 1.695 | 26.652± 1.765 | 26.645± 1.659 | | | |
| 2000 ppm | 72.939± 4.320 | 72.252± 3.721 | 69.134± 4.730 | 68.318± 3.764 | 68.401± 3.303 | 68.876± 3.287 | 69.062± 3.873 | | | |

(HAN300)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 6

| Group Name | Administration (weeks) | | | | | | | | | |
|------------|------------------------|---------------|---------------|---------------|---------------|---------------|---------------|--------------|--|--|
| | 60 | 62 | 64 | 66 | 68 | 70 | 72 | | | |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | | |
| 320 ppm | 10.820± 0.602 | 10.642± 0.668 | 10.558± 0.631 | 10.477± 0.624 | 10.396± 0.687 | 10.082± 0.700 | 10.137± 0.542 | | | |
| 800 ppm | 26.804± 1.529 | 26.472± 1.598 | 25.970± 2.008 | 26.037± 1.758 | 26.090± 1.681 | 25.245± 1.753 | 24.819± 1.889 | | | |
| 2000 ppm | 68.754± 4.103 | 69.804± 3.225 | 66.594± 5.295 | 67.752± 3.709 | 66.631± 3.738 | 65.652± 3.584 | 65.615± 3.006 | | | |

(HAN300)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 7

| Group Name | Administration (weeks) | | | | | | | | | |
|------------|------------------------|---------------|---------------|---------------|---------------|---------------|---------------|--------------|--|--|
| | 74 | 76 | 78 | 80 | 82 | 84 | 86 | | | |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | | |
| 320 ppm | 10.223± 0.629 | 10.064± 1.242 | 10.068± 1.188 | 10.122± 0.738 | 10.091± 0.885 | 10.359± 1.239 | 10.289± 1.392 | | | |
| 800 ppm | 25.819± 2.057 | 24.837± 2.119 | 25.563± 2.163 | 25.677± 2.349 | 25.818± 2.353 | 26.165± 2.408 | 25.528± 3.492 | | | |
| 2000 ppm | 65.049± 3.461 | 64.062± 3.542 | 64.897± 4.172 | 65.203± 4.528 | 65.801± 6.106 | 67.436± 4.462 | 66.670± 5.670 | | | |

(HAN300)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 8

| Group Name | Administration (weeks) | | 90 | 92 | 94 | 96 | 98 | 100 |
|------------|------------------------|--|---------------|---------------|---------------|---------------|---------------|---------------|
| | 88 | | | | | | | |
| Control | 0.000± 0.000 | | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 10.282± 1.021 | | 10.644± 0.823 | 10.675± 1.051 | 10.501± 1.762 | 10.964± 1.006 | 10.805± 1.262 | 10.508± 2.279 |
| 800 ppm | 25.416± 3.361 | | 25.968± 3.894 | 26.746± 2.346 | 27.041± 3.274 | 26.340± 4.499 | 25.841± 4.885 | 26.478± 5.396 |
| 2000 ppm | 64.450± 8.407 | | 67.447± 5.943 | 66.788± 6.228 | 66.994± 5.821 | 66.689± 8.581 | 67.365± 6.006 | 68.964± 6.829 |

(HAN300)

BATS 2

STUDY NO. : 0095
ANIMAL : RAT F344
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 9

| Group Name | Administration (weeks) |
|------------|------------------------|
| | 104 |
| Control | 0.000± 0.000 |
| 320 ppm | 11.116± 1.679 |
| 800 ppm | 25.967± 3.439 |
| 2000 ppm | 68.769± 10.575 |

(HAN300)

BAIS 2

APPENDIX F 2

CHEMICAL INTAKE CHANGES: SUMMARY,RAT: FEMALE

(13Week STUDY)

STUDY NO. : 0095
ANIMAL : RAT F344
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 10

| Group Name | Administration (weeks) | | | | | | |
|------------|------------------------|----------------|-----------------|----------------|----------------|----------------|-----------------|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 27.142± 1.039 | 25.216± 1.063 | 24.178± 1.093 | 22.429± 1.029 | 21.607± 1.112 | 20.215± 0.828 | 19.942± 2.755 |
| 800 ppm | 66.505± 2.929 | 62.828± 2.595 | 59.136± 2.741 | 55.648± 3.345 | 53.306± 2.735 | 50.914± 3.813 | 50.457± 6.386 |
| 2000 ppm | 162.768± 37.616 | 154.916± 6.807 | 146.094± 20.757 | 134.886± 5.901 | 131.161± 6.750 | 123.700± 6.156 | 124.643± 14.315 |

(HAN300)

BAIS 2

STUDY NO. : 0085
 ANIMAL : RAT F344
 UNIT : mg/kg/day
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 11

| Group Name | Administration (weeks) | | | | | | | | | |
|------------|------------------------|-----------------|-----------------|-----------------|----------------|-----------------|-----------------|--------------|--|--|
| | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | | |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | | |
| 320 ppm | 18.403± 1.070 | 18.147± 1.258 | 17.711± 1.186 | 18.231± 3.017 | 17.251± 1.291 | 17.216± 1.808 | 16.603± 1.145 | | | |
| 800 ppm | 47.405± 5.245 | 48.034± 5.927 | 46.239± 6.728 | 46.644± 6.843 | 44.605± 4.860 | 46.490± 9.035 | 44.043± 7.731 | | | |
| 2000 ppm | 115.330± 16.461 | 116.432± 16.476 | 116.203± 19.339 | 114.749± 12.887 | 109.539± 6.904 | 108.781± 14.361 | 106.166± 13.682 | | | |

(HAN300)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 12

| Group Name | Administration (weeks) | | | | | | | | | |
|------------|------------------------|----------------|-----------------|----------------|-----------------|-----------------|-----------------|--------------|--|--|
| | 16 | 18 | 20 | 22 | 24 | 26 | 28 | | | |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | | |
| 320 ppm | 16.806± 1.923 | 16.358± 2.006 | 16.168± 1.663 | 15.639± 1.112 | 16.085± 1.290 | 16.691± 1.531 | 15.921± 1.495 | | | |
| 800 ppm | 43.868± 8.451 | 41.976± 4.644 | 42.333± 5.571 | 41.470± 5.519 | 43.484± 5.840 | 44.224± 7.178 | 42.885± 7.398 | | | |
| 2000 ppm | 107.387± 12.703 | 105.314± 9.589 | 107.635± 17.418 | 103.145± 9.835 | 106.472± 10.132 | 110.138± 17.871 | 106.233± 14.225 | | | |

(HAN300)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
UNIT : mg/kg/d a y
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 13

| Group Name | Administration (weeks) | | | | | | | | | |
|------------|------------------------|-----------------|-----------------|----------------|----------------|-----------------|----------------|--------------|--|--|
| | 30 | 32 | 34 | 36 | 38 | 40 | 42 | | | |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | | |
| 320 ppm | 15.503± 1.309 | 15.662± 1.722 | 16.375± 1.837 | 15.714± 1.409 | 15.842± 1.787 | 15.856± 1.321 | 15.467± 1.360 | | | |
| 800 ppm | 41.245± 6.730 | 40.970± 5.227 | 42.330± 4.969 | 41.381± 5.463 | 42.413± 5.447 | 41.319± 5.241 | 40.869± 5.514 | | | |
| 2000 ppm | 105.301± 9.356 | 104.910± 12.121 | 106.240± 10.853 | 103.594± 8.337 | 102.725± 6.890 | 103.631± 11.004 | 104.091± 9.077 | | | |

(HAN300)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 14

| Group Name | Administration (weeks) | | | | | | | |
|------------|------------------------|---------------|-----------------|----------------|----------------|----------------|----------------|--------------|
| | 44 | 46 | 48 | 52 | 54 | 56 | 58 | |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 15.697± 1.821 | 15.065± 1.715 | 15.460± 1.870 | 15.271± 1.821 | 15.064± 1.972 | 14.912± 1.795 | 14.787± 1.548 | |
| 800 ppm | 42.102± 6.552 | 40.148± 5.728 | 41.197± 5.073 | 38.862± 6.291 | 38.706± 5.122 | 38.058± 4.077 | 38.743± 5.257 | |
| 2000 ppm | 106.719± 15.341 | 99.075± 9.242 | 101.905± 12.577 | 96.330± 11.270 | 97.277± 10.728 | 96.051± 10.145 | 99.518± 11.061 | |

(HAN300)

BAIS 2

STUDY NO. : 0095
 ANIMAL : RAT F344
 UNIT : mg/kg/day
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 15

| Group Name | Administration (weeks) | | | | | | | | | |
|------------|------------------------|---------------|---------------|----------------|---------------|---------------|----------------|--------------|--|--|
| | 60 | 62 | 64 | 66 | 68 | 70 | 72 | | | |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | | |
| 320 ppm | 14.728± 1.768 | 14.863± 1.652 | 14.606± 1.596 | 14.466± 2.018 | 14.209± 1.719 | 13.560± 1.618 | 13.491± 1.653 | | | |
| 800 ppm | 38.789± 5.317 | 38.303± 4.623 | 37.559± 4.384 | 36.979± 3.891 | 36.552± 4.351 | 35.034± 4.622 | 37.540± 7.143 | | | |
| 2000 ppm | 98.093± 9.480 | 99.834± 9.054 | 96.795± 9.691 | 96.382± 10.460 | 93.668± 9.803 | 90.220± 9.690 | 91.911± 10.551 | | | |

(HAN300)

BAIS 2

STUDY NO. : 0095
 ANIMAL : RAT F344
 UNIT : mg/kg/day
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 16

| Group Name | Administration (weeks) | | 76 | 78 | 80 | 82 | 84 | 86 |
|------------|------------------------|--|----------------|----------------|----------------|----------------|----------------|----------------|
| | 74 | | | | | | | |
| Control | 0.000± 0.000 | | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 13.559± 1.684 | | 12.705± 1.851 | 12.921± 1.623 | 12.701± 1.909 | 12.947± 1.935 | 12.953± 1.873 | 13.021± 1.916 |
| 800 ppm | 34.689± 3.841 | | 33.470± 3.985 | 33.902± 4.191 | 33.362± 4.478 | 34.227± 4.919 | 33.988± 5.635 | 33.403± 5.483 |
| 2000 ppm | 90.533± 10.720 | | 85.749± 10.246 | 87.302± 11.303 | 87.949± 11.822 | 87.212± 14.827 | 86.772± 13.913 | 87.471± 12.159 |

(HAN300)

BAIS 2

STUDY NO. : 0095
 ANIMAL : RAT F344
 UNIT : mg/kg/day
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 17

| Group Name | Administration (weeks) | | | | | | |
|------------|------------------------|----------------|----------------|----------------|----------------|----------------|----------------|
| | 88 | 90 | 92 | 94 | 96 | 98 | 100 |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 12.470± 1.871 | 12.627± 1.810 | 12.580± 1.927 | 12.704± 1.805 | 12.792± 1.951 | 12.874± 1.950 | 13.029± 1.800 |
| 800 ppm | 31.569± 6.935 | 32.280± 8.805 | 34.752± 5.930 | 33.817± 5.118 | 33.999± 5.960 | 33.251± 4.952 | 32.623± 5.071 |
| 2000 ppm | 83.297± 12.104 | 86.141± 13.209 | 82.998± 16.234 | 83.075± 19.401 | 82.218± 14.943 | 80.904± 16.669 | 80.276± 15.027 |

(HAN300)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 18

| Group Name | Administration (weeks) |
|------------|------------------------|
| | 104 |
| Control | 0.000± 0.000 |
| 320 ppm | 12.686± 2.231 |
| 800 ppm | 31.831± 6.585 |
| 2000 ppm | 81.341± 14.481 |

(HAN300)

BAIS 2

APPENDIX F 3

CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: MALE (13Week STUDY)

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
UNIT : mg/kg/d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

| Group Name | Administration (weeks) | | | | | | |
|------------|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 55.670± 3.597 | 49.384± 3.977 | 45.278± 4.156 | 48.606± 3.787 | 42.686± 2.995 | 44.983± 4.740 | 47.381± 4.052 |
| 800 ppm | 136.760± 10.363 | 123.968± 10.761 | 111.492± 9.278 | 115.920± 10.810 | 110.654± 9.223 | 114.169± 10.434 | 113.530± 10.120 |
| 2000 ppm | 356.868± 49.758 | 317.709± 34.661 | 299.415± 29.211 | 313.125± 34.327 | 270.193± 23.944 | 284.384± 28.999 | 276.572± 26.162 |

(HAN300)

BAIS2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

| Group Name | Administration (weeks) | | 9 | 10 | 11 | 12 | 13 | 14 |
|------------|------------------------|--|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | 8 | | | | | | | |
| Control | 0.000± 0.000 | | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 45.604± 3.866 | | 42.224± 2.903 | 43.370± 4.015 | 41.427± 4.488 | 41.334± 3.762 | 42.186± 3.089 | 37.296± 3.576 |
| 800 ppm | 116.152± 9.703 | | 105.367± 9.125 | 104.024± 8.493 | 109.147± 11.249 | 109.487± 10.083 | 109.638± 10.104 | 89.261± 8.825 |
| 2000 ppm | 292.435± 24.972 | | 284.628± 24.479 | 276.889± 29.050 | 288.708± 31.127 | 269.277± 20.333 | 278.997± 22.434 | 236.907± 23.070 |

(HAN300)

BAIS 2

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 UNIT : mg/kg/day
 REPORT TYPE : A1 104
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

| Group Name | Administration (weeks) | | | | | | | | | |
|------------|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|--------------|--|--|
| | 16 | 18 | 20 | 22 | 24 | 26 | 28 | | | |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | | |
| 320 ppm | 39.954± 4.140 | 39.935± 3.849 | 38.494± 5.192 | 38.906± 7.044 | 41.117± 5.671 | 42.356± 4.883 | 37.671± 3.379 | | | |
| 800 ppm | 95.539± 9.012 | 100.720± 8.580 | 89.609± 7.589 | 92.647± 6.749 | 103.169± 10.644 | 101.326± 12.595 | 91.897± 8.890 | | | |
| 2000 ppm | 254.214± 18.700 | 259.725± 22.663 | 247.871± 22.038 | 256.240± 22.632 | 266.541± 23.953 | 270.767± 25.540 | 239.078± 24.660 | | | |

(HAN300)

BAIS2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 4

| Group Name | Administration (weeks) | | 32 | 34 | 36 | 38 | 40 | 42 |
|------------|------------------------|--|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | 30 | | | | | | | |
| Control | 0.000± 0.000 | | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 37.097± 3.939 | | 34.789± 3.690 | 38.746± 3.537 | 33.928± 3.330 | 35.120± 3.317 | 37.173± 4.373 | 34.698± 3.149 |
| 800 ppm | 91.338± 8.868 | | 86.769± 7.710 | 90.605± 9.508 | 82.481± 7.327 | 87.527± 9.017 | 88.543± 8.691 | 89.473± 10.367 |
| 2000 ppm | 251.180± 24.473 | | 228.897± 19.308 | 243.530± 25.040 | 219.623± 20.849 | 236.655± 23.499 | 233.058± 24.438 | 217.339± 25.105 |

(HAN300)

BAIS2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 5

| Group Name | Administration (weeks) | | | | | | | | | | | | | |
|------------|------------------------|--------|----------|--------|----------|--------|----------|--------|----------|--------|----------|--------|----------|--------|
| | 44 | | 46 | | 48 | | 50 | | 52 | | 54 | | 56 | |
| Control | 0.000± | 0.000 | 0.000± | 0.000 | 0.000± | 0.000 | 0.000± | 0.000 | 0.000± | 0.000 | 0.000± | 0.000 | 0.000± | 0.000 |
| 320 ppm | 37.316± | 4.226 | 36.181± | 4.308 | 35.082± | 4.187 | 31.641± | 4.735 | 37.400± | 5.183 | 35.944± | 4.477 | 33.863± | 4.983 |
| 800 ppm | 94.618± | 14.451 | 91.249± | 12.369 | 82.589± | 9.151 | 80.211± | 12.868 | 95.138± | 12.647 | 82.869± | 12.272 | 83.476± | 14.363 |
| 2000 ppm | 247.100± | 26.074 | 233.980± | 22.615 | 223.056± | 25.007 | 196.573± | 27.078 | 234.270± | 25.233 | 213.909± | 23.123 | 224.986± | 25.689 |

(HAN300)

BAIS 2

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 UNIT : mg/kg/day
 REPORT TYPE : A1 104
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 6

| Group Name | Administration (weeks) | | | | | | |
|------------|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | 58 | 60 | 62 | 64 | 66 | 68 | 70 |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 34.698± 4.650 | 34.787± 4.625 | 35.350± 4.821 | 33.160± 4.438 | 31.340± 4.479 | 32.835± 4.993 | 35.667± 5.044 |
| 800 ppm | 86.022± 24.355 | 91.056± 18.470 | 88.471± 20.181 | 78.979± 18.287 | 76.467± 27.547 | 83.790± 25.646 | 92.671± 28.170 |
| 2000 ppm | 220.321± 24.456 | 234.167± 26.308 | 216.342± 24.084 | 200.049± 27.071 | 212.740± 27.641 | 212.968± 23.859 | 221.631± 30.106 |

(HAN300)

BAIS 2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 7

| Group Name | Administration (weeks) | | 74 | 76 | 78 | 80 | 82 | 84 |
|------------|------------------------|--|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | 72 | | | | | | | |
| Control | 0.000± 0.000 | | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 36.493± 5.368 | | 34.466± 5.084 | 35.735± 5.228 | 36.230± 4.813 | 37.896± 5.587 | 37.036± 5.713 | 36.785± 5.566 |
| 800 ppm | 90.000± 23.657 | | 84.632± 17.798 | 85.905± 22.264 | 88.446± 18.283 | 97.355± 18.524 | 98.504± 32.935 | 88.071± 17.324 |
| 2000 ppm | 229.515± 27.255 | | 227.371± 29.457 | 229.042± 39.781 | 249.170± 50.081 | 256.812± 56.461 | 252.292± 52.935 | 233.837± 52.067 |

(HAN300)

BAIS 2

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 UNIT : mg/kg/day
 REPORT TYPE : A1 104
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

| Group Name | Administration (weeks) | | 88 | 90 | 92 | 94 | 96 | 98 |
|------------|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|--------------|
| | 86 | 87 | | | | | | |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 36.061± 5.583 | 36.683± 6.070 | 37.117± 6.926 | 36.511± 5.508 | 35.115± 5.654 | 38.681± 6.394 | 37.380± 6.248 | |
| 800 ppm | 87.288± 20.672 | 94.750± 20.591 | 87.450± 20.804 | 84.006± 16.739 | 91.375± 26.587 | 94.602± 31.132 | 82.937± 22.922 | |
| 2000 ppm | 235.661± 49.638 | 241.177± 66.396 | 237.716± 57.170 | 224.986± 55.277 | 249.744± 51.813 | 241.440± 49.852 | 233.435± 51.912 | |

(HAN300)

BAIS2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 9

| Group Name | Administration (weeks) | | |
|------------|------------------------|-----------------|-----------------|
| | 100 | 102 | 104 |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 38.876± 6.401 | 33.974± 5.921 | 44.022± 7.551 |
| 800 ppm | 89.900± 19.028 | 105.580± 20.893 | 104.855± 21.733 |
| 2000 ppm | 263.341± 63.340 | 265.370± 75.273 | 263.143± 62.136 |

(HAN300)

BAIS 2

APPENDIX F 4

CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: FEMALE (13Week STUDY)

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 UNIT : mg/kg/day
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 10

| Group Name | Administration (weeks) | | | | | | |
|------------|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 56.369± 4.173 | 53.330± 4.624 | 52.260± 5.610 | 54.165± 4.397 | 55.739± 4.424 | 56.658± 4.490 | 55.753± 5.827 |
| 800 ppm | 141.390± 10.956 | 134.305± 11.532 | 128.638± 10.999 | 133.822± 10.775 | 144.275± 14.165 | 144.492± 14.514 | 143.993± 14.885 |
| 2000 ppm | 393.408± 54.914 | 373.288± 58.044 | 333.176± 32.679 | 339.215± 30.470 | 353.897± 35.722 | 360.308± 27.463 | 352.165± 26.995 |

(HAN300)

BAIS 2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 11

| Group Name | Administration (weeks) | | | | | | |
|------------|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 56.868± 4.929 | 56.224± 6.137 | 54.483± 4.991 | 57.217± 5.649 | 55.624± 5.793 | 57.672± 6.246 | 53.423± 5.946 |
| 800 ppm | 144.803± 12.908 | 150.340± 14.763 | 142.835± 14.468 | 141.784± 13.925 | 140.593± 14.057 | 148.961± 14.246 | 138.240± 20.927 |
| 2000 ppm | 371.600± 30.431 | 371.756± 30.973 | 349.378± 28.645 | 347.486± 27.806 | 367.138± 33.387 | 385.836± 39.035 | 361.644± 34.687 |

(HAN300)

BAIS 2

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 UNIT : mg/kg/day
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 12

| Group Name | Administration (weeks) | | | | | | |
|------------|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | 16 | 18 | 20 | 22 | 24 | 26 | 28 |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 52.476± 6.477 | 56.589± 6.885 | 49.651± 6.074 | 53.054± 6.565 | 54.052± 7.711 | 53.487± 6.364 | 47.989± 6.118 |
| 800 ppm | 128.965± 14.709 | 142.853± 15.914 | 128.500± 14.561 | 137.282± 18.248 | 146.826± 19.436 | 131.162± 15.014 | 123.786± 17.200 |
| 2000 ppm | 337.175± 29.008 | 359.096± 32.306 | 336.392± 31.458 | 359.490± 30.781 | 365.481± 44.974 | 353.930± 40.590 | 324.754± 26.387 |

(HAN300)

BAIS 2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 13

| Group Name | Administration (weeks) | | | | | | | |
|------------|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|--|
| | 30 | 32 | 34 | 36 | 38 | 40 | 42 | |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | |
| 320 ppm | 49.645± 6.602 | 46.337± 5.319 | 50.773± 6.868 | 50.991± 6.566 | 49.731± 7.483 | 45.031± 6.838 | 49.877± 6.706 | |
| 800 ppm | 125.051± 19.297 | 121.081± 13.930 | 131.021± 19.952 | 126.297± 17.721 | 131.739± 19.426 | 111.951± 14.612 | 121.020± 20.392 | |
| 2000 ppm | 323.961± 33.628 | 316.776± 30.095 | 327.736± 37.861 | 334.899± 36.430 | 353.938± 46.150 | 315.328± 33.056 | 348.117± 41.773 | |

(HAN300)

BAIS 2

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 14

| Group Name | Administration (weeks) | | | | | | |
|------------|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | 44 | 46 | 48 | 50 | 52 | 54 | 56 |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 54.265± 7.573 | 47.574± 5.531 | 48.102± 6.558 | 45.030± 5.847 | 48.835± 6.297 | 45.522± 5.495 | 44.728± 5.553 |
| 800 ppm | 137.870± 18.854 | 124.078± 17.495 | 120.414± 18.806 | 110.151± 16.422 | 129.766± 17.690 | 121.653± 16.422 | 119.864± 15.306 |
| 2000 ppm | 368.034± 53.575 | 339.672± 41.576 | 341.594± 44.821 | 276.559± 34.573 | 345.434± 45.453 | 312.981± 38.308 | 282.059± 39.870 |

(HAN300)

BAIS 2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 15

| Group Name | Administration (weeks) | | | | | | |
|------------|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | 58 | 60 | 62 | 64 | 66 | 68 | 70 |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 49.487± 7.855 | 46.943± 5.085 | 50.001± 6.661 | 42.284± 5.253 | 42.373± 5.911 | 47.818± 6.333 | 47.544± 6.927 |
| 800 ppm | 119.317± 17.205 | 127.876± 15.966 | 121.766± 17.908 | 105.091± 14.468 | 103.012± 16.125 | 120.866± 27.480 | 121.001± 15.649 |
| 2000 ppm | 312.895± 38.930 | 314.974± 39.764 | 321.095± 37.668 | 281.766± 33.876 | 297.225± 37.316 | 299.525± 39.049 | 312.485± 39.980 |

(HAN300)

BAIS 2

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 UNIT : mg/kg/day
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 16

| Group Name | Administration (weeks) | | 74 | 76 | 78 | 80 | 82 | 84 |
|------------|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|--------------|
| | 72 | | | | | | | |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 44.847± 6.384 | 42.244± 5.295 | 46.236± 6.245 | 48.133± 5.849 | 45.278± 5.993 | 49.994± 6.689 | 47.329± 6.517 | |
| 800 ppm | 113.063± 18.752 | 115.707± 27.002 | 115.854± 23.334 | 120.666± 22.049 | 127.641± 27.305 | 124.309± 31.407 | 117.803± 25.257 | |
| 2000 ppm | 306.206± 38.275 | 290.788± 39.367 | 312.696± 41.789 | 334.572± 64.452 | 331.828± 55.134 | 328.625± 56.507 | 319.260± 60.829 | |

(HAN300)

BAIS 2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 17

| Group Name | Administration (weeks) | | | | | | |
|------------|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | 86 | 88 | 90 | 92 | 94 | 96 | 98 |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 47.233± 7.061 | 45.548± 7.394 | 45.888± 6.470 | 43.810± 7.986 | 46.207± 8.153 | 47.490± 8.189 | 48.986± 8.704 |
| 800 ppm | 120.981± 27.761 | 126.434± 28.398 | 122.812± 30.187 | 116.071± 28.501 | 123.714± 34.452 | 132.026± 32.189 | 116.939± 34.281 |
| 2000 ppm | 320.850± 74.304 | 331.765± 75.177 | 329.566± 84.545 | 305.011± 61.185 | 328.372± 73.862 | 342.165± 70.400 | 309.579± 76.994 |

(HAN300)

BAIS 2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 18

| Group Name | Administration (weeks) | | |
|------------|------------------------|-----------------|-----------------|
| | 100 | 102 | 104 |
| Control | 0.000± 0.000 | 0.000± 0.000 | 0.000± 0.000 |
| 320 ppm | 47.346± 7.689 | 46.167± 6.229 | 52.472± 9.479 |
| 800 ppm | 121.303± 34.852 | 114.089± 26.685 | 126.209± 35.505 |
| 2000 ppm | 310.075± 60.609 | 316.290± 56.700 | 345.039± 90.887 |

(HAN300)

BAIS2

APPENDIX G 1

HEMATOLOGY : SUMMARY, RAT : MALE
(2-YEAR STUDY)

STUDY NO. : 0095
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

HEMATOLOGY(1) (SUMMARY)
 SURVIVAL ANIMALS (105)

PAGE : 1

| Group Name | NO. of Animals | RED BLOOD CELL 10 ⁶ /μl | | HEMOGLOBIN g/dl | | HEMATOCRIT % | | MCV fl | | MCH pg | | MCHC g/dl | | PLATELET 10 ³ /μl | |
|------------|-------------------|---------------------------------------|------|--------------------|-----|-----------------|-----|-----------|-------|-----------|------|--------------|-----|---------------------------------|-----|
| Control | 36 | 8.70± | 1.28 | 15.2± | 2.4 | 46.3± | 6.6 | 53.3± | 2.4 | 17.4± | 1.0 | 32.7± | 1.2 | 878± | 171 |
| 320 ppm | 35 | 8.58± | 1.72 | 14.7± | 3.0 | 45.0± | 8.4 | 52.6± | 3.4 | 17.1± | 1.4 | 32.5± | 1.7 | 916± | 246 |
| 800 ppm | 42 | 8.43± | 1.28 | 14.4± | 2.1 | 44.0± | 5.9 | 52.4± | 4.1** | 17.1± | 1.2 | 32.7± | 0.9 | 901± | 231 |
| 2000 ppm | 39 | 8.32± | 1.38 | 13.9± | 2.5 | 42.7± | 6.8 | 51.5± | 2.0** | 16.6± | 1.1* | 32.3± | 1.9 | 937± | 203 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0095
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

HEMATOLOGY(2) (SUMMARY)
 SURVIVAL ANIMALS (105)

PAGE : 1

| Group Name | NO. of Animals | WBC 1 O ³ /μℓ | | Differential N-BAND | | WBC (%) N-SEG | EOSINO | | BASO | | MONO | | LYMPHO | | OTHER | | |
|------------|-------------------|-----------------------------|------|------------------------|---|---------------------|--------|----|------|----|------|----|--------|-----|-------|----|---|
| Control | 36 | 4.75± | 1.47 | 2± | 2 | 48± | 11 | 2± | 2 | 0± | 0 | 4± | 2 | 43± | 10 | 2± | 3 |
| 320 ppm | 35 | 5.23± | 1.71 | 1± | 1 | 47± | 11 | 2± | 2 | 0± | 0 | 4± | 3 | 42± | 10 | 3± | 4 |
| 800 ppm | 42 | 5.09± | 1.70 | 2± | 2 | 48± | 10 | 2± | 1 | 0± | 0 | 5± | 3 | 40± | 10 | 3± | 5 |
| 2000 ppm | 39 | 6.38± | 4.14 | 1± | 1 | 49± | 12 | 1± | 1 | 0± | 0 | 4± | 2 | 42± | 11 | 2± | 2 |

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(JCL71A)

BAIS 2

APPENDIX G 2

HEMATOLOGY : SUMMARY, RAT : FEMALE
(2-YEAR STUDY)

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 2

| Group Name | NO. of Animals | RED BLOOD CELL 10 ⁶ /μl | | HEMOGLOBIN g/dl | | HEMATOCRIT % | | MCV fl | | MCH pg | | MCHC g/dl | | PLATELET 10 ⁹ /μl | |
|------------|-------------------|---------------------------------------|------|--------------------|------|-----------------|-----|-----------|-------|-----------|-------|--------------|-----|---------------------------------|------|
| Control | 40 | 7.61± | 0.94 | 14.2± | 2.1 | 43.2± | 5.4 | 56.9± | 3.8 | 18.6± | 1.6 | 32.6± | 1.8 | 659± | 157 |
| 320 ppm | 43 | 7.90± | 0.74 | 14.5± | 1.4 | 43.7± | 3.8 | 55.5± | 1.9** | 18.3± | 0.7** | 33.0± | 1.1 | 700± | 145 |
| 800 ppm | 44 | 7.60± | 1.20 | 13.8± | 2.6 | 41.9± | 6.9 | 55.1± | 2.7** | 18.0± | 1.3** | 32.6± | 2.0 | 755± | 178* |
| 2000 ppm | 34 | 7.66± | 1.09 | 13.8± | 2.1* | 42.1± | 5.6 | 55.1± | 2.9** | 17.9± | 1.2** | 32.6± | 1.9 | 709± | 136 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 2

| Group Name | NO. of Animals | WBC 10 ³ /μl | | Differential N-BAND | | WBC | (%) N-SEG | EOSINO | | BASO | | MONO | | LYMPHO | | OTHER | |
|------------|-------------------|----------------------------|------|------------------------|---|-----|--------------|--------|---|------|---|------|----|--------|----|-------|----|
| Control | 40 | 3.46± | 4.33 | 2± | 2 | 42± | 13 | 2± | 1 | 0± | 0 | 5± | 3 | 46± | 12 | 4± | 12 |
| 320 ppm | 43 | 3.13± | 2.07 | 1± | 2 | 46± | 13 | 2± | 1 | 0± | 0 | 4± | 2 | 46± | 14 | 2± | 2 |
| 800 ppm | 44 | 3.28± | 2.47 | 2± | 2 | 47± | 11 | 2± | 2 | 0± | 0 | 4± | 2 | 43± | 11 | 2± | 5 |
| 2000 ppm | 34 | 3.59± | 3.11 | 2± | 1 | 44± | 16 | 1± | 1 | 0± | 0 | 3± | 2* | 48± | 16 | 1± | 2 |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX G 3

HEMATOLOGY : SUMMARY, MOSUE : MALE
(2-YEAR STUDY)

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 1

| Group Name | NO. of Animals | RED BLOOD CELL 10 ⁶ /μl | | HEMOGLOBIN g/dl | | HEMATOCRIT % | | MCV fl | | MCH pg | | MCHC g/dl | | PLATELET 10 ³ /μl | |
|------------|-------------------|---------------------------------------|------|--------------------|-----|-----------------|-----|-----------|-----|-----------|-----|--------------|-----|---------------------------------|-----|
| Control | 36 | 9.61± | 0.68 | 14.1± | 1.2 | 43.2± | 3.7 | 45.0± | 1.6 | 14.7± | 0.6 | 32.7± | 0.7 | 2022± | 413 |
| 320 ppm | 42 | 9.49± | 0.95 | 13.9± | 1.3 | 42.5± | 3.9 | 44.9± | 2.1 | 14.7± | 0.7 | 32.7± | 0.8 | 1989± | 454 |
| 800 ppm | 40 | 9.58± | 0.96 | 13.9± | 1.4 | 42.6± | 4.5 | 44.5± | 2.0 | 14.5± | 0.7 | 32.6± | 1.1 | 1885± | 384 |
| 2000 ppm | 40 | 9.17± | 0.76 | 13.5± | 1.2 | 41.4± | 3.7 | 45.1± | 1.8 | 14.7± | 0.7 | 32.6± | 0.8 | 2038± | 454 |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

HEMATOLOGY(2) (SUMMARY)
 SURVIVAL ANIMALS (105)

PAGE : 1

| Group Name | NO. of Animals | WBC 10 ³ /μl | | Differential N-BAND | | WBC | (%) N-SEG | EOSINO | | BASO | | MONO | | LYMPHO | | OTHER | |
|------------|-------------------|----------------------------|-------|------------------------|---|-----|--------------|--------|---|------|---|------|---|--------|----|-------|---|
| Control | 36 | 2.00± | 1.09 | 1± | 1 | 34± | 16 | 2± | 2 | 0± | 0 | 2± | 2 | 62± | 15 | 0± | 1 |
| 320 ppm | 42 | 5.32± | 20.32 | 1± | 1 | 29± | 14 | 2± | 1 | 0± | 0 | 2± | 2 | 65± | 15 | 1± | 2 |
| 800 ppm | 40 | 2.09± | 1.21 | 1± | 1 | 35± | 17 | 1± | 2 | 0± | 0 | 3± | 2 | 59± | 17 | 1± | 3 |
| 2000 ppm | 40 | 2.55± | 3.66 | 1± | 1 | 37± | 15 | 2± | 3 | 0± | 0 | 3± | 3 | 56± | 15 | 1± | 3 |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(JCL71A)

BAIS 2

APPENDIX G 4

HEMATOLOGY : SUMMARY, MOSUE : FEMALE
(2-YEAR STUDY)

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
 SURVIVAL ANIMALS (105)

PAGE : 2

| Group Name | NO. of Animals | RED BLOOD CELL 10 ⁶ /μl | | HEMOGLOBIN g/dl | | HEMATOCRIT % | | MCV fl | | MCH pg | | MCHC g/dl | | PLATELET 10 ³ /μl | |
|------------|-------------------|---------------------------------------|------|--------------------|-------|-----------------|------|-----------|-----|-----------|-------|--------------|-----|---------------------------------|------|
| Control | 31 | 9.05± | 1.23 | 13.7± | 1.6 | 41.9± | 4.4 | 46.8± | 5.0 | 15.2± | 0.9 | 32.6± | 1.7 | 1044± | 438 |
| 320 ppm | 29 | 9.45± | 1.05 | 14.0± | 1.4 | 42.3± | 3.9 | 45.1± | 4.3 | 14.9± | 1.1 | 33.0± | 1.2 | 1192± | 323 |
| 800 ppm | 35 | 8.90± | 1.71 | 13.2± | 2.3 | 40.3± | 5.8 | 46.4± | 7.3 | 15.0± | 1.2 | 32.5± | 2.0 | 1170± | 357 |
| 2000 ppm | 35 | 8.83± | 1.43 | 12.7± | 2.1** | 39.4± | 6.4* | 44.5± | 2.5 | 14.4± | 0.7** | 32.3± | 1.1 | 1304± | 350* |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
 SURVIVAL ANIMALS (105)

PAGE : 2

| Group Name | NO. of Animals | WBC 1 0 ³ /μl | | Differential N-BAND | | WBC (%) N-SEG | | EOSINO | | BASO | | MONO | | LYMPHO | | OTHER | |
|------------|-------------------|-----------------------------|-------|------------------------|---|---------------------|----|--------|---|------|---|------|---|--------|----|-------|---|
| Control | 31 | 7.83± | 33.19 | 2± | 2 | 33± | 15 | 2± | 2 | 0± | 0 | 3± | 2 | 59± | 15 | 2± | 3 |
| 320 ppm | 29 | 6.00± | 24.78 | 1± | 1 | 33± | 16 | 1± | 2 | 0± | 0 | 3± | 2 | 59± | 16 | 2± | 4 |
| 800 ppm | 35 | 10.08± | 39.70 | 1± | 2 | 34± | 20 | 2± | 5 | 0± | 0 | 3± | 2 | 57± | 21 | 3± | 7 |
| 2000 ppm | 35 | 4.57± | 13.35 | 2± | 3 | 33± | 16 | 1± | 3 | 0± | 0 | 3± | 4 | 58± | 16 | 2± | 4 |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX H 1

BIOCHEMISTRY : SUMMARY, RAT : MALE
(2-YEAR STUDY)

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 1

| Group Name | NO. of Animals | TOTAL PROTEIN g/dl | | ALBUMIN g/dl | | A/G RATIO | | T-BILIRUBIN mg/dl | | GLUCOSE mg/dl | | T-CHOLESTEROL mg/dl | | TRIGLYCERIDE mg/dl | |
|------------|-------------------|-----------------------|-----|-----------------|-----|-----------|-----|----------------------|------|------------------|----|------------------------|----|-----------------------|-----|
| Control | 36 | 6.9± | 0.3 | 3.3± | 0.2 | 0.9± | 0.1 | 0.19± | 0.06 | 153± | 28 | 161± | 33 | 158± | 90 |
| 320 ppm | 35 | 6.9± | 0.3 | 3.3± | 0.2 | 0.9± | 0.1 | 0.20± | 0.08 | 157± | 24 | 153± | 42 | 136± | 67 |
| 800 ppm | 42 | 6.8± | 0.4 | 3.2± | 0.2 | 0.9± | 0.1 | 0.20± | 0.03 | 151± | 26 | 161± | 48 | 163± | 108 |
| 2000 ppm | 39 | 6.8± | 0.4 | 3.2± | 0.2 | 0.9± | 0.1 | 0.22± | 0.16 | 160± | 20 | 161± | 36 | 172± | 98 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 2

| Group Name | NO. of Animals | PHOSPHOLIPID mg/dl | | GOT IU/l | | GPT IU/l | | LDH IU/l | | ALP IU/l | | G-GTP IU/l | | CPK IU/l | |
|------------|-------------------|-----------------------|----|-------------|----|-------------|-----|-------------|-----|-------------|----|---------------|---|-------------|----|
| Control | 36 | 252± | 59 | 56± | 13 | 20± | 15 | 194± | 107 | 161± | 40 | 4± | 2 | 77± | 35 |
| 320 ppm | 35 | 240± | 70 | 57± | 14 | 15± | 3 | 194± | 94 | 177± | 91 | 4± | 2 | 69± | 20 |
| 800 ppm | 42 | 251± | 77 | 59± | 15 | 15± | 5 | 165± | 58 | 163± | 36 | 5± | 3 | 65± | 19 |
| 2000 ppm | 39 | 250± | 57 | 59± | 17 | 14± | 3** | 208± | 180 | 187± | 94 | 6± | 3 | 73± | 35 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 3

| Group Name | NO. of Animals | UREA NITROGEN mg/dl | | CREATININE mg/dl | | SODIUM mEq/l | | POTASSIUM mEq/l | | CHLORIDE mEq/l | | CALCIUM mg/dl | | INORGANIC PHOSPHORUS mg/dl | |
|------------|-------------------|------------------------|-----|---------------------|-----|-----------------|---|--------------------|-----|-------------------|---|------------------|-----|-------------------------------|-----|
| Control | 36 | 22.3± | 7.5 | 0.7± | 0.3 | 139± | 2 | 3.8± | 0.3 | 105± | 2 | 10.7± | 0.5 | 4.3± | 1.0 |
| 320 ppm | 35 | 22.8± | 5.9 | 0.7± | 0.1 | 139± | 1 | 3.9± | 0.3 | 105± | 1 | 10.6± | 0.3 | 4.3± | 0.7 |
| 800 ppm | 42 | 23.2± | 7.5 | 0.7± | 0.3 | 139± | 2 | 3.8± | 0.3 | 105± | 2 | 10.7± | 0.5 | 4.3± | 0.9 |
| 2000 ppm | 39 | 25.7± | 7.5 | 0.7± | 0.2 | 139± | 1 | 3.9± | 0.4 | 105± | 2 | 10.7± | 0.3 | 4.4± | 0.8 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX H 2

BIOCHEMISTRY : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 4

| Group Name | NO. of Animals | TOTAL PROTEIN g/dl | | ALBUMIN g/dl | | A/G RATIO | | T-BILIRUBIN mg/dl | | GLUCOSE mg/dl | | T-CHOLESTEROL mg/dl | | TRIGLYCERIDE mg/dl | |
|------------|-------------------|-----------------------|-----|-----------------|-----|-----------|-----|----------------------|------|------------------|----|------------------------|----|-----------------------|----|
| Control | 40 | 7.2± | 0.4 | 3.9± | 0.3 | 1.2± | 0.1 | 0.21± | 0.09 | 158± | 22 | 122± | 22 | 127± | 85 |
| 320 ppm | 43 | 7.3± | 0.5 | 3.9± | 0.4 | 1.2± | 0.1 | 0.20± | 0.06 | 156± | 23 | 118± | 23 | 115± | 66 |
| 800 ppm | 44 | 7.1± | 0.6 | 3.8± | 0.5 | 1.1± | 0.2 | 0.27± | 0.47 | 148± | 28 | 113± | 19 | 100± | 62 |
| 2000 ppm | 34 | 7.2± | 0.6 | 3.9± | 0.3 | 1.2± | 0.2 | 0.23± | 0.13 | 149± | 25 | 124± | 17 | 98± | 52 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 5

| Group Name | NO. of Animals | PHOSPHOLIPID mg/dl | | GOT IU/l | | GPT IU/l | | LDH IU/l | | ALP IU/l | | G-GTP IU/l | | CPK IU/l | |
|------------|-------------------|-----------------------|----|-------------|-----|-------------|----|-------------|------|-------------|-----|---------------|---|-------------|----|
| Control | 40 | 229± | 45 | 108± | 50 | 30± | 10 | 237± | 113 | 130± | 75 | 3± | 2 | 68± | 23 |
| 320 ppm | 43 | 226± | 52 | 105± | 73 | 28± | 14 | 225± | 122 | 131± | 58 | 2± | 1 | 72± | 46 |
| 800 ppm | 44 | 208± | 39 | 172± | 323 | 32± | 18 | 426± | 1292 | 194± | 366 | 3± | 3 | 75± | 48 |
| 2000 ppm | 34 | 227± | 36 | 144± | 84* | 35± | 17 | 271± | 123 | 130± | 118 | 3± | 1 | 76± | 27 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 6

| Group Name | NO. of Animals | UREA NITROGEN mg/dl | | CREATININE mg/dl | | SODIUM mEq/l | | POTASSIUM mEq/l | | CHLORIDE mEq/l | | CALCIUM mg/dl | | INORGANIC PHOSPHORUS mg/dl | |
|------------|-------------------|------------------------|-------|---------------------|-----|-----------------|---|--------------------|-----|-------------------|---|------------------|-----|-------------------------------|-----|
| Control | 40 | 16.3± | 5.1 | 0.5± | 0.1 | 139± | 2 | 3.8± | 0.5 | 105± | 2 | 10.7± | 0.4 | 4.0± | 0.8 |
| 320 ppm | 43 | 17.2± | 6.1 | 0.5± | 0.1 | 138± | 2 | 3.6± | 0.4 | 105± | 2 | 10.7± | 0.5 | 3.7± | 0.9 |
| 800 ppm | 44 | 18.9± | 11.4* | 0.5± | 0.1 | 139± | 2 | 3.8± | 0.5 | 105± | 2 | 10.6± | 0.5 | 3.8± | 0.9 |
| 2000 ppm | 34 | 18.7± | 4.5** | 0.5± | 0.1 | 138± | 2 | 3.8± | 0.5 | 105± | 2 | 10.7± | 0.4 | 3.5± | 1.0 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX H 3

BIOCHEMISTRY : SUMMARY, MOSUE : MALE
(2-YEAR STUDY)

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (105)

PAGE : 1

| Group Name | NO. of Animals | TOTAL PROTEIN g/dl | | ALBUMIN g/dl | | A/G RATIO | | T-BILIRUBIN mg/dl | | GLUCOSE mg/dl | | T-CHOLESTEROL mg/dl | | TRIGLYCERIDE mg/dl | |
|------------|-------------------|-----------------------|-------|-----------------|-----|-----------|-----|----------------------|------|------------------|----|------------------------|----|-----------------------|----|
| Control | 35 | 5.5± | 0.5 | 3.0± | 0.3 | 1.2± | 0.2 | 0.27± | 0.12 | 202± | 43 | 90± | 24 | 50± | 18 |
| 320 ppm | 42 | 5.4± | 0.8 | 2.9± | 0.4 | 1.2± | 0.2 | 0.35± | 0.20 | 203± | 38 | 92± | 33 | 59± | 34 |
| 800 ppm | 40 | 5.6± | 1.0 | 3.1± | 0.5 | 1.2± | 0.2 | 0.32± | 0.14 | 185± | 48 | 109± | 63 | 57± | 22 |
| 2000 ppm | 40 | 5.3± | 0.6** | 2.8± | 0.2 | 1.2± | 0.3 | 0.32± | 0.13 | 188± | 46 | 90± | 18 | 60± | 19 |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 2

| Group Name | NO. of Animals | GOT IU/ℓ | | GPT IU/ℓ | | LDH IU/ℓ | | ALP IU/ℓ | | CPK IU/ℓ | | UREA NITROGEN mg/dℓ | | SODIUM mEq/ℓ | |
|------------|-------------------|-------------|------|-------------|----|-------------|------|-------------|-----|-------------|------|------------------------|------|-----------------|---|
| Control | 35 | 58± | 67 | 16± | 20 | 234± | 128 | 182± | 78 | 24± | 13 | 24.3± | 19.3 | 152± | 2 |
| 320 ppm | 42 | 52± | 36 | 15± | 12 | 251± | 175 | 169± | 37 | 26± | 14 | 20.8± | 3.4 | 151± | 2 |
| 800 ppm | 40 | 104± | 170 | 33± | 64 | 379± | 374 | 207± | 208 | 36± | 34 | 21.8± | 3.9 | 152± | 2 |
| 2000 ppm | 40 | 68± | 30** | 16± | 11 | 297± | 228* | 181± | 45 | 36± | 24** | 22.8± | 13.5 | 152± | 2 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 3

| Group Name | NO. of Animals | POTASSIUM mEq/ℓ | | CHLORIDE mEq/ℓ | | CALCIUM mg/dℓ | | INORGANIC PHOSPHORUS mg/dℓ | |
|------------|-------------------|--------------------|-----|-------------------|---|------------------|-----|-------------------------------|-----|
| Control | 35 | 4.3± | 0.4 | 121± | 2 | 8.8± | 0.5 | 6.8± | 0.8 |
| 320 ppm | 42 | 4.3± | 0.4 | 121± | 3 | 8.7± | 0.5 | 6.9± | 0.8 |
| 800 ppm | 40 | 4.3± | 0.5 | 121± | 4 | 8.9± | 0.7 | 6.9± | 1.2 |
| 2000 ppm | 40 | 4.3± | 0.4 | 123± | 2 | 8.7± | 0.3 | 6.8± | 1.0 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX H 4

BIOCHEMISTRY : SUMMARY, MOSUE : FEMALE
(2-YEAR STUDY)

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 4

| Group Name | NO. of Animals | TOTAL PROTEIN g/dl | | ALBUMIN g/dl | | A/G RATIO | | T-BILIRUBIN mg/dl | | GLUCOSE mg/dl | | T-CHOLESTEROL mg/dl | | TRIGLYCERIDE mg/dl | |
|------------|-------------------|-----------------------|-----|-----------------|-----|-----------|-----|----------------------|------|------------------|----|------------------------|----|-----------------------|----|
| Control | 30 | 5.0± | 0.7 | 2.9± | 0.3 | 1.4± | 0.3 | 0.35± | 0.13 | 163± | 38 | 60± | 19 | 54± | 17 |
| 320 ppm | 28 | 5.1± | 0.6 | 2.9± | 0.2 | 1.4± | 0.3 | 0.33± | 0.14 | 165± | 42 | 63± | 20 | 56± | 16 |
| 800 ppm | 35 | 5.2± | 0.7 | 2.9± | 0.3 | 1.3± | 0.3 | 0.38± | 0.15 | 159± | 43 | 65± | 15 | 64± | 26 |
| 2000 ppm | 35 | 5.0± | 0.5 | 2.8± | 0.3 | 1.3± | 0.2 | 0.43± | 0.21 | 152± | 52 | 70± | 14 | 59± | 17 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 5

| Group Name | NO. of Animals | GOT IU/ℓ | | GPT IU/ℓ | | LDH IU/ℓ | | ALP IU/ℓ | | CPK IU/ℓ | | UREA NITROGEN mg/dℓ | | SODIUM mEq/ℓ | |
|------------|-------------------|-------------|-------|-------------|-----|-------------|------|-------------|-----|-------------|-----|------------------------|------|-----------------|----|
| Control | 30 | 134± | 216 | 46± | 132 | 544± | 946 | 309± | 177 | 46± | 38 | 18.2± | 8.3 | 150± | 2 |
| 320 ppm | 28 | 179± | 473 | 47± | 129 | 502± | 681 | 290± | 111 | 87± | 258 | 18.4± | 13.7 | 150± | 2 |
| 800 ppm | 35 | 95± | 81 | 23± | 25 | 903± | 2907 | 292± | 122 | 69± | 150 | 19.1± | 19.9 | 146± | 25 |
| 2000 ppm | 35 | 539± | 2494* | 122± | 562 | 2089± | 8330 | 344± | 141 | 130± | 204 | 20.4± | 9.0 | 150± | 4 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 6

| Group Name | NO. of Animals | POTASSIUM mEq/ℓ | | CHLORIDE mEq/ℓ | | CALCIUM mg/dℓ | | INORGANIC PHOSPHORUS mg/dℓ | |
|------------|-------------------|--------------------|-----|-------------------|-----|------------------|-----|-------------------------------|-----|
| Control | 30 | 4.3± | 0.5 | 122± | 3 | 8.9± | 0.5 | 6.5± | 1.0 |
| 320 ppm | 28 | 4.4± | 0.5 | 122± | 3 | 8.9± | 0.7 | 6.7± | 0.9 |
| 800 ppm | 35 | 4.2± | 0.9 | 120± | 21 | 8.9± | 0.6 | 6.8± | 2.5 |
| 2000 ppm | 35 | 4.7± | 1.2 | 125± | 3** | 8.7± | 0.5 | 6.8± | 1.2 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

APPENDIX I 1

URINALYSIS : SUMMARY, RAT : MALE
(2-YEAR STUDY)

STUDY NO. : 0095

URINALYSIS

ANIMAL : RAT F344

SAMPLING DATE : 104-6

SEX : MALE

REPORT TYPE : A1

PAGE : 1

| Group Name | NO. of Animals | pH | | | | | | | CHI | Protein | | | | | | CHI | Glucose | | | | | | CHI | Ketone body | | | | | | CHI | Bilirubin | | | | CHI |
|------------|-------------------|-----|-----|-----|-----|-----|-----|-----|-----|---------|---|---|----|----|----|-----|---------|---|---|----|----|----|-----|-------------|---|---|----|----|----|-----|-----------|---|----|----|-----|
| | | 5.0 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | | - | ± | + | 2+ | 3+ | 4+ | | - | ± | + | 2+ | 3+ | 4+ | | - | ± | + | 2+ | 3+ | 4+ | | - | + | 2+ | 3+ | |
| Control | 36 | 0 | 1 | 8 | 15 | 9 | 3 | 0 | | 0 | 0 | 0 | 0 | 7 | 29 | | 36 | 0 | 0 | 0 | 0 | 0 | | 34 | 2 | 0 | 0 | 0 | 0 | | 36 | 0 | 0 | 0 | |
| 320 ppm | 35 | 0 | 0 | 7 | 9 | 13 | 6 | 0 | | 0 | 0 | 0 | 0 | 9 | 26 | | 35 | 0 | 0 | 0 | 0 | 0 | | 35 | 0 | 0 | 0 | 0 | 0 | | 35 | 0 | 0 | 0 | |
| 800 ppm | 42 | 0 | 0 | 15 | 13 | 7 | 6 | 0 | | 0 | 0 | 0 | 4 | 11 | 26 | | 41 | 0 | 0 | 0 | 0 | 0 | | 41 | 0 | 0 | 0 | 0 | 0 | | 41 | 0 | 0 | 0 | |
| 2000 ppm | 41 | 1 | 1 | 10 | 12 | 15 | 2 | 0 | | 0 | 0 | 0 | 2 | 26 | 13 | ** | 41 | 0 | 0 | 0 | 0 | 0 | | 41 | 0 | 0 | 0 | 0 | 0 | | 41 | 0 | 0 | 0 | |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(JCL103)

BAIS2

STUDY NO. : 0095
ANIMAL : RAT F344
SAMPLING DATE : 104-6
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

| Group Name | NO. of Animals | Occult blood | | | | | Urobilinogen | | | | | | |
|------------|-------------------|--------------|----|---|----|----|--------------|----|---|----|----|----|-----|
| | | - | ± | + | 2+ | 3+ | CHI | ± | + | 2+ | 3+ | 4+ | CHI |
| Control | 36 | 30 | 6 | 0 | 0 | 0 | | 36 | 0 | 0 | 0 | 0 | |
| 320 ppm | 35 | 24 | 11 | 0 | 0 | 0 | | 35 | 0 | 0 | 0 | 0 | |
| 800 ppm | 42 | 32 | 7 | 2 | 0 | 0 | | 41 | 0 | 0 | 0 | 0 | |
| 2000 ppm | 41 | 33 | 5 | 3 | 0 | 0 | | 41 | 0 | 0 | 0 | 0 | |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(JCL103)

BAIS2

APPENDIX I 2

URINALYSIS : SUMMARY, RAT : FEMALE
(2-YEAR STUDY)

STUDY NO. : 0095
 ANIMAL : RAT F344
 SAMPLING DATE : 104-6
 SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 3

| Group Name | NO. of Animals | pH_____ | | | | | | | CHI | Protein_____ | | | | | | CHI | Glucose_____ | | | | | | CHI | Ketone body_____ | | | | | | CHI | Bilirubin_____ | | | | CHI |
|------------|-------------------|---------|-----|-----|-----|-----|-----|-----|-----|--------------|---|----|----|----|----|-----|--------------|---|---|----|----|----|-----|------------------|---|---|----|----|----|-----|----------------|---|----|----|-----|
| | | 5.0 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | | - | ± | + | 2+ | 3+ | 4+ | | - | ± | + | 2+ | 3+ | 4+ | | - | ± | + | 2+ | 3+ | 4+ | | - | + | 2+ | 3+ | |
| Control | 42 | 0 | 5 | 9 | 11 | 12 | 5 | 0 | | 0 | 1 | 3 | 6 | 26 | 6 | | 42 | 0 | 0 | 0 | 0 | 0 | | 35 | 7 | 0 | 0 | 0 | 0 | | 41 | 0 | 0 | 1 | |
| 320 ppm | 43 | 0 | 4 | 16 | 8 | 11 | 4 | 0 | | 0 | 1 | 9 | 17 | 13 | 3 | ** | 43 | 0 | 0 | 0 | 0 | 0 | | 40 | 3 | 0 | 0 | 0 | 0 | | 43 | 0 | 0 | 0 | |
| 800 ppm | 44 | 0 | 4 | 13 | 7 | 9 | 11 | 0 | | 0 | 5 | 15 | 17 | 7 | 0 | ** | 44 | 0 | 0 | 0 | 0 | 0 | | 42 | 2 | 0 | 0 | 0 | 0 | | 44 | 0 | 0 | 0 | |
| 2000 ppm | 35 | 0 | 5 | 5 | 10 | 9 | 6 | 0 | | 0 | 8 | 10 | 17 | 0 | 0 | ** | 35 | 0 | 0 | 0 | 0 | 0 | | 34 | 1 | 0 | 0 | 0 | 0 | * | 35 | 0 | 0 | 0 | |

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(JCL103)

BAIS2

STUDY NO. : 0095

URINALYSIS

ANIMAL : RAT F344

SAMPLING DATE : 104-6

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

| Group Name | NO. of Animats | Occult blood | | | | | Urobilinogen | | | | | | |
|------------|-------------------|--------------|---|---|----|----|--------------|----|---|----|----|----|-----|
| | | - | ± | + | 2+ | 3+ | CHI | ± | + | 2+ | 3+ | 4+ | CHI |
| Control | 42 | 39 | 2 | 0 | 1 | 0 | | 41 | 1 | 0 | 0 | 0 | |
| 320 ppm | 43 | 40 | 3 | 0 | 0 | 0 | | 43 | 0 | 0 | 0 | 0 | |
| 800 ppm | 44 | 40 | 3 | 1 | 0 | 0 | | 43 | 1 | 0 | 0 | 0 | |
| 2000 ppm | 35 | 30 | 1 | 3 | 0 | 1 | | 32 | 3 | 0 | 0 | 0 | |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(JCL103)

BATS2

APPENDIX I 3

URINALYSIS : SUMMARY, MOSUE : MALE
(2-YEAR STUDY)

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 SAMPLING DATE : 104-6
 SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 1

| Group Name | NO. of Animals | pH_____ | | | | | | | CHI | Protein_____ | | | | | CHI | Glucose_____ | | | | | CHI | Ketone body_____ | | | | | CHI | Occult blood | | | | | CHI | | | |
|------------|-------------------|---------|-----|-----|-----|-----|-----|-----|-----|--------------|---|----|----|----|-----|--------------|----|---|---|----|-----|------------------|----|----|----|---|-----|--------------|----|----|----|---|-----|---|----|----|
| | | 5.0 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | | - | ± | + | 2+ | 3+ | | 4+ | - | ± | + | 2+ | | 3+ | 4+ | - | ± | + | | 2+ | 3+ | 4+ | - | ± | | + | 2+ | 3+ |
| Control | 36 | 0 | 2 | 8 | 6 | 12 | 8 | 0 | | 0 | 1 | 13 | 22 | 0 | 0 | | 36 | 0 | 0 | 0 | 0 | 0 | | 20 | 16 | 0 | 0 | 0 | 0 | | 35 | 0 | 0 | 0 | 1 | |
| 320 ppm | 43 | 0 | 3 | 10 | 3 | 20 | 7 | 0 | | 0 | 1 | 24 | 17 | 1 | 0 | | 43 | 0 | 0 | 0 | 0 | 0 | | 28 | 15 | 0 | 0 | 0 | 0 | | 40 | 1 | 1 | 1 | 0 | |
| 800 ppm | 40 | 0 | 2 | 9 | 8 | 14 | 7 | 0 | | 0 | 0 | 21 | 18 | 1 | 0 | | 40 | 0 | 0 | 0 | 0 | 0 | | 29 | 10 | 1 | 0 | 0 | 0 | | 31 | 5 | 1 | 0 | 3 | |
| 2000 ppm | 40 | 0 | 1 | 1 | 7 | 20 | 11 | 0 | | 0 | 3 | 26 | 11 | 0 | 0 | * | 40 | 0 | 0 | 0 | 0 | 0 | | 29 | 11 | 0 | 0 | 0 | 0 | | 32 | 3 | 2 | 3 | 0 | |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(JCL104)

BAIS2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
SAMPLING DATE : 104-6
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

| Group Name | NO. of Animals | Urobilinogen ± + 2+ 3+ 4+ CHI |
|------------|-------------------|----------------------------------|
| Control | 36 | 36 0 0 0 0 |
| 320 ppm | 43 | 43 0 0 0 0 |
| 800 ppm | 40 | 40 0 0 0 0 |
| 2000 ppm | 40 | 40 0 0 0 0 |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(JCL104)

BAIS2

APPENDIX I 4

URINALYSIS : SUMMARY, MOSUE : FEMALE
(2-YEAR STUDY)

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 SAMPLING DATE : 104-6
 SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 3

| Group Name | NO. of Animals | pH | | | | | | | CHI | Protein | | | | | CHI | Glucose | | | | | CHI | Ketone body | | | | | CHI | Occult blood | | | | CHI | | | |
|------------|-------------------|-----|-----|-----|-----|-----|-----|-----|-----|---------|----|----|----|----|-----|---------|----|---|---|----|-----|-------------|----|----|----|---|-----|--------------|----|----|----|-----|---|---|----|
| | | 5.0 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | | - | ± | + | 2+ | 3+ | | 4+ | - | ± | + | 2+ | | 3+ | 4+ | - | ± | + | | 2+ | 3+ | 4+ | - | | ± | + | 2+ |
| Control | 31 | 0 | 7 | 5 | 10 | 7 | 2 | 0 | | 0 | 0 | 19 | 10 | 2 | 0 | | 31 | 0 | 0 | 0 | 0 | 0 | | 10 | 15 | 6 | 0 | 0 | 0 | | 21 | 3 | 2 | 3 | 2 |
| 320 ppm | 30 | 0 | 4 | 7 | 7 | 10 | 2 | 0 | | 0 | 2 | 20 | 8 | 0 | 0 | | 30 | 0 | 0 | 0 | 0 | 0 | | 21 | 9 | 0 | 0 | 0 | 0 | ** | 19 | 4 | 3 | 3 | 1 |
| 800 ppm | 35 | 0 | 8 | 5 | 10 | 6 | 6 | 0 | | 0 | 6 | 22 | 7 | 0 | 0 | * | 35 | 0 | 0 | 0 | 0 | 0 | | 26 | 8 | 1 | 0 | 0 | 0 | ** | 21 | 8 | 0 | 5 | 1 |
| 2000 ppm | 36 | 0 | 5 | 4 | 3 | 11 | 13 | 0 | * | 0 | 13 | 21 | 2 | 0 | 0 | ** | 36 | 0 | 0 | 0 | 0 | 0 | | 35 | 1 | 0 | 0 | 0 | 0 | ** | 20 | 4 | 5 | 3 | 4 |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(JCL104)

BAIS2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
SAMPLING DATE : 104-6
SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 4

| Group Name | NO. of Animals | Urobilinogen ± + 2+ 3+ 4+ CHI |
|------------|-------------------|----------------------------------|
| Control | 31 | 31 0 0 0 0 |
| 320 ppm | 30 | 30 0 0 0 0 |
| 800 ppm | 35 | 35 0 0 0 0 |
| 2000 ppm | 36 | 32 4 0 0 0 |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(JCL104)

BAIS2

APPENDIX J 1

GROSS FINDINGS : SUMMARY, RAT : MALE : DEAD AND MORIBUND ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0095
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 1

| Organ | Findings | Group Name NO. of Animals | Control 14 (%) | 320 ppm 15 (%) | 800 ppm 8 (%) | 2000 ppm 11 (%) |
|-------------|------------------|------------------------------|-------------------|-------------------|------------------|--------------------|
| subcutis | mass | | 5 (36) | 6 (40) | 4 (50) | 5 (45) |
| lung | red | | 2 (14) | 4 (27) | 1 (13) | 2 (18) |
| | red patch/zone | | 0 (0) | 0 (0) | 0 (0) | 1 (9) |
| | edema | | 0 (0) | 0 (0) | 1 (13) | 0 (0) |
| | nodule | | 0 (0) | 1 (7) | 0 (0) | 1 (9) |
| | mass | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| lymph node | enlarged | | 1 (7) | 1 (7) | 0 (0) | 1 (9) |
| spleen | enlarged | | 1 (7) | 2 (13) | 2 (25) | 2 (18) |
| | brown patch/zone | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| | nodule | | 2 (14) | 1 (7) | 0 (0) | 0 (0) |
| heart | mass | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| | dilated | | 0 (0) | 0 (0) | 1 (13) | 0 (0) |
| | fluid:brown | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| oral cavity | nodule | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| tongue | nodule | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| | absence | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| forestomach | ulcer | | 3 (21) | 2 (13) | 2 (25) | 1 (9) |
| gl stomach | black patch/zone | | 0 (0) | 0 (0) | 0 (0) | 1 (9) |
| | nodule | | 0 (0) | 0 (0) | 1 (13) | 0 (0) |
| | ulcer | | 0 (0) | 2 (13) | 0 (0) | 1 (9) |
| stomach | fluid:red | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| small intes | adhesion | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 2

| Organ | Findings | Group Name NO. of Animals | Control 14 (%) | 320 ppm 15 (%) | 800 ppm 8 (%) | 2000 ppm 11 (%) |
|-------------|------------------------|------------------------------|-------------------|-------------------|------------------|--------------------|
| small intes | gas | | 0 (0) | 0 (0) | 0 (0) | 1 (9) |
| large intes | nodule | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| liver | enlarged | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| | pale | | 0 (0) | 0 (0) | 0 (0) | 2 (18) |
| | nodule | | 2 (14) | 1 (7) | 0 (0) | 0 (0) |
| | herniation | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| pancreas | nodule | | 1 (7) | 1 (7) | 0 (0) | 1 (9) |
| kidney | granular | | 1 (7) | 0 (0) | 4 (50) | 3 (27) |
| | absence | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| urin bladd | urine:marked retention | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| pituitary | enlarged | | 2 (14) | 7 (47) | 1 (13) | 2 (18) |
| | red patch/zone | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| | black patch/zone | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| | hemorrhage | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| | nodule | | 2 (14) | 1 (7) | 1 (13) | 1 (9) |
| adrenal | enlarged | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| testis | enlarged | | 0 (0) | 0 (0) | 1 (13) | 0 (0) |
| | atrophic | | 2 (14) | 4 (27) | 4 (50) | 2 (18) |
| | red | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| | nodule | | 8 (57) | 9 (60) | 5 (63) | 8 (73) |
| | absence | | 1 (7) | 0 (0) | 1 (13) | 0 (0) |
| epididymis | white patch/zone | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 3

| Organ | Findings | Group Name NO. of Animals | Control 14 (%) | 320 ppm 15 (%) | 800 ppm 8 (%) | 2000 ppm 11 (%) |
|-------------|----------------|------------------------------|-------------------|-------------------|------------------|--------------------|
| epididymis | absence | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| semin ves | absence | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| brain | enlarged | | 0 (0) | 0 (0) | 0 (0) | 1 (9) |
| | red patch/zone | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| | hemorrhage | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| periph nerv | nodule | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| eye | turbid | | 0 (0) | 2 (13) | 0 (0) | 0 (0) |
| | white | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| auditory | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (9) |
| | mass | | 0 (0) | 0 (0) | 0 (0) | 1 (9) |
| muscle | mass | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| peritoneum | nodule | | 2 (14) | 0 (0) | 1 (13) | 0 (0) |
| | mass | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| retroperit | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (9) |
| abdominal c | hemorrhage | | 3 (21) | 0 (0) | 0 (0) | 0 (0) |
| | nodule | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| | mass | | 0 (0) | 0 (0) | 0 (0) | 1 (9) |
| | ascites | | 1 (7) | 0 (0) | 2 (25) | 1 (9) |
| mesenterium | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (9) |
| adipose | nodule | | 2 (14) | 0 (0) | 1 (13) | 0 (0) |
| | thick | | 0 (0) | 0 (0) | 0 (0) | 1 (9) |
| thoracic ca | hemorrhage | | 1 (7) | 1 (7) | 0 (0) | 0 (0) |

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 4

| Organ | Findings | Group Name | Control | 320 ppm | 800 ppm | 2000 ppm |
|-------------|---------------|----------------|---------|---------|---------|----------|
| | | NO. of Animals | 14 (%) | 15 (%) | 8 (%) | 11 (%) |
| thoracic ca | pleural fluid | | 2 (14) | 0 (0) | 2 (25) | 1 (9) |
| other | nodule | | 0 (0) | 2 (13) | 1 (13) | 0 (0) |
| whole body | anemic | | 2 (14) | 0 (0) | 1 (13) | 0 (0) |

(IIP080)

BAIS2

APPENDIX J 2

GROSS FINDINGS : SUMMARY, RAT : FEMALE : DEAD AND MORIBUND ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 5

| Organ | Findings | Group Name NO. of Animals | Control 8 (%) | 320 ppm 7 (%) | 800 ppm 6 (%) | 2000 ppm 15 (%) |
|-------------|------------------|------------------------------|------------------|------------------|------------------|--------------------|
| skin/app | nodule | | 0 (0) | 1 (14) | 0 (0) | 0 (0) |
| | hair | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| subcutis | jaundice | | 0 (0) | 0 (0) | 1 (17) | 0 (0) |
| | mass | | 3 (38) | 5 (71) | 4 (67) | 6 (40) |
| lung | red | | 1 (13) | 1 (14) | 1 (17) | 3 (20) |
| | red patch/zone | | 1 (13) | 0 (0) | 0 (0) | 1 (7) |
| | nodule | | 0 (0) | 0 (0) | 1 (17) | 2 (13) |
| lymph node | enlarged | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| spleen | enlarged | | 2 (25) | 3 (43) | 1 (17) | 3 (20) |
| | black patch/zone | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| | nodule | | 0 (0) | 0 (0) | 0 (0) | 2 (13) |
| heart | dilated | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| tongue | nodule | | 1 (13) | 0 (0) | 0 (0) | 0 (0) |
| forestomach | ulcer | | 1 (13) | 0 (0) | 1 (17) | 0 (0) |
| gl stomach | black patch/zone | | 0 (0) | 1 (14) | 0 (0) | 0 (0) |
| | ulcer | | 0 (0) | 1 (14) | 3 (50) | 2 (13) |
| stomach | ulcer | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| cecum | gas | | 1 (13) | 0 (0) | 0 (0) | 0 (0) |
| liver | pale | | 1 (13) | 0 (0) | 0 (0) | 1 (7) |
| | nodule | | 0 (0) | 0 (0) | 0 (0) | 2 (13) |
| | rough | | 0 (0) | 1 (14) | 0 (0) | 0 (0) |
| | herniation | | 1 (13) | 0 (0) | 1 (17) | 2 (13) |

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 6

| Organ | Findings | Group Name NO. of Animals | Control 8 (%) | 320 ppm 7 (%) | 800 ppm 6 (%) | 2000 ppm 15 (%) |
|-------------|------------------------|------------------------------|------------------|------------------|------------------|--------------------|
| pancreas | enlarged | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| | nodule | | 0 (0) | 0 (0) | 0 (0) | 2 (13) |
| kidney | white patch/zone | | 0 (0) | 1 (14) | 0 (0) | 0 (0) |
| | granular | | 1 (13) | 0 (0) | 0 (0) | 0 (0) |
| | hydronephrosis | | 0 (0) | 2 (29) | 0 (0) | 1 (7) |
| urin bladd | urine:marked retention | | 0 (0) | 2 (29) | 0 (0) | 1 (7) |
| pituitary | enlarged | | 2 (25) | 0 (0) | 1 (17) | 3 (20) |
| | red patch/zone | | 1 (13) | 1 (14) | 0 (0) | 0 (0) |
| | brown patch/zone | | 1 (13) | 0 (0) | 0 (0) | 0 (0) |
| | black patch/zone | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| | nodule | | 1 (13) | 0 (0) | 2 (33) | 1 (7) |
| adrenal | white patch/zone | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| ovary | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| uterus | enlarged | | 0 (0) | 1 (14) | 0 (0) | 0 (0) |
| | nodule | | 1 (13) | 1 (14) | 1 (17) | 4 (27) |
| brain | cyst | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| eye | turbid | | 0 (0) | 1 (14) | 0 (0) | 1 (7) |
| peritoneum | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| | adhesion | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| retroperit | mass | | 0 (0) | 0 (0) | 0 (0) | 2 (13) |
| abdominal c | hemorrhage | | 0 (0) | 0 (0) | 0 (0) | 2 (13) |
| | ascites | | 0 (0) | 3 (43) | 1 (17) | 1 (7) |

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 7

| Organ | Findings | Group Name NO. of Animals | Control 8 (%) | 320 ppm 7 (%) | 800 ppm 6 (%) | 2000 ppm 15 (%) |
|-------------|---------------|------------------------------|------------------|------------------|------------------|--------------------|
| mesenterium | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| thoracic ca | pleural fluid | | 0 (0) | 1 (14) | 0 (0) | 2 (13) |
| whole body | anemic | | 0 (0) | 1 (14) | 0 (0) | 0 (0) |

(HPT080)

BAIS2

APPENDIX J 3

GROSS FINDINGS : SUMMARY, RAT : MALE : SACRIFICED ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0095
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 1

| Organ | Findings | Group Name NO. of Animals | Control 36 (%) | 320 ppm 35 (%) | 800 ppm 42 (%) | 2000 ppm 39 (%) |
|-------------|-------------------|------------------------------|-------------------|-------------------|-------------------|--------------------|
| skin/app | nodule | | 5 (14) | 1 (3) | 0 (0) | 2 (5) |
| | scab | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| subcutis | mass | | 4 (11) | 7 (20) | 15 (36) | 9 (23) |
| lung | red patch/zone | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| | yellow patch/zone | | 1 (3) | 0 (0) | 1 (2) | 0 (0) |
| | nodule | | 4 (11) | 3 (9) | 1 (2) | 3 (8) |
| spleen | enlarged | | 4 (11) | 1 (3) | 2 (5) | 4 (10) |
| | nodule | | 1 (3) | 1 (3) | 1 (2) | 1 (3) |
| | deformed | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| | scarred | | 0 (0) | 2 (6) | 2 (5) | 0 (0) |
| oral cavity | nodule | | 0 (0) | 1 (3) | 0 (0) | 2 (5) |
| forestomach | ulcer | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| stomach | red patch/zone | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| liver | yellow patch/zone | | 1 (3) | 0 (0) | 0 (0) | 1 (3) |
| | nodule | | 1 (3) | 0 (0) | 2 (5) | 4 (10) |
| | cyst | | 0 (0) | 0 (0) | 2 (5) | 0 (0) |
| | nodular | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| | adhesion | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| | herniation | | 0 (0) | 2 (6) | 2 (5) | 3 (8) |
| pancreas | nodule | | 0 (0) | 1 (3) | 1 (2) | 0 (0) |
| kidney | enlarged | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| | cyst | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 2

| Organ | Findings | Group Name NO. of Animals | Control 36 (%) | 320 ppm 35 (%) | 800 ppm 42 (%) | 2000 ppm 39 (%) |
|-------------|----------------|------------------------------|-------------------|-------------------|-------------------|--------------------|
| kidney | granular | | 25 (69) | 25 (71) | 32 (76) | 34 (87) |
| pituitary | enlarged | | 5 (14) | 2 (6) | 1 (2) | 2 (5) |
| | red patch/zone | | 1 (3) | 3 (9) | 0 (0) | 1 (3) |
| | nodule | | 4 (11) | 6 (17) | 3 (7) | 3 (8) |
| thyroid | enlarged | | 4 (11) | 2 (6) | 6 (14) | 3 (8) |
| | nodule | | 1 (3) | 0 (0) | 1 (2) | 1 (3) |
| adrenal | enlarged | | 2 (6) | 1 (3) | 1 (2) | 2 (5) |
| testis | enlarged | | 7 (19) | 7 (20) | 12 (29) | 12 (31) |
| | atrophic | | 8 (22) | 2 (6) | 8 (19) | 4 (10) |
| | red | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| | nodule | | 32 (89) | 34 (97) | 37 (88) | 36 (92) |
| semin ves | enlarged | | 0 (0) | 0 (0) | 1 (2) | 1 (3) |
| eye | turbid | | 0 (0) | 1 (3) | 1 (2) | 0 (0) |
| | white | | 0 (0) | 1 (3) | 4 (10) | 0 (0) |
| | red | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| muscle | nodule | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| peritoneum | nodule | | 0 (0) | 0 (0) | 2 (5) | 0 (0) |
| retroperit | mass | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| | cyst | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| abdominal c | nodule | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| | ascites | | 1 (3) | 0 (0) | 1 (2) | 0 (0) |
| adipose | nodule | | 4 (11) | 6 (17) | 2 (5) | 4 (10) |

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 3

| Organ | Findings | Group Name | Control | 320 ppm | 800 ppm | 2000 ppm |
|------------|----------|----------------|---------|---------|---------|----------|
| | | NO. of Animals | 36 (%) | 35 (%) | 42 (%) | 39 (%) |
| other | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| whole body | anemic | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |

(HPT080)

BAIS2

APPENDIX J 4

GROSS FINDINGS : SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 4

| Organ | Findings | Group Name NO. of Animals | Control 42 (%) | 320 ppm 43 (%) | 800 ppm 44 (%) | 2000 ppm 35 (%) |
|-------------|------------------|------------------------------|-------------------|-------------------|-------------------|--------------------|
| skin/app | nodule | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | scab | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| subcutis | jaundice | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| | mass | | 15 (36) | 11 (26) | 12 (27) | 13 (37) |
| lung | red patch/zone | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| | nodule | | 2 (5) | 0 (0) | 1 (2) | 0 (0) |
| lymph node | enlarged | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| spleen | enlarged | | 6 (14) | 1 (2) | 1 (2) | 1 (3) |
| | nodule | | 1 (2) | 0 (0) | 0 (0) | 1 (3) |
| | deformed | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| | scarred | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| oral cavity | nodule | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| tongue | nodule | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| forestomach | ulcer | | 0 (0) | 0 (0) | 0 (0) | 2 (6) |
| gl stomach | ulcer | | 0 (0) | 1 (2) | 1 (2) | 1 (3) |
| liver | white patch/zone | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| | nodular | | 2 (5) | 0 (0) | 0 (0) | 0 (0) |
| | herniation | | 2 (5) | 2 (5) | 4 (9) | 4 (11) |
| kidney | cyst | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| | deformed | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| | granular | | 3 (7) | 3 (7) | 1 (2) | 2 (6) |
| | nodular | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 5

| Organ | Findings | Group Name NO. of Animals | Control 42 (%) | 320 ppm 43 (%) | 800 ppm 44 (%) | 2000 ppm 35 (%) |
|------------|------------------------|------------------------------|-------------------|-------------------|-------------------|--------------------|
| urin bladd | urine:marked retention | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| pituitary | enlarged | | 10 (24) | 9 (21) | 7 (16) | 6 (17) |
| | white patch/zone | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| | red patch/zone | | 2 (5) | 4 (9) | 3 (7) | 4 (11) |
| | nodule | | 6 (14) | 7 (16) | 10 (23) | 4 (11) |
| thyroid | enlarged | | 0 (0) | 3 (7) | 3 (7) | 2 (6) |
| | nodule | | 1 (2) | 1 (2) | 2 (5) | 2 (6) |
| adrenal | enlarged | | 2 (5) | 2 (5) | 0 (0) | 2 (6) |
| ovary | nodule | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| | cyst | | 0 (0) | 2 (5) | 2 (5) | 1 (3) |
| | fluid:transparent | | 1 (2) | 2 (5) | 0 (0) | 2 (6) |
| uterus | enlarged | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | atrophic | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | nodule | | 8 (19) | 6 (14) | 7 (16) | 5 (14) |
| | dilated lumen | | 0 (0) | 1 (2) | 1 (2) | 3 (9) |
| vagina | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| eye | turbid | | 1 (2) | 2 (5) | 0 (0) | 1 (3) |
| | white | | 0 (0) | 2 (5) | 2 (5) | 0 (0) |
| auditory | nodule | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| adipose | nodule | | 2 (5) | 2 (5) | 1 (2) | 2 (6) |
| whole body | anemic | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |

APPENDIX J 5

GROSS FINDINGS : SUMMARY, MOSUE : MALE : DEAD AND MORIBUND ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 1

| Organ | Findings | Group Name NO. of Animals | Control 14 (%) | 320 ppm 7 (%) | 800 ppm 10 (%) | 2000 ppm 10 (%) |
|-------------|----------------------------|------------------------------|-------------------|------------------|-------------------|--------------------|
| skin/app | nodule | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| | thick | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |
| subcutis | edema | | 2 (14) | 0 (0) | 2 (20) | 0 (0) |
| | mass | | 0 (0) | 1 (14) | 0 (0) | 1 (10) |
| lung | red | | 1 (7) | 0 (0) | 2 (20) | 0 (0) |
| | red patch/zone | | 1 (7) | 0 (0) | 1 (10) | 0 (0) |
| | nodule | | 2 (14) | 1 (14) | 2 (20) | 0 (0) |
| lymph node | enlarged | | 2 (14) | 2 (29) | 3 (30) | 2 (20) |
| thymus | enlarged | | 0 (0) | 1 (14) | 0 (0) | 0 (0) |
| spleen | enlarged | | 3 (21) | 1 (14) | 3 (30) | 2 (20) |
| | accentuation of white pulp | | 1 (7) | 0 (0) | 1 (10) | 0 (0) |
| heart | dilated | | 2 (14) | 0 (0) | 2 (20) | 0 (0) |
| tooth | absence | | 1 (7) | 0 (0) | 1 (10) | 0 (0) |
| salivary gl | enlarged | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| | nodule | | 0 (0) | 1 (14) | 0 (0) | 0 (0) |
| forestomach | nodule | | 0 (0) | 0 (0) | 1 (10) | 0 (0) |
| gl stomach | ulcer | | 0 (0) | 0 (0) | 1 (10) | 0 (0) |
| stomach | fluid:brown | | 0 (0) | 0 (0) | 1 (10) | 0 (0) |
| duodenum | nodule | | 0 (0) | 1 (14) | 0 (0) | 0 (0) |
| | fluid:brown | | 0 (0) | 0 (0) | 1 (10) | 0 (0) |
| jejunum | red | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| ileum | red | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 2

| Organ | Findings | Group Name NO. of Animals | Control 14 (%) | 320 ppm 7 (%) | 800 ppm 10 (%) | 2000 ppm 10 (%) |
|------------|------------------------|------------------------------|-------------------|------------------|-------------------|--------------------|
| ileum | nodule | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| liver | enlarged | | 1 (7) | 0 (0) | 1 (10) | 1 (10) |
| | pale | | 1 (7) | 0 (0) | 0 (0) | 1 (10) |
| | white | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |
| | white patch/zone | | 2 (14) | 1 (14) | 1 (10) | 0 (0) |
| | red patch/zone | | 1 (7) | 0 (0) | 1 (10) | 0 (0) |
| | nodule | | 8 (57) | 0 (0) | 3 (30) | 3 (30) |
| | rough | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| | nodular | | 1 (7) | 1 (14) | 0 (0) | 0 (0) |
| | | | | | | |
| gall bladd | fluid:red | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| | fluid:black | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |
| pancreas | nodule | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| kidney | pale | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| | nodule | | 1 (7) | 1 (14) | 0 (0) | 0 (0) |
| | cyst | | 0 (0) | 1 (14) | 0 (0) | 0 (0) |
| | hydronephrosis | | 1 (7) | 0 (0) | 1 (10) | 0 (0) |
| urin bladd | nodule | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| | urine:marked retention | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |
| pituitary | enlarged | | 0 (0) | 1 (14) | 0 (0) | 0 (0) |
| epididymis | nodule | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| semin ves | nodule | | 0 (0) | 0 (0) | 0 (0) | 2 (20) |
| prostate | enlarged | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 3

| Organ | Findings | Group Name NO. of Animals | Control 14 (%) | 320 ppm 7 (%) | 800 ppm 10 (%) | 2000 ppm 10 (%) |
|-------------|----------------|------------------------------|-------------------|------------------|-------------------|--------------------|
| prostate | red patch/zone | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |
| | nodule | | 0 (0) | 1 (14) | 0 (0) | 0 (0) |
| brain | cyst | | 0 (0) | 0 (0) | 1 (10) | 0 (0) |
| periph nerv | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |
| Harder gl | enlarged | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |
| | nodule | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| muscle | mass | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| mediastinum | nodule | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| retroperit | nodule | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| abdominal c | hemorrhage | | 1 (7) | 0 (0) | 1 (10) | 3 (30) |
| | mass | | 0 (0) | 0 (0) | 1 (10) | 0 (0) |
| | ascites | | 1 (7) | 0 (0) | 2 (20) | 3 (30) |
| mesenterium | nodule | | 3 (21) | 0 (0) | 0 (0) | 0 (0) |
| adipose | brown | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| | red patch/zone | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| | nodule | | 1 (7) | 2 (28) | 0 (0) | 0 (0) |
| thoracic ca | pleural fluid | | 3 (21) | 0 (0) | 3 (30) | 1 (10) |
| whole body | anemic | | 1 (7) | 0 (0) | 1 (10) | 0 (0) |
| | wasting | | 0 (0) | 1 (14) | 0 (0) | 0 (0) |

APPENDIX J 6

GROSS FINDINGS : SUMMARY, MOSUE : FEMALE : DEAD AND MORIBUND ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 4

| Organ | Findings | Group Name NO. of Animals | Control 19 (%) | 320 ppm 20 (%) | 800 ppm 15 (%) | 2000 ppm 15 (%) |
|-------------|------------------|------------------------------|-------------------|-------------------|-------------------|--------------------|
| subcutis | edema | | 6 (32) | 4 (20) | 2 (13) | 2 (13) |
| | mass | | 1 (5) | 3 (15) | 2 (13) | 2 (13) |
| lung | red | | 1 (5) | 2 (10) | 2 (13) | 1 (7) |
| | red patch/zone | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| | congestion | | 1 (5) | 1 (5) | 0 (0) | 0 (0) |
| | edema | | 0 (0) | 1 (5) | 0 (0) | 0 (0) |
| | nodule | | 2 (11) | 1 (5) | 2 (13) | 0 (0) |
| | atelectasis | | 0 (0) | 0 (0) | 1 (7) | 0 (0) |
| lymph node | enlarged | | 5 (26) | 6 (30) | 3 (20) | 3 (20) |
| thymus | enlarged | | 1 (5) | 0 (0) | 0 (0) | 0 (0) |
| spleen | enlarged | | 4 (21) | 5 (25) | 5 (33) | 3 (20) |
| | nodule | | 2 (11) | 1 (5) | 0 (0) | 0 (0) |
| heart | dilated | | 1 (5) | 0 (0) | 2 (13) | 1 (7) |
| gl stomach | black patch/zone | | 1 (5) | 1 (5) | 1 (7) | 0 (0) |
| | ulcer | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| stomach | nodule | | 0 (0) | 1 (5) | 0 (0) | 0 (0) |
| | gas | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| | fluid:red | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| jejunum | nodule | | 0 (0) | 1 (5) | 0 (0) | 0 (0) |
| ileum | nodule | | 0 (0) | 1 (5) | 0 (0) | 0 (0) |
| | erosion | | 0 (0) | 0 (0) | 1 (7) | 0 (0) |
| large intes | gas | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 5

| Organ | Findings | Group Name NO. of Animals | Control 19 (%) | 320 ppm 20 (%) | 800 ppm 15 (%) | 2000 ppm 15 (%) |
|------------|------------------------|------------------------------|-------------------|-------------------|-------------------|--------------------|
| liver | enlarged | | 2 (11) | 2 (10) | 0 (0) | 1 (7) |
| | pale | | 0 (0) | 0 (0) | 2 (13) | 0 (0) |
| | white | | 1 (5) | 0 (0) | 0 (0) | 0 (0) |
| | white patch/zone | | 3 (16) | 4 (20) | 2 (13) | 1 (7) |
| | red patch/zone | | 1 (5) | 0 (0) | 1 (7) | 0 (0) |
| | congestion | | 1 (5) | 0 (0) | 0 (0) | 0 (0) |
| | nodule | | 4 (21) | 2 (10) | 3 (20) | 3 (20) |
| | granular | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| | nodular | | 2 (11) | 1 (5) | 1 (7) | 1 (7) |
| | adhesion | | 0 (0) | 1 (5) | 0 (0) | 0 (0) |
| pancreas | nodule | | 0 (0) | 2 (10) | 0 (0) | 1 (7) |
| kidney | enlarged | | 0 (0) | 1 (5) | 3 (20) | 0 (0) |
| | pale | | 2 (11) | 1 (5) | 0 (0) | 0 (0) |
| | brown | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| | white patch/zone | | 0 (0) | 1 (5) | 0 (0) | 0 (0) |
| | granular | | 0 (0) | 0 (0) | 0 (0) | 2 (13) |
| | hydronephrosis | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| | fluid:brown | | 0 (0) | 1 (5) | 0 (0) | 0 (0) |
| urin bladd | urine:marked retention | | 1 (5) | 0 (0) | 0 (0) | 1 (7) |
| pituitary | enlarged | | 0 (0) | 1 (5) | 0 (0) | 0 (0) |
| | nodule | | 0 (0) | 2 (10) | 0 (0) | 0 (0) |
| ovary | enlarged | | 2 (11) | 5 (25) | 1 (7) | 0 (0) |

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 6

| Organ | Findings | Group Name NO. of Animals | Control 19 (%) | 320 ppm 20 (%) | 800 ppm 15 (%) | 2000 ppm 15 (%) |
|-------------|-------------------|------------------------------|-------------------|-------------------|-------------------|--------------------|
| ovary | cyst | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| | fluid | | 0 (0) | 2 (10) | 1 (7) | 0 (0) |
| | fluid:red | | 1 (5) | 0 (0) | 0 (0) | 1 (7) |
| | fluid:transparent | | 1 (5) | 2 (10) | 2 (13) | 2 (13) |
| uterus | enlarged | | 1 (5) | 4 (20) | 2 (13) | 0 (0) |
| | nodule | | 5 (26) | 4 (20) | 4 (27) | 4 (27) |
| | mass | | 1 (5) | 0 (0) | 0 (0) | 0 (0) |
| | nodular | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| | dilated | | 0 (0) | 0 (0) | 1 (7) | 0 (0) |
| | dilated lumen | | 2 (11) | 0 (0) | 0 (0) | 2 (13) |
| periph nerv | swollen | | 0 (0) | 0 (0) | 1 (7) | 0 (0) |
| eye | red | | 0 (0) | 0 (0) | 1 (7) | 0 (0) |
| Harder gl | enlarged | | 1 (5) | 0 (0) | 0 (0) | 0 (0) |
| | nodule | | 0 (0) | 1 (5) | 0 (0) | 0 (0) |
| mediastinum | mass | | 1 (5) | 0 (0) | 0 (0) | 2 (13) |
| peritoneum | nodule | | 0 (0) | 0 (0) | 1 (7) | 1 (7) |
| | mass | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| | nodular | | 0 (0) | 0 (0) | 1 (7) | 0 (0) |
| retroperit | mass | | 0 (0) | 0 (0) | 0 (0) | 1 (7) |
| abdominal c | hemorrhage | | 1 (5) | 3 (15) | 2 (13) | 3 (20) |
| | ascites | | 5 (26) | 6 (30) | 3 (20) | 4 (27) |
| adipose | thick | | 1 (5) | 0 (0) | 0 (0) | 0 (0) |

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 7

| Organ | Findings | Group Name NO. of Animals | Control 19 (%) | 320 ppm 20 (%) | 800 ppm 15 (%) | 2000 ppm 15 (%) |
|-------------|---------------|------------------------------|-------------------|-------------------|-------------------|--------------------|
| thoracic ca | hemorrhage | | 0 (0) | 1 (5) | 1 (7) | 0 (0) |
| | pleural fluid | | 5 (26) | 8 (40) | 5 (33) | 7 (47) |
| whole body | anemic | | 2 (11) | 1 (5) | 1 (7) | 2 (13) |
| | wasting | | 1 (5) | 1 (5) | 0 (0) | 0 (0) |

(HPT080)

BAIS2

APPENDIX J 7

GROSS FINDINGS : SUMMARY, MOSUE : MALE : SACRIFICED ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 1

| Organ | Findings | Group Name NO. of Animals | Control 36 (%) | 320 ppm 43 (%) | 800 ppm 40 (%) | 2000 ppm 40 (%) |
|-------------|----------------------------|------------------------------|-------------------|-------------------|-------------------|--------------------|
| skin/app | scab | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| subcutis | mass | | 1 (3) | 0 (0) | 1 (3) | 0 (0) |
| lung | white | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| | white patch/zone | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| | nodule | | 11 (31) | 4 (9) | 9 (23) | 6 (15) |
| lymph node | enlarged | | 2 (6) | 5 (12) | 6 (15) | 4 (10) |
| | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| thymus | enlarged | | 2 (6) | 0 (0) | 0 (0) | 0 (0) |
| | nodule | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| spleen | enlarged | | 0 (0) | 1 (2) | 1 (3) | 5 (13) |
| | white patch/zone | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| | black patch/zone | | 0 (0) | 2 (5) | 2 (5) | 0 (0) |
| | nodule | | 3 (8) | 2 (5) | 2 (5) | 2 (5) |
| | adhesion | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| | accentuation of white pulp | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| salivary gl | nodule | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| forestomach | nodule | | 0 (0) | 1 (2) | 0 (0) | 1 (3) |
| stomach | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| jejunum | nodule | | 1 (3) | 0 (0) | 1 (3) | 0 (0) |
| liver | white patch/zone | | 1 (3) | 2 (5) | 3 (8) | 0 (0) |
| | red patch/zone | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| | nodule | | 9 (25) | 9 (21) | 12 (30) | 11 (28) |

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 2

| Organ | Findings | Group Name NO. of Animals | Control 36 (%) | 320 ppm 43 (%) | 800 ppm 40 (%) | 2000 ppm 40 (%) |
|-------------|------------------|------------------------------|-------------------|-------------------|-------------------|--------------------|
| Liver | deformed | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| pancreas | nodule | | 0 (0) | 1 (2) | 1 (3) | 1 (3) |
| | cyst | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| kidney | adhesion | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| | hydronephrosis | | 1 (3) | 0 (0) | 2 (5) | 0 (0) |
| urin bladd | thick | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| thyroid | dark | | 0 (0) | 0 (0) | 0 (0) | 40 (100) |
| testis | atrophic | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| | white patch/zone | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| | absence | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| epididymis | red patch/zone | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| | nodule | | 1 (3) | 1 (2) | 1 (3) | 0 (0) |
| semin ves | enlarged | | 3 (8) | 1 (2) | 1 (3) | 1 (3) |
| | brown | | 6 (17) | 0 (0) | 2 (5) | 0 (0) |
| | red patch/zone | | 1 (3) | 0 (0) | 1 (3) | 0 (0) |
| | nodule | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| prep/cli gl | nodule | | 7 (19) | 13 (30) | 9 (23) | 6 (15) |
| peritoneum | adhesion | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| retroperit | mass | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| abdominal c | ascites | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| mesenterium | hemorrhage | | 0 (0) | 2 (5) | 0 (0) | 0 (0) |
| adipose | nodule | | 5 (14) | 6 (14) | 7 (18) | 9 (23) |

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 3

| Organ | Findings | Group Name NO. of Animals | Control | 320 ppm | 800 ppm | 2000 ppm |
|-------------|----------|------------------------------|---------|---------|---------|----------|
| | | | 36 (%) | 43 (%) | 40 (%) | 40 (%) |
| thoracic ca | nodule | | 0 (0) | 2 (5) | 0 (0) | 0 (0) |
| whole body | anemic | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |

(HPT080)

BAIS2

APPENDIX J 8

GROSS FINDINGS : SUMMARY, MOSUE : FEMALE : SACRIFICED ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0096
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 4

| Organ | Findings | Group Name NO. of Animals | Control 31 (%) | 320 ppm 30 (%) | 800 ppm 35 (%) | 2000 ppm 35 (%) |
|-------------|----------------------------|------------------------------|-------------------|-------------------|-------------------|--------------------|
| skin/app | nodule | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| subcutis | mass | | 2 (6) | 0 (0) | 0 (0) | 1 (3) |
| lung | white patch/zone | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| | nodule | | 3 (10) | 3 (10) | 4 (11) | 1 (3) |
| lymph node | enlarged | | 4 (13) | 3 (10) | 3 (9) | 5 (14) |
| | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| thymus | enlarged | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| | dark | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| spleen | enlarged | | 4 (13) | 1 (3) | 5 (14) | 3 (9) |
| | white patch/zone | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| | black patch/zone | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| | nodule | | 1 (3) | 0 (0) | 1 (3) | 2 (6) |
| | deformed | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| | accentuation of white pulp | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| forestomach | nodule | | 0 (0) | 1 (3) | 1 (3) | 1 (3) |
| stomach | black patch/zone | | 0 (0) | 1 (3) | 0 (0) | 1 (3) |
| | ulcer | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| large intes | thick | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| liver | enlarged | | 3 (10) | 0 (0) | 1 (3) | 1 (3) |
| | atrophic | | 1 (3) | 0 (0) | 1 (3) | 1 (3) |
| | white patch/zone | | 2 (6) | 0 (0) | 3 (9) | 0 (0) |
| | red patch/zone | | 0 (0) | 0 (0) | 1 (3) | 2 (6) |

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 5

| Organ | Findings | Group Name NO. of Animals | Control 31 (%) | 320 ppm 30 (%) | 800 ppm 35 (%) | 2000 ppm 35 (%) |
|------------|-------------------|------------------------------|-------------------|-------------------|-------------------|--------------------|
| liver | yellow patch/zone | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| | black patch/zone | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| | nodule | | 4 (13) | 7 (23) | 10 (29) | 4 (11) |
| | deformed | | 0 (0) | 0 (0) | 2 (6) | 0 (0) |
| | adhesion | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| gall bladd | dilated | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| pancreas | nodule | | 0 (0) | 0 (0) | 2 (6) | 3 (9) |
| kidney | enlarged | | 0 (0) | 1 (3) | 0 (0) | 1 (3) |
| | pale | | 1 (3) | 0 (0) | 1 (3) | 0 (0) |
| | white patch/zone | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| | nodule | | 0 (0) | 1 (3) | 1 (3) | 1 (3) |
| | hydronephrosis | | 1 (3) | 1 (3) | 3 (9) | 2 (6) |
| pituitary | enlarged | | 0 (0) | 2 (7) | 0 (0) | 0 (0) |
| | red patch/zone | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| | nodule | | 1 (3) | 3 (10) | 0 (0) | 1 (3) |
| | cyst | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| thyroid | dark | | 0 (0) | 0 (0) | 2 (6) | 33 (94) |
| adrenal | enlarged | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| ovary | enlarged | | 0 (0) | 1 (3) | 0 (0) | 1 (3) |
| | cyst | | 0 (0) | 0 (0) | 1 (3) | 1 (3) |
| | fluid:red | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| | fluid:transparent | | 10 (32) | 14 (47) | 11 (31) | 13 (37) |

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 6

| Organ | Findings | Group Name NO. of Animals | Control 31 (%) | 320 ppm 30 (%) | 800 ppm 35 (%) | 2000 ppm 35 (%) |
|-------------|----------------|------------------------------|-------------------|-------------------|-------------------|--------------------|
| uterus | nodule | | 7 (23) | 3 (10) | 4 (11) | 4 (11) |
| | nodular | | 7 (23) | 10 (33) | 7 (20) | 11 (31) |
| | dilated lumen | | 0 (0) | 1 (3) | 2 (6) | 0 (0) |
| brain | red patch/zone | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| Harder gl | white | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| | nodule | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| muscle | nodule | | 1 (3) | 0 (0) | 0 (0) | 1 (3) |
| mediastinum | mass | | 0 (0) | 1 (3) | 1 (3) | 1 (3) |
| peritoneum | nodule | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| retroperit | nodule | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| | mass | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| abdominal c | ascites | | 3 (10) | 1 (3) | 3 (9) | 0 (0) |
| adipose | nodule | | 2 (6) | 1 (3) | 2 (6) | 2 (6) |
| | thick | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| thoracic ca | pleural fluid | | 1 (3) | 2 (7) | 2 (6) | 1 (3) |

APPENDIX K 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : MALE
(2-YEAR STUDY)

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 1

| Group Name | NO. of Animals | Body Weight | | ADRENALS | | TESTES | | HEART | | LUNGS | | KIDNEYS | |
|------------|-------------------|-------------|------|----------|--------|--------|-------|--------|-------|--------|-------|---------|-------|
| Control | 36 | 422± | 25 | 0.079± | 0.025 | 4.481± | 1.805 | 1.259± | 0.102 | 1.396± | 0.075 | 3.046± | 0.440 |
| 320 ppm | 35 | 416± | 32 | 0.118± | 0.255 | 4.892± | 1.332 | 1.235± | 0.128 | 1.416± | 0.103 | 3.003± | 0.211 |
| 800 ppm | 42 | 415± | 52 | 0.079± | 0.042 | 4.734± | 1.913 | 1.226± | 0.083 | 1.403± | 0.059 | 3.289± | 1.028 |
| 2000 ppm | 39 | 388± | 33** | 0.166± | 0.603* | 4.624± | 1.862 | 1.240± | 0.160 | 1.440± | 0.280 | 3.022± | 0.267 |

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 2

| Group Name | NO. of Animals | SPLEEN | | LIVER | | BRAIN | |
|------------|-------------------|--------|-------|---------|-------|--------|-------|
| Control | 36 | 1.223± | 0.484 | 12.219± | 1.405 | 2.038± | 0.054 |
| 320 ppm | 35 | 1.199± | 0.286 | 12.130± | 1.108 | 2.040± | 0.054 |
| 800 ppm | 42 | 1.225± | 0.344 | 12.861± | 1.782 | 2.042± | 0.052 |
| 2000 ppm | 39 | 1.204± | 0.465 | 12.812± | 1.535 | 2.041± | 0.053 |

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL040)

BAIS2

APPENDIX K 2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : FEMALE
(2-YEAR STUDY)

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 1

| Group Name | NO. of Animals | Body Weight | ADRENALS | TESTES | HEART | LUNGS | KIDNEYS |
|------------|-------------------|-------------|--------------|--------------|--------------|--------------|--------------|
| Control | 36 | 39.7± 5.9 | 0.009± 0.002 | 0.220± 0.026 | 0.181± 0.013 | 0.208± 0.077 | 0.623± 0.332 |
| 320 ppm | 43 | 40.5± 6.3 | 0.009± 0.002 | 0.208± 0.032 | 0.177± 0.016 | 0.194± 0.029 | 0.578± 0.163 |
| 800 ppm | 40 | 39.4± 6.5 | 0.009± 0.002 | 0.204± 0.031 | 0.183± 0.019 | 0.208± 0.096 | 0.622± 0.347 |
| 2000 ppm | 40 | 38.1± 5.9 | 0.009± 0.002 | 0.211± 0.023 | 0.185± 0.013 | 0.200± 0.044 | 0.544± 0.053 |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL040)

BAIS2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 2

| Group Name | NO. of Animals | SPLEEN | | LIVER | | BRAIN | |
|------------|-------------------|--------|-------|--------|-------|--------|-------|
| Control | 36 | 0.086± | 0.107 | 1.265± | 0.234 | 0.457± | 0.012 |
| 320 ppm | 43 | 0.104± | 0.174 | 1.320± | 0.329 | 0.453± | 0.015 |
| 800 ppm | 40 | 0.095± | 0.109 | 1.447± | 0.595 | 0.457± | 0.022 |
| 2000 ppm | 40 | 0.156± | 0.238 | 1.283± | 0.228 | 0.448± | 0.016 |

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL040)

BAIS2

APPENDIX K 3

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : MALE
(2-YEAR STUDY)

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 3

| Group Name | NO. of Animals | Body Weight | ADRENALS | OVARIES | HEART | LUNGS | KIDNEYS |
|------------|-------------------|-------------|---------------|--------------|---------------|--------------|--------------|
| Control | 42 | 312± 46 | 0.097± 0.126 | 0.124± 0.032 | 0.957± 0.129 | 1.106± 0.365 | 2.014± 0.151 |
| 320 ppm | 43 | 311± 35 | 0.078± 0.039 | 0.172± 0.198 | 0.931± 0.093 | 1.006± 0.078 | 2.009± 0.213 |
| 800 ppm | 44 | 291± 42 | 0.068± 0.011 | 0.113± 0.022 | 0.908± 0.118 | 1.013± 0.108 | 1.996± 0.274 |
| 2000 ppm | 35 | 274± 34** | 0.094± 0.165* | 0.154± 0.240 | 0.885± 0.089* | 1.005± 0.102 | 1.920± 0.193 |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL040)

BAIS2

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 4

| Group Name | NO. of Animals | SPLEEN | | LIVER | | BRAIN | |
|------------|-------------------|--------|-------|--------|-------|--------|-------|
| Control | 42 | 1.152± | 1.309 | 7.973± | 1.227 | 1.862± | 0.052 |
| 320 ppm | 43 | 0.642± | 0.190 | 7.602± | 1.022 | 1.855± | 0.044 |
| 800 ppm | 44 | 0.709± | 0.534 | 7.468± | 1.341 | 1.861± | 0.077 |
| 2000 ppm | 35 | 0.732± | 0.544 | 7.360± | 0.935 | 1.867± | 0.051 |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL040)

BAIS2

APPENDIX K 4

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : FEMALE
(2-YEAR STUDY)

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 3

| Group Name | NO. of Animals | Body Weight | ADRENALS | | OVARIES | | HEART | | LUNGS | | KIDNEYS | |
|------------|-------------------|-------------|----------|-------|---------|-------|--------|-------|--------|-------|---------|-------|
| Control | 31 | 30.8± 4.4 | 0.012± | 0.002 | 0.084± | 0.200 | 0.138± | 0.013 | 0.186± | 0.034 | 0.423± | 0.178 |
| 320 ppm | 30 | 31.0± 4.0 | 0.012± | 0.002 | 0.081± | 0.126 | 0.141± | 0.013 | 0.191± | 0.057 | 0.527± | 0.542 |
| 800 ppm | 35 | 30.4± 5.0 | 0.012± | 0.003 | 0.094± | 0.126 | 0.141± | 0.016 | 0.184± | 0.027 | 0.461± | 0.253 |
| 2000 ppm | 35 | 27.7± 3.5* | 0.014± | 0.018 | 0.083± | 0.096 | 0.149± | 0.025 | 0.175± | 0.017 | 0.475± | 0.497 |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL040)

BAIS2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 4

| Group Name | NO. of Animals | SPLEEN | | LIVER | | BRAIN | |
|------------|-------------------|--------|-------|--------|-------|--------|---------|
| Control | 31 | 0.177± | 0.179 | 1.591± | 1.020 | 0.465± | 0.015 |
| 320 ppm | 30 | 0.107± | 0.073 | 1.191± | 0.254 | 0.465± | 0.015 |
| 800 ppm | 35 | 0.194± | 0.205 | 1.440± | 1.176 | 0.462± | 0.014 |
| 2000 ppm | 35 | 0.201± | 0.341 | 1.261± | 0.381 | 0.453± | 0.017** |

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX L 1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE
(2-YEAR STUDY)

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 1

| Group Name | NO. of Animals | Body Weight (g) | ADRENALS | TESTES | HEART | LUNGS | KIDNEYS |
|------------|-------------------|--------------------|--------------|--------------|---------------|----------------|----------------|
| Control | 36 | 422± 25 | 0.019± 0.007 | 1.057± 0.410 | 0.299± 0.031 | 0.332± 0.028 | 0.727± 0.136 |
| 320 ppm | 35 | 416± 32 | 0.028± 0.059 | 1.182± 0.330 | 0.299± 0.038 | 0.342± 0.035 | 0.727± 0.075 |
| 800 ppm | 42 | 415± 52 | 0.019± 0.010 | 1.142± 0.454 | 0.299± 0.038 | 0.342± 0.040 | 0.808± 0.306 |
| 2000 ppm | 39 | 388± 33** | 0.045± 0.173 | 1.198± 0.501 | 0.321± 0.045* | 0.373± 0.081** | 0.782± 0.084** |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 2

| Group Name | NO. of Animals | SPLEEN | LIVER | BRAIN |
|------------|-------------------|--------------|----------------|----------------|
| Control | 36 | 0.289± 0.112 | 2.905± 0.387 | 0.485± 0.033 |
| 320 ppm | 35 | 0.291± 0.079 | 2.929± 0.281 | 0.493± 0.036 |
| 800 ppm | 42 | 0.297± 0.082 | 3.111± 0.395* | 0.499± 0.062 |
| 2000 ppm | 39 | 0.310± 0.117 | 3.306± 0.369** | 0.529± 0.041** |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX L 2

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 3

| Group Name | NO. of Animals | Body Weight (g) | ADRENALS | OVARIES | HEART | LUNGS | KIDNEYS |
|------------|-------------------|--------------------|--------------|--------------|--------------|----------------|----------------|
| Control | 42 | 312± 46 | 0.032± 0.041 | 0.041± 0.014 | 0.319± 0.107 | 0.383± 0.280 | 0.671± 0.191 |
| 320 ppm | 43 | 311± 35 | 0.025± 0.013 | 0.057± 0.071 | 0.302± 0.041 | 0.327± 0.048 | 0.652± 0.088 |
| 800 ppm | 44 | 291± 42 | 0.024± 0.005 | 0.039± 0.007 | 0.317± 0.055 | 0.356± 0.072 | 0.701± 0.174* |
| 2000 ppm | 35 | 274± 34** | 0.035± 0.062 | 0.055± 0.082 | 0.328± 0.058 | 0.374± 0.077** | 0.709± 0.113** |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL042)

BAIS2

STUDY NO. : 0095
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 4

| Group Name | NO. of Animals | SPLEEN | LIVER | BRAIN |
|------------|-------------------|--------------|---------------|----------------|
| Control | 42 | 0.424± 0.675 | 2.638± 0.778 | 0.616± 0.134 |
| 320 ppm | 43 | 0.207± 0.057 | 2.452± 0.280 | 0.604± 0.077 |
| 800 ppm | 44 | 0.251± 0.218 | 2.597± 0.564 | 0.652± 0.103* |
| 2000 ppm | 35 | 0.285± 0.301 | 2.707± 0.385* | 0.690± 0.087** |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX L 3

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : MALE
(2-YEAR STUDY)

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 1

| Group Name | NO. of Animals | Body Weight (g) | ADRENALS | TESTES | HEART | LUNGS | KIDNEYS |
|------------|-------------------|--------------------|--------------|--------------|--------------|--------------|--------------|
| Control | 36 | 39.7± 5.9 | 0.023± 0.006 | 0.568± 0.122 | 0.466± 0.081 | 0.534± 0.191 | 1.703± 1.622 |
| 320 ppm | 43 | 40.5± 6.3 | 0.022± 0.006 | 0.519± 0.098 | 0.444± 0.060 | 0.489± 0.101 | 1.445± 0.385 |
| 800 ppm | 40 | 39.4± 6.5 | 0.024± 0.007 | 0.532± 0.123 | 0.478± 0.097 | 0.540± 0.229 | 1.622± 0.943 |
| 2000 ppm | 40 | 38.1± 5.9 | 0.025± 0.007 | 0.563± 0.088 | 0.496± 0.086 | 0.542± 0.180 | 1.454± 0.220 |

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 2

| Group Name | NO. of Animals | SPLEEN | LIVER | BRAIN |
|------------|-------------------|---------------|--------------|--------------|
| Control | 36 | 0.221± 0.292 | 3.221± 0.573 | 1.182± 0.207 |
| 320 ppm | 43 | 0.267± 0.442 | 3.320± 1.018 | 1.144± 0.176 |
| 800 ppm | 40 | 0.256± 0.318 | 3.795± 1.822 | 1.198± 0.253 |
| 2000 ppm | 40 | 0.429± 0.720* | 3.415± 0.620 | 1.209± 0.219 |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX L 4

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 3

| Group Name | NO. of Animals | Body Weight (g) | ADRENALS | OVARIES | HEART | LUNGS | KIDNEYS |
|------------|-------------------|--------------------|--------------|--------------|----------------|--------------|--------------|
| Control | 31 | 30.8± 4.4 | 0.040± 0.009 | 0.272± 0.652 | 0.457± 0.072 | 0.616± 0.140 | 1.446± 0.962 |
| 320 ppm | 30 | 31.0± 4.0 | 0.039± 0.008 | 0.264± 0.432 | 0.462± 0.068 | 0.626± 0.194 | 1.786± 2.130 |
| 800 ppm | 35 | 30.4± 5.0 | 0.040± 0.010 | 0.319± 0.467 | 0.472± 0.073 | 0.621± 0.135 | 1.564± 0.937 |
| 2000 ppm | 35 | 27.7± 3.5* | 0.050± 0.055 | 0.293± 0.335 | 0.547± 0.120** | 0.645± 0.119 | 1.709± 1.668 |

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0096
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 4

| Group Name | NO. of Animals | SPLEEN | LIVER | BRAIN |
|------------|-------------------|--------------|--------------|--------------|
| Control | 31 | 0.606± 0.670 | 5.329± 3.825 | 1.546± 0.253 |
| 320 ppm | 30 | 0.349± 0.231 | 3.869± 0.786 | 1.527± 0.216 |
| 800 ppm | 35 | 0.650± 0.703 | 4.813± 4.065 | 1.564± 0.283 |
| 2000 ppm | 35 | 0.771± 1.462 | 4.629± 1.660 | 1.663± 0.218 |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL042)

BAIS 2