

β-クロロプロピオン酸のラット及びマウスを用いた
経口投与によるがん原性予備試験(混水試験)報告書

APPENDIX

(B1- 1 ～C2)

1 3 Week STUDY NO.0107 ; 0108

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APPENDIX B 1-1

CLINICAL OBSERVATION : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 1

| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-----------------|------------|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|
| | | 0-0 | 1-7 | 2-7 | 3-7 | 4-7 | 5-7 | 6-7 | 7-7 | 8-7 | 9-7 | 10-7 | 11-7 | 12-7 | 13-7 |
| | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| LOSS OF HAIR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 500 ppm | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 8000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| GUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 500 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 8000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SORE OF SOLE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 3 | 8 |
| | 500 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| | 2000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 3 |
| | 4000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 8000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DEFECT OF TEETH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 500 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4000 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 8000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 500 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 8000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0107
 ANIMAL : RAT F344
 REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 2

| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------|------------|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|
| | | 0-0 | 1-7 | 2-7 | 3-7 | 4-7 | 5-7 | 6-7 | 7-7 | 8-7 | 9-7 | 10-7 | 11-7 | 12-7 | 13-7 |
| | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| TORTICOLLIS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 500 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| | 2000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 8000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOOSE STOOL | Control | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 500 ppm | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 |
| | 8000 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

(HAN190)

BAIS 2

APPENDIX B 1-2

CLINICAL OBSERVATION : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 3

| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-----------------------|------------|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|
| | | 0-0 | 1-7 | 2-7 | 3-7 | 4-7 | 5-7 | 6-7 | 7-7 | 8-7 | 9-7 | 10-7 | 11-7 | 12-7 | 13-7 |
| | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| LOSS OF HAIR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 500 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| | 4000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 8000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERI GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 500 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 8000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| GUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 500 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 8000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 500 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4000 ppm | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 8000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SORE OF SOLE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 500 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 8000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

APPENDIX B 1-3

CLINICAL OBSERVATION : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 1

| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------|------------|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|
| | | 0-0 | 1-7 | 2-7 | 3-7 | 4-7 | 5-7 | 6-7 | 7-7 | 8-7 | 9-7 | 10-7 | 11-7 | 12-7 | 13-7 |
| | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| PILOERECTION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 8000 ppm | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 16000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOSS OF HAIR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 2 | 2 | 2 | 3 | 3 |
| | 1000 ppm | 0 | 0 | 0 | 0 | 1 | 2 | 2 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |
| | 2000 ppm | 0 | 1 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 5 |
| | 4000 ppm | 0 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 3 | 4 | 4 | 4 | 5 | 5 |
| | 8000 ppm | 0 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 16000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

(HAN190)

BAIS 2

APPENDIX B 1-4

CLINICAL OBSERVATION : SUMMARY, MOSUE: FEMALE

(13Week STUDY)

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 2

| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------|------------|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|
| | | 0-0 | 1-7 | 2-7 | 3-7 | 4-7 | 5-7 | 6-7 | 7-7 | 8-7 | 9-7 | 10-7 | 11-7 | 12-7 | 13-7 |
| | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| LOSS OF HAIR | Control | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 3 | 3 | 4 | 4 | 5 | 5 |
| | 1000 ppm | 0 | 0 | 0 | 0 | 2 | 3 | 3 | 5 | 6 | 6 | 6 | 8 | 8 | 8 |
| | 2000 ppm | 0 | 0 | 1 | 2 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 6 | 6 | 6 |
| | 4000 ppm | 0 | 0 | 0 | 1 | 1 | 4 | 4 | 5 | 6 | 7 | 8 | 8 | 8 | 8 |
| | 8000 ppm | 0 | 1 | 1 | 1 | 1 | 2 | 2 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| | 16000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

(HAN190)

BAIS 2

APPENDIX B 2-1

BODY WEIGHT CHANGES :SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

| Group Name | Administration | | week-day | | | | | | | | | |
|------------|----------------|---|----------|-----|------|------|------|------|------|------|------|------|
| | 0-0 | | 1-7 | | 2-7 | | 3-7 | | 4-7 | | 5-7 | |
| Control | 128± | 5 | 163± | 9 | 193± | 10 | 221± | 12 | 244± | 12 | 261± | 12 |
| 500 ppm | 128± | 6 | 162± | 7 | 196± | 9 | 223± | 8 | 244± | 9 | 261± | 7 |
| 1000 ppm | 128± | 6 | 162± | 7 | 197± | 8 | 226± | 8 | 249± | 8 | 266± | 8 |
| 2000 ppm | 128± | 6 | 159± | 7 | 193± | 9 | 222± | 10 | 245± | 10 | 263± | 11 |
| 4000 ppm | 128± | 6 | 157± | 7 | 190± | 7 | 218± | 7 | 239± | 9 | 255± | 9 |
| 8000 ppm | 128± | 6 | 151± | 7** | 179± | 10** | 204± | 10** | 223± | 11** | 238± | 10** |

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

| Group Name | Administration week-day | | 7-7 | | 8-7 | | 9-7 | | 10-7 | | 11-7 | | 12-7 | | 13-7 | |
|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|-----|------|--|
| | | | | | | | | | | | | | | | | |
| Control | 289± | 13 | 303± | 14 | 313± | 14 | 320± | 15 | 327± | 15 | 334± | 16 | 341± | 15 | | |
| 500 ppm | 287± | 9 | 301± | 8 | 312± | 9 | 319± | 9 | 327± | 8 | 333± | 9 | 339± | 10 | | |
| 1000 ppm | 292± | 7 | 305± | 9 | 316± | 10 | 324± | 9 | 331± | 10 | 337± | 9 | 343± | 10 | | |
| 2000 ppm | 291± | 12 | 304± | 13 | 315± | 13 | 323± | 14 | 329± | 13 | 334± | 15 | 341± | 15 | | |
| 4000 ppm | 280± | 11 | 293± | 11 | 303± | 12 | 310± | 13 | 316± | 13 | 322± | 13 | 328± | 13 | | |
| 8000 ppm | 258± | 10** | 267± | 11** | 276± | 10** | 283± | 10** | 287± | 10** | 293± | 11** | 297± | 9** | | |

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

Test of Dunnett

(HAN260)

BAIS 2

APPENDIX B 2-2

BODY WEIGHT CHANGES : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

| Group Name | Administration | | week-day | | | | | | | | | |
|------------|----------------|---|----------|-----|------|----|------|-----|------|-----|------|-----|
| | 0-0 | | 1-7 | | 2-7 | | 3-7 | | 4-7 | | 5-7 | |
| Control | 108± | 4 | 126± | 3 | 141± | 5 | 155± | 3 | 164± | 5 | 174± | 5 |
| 500 ppm | 108± | 4 | 126± | 5 | 142± | 6 | 156± | 7 | 167± | 8 | 176± | 8 |
| 1000 ppm | 108± | 4 | 125± | 4 | 142± | 5 | 157± | 5 | 166± | 5 | 176± | 6 |
| 2000 ppm | 108± | 4 | 126± | 6 | 142± | 6 | 157± | 6 | 165± | 7 | 174± | 9 |
| 4000 ppm | 108± | 4 | 122± | 5 | 139± | 5 | 152± | 6 | 159± | 7 | 167± | 6 |
| 8000 ppm | 108± | 3 | 118± | 3** | 135± | 4* | 146± | 4** | 152± | 5** | 159± | 4** |

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

| Group Name | Administration | | week-day | | | | | | | | | | | | | |
|------------|----------------|-----|----------|-----|------|-----|------|-----|------|-----|------|-----|------|-----|--|--|
| | 7-7 | | 8-7 | | 9-7 | | 10-7 | | 11-7 | | 12-7 | | 13-7 | | | |
| Control | 186± | 6 | 191± | 6 | 199± | 9 | 201± | 8 | 204± | 9 | 207± | 10 | 209± | 7 | | |
| 500 ppm | 191± | 11 | 196± | 14 | 201± | 11 | 204± | 14 | 210± | 13 | 211± | 14 | 214± | 15 | | |
| 1000 ppm | 189± | 7 | 193± | 8 | 200± | 9 | 203± | 8 | 207± | 9 | 209± | 8 | 211± | 8 | | |
| 2000 ppm | 189± | 11 | 194± | 11 | 200± | 10 | 202± | 10 | 205± | 9 | 208± | 11 | 209± | 11 | | |
| 4000 ppm | 180± | 8 | 185± | 9 | 189± | 9 | 194± | 9 | 197± | 10 | 200± | 11 | 203± | 10 | | |
| 8000 ppm | 171± | 4** | 174± | 5** | 179± | 4** | 182± | 5** | 184± | 4** | 186± | 5** | 189± | 5** | | |

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

Test of Dunnett

(HAN260)

BAIS 2

APPENDIX B 2-3

BODY WEIGHT CHANGES :SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

| Group Name | Administration week-day | | | | | | |
|------------|-------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 0-0 | 1-7 | 2-7 | 3-7 | 4-7 | 5-7 | 6-7 |
| Control | 23.4± 0.8 | 24.5± 1.0 | 25.8± 0.9 | 26.6± 0.8 | 27.6± 1.2 | 28.4± 1.2 | 29.5± 1.6 |
| 1000 ppm | 23.4± 0.9 | 24.5± 0.9 | 25.8± 1.0 | 26.7± 1.0 | 27.4± 1.1 | 28.5± 1.4 | 28.9± 1.2 |
| 2000 ppm | 23.4± 0.9 | 24.5± 0.9 | 25.4± 0.9 | 26.3± 1.1 | 26.8± 1.0 | 27.9± 1.1 | 28.2± 1.3 |
| 4000 ppm | 23.4± 0.9 | 24.1± 0.9 | 24.9± 1.0 | 25.7± 1.0 | 26.1± 1.0* | 26.8± 0.9* | 27.3± 1.2** |
| 8000 ppm | 23.4± 0.8 | 23.4± 0.8* | 24.0± 1.2** | 24.7± 1.1** | 25.2± 1.2** | 25.9± 1.2** | 26.1± 1.3** |
| 16000 ppm | 23.4± 0.8 | 22.2± 0.9** | 22.7± 0.8** | 23.4± 0.8** | 23.9± 1.0** | 24.1± 0.9** | 24.6± 1.0** |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

| Group Name | Administration week-day | | | | | | |
|------------|-------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 7-7 | 8-7 | 9-7 | 10-7 | 11-7 | 12-7 | 13-7 |
| Control | 30.3± 1.6 | 31.1± 1.5 | 32.0± 1.7 | 33.0± 1.8 | 33.9± 1.8 | 34.7± 1.7 | 35.7± 1.9 |
| 1000 ppm | 29.6± 1.4 | 30.3± 1.6 | 31.2± 1.5 | 31.8± 1.7 | 32.7± 1.6 | 33.2± 1.8 | 34.2± 2.0 |
| 2000 ppm | 28.9± 1.3 | 29.4± 1.4* | 30.2± 1.6* | 30.5± 1.7** | 31.5± 2.0* | 31.9± 2.0** | 33.0± 2.1* |
| 4000 ppm | 27.8± 1.1** | 28.2± 1.3** | 28.8± 1.3** | 29.5± 1.4** | 30.0± 1.6** | 30.6± 1.6** | 31.3± 1.6** |
| 8000 ppm | 26.7± 1.6** | 27.1± 1.5** | 27.8± 1.7** | 27.9± 1.9** | 28.2± 2.1** | 28.9± 2.3** | 29.3± 2.3** |
| 16000 ppm | 25.0± 1.1** | 25.5± 1.2** | 25.7± 1.2** | 25.9± 1.1** | 26.0± 1.2** | 26.5± 1.3** | 26.3± 1.6** |

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

Test of Dunnett

(IAN260)

BAIS 2

APPENDIX B 2-4

BODY WEIGHT CHANGES : SUMMARY, MOSUE: FEMALE

(13Week STUDY)

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

| Group Name | Administration week-day | | | | | | |
|------------|-------------------------|-----------|-------------|------------|------------|-----------|-------------|
| | 0-0 | 1-7 | 2-7 | 3-7 | 4-7 | 5-7 | 6-7 |
| Control | 18.8± 0.9 | 19.1± 1.0 | 20.1± 1.0 | 20.3± 1.4 | 20.3± 1.2 | 20.7± 1.1 | 21.3± 1.4 |
| 1000 ppm | 18.8± 0.8 | 19.0± 0.8 | 19.9± 1.0 | 20.2± 0.9 | 20.6± 0.7 | 20.9± 1.0 | 21.6± 0.7 |
| 2000 ppm | 18.8± 0.8 | 19.2± 0.7 | 19.9± 0.7 | 19.9± 0.8 | 20.4± 0.9 | 20.8± 1.1 | 21.2± 1.0 |
| 4000 ppm | 18.8± 0.7 | 19.2± 0.8 | 19.9± 0.6 | 20.0± 0.9 | 20.1± 0.7 | 20.2± 0.6 | 20.8± 0.7 |
| 8000 ppm | 18.8± 0.7 | 18.7± 0.7 | 19.4± 1.1 | 20.1± 1.2 | 20.1± 1.3 | 20.3± 1.1 | 20.7± 0.9 |
| 16000 ppm | 18.8± 0.8 | 18.3± 0.9 | 18.5± 1.0** | 18.9± 0.7* | 19.1± 0.7* | 19.6± 0.7 | 19.7± 0.9** |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

| Group Name | Administration week-day | | | | | | |
|------------|-------------------------|-----------|-------------|-------------|-------------|-----------|-----------|
| | 7-7 | 8-7 | 9-7 | 10-7 | 11-7 | 12-7 | 13-7 |
| Control | 21.5± 1.2 | 22.5± 1.4 | 23.1± 1.2 | 22.9± 1.0 | 23.5± 1.9 | 23.4± 1.3 | 23.9± 1.2 |
| 1000 ppm | 21.7± 0.9 | 22.3± 0.7 | 23.1± 0.9 | 22.4± 1.1 | 22.9± 1.0 | 23.2± 1.4 | 23.5± 1.1 |
| 2000 ppm | 21.3± 0.8 | 22.2± 1.2 | 22.4± 1.2 | 22.9± 1.0 | 22.8± 1.1 | 23.2± 0.8 | 23.4± 1.7 |
| 4000 ppm | 21.3± 0.7 | 22.3± 1.3 | 22.4± 1.1 | 22.7± 1.6 | 22.7± 1.0 | 22.6± 1.4 | 22.9± 1.3 |
| 8000 ppm | 21.4± 0.7 | 22.2± 1.2 | 22.7± 1.8 | 22.4± 1.1 | 23.0± 1.2 | 22.8± 1.7 | 23.4± 1.1 |
| 16000 ppm | 20.3± 0.9* | 21.0± 1.0 | 21.0± 0.8** | 21.3± 0.8** | 21.6± 0.9** | 21.8± 0.9 | 22.5± 0.9 |

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX B 3-1

WATER CONSUMPTION CHANGES : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

| Group Name | Administration 1-3(3) | week-day(effective) 1-7(4) | 2-3(3) | 2-7(4) | 3-3(3) | 3-7(4) | 4-3(3) |
|------------|--------------------------|-------------------------------|-------------|-------------|-------------|-------------|-------------|
| Control | 18.8± 1.4 | 20.0± 1.9 | 21.4± 2.8 | 23.2± 2.6 | 22.8± 2.6 | 23.2± 3.0 | 22.1± 2.2 |
| 500 ppm | 18.9± 1.1 | 19.8± 0.8 | 20.5± 1.1 | 21.6± 1.6 | 22.0± 1.3 | 22.8± 1.5 | 22.2± 1.3 |
| 1000 ppm | 17.6± 1.1 | 17.7± 0.9** | 18.3± 0.9 | 20.0± 1.1 | 20.1± 1.0 | 20.7± 0.7 | 20.0± 0.5 |
| 2000 ppm | 15.7± 1.1** | 16.2± 1.3** | 16.6± 1.5** | 17.7± 1.2** | 18.2± 1.0** | 18.8± 1.6* | 18.2± 1.4* |
| 4000 ppm | 14.5± 0.8** | 15.8± 1.0** | 16.2± 1.2** | 17.5± 1.0** | 17.4± 1.4** | 18.2± 1.3** | 17.5± 1.6** |
| 8000 ppm | 12.9± 1.0** | 15.9± 1.2** | 18.0± 4.6** | 19.2± 5.5** | 16.1± 1.1** | 16.6± 1.4** | 16.1± 1.2** |

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 4-7(4) | 5-3(3) | 5-7(4) | 6-3(3) | 6-7(4) | 7-3(3) | 7-7(4) |
| Control | 23.0± 2.5 | 23.5± 4.6 | 22.2± 2.2 | 22.6± 3.1 | 22.1± 2.0 | 22.9± 2.9 | 22.6± 3.9 |
| 500 ppm | 23.3± 0.9 | 23.9± 2.6 | 23.9± 2.8 | 23.6± 1.8 | 23.6± 2.1 | 22.3± 1.3 | 22.2± 1.2 |
| 1000 ppm | 21.4± 0.4 | 20.2± 0.7 | 21.1± 0.9 | 21.3± 0.7 | 21.3± 1.0 | 20.8± 1.1 | 20.7± 0.9 |
| 2000 ppm | 19.0± 1.3** | 18.2± 1.4** | 18.7± 1.4* | 18.6± 1.8* | 18.5± 1.5** | 18.0± 1.4** | 18.6± 1.3* |
| 4000 ppm | 18.8± 1.6** | 18.2± 1.3** | 18.5± 1.3* | 18.0± 1.5** | 18.6± 1.7** | 17.8± 1.5** | 18.0± 1.3** |
| 8000 ppm | 16.6± 1.4** | 16.3± 1.2** | 16.3± 1.5** | 16.2± 1.4** | 16.1± 1.3** | 15.1± 1.2** | 15.2± 1.3** |

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

Test of Dunnett

(IIAN260)

BAIS2

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

| Group Name | Administration 8-3(3) | week-day(effective) 8-7(4) | 9-3(3) | 9-7(4) | 10-3(3) | 10-7(4) | 11-3(3) |
|------------|--------------------------|-------------------------------|-------------|-------------|-------------|-------------|-------------|
| Control | 21.0± 1.6 | 22.1± 2.2 | 21.4± 1.9 | 22.3± 2.8 | 21.4± 1.9 | 21.6± 1.8 | 21.4± 2.1 |
| 500 ppm | 21.5± 1.3 | 22.3± 1.1 | 23.0± 2.0 | 24.0± 2.9 | 21.3± 1.6 | 21.9± 1.7 | 21.6± 2.0 |
| 1000 ppm | 20.3± 0.8 | 21.0± 1.0 | 21.1± 1.1 | 20.6± 1.2 | 20.4± 1.3 | 20.1± 0.7 | 19.9± 0.9 |
| 2000 ppm | 18.0± 1.1** | 18.6± 1.4** | 18.3± 1.0** | 18.1± 1.0* | 17.7± 0.7** | 17.7± 1.0** | 16.4± 0.8** |
| 4000 ppm | 17.2± 1.2** | 18.1± 1.1** | 18.2± 1.3** | 17.8± 1.4** | 17.6± 1.2** | 17.7± 1.4** | 17.9± 1.6* |
| 8000 ppm | 15.5± 1.3** | 15.3± 1.1** | 15.5± 1.0** | 15.5± 1.4** | 15.0± 1.2** | 15.1± 1.2** | 15.2± 1.0** |

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

| Group Name | Administration week-day(effective) | | | | |
|------------|------------------------------------|-------------|-------------|-------------|-------------|
| | 11-7(4) | 12-3(3) | 12-7(4) | 13-3(3) | 13-7(4) |
| Control | 21.5± 2.4 | 20.5± 1.1 | 21.3± 2.4 | 20.3± 1.5 | 20.4± 1.5 |
| 500 ppm | 21.5± 2.8 | 21.2± 2.2 | 22.0± 2.9 | 20.7± 1.5 | 21.0± 1.9 |
| 1000 ppm | 19.6± 0.7 | 19.0± 1.0 | 19.9± 1.1 | 19.4± 0.9 | 19.9± 0.8 |
| 2000 ppm | 17.7± 0.6** | 17.0± 1.3** | 17.6± 1.0** | 17.4± 0.9** | 17.8± 0.9* |
| 4000 ppm | 17.4± 1.4** | 17.3± 1.2** | 17.5± 1.7* | 17.0± 0.9** | 17.6± 0.8** |
| 8000 ppm | 14.9± 1.1** | 15.2± 1.3** | 14.8± 1.1** | 14.2± 1.1** | 15.2± 1.0** |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

APPENDIX B 3-2

WATER CONSUMPTION CHANGES : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 1-3(3) | 1-7(4) | 2-3(3) | 2-7(4) | 3-3(3) | 3-7(4) | 4-3(3) |
| Control | 16.9± 1.4 | 19.6± 4.9 | 22.2± 13.4 | 18.5± 2.4 | 18.4± 2.6 | 19.0± 2.3 | 17.8± 2.1 |
| 500 ppm | 17.7± 1.1 | 18.6± 1.2 | 19.3± 3.1 | 21.0± 5.7 | 22.4± 8.9 | 22.7± 7.8 | 25.6± 14.6 |
| 1000 ppm | 15.9± 0.7 | 16.6± 1.0 | 17.3± 1.2 | 17.5± 1.5 | 17.6± 2.1 | 20.8± 8.0 | 18.9± 5.1 |
| 2000 ppm | 14.3± 1.3** | 15.7± 1.6 | 15.2± 1.3 | 16.0± 1.1 | 16.0± 1.2 | 16.5± 1.2 | 15.7± 1.3 |
| 4000 ppm | 12.7± 0.9** | 13.6± 1.0** | 13.8± 0.8** | 14.5± 1.0** | 14.2± 1.1** | 14.7± 1.1** | 13.8± 1.7* |
| 8000 ppm | 10.8± 1.0** | 12.3± 0.8** | 12.5± 0.8** | 13.1± 1.0** | 12.5± 0.9** | 12.7± 1.1** | 11.6± 1.0** |

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

Test of Dunnett

(IAN260)

BAIS 2

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 6

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|-------------|-------------|------------|------------|-------------|-------------|
| | 4-7(4) | 5-3(3) | 5-7(4) | 6-3(3) | 6-7(4) | 7-3(3) | 7-7(4) |
| Control | 18.8± 1.6 | 17.8± 1.6 | 17.9± 1.3 | 17.3± 1.8 | 18.1± 1.2 | 17.7± 1.6 | 19.8± 4.6 |
| 500 ppm | 23.4± 9.3 | 26.7± 12.0 | 21.9± 4.4 | 28.7± 13.7 | 26.5± 7.5 | 29.0± 10.2 | 24.1± 8.5 |
| 1000 ppm | 20.3± 5.3 | 19.2± 5.6 | 21.7± 8.3 | 18.8± 4.2 | 20.9± 7.0 | 21.6± 13.0 | 21.0± 7.5 |
| 2000 ppm | 16.2± 1.6 | 15.5± 1.7 | 16.6± 1.2 | 15.9± 1.2 | 16.1± 1.2 | 15.6± 1.6 | 16.5± 1.1 |
| 4000 ppm | 14.1± 1.5** | 14.2± 1.1* | 14.6± 1.4* | 13.3± 1.6* | 14.5± 1.4* | 13.7± 1.5* | 14.2± 1.7** |
| 8000 ppm | 12.2± 0.7** | 13.6± 4.4** | 12.6± 1.4** | 14.9± 7.0 | 15.5± 7.9* | 10.9± 0.9** | 11.8± 0.7** |

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 7

| Group Name | Administration 8-3(3) | week-day(effective) 8-7(4) | 9-3(3) | 9-7(4) | 10-3(3) | 10-7(4) | 11-3(3) |
|------------|--------------------------|-------------------------------|-------------|-------------|-------------|-------------|-------------|
| Control | 21.2± 8.3 | 19.3± 3.0 | 23.9± 14.5 | 20.2± 3.1 | 23.5± 14.2 | 20.3± 3.8 | 24.5± 14.4 |
| 500 ppm | 31.9± 16.4 | 26.0± 7.8 | 28.2± 11.0 | 26.5± 9.2 | 29.4± 15.8 | 26.6± 8.9 | 25.2± 11.5 |
| 1000 ppm | 19.4± 5.8 | 20.0± 5.5 | 21.7± 8.9 | 21.0± 7.1 | 19.5± 5.5 | 19.6± 5.5 | 18.3± 3.8 |
| 2000 ppm | 15.0± 0.8 | 16.3± 1.4 | 16.0± 1.0 | 15.9± 1.9 | 15.1± 1.1 | 15.3± 1.1 | 14.1± 0.9* |
| 4000 ppm | 13.2± 1.0** | 14.1± 1.8* | 13.8± 1.4** | 13.0± 1.4** | 13.5± 1.1** | 13.4± 1.3** | 13.2± 1.4** |
| 8000 ppm | 11.0± 0.6** | 11.4± 0.6** | 11.4± 0.7** | 11.4± 0.5** | 12.5± 3.9** | 11.7± 0.9** | 11.5± 1.0** |

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

| Group Name | Administration week-day(effective) | | | | |
|------------|------------------------------------|-------------|-------------|-------------|-------------|
| | 11-7(4) | 12-3(3) | 12-7(4) | 13-3(3) | 13-7(4) |
| Control | 21.0± 4.7 | 19.0± 2.8 | 21.7± 6.0 | 22.2± 6.5 | 23.7± 10.0 |
| 500 ppm | 24.4± 4.7 | 29.8± 15.6 | 23.6± 7.3 | 29.6± 14.3 | 25.9± 9.2 |
| 1000 ppm | 18.1± 3.9 | 17.5± 4.5 | 18.3± 4.1 | 18.8± 5.9 | 18.4± 5.7 |
| 2000 ppm | 14.9± 1.2 | 14.5± 1.4 | 14.8± 1.0 | 14.7± 0.8* | 14.9± 1.2 |
| 4000 ppm | 13.4± 1.2** | 13.4± 1.4** | 13.4± 1.5** | 12.7± 1.2** | 13.6± 1.4** |
| 8000 ppm | 10.7± 0.5** | 11.0± 0.7** | 10.8± 0.8** | 11.5± 1.9** | 13.3± 3.8** |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(HAN260)

BAIS2

APPENDIX B 3-3

WATER CONSUMPTION CHANGES : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|------------|------------|------------|------------|------------|------------|
| | 1-3(3) | 1-7(4) | 2-3(3) | 2-7(4) | 3-3(3) | 3-7(4) | 4-3(3) |
| Control | 4.3± 0.5 | 4.5± 0.3 | 4.1± 0.4 | 4.3± 0.4 | 3.8± 0.3 | 4.0± 0.3 | 4.0± 0.4 |
| 1000 ppm | 4.4± 0.4 | 4.7± 0.3 | 4.2± 0.4 | 4.4± 0.3 | 3.9± 0.3 | 4.1± 0.3 | 4.1± 0.3 |
| 2000 ppm | 4.3± 0.5 | 4.5± 0.5 | 4.0± 0.5 | 3.9± 0.6 | 3.5± 0.6 | 3.6± 0.5 | 3.2± 0.5** |
| 4000 ppm | 3.8± 0.4* | 3.5± 0.3** | 3.2± 0.8 | 3.3± 0.8 | 2.9± 0.4 | 3.0± 0.4* | 2.8± 0.4** |
| 8000 ppm | 3.0± 0.5** | 2.7± 0.5** | 2.5± 0.6** | 2.4± 0.5** | 2.2± 0.5** | 2.3± 0.5** | 2.2± 0.4** |
| 16000 ppm | 1.9± 0.2** | 2.1± 0.2** | 2.0± 0.2** | 1.8± 0.2** | 1.8± 0.1** | 1.8± 0.2** | 1.8± 0.2** |

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|------------|------------|------------|------------|------------|------------|
| | 4-7(4) | 5-3(3) | 5-7(4) | 6-3(3) | 6-7(4) | 7-3(3) | 7-7(4) |
| Control | 4.1± 0.4 | 3.8± 0.3 | 4.0± 0.4 | 3.9± 0.4 | 4.0± 0.4 | 3.9± 0.4 | 3.9± 0.4 |
| 1000 ppm | 4.2± 0.3 | 3.8± 0.3 | 3.9± 0.3 | 3.8± 0.3 | 4.0± 0.2 | 3.7± 0.3 | 3.9± 0.2 |
| 2000 ppm | 3.5± 0.4* | 3.3± 0.4* | 3.4± 0.4** | 3.2± 0.4** | 3.3± 0.3 | 3.2± 0.3** | 3.3± 0.3 |
| 4000 ppm | 2.9± 0.4** | 3.0± 0.5** | 3.0± 0.5** | 2.9± 0.5** | 3.1± 0.6* | 2.9± 0.4** | 2.9± 0.3** |
| 8000 ppm | 2.3± 0.4** | 2.4± 0.3** | 2.4± 0.4** | 2.3± 0.3** | 2.4± 0.5** | 2.3± 0.3** | 2.6± 0.4** |
| 16000 ppm | 1.8± 0.2** | 1.8± 0.2** | 1.8± 0.2** | 1.8± 0.2** | 1.8± 0.2** | 1.7± 0.2** | 1.9± 0.1** |

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

| Group Name | Administration 8-3(3) | week-day(effective) 8-7(4) | 9-3(3) | 9-7(4) | 10-3(3) | 10-7(4) | 11-3(3) |
|------------|--------------------------|-------------------------------|------------|------------|------------|------------|------------|
| Control | 3.9± 0.4 | 3.8± 0.4 | 3.9± 0.6 | 3.8± 0.4 | 3.9± 0.5 | 3.9± 0.5 | 3.7± 0.3 |
| 1000 ppm | 3.9± 0.2 | 3.7± 0.4 | 3.8± 0.4 | 3.8± 0.3 | 3.8± 0.4 | 3.7± 0.3 | 3.6± 0.5 |
| 2000 ppm | 3.1± 0.3** | 3.1± 0.3 | 3.2± 0.2 | 3.2± 0.3** | 2.7± 0.3** | 3.1± 0.3 | 3.0± 0.3** |
| 4000 ppm | 2.9± 0.4** | 2.8± 0.3* | 2.9± 0.5* | 2.7± 0.3** | 2.7± 0.3** | 2.7± 0.3** | 2.7± 0.3** |
| 8000 ppm | 2.5± 0.5** | 2.3± 0.3** | 2.5± 0.4** | 2.4± 0.3** | 2.3± 0.3** | 2.4± 0.4** | 2.4± 0.4** |
| 16000 ppm | 1.9± 0.3** | 1.8± 0.1** | 1.7± 0.1** | 1.8± 0.1** | 1.8± 0.3** | 1.7± 0.1** | 1.7± 0.2** |

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

Test of Dunnett

(HAN260)

BATS2

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

| Group Name | Administration week-day(effective) | | | | |
|------------|------------------------------------|------------|------------|------------|------------|
| | 11-7(4) | 12-3(3) | 12-7(4) | 13-3(3) | 13-7(4) |
| Control | 3.8± 0.5 | 3.8± 0.4 | 3.8± 0.5 | 3.6± 0.5 | 3.6± 0.4 |
| 1000 ppm | 3.7± 0.4 | 3.7± 0.4 | 3.7± 0.4 | 3.4± 0.3 | 3.6± 0.4 |
| 2000 ppm | 3.1± 0.3** | 3.0± 0.3** | 3.0± 0.3** | 2.9± 0.3** | 3.1± 0.4** |
| 4000 ppm | 2.7± 0.2** | 2.7± 0.3** | 2.7± 0.3** | 2.6± 0.3** | 2.6± 0.3** |
| 8000 ppm | 2.4± 0.6** | 2.4± 0.4** | 2.4± 0.3** | 2.3± 0.3** | 2.3± 0.4** |
| 16000 ppm | 1.8± 0.3** | 1.8± 0.4** | 1.8± 0.3** | 1.5± 0.3** | 1.7± 0.3** |

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

Test of Dunnett

APPENDIX B 3-4

WATER CONSUMPTION CHANGES : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

| Group Name | Administration 1-3(3) | week-day(effective) 1-7(4) | 2-3(3) | 2-7(4) | 3-3(3) | 3-7(4) | 4-3(3) |
|------------|--------------------------|-------------------------------|------------|------------|------------|------------|------------|
| Control | 4.0± 0.5 | 4.2± 0.5 | 4.4± 0.7 | 4.4± 0.5 | 4.1± 0.4 | 4.3± 0.5 | 4.3± 0.3 |
| 1000 ppm | 4.3± 0.4 | 4.9± 0.8 | 5.3± 1.8 | 4.7± 0.7 | 4.7± 1.1 | 4.7± 0.8 | 5.3± 1.8 |
| 2000 ppm | 4.5± 0.5 | 4.5± 0.6 | 4.8± 1.7 | 4.7± 0.9 | 4.2± 1.3 | 4.1± 0.6 | 4.3± 0.5 |
| 4000 ppm | 3.8± 0.2 | 3.8± 0.3 | 3.5± 0.9 | 3.9± 0.6 | 3.5± 0.4 | 4.0± 0.9 | 3.9± 0.4 |
| 8000 ppm | 2.9± 0.2* | 2.9± 0.3* | 2.7± 0.3** | 2.9± 0.3** | 2.9± 0.5** | 3.0± 0.4** | 3.0± 0.5** |
| 16000 ppm | 1.8± 0.3** | 2.3± 0.3** | 2.3± 0.5** | 2.2± 0.5** | 2.4± 0.7** | 2.3± 0.4** | 2.2± 0.5** |

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 6

| Group Name | Administration 4-7(4) | week-day(effective) 5-3(3) | 5-7(4) | 6-3(3) | 6-7(4) | 7-3(3) | 7-7(4) |
|------------|--------------------------|-------------------------------|------------|------------|------------|------------|------------|
| Control | 4.2± 0.3 | 4.4± 0.6 | 4.2± 0.5 | 4.2± 0.5 | 4.4± 0.5 | 4.8± 0.6 | 4.5± 0.4 |
| 1000 ppm | 4.8± 0.8* | 4.6± 0.6 | 4.4± 0.3 | 4.4± 0.3 | 4.6± 0.4 | 4.4± 0.5 | 4.6± 0.6 |
| 2000 ppm | 4.2± 0.4 | 3.9± 0.3 | 4.0± 0.4 | 4.0± 0.5 | 4.3± 0.4 | 4.2± 0.6 | 4.4± 0.9 |
| 4000 ppm | 4.0± 0.6 | 3.8± 0.5 | 4.0± 0.6 | 3.8± 0.4 | 4.0± 0.3 | 3.9± 0.5* | 4.3± 0.6 |
| 8000 ppm | 3.2± 0.7** | 3.4± 0.6** | 3.4± 0.5** | 3.3± 0.4** | 3.5± 0.5* | 3.1± 0.4** | 3.4± 0.3** |
| 16000 ppm | 2.4± 0.4** | 2.6± 0.7** | 2.6± 0.6** | 2.7± 0.9** | 3.0± 1.0** | 2.9± 1.0** | 2.9± 0.9** |

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 7

| Group Name | Administration 8-3(3) | week-day(effective) 8-7(4) | 9-3(3) | 9-7(4) | 10-3(3) | 10-7(4) | 11-3(3) |
|------------|--------------------------|-------------------------------|------------|------------|------------|------------|------------|
| Control | 4.9± 0.6 | 4.4± 0.4 | 4.9± 0.4 | 4.7± 0.6 | 4.8± 0.5 | 4.8± 0.6 | 4.8± 0.5 |
| 1000 ppm | 4.5± 0.4 | 4.6± 0.7 | 5.0± 0.6 | 4.3± 0.4 | 4.5± 0.5 | 4.3± 0.3 | 4.6± 0.4 |
| 2000 ppm | 4.6± 1.0 | 4.4± 0.8 | 4.4± 0.5 | 4.3± 0.6 | 4.0± 0.5 | 4.2± 0.6 | 4.5± 0.9 |
| 4000 ppm | 4.3± 1.1 | 3.9± 0.6 | 4.9± 2.1 | 4.2± 0.9 | 4.3± 0.9 | 4.6± 1.7 | 4.9± 2.4 |
| 8000 ppm | 3.4± 0.6** | 3.4± 0.7** | 3.2± 0.5** | 3.2± 0.3** | 3.3± 0.8** | 3.3± 0.5** | 3.5± 0.5** |
| 16000 ppm | 3.3± 1.0** | 3.2± 0.9** | 3.5± 1.1** | 3.5± 1.1* | 3.9± 1.5 | 3.6± 1.3* | 3.4± 0.8** |

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

| Group Name | Administration week-day(effective) | | | | |
|------------|------------------------------------|------------|-----------|------------|------------|
| | 11-7(4) | 12-3(3) | 12-7(4) | 13-3(3) | 13-7(4) |
| Control | 4.6± 0.5 | 4.6± 0.6 | 4.6± 0.5 | 4.7± 0.4 | 4.5± 0.4 |
| 1000 ppm | 4.2± 0.3 | 4.1± 0.4 | 4.2± 0.3 | 4.6± 0.4 | 4.1± 0.3 |
| 2000 ppm | 4.1± 0.5 | 4.1± 0.5 | 4.1± 0.6 | 4.3± 0.4 | 4.1± 0.5 |
| 4000 ppm | 3.9± 1.0* | 4.9± 2.7 | 4.6± 1.8 | 4.3± 1.7 | 4.3± 1.8 |
| 8000 ppm | 3.6± 1.1** | 3.4± 1.0** | 3.7± 1.4* | 3.6± 1.5** | 3.3± 0.5** |
| 16000 ppm | 3.4± 0.6** | 3.5± 1.0* | 3.5± 0.8* | 3.6± 1.0* | 3.4± 0.9** |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 2

APPENDIX B 4-1

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 1-7(7) | 2-7(7) | 3-7(7) | 4-7(7) | 5-7(7) | 6-7(7) | 7-7(7) |
| Control | 14.7± 1.0 | 15.9± 1.1 | 16.9± 1.5 | 17.1± 0.8 | 17.0± 0.7 | 16.6± 0.7 | 16.9± 0.7 |
| 500 ppm | 14.3± 0.6 | 15.7± 0.8 | 16.3± 0.6 | 16.4± 0.7 | 16.6± 0.7 | 16.8± 0.8 | 16.7± 0.8 |
| 1000 ppm | 14.4± 1.3 | 15.9± 0.8 | 16.7± 0.6 | 17.0± 0.7 | 16.7± 0.8 | 16.7± 0.7 | 16.8± 0.8 |
| 2000 ppm | 13.5± 0.9 | 15.2± 1.0 | 16.4± 0.9 | 16.4± 0.5 | 16.4± 0.5 | 16.3± 0.6 | 16.5± 0.6 |
| 4000 ppm | 13.3± 0.5* | 14.9± 0.6 | 15.8± 0.8 | 16.0± 0.8** | 16.2± 0.8 | 16.0± 0.8 | 16.3± 0.9 |
| 8000 ppm | 12.5± 0.5** | 13.7± 1.1** | 14.5± 1.0** | 14.8± 0.8** | 15.1± 0.8** | 14.9± 0.8** | 14.9± 1.0** |

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

Test of Dunnett

(I1AN260)

BAIS2

STUDY NO. : 0107
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

| Group Name | Administration week-day(effective) 8-7(7) | 9-7(7) | 10-7(7) | 11-7(7) | 12-7(7) | 13-7(7) |
|------------|--|-------------|-------------|-------------|-------------|-------------|
| Control | 16.9± 1.0 | 17.1± 1.1 | 16.3± 1.1 | 16.4± 0.9 | 16.3± 1.1 | 16.4± 1.0 |
| 500 ppm | 16.9± 0.9 | 17.0± 1.1 | 16.1± 1.0 | 16.3± 0.8 | 16.0± 0.8 | 15.9± 1.1 |
| 1000 ppm | 17.2± 0.7 | 17.1± 0.8 | 16.6± 0.8 | 16.4± 0.8 | 16.1± 0.6 | 16.4± 0.6 |
| 2000 ppm | 16.6± 0.6 | 16.8± 0.5 | 16.0± 0.9 | 15.8± 0.5 | 15.9± 0.6 | 16.2± 0.5 |
| 4000 ppm | 16.2± 0.9 | 16.5± 0.9 | 15.8± 1.0 | 15.9± 0.9 | 15.6± 0.7 | 15.9± 0.8 |
| 8000 ppm | 14.9± 1.0** | 15.1± 0.8** | 14.4± 0.8** | 14.8± 0.7** | 14.6± 0.8** | 14.5± 0.6** |

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX B 4-2

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 1-7(7) | 2-7(7) | 3-7(7) | 4-7(7) | 5-7(7) | 6-7(7) | 7-7(7) |
| Control | 11.9± 0.6 | 12.2± 0.6 | 12.6± 0.5 | 12.7± 0.7 | 13.0± 0.9 | 12.6± 0.6 | 12.9± 0.9 |
| 500 ppm | 11.8± 0.7 | 12.2± 1.0 | 12.8± 1.0 | 13.0± 0.9 | 13.4± 1.0 | 13.1± 1.1 | 13.4± 1.2 |
| 1000 ppm | 11.5± 0.4 | 12.3± 0.6 | 12.8± 0.6 | 12.6± 0.7 | 12.7± 0.8 | 12.5± 0.9 | 12.4± 0.7 |
| 2000 ppm | 11.6± 0.9 | 12.2± 0.7 | 12.4± 0.7 | 12.2± 0.6 | 12.7± 0.7 | 12.3± 0.8 | 12.5± 0.8 |
| 4000 ppm | 10.9± 0.5** | 11.6± 0.5 | 11.8± 0.7* | 11.4± 0.6** | 11.8± 0.7** | 11.2± 0.7** | 11.6± 0.8** |
| 8000 ppm | 10.1± 0.8** | 10.8± 0.6** | 10.9± 0.6** | 10.7± 0.4** | 11.0± 0.7** | 10.6± 0.5** | 10.7± 0.6** |

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

| Group Name | Administration week-day(effective) | | | | | |
|------------|------------------------------------|-------------|-------------|-------------|-------------|-------------|
| | 8-7(7) | 9-7(7) | 10-7(7) | 11-7(7) | 12-7(7) | 13-7(7) |
| Control | 12.5± 0.9 | 12.9± 1.2 | 12.2± 1.1 | 12.1± 0.7 | 11.9± 0.9 | 12.1± 0.6 |
| 500 ppm | 12.6± 1.3 | 13.1± 0.9 | 12.6± 1.0 | 12.8± 1.0 | 12.1± 0.9 | 12.3± 1.0 |
| 1000 ppm | 12.2± 1.0 | 12.5± 0.8 | 12.0± 0.7 | 12.2± 0.8 | 11.6± 0.7 | 11.7± 0.6 |
| 2000 ppm | 12.4± 0.8 | 12.7± 0.7 | 12.1± 0.9 | 11.7± 0.7 | 11.7± 0.7 | 11.6± 0.5 |
| 4000 ppm | 11.5± 0.8 | 11.7± 1.0* | 11.4± 0.8 | 11.5± 0.8 | 11.1± 1.0 | 11.0± 0.7** |
| 8000 ppm | 10.6± 0.5** | 10.8± 0.4** | 10.5± 0.6** | 10.5± 0.5** | 10.3± 0.5** | 10.3± 0.4** |

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

Test of Dunnett

APPENDIX B 4-3

FOOD CONSUMPTION CHANGES : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|------------|----------|------------|------------|------------|------------|
| | 1-7(7) | 2-7(7) | 3-7(7) | 4-7(7) | 5-7(7) | 6-7(7) | 7-7(7) |
| Control | 3.6± 0.2 | 3.5± 0.1 | 3.6± 0.1 | 3.6± 0.2 | 3.6± 0.2 | 3.8± 0.2 | 3.8± 0.2 |
| 1000 ppm | 3.6± 0.3 | 3.6± 0.1 | 3.5± 0.1 | 3.7± 0.1 | 3.5± 0.2 | 3.7± 0.1 | 3.8± 0.2 |
| 2000 ppm | 3.6± 0.2 | 3.5± 0.2 | 3.6± 0.2 | 3.5± 0.1 | 3.5± 0.2 | 3.7± 0.1 | 3.7± 0.1 |
| 4000 ppm | 3.6± 0.3 | 3.5± 0.2 | 3.6± 0.2 | 3.4± 0.1 | 3.5± 0.1 | 3.6± 0.1 | 3.7± 0.1 |
| 8000 ppm | 3.5± 0.2 | 3.5± 0.3 | 3.7± 0.4 | 3.5± 0.3 | 3.4± 0.4 | 3.5± 0.3** | 3.6± 0.3* |
| 16000 ppm | 3.1± 0.1** | 3.2± 0.2** | 3.3± 0.2 | 3.2± 0.3** | 3.1± 0.2** | 3.2± 0.2** | 3.3± 0.1** |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

| Group Name | Administration 8-7(7) | week-day(effective) 9-7(7) | 10-7(7) | 11-7(7) | 12-7(7) | 13-7(7) |
|------------|--------------------------|-------------------------------|------------|------------|------------|------------|
| Control | 4.0± 0.2 | 4.0± 0.2 | 4.1± 0.8 | 4.1± 0.2 | 4.1± 0.2 | 4.1± 0.2 |
| 1000 ppm | 3.9± 0.2 | 4.1± 0.2 | 4.0± 0.2 | 4.0± 0.3 | 4.1± 0.2 | 4.1± 0.2 |
| 2000 ppm | 3.9± 0.2 | 3.8± 0.2 | 3.8± 0.2 | 4.0± 0.2 | 3.9± 0.1 | 4.1± 0.6 |
| 4000 ppm | 3.8± 0.2 | 3.9± 0.1 | 3.8± 0.2 | 3.8± 0.2 | 3.8± 0.2* | 3.8± 0.2 |
| 8000 ppm | 3.7± 0.3** | 3.8± 0.3** | 3.6± 0.3* | 3.6± 0.3** | 3.6± 0.4** | 3.6± 0.3** |
| 16000 ppm | 3.5± 0.1** | 3.4± 0.1** | 3.4± 0.1** | 3.3± 0.2** | 3.3± 0.2** | 3.2± 0.2** |

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX B 4-4

FOOD CONSUMPTION CHANGES : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

| Group Name | Administration 1-7(7) | week-day(effective) 2-7(7) | 3-7(7) | 4-7(7) | 5-7(7) | 6-7(7) | 7-7(7) |
|------------|--------------------------|-------------------------------|-----------|------------|------------|------------|------------|
| Control | 2.9± 0.3 | 3.2± 0.3 | 3.2± 0.3 | 3.3± 0.3 | 3.4± 0.3 | 3.6± 0.3 | 3.7± 0.3 |
| 1000 ppm | 3.0± 0.2 | 3.1± 0.2 | 3.1± 0.3 | 3.4± 0.2 | 3.4± 0.2 | 3.5± 0.1 | 3.7± 0.2 |
| 2000 ppm | 3.0± 0.3 | 3.1± 0.2 | 3.1± 0.3 | 3.3± 0.2 | 3.4± 0.2 | 3.4± 0.3 | 3.7± 0.3 |
| 4000 ppm | 3.0± 0.2 | 3.1± 0.2 | 3.1± 0.2 | 3.3± 0.2 | 3.3± 0.2 | 3.5± 0.3 | 3.7± 0.2 |
| 8000 ppm | 2.9± 0.2 | 3.2± 0.2 | 3.2± 0.6 | 3.3± 0.2 | 3.3± 0.2 | 3.5± 0.2 | 3.7± 0.2 |
| 16000 ppm | 2.6± 0.2** | 2.7± 0.2** | 2.8± 0.2* | 2.9± 0.1** | 3.0± 0.1** | 3.0± 0.2** | 3.3± 0.2** |

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

| Group Name | Administration 8-7(7) | week-day(effective) 9-7(7) | 10-7(7) | 11-7(7) | 12-7(7) | 13-7(7) |
|------------|--------------------------|-------------------------------|------------|------------|------------|------------|
| Control | 4.0± 0.3 | 4.1± 0.3 | 4.0± 0.3 | 4.0± 0.3 | 3.9± 0.4 | 4.1± 0.3 |
| 1000 ppm | 3.9± 0.2 | 4.0± 0.2 | 3.8± 0.3 | 3.9± 0.3 | 3.7± 0.3 | 3.8± 0.3 |
| 2000 ppm | 3.8± 0.3 | 3.9± 0.2 | 3.7± 0.2 | 3.7± 0.3 | 3.8± 0.2 | 3.8± 0.3 |
| 4000 ppm | 3.9± 0.3 | 3.8± 0.2 | 3.9± 0.4 | 3.7± 0.3* | 3.6± 0.2 | 3.8± 0.4 |
| 8000 ppm | 3.9± 0.3 | 3.8± 0.5 | 3.8± 0.3 | 3.8± 0.3 | 3.7± 0.4 | 3.8± 0.2 |
| 16000 ppm | 3.5± 0.2** | 3.5± 0.2** | 3.5± 0.1** | 3.5± 0.2** | 3.4± 0.2** | 3.6± 0.2** |

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX B 5-1

CHEMICAL INTAKE CHANGES: SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 13
 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 | 0.000± 0.000 | | |
| 500 ppm | 61.208± 3.044 | 54.914± 2.726 | 51.181± 2.955 | 47.890± 1.738 | 45.889± 5.933 | 43.057± 4.215 | 38.726± 1.875 | | | |
| 1000 ppm | 109.420± 5.253 | 101.428± 5.006 | 91.772± 3.786 | 86.240± 3.146 | 79.327± 4.759 | 75.915± 3.991 | 70.808± 3.400 | | | |
| 2000 ppm | 204.116± 10.783 | 183.416± 7.069 | 169.033± 8.353 | 154.861± 6.997 | 142.349± 8.480 | 132.759± 7.634 | 127.870± 5.458 | | | |
| 4000 ppm | 401.980± 18.767 | 369.215± 19.642 | 334.215± 22.514 | 315.652± 24.012 | 289.500± 21.544 | 277.857± 25.619 | 257.416± 17.232 | | | |
| 8000 ppm | 842.948± 59.325 | 865.899± 281.183 | 650.877± 31.839 | 593.916± 30.575 | 548.720± 35.604 | 514.669± 25.430 | 471.501± 23.236 | | | |

(IAN300)

BAIS 2

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : mg/kg/day
 REPORT TYPE : A1 13
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

| Group Name | Administration (weeks) | | | | | | | | | |
|------------|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|--|--|--|--|
| | 8 | 9 | 10 | 11 | 12 | 13 | | | | |
| 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 | | | | |
| 500 ppm | 37.003± 1.730 | 38.411± 4.823 | 34.371± 3.058 | 32.865± 4.588 | 33.067± 4.705 | 31.004± 2.853 | | | | |
| 1000 ppm | 68.839± 3.423 | 65.159± 3.453 | 62.269± 2.900 | 59.197± 2.751 | 59.209± 3.588 | 58.033± 3.401 | | | | |
| 2000 ppm | 122.138± 7.038 | 114.854± 4.056 | 109.696± 5.364 | 107.356± 3.192 | 105.382± 4.165 | 104.560± 4.024 | | | | |
| 4000 ppm | 248.015± 13.088 | 234.982± 12.597 | 228.725± 10.863 | 219.977± 12.544 | 216.674± 13.912 | 214.727± 7.245 | | | | |
| 8000 ppm | 459.392± 17.253 | 448.764± 31.362 | 427.360± 19.957 | 414.379± 17.683 | 405.345± 18.807 | 408.979± 18.111 | | | | |

(HAN300)

BAIS2

APPENDIX B 5-2

CHEMICAL INTAKE CHANGES: SUMMARY,RAT: FEMALE

(13Week STUDY)

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : mg/kg/day
 REPORT TYPE : A1 13
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

| 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 |
| 500 ppm | 74.058± 5.550 | 73.965± 21.841 | 73.090± 27.107 | 69.358± 27.878 | 61.755± 13.529 | 73.608± 24.518 | 63.615± 26.230 |
| 1000 ppm | 132.266± 7.372 | 122.637± 9.960 | 133.179± 52.705 | 122.869± 35.248 | 123.466± 48.252 | 115.208± 42.110 | 110.287± 38.639 |
| 2000 ppm | 248.512± 20.291 | 225.251± 13.428 | 209.743± 14.563 | 196.141± 19.430 | 190.735± 12.616 | 177.888± 10.810 | 175.328± 10.939 |
| 4000 ppm | 446.786± 23.016 | 418.479± 33.265 | 386.813± 25.406 | 355.514± 34.599 | 348.944± 30.721 | 336.481± 32.325 | 315.235± 30.602 |
| 8000 ppm | 835.453± 52.550 | 775.400± 49.285 | 693.775± 44.863 | 639.918± 22.074 | 634.418± 60.136 | 742.731± 355.721 | 552.283± 31.006 |

(HAN300)

BAIS 2

STUDY NO. : 0107
 ANIMAL : RAT F344
 UNIT : mg/kg/day
 REPORT TYPE : A1 13
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

| Group Name | Administration (weeks) | | | | | |
|------------|------------------------|-----------------|-----------------|-----------------|-----------------|------------------|
| | 8 | 9 | 10 | 11 | 12 | 13 |
| 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 |
| 500 ppm | 67.192± 25.269 | 64.435± 22.889 | 66.513± 22.477 | 58.217± 15.428 | 55.828± 18.464 | 61.839± 25.537 |
| 1000 ppm | 104.160± 30.031 | 105.084± 35.262 | 96.645± 27.579 | 87.707± 19.613 | 87.420± 19.839 | 87.403± 29.536 |
| 2000 ppm | 168.832± 15.442 | 159.309± 21.412 | 151.836± 11.804 | 145.385± 10.496 | 142.549± 10.557 | 142.858± 11.760 |
| 4000 ppm | 304.655± 34.915 | 274.943± 22.677 | 276.072± 20.515 | 271.643± 16.877 | 267.872± 22.133 | 267.622± 18.639 |
| 8000 ppm | 522.805± 22.455 | 510.576± 22.007 | 511.746± 34.487 | 466.066± 12.497 | 463.763± 27.768 | 564.093± 159.275 |

(HAN300)

BAIS 2

APPENDIX B 5-3

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

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 13
 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 |
| 1000 ppm | 191.234± 14.975 | 169.576± 15.899 | 152.478± 14.862 | 154.136± 13.169 | 137.022± 11.692 | 137.661± 10.239 | 132.244± 10.569 |
| 2000 ppm | 366.031± 39.518 | 302.968± 39.306 | 277.327± 37.620 | 264.795± 36.848 | 243.336± 29.110 | 236.366± 22.666 | 227.666± 23.677 |
| 4000 ppm | 577.371± 53.145 | 532.919±125.103 | 468.835± 57.452 | 449.500± 70.694 | 449.862± 85.029 | 448.450±103.899 | 410.862± 51.246 |
| 8000 ppm | 937.145±180.553 | 799.549±144.257 | 733.051±141.414 | 727.384±111.321 | 739.391± 97.942 | 744.345±124.943 | 774.836±117.102 |
| 16000 ppm | 1525.140±141.786 | 1284.177±130.762 | 1217.216±106.089 | 1227.386±148.734 | 1201.969±134.789 | 1179.683± 99.415 | 1234.630± 77.405 |

(HAN300)

BAIS 2

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : mg/kg/day
 REPORT TYPE : A1 13
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

| Group Name | Administration (weeks) | | | | | |
|------------|------------------------|------------------|-------------------|-------------------|-------------------|-------------------|
| | 8 | 9 | 10 | 11 | 12 | 13 |
| 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 |
| 1000 ppm | 120.848± 14.503 | 122.454± 10.802 | 117.967± 10.967 | 112.585± 13.370 | 110.879± 11.828 | 105.181± 11.943 |
| 2000 ppm | 210.802± 21.516 | 211.972± 18.976 | 200.533± 18.115 | 196.306± 16.192 | 189.271± 20.515 | 187.657± 27.369 |
| 4000 ppm | 400.882± 56.919 | 379.080± 51.124 | 371.091± 50.901 | 363.669± 40.370 | 347.211± 44.216 | 332.363± 46.906 |
| 8000 ppm | 690.809± 87.709 | 701.449± 96.117 | 693.337± 110.700 | 688.062± 169.473 | 667.301± 85.667 | 632.034± 98.542 |
| 16000 ppm | 1130.424± 91.677 | 1104.435± 91.427 | 1076.627± 106.761 | 1095.528± 212.616 | 1101.991± 202.515 | 1001.945± 139.359 |

(HAN300)

BAIS 2

APPENDIX B 5-4

CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: FEMALE

(13Week STUDY)

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : mg/kg/day
 REPORT TYPE : A1 13
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

| 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 |
| 1000 ppm | 257.011± 42.910 | 235.724± 42.880 | 231.762± 39.830 | 235.853± 44.760 | 208.670± 16.783 | 213.480± 24.305 | 210.307± 23.102 |
| 2000 ppm | 467.368± 58.751 | 468.506± 93.391 | 414.893± 49.082 | 415.140± 40.767 | 386.703± 39.047 | 406.631± 44.892 | 411.125± 94.966 |
| 4000 ppm | 788.179± 84.192 | 785.706± 138.276 | 804.533± 186.287 | 794.410± 110.895 | 797.309± 104.176 | 774.029± 72.709 | 802.641± 115.127 |
| 8000 ppm | 1243.320± 118.480 | 1196.236± 130.745 | 1205.963± 196.137 | 1301.846± 333.717 | 1353.603± 193.338 | 1349.491± 222.254 | 1258.380± 100.046 |
| 16000 ppm | 2014.469± 291.718 | 1930.380± 444.654 | 1909.777± 354.069 | 2005.859± 381.006 | 2095.604± 496.330 | 2466.654± 824.768 | 2311.581± 656.203 |

(HAN300)

BAIS 2

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 13
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

| Group Name | Administration (weeks) | | | | | |
|------------|------------------------|------------------|------------------|------------------|------------------|------------------|
| | 8 | 9 | 10 | 11 | 12 | 13 |
| 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 |
| 1000 ppm | 205.283± 28.050 | 185.925± 17.278 | 190.870± 16.286 | 183.336± 11.872 | 181.500± 10.375 | 173.202± 10.142 |
| 2000 ppm | 402.510± 89.938 | 384.755± 62.500 | 368.641± 57.810 | 357.980± 45.868 | 355.554± 48.390 | 352.408± 45.482 |
| 4000 ppm | 708.116±119.631 | 747.713±147.134 | 805.808±314.958 | 683.418±170.044 | 833.679±382.211 | 749.542±323.092 |
| 8000 ppm | 1228.809±273.438 | 1128.758±135.663 | 1187.633±207.839 | 1248.901±441.618 | 1315.623±621.771 | 1123.225±187.349 |
| 16000 ppm | 2452.155±717.323 | 2674.701±841.316 | 2740.781±975.938 | 2506.571±523.676 | 2589.617±643.889 | 2390.382±641.388 |

(HAN300)

BAIS 2

APPENDIX B 6-1

HEMATOLOGY : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0107
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

HEMATOLOGY(1) (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 1

| Group Name | NO. of Animals | RED BLOOD CELL 10 ⁶ /μl | | HEMOGLOBIN g/dl | | HEMATOCRIT % | | MCV fl | | PLATELET 10 ³ /μl | |
|------------|-------------------|---------------------------------------|------|--------------------|-----|-----------------|-----|-----------|-----|---------------------------------|----|
| Control | 10 | 9.39± | 0.25 | 16.2± | 0.4 | 44.5± | 1.5 | 47.4± | 0.7 | 744± | 48 |
| 500 ppm | 10 | 9.31± | 0.32 | 16.0± | 0.5 | 44.2± | 1.7 | 47.5± | 0.5 | 764± | 54 |
| 1000 ppm | 10 | 9.44± | 0.23 | 16.1± | 0.3 | 44.7± | 1.1 | 47.3± | 0.5 | 743± | 52 |
| 2000 ppm | 10 | 9.34± | 0.24 | 15.8± | 0.4 | 44.1± | 2.0 | 47.2± | 1.0 | 744± | 48 |
| 4000 ppm | 10 | 9.32± | 0.30 | 15.8± | 0.5 | 43.7± | 1.7 | 46.9± | 0.7 | 720± | 78 |
| 8000 ppm | 10 | 9.23± | 0.40 | 15.6± | 0.6 | 43.5± | 2.3 | 47.1± | 0.7 | 701± | 80 |

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

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

| Group Name | NO. of Animals | WBC 1 O ³ /μℓ | | Differential N-BAND | | WBC (%) N-SEG | EOSINO | | BASO | | MONO | | LYMPHO | | OTHER | | |
|------------|-------------------|-----------------------------|------|------------------------|---|---------------------|--------|----|------|----|------|----|--------|-----|-------|----|---|
| Control | 10 | 4.39± | 1.19 | 0± | 0 | 28± | 6 | 1± | 1 | 0± | 0 | 5± | 1 | 65± | 6 | 1± | 1 |
| 500 ppm | 10 | 4.63± | 1.07 | 0± | 0 | 24± | 5 | 2± | 2 | 0± | 0 | 4± | 2 | 69± | 4 | 1± | 1 |
| 1000 ppm | 10 | 5.00± | 1.28 | 0± | 0 | 26± | 4 | 2± | 1 | 0± | 0 | 3± | 2 | 68± | 5 | 1± | 1 |
| 2000 ppm | 10 | 4.32± | 1.15 | 0± | 1 | 28± | 7 | 1± | 1 | 0± | 0 | 5± | 2 | 65± | 7 | 1± | 1 |
| 4000 ppm | 10 | 3.81± | 1.20 | 0± | 1 | 26± | 7 | 2± | 1 | 0± | 0 | 4± | 1 | 67± | 9 | 1± | 1 |
| 8000 ppm | 10 | 4.85± | 3.39 | 0± | 1 | 24± | 6 | 1± | 1 | 0± | 0 | 5± | 2 | 68± | 9 | 1± | 1 |

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

Test of Dunnett

(JCL71A)

BAIS 2

APPENDIX B 6-2

HEMATOLOGY : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0107
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 2

| Group Name | NO. of Animals | RED BLOOD CELL 10 ⁶ /μl | | HEMOGLOBIN g/dl | | HEMATOCRIT % | | MCV fl | | PLATELET 10 ³ /μl | |
|------------|-------------------|---------------------------------------|------|--------------------|-----|-----------------|-----|-----------|-----|---------------------------------|-----|
| Control | 10 | 8.61± | 0.22 | 16.0± | 0.4 | 43.8± | 2.0 | 50.9± | 1.2 | 762± | 66 |
| 500 ppm | 10 | 8.54± | 0.34 | 15.8± | 0.5 | 43.1± | 2.1 | 50.5± | 0.8 | 761± | 46 |
| 1000 ppm | 10 | 8.60± | 0.27 | 15.8± | 0.4 | 43.6± | 2.1 | 50.7± | 1.0 | 760± | 104 |
| 2000 ppm | 10 | 8.49± | 0.23 | 15.7± | 0.5 | 42.7± | 1.7 | 50.3± | 0.8 | 789± | 73 |
| 4000 ppm | 10 | 8.45± | 0.32 | 15.5± | 0.6 | 42.9± | 2.5 | 50.7± | 1.2 | 703± | 113 |
| 8000 ppm | 10 | 8.49± | 0.31 | 15.5± | 0.4 | 42.7± | 2.6 | 50.3± | 1.3 | 730± | 45 |

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0107
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 2

| Group Name | NO. of Animals | WBC 10 ³ /μl | | Differential N-BAND | | WBC (%) N-SEG | | EOSINO | | BASO | | MONO | | LYMPHO | | OTHER | |
|------------|-------------------|----------------------------|------|------------------------|---|---------------------|----|--------|---|------|---|------|---|--------|---|-------|---|
| Control | 10 | 2.74± | 0.91 | 0± | 0 | 24± | 8 | 2± | 1 | 0± | 0 | 5± | 1 | 69± | 7 | 1± | 1 |
| 500 ppm | 10 | 2.82± | 0.98 | 0± | 1 | 24± | 8 | 2± | 1 | 0± | 0 | 4± | 2 | 69± | 9 | 1± | 1 |
| 1000 ppm | 10 | 2.55± | 0.84 | 0± | 0 | 20± | 5 | 1± | 1 | 0± | 0 | 5± | 2 | 73± | 5 | 1± | 1 |
| 2000 ppm | 10 | 3.13± | 0.73 | 1± | 1 | 22± | 4 | 2± | 1 | 0± | 0 | 5± | 1 | 71± | 5 | 1± | 1 |
| 4000 ppm | 10 | 2.45± | 1.02 | 0± | 0 | 20± | 10 | 2± | 1 | 0± | 0 | 5± | 2 | 72± | 9 | 1± | 1 |
| 8000 ppm | 10 | 2.47± | 0.63 | 1± | 1 | 18± | 5 | 1± | 1 | 0± | 0 | 5± | 2 | 74± | 4 | 1± | 1 |

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

Test of Dunnett

(JCL71A)

BAIS 2

APPENDIX B 6-3

HEMATOLOGY : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

| Group Name | NO. of Animals | RED BLOOD CELL 10 ⁶ /μl | | HEMOGLOBIN g/dl | | HEMATOCRIT % | | MCV fl | | PLATELET 10 ³ /μl | |
|------------|-------------------|---------------------------------------|------|--------------------|-----|-----------------|-----|-----------|-----|---------------------------------|-----|
| Control | 9 | 10.54± | 0.68 | 15.8± | 0.9 | 46.1± | 2.8 | 43.7± | 0.9 | 1437± | 209 |
| 1000 ppm | 10 | 10.28± | 0.83 | 15.5± | 1.4 | 44.9± | 4.0 | 43.6± | 0.8 | 1410± | 171 |
| 2000 ppm | 10 | 10.15± | 0.70 | 15.2± | 0.9 | 43.9± | 2.9 | 43.3± | 0.5 | 1441± | 81 |
| 4000 ppm | 10 | 10.13± | 0.75 | 15.3± | 1.1 | 43.8± | 3.4 | 43.3± | 0.5 | 1376± | 171 |
| 8000 ppm | 10 | 10.05± | 0.37 | 14.9± | 0.5 | 43.6± | 1.9 | 43.4± | 0.6 | 1374± | 167 |
| 16000 ppm | 9 | 9.97± | 1.06 | 14.7± | 1.5 | 43.2± | 4.6 | 43.3± | 0.4 | 1244± | 159 |

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (13)

| Group Name | NO. of Animals | WBC 10 ³ /μl | | Differential N-BAND | | WBC (%) N-SEG | | EOSINO | | BASO | | MONO | | LYMPHO | | OTHER | |
|------------|-------------------|----------------------------|------|------------------------|---|---------------------|---|--------|---|------|---|------|---|--------|---|-------|---|
| Control | 9 | 2.15± | 1.85 | 1± | 1 | 14± | 5 | 1± | 1 | 0± | 0 | 1± | 1 | 83± | 6 | 0± | 1 |
| 1000 ppm | 10 | 1.91± | 1.80 | 1± | 1 | 15± | 6 | 2± | 2 | 0± | 0 | 1± | 1 | 82± | 6 | 0± | 0 |
| 2000 ppm | 10 | 1.74± | 1.07 | 1± | 1 | 17± | 7 | 1± | 1 | 0± | 0 | 1± | 1 | 80± | 7 | 0± | 0 |
| 4000 ppm | 10 | 1.42± | 0.66 | 1± | 1 | 19± | 6 | 1± | 1 | 0± | 0 | 1± | 1 | 79± | 6 | 0± | 0 |
| 8000 ppm | 10 | 1.37± | 0.75 | 1± | 2 | 18± | 8 | 1± | 1 | 0± | 0 | 0± | 1 | 79± | 8 | 0± | 0 |
| 16000 ppm | 9 | 1.29± | 0.94 | 1± | 1 | 20± | 7 | 1± | 1 | 0± | 0 | 0± | 1 | 78± | 6 | 0± | 0 |

Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Dunnett

APPENDIX B 6-4

HEMATOLOGY : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 2

| Group Name | NO. of Animals | RED BLOOD CELL 10 ⁶ /μl | | HEMOGLOBIN g/dl | | HEMATOCRIT % | | MCV fl | | PLATELET 10 ³ /μl | |
|------------|-------------------|---------------------------------------|------|--------------------|-----|-----------------|-----|-----------|-----|---------------------------------|-----|
| Control | 10 | 9.89± | 0.40 | 15.2± | 0.8 | 43.4± | 1.9 | 43.9± | 0.8 | 1068± | 376 |
| 1000 ppm | 10 | 9.86± | 0.54 | 15.1± | 0.8 | 42.8± | 2.7 | 43.4± | 0.7 | 1156± | 273 |
| 2000 ppm | 9 | 10.01± | 0.71 | 15.2± | 1.0 | 43.9± | 3.2 | 43.9± | 0.5 | 1242± | 106 |
| 4000 ppm | 10 | 10.01± | 0.59 | 15.3± | 0.9 | 43.1± | 2.7 | 43.1± | 0.9 | 1263± | 120 |
| 8000 ppm | 10 | 10.02± | 0.49 | 15.4± | 0.7 | 43.7± | 2.0 | 43.6± | 0.6 | 1218± | 65 |
| 16000 ppm | 10 | 9.71± | 0.46 | 15.1± | 0.6 | 42.9± | 2.0 | 44.2± | 0.9 | 1124± | 71 |

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

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

| Group Name | NO. of Animals | WBC 10 ³ /μl | | Differential N-BAND | | WBC (%) N-SEG | | EOSINO | | BASO | | MONO | | LYMPHO | | OTHER | |
|------------|-------------------|----------------------------|------|------------------------|---|---------------------|----|--------|---|------|---|------|---|--------|----|-------|---|
| Control | 10 | 1.01± | 0.71 | 1± | 2 | 15± | 6 | 0± | 1 | 0± | 0 | 1± | 1 | 83± | 7 | 0± | 1 |
| 1000 ppm | 10 | 0.76± | 0.25 | 1± | 1 | 22± | 9 | 1± | 1 | 0± | 0 | 1± | 1 | 76± | 9 | 0± | 1 |
| 2000 ppm | 9 | 1.01± | 0.69 | 1± | 1 | 16± | 8 | 1± | 2 | 0± | 0 | 0± | 0 | 81± | 9 | 0± | 1 |
| 4000 ppm | 10 | 0.68± | 0.25 | 2± | 3 | 19± | 14 | 1± | 2 | 0± | 0 | 1± | 1 | 77± | 17 | 1± | 1 |
| 8000 ppm | 10 | 0.79± | 0.43 | 1± | 1 | 21± | 6 | 1± | 1 | 0± | 0 | 1± | 1 | 77± | 6 | 0± | 0 |
| 16000 ppm | 10 | 0.50± | 0.31 | 1± | 1 | 16± | 12 | 0± | 0 | 0± | 0 | 0± | 0 | 82± | 12 | 0± | 0 |

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

Test of Dunnett

(JCL71A)

BAIS 2

APPENDIX B 7-1

BIOCHEMISTRY : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0107
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 1

| Group Name | NO. of Animals | TOTAL PROTEIN g/dl | | ALBUMIN g/dl | | A/G RATIO | | T-BILIRUBIN mg/dl | | GOT IU/l | | GPT IU/l | | LDH IU/l | |
|------------|-------------------|-----------------------|-------|-----------------|-------|-----------|-------|----------------------|------|-------------|----|-------------|-----|-------------|-----|
| Control | 10 | 6.9± | 0.2 | 3.8± | 0.1 | 1.3± | 0.0 | 0.32± | 0.05 | 82± | 15 | 26± | 2 | 191± | 86 |
| 500 ppm | 10 | 6.9± | 0.1 | 3.9± | 0.1 | 1.3± | 0.1 | 0.29± | 0.06 | 84± | 20 | 26± | 5 | 163± | 42 |
| 1000 ppm | 10 | 6.8± | 0.2 | 3.8± | 0.1 | 1.3± | 0.0 | 0.33± | 0.08 | 89± | 18 | 29± | 5 | 195± | 58 |
| 2000 ppm | 10 | 6.8± | 0.1 | 3.8± | 0.1 | 1.3± | 0.1 | 0.31± | 0.05 | 89± | 17 | 29± | 10 | 223± | 120 |
| 4000 ppm | 10 | 6.6± | 0.2** | 3.7± | 0.1 | 1.3± | 0.1 | 0.30± | 0.06 | 81± | 21 | 23± | 6 | 185± | 76 |
| 8000 ppm | 10 | 6.3± | 0.2** | 3.6± | 0.1** | 1.4± | 0.1** | 0.27± | 0.04 | 68± | 7 | 19± | 2** | 150± | 36 |

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0107
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 2

| Group Name | NO. of Animals | ALP I U / ℓ | | G-GTP I U / ℓ | | CPK I U / ℓ | | GLUCOSE mg / dl | | T-CHOLESTEROL mg / dl | | TRIGLYCERIDE mg / dl | | PHOSPHOLIPID mg / dl | |
|------------|-------------------|---------------------|----|-----------------------|---|---------------------|----|--------------------|----|--------------------------|-----|-------------------------|----|-------------------------|-----|
| Control | 10 | 296 \pm | 18 | 2 \pm | 1 | 99 \pm | 25 | 203 \pm | 10 | 55 \pm | 4 | 103 \pm | 22 | 112 \pm | 7 |
| 500 ppm | 10 | 305 \pm | 19 | 2 \pm | 1 | 88 \pm | 7 | 207 \pm | 12 | 52 \pm | 4 | 100 \pm | 17 | 108 \pm | 9 |
| 1000 ppm | 10 | 300 \pm | 13 | 2 \pm | 1 | 99 \pm | 25 | 208 \pm | 18 | 54 \pm | 3 | 113 \pm | 37 | 113 \pm | 12 |
| 2000 ppm | 10 | 300 \pm | 24 | 2 \pm | 1 | 93 \pm | 19 | 204 \pm | 18 | 56 \pm | 4 | 117 \pm | 26 | 116 \pm | 9 |
| 4000 ppm | 10 | 297 \pm | 31 | 2 \pm | 0 | 92 \pm | 14 | 207 \pm | 16 | 52 \pm | 3 | 93 \pm | 17 | 111 \pm | 7 |
| 8000 ppm | 10 | 305 \pm | 15 | 1 \pm | 1 | 87 \pm | 13 | 197 \pm | 19 | 46 \pm | 3** | 81 \pm | 17 | 99 \pm | 6** |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 3

| Group Name | NO. of Animals | UREA NITROGEN mg/dl | | CREATININE mg/dl | | CALCIUM mg/dl | | INORGANIC PHOSPHORUS mg/dl | | SODIUM mEq/l | | POTASSIUM mEq/l | | CHLORIDE mEq/l | |
|------------|-------------------|------------------------|-----|---------------------|-----|------------------|-------|-------------------------------|-----|-----------------|-----|--------------------|-----|-------------------|---|
| Control | 10 | 18.5± | 0.7 | 0.5± | 0.0 | 10.5± | 0.2 | 5.2± | 0.7 | 141± | 1 | 3.5± | 0.2 | 105± | 1 |
| 500 ppm | 10 | 18.3± | 1.0 | 0.6± | 0.1 | 10.5± | 0.2 | 5.2± | 0.8 | 141± | 1 | 3.3± | 0.3 | 105± | 1 |
| 1000 ppm | 10 | 18.0± | 0.9 | 0.5± | 0.0 | 10.5± | 0.2 | 5.2± | 0.9 | 141± | 1 | 3.4± | 0.3 | 106± | 1 |
| 2000 ppm | 10 | 18.8± | 1.1 | 0.5± | 0.0 | 10.5± | 0.3 | 5.3± | 1.1 | 139± | 2 | 3.8± | 0.7 | 105± | 2 |
| 4000 ppm | 10 | 18.4± | 1.1 | 0.6± | 0.1 | 10.4± | 0.3 | 5.0± | 0.8 | 140± | 2 | 3.5± | 0.2 | 107± | 2 |
| 8000 ppm | 10 | 18.0± | 1.4 | 0.5± | 0.0 | 10.2± | 0.2** | 4.8± | 0.6 | 138± | 1** | 3.7± | 0.3 | 107± | 2 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX B 7-2

BIOCHEMISTRY : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 4

| Group Name | NO. of Animals | TOTAL PROTEIN g / dl | | ALBUMIN g / dl | | A/G RATIO | | T-BILIRUBIN mg / dl | | GOT I U / l | | GPT I U / l | | LDH I U / l | |
|------------|-------------------|-------------------------|-------|-------------------|-------|-----------|-------|------------------------|------|----------------|----|----------------|---|----------------|-----|
| Control | 10 | 6.8± | 0.2 | 3.8± | 0.1 | 1.3± | 0.0 | 0.44± | 0.16 | 73± | 9 | 22± | 6 | 215± | 48 |
| 500 ppm | 10 | 6.8± | 0.2 | 3.8± | 0.1 | 1.3± | 0.1 | 0.43± | 0.14 | 67± | 7 | 21± | 4 | 182± | 47 |
| 1000 ppm | 10 | 6.8± | 0.2 | 3.9± | 0.2 | 1.3± | 0.1 | 0.41± | 0.17 | 73± | 12 | 21± | 5 | 248± | 147 |
| 2000 ppm | 10 | 6.6± | 0.1 | 3.8± | 0.1 | 1.3± | 0.1 | 0.39± | 0.06 | 70± | 11 | 22± | 7 | 169± | 46 |
| 4000 ppm | 10 | 6.6± | 0.2* | 3.8± | 0.1 | 1.3± | 0.1 | 0.44± | 0.12 | 65± | 7 | 18± | 5 | 218± | 73 |
| 8000 ppm | 10 | 6.3± | 0.2** | 3.6± | 0.1** | 1.4± | 0.1** | 0.43± | 0.11 | 62± | 4* | 17± | 2 | 188± | 49 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 5

| Group Name | NO. of Animals | ALP I U / ℓ | | G-GTP I U / ℓ | | CPK I U / ℓ | | GLUCOSE mg / dl | | T-CHOLESTEROL mg / dl | | TRIGLYCERIDE mg / dl | | PHOSPHOLIPID mg / dl | |
|------------|-------------------|---------------------|----|-----------------------|---|---------------------|----|--------------------|----|--------------------------|-----|-------------------------|---|-------------------------|------|
| Control | 10 | 200± | 25 | 2± | 1 | 102± | 18 | 152± | 11 | 76± | 5 | 38± | 5 | 148± | 8 |
| 500 ppm | 10 | 202± | 14 | 2± | 1 | 92± | 19 | 162± | 7 | 74± | 5 | 40± | 9 | 144± | 9 |
| 1000 ppm | 10 | 203± | 20 | 2± | 1 | 108± | 35 | 157± | 14 | 76± | 7 | 37± | 4 | 147± | 11 |
| 2000 ppm | 10 | 193± | 9 | 2± | 1 | 87± | 13 | 163± | 8 | 73± | 5 | 36± | 7 | 143± | 7 |
| 4000 ppm | 10 | 215± | 24 | 3± | 1 | 102± | 20 | 160± | 16 | 69± | 6* | 38± | 6 | 137± | 9 |
| 8000 ppm | 10 | 205± | 16 | 2± | 1 | 92± | 17 | 168± | 11 | 65± | 6** | 31± | 5 | 127± | 11** |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0107
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 6

| Group Name | NO. of Animals | UREA NITROGEN mg/dl | | CREATININE mg/dl | | CALCIUM mg/dl | | INORGANIC PHOSPHORUS mg/dl | | SODIUM mEq/l | | POTASSIUM mEq/l | | CHLORIDE mEq/l | |
|------------|-------------------|------------------------|-----|---------------------|-----|------------------|-----|-------------------------------|-----|-----------------|-----|--------------------|-----|-------------------|---|
| Control | 10 | 19.3± | 2.7 | 0.5± | 0.1 | 10.4± | 0.4 | 4.8± | 1.8 | 141± | 1 | 3.9± | 1.1 | 108± | 2 |
| 500 ppm | 10 | 19.5± | 2.2 | 0.5± | 0.1 | 10.2± | 0.3 | 3.9± | 1.4 | 141± | 1 | 3.4± | 0.2 | 108± | 2 |
| 1000 ppm | 10 | 18.5± | 1.1 | 0.5± | 0.0 | 10.4± | 0.4 | 4.8± | 1.6 | 141± | 1 | 3.9± | 0.8 | 108± | 2 |
| 2000 ppm | 10 | 18.1± | 1.8 | 0.5± | 0.0 | 10.2± | 0.2 | 4.3± | 1.4 | 140± | 1 | 3.5± | 0.3 | 108± | 1 |
| 4000 ppm | 10 | 18.3± | 1.4 | 0.5± | 0.0 | 10.4± | 0.2 | 4.8± | 1.6 | 140± | 2 | 4.1± | 1.2 | 108± | 2 |
| 8000 ppm | 10 | 19.4± | 1.8 | 0.5± | 0.1 | 10.1± | 0.3 | 4.5± | 1.5 | 139± | 2** | 3.9± | 0.7 | 108± | 2 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

APPENDIX B 7-3

BIOCHEMISTRY : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 1

| Group Name | NO. of Animals | TOTAL PROTEIN g/dl | | ALBUMIN g/dl | | A/G RATIO | | T-BILIRUBIN mg/dl | | GOT IU/l | | GPT IU/l | | LDH IU/l | |
|------------|-------------------|-----------------------|-------|-----------------|-------|-----------|------|----------------------|------|-------------|----|-------------|---|-------------|-----|
| Control | 9 | 5.7± | 0.2 | 3.3± | 0.1 | 1.4± | 0.1 | 0.79± | 0.41 | 51± | 7 | 14± | 3 | 464± | 247 |
| 1000 ppm | 10 | 5.6± | 0.3 | 3.3± | 0.2 | 1.4± | 0.1 | 0.88± | 0.50 | 50± | 11 | 14± | 2 | 488± | 352 |
| 2000 ppm | 10 | 5.5± | 0.2 | 3.2± | 0.1 | 1.4± | 0.0 | 0.64± | 0.33 | 44± | 9 | 12± | 1 | 345± | 224 |
| 4000 ppm | 9 | 5.4± | 0.2 | 3.1± | 0.1 | 1.4± | 0.1 | 0.71± | 0.22 | 50± | 5 | 13± | 3 | 453± | 158 |
| 8000 ppm | 10 | 5.3± | 0.3** | 3.1± | 0.1* | 1.4± | 0.1 | 0.64± | 0.37 | 48± | 10 | 13± | 2 | 447± | 298 |
| 16000 ppm | 9 | 5.1± | 0.3** | 3.0± | 0.2** | 1.5± | 0.1* | 0.59± | 0.25 | 49± | 14 | 13± | 3 | 397± | 249 |

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

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

| Group Name | NO. of Animals | ALP I U / ℓ | | CPK I U / ℓ | | GLUCOSE mg / dl | | T-CHOLESTEROL mg / dl | | TRIGLYCERIDE mg / dl | | UREA NITROGEN mg / dl | | CALCIUM mg / dl | |
|------------|-------------------|---------------------|----|---------------------|----|--------------------|----|--------------------------|------|-------------------------|------|--------------------------|-------|--------------------|-------|
| Control | 9 | 197± | 15 | 74± | 80 | 238± | 19 | 89± | 4 | 99± | 7 | 29.5± | 2.3 | 9.2± | 0.3 |
| 1000 ppm | 10 | 193± | 12 | 46± | 15 | 212± | 30 | 87± | 6 | 85± | 13 | 28.3± | 2.4 | 9.2± | 0.4 |
| 2000 ppm | 10 | 198± | 12 | 49± | 19 | 227± | 33 | 82± | 5 | 71± | 15** | 26.7± | 3.1 | 9.0± | 0.3 |
| 4000 ppm | 9 | 185± | 10 | 50± | 13 | 198± | 40 | 72± | 4** | 68± | 14** | 25.9± | 2.5* | 8.7± | 0.2* |
| 8000 ppm | 10 | 187± | 22 | 70± | 52 | 206± | 50 | 69± | 6** | 57± | 10** | 26.4± | 2.8* | 8.9± | 0.4 |
| 16000 ppm | 9 | 200± | 16 | 81± | 44 | 195± | 37 | 66± | 10** | 49± | 9** | 23.3± | 2.2** | 8.6± | 0.3** |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 3

| Group Name | NO. of Animals | INORGANIC PHOSPHORUS mg/dl | | SODIUM mEq/l | | POTASSIUM mEq/l | | CHLORIDE mEq/l | |
|------------|-------------------|-------------------------------|-----|-----------------|---|--------------------|------|-------------------|---|
| Control | 9 | 8.0± | 1.2 | 152± | 1 | 5.2± | 0.7 | 121± | 3 |
| 1000 ppm | 10 | 7.4± | 1.8 | 151± | 2 | 5.2± | 0.8 | 120± | 2 |
| 2000 ppm | 10 | 7.1± | 1.3 | 151± | 1 | 4.5± | 0.5* | 121± | 2 |
| 4000 ppm | 9 | 7.1± | 0.7 | 151± | 3 | 4.5± | 0.3* | 123± | 2 |
| 8000 ppm | 10 | 7.1± | 1.5 | 151± | 2 | 4.6± | 0.5 | 122± | 3 |
| 16000 ppm | 9 | 6.8± | 1.5 | 151± | 2 | 4.4± | 0.6* | 123± | 2 |

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

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX B 7-4

BIOCHEMISTRY : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 4

| Group Name | NO. of Animals | TOTAL PROTEIN g/dℓ | | ALBUMIN g/dℓ | | A/G RATIO | | T-BILIRUBIN mg/dℓ | | GOT I U/ℓ | | GPT I U/ℓ | | LDH I U/ℓ | |
|------------|-------------------|-----------------------|------|-----------------|-----|-----------|-----|----------------------|------|--------------|----|--------------|---|--------------|-----|
| Control | 10 | 5.4± | 0.3 | 3.4± | 0.2 | 1.7± | 0.1 | 0.68± | 0.30 | 68± | 29 | 16± | 5 | 402± | 209 |
| 1000 ppm | 9 | 5.4± | 0.2 | 3.4± | 0.1 | 1.7± | 0.1 | 0.64± | 0.23 | 75± | 24 | 18± | 5 | 430± | 160 |
| 2000 ppm | 8 | 5.4± | 0.2 | 3.4± | 0.1 | 1.7± | 0.1 | 0.61± | 0.15 | 75± | 26 | 19± | 7 | 377± | 134 |
| 4000 ppm | 10 | 5.4± | 0.2 | 3.3± | 0.2 | 1.7± | 0.3 | 0.62± | 0.16 | 83± | 40 | 20± | 6 | 433± | 220 |
| 8000 ppm | 10 | 5.4± | 0.2 | 3.4± | 0.1 | 1.7± | 0.1 | 0.59± | 0.26 | 65± | 15 | 15± | 3 | 364± | 101 |
| 16000 ppm | 10 | 5.1± | 0.2* | 3.3± | 0.1 | 1.8± | 0.1 | 0.50± | 0.23 | 69± | 21 | 16± | 4 | 351± | 144 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 5

| Group Name | NO. of Animals | ALP I U / ℓ | | CPK I U / ℓ | | GLUCOSE mg / dl | | T-CHOLESTEROL mg / dl | | TRIGLYCERIDE mg / dl | | UREA NITROGEN mg / dl | | CALCIUM mg / dl | |
|------------|-------------------|---------------------|----|---------------------|----|--------------------|----|--------------------------|-----|-------------------------|----|--------------------------|-----|--------------------|-----|
| Control | 10 | 313± | 46 | 66± | 31 | 163± | 26 | 71± | 7 | 45± | 11 | 25.0± | 5.0 | 8.9± | 0.2 |
| 1000 ppm | 9 | 343± | 31 | 80± | 28 | 153± | 17 | 69± | 7 | 44± | 9 | 24.0± | 2.3 | 8.9± | 0.4 |
| 2000 ppm | 8 | 344± | 50 | 87± | 45 | 162± | 16 | 71± | 9 | 48± | 15 | 23.3± | 1.9 | 8.8± | 0.2 |
| 4000 ppm | 10 | 325± | 82 | 106± | 83 | 171± | 27 | 64± | 7 | 45± | 11 | 24.8± | 3.6 | 8.8± | 0.3 |
| 8000 ppm | 10 | 318± | 27 | 73± | 37 | 167± | 25 | 65± | 8 | 41± | 7 | 22.6± | 1.4 | 8.7± | 0.3 |
| 16000 ppm | 10 | 317± | 41 | 86± | 42 | 159± | 21 | 51± | 9** | 37± | 11 | 25.1± | 2.6 | 8.6± | 0.3 |

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 6

| Group Name | NO. of Animals | INORGANIC PHOSPHORUS mg/dl | | SODIUM mEq/l | | POTASSIUM mEq/l | | CHLORIDE mEq/l | |
|------------|-------------------|-------------------------------|-----|-----------------|---|--------------------|-----|-------------------|---|
| Control | 10 | 6.9± | 1.2 | 150± | 1 | 4.6± | 0.4 | 123± | 2 |
| 1000 ppm | 9 | 7.2± | 0.8 | 151± | 2 | 4.5± | 0.5 | 124± | 2 |
| 2000 ppm | 8 | 7.1± | 0.7 | 151± | 1 | 4.4± | 0.3 | 124± | 1 |
| 4000 ppm | 10 | 6.6± | 0.8 | 150± | 3 | 4.8± | 0.4 | 124± | 2 |
| 8000 ppm | 10 | 6.2± | 0.6 | 151± | 2 | 4.8± | 0.5 | 124± | 2 |
| 16000 ppm | 10 | 6.2± | 0.8 | 149± | 4 | 4.3± | 0.5 | 124± | 4 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

APPENDIX B 8-1

URINALYSIS : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0107
 ANIMAL : RAT F344
 SAMPLING DATE : 013-5
 SEX : MALE

URINALYSIS

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+ |
| Control | 10 | 0 | 0 | 0 | 0 | 1 | 9 | 0 | | 0 | 0 | 5 | 5 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 4 | 6 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 |
| 500 ppm | 10 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | | 0 | 0 | 6 | 4 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 5 | 5 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 |
| 1000 ppm | 10 | 0 | 0 | 0 | 0 | 0 | 9 | 1 | | 0 | 0 | 5 | 5 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 5 | 5 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 |
| 2000 ppm | 10 | 0 | 0 | 0 | 0 | 1 | 8 | 1 | | 0 | 0 | 4 | 6 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 3 | 7 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 |
| 4000 ppm | 10 | 0 | 0 | 0 | 1 | 2 | 7 | 0 | | 0 | 0 | 4 | 6 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 2 | 8 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 |
| 8000 ppm | 10 | 0 | 0 | 1 | 1 | 5 | 3 | 0 | | 0 | 0 | 4 | 6 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 2 | 8 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 |

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

Test of CHI SQUARE

(JCL101)

BAIS2

STUDY NO. : 0107
ANIMAL : RAT F344
SAMPLING DATE : 013-5
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

| Group Name | NO. of Animals | Occult blood | | | | | CHI | Urobilinogen | | | | | CHI |
|------------|-------------------|--------------|---|---|----|----|-----|--------------|---|----|----|----|-----|
| | | - | ± | + | 2+ | 3+ | | ± | + | 2+ | 3+ | 4+ | |
| Control | 10 | 10 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 |
| 500 ppm | 10 | 10 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 |
| 1000 ppm | 10 | 10 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 |
| 2000 ppm | 10 | 10 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 |
| 4000 ppm | 10 | 10 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 |
| 8000 ppm | 10 | 8 | 2 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 |

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

Test of CHI SQUARE

(JCL101)

BAIS 2

APPENDIX B 8-2

URINALYSIS : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0107

ANIMAL : RAT F344

SAMPLING DATE : 013-5

SEX : FEMALE

REPORT TYPE : A1

URINALYSIS

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 | 10 | 0 | 0 | 0 | 0 | 1 | 8 | 1 | | 0 | 5 | 4 | 0 | 0 | 1 | | 10 | 0 | 0 | 0 | 0 | 0 | | 9 | 1 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | |
| 500 ppm | 10 | 0 | 0 | 0 | 0 | 0 | 9 | 1 | | 0 | 3 | 6 | 1 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 9 | 1 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | |
| 1000 ppm | 10 | 0 | 0 | 0 | 0 | 1 | 8 | 1 | | 0 | 2 | 7 | 1 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 9 | 1 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | |
| 2000 ppm | 10 | 0 | 0 | 1 | 0 | 1 | 7 | 1 | | 0 | 0 | 10 | 0 | 0 | 0 | * | 10 | 0 | 0 | 0 | 0 | 0 | | 8 | 2 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | |
| 4000 ppm | 10 | 0 | 0 | 0 | 2 | 3 | 4 | 1 | | 0 | 0 | 9 | 1 | 0 | 0 | * | 10 | 0 | 0 | 0 | 0 | 0 | | 5 | 5 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | |
| 8000 ppm | 10 | 0 | 1 | 1 | 4 | 3 | 1 | 0 | * | 0 | 0 | 7 | 3 | 0 | 0 | * | 10 | 0 | 0 | 0 | 0 | 0 | | 3 | 7 | 0 | 0 | 0 | 0 | ** | 10 | 0 | 0 | 0 | |

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

Test of CHI SQUARE

(JCL101)

BAIS2

STUDY NO. : 0107
ANIMAL : RAT F344
SAMPLING DATE : 013-5
SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 4

| Group Name | NO. of Animals | Occult blood | | | | | Urobilinogen | | | | |
|------------|-------------------|--------------|---|---|----|----|--------------|---|----|----|----|
| | | - | ± | + | 2+ | 3+ | ± | + | 2+ | 3+ | 4+ |
| Control | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |
| 500 ppm | 10 | 9 | 1 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |
| 1000 ppm | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |
| 2000 ppm | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |
| 4000 ppm | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |
| 8000 ppm | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |

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

Test of CHI SQUARE

(JCL101)

BAIS 2

APPENDIX B 8-3

URINALYSIS : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 SAMPLING DATE : 013-4
 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 | 10 | 0 | 0 | 0 | 0 | 0 | 9 | 1 | | 0 | 0 | 7 | 3 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 3 | 7 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | |
| 1000 ppm | 10 | 0 | 0 | 0 | 0 | 3 | 6 | 1 | | 0 | 0 | 6 | 4 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 6 | 4 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | |
| 2000 ppm | 10 | 0 | 0 | 0 | 0 | 5 | 4 | 1 | * | 0 | 0 | 3 | 7 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 4 | 6 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | |
| 4000 ppm | 10 | 0 | 0 | 0 | 2 | 6 | 2 | 0 | ** | 0 | 0 | 3 | 7 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 4 | 5 | 1 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | |
| 8000 ppm | 10 | 0 | 0 | 6 | 1 | 3 | 0 | 0 | ** | 0 | 0 | 1 | 9 | 0 | 0 | ** | 10 | 0 | 0 | 0 | 0 | 0 | | 5 | 5 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | |
| 16000 ppm | 10 | 0 | 2 | 8 | 0 | 0 | 0 | 0 | ** | 0 | 0 | 1 | 9 | 0 | 0 | ** | 10 | 0 | 0 | 0 | 0 | 0 | | 2 | 6 | 2 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | |

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

Test of CHI SQUARE

(JCL101)

BAIS2

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-4
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

| Group Name | NO. of Animals | Urobilinogen ± + 2+ 3+ 4+ CHI |
|------------|-------------------|----------------------------------|
| Control | 10 | 10 0 0 0 0 |
| 1000 ppm | 10 | 10 0 0 0 0 |
| 2000 ppm | 10 | 10 0 0 0 0 |
| 4000 ppm | 10 | 10 0 0 0 0 |
| 8000 ppm | 10 | 10 0 0 0 0 |
| 16000 ppm | 10 | 10 0 0 0 0 |

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

Test of CHI SQUARE

(JCL101)

BAIS2

APPENDIX B 8-4

URINALYSIS : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 SAMPLING DATE : 013-4
 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+ | 3+ |
| Control | 10 | 0 | 0 | 2 | 1 | 3 | 4 | 0 | | 0 | 1 | 6 | 3 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 0 | 9 | 1 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | |
| 1000 ppm | 10 | 0 | 0 | 1 | 2 | 4 | 3 | 0 | | 0 | 0 | 5 | 5 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 0 | 9 | 1 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | |
| 2000 ppm | 10 | 0 | 0 | 3 | 3 | 2 | 2 | 0 | | 0 | 1 | 6 | 3 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 1 | 8 | 1 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | |
| 4000 ppm | 10 | 1 | 1 | 2 | 2 | 2 | 1 | 1 | | 0 | 0 | 3 | 5 | 0 | 2 | | 10 | 0 | 0 | 0 | 0 | 0 | | 2 | 8 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | |
| 8000 ppm | 10 | 0 | 1 | 4 | 3 | 1 | 1 | 0 | | 0 | 0 | 0 | 10 | 0 | 0 | ** | 10 | 0 | 0 | 0 | 0 | 0 | | 2 | 2 | 6 | 0 | 0 | 0 | ** | 10 | 0 | 0 | 0 | 0 | |
| 16000 ppm | 10 | 0 | 4 | 5 | 0 | 0 | 1 | 0 | * | 0 | 0 | 3 | 7 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 0 | 2 | 8 | 0 | 0 | 0 | ** | 10 | 0 | 0 | 0 | 0 | |

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

Test of CHI SQUARE

(JCL101)

BAIS2

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-4
SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 4

| Group Name | NO. of Animals | Urobilinogen ± + 2+ 3+ 4+ CHI |
|------------|-------------------|----------------------------------|
| Control | 10 | 10 0 0 0 0 |
| 1000 ppm | 10 | 10 0 0 0 0 |
| 2000 ppm | 10 | 10 0 0 0 0 |
| 4000 ppm | 10 | 10 0 0 0 0 |
| 8000 ppm | 10 | 10 0 0 0 0 |
| 16000 ppm | 10 | 10 0 0 0 0 |

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

Test of CHI SQUARE

(JCL101)

BAIS2

APPENDIX B 9-1

GROSS FINDINGS : SUMMARY, RAT : MALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 1

| Organ | Findings | Group Name NO. of Animals | Control | 500 ppm | 1000 ppm | 2000 ppm |
|-------------|------------|------------------------------|---------|---------|----------|----------|
| | | | 10 (%) | 10 (%) | 10 (%) | 10 (%) |
| thymus | red zone | | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Liver | herniation | | 0 (0) | 1 (10) | 1 (10) | 0 (0) |
| abdominal c | nodule | | 2 (20) | 0 (0) | 0 (0) | 1 (10) |

(HPT080)

BAIS 2

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 2

| Organ | Findings | Group Name | 4000 ppm | 8000 ppm |
|-------------|------------|----------------|----------|----------|
| | | NO. of Animals | 10 (%) | 10 (%) |
| thymus | red zone | | 1 (10) | 0 (0) |
| liver | herniation | | 1 (10) | 0 (0) |
| abdominal c | nodule | | 0 (0) | 0 (0) |

(HPT080)

BAIS 2

APPENDIX B 9-2

GROSS FINDINGS : SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 3

| Organ | Findings | Group Name NO. of Animals | Control 10 (%) | 500 ppm 10 (%) | 1000 ppm 10 (%) | 2000 ppm 10 (%) |
|-------|-------------------|------------------------------|-------------------|-------------------|--------------------|--------------------|
| lung | white zone | | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| liver | herniation | | 2 (20) | 0 (0) | 0 (0) | 1 (10) |
| ovary | fluid:transparent | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |

(HPT080)

BAIS 2

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 4

| Organ | Findings | Group Name | 4000 ppm | 8000 ppm |
|-------|-------------------|----------------|----------|----------|
| | | NO. of Animals | 10 (%) | 10 (%) |
| lung | white zone | | 1 (10) | 0 (0) |
| liver | herniation | | 0 (0) | 0 (0) |
| ovary | fluid:transparent | | 0 (0) | 0 (0) |

(HPT080)

BA1S2

APPENDIX B 9-3

GROSS FINDINGS : SUMMARY, MOUSE: MALE :SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 1

| Organ | Findings | Group Name | Control | 1000 ppm | 2000 ppm | 4000 ppm |
|--------|----------------|----------------|---------|----------|----------|----------|
| | | NO. of Animals | 10 (%) | 10 (%) | 10 (%) | 10 (%) |
| spleen | black zone | | 1 (10) | 1 (10) | 1 (10) | 0 (0) |
| kidney | hydronephrosis | | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| testis | atrophic | | 0 (0) | 1 (10) | 0 (0) | 0 (0) |

(HPT080)

BAIS 2

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 2

| Organ | Findings | Group Name | 8000 ppm | 16000 ppm |
|--------|----------------|----------------|----------|-----------|
| | | NO. of Animals | 10 (%) | 10 (%) |
| spleen | black zone | | 3 (30) | 3 (30) |
| kidney | hydronephrosis | | 1 (10) | 0 (0) |
| testis | atrophic | | 0 (0) | 0 (0) |

(IPT080)

BAIS 2

APPENDIX B 9-4

GROSS FINDINGS : SUMMARY, MOUSE: FEMALE :SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 3

| Organ | Findings | Group Name NO. of Animals | Control 10 (%) | 1000 ppm 10 (%) | 2000 ppm 10 (%) | 4000 ppm 10 (%) |
|--------|------------|------------------------------|-------------------|--------------------|--------------------|--------------------|
| lung | red zone | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |
| spleen | black zone | | 2 (20) | 0 (0) | 1 (10) | 0 (0) |
| ovary | cyst | | 0 (0) | 1 (10) | 1 (10) | 0 (0) |

(HPT080)

BAIS 2

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 4

| Organ_____ | Findings_____ | Group Name NO. of Animals | 8000 ppm | 16000 ppm |
|------------|---------------|------------------------------|----------|-----------|
| | | | 10 (%) | 10 (%) |
| lung | red zone | | 0 (0) | 0 (0) |
| spleen | black zone | | 0 (0) | 3 (30) |
| ovary | cyst | | 1 (10) | 0 (0) |

(HPT080)

BAIS2

APPENDIX B 10-1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

| Group Name | NO. of Animals | Body Weight | THYMUS | ADRENALS | TESTES | HEART | LUNGS |
|------------|-------------------|-------------|----------------|---------------|--------------|---------------|----------------|
| Control | 10 | 314± 16 | 0.252± 0.026 | 0.054± 0.005 | 2.833± 0.095 | 0.946± 0.062 | 1.005± 0.036 |
| 500 ppm | 10 | 312± 8 | 0.234± 0.028 | 0.053± 0.004 | 2.830± 0.090 | 0.943± 0.039 | 1.002± 0.018 |
| 1000 ppm | 10 | 317± 11 | 0.241± 0.016 | 0.055± 0.004 | 2.849± 0.098 | 0.950± 0.046 | 0.994± 0.029 |
| 2000 ppm | 10 | 318± 14 | 0.249± 0.038 | 0.055± 0.006 | 2.915± 0.083 | 0.953± 0.069 | 1.027± 0.050 |
| 4000 ppm | 10 | 306± 11 | 0.242± 0.033 | 0.051± 0.004 | 2.851± 0.114 | 0.948± 0.058 | 1.005± 0.041 |
| 8000 ppm | 10 | 278± 9** | 0.204± 0.019** | 0.049± 0.003* | 2.748± 0.127 | 0.876± 0.044* | 0.941± 0.039** |

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

| Group Name | NO. of Animals | KIDNEYS | | SPLEEN | | LIVER | | BRAIN | |
|------------|-------------------|---------|-------|--------|---------|--------|---------|--------|---------|
| Control | 10 | 1.888± | 0.099 | 0.542± | 0.031 | 7.796± | 0.495 | 1.898± | 0.033 |
| 500 ppm | 10 | 1.822± | 0.073 | 0.538± | 0.013 | 7.831± | 0.268 | 1.907± | 0.042 |
| 1000 ppm | 10 | 1.871± | 0.103 | 0.540± | 0.026 | 8.024± | 0.359 | 1.900± | 0.044 |
| 2000 ppm | 10 | 1.967± | 0.106 | 0.540± | 0.036 | 8.329± | 0.372* | 1.915± | 0.036 |
| 4000 ppm | 10 | 1.870± | 0.089 | 0.527± | 0.030 | 7.804± | 0.367 | 1.886± | 0.028 |
| 8000 ppm | 10 | 1.806± | 0.061 | 0.492± | 0.025** | 7.004± | 0.403** | 1.833± | 0.058** |

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX B 10-2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 3

| Group Name | NO. of Animals | Body Weight | | THYMUS | | ADRENALS | | OVARIES | | HEART | | LUNGS | |
|------------|-------------------|-------------|-----|--------|-------|----------|--------|---------|-------|--------|-------|--------|---------|
| Control | 10 | 193± | 8 | 0.209± | 0.021 | 0.062± | 0.004 | 0.103± | 0.012 | 0.646± | 0.035 | 0.792± | 0.033 |
| 500 ppm | 10 | 197± | 14 | 0.216± | 0.024 | 0.065± | 0.007 | 0.097± | 0.012 | 0.666± | 0.048 | 0.802± | 0.032 |
| 1000 ppm | 10 | 195± | 7 | 0.217± | 0.027 | 0.064± | 0.004 | 0.104± | 0.014 | 0.668± | 0.035 | 0.798± | 0.042 |
| 2000 ppm | 10 | 195± | 10 | 0.212± | 0.031 | 0.063± | 0.004 | 0.102± | 0.012 | 0.664± | 0.044 | 0.792± | 0.040 |
| 4000 ppm | 10 | 187± | 10 | 0.203± | 0.021 | 0.060± | 0.003 | 0.098± | 0.011 | 0.652± | 0.048 | 0.787± | 0.043 |
| 8000 ppm | 10 | 177± | 4** | 0.186± | 0.017 | 0.056± | 0.004* | 0.098± | 0.014 | 0.623± | 0.027 | 0.739± | 0.023** |

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 4

| Group Name | NO. of Animals | KIDNEYS | | SPLEEN | | LIVER | | BRAIN | |
|------------|-------------------|---------|-------|--------|-------|--------|---------|--------|---------|
| Control | 10 | 1.271± | 0.048 | 0.398± | 0.026 | 4.623± | 0.256 | 1.793± | 0.043 |
| 500 ppm | 10 | 1.245± | 0.081 | 0.402± | 0.043 | 4.588± | 0.285 | 1.793± | 0.034 |
| 1000 ppm | 10 | 1.257± | 0.081 | 0.395± | 0.029 | 4.607± | 0.185 | 1.775± | 0.034 |
| 2000 ppm | 10 | 1.272± | 0.058 | 0.400± | 0.029 | 4.599± | 0.285 | 1.773± | 0.033 |
| 4000 ppm | 10 | 1.285± | 0.068 | 0.391± | 0.026 | 4.606± | 0.258 | 1.746± | 0.040* |
| 8000 ppm | 10 | 1.239± | 0.049 | 0.364± | 0.017 | 4.235± | 0.056** | 1.727± | 0.042** |

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX B 10-3

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

| Group Name | NO. of Animals | Body Weight | THYMUS | ADRENALS | TESTES | HEART | LUNGS |
|------------|-------------------|-------------|----------------|--------------|--------------|----------------|---------------|
| Control | 10 | 32.2± 1.8 | 0.040± 0.005 | 0.008± 0.002 | 0.209± 0.021 | 0.152± 0.013 | 0.148± 0.007 |
| 1000 ppm | 10 | 30.8± 2.0 | 0.039± 0.005 | 0.007± 0.002 | 0.227± 0.060 | 0.151± 0.017 | 0.153± 0.015 |
| 2000 ppm | 10 | 29.6± 2.1* | 0.039± 0.006 | 0.008± 0.002 | 0.214± 0.029 | 0.144± 0.012 | 0.148± 0.006 |
| 4000 ppm | 10 | 28.1± 1.6** | 0.036± 0.005 | 0.008± 0.002 | 0.207± 0.033 | 0.140± 0.007 | 0.147± 0.009 |
| 8000 ppm | 10 | 26.6± 2.2** | 0.033± 0.003** | 0.009± 0.002 | 0.222± 0.025 | 0.136± 0.011* | 0.144± 0.007 |
| 16000 ppm | 10 | 24.2± 1.4** | 0.030± 0.003** | 0.008± 0.001 | 0.225± 0.026 | 0.127± 0.009** | 0.138± 0.007* |

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

Test of Dunnett

(HCL040)

BAIS2

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 2

| Group Name | NO. of Animals | KIDNEYS | | SPLEEN | | LIVER | | BRAIN | |
|------------|-------------------|---------|-------|--------|---------|--------|---------|--------|-------|
| Control | 10 | 0.449± | 0.022 | 0.051± | 0.005 | 1.214± | 0.059 | 0.442± | 0.009 |
| 1000 ppm | 10 | 0.431± | 0.019 | 0.049± | 0.004 | 1.156± | 0.057 | 0.443± | 0.010 |
| 2000 ppm | 10 | 0.436± | 0.030 | 0.049± | 0.004 | 1.164± | 0.071 | 0.446± | 0.014 |
| 4000 ppm | 10 | 0.445± | 0.017 | 0.049± | 0.008 | 1.151± | 0.064 | 0.437± | 0.015 |
| 8000 ppm | 10 | 0.423± | 0.026 | 0.049± | 0.006 | 1.111± | 0.092* | 0.439± | 0.012 |
| 16000 ppm | 10 | 0.424± | 0.020 | 0.042± | 0.006** | 1.054± | 0.092** | 0.436± | 0.012 |

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX B 10-4

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 3

| Group Name | NO. of Animals | Body Weight | THYMUS | ADRENALS | OVARIES | HEART | LUNGS |
|------------|----------------|-------------|--------------|--------------|--------------|--------------|----------------|
| Control | 10 | 20.4± 1.1 | 0.038± 0.004 | 0.011± 0.002 | 0.029± 0.005 | 0.117± 0.007 | 0.145± 0.009 |
| 1000 ppm | 10 | 20.3± 1.0 | 0.037± 0.005 | 0.011± 0.002 | 0.027± 0.004 | 0.114± 0.004 | 0.139± 0.005 |
| 2000 ppm | 10 | 20.5± 1.5 | 0.038± 0.007 | 0.010± 0.001 | 0.030± 0.004 | 0.114± 0.005 | 0.138± 0.008 |
| 4000 ppm | 10 | 20.1± 1.4 | 0.036± 0.009 | 0.009± 0.002 | 0.026± 0.004 | 0.113± 0.007 | 0.138± 0.009 |
| 8000 ppm | 10 | 20.3± 1.2 | 0.038± 0.004 | 0.010± 0.001 | 0.029± 0.004 | 0.115± 0.010 | 0.137± 0.008 |
| 16000 ppm | 10 | 19.8± 0.8 | 0.037± 0.003 | 0.010± 0.002 | 0.025± 0.003 | 0.111± 0.006 | 0.131± 0.006** |

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 4

| Group Name | NO. of Animals | KIDNEYS | | SPLEEN | | LIVER | | BRAIN | |
|------------|-------------------|---------|---------|--------|-------|--------|-------|--------|---------|
| Control | 10 | 0.287± | 0.019 | 0.053± | 0.005 | 0.868± | 0.071 | 0.456± | 0.017 |
| 1000 ppm | 10 | 0.283± | 0.016 | 0.054± | 0.010 | 0.865± | 0.068 | 0.454± | 0.011 |
| 2000 ppm | 10 | 0.287± | 0.011 | 0.054± | 0.008 | 0.925± | 0.070 | 0.449± | 0.012 |
| 4000 ppm | 10 | 0.290± | 0.018 | 0.054± | 0.014 | 0.924± | 0.097 | 0.455± | 0.012 |
| 8000 ppm | 10 | 0.313± | 0.025** | 0.052± | 0.006 | 0.939± | 0.077 | 0.448± | 0.015 |
| 16000 ppm | 10 | 0.325± | 0.017** | 0.048± | 0.005 | 0.918± | 0.064 | 0.435± | 0.007** |

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX B 11-1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

| Group Name | NO. of Animals | Body Weight (g) | THYMUS | ADRENALS | TESTES | HEART | LUNGS |
|------------|-------------------|--------------------|--------------|--------------|----------------|--------------|----------------|
| Control | 10 | 314± 16 | 0.081± 0.008 | 0.017± 0.001 | 0.906± 0.052 | 0.302± 0.015 | 0.321± 0.011 |
| 500 ppm | 10 | 312± 8 | 0.075± 0.009 | 0.017± 0.001 | 0.906± 0.022 | 0.302± 0.011 | 0.321± 0.010 |
| 1000 ppm | 10 | 317± 11 | 0.076± 0.005 | 0.017± 0.001 | 0.899± 0.033 | 0.299± 0.010 | 0.314± 0.015 |
| 2000 ppm | 10 | 318± 14 | 0.078± 0.011 | 0.017± 0.002 | 0.918± 0.037 | 0.299± 0.016 | 0.323± 0.016 |
| 4000 ppm | 10 | 306± 11 | 0.079± 0.010 | 0.017± 0.002 | 0.932± 0.028 | 0.310± 0.014 | 0.328± 0.010 |
| 8000 ppm | 10 | 278± 9** | 0.073± 0.007 | 0.018± 0.001 | 0.980± 0.020** | 0.315± 0.013 | 0.330± 0.008** |

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

| Group Name | NO. of Animals | KIDNEYS | SPLEEN | LIVER | BRAIN |
|------------|-------------------|----------------|--------------|----------------|----------------|
| Control | 10 | 0.603± 0.026 | 0.173± 0.007 | 2.486± 0.065 | 0.607± 0.027 |
| 500 ppm | 10 | 0.583± 0.016 | 0.172± 0.007 | 2.507± 0.038 | 0.611± 0.012 |
| 1000 ppm | 10 | 0.590± 0.020 | 0.170± 0.009 | 2.529± 0.070 | 0.599± 0.022 |
| 2000 ppm | 10 | 0.618± 0.023 | 0.170± 0.007 | 2.619± 0.082** | 0.603± 0.022 |
| 4000 ppm | 10 | 0.611± 0.023 | 0.172± 0.007 | 2.550± 0.089 | 0.617± 0.023 |
| 8000 ppm | 10 | 0.650± 0.012** | 0.177± 0.010 | 2.520± 0.094 | 0.660± 0.016** |

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

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX B 11-2

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 3

| Group Name | NO. of Animals | Body Weight (g) | THYMUS | ADRENALS | OVARIES | HEART | LUNGS |
|------------|-------------------|--------------------|--------------|--------------|--------------|--------------|--------------|
| Control | 10 | 193± 8 | 0.108± 0.011 | 0.032± 0.003 | 0.054± 0.007 | 0.335± 0.012 | 0.410± 0.020 |
| 500 ppm | 10 | 197± 14 | 0.109± 0.009 | 0.033± 0.003 | 0.049± 0.006 | 0.338± 0.016 | 0.408± 0.028 |
| 1000 ppm | 10 | 195± 7 | 0.111± 0.013 | 0.033± 0.002 | 0.054± 0.008 | 0.343± 0.015 | 0.409± 0.022 |
| 2000 ppm | 10 | 195± 10 | 0.109± 0.013 | 0.032± 0.002 | 0.052± 0.005 | 0.341± 0.014 | 0.407± 0.015 |
| 4000 ppm | 10 | 187± 10 | 0.109± 0.008 | 0.032± 0.002 | 0.052± 0.005 | 0.348± 0.016 | 0.421± 0.018 |
| 8000 ppm | 10 | 177± 4** | 0.105± 0.009 | 0.032± 0.003 | 0.056± 0.008 | 0.353± 0.013 | 0.418± 0.014 |

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 4

| Group Name | NO. of Animals | KIDNEYS | SPLEEN | LIVER | BRAIN |
|------------|-------------------|----------------|--------------|--------------|--------------|
| Control | 10 | 0.658± 0.028 | 0.206± 0.009 | 2.395± 0.139 | 0.929± 0.044 |
| 500 ppm | 10 | 0.632± 0.020 | 0.205± 0.025 | 2.330± 0.078 | 0.913± 0.060 |
| 1000 ppm | 10 | 0.644± 0.033 | 0.203± 0.018 | 2.363± 0.097 | 0.911± 0.036 |
| 2000 ppm | 10 | 0.654± 0.021 | 0.206± 0.017 | 2.364± 0.092 | 0.913± 0.043 |
| 4000 ppm | 10 | 0.688± 0.034 | 0.210± 0.019 | 2.463± 0.097 | 0.935± 0.052 |
| 8000 ppm | 10 | 0.701± 0.018** | 0.206± 0.012 | 2.397± 0.046 | 0.978± 0.024 |

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

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX B 11-3

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

| Group Name | NO. of Animals | Body Weight (g) | THYMUS | ADRENALS | TESTES | HEART | LUNGS |
|------------|-------------------|--------------------|--------------|----------------|----------------|---------------|----------------|
| Control | 10 | 32.2± 1.8 | 0.124± 0.011 | 0.023± 0.005 | 0.651± 0.081 | 0.473± 0.049 | 0.461± 0.024 |
| 1000 ppm | 10 | 30.8± 2.0 | 0.125± 0.015 | 0.022± 0.004 | 0.746± 0.229 | 0.491± 0.064 | 0.498± 0.066 |
| 2000 ppm | 10 | 29.6± 2.1* | 0.133± 0.018 | 0.028± 0.007 | 0.724± 0.105 | 0.488± 0.052 | 0.500± 0.034 |
| 4000 ppm | 10 | 28.1± 1.6** | 0.127± 0.016 | 0.030± 0.007 | 0.737± 0.110 | 0.500± 0.021 | 0.526± 0.043** |
| 8000 ppm | 10 | 26.6± 2.2** | 0.125± 0.013 | 0.034± 0.009** | 0.839± 0.116* | 0.510± 0.035 | 0.542± 0.037** |
| 16000 ppm | 10 | 24.2± 1.4** | 0.125± 0.014 | 0.034± 0.006** | 0.937± 0.128** | 0.526± 0.026* | 0.571± 0.041** |

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

| Group Name | NO. of Animals | KIDNEYS | SPLEEN | LIVER | BRAIN |
|------------|-------------------|----------------|----------------|----------------|----------------|
| Control | 10 | 1.395± 0.086 | 0.157± 0.012 | 3.771± 0.179 | 1.375± 0.085 |
| 1000 ppm | 10 | 1.402± 0.097 | 0.157± 0.012 | 3.752± 0.105 | 1.441± 0.101 |
| 2000 ppm | 10 | 1.477± 0.130 | 0.164± 0.009 | 3.933± 0.130 | 1.511± 0.092* |
| 4000 ppm | 10 | 1.588± 0.070** | 0.176± 0.031 | 4.099± 0.125** | 1.561± 0.101** |
| 8000 ppm | 10 | 1.595± 0.110** | 0.185± 0.023** | 4.178± 0.187** | 1.658± 0.116** |
| 16000 ppm | 10 | 1.755± 0.076** | 0.173± 0.016 | 4.353± 0.159** | 1.807± 0.114** |

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

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX B 11-4

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 3

| Group Name | NO. of Animals | Body Weight (g) | THYMUS | ADRENALS | OVARIES | HEART | LUNGS |
|------------|-------------------|--------------------|--------------|--------------|--------------|--------------|--------------|
| Control | 10 | 20.4± 1.1 | 0.188± 0.024 | 0.054± 0.011 | 0.140± 0.022 | 0.573± 0.033 | 0.709± 0.047 |
| 1000 ppm | 10 | 20.3± 1.0 | 0.180± 0.021 | 0.052± 0.006 | 0.134± 0.020 | 0.564± 0.029 | 0.686± 0.028 |
| 2000 ppm | 10 | 20.5± 1.5 | 0.185± 0.032 | 0.051± 0.003 | 0.146± 0.016 | 0.556± 0.042 | 0.676± 0.052 |
| 4000 ppm | 10 | 20.1± 1.4 | 0.180± 0.033 | 0.046± 0.009 | 0.128± 0.020 | 0.566± 0.035 | 0.690± 0.041 |
| 8000 ppm | 10 | 20.3± 1.2 | 0.188± 0.025 | 0.049± 0.005 | 0.142± 0.016 | 0.564± 0.026 | 0.678± 0.031 |
| 16000 ppm | 10 | 19.8± 0.8 | 0.188± 0.014 | 0.051± 0.010 | 0.126± 0.014 | 0.563± 0.028 | 0.662± 0.036 |

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 4

| Group Name | NO. of Animals | KIDNEYS | SPLEEN | LIVER | BRAIN |
|------------|-------------------|----------------|--------------|----------------|--------------|
| Control | 10 | 1.403± 0.074 | 0.260± 0.019 | 4.245± 0.197 | 2.235± 0.098 |
| 1000 ppm | 10 | 1.397± 0.089 | 0.263± 0.040 | 4.261± 0.235 | 2.242± 0.101 |
| 2000 ppm | 10 | 1.400± 0.088 | 0.262± 0.027 | 4.507± 0.180 | 2.193± 0.109 |
| 4000 ppm | 10 | 1.450± 0.086 | 0.270± 0.076 | 4.621± 0.538 | 2.277± 0.117 |
| 8000 ppm | 10 | 1.545± 0.081** | 0.257± 0.030 | 4.631± 0.219** | 2.212± 0.101 |
| 16000 ppm | 10 | 1.641± 0.060** | 0.240± 0.022 | 4.635± 0.262** | 2.200± 0.095 |

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

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX B 12-1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 1

| Organ | Findings | Group Name No. of Animals | Control 10 | | | | 500 ppm 10 | | | | 1000 ppm 10 | | | | 2000 ppm 10 | | | |
|----------------------------------|---|------------------------------|---------------|------------|------------|------------|---------------|--------------|------------|------------|----------------|------------|------------|------------|----------------|------------|------------|------------|
| | | | <1> (%) | <2> (%) | <3> (%) | <4> (%) | <1> (%) | <2> (%) | <3> (%) | <4> (%) | <1> (%) | <2> (%) | <3> (%) | <4> (%) | <1> (%) | <2> (%) | <3> (%) | <4> (%) |
| [Circulatory system] | | | | | | | | | | | | | | | | | | |
| heart | granulation | | 2 (20) | 0 (0) | 0 (0) | 0 (0) | 2 (20) | 0 (0) | 0 (0) | 0 (0) | 4 (40) | 0 (0) | 0 (0) | 0 (0) | 5 (50) | 0 (0) | 0 (0) | 0 (0) |
| | myocardial degeneration | | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| [Digestive system] | | | | | | | | | | | | | | | | | | |
| liver | herniation | | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | | | | | | | | | | | | | | | | | | |
| [Urinary system] | | | | | | | | | | | | | | | | | | |
| kidney | basophilic change | | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | eosinophilic body | | 0 (0) | 9 (90) | 0 (0) | 0 (0) | 0 (0) | 10 (100) | 0 (0) | 0 (0) | 0 (0) | 9 (90) | 0 (0) | 0 (0) | 0 (0) | 9 (90) | 0 (0) | 0 (0) |
| | mineralization:cortico-medullary junction | | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) |
| [Special sense organs/appandage] | | | | | | | | | | | | | | | | | | |
| Harder gl | granulation | | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | | | | | | | | | | | | | | | | | | |
| [Body cavities] | | | | | | | | | | | | | | | | | | |
| adipose | granulation | | 2 (20) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| | | | | | | | | | | | | | | | | | | |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 2

| | | Group Name | 4000 ppm | | | | 8000 ppm | | | |
|----------------------------------|---|----------------|-------------|------------|------------|------------|-------------|------------|------------|--|
| | | No. of Animals | 10 | | | | 10 | | | |
| Organ_____ | Findings_____ | <1> (%) | <2> (%) | <3> (%) | <4> (%) | <1> (%) | <2> (%) | <3> (%) | <4> (%) | |
| [Circulatory system] | | | | | | | | | | |
| heart | granulation | 4 (40) | 0 (0) | 0 (0) | 0 (0) | 2 (20) | 0 (0) | 0 (0) | 0 (0) | |
| | myocardial degeneration | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| [Digestive system] | | | | | | | | | | |
| liver | herniation | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| | | | | | | | | | | |
| [Urinary system] | | | | | | | | | | |
| kidney | basophilic change | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| | eosinophilic body | 0 (0) | 10 (100) | 0 (0) | 0 (0) | 0 (0) | 10 (100) | 0 (0) | 0 (0) | |
| | mineralization:cortico-medullary junction | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| [Special sense organs/appandage] | | | | | | | | | | |
| Harder gl | granulation | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| | | | | | | | | | | |
| [Body cavities] | | | | | | | | | | |
| adipose | granulation | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| | | | | | | | | | | |

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

APPENDIX B 12-2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0107
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 3

| Organ_____ | Findings_____ | Group Name | Control | | | | 500 ppm | | | | 1000 ppm | | | | 2000 ppm | | | |
|----------------------------------|---|----------------|------------|-----------|-----------|-----------|-------------|------------|-----------|-----------|-------------|-----------|-----------|-----------|-------------|------------|-----------|-----------|
| | | No. of Animals | 10 | | | | 10 | | | | 10 | | | | 10 | | | |
| | | | <1> | <2> | <3> | <4> | <1> | <2> | <3> | <4> | <1> | <2> | <3> | <4> | <1> | <2> | <3> | <4> |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| [Hematopoietic system] | | | | | | | | | | | | | | | | | | |
| bone marrow | granulation | | 2 (20) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 3 (30) | 0 (0) | 0 (0) |
| [Circulatory system] | | | | | | | | | | | | | | | | | | |
| heart | granulation | | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 2 (20) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| [Digestive system] | | | | | | | | | | | | | | | | | | |
| liver | herniation | | 2 (20) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| | granulation | | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| [Urinary system] | | | | | | | | | | | | | | | | | | |
| kidney | mineralization:cortico-medullary junction | | 9 (90) | 0 (0) | 0 (0) | 0 (0) | 10 (100) | 0 (0) | 0 (0) | 0 (0) | 10 (100) | 0 (0) | 0 (0) | 0 (0) | 10 (100) | 0 (0) | 0 (0) | 0 (0) |
| [Special sense organs/appandage] | | | | | | | | | | | | | | | | | | |
| Harder gl | granulation | | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 3 (30) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) |

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0107
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (13w)

PAGE : 4

| Organ | Findings | Group Name No. of Animals | | | | 4000 ppm 10 | | | | 8000 ppm 10 | | | |
|----------------------------------|---|------------------------------|------------|-----------|-----------|----------------|-----------|-----------|-----------|----------------|-----------|-----------|-----------|
| | | <1> | <2> | <3> | <4> | <1> | <2> | <3> | <4> | <1> | <2> | <3> | <4> |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| [Hematopoietic system] | | | | | | | | | | | | | |
| bone marrow | granulation | 1 (10) | 1 (10) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| [Circulatory system] | | | | | | | | | | | | | |
| heart | granulation | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| [Digestive system] | | | | | | | | | | | | | |
| liver | herniation | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | granulation | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| [Urinary system] | | | | | | | | | | | | | |
| kidney | mineralization:cortico-medullary junction | 10 (100) | 0 (0) | 0 (0) | 0 (0) | 6 (60) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| [Special sense organs/appandage] | | | | | | | | | | | | | |
| Harder gl | granulation | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

APPENDIX B 12-3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : MALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 1

| Organ | Findings | Group Name | Control | | | | 1000 ppm | | | | 2000 ppm | | | | 4000 ppm | | | |
|------------------------|--|----------------|-------------|-------------|------------|------------|-------------|------------|------------|------------|-------------|------------|------------|------------|-------------|-------------|------------|------------|
| | | No. of Animals | 10 | | | | 10 | | | | 10 | | | | 10 | | | |
| | | | <1> | <2> | <3> | <4> | <1> | <2> | <3> | <4> | <1> | <2> | <3> | <4> | <1> | <2> | <3> | <4> |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| [Respiratory system] | | | | | | | | | | | | | | | | | | |
| nasal cavit | eosinophilic change:respiratory epithelium | | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 3 (30) | 1 (10) | 0 (0) | 0 (0) |
| [Hematopoietic system] | | | | | | | | | | | | | | | | | | |
| spleen | deposit of melanin | | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| [Circulatory system] | | | | | | | | | | | | | | | | | | |
| heart | mineralization | | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| [Digestive system] | | | | | | | | | | | | | | | | | | |
| liver | granulation | | 3 (30) | 0 (0) | 0 (0) | 0 (0) | 4 (40) | 0 (0) | 0 (0) | 0 (0) | 2 (20) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| pancreas | vacuolic change | | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| [Urinary system] | | | | | | | | | | | | | | | | | | |
| kidney | hydronephrosis | | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| [Reproductive system] | | | | | | | | | | | | | | | | | | |
| testis | atrophy | | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (13W)

PAGE : 2

| | | Group Name | 8000 ppm | | | | 16000 ppm | | | |
|------------------------|--|----------------|------------|------------|------------|------------|------------|------------|------------|------------|
| | | No. of Animals | 10 | | | | 10 | | | |
| Organ_____ | Findings_____ | | <1> (%) | <2> (%) | <3> (%) | <4> (%) | <1> (%) | <2> (%) | <3> (%) | <4> (%) |
| [Respiratory system] | | | | | | | | | | |
| nasal cavit | eosinophilic change:respiratory epithelium | | 2 (20) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| [Hematopoietic system] | | | | | | | | | | |
| spleen | deposit of melanin | | 3 (30) | 0 (0) | 0 (0) | 0 (0) | 2 (20) | 0 (0) | 0 (0) | 0 (0) |
| [Circulatory system] | | | | | | | | | | |
| heart | mineralization | | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| [Digestive system] | | | | | | | | | | |
| liver | granulation | | 3 (30) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| pancreas | vacuolic change | | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| [Urinary system] | | | | | | | | | | |
| kidney | hydronephrosis | | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| [Reproductive system] | | | | | | | | | | |
| testis | atrophy | | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 3

| Organ_____ | Findings_____ | Group Name No. of Animals | Control 10 | | | | 1000 ppm 10 | | | | 2000 ppm 10 | | | | 4000 ppm 10 | | | |
|-----------------------|------------------|------------------------------|---------------|------------|------------|------------|----------------|------------|------------|------------|----------------|------------|------------|------------|----------------|------------|------------|------------|
| | | | <1> (%) | <2> (%) | <3> (%) | <4> (%) | <1> (%) | <2> (%) | <3> (%) | <4> (%) | <1> (%) | <2> (%) | <3> (%) | <4> (%) | <1> (%) | <2> (%) | <3> (%) | <4> (%) |
| [Reproductive system] | | | | | | | | | | | | | | | | | | |
| testis | mineralization | | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| epididymis | decreased:sperma | | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| [Body cavities] | | | | | | | | | | | | | | | | | | |
| adipose | granulation | | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(IPT150)

BA1S2

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (13W)

PAGE : 4

| Organ | Findings | Group Name No. of Animals | 8000 ppm | | | | 16000 ppm | | | |
|-----------------------|------------------|------------------------------|----------|-------|-------|-------|-----------|-------|-------|-------|
| | | | 10 | | | | 10 | | | |
| | | | <1> | <2> | <3> | <4> | <1> | <2> | <3> | <4> |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| [Reproductive system] | | | | | | | | | | |
| testis | mineralization | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| epididymis | decreased:sperma | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| [Body cavities] | | | | | | | | | | |
| adipose | granulation | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(HPT150)

BA1S2

APPENDIX B 12-4

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : FEMALE : SACRIFICED ANIMALS

(13Week STUDY))

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 5

| Organ | Findings | Group Name | Control | | | | 1000 ppm | | | | 2000 ppm | | | | 4000 ppm | | | |
|------------------------|--|----------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|--|
| | | No. of Animals | 10 | | | | 10 | | | | 10 | | | | 10 | | | |
| | | <1> (%) | <2> (%) | <3> (%) | <4> (%) | <1> (%) | <2> (%) | <3> (%) | <4> (%) | <1> (%) | <2> (%) | <3> (%) | <4> (%) | <1> (%) | <2> (%) | <3> (%) | <4> (%) | |
| [Respiratory system] | | | | | | | | | | | | | | | | | | |
| nasal cavit | eosinophilic change:respiratory epithelium | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 2 (20) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 1 (10) | 0 (0) | 0 (0) | 5 (50) | 1 (10) | 0 (0) | 0 (0) | |
| lung | hemorrhage | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | |
| [Hematopoietic system] | | | | | | | | | | | | | | | | | | |
| bone marrow | necrosis:focal | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | |
| spleen | deposit of melanin | 2 (20) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| [Digestive system] | | | | | | | | | | | | | | | | | | |
| liver | inflammatory infiltration | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | |
| | granulation | 3 (30) | 0 (0) | 0 (0) | 0 (0) | 2 (20) | 0 (0) | 0 (0) | 0 (0) | 4 (40) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| [Endocrine system] | | | | | | | | | | | | | | | | | | |
| adrenal | deposit of melanin | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| [Reproductive system] | | | | | | | | | | | | | | | | | | |
| ovary | cyst | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (13W)

PAGE : 6

| Organ | Findings | Group Name No. of Animals | | | | 8000 ppm 10 | | | | 16000 ppm 10 | | | |
|------------------------|--|------------------------------|-----------|-----------|-------------|----------------|-----------|-----------|--------------|-----------------|-----|-----|-----|
| | | <1> | <2> | <3> | <4> | <1> | <2> | <3> | <4> | <1> | <2> | <3> | <4> |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| [Respiratory system] | | | | | | | | | | | | | |
| nasal cavit | eosinophilic change:respiratory epithelium | 7 (70) | 0 (0) | 0 (0) | 0 * (0) | 8 (80) | 0 (0) | 0 (0) | 0 ** (0) | | | | |
| lung | hemorrhage | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | | | |
| [Hematopoietic system] | | | | | | | | | | | | | |
| bone marrow | necrosis:focal | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | | | |
| spleen | deposit of melanin | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 3 (30) | 0 (0) | 0 (0) | 0 (0) | | | | |
| [Digestive system] | | | | | | | | | | | | | |
| liver | inflammatory infiltration | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | | | |
| | granulation | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 2 (20) | 0 (0) | 0 (0) | 0 (0) | | | | |
| [Endocrine system] | | | | | | | | | | | | | |
| adrenal | deposit of melanin | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | | | |
| [Reproductive system] | | | | | | | | | | | | | |
| ovary | cyst | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | | | |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0108
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (13W)

PAGE : 7

| Organ_____ | Findings_____ | Group Name No. of Animals | | | | Control 10 | | | | 1000 ppm 10 | | | | 2000 ppm 10 | | | | 4000 ppm 10 | | | | | | | |
|--------------------------|--------------------------------|-------------------------------|------------|------------|------------|--------------------|------------|------------|------------|----------------|------------|------------|------------|----------------|------------|------------|------------|----------------|--|--|--|------------|--|--|--|
| | | <1> (%) | <2> (%) | <3> (%) | <4> (%) | <1> (%) | <2> (%) | <3> (%) | <4> (%) | <1> (%) | <2> (%) | <3> (%) | <4> (%) | <1> (%) | <2> (%) | <3> (%) | <4> (%) | | | | | | | | |
| [Reproductive system] | | | | | | | | | | | | | | | | | | | | | | | | | |
| uterus | cystic endometrial hyperplasia | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 2 (20) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) | | | | | | | | |
| Significant difference : | | * : P ≤ 0.05 ** : P ≤ 0.01 | | | | Test of Chi Square | | | | <1>:Slight | | | | <2>:Moderate | | | | <3>:Marked | | | | <4>:Severe | | | |
| (HPT150) | | | | | | | | | | | | | | | | | | BA15 | | | | | | | |

STUDY NO. : 0108
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 8

| Organ | Findings | Group Name No. of Animals | | | | 8000 ppm 10 | | | | 16000 ppm 10 | | | |
|-------|----------|------------------------------|-----|-----|-----|----------------|-----|-----|-----|-----------------|-----|-----|-----|
| | | <1> | <2> | <3> | <4> | <1> | <2> | <3> | <4> | <1> | <2> | <3> | <4> |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |

[Reproductive system]

| | | | | | | | | | |
|--------|--------------------------------|--------|-------|-------|-------|--------|-------|-------|-------|
| uterus | cystic endometrial hyperplasia | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (20) | (0) | (0) | (0) | (10) | (0) | (0) | (0) |

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(IPT150)

BAIS2

APPENDIX B 13-1

IDENTITY OF β -CHLOROPROPIONIC ACID

(13Week STUDY)

IDENTITY OF β -CHLOROPROPIONIC ACID(THIRTEEN-WEEK STUDIES)

Lot no. FB0 01

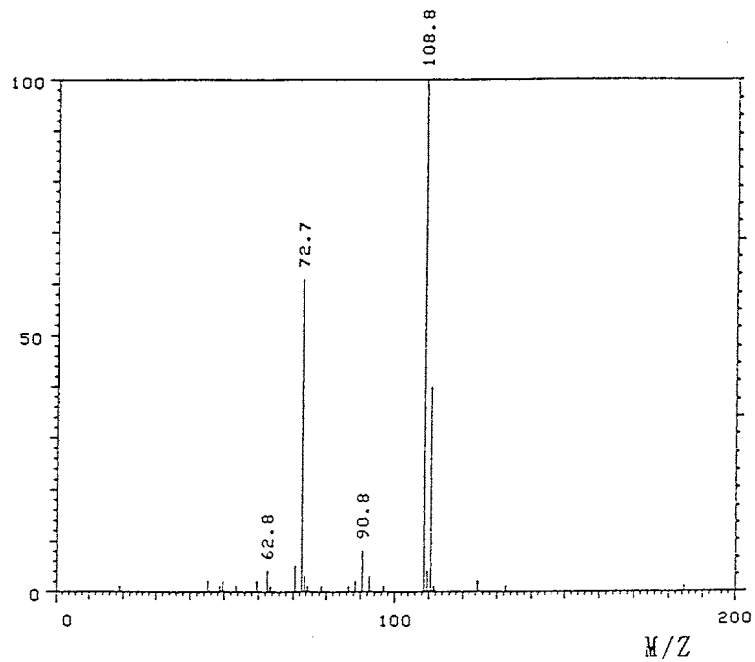
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B

Ionization : CI(Chemical Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

Result:

Molecular Weight

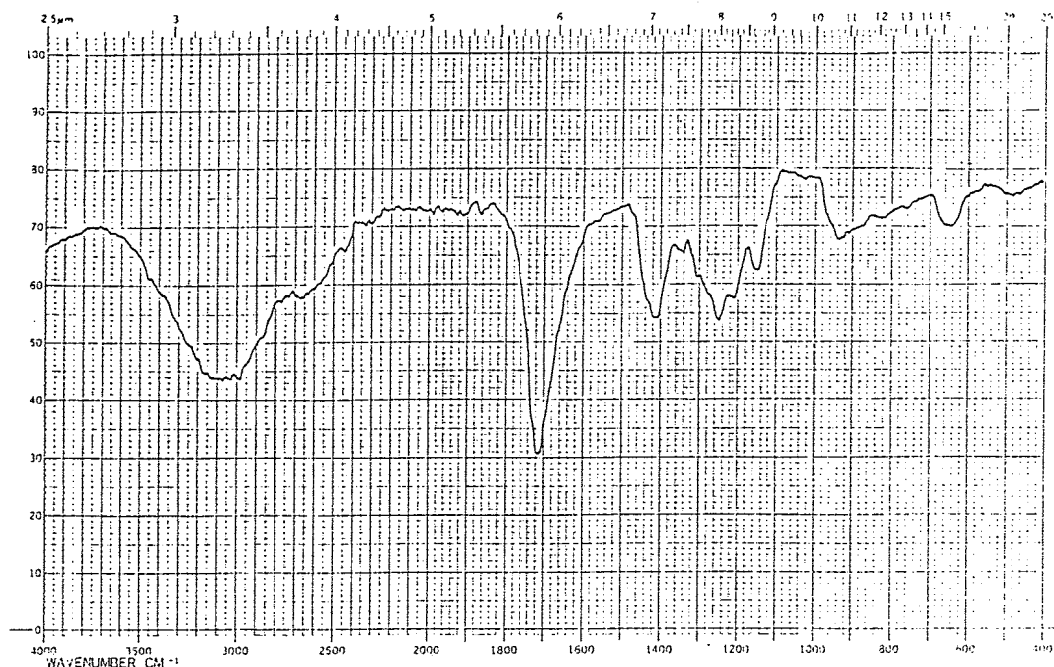
Calculated Value 109.0

(+H⁺)

Determined Value 108.8

Infrared Spectrometry

Instrument : Hitachi 270-30
Cell : KBr
Slit : Medium



Infrared Spectrum of Test Substance

| Results: | <u>Determined Value</u> Wave Number(cm^{-1}) | <u>Literature Values*</u> Wave Number(cm^{-1}) |
|----------|--|---|
| | 620~700 | 620~700 |
| | 850~1000 | 850~1000 |
| | 1100~1170 | 1100~1170 |
| | 1180~1320 | 1180~1320 |
| | 1380~1460 | 1380~1460 |
| | 1600~1800 | 1600~1800 |
| | 2800~3400 | 2800~3400 |
| | | (*Performed by the WAKO PURE CHEMICAL INDUSTRIES, LTD.) |

2. Conclusions: The result of the mass spectrum agreed with the calculated value and the infrared spectrum agreed with the literature values. Consequently, the test substance was identified as β -chloropropionic acid.

APPENDIX B 13-2

STABILITY OF β -CHLOROPROPIONIC ACID

(13Week STUDY)

STABILITY OF β -CHLOROPROPIONIC ACID(THIRTEEN-WEEK STUDIES)

Lot no. FBO 01

1. Sample: This lot was used from 1988.09.12 to 1988.12.21. Test substance was stored at 5°C.

2. Infrared Spectrometry

Instrument : Hitachi 270-30

Cell : KBr

Slit : Medium

Results: Infrared spectrum of the test substance agreed with before use and after use.

| <u>1988.09.07(date analyzed)</u> | <u>1988.12.22(date analyzed)</u> |
|----------------------------------|----------------------------------|
| Wave Number(cm^{-1}) | Wave Number(cm^{-1}) |
| 620~ 700 | 620~ 700 |
| 850~1000 | 850~1000 |
| 1100~1170 | 1100~1170 |
| 1180~1320 | 1180~1320 |
| 1380~1460 | 1380~1460 |
| 1600~1800 | 1600~1800 |
| 2800~3400 | 2800~3400 |

3. Gas Chromatography

Instrument: Hewlett Packard 5890A

Column: FALM(2mm ϕ \times 2m)

Column Temperature: 160°C

Flow Rate: 28 ml/min

Detector: FID(Flame Ionization)

Injection Volume: 1 μ l

Results: Gas chromatography indicated one major peak(peak No.4) and three impurities(peak No.1,2,3 < 6% of total area) analyzed at 1988.09.07 and one major peak(peak No.5) and three impurities(peak No.1,2,3,4 < 8% of total area) analyzed at 1988.12.22. The new treace impurity peak in the test substance analyzed at 1988.12.22 was less than 0.8% of total peak.

| Date | Peak No. | Retention Time(min) | AREA COUNT | (percent of total peak) |
|-------------------------------|----------|---------------------|------------|-------------------------|
| 1988.09.07 (date analyzed) | 1 | 0.048 | 513 | 0.58 |
| | 2 | 0.293 | 2641 | 2.98 |
| | 3 | 0.932 | 1948 | 2.20 |
| | 4 | 4.337 | 83526 | 94.24 |
| 1988.12.22 (date analyzed) | 1 | 0.033 | 436 | 0.49 |
| | 2 | 0.285 | 3481 | 3.92 |
| | 3 | 0.797 | 667 | 0.75 |
| | 4 | 0.942 | 2641 | 2.97 |
| | 5 | 4.323 | 81685 | 91.87 |

4. Conclusions: The results indicated that the test substance did not change when stored in the dark at 5°C during this period(for about 15 weeks).

APPENDIX B 13-3

CONCENTRATION OF β -CHLOROPROPIONIC ACID IN DRINKING WATER

(13Week STUDY)

CONCENTRATION OF β -CHLOROPROPIONIC ACID IN DRINKING WATER(THIRTEEN-WEEK STUDIES)

(Rat)

| Date analyzed | Target Concentration(ppm) | | | | |
|---------------|---------------------------|---------------|---------------|---------------|---------------|
| | 500 | 1000 | 2000 | 4000 | 8000 |
| 1988.09.19 | 489.3(97.9)* | 1124.7(112.5) | 2100.2(105.0) | 3810.3(95.3) | 7474.6(93.4) |

(Mouse)

| Date analyzed | Target Concentration(ppm) | | | | |
|---------------|---------------------------|---------------|---------------|---------------|----------------|
| | 1000 | 2000 | 4000 | 8000 | 16000 |
| 1988.09.19 | 1124.7(112.5)* | 2100.2(105.0) | 3810.3(95.3) | 7474.6(93.4) | 16548.9(103.4) |

(*) % of target concentration

Analytical method: The sample were analyzed by the HPLC.

| | | | |
|---------------------|---|-------------------|---------------|
| Instrument | : Hewlett Packard 5890A | Flow Rate | : 1ml/min |
| Column | : ULTRON PS-80H(8mm ϕ \times 30cm) | Detector | : UV(205nm) |
| Column Temperature: | 55°C | Internal Standard | : Citric acid |
| Carrier | : Water(pH 2.3 phosphate buffer) | Injection Volume | : 10 μ l |

APPENDIX B 13-4

STABILITY OF β -CHLOROPROPIONIC ACID IN DRINKING WATER

(13Week STUDY)

STABILITY OF β -CHLOROPROPIONIC ACID IN DRINKING WATER(THIRTEEN-WEEK STUDIES)

(Rat)

| Date analyzed | Target Concentration(ppm) | | | | |
|---------------|---------------------------|--------|--------|--------|--------|
| | 500 | 1000 | 2000 | 4000 | 8000 |
| 1988.09.19(a) | 489.3 | 1124.7 | 2100.2 | 3810.3 | 7474.6 |
| 1988.09.23(b) | 484.3 | 976.3 | 2031.5 | 4088.8 | 8347.2 |

(Mouse)

| Date analyzed | Target Concentration(ppm) | | | | |
|---------------|---------------------------|--------|--------|--------|---------|
| | 1000 | 2000 | 4000 | 8000 | 16000 |
| 1987.12.10(a) | 1124.7 | 2100.2 | 3810.3 | 7474.6 | 16548.9 |
| 1987.12.14(b) | 976.3 | 2031.5 | 4088.8 | 8347.2 | 16406.7 |

(a) Date of preparation

(b) The stability of β -Chloropropionic acid in drinking water was established for 4 days when stored at 25°C.

Analytical method: The sample were analyzed by the HPLC.

Instrument : Hewlett Packard 5890A
 Column : ULTRON PS-80H(8mm ϕ \times 30cm)
 Column Temperature: 55°C
 Carrier : Water(pH 2.3 phosphate buffer)

Flow Rate : 1ml/min
 Detector : UV(205nm)
 Internal Standard : Citric acid
 Injection Volume : 10 μ l

APPENDIX C 1

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINARYSIS

| Item | Method | Unit |
|--|---|-----------------------|
| Hematology | | |
| Red blood cell (RBC) | Aperture impedance method ¹⁾ | $\times 10^6 / \mu l$ |
| Hemoglobin (Hgb) | Cyanmethemoglobin method ¹⁾ | g/dl |
| Hematocrit (Hct) | Calculated as $RBC \times MCV / 10$ ¹⁾ | % |
| Mean corpuscular volume (MCV) | Aperture impedance method ¹⁾ | fl |
| Mean corpuscular hemoglobin (MCH) | Calculated as $Hgb / RBC \times 10$ ¹⁾ | pg |
| Mean corpuscular hemoglobin concentration (MCHC) | Calculated as $Hgb / Hct \times 10$ ¹⁾ | g/dl |
| Platelet | Aperture impedance method ¹⁾ | $\times 10^3 / \mu l$ |
| White blood cell (WBC) | Aperture impedance method ¹⁾ | $\times 10^3 / \mu l$ |
| Differential WBC | Pattern recognition method ²⁾ | % |
| Biochemistry | | |
| Total protein (TP) | Biuret method ³⁾ | g/dl |
| Albumin (Alb) | BCG method ³⁾ | g/dl |
| A/G ratio | Calculated as $Alb / (TP - Alb)$ ³⁾ | |
| T-bilirubin | Michaelson method ³⁾ | mg/dl |
| Glucose | Enzymatic method (HK · G-6-PDH) ³⁾ | mg/dl |
| T-cholesterol | Enzymatic method (CEH · COD · POD) ³⁾ | mg/dl |
| Triglyceride | Enzymatic method (GK · GPO · POD) ³⁾ | mg/dl |
| Phospholipid | Enzymatic method (PLD · COD · POD) ³⁾ | mg/dl |
| Glutamic oxaloacetic transaminase (GOT) | Karmen method ³⁾ | IU/l |
| Glutamic pyruvic transaminase (GPT) | Karmen method ³⁾ | IU/l |
| Lactate dehydrogenase (LDH) | Wroblewski-LaDue method ³⁾ | IU/l |
| Alkaline phosphatase (ALP) | GSCC method ³⁾ | IU/l |
| γ -Glutamyl transaminase (G-GTP) | L- γ -Glutamyl p-nitroanilide substrate method ³⁾ | IU/l |
| Creatine phosphokinase (CPK) | GSCC method ³⁾ | IU/l |
| Urea nitrogen | Enzymatic method (Ureadse · GLDH) ³⁾ | mg/dl |
| Creatinine | Jaffe method ³⁾ | mg/dl |
| Sodium | Flame photometry ⁴⁾ | mEq/l |
| Potassium | Flame photometry ⁴⁾ | mEq/l |
| Chloride | Coulometric titration ⁴⁾ | mEq/l |
| Calcium | OCPC method ³⁾ | mg/dl |
| Inorganic phosphorus | Enzymatic method (SPL · PGM · G-6-PDH) ³⁾ | mg/dl |
| Urinalysis | | |
| pH, Protein, Glucose, Ketone body, Bilirubin, Occult Blood, Urobilinogen | Urinalysis reagent paper method ⁵⁾ | |

1) Automatic blood cell analyzer (Coulter counter SP : Coulter Electronics Inc.)

2) Automatic blood cell differential analyzer (Hematrak 590 : Geometric Data a Smithkline Company)

3) Automatic analyzer (Hitachi 705 : Hitachi ,Ltd.)

4) Flame photometer (Hitachi 750 : Hitachi ,Ltd.)

5) Ames reagent strips for urinalysis (Multistix, Uro-Labstix : Miles Sankyo Co.,Ltd.)

APPENDIX C 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY

| | TEST ITEM | DECIMAL PLACE | UNIT |
|--------------|----------------------|---------------|---------------------|
| HEMATOLOGY | Red blood cell | 2 | $10^6/\mu l$ |
| | Hemoglobin | 1 | g/dl |
| | Hematocrit | 1 | % |
| | MCV | 1 | fl |
| | MCH | 1 | pg |
| | MCHC | 1 | g/dl |
| | Platelet | 0 | $\times 10^3/\mu l$ |
| | White blood cell | 2 | $\times 10^3/\mu l$ |
| | Differential WBC | 0 | % |
| BIOCHEMISTRY | Total protein | 1 | g/dl |
| | Albumin | 1 | g/dl |
| | A/G ratio | 1 | — |
| | T-bilirubin | 2 | mg/dl |
| | Glucose | 0 | mg/dl |
| | T-cholesterol | 0 | mg/dl |
| | Triglyceride | 0 | mg/dl |
| | Phospholipid | 0 | mg/dl |
| | GOT | 0 | IU/l |
| | GPT | 0 | IU/l |
| | LDH | 0 | IU/l |
| | ALP | 0 | IU/l |
| | γ -GTP | 0 | IU/l |
| | CPK | 0 | IU/l |
| | Urea nitrogen | 1 | mg/dl |
| | Creatinine | 1 | mg/dl |
| | Sodium | 0 | mEq/l |
| | Potassium | 1 | mEq/l |
| | Chloride | 0 | mEq/l |
| | Calcium | 1 | mg/dl |
| | Inorganic phosphorus | 1 | mg/dl |