

クロトンアルデヒドのマウスを用いた
吸入によるがん原性試験報告書

試験番号 0319

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APPENDIX A 1

CLINICAL OBSERVATION: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| | | 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 | 14-7 |
| DEATH | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 6ppm | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MORIBUND SACRIFICE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOCERECTION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | 0ppm | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 |
| | 3ppm | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 3 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| M. EYE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 15-7 | 16-7 | 17-7 | 18-7 | 19-7 | 20-7 | 21-7 | 22-7 | 23-7 | 24-7 | 25-7 | 26-7 | 27-7 | 28-7 |
| DEATH | 0ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
| | 3ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| MORIBUND SACRIFICE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | 0ppm | 1 | 2 | 2 | 3 | 4 | 4 | 4 | 4 | 4 | 5 | 5 | 5 | 4 | 3 |
| | 3ppm | 3 | 4 | 4 | 4 | 4 | 4 | 5 | 5 | 5 | 7 | 7 | 7 | 7 | 8 |
| | 6ppm | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 12ppm | 1 | 2 | 2 | 6 | 6 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
| M. EYE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 29-7 | 30-7 | 31-7 | 32-7 | 33-7 | 34-7 | 35-7 | 36-7 | 37-7 | 38-7 | 39-7 | 40-7 | 41-7 | 42-7 |
| DEATH | 0ppm | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 3ppm | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| MORIBUND SACRIFICE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOBRECTION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | 0ppm | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 3ppm | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 7 | 7 |
| | 6ppm | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 12ppm | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 5 | 5 | 5 | 6 | 6 | 6 | 6 |
| M. EYE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | 46-7 | 47-7 | 48-7 | 49-7 | 50-7 | 51-7 | 52-7 | 53-7 | 54-7 | 55-7 | 56-7 |
|-------------------------|------------|-------------------------|------|------|--|------|------|------|------|------|------|------|------|------|------|------|
| | | 43-7 | 44-7 | 45-7 | | | | | | | | | | | | |
| DEATH | 0ppm | 3 | 3 | 3 | | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 3ppm | 3 | 3 | 3 | | 3 | 4 | 4 | 4 | 4 | 4 | 5 | 5 | 5 | 6 | 6 |
| | 6ppm | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 |
| MORIBUND SACRIFICE | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | 0ppm | 5 | 5 | 5 | | 5 | 5 | 5 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| | 3ppm | 7 | 7 | 7 | | 7 | 6 | 6 | 6 | 6 | 6 | 5 | 5 | 5 | 4 | 4 |
| | 6ppm | 3 | 3 | 3 | | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 |
| | 12ppm | 6 | 6 | 6 | | 6 | 6 | 6 | 6 | 6 | 6 | 5 | 5 | 5 | 5 | 5 |
| M. EYE | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
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CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 57-7 | 58-7 | 59-7 | 60-7 | 61-7 | 62-7 | 63-7 | 64-7 | 65-7 | 66-7 | 67-7 | 68-7 | 69-7 | 70-7 |
| DEATH | 0ppm | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 3ppm | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 8 | 8 |
| | 6ppm | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |
| | 12ppm | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| MORIBUND SACRIFICE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | 0ppm | 4 | 4 | 4 | 4 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| | 3ppm | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| | 6ppm | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 12ppm | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| M. EYE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 71-7 | 72-7 | 73-7 | 74-7 | 75-7 | 76-7 | 77-7 | 78-7 | 79-7 | 80-7 | 81-7 | 82-7 | 83-7 | 84-7 |
| DEATH | 0ppm | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 5 | 5 | 5 |
| | 3ppm | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 10 | 10 |
| | 6ppm | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| | 12ppm | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 4 | 4 | 4 |
| MORIBUND SACRIFICE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 6ppm | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOBRECTION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| INTERNAL MASS | 0ppm | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 7 | 8 | 7 | 8 | 8 | 8 |
| | 3ppm | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 2 | 3 | 4 | 3 | 3 |
| | 6ppm | 4 | 3 | 2 | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 5 | 5 | 5 |
| M. EYE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 85-7 | 86-7 | 87-7 | 88-7 | 89-7 | 90-7 | 91-7 | 92-7 | 93-7 | 94-7 | 95-7 | 96-7 | 97-7 | 98-7 |
| DEATH | 0ppm | 5 | 5 | 6 | 6 | 6 | 6 | 7 | 8 | 8 | 9 | 10 | 11 | 11 | 12 |
| | 3ppm | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 12 | 13 | 15 |
| | 6ppm | 5 | 5 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| | 12ppm | 4 | 4 | 4 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| MORIBUND SACRIFICE | 0ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 3 |
| | 3ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |
| | 12ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | 0ppm | 9 | 9 | 9 | 8 | 8 | 9 | 8 | 7 | 7 | 6 | 6 | 6 | 6 | 5 |
| | 3ppm | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 3 | 2 |
| | 6ppm | 2 | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 |
| | 12ppm | 5 | 5 | 5 | 4 | 4 | 4 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| M. EYE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 |
| | 6ppm | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | |
|-------------------------|------------|-------------------------|-------|-------|-------|-------|-------|
| | | 99-7 | 100-7 | 101-7 | 102-7 | 103-7 | 104-7 |
| DEATH | 0ppm | 12 | 12 | 13 | 13 | 13 | 14 |
| | 3ppm | 15 | 15 | 15 | 16 | 16 | 17 |
| | 6ppm | 7 | 7 | 7 | 8 | 8 | 8 |
| | 12ppm | 5 | 5 | 5 | 5 | 5 | 5 |
| MORIBUND SACRIFICE | 0ppm | 3 | 3 | 3 | 3 | 3 | 3 |
| | 3ppm | 1 | 2 | 3 | 3 | 3 | 3 |
| | 6ppm | 4 | 4 | 4 | 4 | 4 | 4 |
| | 12ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 1 | 1 | 1 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 1 | 1 | 1 |
| INTERNAL MASS | 0ppm | 4 | 4 | 3 | 4 | 4 | 5 |
| | 3ppm | 2 | 2 | 2 | 3 | 3 | 4 |
| | 6ppm | 1 | 1 | 1 | 1 | 2 | 2 |
| | 12ppm | 5 | 6 | 6 | 7 | 7 | 7 |
| M. EYE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| | | 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 | 14-7 |
| M. PERI MOUTH | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR. DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HINDLIMB | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 15-7 | 16-7 | 17-7 | 18-7 | 19-7 | 20-7 | 21-7 | 22-7 | 23-7 | 24-7 | 25-7 | 26-7 | 27-7 | 28-7 |
| M. PERI MOUTH | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR. DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HINDLIMB | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 29-7 | 30-7 | 31-7 | 32-7 | 33-7 | 34-7 | 35-7 | 36-7 | 37-7 | 38-7 | 39-7 | 40-7 | 41-7 | 42-7 |
| M. PERI MOUTH | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR. DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HINDLIMB | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 43-7 | 44-7 | 45-7 | 46-7 | 47-7 | 48-7 | 49-7 | 50-7 | 51-7 | 52-7 | 53-7 | 54-7 | 55-7 | 56-7 |
| M. PERI MOUTH | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR. DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HINDLIMB | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 57-7 | 58-7 | 59-7 | 60-7 | 61-7 | 62-7 | 63-7 | 64-7 | 65-7 | 66-7 | 67-7 | 68-7 | 69-7 | 70-7 |
| M. PERI MOUTH | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR. DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HINDLIMB | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 71-7 | 72-7 | 73-7 | 74-7 | 75-7 | 76-7 | 77-7 | 78-7 | 79-7 | 80-7 | 81-7 | 82-7 | 83-7 | 84-7 |
| M. PERI MOUTH | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR. DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HINDLIMB | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 85-7 | 86-7 | 87-7 | 88-7 | 89-7 | 90-7 | 91-7 | 92-7 | 93-7 | 94-7 | 95-7 | 96-7 | 97-7 | 98-7 |
| M. PERI MOUTH | 0ppm | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 1 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR. DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HINDLIMB | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | |
|---------------------|------------|-------------------------|-------|-------|-------|-------|-------|
| | | 99-7 | 100-7 | 101-7 | 102-7 | 103-7 | 104-7 |
| M. PERI MOUTH | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | 0ppm | 0 | 0 | 0 | 1 | 1 | 1 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR. DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 1 | 1 | 1 | 1 |
| M. HINDLIMB | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 1 | 1 | 1 | 1 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 1 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| | | 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 | 14-7 |
| EROSION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ABNORMAL RESPIRA. SOUND | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

(HAN190)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 15-7 | 16-7 | 17-7 | 18-7 | 19-7 | 20-7 | 21-7 | 22-7 | 23-7 | 24-7 | 25-7 | 26-7 | 27-7 | 28-7 |
| EROSION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ABNORMAL RESPIRA. SOUND | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

(HAN190)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 19

| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 29-7 | 30-7 | 31-7 | 32-7 | 33-7 | 34-7 | 35-7 | 36-7 | 37-7 | 38-7 | 39-7 | 40-7 | 41-7 | 42-7 |
| EROSION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ABNORMAL RESPIRA. SOUND | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

(HAN190)

BAIS 3

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 20

| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 43-7 | 44-7 | 45-7 | 46-7 | 47-7 | 48-7 | 49-7 | 50-7 | 51-7 | 52-7 | 53-7 | 54-7 | 55-7 | 56-7 |
| EROSION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ABNORMAL RESPIRA. SOUND | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

(HAN190)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 21

| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 57-7 | 58-7 | 59-7 | 60-7 | 61-7 | 62-7 | 63-7 | 64-7 | 65-7 | 66-7 | 67-7 | 68-7 | 69-7 | 70-7 |
| EROSION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ABNORMAL RESPIRA. SOUND | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

(HAN190)

BAIS 8

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 22

| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 71-7 | 72-7 | 73-7 | 74-7 | 75-7 | 76-7 | 77-7 | 78-7 | 79-7 | 80-7 | 81-7 | 82-7 | 83-7 | 84-7 |
| EROSION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ABNORMAL RESPIRA. SOUND | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

(HAN190)

BAIS 3

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 23

| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 85-7 | 86-7 | 87-7 | 88-7 | 89-7 | 90-7 | 91-7 | 92-7 | 93-7 | 94-7 | 95-7 | 96-7 | 97-7 | 98-7 |
| EROSION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ABNORMAL RESPIRA. SOUND | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

(HAN190)

BAIS 3

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 24

| Clinical sign | Group Name | Administration Week-day | | | | | |
|-------------------------|------------|-------------------------|-------|-------|-------|-------|-------|
| | | 99-7 | 100-7 | 101-7 | 102-7 | 103-7 | 104-7 |
| EROSION | 0ppm | 1 | 1 | 1 | 1 | 2 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 1 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 1 | 1 |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 1 | 0 | 1 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| ABNORMAL RESPIRA. SOUND | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 1 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |

(HAN190)

BAIS 3

APPENDIX A 2

CLINICAL OBSERVATION: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 25

| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| | | 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 | 14-7 |
| DEATH | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MORIBUND SACRIFICE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 26

| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 15-7 | 16-7 | 17-7 | 18-7 | 19-7 | 20-7 | 21-7 | 22-7 | 23-7 | 24-7 | 25-7 | 26-7 | 27-7 | 28-7 |
| DEATH | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MORIBUND SACRIFICE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 29-7 | 30-7 | 31-7 | 32-7 | 33-7 | 34-7 | 35-7 | 36-7 | 37-7 | 38-7 | 39-7 | 40-7 | 41-7 | 42-7 |
| DEATH | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| MORIBUND SACRIFICE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 43-7 | 44-7 | 45-7 | 46-7 | 47-7 | 48-7 | 49-7 | 50-7 | 51-7 | 52-7 | 53-7 | 54-7 | 55-7 | 56-7 |
| DEATH | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| MORIBUND SACRIFICE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 57-7 | 58-7 | 59-7 | 60-7 | 61-7 | 62-7 | 63-7 | 64-7 | 65-7 | 66-7 | 67-7 | 68-7 | 69-7 | 70-7 |
| DEATH | 0ppm | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3ppm | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 |
| MORIBUND SACRIFICE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | 0ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 71-7 | 72-7 | 73-7 | 74-7 | 75-7 | 76-7 | 77-7 | 78-7 | 79-7 | 80-7 | 81-7 | 82-7 | 83-7 | 84-7 |
| DEATH | 0ppm | 1 | 1 | 1 | 2 | 3 | 4 | 4 | 4 | 6 | 6 | 6 | 6 | 6 | 6 |
| | 3ppm | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 6 | 6 | 6 | 6 | 8 | 8 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 3 | 4 | 4 | 4 | 4 | 4 |
| | 12ppm | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |
| MORIBUND SACRIFICE | 0ppm | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3ppm | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | 0ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-------------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 85-7 | 86-7 | 87-7 | 88-7 | 89-7 | 90-7 | 91-7 | 92-7 | 93-7 | 94-7 | 95-7 | 96-7 | 97-7 | 98-7 |
| DEATH | 0ppm | 6 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 9 | 11 | 11 | 11 | 11 |
| | 3ppm | 8 | 8 | 8 | 10 | 10 | 10 | 10 | 11 | 11 | 12 | 13 | 13 | 14 | 15 |
| | 6ppm | 4 | 5 | 5 | 5 | 6 | 6 | 7 | 7 | 8 | 8 | 10 | 10 | 11 | 12 |
| | 12ppm | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 |
| MORIBUND SACRIFICE | 0ppm | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 4 | 6 | 6 | 6 | 6 | 6 | 6 |
| | 3ppm | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 12ppm | 1 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | 0ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOBRECTION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 1 |
| | 12ppm | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | |
|-------------------------|------------|-------------------------|-------|-------|-------|-------|-------|
| | | 99-7 | 100-7 | 101-7 | 102-7 | 103-7 | 104-7 |
| DEATH | 0ppm | 13 | 13 | 13 | 13 | 14 | 14 |
| | 3ppm | 15 | 15 | 15 | 16 | 17 | 19 |
| | 6ppm | 12 | 13 | 14 | 15 | 15 | 17 |
| | 12ppm | 7 | 8 | 10 | 11 | 11 | 11 |
| MORIBUND SACRIFICE | 0ppm | 6 | 6 | 6 | 6 | 6 | 6 |
| | 3ppm | 5 | 5 | 5 | 5 | 6 | 6 |
| | 6ppm | 3 | 3 | 3 | 3 | 3 | 3 |
| | 12ppm | 5 | 5 | 5 | 5 | 5 | 5 |
| LOCOMOTOR MOVEMENT DECR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | 0ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | 0ppm | 0 | 0 | 0 | 0 | 0 | 1 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOBRECTION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | 0ppm | 0 | 0 | 0 | 1 | 2 | 2 |
| | 3ppm | 0 | 1 | 1 | 2 | 1 | 2 |
| | 6ppm | 1 | 1 | 1 | 0 | 0 | 1 |
| | 12ppm | 1 | 0 | 0 | 0 | 0 | 1 |
| EXOPHTHALMOS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 1 | 1 | 1 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-----------------|------------|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| | | 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 | 14-7 |
| CORNEAL OPACITY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| M. EYE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ORAL CAVITY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-----------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 15-7 | 16-7 | 17-7 | 18-7 | 19-7 | 20-7 | 21-7 | 22-7 | 23-7 | 24-7 | 25-7 | 26-7 | 27-7 | 28-7 |
| CORNEAL OPACITY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 2 | 2 | 2 | 2 | 2 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| M. EYE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ORAL CAVITY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
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| Clinical sign | Group Name | Administration Week-day | | 31-7 | 32-7 | 33-7 | 34-7 | 35-7 | 36-7 | 37-7 | 38-7 | 39-7 | 40-7 | 41-7 | 42-7 |
|-----------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 29-7 | 30-7 | | | | | | | | | | | | |
| CORNEAL OPACITY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| M. EYE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ORAL CAVITY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-----------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 43-7 | 44-7 | 45-7 | 46-7 | 47-7 | 48-7 | 49-7 | 50-7 | 51-7 | 52-7 | 53-7 | 54-7 | 55-7 | 56-7 |
| CORNEAL OPACITY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 12ppm | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| M. EYE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ORAL CAVITY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-----------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 57-7 | 58-7 | 59-7 | 60-7 | 61-7 | 62-7 | 63-7 | 64-7 | 65-7 | 66-7 | 67-7 | 68-7 | 69-7 | 70-7 |
| CORNEAL OPACITY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 4 | 4 | 4 | 4 |
| | 3ppm | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 |
| | 12ppm | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 |
| M. EYE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ORAL CAVITY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| M. NECK | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-----------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 71-7 | 72-7 | 73-7 | 74-7 | 75-7 | 76-7 | 77-7 | 78-7 | 79-7 | 80-7 | 81-7 | 82-7 | 83-7 | 84-7 |
| CORNEAL OPACITY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| INTERNAL MASS | 0ppm | 4 | 4 | 5 | 3 | 3 | 3 | 3 | 3 | 1 | 1 | 2 | 2 | 3 | 3 |
| | 3ppm | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 5 | 5 | 5 | 4 | 4 |
| | 6ppm | 3 | 3 | 3 | 3 | 5 | 5 | 5 | 4 | 3 | 3 | 3 | 5 | 5 | 5 |
| | 12ppm | 4 | 4 | 4 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 8 | 8 | 7 |
| M. EYE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| M. ORAL CAVITY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| M. NECK | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|-----------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 85-7 | 86-7 | 87-7 | 88-7 | 89-7 | 90-7 | 91-7 | 92-7 | 93-7 | 94-7 | 95-7 | 96-7 | 97-7 | 98-7 |
| CORNEAL OPACITY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | 0ppm | 3 | 2 | 2 | 6 | 5 | 5 | 5 | 4 | 4 | 4 | 3 | 4 | 3 | 3 |
| | 3ppm | 4 | 4 | 4 | 6 | 6 | 6 | 6 | 5 | 7 | 6 | 5 | 6 | 7 | 7 |
| | 6ppm | 5 | 4 | 4 | 4 | 4 | 4 | 6 | 7 | 5 | 5 | 5 | 5 | 5 | 5 |
| | 12ppm | 7 | 5 | 5 | 4 | 5 | 5 | 7 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
| M. EYE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ORAL CAVITY | 0ppm | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| M. NECK | 0ppm | 1 | 1 | 1 | 2 | 2 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| M. BREAST | 0ppm | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
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| Clinical sign | Group Name | Administration Week-day | | | | | |
|-----------------|------------|-------------------------|-------|-------|-------|-------|-------|
| | | 99-7 | 100-7 | 101-7 | 102-7 | 103-7 | 104-7 |
| CORNEAL OPACITY | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | 0ppm | 4 | 4 | 4 | 4 | 3 | 5 |
| | 3ppm | 7 | 7 | 7 | 8 | 6 | 6 |
| | 6ppm | 5 | 5 | 8 | 7 | 8 | 7 |
| | 12ppm | 6 | 5 | 4 | 5 | 5 | 5 |
| M. EYE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ORAL CAVITY | 0ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| M. NECK | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 1 |
| | 12ppm | 1 | 1 | 1 | 0 | 0 | 0 |
| M. BREAST | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 1 | 1 | 1 | 1 | 1 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |

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CLINICAL OBSERVATION (SUMMARY)
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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| | | 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 | 14-7 |
| M. INTERSCAPULUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANUS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EROSION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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REPORT TYPE : A1 104

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 15-7 | 16-7 | 17-7 | 18-7 | 19-7 | 20-7 | 21-7 | 22-7 | 23-7 | 24-7 | 25-7 | 26-7 | 27-7 | 28-7 |
| M. INTERSCAPULUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANUS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EROSION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 29-7 | 30-7 | 31-7 | 32-7 | 33-7 | 34-7 | 35-7 | 36-7 | 37-7 | 38-7 | 39-7 | 40-7 | 41-7 | 42-7 |
| M. INTERSCAPULUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANUS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EROSION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 43-7 | 44-7 | 45-7 | 46-7 | 47-7 | 48-7 | 49-7 | 50-7 | 51-7 | 52-7 | 53-7 | 54-7 | 55-7 | 56-7 |
| M. INTERSCAPULUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANUS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 |
| ANEMIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EROSION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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ANIMAL : MOUSE Crj:BDF1
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| Clinical sign | Group Name | Administration Week-day | | | | 60-7 | 61-7 | 62-7 | 63-7 | 64-7 | 65-7 | 66-7 | 67-7 | 68-7 | 69-7 | 70-7 |
|---------------------|------------|-------------------------|------|------|--|------|------|------|------|------|------|------|------|------|------|------|
| | | 57-7 | 58-7 | 59-7 | | | | | | | | | | | | |
| M. INTERSCAPULUM | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANUS | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 1 | 1 | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EROSION | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 71-7 | 72-7 | 73-7 | 74-7 | 75-7 | 76-7 | 77-7 | 78-7 | 79-7 | 80-7 | 81-7 | 82-7 | 83-7 | 84-7 |
| M. INTERSCAPULUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANUS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EROSION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 85-7 | 86-7 | 87-7 | 88-7 | 89-7 | 90-7 | 91-7 | 92-7 | 93-7 | 94-7 | 95-7 | 96-7 | 97-7 | 98-7 |
| M. INTERSCAPULUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANUS | 0ppm | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EROSION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | |
|---------------------|------------|-------------------------|-------|-------|-------|-------|-------|
| | | 99-7 | 100-7 | 101-7 | 102-7 | 103-7 | 104-7 |
| M. INTERSCAPULUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 1 | 1 | 1 | 1 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | 0ppm | 0 | 0 | 0 | 2 | 2 | 2 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANUS | 0ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| EROSION | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 1 | 1 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | 0ppm | 0 | 0 | 0 | 1 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| | | 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 | 14-7 |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

(HAN190)

BALS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 15-7 | 16-7 | 17-7 | 18-7 | 19-7 | 20-7 | 21-7 | 22-7 | 23-7 | 24-7 | 25-7 | 26-7 | 27-7 | 28-7 |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 29-7 | 30-7 | 31-7 | 32-7 | 33-7 | 34-7 | 35-7 | 36-7 | 37-7 | 38-7 | 39-7 | 40-7 | 41-7 | 42-7 |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 43-7 | 44-7 | 45-7 | 46-7 | 47-7 | 48-7 | 49-7 | 50-7 | 51-7 | 52-7 | 53-7 | 54-7 | 55-7 | 56-7 |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | 60-7 | 61-7 | 62-7 | 63-7 | 64-7 | 65-7 | 66-7 | 67-7 | 68-7 | 69-7 | 70-7 |
|---------------------|------------|-------------------------|------|------|--|------|------|------|------|------|------|------|------|------|------|------|
| | | 57-7 | 58-7 | 59-7 | | | | | | | | | | | | |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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BAIS 3

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 71-7 | 72-7 | 73-7 | 74-7 | 75-7 | 76-7 | 77-7 | 78-7 | 79-7 | 80-7 | 81-7 | 82-7 | 83-7 | 84-7 |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

(HAN190)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 55

| Clinical sign | Group Name | Administration Week-day | | | | | | | | | | | | | |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 85-7 | 86-7 | 87-7 | 88-7 | 89-7 | 90-7 | 91-7 | 92-7 | 93-7 | 94-7 | 95-7 | 96-7 | 97-7 | 98-7 |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 12ppm | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

(HAN190)

BAIS 3

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 56

| Clinical sign | Group Name | Administration Week-day | | | | | |
|---------------------|------------|-------------------------|-------|-------|-------|-------|-------|
| | | 99-7 | 100-7 | 101-7 | 102-7 | 103-7 | 104-7 |
| TORTICOLLIS | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| IRREGULAR BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 1 | 1 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | 0ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12ppm | 0 | 0 | 0 | 0 | 0 | 0 |

(HAN190)

BAIS 3

APPENDIX B 1

BODY WEIGHT CHANGES: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 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 |
| 0ppm | 22.1± 0.8 | 23.6± 1.1 | 24.2± 1.4 | 24.8± 1.9 | 25.5± 1.7 | 26.1± 1.7 | 26.8± 1.8 |
| 3ppm | 22.1± 0.8 | 23.3± 1.2 | 23.9± 1.2 | 24.3± 1.7 | 24.9± 1.7 | 25.5± 1.7 | 26.1± 1.5 |
| 6ppm | 22.1± 0.8 | 23.4± 0.9 | 23.9± 1.2 | 24.4± 1.5 | 25.2± 1.1 | 25.8± 1.2 | 26.0± 1.2 |
| 12ppm | 22.1± 0.8 | 22.3± 1.0** | 22.0± 1.0** | 22.2± 1.0** | 22.5± 1.2** | 23.2± 1.2** | 23.9± 1.0** |

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 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 |
|---|-------------------------|-------------|-------------|-------------|-------------|-------------|-------------|------|
| 0ppm | 27.2± 2.2 | 27.8± 2.2 | 28.5± 2.5 | 29.1± 2.8 | 29.7± 2.8 | 30.3± 3.0 | 30.9± 3.1 | |
| 3ppm | 26.6± 1.6 | 27.1± 1.8 | 27.6± 2.4 | 28.3± 2.0 | 29.0± 2.1 | 29.5± 2.2 | 30.1± 2.3 | |
| 6ppm | 26.3± 1.4* | 27.0± 1.4 | 27.3± 1.3 | 28.0± 1.5 | 28.2± 1.4* | 28.7± 1.6 | 29.4± 1.7 | |
| 12ppm | 23.8± 1.1** | 24.6± 1.2** | 24.2± 1.2** | 24.3± 1.1** | 24.2± 1.6** | 24.9± 1.2** | 24.8± 1.3** | |
| Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett | | | | | | | | |

(HAN260)

BAIS 8

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

| Group Name | Administration week-day | | | | | | |
|------------|-------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 14-7 | 18-7 | 22-7 | 26-7 | 30-7 | 34-7 | 38-7 |
| 0ppm | 31.5± 3.3 | 34.0± 3.1 | 35.9± 3.8 | 37.6± 4.4 | 38.8± 4.8 | 40.6± 5.3 | 42.2± 5.5 |
| 3ppm | 30.9± 2.3 | 33.3± 2.7 | 35.1± 3.2 | 36.8± 3.4 | 38.1± 3.7 | 40.2± 3.9 | 41.8± 4.2 |
| 6ppm | 30.3± 1.6 | 31.9± 2.1* | 33.3± 2.2* | 35.1± 2.6 | 36.1± 2.9 | 37.3± 3.1 | 38.7± 3.3* |
| 12ppm | 25.3± 1.2** | 26.1± 1.3** | 26.7± 1.4** | 27.7± 1.4** | 27.8± 1.6** | 28.0± 1.6** | 29.1± 1.8** |

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

| Group Name | Administration week-day | | | | | | |
|------------|-------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 42-7 | 46-7 | 50-7 | 54-7 | 58-7 | 62-7 | 66-7 |
| 0ppm | 43.1± 5.6 | 44.0± 5.7 | 44.7± 6.0 | 45.6± 6.0 | 46.3± 6.1 | 47.2± 6.1 | 47.9± 6.1 |
| 3ppm | 42.9± 4.4 | 43.8± 4.3 | 44.9± 4.4 | 46.1± 4.5 | 46.5± 5.9 | 47.5± 4.7 | 48.8± 4.6 |
| 6ppm | 39.6± 3.5 | 40.6± 3.6 | 41.2± 3.8 | 41.9± 3.9* | 43.3± 4.1 | 43.4± 4.1* | 44.7± 4.5 |
| 12ppm | 29.1± 1.8** | 29.4± 2.0** | 30.6± 2.3** | 30.4± 2.2** | 31.6± 2.4** | 31.1± 2.5** | 31.5± 2.6** |

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

| Group Name | Administration week-day | | | | | | |
|------------|-------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 70-7 | 74-7 | 78-7 | 82-7 | 86-7 | 90-7 | 94-7 |
| 0ppm | 48.8± 6.0 | 50.1± 6.1 | 50.7± 6.2 | 50.7± 6.5 | 50.4± 7.0 | 49.6± 7.7 | 50.4± 7.9 |
| 3ppm | 50.0± 4.6 | 51.0± 4.5 | 51.1± 5.4 | 51.5± 6.2 | 52.3± 5.1 | 52.5± 5.5 | 52.3± 5.9 |
| 6ppm | 45.1± 4.7* | 46.6± 5.3 | 46.9± 4.8* | 47.0± 4.9 | 46.6± 5.1 | 47.0± 5.3 | 47.1± 5.6 |
| 12ppm | 31.7± 2.7** | 32.5± 2.7** | 32.6± 2.9** | 32.4± 2.7** | 32.4± 2.7** | 33.6± 2.6** | 33.5± 2.8** |

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

Test of Dunnett

(HAN260)

BAIS 8

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 104
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 6

| Group Name | Administration week-day | | |
|------------|-------------------------|-------------|-------------|
| | 98-7 | 102-7 | 104-7 |
| 0ppm | 49.5± 8.7 | 49.6± 6.2 | 49.0± 6.1 |
| 3ppm | 52.2± 7.3 | 50.7± 6.6 | 49.4± 7.1 |
| 6ppm | 46.8± 6.5 | 45.8± 5.8 | 44.3± 6.0 |
| 12ppm | 33.6± 2.7** | 33.0± 2.9** | 32.1± 3.1** |

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

Test of Dunnett

(HAN260)

BAIS 8

APPENDIX B 2

BODY WEIGHT CHANGES: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE CrJ:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 7

| Group Name | Administration week-day | | | | | | |
|------------|-------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 0-0 | 1-7 | 2-7 | 3-7 | 4-7 | 5-7 | 6-7 |
| 0ppm | 18.6± 0.8 | 19.7± 0.8 | 20.3± 0.7 | 20.9± 0.9 | 21.6± 0.8 | 22.2± 0.8 | 22.7± 0.8 |
| 3ppm | 18.6± 0.8 | 19.4± 1.0 | 20.0± 1.0 | 20.7± 1.0 | 21.4± 1.1 | 22.1± 1.2 | 22.6± 1.2 |
| 6ppm | 18.6± 0.8 | 19.5± 0.9 | 20.1± 0.9 | 20.7± 0.8 | 21.5± 0.9 | 22.0± 1.0 | 22.4± 1.0 |
| 12ppm | 18.6± 0.8 | 19.0± 1.0** | 18.9± 0.8** | 19.4± 0.8** | 19.8± 0.8** | 20.5± 1.0** | 21.3± 1.1** |

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

| Group Name | Administration week-day | | | | | | |
|------------|-------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 7-7 | 8-7 | 9-7 | 10-7 | 11-7 | 12-7 | 13-7 |
| 0ppm | 23.1± 1.1 | 23.8± 1.0 | 23.9± 1.1 | 24.4± 1.2 | 24.7± 1.1 | 24.8± 1.3 | 25.4± 1.4 |
| 3ppm | 23.1± 1.2 | 23.3± 1.3 | 23.6± 1.5 | 23.8± 1.2* | 24.3± 1.5 | 24.5± 1.5 | 24.9± 1.5 |
| 6ppm | 22.8± 0.9 | 23.6± 1.2 | 23.4± 1.4 | 23.8± 1.2* | 24.3± 1.3 | 24.4± 1.2 | 24.7± 1.2* |
| 12ppm | 21.5± 1.0** | 22.5± 1.0** | 22.2± 1.2** | 22.2± 0.9** | 22.3± 1.0** | 22.7± 1.1** | 23.0± 1.1** |

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 9

| Group Name | Administration week-day | | | | | | |
|------------|-------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 14-7 | 18-7 | 22-7 | 26-7 | 30-7 | 34-7 | 38-7 |
| 0ppm | 25.3± 1.3 | 27.0± 1.8 | 27.5± 1.9 | 28.4± 2.3 | 28.7± 2.3 | 29.7± 2.9 | 30.7± 3.1 |
| 3ppm | 25.1± 1.8 | 26.2± 1.8 | 27.0± 1.9 | 27.4± 2.2 | 28.5± 2.2 | 28.9± 2.6 | 29.8± 3.1 |
| 6ppm | 25.3± 1.6 | 26.0± 1.6* | 27.1± 2.1 | 27.7± 2.3 | 28.4± 2.5 | 28.8± 2.8 | 29.9± 3.3 |
| 12ppm | 23.4± 1.0** | 23.7± 1.2** | 24.4± 1.2** | 24.7± 1.1** | 25.0± 1.2** | 25.0± 1.3** | 25.7± 1.4** |

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 10

| Group Name | Administration week-day | | | | | | |
|------------|-------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 42-7 | 46-7 | 50-7 | 54-7 | 58-7 | 62-7 | 66-7 |
| 0ppm | 31.2± 3.5 | 31.7± 3.1 | 31.8± 3.3 | 32.4± 3.5 | 32.3± 3.3 | 33.1± 3.2 | 33.6± 3.7 |
| 3ppm | 29.9± 2.6 | 30.4± 3.0 | 31.0± 3.2 | 31.4± 3.9 | 32.2± 3.8 | 32.7± 3.8 | 33.0± 4.5 |
| 6ppm | 30.4± 3.2 | 30.7± 3.1 | 30.9± 3.0 | 31.3± 3.5 | 32.1± 3.9 | 32.7± 3.6 | 33.1± 3.7 |
| 12ppm | 25.3± 1.4** | 25.6± 1.5** | 26.1± 1.4** | 25.9± 1.6** | 26.8± 1.9** | 26.3± 2.0** | 26.5± 2.4** |

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 11

| Group Name | Administration week-day | | | | | | |
|---|-------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 70-7 | 74-7 | 78-7 | 82-7 | 86-7 | 90-7 | 94-7 |
| 0ppm | 33.8± 4.0 | 34.9± 4.5 | 34.8± 5.7 | 34.1± 4.5 | 34.1± 4.2 | 34.1± 4.4 | 34.5± 4.2 |
| 3ppm | 33.2± 4.2 | 34.8± 4.5 | 35.3± 5.3 | 35.2± 5.8 | 35.8± 5.6 | 36.0± 5.8 | 36.0± 5.7 |
| 6ppm | 33.6± 3.7 | 34.6± 3.9 | 34.1± 4.1 | 35.5± 4.0 | 35.4± 3.8 | 35.8± 4.5 | 36.4± 5.0 |
| 12ppm | 26.3± 2.0** | 27.0± 2.2** | 26.5± 2.5** | 27.2± 2.8** | 27.5± 3.3** | 27.4± 2.4** | 27.5± 2.4** |
| Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett | | | | | | | |

(HAN260)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 12

| Group Name | Administration week-day | | |
|------------|-------------------------|-------------|-------------|
| | 98-7 | 102-7 | 104-7 |
| 0ppm | 34.2± 4.4 | 34.2± 5.0 | 34.3± 6.3 |
| 3ppm | 35.9± 5.8 | 36.2± 5.6 | 35.2± 5.2 |
| 6ppm | 36.1± 4.4 | 35.1± 4.6 | 34.5± 4.6 |
| 12ppm | 27.7± 2.6** | 27.4± 2.4** | 27.0± 2.2** |

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

Test of Dunnett

(HAN260)

BAIS 3

APPENDIX C 1

FOOD CONSUMPTION CHANGES: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|------------|------------|------------|------------|------------|------------|
| | 1-7 (6) | 2-7 (7) | 3-7 (7) | 4-7 (7) | 5-7 (7) | 6-7 (7) | 7-7 (7) |
| 0ppm | 4.1± 0.3 | 3.7± 0.3 | 3.9± 0.5 | 4.0± 0.3 | 4.1± 0.3 | 4.2± 0.3 | 4.2± 0.3 |
| 3ppm | 3.9± 0.4 | 3.7± 0.3 | 3.9± 0.4 | 4.0± 0.3 | 4.1± 0.3 | 4.1± 0.3 | 4.2± 0.3 |
| 6ppm | 4.0± 0.3 | 3.7± 0.3 | 3.7± 0.3 | 3.9± 0.2 | 4.0± 0.2 | 4.0± 0.2** | 4.0± 0.2* |
| 12ppm | 3.7± 0.3** | 3.2± 0.2** | 3.4± 0.2** | 3.5± 0.2** | 3.8± 0.2** | 3.8± 0.2** | 3.8± 0.2** |

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 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) | 14-7(7) |
| 0ppm | 4.3± 0.3 | 4.4± 0.3 | 4.4± 0.4 | 4.4± 0.3 | 4.4± 0.4 | 4.4± 0.4 | 4.5± 0.4 |
| 3ppm | 4.2± 0.3 | 4.3± 0.4 | 4.4± 0.4 | 4.4± 0.4 | 4.5± 0.4 | 4.4± 0.3 | 4.5± 0.3 |
| 6ppm | 4.1± 0.2 | 4.2± 0.2 | 4.1± 0.2** | 4.1± 0.2** | 4.2± 0.3* | 4.3± 0.2 | 4.4± 0.2 |
| 12ppm | 3.9± 0.2** | 3.9± 0.2** | 3.8± 0.2** | 3.7± 0.3** | 3.9± 0.3** | 3.7± 0.2** | 3.8± 0.2** |

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|------------|------------|------------|------------|------------|------------|
| | 18-7(7) | 22-7(7) | 26-7(7) | 30-7(7) | 34-7(7) | 38-7(7) | 42-7(7) |
| 0ppm | 4.6± 0.3 | 4.8± 0.6 | 4.6± 0.3 | 4.7± 0.3 | 4.7± 0.3 | 4.9± 0.3 | 4.9± 0.4 |
| 3ppm | 4.6± 0.4 | 4.6± 0.4 | 4.5± 0.3 | 4.6± 0.4 | 4.7± 0.4 | 4.8± 0.4 | 4.9± 0.4 |
| 6ppm | 4.4± 0.2* | 4.5± 0.3* | 4.4± 0.2* | 4.3± 0.2** | 4.5± 0.2** | 4.6± 0.2** | 4.6± 0.3* |
| 12ppm | 3.9± 0.2** | 3.9± 0.2** | 3.9± 0.2** | 3.8± 0.2** | 3.8± 0.2** | 3.9± 0.2** | 3.9± 0.3** |

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|------------|------------|------------|------------|------------|------------|
| | 46-7(7) | 50-7(7) | 54-7(7) | 58-7(7) | 62-7(7) | 66-7(7) | 70-7(7) |
| 0ppm | 5.0± 0.3 | 5.0± 0.4 | 5.1± 0.3 | 5.2± 0.4 | 5.2± 0.4 | 5.2± 0.5 | 5.3± 0.4 |
| 3ppm | 4.9± 0.4 | 4.9± 0.4 | 5.1± 0.3 | 5.0± 0.5 | 5.1± 0.4 | 5.2± 0.3 | 5.3± 0.4 |
| 6ppm | 4.7± 0.3** | 4.8± 0.3* | 4.8± 0.2** | 5.0± 0.3 | 4.8± 0.3** | 4.9± 0.4* | 5.0± 0.3** |
| 12ppm | 3.9± 0.2** | 4.2± 0.3** | 4.0± 0.3** | 4.3± 0.3** | 4.0± 0.2** | 4.0± 0.2** | 4.2± 0.2** |

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

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|------------|------------|------------|------------|------------|------------|
| | 74-7(7) | 78-7(7) | 82-7(7) | 86-7(7) | 90-7(7) | 94-7(7) | 98-7(7) |
| 0ppm | 5.4± 0.4 | 5.2± 0.4 | 5.4± 0.5 | 5.4± 0.6 | 5.2± 0.5 | 5.3± 0.5 | 5.3± 0.8 |
| 3ppm | 5.3± 0.4 | 5.2± 0.6 | 5.3± 0.6 | 5.5± 0.4 | 5.3± 0.4 | 5.3± 0.5 | 5.4± 0.7 |
| 6ppm | 5.3± 0.4 | 4.9± 0.2* | 5.1± 0.3 | 5.2± 0.5 | 5.0± 0.4 | 5.1± 0.4 | 5.0± 0.9 |
| 12ppm | 4.3± 0.3** | 4.1± 0.2** | 4.2± 0.2** | 4.4± 0.3** | 4.2± 0.3** | 4.3± 0.2** | 4.3± 0.2** |

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 104
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 6

| Group Name | Administration week-day(effective) | |
|---|------------------------------------|------------|
| | 102-7(7) | 104-7(7) |
| 0ppm | 5.3± 0.5 | 5.1± 0.4 |
| 3ppm | 5.1± 0.7 | 4.9± 0.5 |
| 6ppm | 5.0± 0.4 | 4.7± 0.4** |
| 12ppm | 4.3± 0.3** | 4.0± 0.3** |
| Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett | | |

(HAN260)

BAIS 3

APPENDIX C 2

FOOD CONSUMPTION CHANGES: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 7

| Group Name | Administration week-day(effective) | | | | | | |
|---|------------------------------------|------------|------------|------------|------------|-----------|------------|
| | 1-7(8) | 2-7(7) | 3-7(7) | 4-7(7) | 5-7(7) | 6-7(7) | 7-7(7) |
| 0ppm | 3.6± 0.3 | 3.2± 0.2 | 3.5± 0.2 | 3.7± 0.3 | 3.9± 0.3 | 3.9± 0.3 | 4.0± 0.3 |
| 3ppm | 3.4± 0.3** | 3.1± 0.3 | 3.5± 0.2 | 3.7± 0.2 | 3.9± 0.3 | 3.9± 0.3 | 4.1± 0.3 |
| 6ppm | 3.4± 0.3* | 3.2± 0.2 | 3.4± 0.2 | 3.7± 0.3 | 3.9± 0.3 | 3.9± 0.3 | 4.0± 0.3 |
| 12ppm | 3.4± 0.3** | 3.0± 0.2** | 3.2± 0.2** | 3.4± 0.2** | 3.6± 0.2** | 3.8± 0.2* | 3.8± 0.3** |
| Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett | | | | | | | |

(HAN260)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|----------|------------|------------|------------|------------|------------|
| | 8-7(7) | 9-7(7) | 10-7(7) | 11-7(7) | 12-7(7) | 13-7(7) | 14-7(7) |
| 0ppm | 4.2± 0.2 | 4.1± 0.3 | 4.2± 0.3 | 4.2± 0.3 | 4.2± 0.3 | 4.3± 0.4 | 4.2± 0.3 |
| 3ppm | 4.1± 0.3 | 4.2± 0.3 | 4.2± 0.3 | 4.3± 0.3 | 4.2± 0.3 | 4.3± 0.3 | 4.2± 0.3 |
| 6ppm | 4.2± 0.3 | 4.1± 0.3 | 4.2± 0.3 | 4.2± 0.3 | 4.2± 0.3 | 4.2± 0.2 | 4.2± 0.3 |
| 12ppm | 4.0± 0.2** | 4.0± 0.2 | 3.9± 0.2** | 3.9± 0.2** | 4.0± 0.2** | 3.9± 0.2** | 3.9± 0.2** |

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

Test of Dunnett

(HAN260)

BAIS 8

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 9

| Group Name | Administration 18-7(7) | week-day(effective) 22-7(7) | 26-7(7) | 30-7(7) | 34-7(7) | 38-7(7) | 42-7(7) |
|------------|---------------------------|--------------------------------|------------|------------|------------|------------|------------|
| 0ppm | 4.4± 0.3 | 4.4± 0.3 | 4.4± 0.5 | 4.4± 0.4 | 4.6± 0.5 | 4.6± 0.5 | 4.6± 0.5 |
| 3ppm | 4.4± 0.5 | 4.5± 0.4 | 4.3± 0.4 | 4.4± 0.4 | 4.5± 0.5 | 4.7± 0.4 | 4.6± 0.4 |
| 6ppm | 4.3± 0.3 | 4.5± 0.3 | 4.3± 0.4 | 4.3± 0.4 | 4.4± 0.4 | 4.5± 0.7 | 4.5± 0.3 |
| 12ppm | 4.1± 0.3** | 4.1± 0.3** | 4.0± 0.3** | 3.9± 0.3** | 3.9± 0.2** | 4.1± 0.2** | 4.0± 0.3** |

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 10

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|------------|------------|------------|------------|------------|------------|
| | 46-7(7) | 50-7(7) | 54-7(7) | 58-7(7) | 62-7(7) | 66-7(7) | 70-7(7) |
| 0ppm | 4.6± 0.5 | 4.6± 0.4 | 4.7± 0.5 | 4.7± 0.5 | 4.8± 0.5 | 4.8± 0.6 | 4.8± 0.5 |
| 3ppm | 4.6± 0.5 | 4.7± 0.5 | 4.7± 0.6 | 4.7± 0.5 | 4.7± 0.5 | 4.9± 0.7 | 4.7± 0.6 |
| 6ppm | 4.5± 0.5 | 4.6± 0.4 | 4.8± 0.4 | 4.6± 0.6 | 4.7± 0.5 | 4.6± 0.7 | 4.9± 0.5 |
| 12ppm | 4.0± 0.3** | 4.1± 0.3** | 4.0± 0.3** | 4.2± 0.3** | 3.9± 0.3** | 4.0± 0.4** | 4.0± 0.3** |

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 11

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|------------|------------|------------|------------|------------|------------|
| | 74-7(7) | 78-7(7) | 82-7(7) | 86-7(7) | 90-7(7) | 94-7(7) | 98-7(7) |
| 0ppm | 4.9± 0.6 | 4.6± 0.9 | 4.8± 0.7 | 4.9± 0.8 | 4.9± 0.9 | 5.0± 0.5 | 5.1± 1.0 |
| 3ppm | 4.8± 0.5 | 4.8± 0.7 | 4.8± 0.8 | 5.0± 0.7 | 4.9± 0.6 | 4.9± 0.8 | 5.1± 0.7 |
| 6ppm | 4.9± 0.7 | 4.5± 0.7 | 4.9± 0.6 | 5.2± 0.5 | 4.8± 0.6 | 5.0± 0.9 | 5.3± 1.0 |
| 12ppm | 4.0± 0.6** | 3.8± 0.4** | 3.9± 0.3** | 4.3± 0.4** | 4.0± 0.4** | 4.1± 0.4** | 4.2± 0.4** |

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 12

| Group Name | Administration week-day(effective) | |
|------------|------------------------------------|------------|
| | 102-7 (7) | 104-7 (7) |
| 0ppm | 5.1± 0.8 | 4.9± 0.6 |
| 3ppm | 4.9± 0.8 | 4.6± 0.7 |
| 6ppm | 4.9± 0.8 | 4.6± 0.6 |
| 12ppm | 4.3± 0.4** | 3.9± 0.3** |

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

Test of Dunnett

(HAN260)

BAIS 3

APPENDIX D 1

HEMATOLOGY: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 1

| Group Name | NO. of Animals | RED BLOOD CELL 10 ⁶ /μl | | HEMOGLOBIN g/dl | | HEMATOCRIT % | | MCV fl | | MCH pg | | MCHC g/dl | | PLATELET 10 ³ /μl | |
|------------|-------------------|---------------------------------------|------|--------------------|-----|-----------------|-----|-----------|-----|-----------|-----|--------------|-----|---------------------------------|-----|
| 0ppm | 32 | 9.81± | 0.81 | 14.0± | 1.1 | 45.6± | 3.5 | 46.6± | 1.2 | 14.3± | 0.4 | 30.7± | 0.4 | 1834± | 323 |
| 3ppm | 29 | 9.56± | 1.57 | 13.6± | 2.0 | 44.7± | 6.0 | 47.1± | 4.0 | 14.3± | 1.0 | 30.3± | 0.7 | 1723± | 343 |
| 6ppm | 37 | 9.63± | 1.01 | 13.8± | 1.3 | 45.0± | 3.8 | 46.9± | 2.3 | 14.4± | 0.6 | 30.6± | 0.7 | 1834± | 416 |
| 12ppm | 42 | 9.91± | 0.44 | 14.2± | 0.7 | 46.4± | 2.2 | 46.8± | 1.1 | 14.4± | 0.3 | 30.7± | 0.4 | 1786± | 193 |

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

Test of Dunnett

(HCL070)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 2

| Group Name | NO. of Animals | WBC 10 ³ /μl | | Differential N-BAND | | WBC (%) N-SEG | | EOSINO | | BASO | | MONO | | LYMPHO | | OTHER | |
|------------|-------------------|----------------------------|--------|------------------------|-----|------------------|----|--------|---|------|---|------|---|--------|----|-------|---|
| 0ppm | 32 | 2.94± | 1.11 | 4± | 2 | 29± | 13 | 1± | 1 | 0± | 0 | 5± | 2 | 61± | 15 | 1± | 1 |
| 3ppm | 29 | 3.44± | 2.72 | 2± | 2 | 28± | 14 | 1± | 1 | 0± | 0 | 5± | 2 | 62± | 16 | 1± | 2 |
| 6ppm | 37 | 3.26± | 5.58 | 3± | 2 | 29± | 16 | 1± | 1 | 0± | 0 | 4± | 2 | 62± | 16 | 1± | 3 |
| 12ppm | 42 | 1.40± | 0.60** | 2± | 2** | 32± | 15 | 1± | 1 | 0± | 0 | 5± | 3 | 60± | 16 | 1± | 1 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 3

APPENDIX D 2

HEMATOLOGY: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 3

| Group Name | NO. of Animals | RED BLOOD CELL 10 ⁶ /μl | | HEMOGLOBIN g/dl | | HEMATOCRIT % | | MCV fl | | MCH pg | | MCHC g/dl | | PLATELET 10 ³ /μl | |
|------------|-------------------|---------------------------------------|------|--------------------|-----|-----------------|-----|-----------|-----|-----------|-----|--------------|-----|---------------------------------|-----|
| 0ppm | 29 | 8.87± | 2.13 | 12.8± | 2.8 | 41.7± | 8.0 | 48.0± | 5.1 | 14.5± | 0.7 | 30.4± | 1.9 | 1074± | 414 |
| 3ppm | 24 | 9.05± | 1.27 | 13.3± | 1.7 | 42.9± | 5.2 | 47.7± | 3.8 | 14.7± | 0.9 | 30.9± | 0.8 | 1152± | 249 |
| 6ppm | 28 | 9.10± | 1.59 | 13.3± | 2.3 | 43.0± | 6.7 | 47.6± | 2.9 | 14.7± | 0.5 | 30.9± | 1.1 | 1087± | 330 |
| 12ppm | 34 | 9.43± | 1.16 | 13.7± | 1.5 | 44.4± | 4.3 | 47.4± | 3.1 | 14.6± | 0.6 | 30.8± | 0.8 | 1142± | 291 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 4

| Group Name | NO. of Animals | WBC 10 ³ /μl | | Differential N-BAND | | WBC (%) N-SEG | | EOSINO | | BASO | | MONO | | LYMPHO | | OTHER | |
|------------|-------------------|----------------------------|------|------------------------|---|------------------|----|--------|---|------|---|------|---|--------|----|-------|----|
| 0ppm | 29 | 2.63± | 4.62 | 4± | 5 | 32± | 15 | 1± | 2 | 0± | 0 | 5± | 3 | 53± | 16 | 6± | 14 |
| 3ppm | 24 | 2.30± | 1.68 | 3± | 3 | 34± | 17 | 1± | 2 | 0± | 0 | 5± | 3 | 54± | 21 | 3± | 8 |
| 6ppm | 28 | 3.11± | 4.45 | 3± | 3 | 27± | 16 | 1± | 2 | 0± | 0 | 5± | 3 | 59± | 19 | 6± | 13 |
| 12ppm | 34 | 2.18± | 3.08 | 1± | 2 | 35± | 18 | 1± | 1 | 0± | 0 | 4± | 3 | 56± | 17 | 3± | 7 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 3

APPENDIX E 1

BIOCHEMISTRY: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 1

| Group Name | NO. of Animals | TOTAL PROTEIN g/dl | | ALBUMIN g/dl | | A/G RATIO | | T-BILIRUBIN mg/dl | | GLUCOSE mg/dl | | T-CHOLESTEROL mg/dl | | TRIGLYCERIDE mg/dl | |
|------------|-------------------|-----------------------|-----|-----------------|-----|-----------|------|----------------------|------|------------------|----|------------------------|------|-----------------------|-----|
| 0ppm | 32 | 5.0± | 0.5 | 2.7± | 0.3 | 1.2± | 0.2 | 0.14± | 0.02 | 194± | 32 | 94± | 23 | 39± | 11 |
| 3ppm | 29 | 4.9± | 0.9 | 2.7± | 0.5 | 1.2± | 0.2 | 0.14± | 0.03 | 185± | 49 | 102± | 51 | 39± | 13 |
| 6ppm | 37 | 5.0± | 0.7 | 2.7± | 0.4 | 1.2± | 0.2 | 0.13± | 0.02 | 197± | 34 | 97± | 36 | 35± | 12 |
| 12ppm | 42 | 4.9± | 0.4 | 2.7± | 0.2 | 1.3± | 0.1* | 0.15± | 0.02 | 184± | 25 | 77± | 20** | 25± | 8** |

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

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 2

| Group Name | NO. of Animals | PHOSPHOLIPID mg/dl | | GOT I U/l | | GPT I U/l | | LDH I U/l | | ALP I U/l | | G-GTP I U/l | | CPK I U/l | |
|------------|-------------------|-----------------------|------|--------------|-----|--------------|------|--------------|------|--------------|------|----------------|---|--------------|----|
| 0ppm | 32 | 176± | 33 | 81± | 81 | 40± | 42 | 304± | 146 | 123± | 38 | 2± | 1 | 48± | 16 |
| 3ppm | 29 | 187± | 94 | 225± | 589 | 111± | 299 | 515± | 825 | 125± | 48 | 2± | 1 | 61± | 86 |
| 6ppm | 37 | 179± | 56 | 72± | 48 | 41± | 54 | 283± | 150 | 118± | 25 | 2± | 1 | 52± | 28 |
| 12ppm | 42 | 145± | 28** | 73± | 107 | 36± | 76** | 234± | 80** | 161± | 32** | 1± | 2 | 59± | 27 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 3

| Group Name | NO. of Animals | UREA NITROGEN mg/dl | | SODIUM mEq/l | | POTASSIUM mEq/l | | CHLORIDE mEq/l | | CALCIUM mg/dl | | INORGANIC PHOSPHORUS mg/dl | |
|------------|-------------------|------------------------|------|-----------------|---|--------------------|-----|-------------------|---|------------------|------|-------------------------------|-----|
| 0ppm | 32 | 22.2± | 3.0 | 153± | 2 | 4.1± | 0.4 | 122± | 3 | 8.7± | 0.4 | 6.7± | 0.8 |
| 3ppm | 29 | 25.5± | 13.3 | 154± | 2 | 4.2± | 0.5 | 122± | 3 | 8.9± | 0.5 | 6.7± | 0.9 |
| 6ppm | 37 | 23.3± | 3.7 | 153± | 1 | 4.2± | 0.3 | 122± | 3 | 8.8± | 0.6 | 6.7± | 0.7 |
| 12ppm | 42 | 23.6± | 3.2 | 154± | 2 | 4.2± | 0.4 | 123± | 3 | 8.5± | 0.3* | 7.0± | 0.9 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 3

APPENDIX E 2

BIOCHEMISTRY: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 4

| Group Name | NO. of Animals | TOTAL PROTEIN g/dl | | ALBUMIN g/dl | | A/G RATIO | | T-BILIRUBIN mg/dl | | GLUCOSE mg/dl | | T-CHOLESTEROL mg/dl | | TRIGLYCERIDE mg/dl | |
|------------|-------------------|-----------------------|-----|-----------------|------|-----------|-----|----------------------|------|------------------|------|------------------------|-----|-----------------------|----|
| 0ppm | 29 | 4.8± | 0.9 | 2.7± | 0.4 | 1.3± | 0.3 | 0.15± | 0.05 | 139± | 33 | 77± | 70 | 24± | 9 |
| 3ppm | 24 | 5.0± | 0.7 | 2.8± | 0.4 | 1.2± | 0.2 | 0.15± | 0.04 | 142± | 31 | 98± | 103 | 38± | 31 |
| 6ppm | 28 | 4.8± | 0.5 | 2.7± | 0.2 | 1.3± | 0.2 | 0.16± | 0.09 | 147± | 46 | 69± | 25 | 25± | 9 |
| 12ppm | 34 | 4.8± | 0.4 | 2.8± | 0.2* | 1.4± | 0.2 | 0.15± | 0.03 | 165± | 25** | 65± | 11 | 21± | 7 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 5

| Group Name | NO. of Animals | PHOSPHOLIPID mg/dl | | GOT IU/l | | GPT IU/l | | LDH IU/l | | ALP IU/l | | G-GTP IU/l | | CPK IU/l | |
|------------|-------------------|-----------------------|-----|-------------|-----|-------------|-----|-------------|------|-------------|-------|---------------|---|-------------|-----|
| 0ppm | 29 | 143± | 109 | 117± | 106 | 46± | 65 | 565± | 519 | 185± | 89 | 2± | 1 | 130± | 102 |
| 3ppm | 24 | 176± | 161 | 121± | 116 | 44± | 49 | 498± | 511 | 156± | 80 | 2± | 1 | 84± | 56 |
| 6ppm | 28 | 132± | 48 | 163± | 265 | 74± | 137 | 695± | 1243 | 193± | 90 | 2± | 1 | 93± | 93 |
| 12ppm | 34 | 122± | 23 | 95± | 67 | 41± | 66 | 428± | 503 | 422± | 184** | 2± | 4 | 107± | 64 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 6

| Group Name | NO. of Animals | UREA NITROGEN mg/dl | | SODIUM mEq/l | | POTASSIUM mEq/l | | CHLORIDE mEq/l | | CALCIUM mg/dl | | INORGANIC PHOSPHORUS mg/dl | |
|------------|-------------------|------------------------|------|-----------------|---|--------------------|-----|-------------------|---|------------------|------|-------------------------------|-----|
| 0ppm | 29 | 23.8± | 15.1 | 153± | 3 | 4.1± | 0.6 | 123± | 5 | 8.9± | 0.6 | 6.8± | 1.1 |
| 3ppm | 24 | 19.6± | 10.8 | 152± | 3 | 4.2± | 0.4 | 122± | 4 | 9.2± | 0.7* | 6.5± | 1.2 |
| 6ppm | 28 | 23.3± | 22.8 | 152± | 2 | 4.1± | 0.8 | 123± | 3 | 8.9± | 0.4 | 6.9± | 1.9 |
| 12ppm | 34 | 22.6± | 14.3 | 153± | 2 | 4.1± | 0.5 | 124± | 2 | 8.7± | 0.3 | 6.8± | 1.1 |

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

Test of Dunnett

(HCL074)

BAIS 3

APPENDIX F 1

URINALYSIS: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 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+ |
| 0ppm | 33 | 0 | 2 | 8 | 9 | 10 | 3 | 1 | | 0 | 4 | 27 | 2 | 0 | 0 | | 33 | 0 | 0 | 0 | 0 | 0 | | 22 | 10 | 1 | 0 | 0 | 0 | | 33 | 0 | 0 | 0 | 0 |
| 3ppm | 30 | 0 | 1 | 10 | 8 | 8 | 2 | 1 | | 0 | 3 | 23 | 4 | 0 | 0 | | 30 | 0 | 0 | 0 | 0 | 0 | | 19 | 7 | 4 | 0 | 0 | 0 | | 28 | 0 | 0 | 1 | 1 |
| 6ppm | 38 | 0 | 2 | 7 | 11 | 13 | 5 | 0 | | 0 | 2 | 34 | 2 | 0 | 0 | | 38 | 0 | 0 | 0 | 0 | 0 | | 21 | 14 | 3 | 0 | 0 | 0 | | 35 | 1 | 0 | 1 | 1 |
| 12ppm | 43 | 0 | 4 | 5 | 4 | 23 | 6 | 1 | | 0 | 1 | 37 | 5 | 0 | 0 | | 43 | 0 | 0 | 0 | 0 | 0 | | 13 | 17 | 13 | 0 | 0 | 0 | ** | 39 | 0 | 3 | 0 | 1 |

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

Test of CHI SQUARE

(HCL101)

BAIS 3

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

| Group Name | NO. of Animals | Urobilinogen | | | | | CHI |
|------------|-------------------|--------------|---|----|----|----|-----|
| | | ± | + | 2+ | 3+ | 4+ | |
| 0ppm | 33 | 33 | 0 | 0 | 0 | 0 | 0 |
| 3ppm | 30 | 30 | 0 | 0 | 0 | 0 | 0 |
| 6ppm | 38 | 38 | 0 | 0 | 0 | 0 | 0 |
| 12ppm | 43 | 43 | 0 | 0 | 0 | 0 | 0 |

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

Test of CHI SQUARE

(HCL101)

BAIS 3

APPENDIX F 2

URINALYSIS: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 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+ | 4+ | | |
| 0ppm | 30 | 0 | 2 | 0 | 5 | 8 | 14 | 1 | | 0 | 1 | 16 | 11 | 2 | 0 | | 30 | 0 | 0 | 0 | 0 | 0 | | 7 | 22 | 0 | 1 | 0 | 0 | | 20 | 4 | 3 | 0 | 3 | | | |
| 3ppm | 24 | 0 | 0 | 3 | 2 | 13 | 6 | 0 | * | 0 | 5 | 12 | 5 | 1 | 1 | | 24 | 0 | 0 | 0 | 0 | 0 | | 7 | 15 | 1 | 1 | 0 | 0 | | 23 | 0 | 0 | 1 | 0 | * | | |
| 6ppm | 31 | 0 | 1 | 2 | 4 | 12 | 10 | 2 | | 0 | 10 | 12 | 9 | 0 | 0 | * | 31 | 0 | 0 | 0 | 0 | 0 | | 14 | 12 | 4 | 0 | 1 | 0 | * | 26 | 0 | 2 | 0 | 3 | | | |
| 12ppm | 34 | 0 | 1 | 0 | 5 | 15 | 12 | 1 | | 0 | 5 | 19 | 9 | 1 | 0 | | 34 | 0 | 0 | 0 | 0 | 0 | | 5 | 27 | 2 | 0 | 0 | 0 | | 29 | 2 | 0 | 0 | 3 | | | |

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

Test of CHI SQUARE

(HCL101)

BAIS 3

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 4

| Group Name | NO. of Animals | Urobilinogen | | | | | CHI |
|------------|-------------------|--------------|---|----|----|----|-----|
| | | ± | + | 2+ | 3+ | 4+ | |
| 0ppm | 30 | 30 | 0 | 0 | 0 | 0 | 0 |
| 3ppm | 24 | 24 | 0 | 0 | 0 | 0 | 0 |
| 6ppm | 31 | 31 | 0 | 0 | 0 | 0 | 0 |
| 12ppm | 34 | 34 | 0 | 0 | 0 | 0 | 0 |

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

Test of CHI SQUARE

(HCL101)

BAIS 3

APPENDIX G 1

GROSS FINDINGS: SUMMARY, MOUSE: MALE: ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 1

| Organ | Findings | Group Name NO. of Animals | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|-------------|------------|------------------------------|------|-------|------|-------|------|-------|-------|-------|
| | | | 50 | (%) | 50 | (%) | 50 | (%) | 49 | (%) |
| skin/app | erosion | | 0 | (0) | 1 | (2) | 2 | (4) | 1 | (2) |
| subcutis | edema | | 0 | (0) | 0 | (0) | 2 | (4) | 0 | (0) |
| | mass | | 1 | (2) | 2 | (4) | 1 | (2) | 1 | (2) |
| lung | red zone | | 0 | (0) | 0 | (0) | 1 | (2) | 1 | (2) |
| | nodule | | 12 | (24) | 10 | (20) | 10 | (20) | 2 | (4) |
| lymph node | enlarged | | 9 | (18) | 5 | (10) | 8 | (16) | 2 | (4) |
| spleen | enlarged | | 6 | (12) | 3 | (6) | 5 | (10) | 0 | (0) |
| | white zone | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| | black zone | | 0 | (0) | 1 | (2) | 1 | (2) | 3 | (6) |
| | hemorrhage | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| | nodule | | 1 | (2) | 1 | (2) | 0 | (0) | 2 | (4) |
| | deformed | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| | nodular | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| salivary gl | enlarged | | 1 | (2) | 0 | (0) | 0 | (0) | 0 | (0) |
| | nodule | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| small intes | nodule | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (2) |
| | fluid | | 1 | (2) | 0 | (0) | 0 | (0) | 0 | (0) |
| liver | enlarged | | 1 | (2) | 0 | (0) | 0 | (0) | 0 | (0) |
| | pale | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| | white zone | | 0 | (0) | 3 | (6) | 2 | (4) | 1 | (2) |
| | red zone | | 2 | (4) | 1 | (2) | 3 | (6) | 0 | (0) |
| | nodule | | 18 | (36) | 17 | (34) | 13 | (26) | 7 | (14) |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 2

| Organ | Findings | Group Name NO. of Animals | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|-------------|------------------------|------------------------------|------|-------|------|-------|------|-------|-------|-------|
| | | | 50 | (%) | 50 | (%) | 50 | (%) | 49 | (%) |
| liver | deformed | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| | adhesion | | 1 | (2) | 0 | (0) | 0 | (0) | 0 | (0) |
| kidney | enlarged | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| | white zone | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| | nodule | | 2 | (4) | 2 | (4) | 1 | (2) | 0 | (0) |
| | cyst | | 0 | (0) | 1 | (2) | 1 | (2) | 0 | (0) |
| | adhesion | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| | hydronephrosis | | 10 | (20) | 10 | (20) | 2 | (4) | 8 | (16) |
| urin bladd | nodule | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| | dilated | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| | urine:marked retention | | 0 | (0) | 2 | (4) | 2 | (4) | 1 | (2) |
| testis | enlarged | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| | absence | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (2) |
| epididymis | enlarged | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| | red zone | | 1 | (2) | 0 | (0) | 0 | (0) | 0 | (0) |
| | nodule | | 1 | (2) | 1 | (2) | 2 | (4) | 1 | (2) |
| prep/cli gl | nodule | | 2 | (4) | 0 | (0) | 0 | (0) | 0 | (0) |
| | cyst | | 3 | (6) | 2 | (4) | 5 | (10) | 0 | (0) |
| brain | red zone | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (2) |
| | hemorrhage | | 1 | (2) | 0 | (0) | 0 | (0) | 0 | (0) |
| periph nerv | nodule | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| Harder gl | enlarged | | 0 | (0) | 1 | (2) | 1 | (2) | 1 | (2) |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 3

| Organ | Findings | Group Name NO. of Animals | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|-------------|------------------|------------------------------|------|------|------|------|------|-------|-------|------|
| | | | 50 | (%) | 50 | (%) | 50 | (%) | 49 | (%) |
| Harder gl | nodule | | 1 | (2) | 1 | (2) | 1 | (2) | 0 | (0) |
| bone | nodule | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (2) |
| | thick | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| abdominal c | ascites | | 3 | (6) | 4 | (8) | 3 | (6) | 2 | (4) |
| mesenterium | nodule | | 1 | (2) | 1 | (2) | 0 | (0) | 0 | (0) |
| thoracic ca | pleural fluid | | 4 | (8) | 3 | (6) | 5 | (10) | 0 | (0) |
| other | lower jaw:nodule | | 1 | (2) | 0 | (0) | 0 | (0) | 0 | (0) |

(HPT080)

BAIS 3

APPENDIX G2

GROSS FINDINGS: SUMMARY, MOUSE: MALE: DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

| Organ | Findings | Group Name NO. of Animals | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|-------------|------------|------------------------------|------|-------|------|-------|------|-------|-------|-------|
| | | | 17 | (%) | 20 | (%) | 12 | (%) | 6 | (%) |
| skin/app | erosion | | 0 | (0) | 0 | (0) | 1 | (8) | 0 | (0) |
| subcutis | edema | | 0 | (0) | 0 | (0) | 2 | (17) | 0 | (0) |
| | mass | | 0 | (0) | 0 | (0) | 1 | (8) | 0 | (0) |
| lung | red zone | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (17) |
| | nodule | | 1 | (6) | 3 | (15) | 1 | (8) | 0 | (0) |
| lymph node | enlarged | | 6 | (35) | 2 | (10) | 3 | (25) | 0 | (0) |
| spleen | enlarged | | 4 | (24) | 1 | (5) | 4 | (33) | 0 | (0) |
| | white zone | | 0 | (0) | 1 | (5) | 0 | (0) | 0 | (0) |
| | hemorrhage | | 0 | (0) | 0 | (0) | 1 | (8) | 0 | (0) |
| | nodule | | 1 | (6) | 1 | (5) | 0 | (0) | 0 | (0) |
| | nodular | | 0 | (0) | 0 | (0) | 1 | (8) | 0 | (0) |
| salivary gl | enlarged | | 1 | (6) | 0 | (0) | 0 | (0) | 0 | (0) |
| | nodule | | 0 | (0) | 0 | (0) | 1 | (8) | 0 | (0) |
| small intes | fluid | | 1 | (6) | 0 | (0) | 0 | (0) | 0 | (0) |
| liver | enlarged | | 1 | (6) | 0 | (0) | 0 | (0) | 0 | (0) |
| | pale | | 0 | (0) | 0 | (0) | 1 | (8) | 0 | (0) |
| | white zone | | 0 | (0) | 1 | (5) | 0 | (0) | 0 | (0) |
| | red zone | | 1 | (6) | 0 | (0) | 0 | (0) | 0 | (0) |
| | nodule | | 4 | (24) | 5 | (25) | 1 | (8) | 0 | (0) |
| | deformed | | 0 | (0) | 1 | (5) | 0 | (0) | 0 | (0) |
| | adhesion | | 1 | (6) | 0 | (0) | 0 | (0) | 0 | (0) |
| kidney | enlarged | | 0 | (0) | 1 | (5) | 0 | (0) | 0 | (0) |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

| Organ | Findings | Group Name NO. of Animals | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|-------------|------------------------|------------------------------|------|-------|------|-------|------|-------|-------|-------|
| | | | 17 | (%) | 20 | (%) | 12 | (%) | 6 | (%) |
| kidney | white zone | | 0 | (0) | 1 | (5) | 0 | (0) | 0 | (0) |
| | nodule | | 0 | (0) | 2 | (10) | 1 | (8) | 0 | (0) |
| | cyst | | 0 | (0) | 1 | (5) | 1 | (8) | 0 | (0) |
| | adhesion | | 0 | (0) | 1 | (5) | 0 | (0) | 0 | (0) |
| | hydronephrosis | | 6 | (35) | 8 | (40) | 1 | (8) | 4 | (67) |
| urin bladd | nodule | | 0 | (0) | 1 | (5) | 0 | (0) | 0 | (0) |
| | dilated | | 0 | (0) | 1 | (5) | 0 | (0) | 0 | (0) |
| | urine:marked retention | | 0 | (0) | 2 | (10) | 2 | (17) | 1 | (17) |
| epididymis | red zone | | 1 | (6) | 0 | (0) | 0 | (0) | 0 | (0) |
| prep/cli gl | nodule | | 2 | (12) | 0 | (0) | 0 | (0) | 0 | (0) |
| brain | red zone | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (17) |
| | hemorrhage | | 1 | (6) | 0 | (0) | 0 | (0) | 0 | (0) |
| periph nerv | nodule | | 0 | (0) | 1 | (5) | 0 | (0) | 0 | (0) |
| Harder gl | enlarged | | 0 | (0) | 1 | (5) | 0 | (0) | 0 | (0) |
| bone | nodule | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (17) |
| abdominal c | ascites | | 3 | (18) | 4 | (20) | 3 | (25) | 2 | (33) |
| thoracic ca | pleural fluid | | 4 | (24) | 2 | (10) | 4 | (33) | 0 | (0) |
| other | lower jaw:nodule | | 1 | (6) | 0 | (0) | 0 | (0) | 0 | (0) |

APPENDIX G 3

GROSS FINDINGS: SUMMARY, MOUSE : MALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 1

| Organ | Findings | Group Name NO. of Animals | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|-------------|----------------|------------------------------|------|-------|------|-------|------|-------|-------|-------|
| | | | 33 | (%) | 30 | (%) | 38 | (%) | 43 | (%) |
| skin/app | erosion | | 0 | (0) | 1 | (3) | 1 | (3) | 1 | (2) |
| subcutis | mass | | 1 | (3) | 2 | (7) | 0 | (0) | 1 | (2) |
| lung | red zone | | 0 | (0) | 0 | (0) | 1 | (3) | 0 | (0) |
| | nodule | | 11 | (33) | 7 | (23) | 9 | (24) | 2 | (5) |
| lymph node | enlarged | | 3 | (9) | 3 | (10) | 5 | (13) | 2 | (5) |
| spleen | enlarged | | 2 | (6) | 2 | (7) | 1 | (3) | 0 | (0) |
| | black zone | | 0 | (0) | 1 | (3) | 1 | (3) | 3 | (7) |
| | nodule | | 0 | (0) | 0 | (0) | 0 | (0) | 2 | (5) |
| | deformed | | 0 | (0) | 1 | (3) | 0 | (0) | 0 | (0) |
| small intes | nodule | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (2) |
| liver | white zone | | 0 | (0) | 2 | (7) | 2 | (5) | 1 | (2) |
| | red zone | | 1 | (3) | 1 | (3) | 3 | (8) | 0 | (0) |
| | nodule | | 14 | (42) | 12 | (40) | 12 | (32) | 7 | (16) |
| kidney | nodule | | 2 | (6) | 0 | (0) | 0 | (0) | 0 | (0) |
| | hydronephrosis | | 4 | (12) | 2 | (7) | 1 | (3) | 4 | (9) |
| testis | enlarged | | 0 | (0) | 1 | (3) | 0 | (0) | 0 | (0) |
| | absence | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (2) |
| epididymis | enlarged | | 0 | (0) | 1 | (3) | 0 | (0) | 0 | (0) |
| | nodule | | 1 | (3) | 1 | (3) | 2 | (5) | 1 | (2) |
| prep/cli gl | cyst | | 3 | (9) | 2 | (7) | 5 | (13) | 0 | (0) |
| Harder gl | enlarged | | 0 | (0) | 0 | (0) | 1 | (3) | 1 | (2) |
| | nodule | | 1 | (3) | 1 | (3) | 1 | (3) | 0 | (0) |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 2

| Organ | Findings | Group Name NO. of Animals | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|-------------|---------------|------------------------------|------|------|------|------|------|------|-------|------|
| | | | 33 | (%) | 30 | (%) | 38 | (%) | 43 | (%) |
| bone | thick | | 0 | (0) | 1 | (3) | 0 | (0) | 0 | (0) |
| mesenterium | nodule | | 1 | (3) | 1 | (3) | 0 | (0) | 0 | (0) |
| thoracic ca | pleural fluid | | 0 | (0) | 1 | (3) | 1 | (3) | 0 | (0) |

(HPT080)

BAIS 3

APPENDIX G 4

GROSS FINDINGS: SUMMARY, MOUSE: FEMALE: ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 4

| Organ | Findings | Group Name NO. of Animals | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|-------------|----------------------------|------------------------------|------|-------|------|-------|------|-------|-------|-------|
| | | | 50 | (%) | 50 | (%) | 50 | (%) | 50 | (%) |
| skin/app | nodule | | 1 | (2) | 1 | (2) | 1 | (2) | 0 | (0) |
| subcutis | red zone | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| | edema | | 4 | (8) | 6 | (12) | 4 | (8) | 3 | (6) |
| | mass | | 4 | (8) | 1 | (2) | 0 | (0) | 3 | (6) |
| | | | | | | | | | | |
| lung | red | | 0 | (0) | 1 | (2) | 1 | (2) | 0 | (0) |
| | red zone | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| | edema | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (2) |
| | nodule | | 4 | (8) | 3 | (6) | 6 | (12) | 3 | (6) |
| lymph node | enlarged | | 10 | (20) | 12 | (24) | 14 | (28) | 3 | (6) |
| spleen | enlarged | | 12 | (24) | 11 | (22) | 13 | (26) | 5 | (10) |
| | black zone | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| | nodule | | 2 | (4) | 0 | (0) | 0 | (0) | 0 | (0) |
| | accentuation of white pulp | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| heart | hypertrophy | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (2) |
| | adhesion | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| | thick | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| gl stomach | thick | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| stomach | nodule | | 1 | (2) | 0 | (0) | 0 | (0) | 0 | (0) |
| small intes | nodule | | 1 | (2) | 1 | (2) | 0 | (0) | 1 | (2) |
| cecum | cyst | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (2) |
| anus | thick | | 1 | (2) | 0 | (0) | 0 | (0) | 0 | (0) |
| liver | enlarged | | 2 | (4) | 5 | (10) | 0 | (0) | 2 | (4) |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 5

| Organ | Findings | Group Name NO. of Animals | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|------------|------------------------|------------------------------|------|-------|------|-------|------|-------|-------|-------|
| | | | 50 | (%) | 50 | (%) | 50 | (%) | 50 | (%) |
| liver | white zone | | 6 | (12) | 4 | (8) | 2 | (4) | 4 | (8) |
| | red zone | | 2 | (4) | 4 | (8) | 6 | (12) | 4 | (8) |
| | nodule | | 7 | (14) | 6 | (12) | 5 | (10) | 2 | (4) |
| | pleural fluid | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| gall bladd | cyst | | 1 | (2) | 0 | (0) | 0 | (0) | 0 | (0) |
| | dilated | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| kidney | enlarged | | 2 | (4) | 0 | (0) | 0 | (0) | 0 | (0) |
| | pale | | 0 | (0) | 2 | (4) | 0 | (0) | 0 | (0) |
| | hydronephrosis | | 1 | (2) | 4 | (8) | 1 | (2) | 5 | (10) |
| urin bladd | red zone | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (2) |
| | urine:marked retention | | 1 | (2) | 0 | (0) | 0 | (0) | 1 | (2) |
| pituitary | enlarged | | 1 | (2) | 6 | (12) | 1 | (2) | 2 | (4) |
| | red zone | | 1 | (2) | 2 | (4) | 0 | (0) | 0 | (0) |
| | nodule | | 0 | (0) | 1 | (2) | 1 | (2) | 1 | (2) |
| adrenal | enlarged | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (2) |
| ovary | enlarged | | 4 | (8) | 5 | (10) | 2 | (4) | 3 | (6) |
| | nodule | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| | cyst | | 14 | (28) | 9 | (18) | 17 | (34) | 21 | (42) |
| uterus | enlarged | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| | nodule | | 13 | (26) | 10 | (20) | 6 | (12) | 12 | (24) |
| | cyst | | 0 | (0) | 2 | (4) | 0 | (0) | 0 | (0) |
| vagina | nodule | | 1 | (2) | 0 | (0) | 0 | (0) | 0 | (0) |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 6

| Organ | Findings | Group Name NO. of Animals | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|-------------|---------------|------------------------------|------|-------|------|-------|------|-------|-------|-------|
| | | | 50 | (%) | 50 | (%) | 50 | (%) | 50 | (%) |
| brain | red zone | | 1 | (2) | 1 | (2) | 0 | (0) | 0 | (0) |
| | hemorrhage | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| spinal cord | yellow zone | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| Harder gl | enlarged | | 0 | (0) | 2 | (4) | 0 | (0) | 0 | (0) |
| | nodule | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (2) |
| mediastinum | yellow | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (2) |
| | mass | | 1 | (2) | 2 | (4) | 2 | (4) | 0 | (0) |
| peritoneum | hemorrhage | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| | nodule | | 1 | (2) | 0 | (0) | 0 | (0) | 0 | (0) |
| | mass | | 1 | (2) | 0 | (0) | 0 | (0) | 0 | (0) |
| | adhesion | | 0 | (0) | 0 | (0) | 1 | (2) | 0 | (0) |
| | thick | | 0 | (0) | 1 | (2) | 0 | (0) | 1 | (2) |
| retroperit | nodule | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (2) |
| | mass | | 1 | (2) | 0 | (0) | 0 | (0) | 0 | (0) |
| abdominal c | hemorrhage | | 0 | (0) | 2 | (4) | 1 | (2) | 0 | (0) |
| | ascites | | 10 | (20) | 10 | (20) | 10 | (20) | 4 | (8) |
| mesenterium | nodule | | 0 | (0) | 1 | (2) | 0 | (0) | 0 | (0) |
| thoracic ca | cyst | | 1 | (2) | 0 | (0) | 0 | (0) | 0 | (0) |
| | pleural fluid | | 7 | (14) | 15 | (30) | 10 | (20) | 5 | (10) |
| other | ear:nodule | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (2) |

APPENDIX G 5

GROSS FINDINGS: SUMMARY, MOUSE: FEMALE: DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 3

| Organ | Findings | Group Name NO. of Animals | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|------------|-------------|------------------------------|------|-------|------|-------|------|-------|-------|-------|
| | | | 20 | (%) | 25 | (%) | 20 | (%) | 16 | (%) |
| subcutis | red zone | | 0 | (0) | 1 | (4) | 0 | (0) | 0 | (0) |
| | edema | | 3 | (15) | 6 | (24) | 4 | (20) | 3 | (19) |
| | mass | | 1 | (5) | 1 | (4) | 0 | (0) | 2 | (13) |
| lung | red | | 0 | (0) | 1 | (4) | 1 | (5) | 0 | (0) |
| | red zone | | 0 | (0) | 1 | (4) | 0 | (0) | 0 | (0) |
| | edema | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (6) |
| | nodule | | 0 | (0) | 1 | (4) | 2 | (10) | 0 | (0) |
| lymph node | enlarged | | 5 | (25) | 7 | (28) | 10 | (50) | 2 | (13) |
| spleen | enlarged | | 6 | (30) | 9 | (36) | 6 | (30) | 2 | (13) |
| | black zone | | 0 | (0) | 0 | (0) | 1 | (5) | 0 | (0) |
| | nodule | | 2 | (10) | 0 | (0) | 0 | (0) | 0 | (0) |
| heart | hypertrophy | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (6) |
| | adhesion | | 0 | (0) | 1 | (4) | 0 | (0) | 0 | (0) |
| | thick | | 0 | (0) | 0 | (0) | 1 | (5) | 0 | (0) |
| gl stomach | thick | | 0 | (0) | 0 | (0) | 1 | (5) | 0 | (0) |
| stomach | nodule | | 1 | (5) | 0 | (0) | 0 | (0) | 0 | (0) |
| cecum | cyst | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (6) |
| liver | enlarged | | 1 | (5) | 5 | (20) | 0 | (0) | 2 | (13) |
| | white zone | | 4 | (20) | 4 | (16) | 2 | (10) | 3 | (19) |
| | red zone | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (6) |
| | nodule | | 2 | (10) | 3 | (12) | 3 | (15) | 2 | (13) |
| gall bladd | cyst | | 1 | (5) | 0 | (0) | 0 | (0) | 0 | (0) |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 4

| Organ | Findings | Group Name NO. of Animals | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|-------------|------------------------|------------------------------|------|-------|------|-------|------|-------|-------|-------|
| | | | 20 | (%) | 25 | (%) | 20 | (%) | 16 | (%) |
| gall bladd | dilated | | 0 | (0) | 0 | (0) | 1 | (5) | 0 | (0) |
| kidney | enlarged | | 2 | (10) | 0 | (0) | 0 | (0) | 0 | (0) |
| | pale | | 0 | (0) | 2 | (8) | 0 | (0) | 0 | (0) |
| | hydronephrosis | | 0 | (0) | 2 | (8) | 1 | (5) | 3 | (19) |
| urin bladd | red zone | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (6) |
| | urine:marked retention | | 1 | (5) | 0 | (0) | 0 | (0) | 0 | (0) |
| pituitary | enlarged | | 1 | (5) | 2 | (8) | 0 | (0) | 2 | (13) |
| | red zone | | 1 | (5) | 0 | (0) | 0 | (0) | 0 | (0) |
| | nodule | | 0 | (0) | 1 | (4) | 0 | (0) | 0 | (0) |
| ovary | enlarged | | 2 | (10) | 4 | (16) | 1 | (5) | 2 | (13) |
| | cyst | | 2 | (10) | 1 | (4) | 3 | (15) | 0 | (0) |
| uterus | enlarged | | 0 | (0) | 0 | (0) | 1 | (5) | 0 | (0) |
| | nodule | | 9 | (45) | 7 | (28) | 3 | (15) | 7 | (44) |
| | cyst | | 0 | (0) | 1 | (4) | 0 | (0) | 0 | (0) |
| vagina | nodule | | 1 | (5) | 0 | (0) | 0 | (0) | 0 | (0) |
| brain | red zone | | 1 | (5) | 1 | (4) | 0 | (0) | 0 | (0) |
| | hemorrhage | | 0 | (0) | 0 | (0) | 1 | (5) | 0 | (0) |
| spinal cord | yellow zone | | 0 | (0) | 0 | (0) | 1 | (5) | 0 | (0) |
| Harder gl | enlarged | | 0 | (0) | 2 | (8) | 0 | (0) | 0 | (0) |
| | nodule | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (6) |
| mediastinum | yellow | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (6) |
| | mass | | 0 | (0) | 2 | (8) | 2 | (10) | 0 | (0) |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 5

| Organ | Findings | Group Name NO. of Animals | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|-------------|---------------|------------------------------|------|-------|------|-------|------|-------|-------|-------|
| | | | 20 | (%) | 25 | (%) | 20 | (%) | 16 | (%) |
| peritoneum | hemorrhage | | 0 | (0) | 0 | (0) | 1 | (5) | 0 | (0) |
| | nodule | | 1 | (5) | 0 | (0) | 0 | (0) | 0 | (0) |
| | mass | | 1 | (5) | 0 | (0) | 0 | (0) | 0 | (0) |
| | thick | | 0 | (0) | 1 | (4) | 0 | (0) | 1 | (6) |
| retroperit | nodule | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (6) |
| abdominal c | hemorrhage | | 0 | (0) | 2 | (8) | 1 | (5) | 0 | (0) |
| | ascites | | 5 | (25) | 7 | (28) | 6 | (30) | 4 | (25) |
| mesenterium | nodule | | 0 | (0) | 1 | (4) | 0 | (0) | 0 | (0) |
| thoracic ca | pleural fluid | | 3 | (15) | 14 | (56) | 6 | (30) | 5 | (31) |

(HPT080)

BAIS 3

APPENDIX G 6

GROSS FINDINGS: SUMMARY, MOUSE : FEMALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 3

| Organ | Findings | Group Name NO. of Animals | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|-------------|----------------------------|------------------------------|------|-------|------|-------|------|-------|-------|------|
| | | | 30 | (%) | 25 | (%) | 30 | (%) | 34 | (%) |
| skin/app | nodule | | 1 | (3) | 1 | (4) | 1 | (3) | 0 | (0) |
| subcutis | edema | | 1 | (3) | 0 | (0) | 0 | (0) | 0 | (0) |
| | mass | | 3 | (10) | 0 | (0) | 0 | (0) | 1 | (3) |
| lung | nodule | | 4 | (13) | 2 | (8) | 4 | (13) | 3 | (9) |
| lymph node | enlarged | | 5 | (17) | 5 | (20) | 4 | (13) | 1 | (3) |
| spleen | enlarged | | 6 | (20) | 2 | (8) | 7 | (23) | 3 | (9) |
| | accentuation of white pulp | | 0 | (0) | 0 | (0) | 1 | (3) | 0 | (0) |
| small intes | nodule | | 1 | (3) | 1 | (4) | 0 | (0) | 1 | (3) |
| anus | thick | | 1 | (3) | 0 | (0) | 0 | (0) | 0 | (0) |
| liver | enlarged | | 1 | (3) | 0 | (0) | 0 | (0) | 0 | (0) |
| | white zone | | 2 | (7) | 0 | (0) | 0 | (0) | 1 | (3) |
| | red zone | | 2 | (7) | 4 | (16) | 6 | (20) | 3 | (9) |
| | nodule | | 5 | (17) | 3 | (12) | 2 | (7) | 0 | (0) |
| | pleural fluid | | 0 | (0) | 0 | (0) | 1 | (3) | 0 | (0) |
| kidney | hydronephrosis | | 1 | (3) | 2 | (8) | 0 | (0) | 2 | (6) |
| urin bladd | urine:marked retention | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (3) |
| pituitary | enlarged | | 0 | (0) | 4 | (16) | 1 | (3) | 0 | (0) |
| | red zone | | 0 | (0) | 2 | (8) | 0 | (0) | 0 | (0) |
| | nodule | | 0 | (0) | 0 | (0) | 1 | (3) | 1 | (3) |
| adrenal | enlarged | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (3) |
| ovary | enlarged | | 2 | (7) | 1 | (4) | 1 | (3) | 1 | (3) |
| | nodule | | 0 | (0) | 0 | (0) | 1 | (3) | 0 | (0) |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 4

| Organ | Findings | Group Name NO. of Animals | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|-------------|---------------|------------------------------|------|-------|------|-------|------|-------|-------|-------|
| | | | 30 | (%) | 25 | (%) | 30 | (%) | 34 | (%) |
| ovary | cyst | | 12 | (40) | 8 | (32) | 14 | (47) | 21 | (62) |
| uterus | nodule | | 4 | (13) | 3 | (12) | 3 | (10) | 5 | (15) |
| | cyst | | 0 | (0) | 1 | (4) | 0 | (0) | 0 | (0) |
| mediastinum | mass | | 1 | (3) | 0 | (0) | 0 | (0) | 0 | (0) |
| peritoneum | adhesion | | 0 | (0) | 0 | (0) | 1 | (3) | 0 | (0) |
| retroperit | mass | | 1 | (3) | 0 | (0) | 0 | (0) | 0 | (0) |
| abdominal c | ascites | | 5 | (17) | 3 | (12) | 4 | (13) | 0 | (0) |
| thoracic ca | cyst | | 1 | (3) | 0 | (0) | 0 | (0) | 0 | (0) |
| | pleural fluid | | 4 | (13) | 1 | (4) | 4 | (13) | 0 | (0) |
| other | ear:nodule | | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (3) |

(HPT080)

BAIS 3

APPENDIX H 1

ORGAN WEIGHT , ABSOLUTE: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

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

PAGE : 1

| Group Name | NO. of Animals | Body Weight | ADRENALS | TESTES | HEART | LUNGS | KIDNEYS |
|------------|-------------------|-------------|----------------|----------------|----------------|---------------|----------------|
| 0ppm | 33 | 45.1± 5.9 | 0.016± 0.005 | 0.207± 0.032 | 0.242± 0.031 | 0.249± 0.083 | 1.250± 1.846 |
| 3ppm | 30 | 44.7± 7.3 | 0.016± 0.004 | 0.231± 0.110 | 0.240± 0.034 | 0.269± 0.144 | 0.673± 0.042 |
| 6ppm | 38 | 40.6± 6.1 | 0.015± 0.004 | 0.202± 0.036 | 0.232± 0.024 | 0.277± 0.194 | 0.734± 0.508 |
| 12ppm | 43 | 29.7± 2.9** | 0.013± 0.003** | 0.174± 0.042** | 0.191± 0.022** | 0.210± 0.021* | 0.971± 1.467** |

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

Test of Dunnett

(HCL040)

BAIS 3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

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

PAGE : 2

| Group Name | NO. of Animals | SPLEEN | | LIVER | | BRAIN | |
|------------|-------------------|--------|---------|--------|---------|--------|--------|
| 0ppm | 33 | 0.106± | 0.131 | 1.750± | 0.447 | 0.464± | 0.017 |
| 3ppm | 30 | 0.136± | 0.155 | 1.910± | 0.717 | 0.457± | 0.018 |
| 6ppm | 38 | 0.086± | 0.071 | 1.616± | 0.415 | 0.463± | 0.015 |
| 12ppm | 43 | 0.059± | 0.049** | 1.215± | 0.202** | 0.454± | 0.016* |

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

Test of Dunnett

(HCL040)

BAIS 3

APPENDIX H2

ORGAN WEIGHT , ABSOLUTE: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

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

PAGE : 3

| Group Name | NO. of Animals | Body Weight | ADRENALS | OVARIES | HEART | LUNGS | KIDNEYS |
|------------|-------------------|-------------|--------------|--------------|----------------|--------------|----------------|
| 0ppm | 30 | 30.4± 6.7 | 0.016± 0.004 | 0.052± 0.031 | 0.197± 0.045 | 0.234± 0.045 | 0.495± 0.095 |
| 3ppm | 25 | 31.0± 4.9 | 0.019± 0.006 | 0.177± 0.599 | 0.201± 0.027 | 0.234± 0.039 | 0.622± 0.567 |
| 6ppm | 30 | 30.5± 4.7 | 0.016± 0.003 | 0.085± 0.109 | 0.184± 0.026 | 0.247± 0.053 | 0.466± 0.042 |
| 12ppm | 34 | 24.1± 2.1** | 0.022± 0.044 | 0.157± 0.380 | 0.152± 0.018** | 0.217± 0.058 | 0.509± 0.486** |

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

Test of Dunnett

(HCL040)

BAIS 3

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

PAGE : 4

| Group Name | NO. of Animals | SPLEEN | | LIVER | | BRAIN | |
|------------|-------------------|--------|---------|--------|---------|--------|-------|
| 0ppm | 30 | 0.231± | 0.248 | 1.834± | 1.063 | 0.478± | 0.016 |
| 3ppm | 25 | 0.148± | 0.146 | 1.621± | 0.444 | 0.482± | 0.018 |
| 6ppm | 30 | 0.389± | 0.583 | 1.664± | 0.456 | 0.485± | 0.021 |
| 12ppm | 34 | 0.160± | 0.393** | 1.214± | 0.296** | 0.469± | 0.016 |

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

Test of Dunnett

(HCL040)

BAIS 3

APPENDIX I 1

ORGAN WEIGHT, RELATIVE: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE : 1

| Group Name | NO. of Animals | Body Weight (g) | ADRENALS | TESTES | HEART | LUNGS | KIDNEYS |
|------------|-------------------|--------------------|----------------|----------------|----------------|----------------|----------------|
| 0ppm | 33 | 45.1± 5.9 | 0.036± 0.013 | 0.464± 0.076 | 0.541± 0.073 | 0.555± 0.171 | 2.909± 4.508 |
| 3ppm | 30 | 44.7± 7.3 | 0.036± 0.009 | 0.531± 0.278 | 0.551± 0.124 | 0.612± 0.323 | 1.550± 0.291 |
| 6ppm | 38 | 40.6± 6.1 | 0.037± 0.011 | 0.507± 0.116 | 0.585± 0.109 | 0.722± 0.640 | 1.871± 1.476 |
| 12ppm | 43 | 29.7± 2.9** | 0.044± 0.010** | 0.587± 0.141** | 0.646± 0.101** | 0.711± 0.087** | 3.228± 4.735** |

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

Test of Dunnett

(HCL042)

BAIS 3

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE : 2

| Group Name | NO. of Animals | SPLEEN | LIVER | BRAIN |
|------------|-------------------|--------------|----------------|----------------|
| 0ppm | 33 | 0.238± 0.293 | 3.928± 1.098 | 1.046± 0.143 |
| 3ppm | 30 | 0.329± 0.404 | 4.469± 2.208 | 1.051± 0.184 |
| 6ppm | 38 | 0.218± 0.171 | 4.073± 1.230 | 1.169± 0.195** |
| 12ppm | 43 | 0.202± 0.168 | 4.115± 0.773** | 1.540± 0.146** |

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

Test of Dunnett

(HCL042)

BAIS 3

APPENDIX 12

ORGAN WEIGHT, RELATIVE: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: %

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

PAGE : 3

| Group Name | NO. of Animals | Body Weight (g) | ADRENALS | OVARIES | HEART | LUNGS | KIDNEYS |
|------------|-------------------|--------------------|--------------|---------------|--------------|---------------|--------------|
| 0ppm | 30 | 30.4± 6.7 | 0.055± 0.015 | 0.172± 0.098 | 0.656± 0.109 | 0.785± 0.137 | 1.665± 0.341 |
| 3ppm | 25 | 31.0± 4.9 | 0.061± 0.014 | 0.516± 1.688 | 0.661± 0.119 | 0.768± 0.159 | 2.045± 1.894 |
| 6ppm | 30 | 30.5± 4.7 | 0.053± 0.009 | 0.280± 0.363 | 0.613± 0.108 | 0.824± 0.196 | 1.555± 0.230 |
| 12ppm | 34 | 24.1± 2.1** | 0.090± 0.185 | 0.600± 1.286* | 0.633± 0.074 | 0.899± 0.203* | 2.105± 1.958 |

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

Test of Dunnett

(HCL042)

BAIS 8

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE : 4

| Group Name | NO. of Animals | SPLEEN | LIVER | BRAIN |
|------------|-------------------|----------------|--------------|----------------|
| 0ppm | 30 | 0.726± 0.628 | 6.067± 3.088 | 1.626± 0.261 |
| 3ppm | 25 | 0.455± 0.349 | 5.221± 1.007 | 1.593± 0.262 |
| 6ppm | 30 | 1.229± 1.733 | 5.505± 1.459 | 1.624± 0.245 |
| 12ppm | 34 | 0.610± 1.299** | 5.010± 0.928 | 1.959± 0.171** |

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

Test of Dunnett

(HCL042)

BAIS 3

APPENDIX J 1

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY,
MOUSE: MALE: ALL ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 1

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------------------|---|---------------------------------------|--------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|--------|--------|--------|-------|--------|--------|--------|-------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 49 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Integumentary system/appandage} | | | | | | | | | | | | | | | | | | | | | |
| skin/app | inflammation | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | | |
| | | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (0) | (2) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | exudate | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | | |
| | | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 2 | 19 | 7 | 0 ** | 0 | 19 | 7 | 0 ** |
| | | (0) | (0) | (4) | (0) | (0) | (0) | (2) | (0) | (0) | (2) | (0) | (0) | (4) | (39) | (14) | (0) | (4) | (39) | (14) | (0) |
| | hyperplasia:gland | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 19 | 0 | 0 | 0 ** | 0 | 19 | 0 | 0 ** |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (39) | (0) | (0) | (0) | (39) | (0) | (0) | (0) |
| | eosinophilic change:olfactory epithelium | 20 | 6 | 0 | 0 | 10 | 4 | 0 | 0 * | 12 | 2 | 0 | 0 * | 16 | 9 | 0 | 0 | 0 | 16 | 9 | 0 |
| | | (40) | (12) | (0) | (0) | (20) | (8) | (0) | (0) | (24) | (4) | (0) | (0) | (33) | (18) | (0) | (0) | (33) | (18) | (0) | (0) |
| | eosinophilic change:respiratory epithelium | 8 | 3 | 0 | 0 | 5 | 0 | 1 | 0 | 1 | 1 | 0 | 0 * | 4 | 2 | 1 | 0 | 0 | 4 | 2 | 1 |
| | | (16) | (6) | (0) | (0) | (10) | (0) | (2) | (0) | (2) | (2) | (0) | (0) | (8) | (4) | (2) | (0) | (8) | (4) | (2) | (0) |
| | inflammation:respiratory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 0 | 5 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (10) | (0) | (0) | (0) |
| | respiratory metaplasia:olfactory epithelium | 18 | 2 | 0 | 0 | 18 | 1 | 0 | 0 | 7 | 1 | 0 | 0 * | 18 | 28 | 1 | 0 ** | 0 | 18 | 28 | 1 |
| | | (36) | (4) | (0) | (0) | (36) | (2) | (0) | (0) | (14) | (2) | (0) | (0) | (37) | (57) | (2) | (0) | (37) | (57) | (2) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 2

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|---|---------------------------------------|-----------|-----------|-----------|------------|------------|-----------|-----------|-------------|-------------|-----------|-----------|-------------|-------------|-----------|-----------|-----------|-----------|-----------|-----------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 49 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | | |
| | respiratory metaplasia:gland | 13 (26) | 4 (8) | 0 (0) | 0 (0) | 8 (16) | 5 (10) | 0 (0) | 0 (0) | 10 (20) | 2 (4) | 0 (0) | 0 (0) | 16 (33) | 25 (51) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | inflammation:transitional epithelium | 1 (2) | 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) | 0 (0) | 0 (0) | 0 (0) |
| | squamous cell metaplasia: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) | 19 (39) | 15 (31) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | cuboidal change:respiratory epithelium | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 6 (12) | 12 (24) | 0 (0) | 0 (0) | 13 (27) | 18 (37) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | atrophy:olfactory 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) | 30 (61) | 12 (24) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | atrophy: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) | 9 (18) | 2 (4) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | necrosis:olfactory 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) | 2 (4) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | edema:lamina propria | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 19 (39) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 3

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|------------------------------------|---------------------------------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|--------------|------------|------------|---------------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 49 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | necrosis: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) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 12 (24) | 4 (8) | 0 (0) | 0 (0) ** |
| | hyperplasia: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) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 3 (6) | 0 (0) | 0 (0) | 0 (0) |
| nasopharynx | eosinophilic 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) | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | | | | | | | | | | | | | | | | | | | | | |
| trachea | eosinophilic change | 0 (0) | 0 (0) | 1 (2) | 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) | 0 (0) |
| | necrosis: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) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| | | | | | | | | | | | | | | | | | | | | | |
| lung | congestion | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 3 (6) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| | hemorrhage | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 3 (6) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 1 (2) | 0 (0) | 0 (0) |
| | | | | | | | | | | | | | | | | | | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 4

| Organ | Findings | Group Name No. of Animals on Study | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|------------------------------|---------------------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 49 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| lung | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | | |
| | edema | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (2) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | thrombus | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | necrosis:focal | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory infiltration | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) |
| | perivascular inflammation | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | fibrosis | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | accumulation of foamy cells | 1 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (2) | (4) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (4) | (0) | (0) | (0) |
| | bronchiolar cell hyperplasia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 5

| | | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------------|---------------------------------------|---------------------------------------|-------|-------|-------|-------|-------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|--|--|--|
| | | 50 | | | | 50 | | | | 50 | | | | 49 | | | | | | | |
| Organ | Findings | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | | | |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | | | |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| lung | | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | |
| | bronchiolar-alveolar cell hyperplasia | | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | | | |
| | | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | | | |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | | | | |
| bone marrow | | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | |
| | myelofibrosis | | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | |
| | | | (4) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | | | |
| | erythropoiesis:increased | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | | | |
| | granulopoiesis:increased | | 1 | 0 | 0 | 0 | 4 | 1 | 0 | 0 | 5 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | |
| | | | (2) | (0) | (0) | (0) | (8) | (2) | (0) | (0) | (10) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | | | |
| lymph node | | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | |
| | lymphadenitis | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | | | |
| thymus | | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | |
| | cyst | | 4 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | | | |
| | | | (8) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 6

| | | Group Name | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------------|------------------------------|-------------------------|-------|------|------|------|-------|-------|------|------|------|------|------|------|-------|------|------|------|
| | | No. of Animals on Study | 50 | | | | 50 | | | | 50 | | | | 49 | | | |
| Organ | Findings | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | |
| spleen | | | <50> | | | | <50> | | | | <50> | | | | <49> | | | |
| | deposit of melanin | | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 4 | 0 | 0 | 0 |
| | | | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (8) | (0) | (0) | (0) |
| | extramedullary hematopoiesis | | 7 | 1 | 2 | 0 | 6 | 5 | 0 | 0 | 4 | 4 | 1 | 0 | 1 | 1 | 0 | 0 |
| | | | (14) | (2) | (4) | (0) | (12) | (10) | (0) | (0) | (8) | (8) | (2) | (0) | (2) | (2) | (0) | (0) |
| | follicular hyperplasia | | 4 | 2 | 0 | 0 | 2 | 1 | 0 | 0 | 3 | 1 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (8) | (4) | (0) | (0) | (4) | (2) | (0) | (0) | (6) | (2) | (0) | (0) | (2) | (0) | (0) | (0) |
| {Circulatory system} | | | | | | | | | | | | | | | | | | |
| heart | | | <50> | | | | <50> | | | | <50> | | | | <49> | | | |
| | thrombus | | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | necrosis:focal | | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) |
| | mineralization | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) |
| | myocardial fibrosis | | 3 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 2 | 2 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (6) | (2) | (0) | (0) | (2) | (2) | (0) | (0) | (4) | (4) | (0) | (0) | (2) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 7

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|---------------------------|---------------------------------------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 49 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Circulatory system} | | | | | | | | | | | | | | | | | | | | | |
| heart | arteritis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | endocardial hyperplasia | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| tooth | dysplasia | 25 | 1 | 0 | 0 | 18 | 0 | 0 | 0 | 20 | 0 | 0 | 0 | 23 | 0 | 0 | 0 | 23 | 0 | 0 | 0 |
| | | (50) | (2) | (0) | (0) | (36) | (0) | (0) | (0) | (40) | (0) | (0) | (0) | (47) | (0) | (0) | (0) | (47) | (0) | (0) | (0) |
| tongue | arteritis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (4) | (0) | (0) |
| salivary gl | lymphocytic infiltration | 14 | 0 | 0 | 0 | 18 | 0 | 0 | 0 | 25 | 0 | 0 | 0 * | 13 | 0 | 0 | 0 | 13 | 0 | 0 | 0 |
| | | (28) | (0) | (0) | (0) | (36) | (0) | (0) | (0) | (50) | (0) | (0) | (0) | (27) | (0) | (0) | (0) | (27) | (0) | (0) | (0) |
| stomach | inflammatory infiltration | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 8

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|-------------------------------|---------------------------------------|--------|--------|-------|--------|--------|--------|-------|--------|--------|--------|-------|--------|--------|-------|-------|--------|--------|-------|-------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 49 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| stomach | | <49> | | | | <50> | | | | <50> | | | | <49> | | | | | | | |
| | erosion:forestomach | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | ulcer:forestomach | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | hyperplasia:forestomach | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 2 | 2 | 0 | 0 |
| | | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (2) | (2) | (0) | (0) |
| | erosion:glandular stomach | 0 | 1 | 0 | 0 | 4 | 1 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (0) | (2) | (0) | (0) | (8) | (2) | (0) | (0) | (4) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (4) | (0) | (0) | (0) |
| | hyperplasia:glandular stomach | 11 | 27 | 7 | 0 | 11 | 27 | 5 | 0 | 19 | 19 | 7 | 0 | 25 | 19 | 1 | 0 * | 51 | 39 | 2 | 0 |
| | | (22) | (55) | (14) | (0) | (22) | (54) | (10) | (0) | (38) | (38) | (14) | (0) | (51) | (39) | (2) | (0) | (51) | (39) | (2) | (0) |
| small intes | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | | |
| | lymphadenitis | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| liver | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | | |
| | angiectasis | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (2) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 9

| Organ | Findings | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|------------------------------|-------|------|------|------|-------|------|------|------|-------|------|------|------|-------|------|------|------|
| | | 50 | | | | 50 | | | | 50 | | | | 49 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | |
| liver | | <50> | | | | <50> | | | | <50> | | | | <49> | | | |
| | necrosis:central | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | necrosis:focal | 0 | 2 | 1 | 0 | 3 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (0) | (4) | (2) | (0) | (6) | (2) | (0) | (0) | (2) | (2) | (0) | (0) | (4) | (0) | (0) | (0) |
| | fatty change | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory infiltration | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory cell nest | 20 | 0 | 0 | 0 | 19 | 0 | 0 | 0 | 25 | 1 | 0 | 0 | 28 | 0 | 0 | 0 |
| | | (40) | (0) | (0) | (0) | (38) | (0) | (0) | (0) | (50) | (2) | (0) | (0) | (57) | (0) | (0) | (0) |
| | clear cell focus | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (2) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (0) | (0) | (0) | (0) |
| | basophilic cell focus | 4 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (8) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | mobilization of Kupffer cell | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
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HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 10

| | | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|-------------------|---------------------------------------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|-------|--|--|--|
| | | 50 | | | | 50 | | | | 50 | | | | 49 | | | | | | | |
| Organ | Findings | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | | | |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | | | |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| liver | biliary cyst | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | |
| | | 2 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (4) | (0) | (2) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | |
| pancreas | atrophy | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | |
| | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | | | |
| {Urinary system} | | | | | | | | | | | | | | | | | | | | | |
| kidney | infarct | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | | | | |
| | cyst | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | | | | |
| | hyaline droplet | | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | |
| | basophilic change | | 15 | 0 | 0 | 0 | 9 | 0 | 0 | 0 | 18 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | | | |
| | | (30) | (0) | (0) | (0) | (18) | (0) | (0) | (0) | (36) | (0) | (0) | (0) | (20) | (0) | (0) | (0) | (0) | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
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 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
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HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 11

| Organ | Findings | Group Name No. of Animals on Study | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------|---|---------------------------------------|-------|--------|-------|--------|-------|--------|-------|--------|-------|-------|-------|--------|-------|--------|-------|-------|-------|-------|-------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 49 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Urinary system} | | | | | | | | | | | | | | | | | | | | | |
| kidney | | | | | | | | | | | | | | | | | | | | | |
| | hyaline cast | <50> | | | | <50> | | | | <50> | | | | <49> | | | | <49> | | | |
| | | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | lymphocytic infiltration | 17 | 0 | 0 | 0 | 11 | 0 | 0 | 0 | 12 | 1 | 0 | 0 | 7 | 0 | 0 | 0 | 0 | 0 | 0 | * |
| | | (34) | (0) | (0) | (0) | (22) | (0) | (0) | (0) | (24) | (2) | (0) | (0) | (14) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory polyp | 1 | 1 | 3 | 0 | 0 | 1 | 7 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (2) | (6) | (0) | (0) | (2) | (14) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) |
| | hydronephrosis | 0 | 0 | 9 | 1 | 0 | 2 | 9 | 0 | 0 | 1 | 3 | 0 | 0 | 1 | 6 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (18) | (2) | (0) | (4) | (18) | (0) | (0) | (2) | (6) | (0) | (0) | (2) | (12) | (0) | (0) | (0) | (0) | (0) |
| | tubular necrosis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | mineralization:cortico-medullary junction | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | mineralization:pelvis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | mineralization:cortex | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
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STUDY NO. : 0319
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 REPORT TYPE : A1
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HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 12

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|--------------------------|---------------------------------------|-------|-------|-------|-------|-------|-------|-------|--------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 49 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Urinary system} | | | | | | | | | | | | | | | | | | | | | |
| kidney | dilatation:tubular lumen | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | (2) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) |
| | glomerulosclerosis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (2) | (0) | (0) |
| urin bladd | | | | | | | | | | | | | | | | | | | | | |
| | inflammation | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) |
| | lymphocytic infiltration | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | xanthogranuloma | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Endocrine system} | | | | | | | | | | | | | | | | | | | | | |
| pituitary | | | | | | | | | | | | | | | | | | | | | |
| | hyperplasia | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 13

| Organ | Findings | Group Name No. of Animals on Study | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|---------------------------|---------------------------------------|------|------|-------|-------|------|------|-------|-------|------|------|-------|-------|------|------|------|-------|--|--|--|
| | | 50 | | | | 50 | | | | 50 | | | | 49 | | | | | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | | | |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | | | |
| {Endocrine system} | | | | | | | | | | | | | | | | | | | | | |
| pituitary | | <48> | | | | <50> | | | | <50> | | | | <48> | | | | | | | |
| | Rathke pouch | 5 | 0 | 0 | 0 | 7 | 0 | 0 | 0 | 7 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | | | | |
| | | (10) | (0) | (0) | (0) | (14) | (0) | (0) | (0) | (14) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | | | | |
| thyroid | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | | |
| | arteritis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | | | | |
| parathyroid | | <21> | | | | <23> | | | | <28> | | | | <28> | | | | | | | |
| | cyst | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (11) | (0) | (0) | (0) | | | | |
| adrenal | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | | |
| | deposit of melanin | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |
| | spindle-cell hyperplasia | 25 | 1 | 0 | 0 | 26 | 1 | 0 | 0 | 26 | 0 | 0 | 0 | 31 | 2 | 0 | 0 | | | | |
| | | (50) | (2) | (0) | (0) | (52) | (2) | (0) | (0) | (52) | (0) | (0) | (0) | (63) | (4) | (0) | (0) | | | | |
| | hyperplasia:cortical cell | 7 | 2 | 0 | 0 | 7 | 2 | 0 | 0 | 13 | 5 | 0 | 0 | 5 | 3 | 0 | 0 | | | | |
| | (14) | (4) | (0) | (0) | (14) | (4) | (0) | (0) | (26) | (10) | (0) | (0) | (10) | (6) | (0) | (0) | | | | | |
| | focal fatty change:cortex | 4 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | | | | |
| | | (8) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (4) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 14

| | | Group Name | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|-------------------------|----------------|-------------------------|--------|-------|-------|--------|--------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|-------|-------|--|--|
| | | No. of Animals on Study | | | | 50 | | | | 50 | | | | 50 | | | | 49 | | | |
| Organ | Findings | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | | | |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | | | |
| {Reproductive system} | | | | | | | | | | | | | | | | | | | | | |
| testis | mineralization | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | |
| | | 30 | 6 | 0 | 0 | 25 | 5 | 0 | 0 | 27 | 4 | 0 | 0 | 27 | 0 | 0 | 0 | * | | | |
| | | (60) | (12) | (0) | (0) | (50) | (10) | (0) | (0) | (54) | (8) | (0) | (0) | (55) | (0) | (0) | (0) | (0) | | | |
| epididymis | hemorrhage | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | |
| | | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | | | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | |
| | inflammation | | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | | | | (2) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | |
| spermatogenic granuloma | | | 1 | 3 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | |
| | | | | (2) | (6) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | | | |
| xanthogranuloma | | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | | | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | |
| prep/cli gl | duct ectasia | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | |
| | | 0 | 3 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | | | | (0) | (6) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | | | |
| {Nervous system} | | | | | | | | | | | | | | | | | | | | | |
| brain | hemorrhage | | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 15

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------------------|--------------------------|---------------------------------------|------|------|------|-------|------|------|------|-------|------|------|------|-------|------|------|------|-------|------|------|------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 49 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Nervous system} | | | | | | | | | | | | | | | | | | | | | |
| brain | | | | | | | | | | | | | | | | | | | | | |
| | mineralization | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | | |
| | | 24 | 0 | 0 | 0 | 24 | 0 | 0 | 0 | 13 | 0 | 0 | 0 * | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 ** |
| | | (48) | (0) | (0) | (0) | (48) | (0) | (0) | (0) | (26) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | gliosis | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) |
| {Special sense organs/appendage} | | | | | | | | | | | | | | | | | | | | | |
| eye | | | | | | | | | | | | | | | | | | | | | |
| | keratitis | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | | |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| Harder gl | | | | | | | | | | | | | | | | | | | | | |
| | lymphocytic infiltration | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | | |
| | | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (4) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyperplasia | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | | |
| | | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (4) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Musculoskeletal system} | | | | | | | | | | | | | | | | | | | | | |
| muscle | | | | | | | | | | | | | | | | | | | | | |
| | mineralization | <50> | | | | <50> | | | | <50> | | | | <49> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 16

| Organ_____ | Findings_____ | Group Name | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------|---------------|-------------------------|-----|-----|-----|------|-----|-----|-----|------|-----|-----|-----|------|-----|-----|-----|-------|--|--|--|
| | | No. of Animals on Study | | | | 50 | | | | 50 | | | | 50 | | | | 49 | | | |
| | | Grade | | | | | | | | | | | | | | | | | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | | | | |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | | | |

{Musculoskeletal system}

| | | | | | | | | | | | | | | | | | |
|------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| bone | hyperplasia | <50> | | | | <50> | | | | <50> | | | | <49> | | | |
| | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

(HPT150)

BAIS3

APPENDIX J 2

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY,
MOUSE: MALE: DEAD AND MORIBUND ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 1

| Organ | Findings | Group Name No. of Animals on Study | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------------------|---|---------------------------------------|--------|-------|-------|--------|--------|-------|-------|--------|-------|-------|-------|--------|--------|--------|-------|-------|-------|-------|-------|
| | | Grade | | | | 17 | | | | 20 | | | | 12 | | | | 6 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Integumentary system/appandage} | | | | | | | | | | | | | | | | | | | | | |
| skin/app | inflammation | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | exudate | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (6) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (17) | (17) | (0) | (0) | (0) | (0) | (0) |
| | hyperplasia:gland | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | eosinophilic change:olfactory epithelium | 4 | 3 | 0 | 0 | 3 | 4 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 4 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (24) | (18) | (0) | (0) | (15) | (20) | (0) | (0) | (8) | (8) | (0) | (0) | (17) | (67) | (0) | (0) | (0) | (0) | (0) | (0) |
| | eosinophilic change:respiratory epithelium | 3 | 1 | 0 | 0 | 4 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (18) | (6) | (0) | (0) | (20) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | respiratory metaplasia:olfactory epithelium | 3 | 1 | 0 | 0 | 6 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 2 | 0 | 0 * | 0 | 0 | 0 | 0 |
| | | (18) | (6) | (0) | (0) | (30) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (50) | (33) | (0) | (0) | (0) | (0) | (0) | (0) |
| | respiratory metaplasia:gland | 2 | 2 | 0 | 0 | 3 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (12) | (12) | (0) | (0) | (15) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (17) | (33) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 2

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|---|---------------------------------------|------|------|------|------|------|------|------|-------|-------|------|------|------|-------|------|------|-------|-------|------|------|
| | | Grade | | | | 17 | | | | 20 | | | | 12 | | | | 6 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | inflammation:transitional epithelium | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | squamous cell metaplasia:respiratory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 2 | 0 | 0 ** |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (50) | (33) | (0) | (0) |
| | cuboidal change:respiratory epithelium | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | 5 | 0 | 0 ** | 0 | 5 | 0 | 0 ** | 0 | 5 | 0 | 0 ** |
| | | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (17) | (42) | (0) | (0) | (0) | (83) | (0) | (0) | (0) | (83) | (0) | (0) |
| | atrophy:olfactory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 2 | 0 | 0 ** |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (50) | (33) | (0) | (0) |
| | atrophy:respiratory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (17) | (0) | (0) | (0) |
| | edema:lamina propria | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 0 * |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (50) | (0) | (0) | (0) |
| | necrosis:respiratory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 1 | 0 | 0 ** |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (33) | (17) | (0) | (0) |
| | hyperplasia:respiratory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (17) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 3

| Organ | Findings | Group Name No. of Animals on Study | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|---------------------------|---------------------------------------|-------|-------|-------|-------|--------|-------|-------|-------|-------|-------|-------|-------|--------|-------|-------|-------|-------|-------|-------|
| | | Grade | | | | 17 | | | | 20 | | | | 12 | | | | 6 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| trachea | eosinophilic change | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| lung | congestion | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | | 1 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (6) | (0) | (0) | (0) | (0) | (15) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hemorrhage | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (8) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (0) | (0) | (0) |
| | edema | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (6) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | thrombus | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | necrosis:focal | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory infiltration | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | perivascular inflammation | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 4

| Organ | Findings | Group Name No. of Animals on Study Grade | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------------|------------------------------|--|------|-------|------|-------|-------|------|------|-------|-------|------|------|-------|-------|------|------|-------|-------|------|------|
| | | 17 | | | | 20 | | | | 12 | | | | 6 | | | | | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| lung | | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | accumulation of foamy cells | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | (17) | (0) | (0) | (0) |
| | | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | | | | |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | | | | |
| bone marrow | | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | myelofibrosis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | (17) | (0) | (0) | (0) |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | | | | |
| | granulopoiesis:increased | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | (0) | (0) | (0) | (0) |
| | | (0) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (25) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |
| thymus | | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | cyst | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | (0) | (0) | (0) | (0) |
| | | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |
| spleen | | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | extramedullary hematopoiesis | 5 | 1 | 2 | 0 | 4 | 3 | 0 | 0 | 0 | 4 | 1 | 0 | 0 | 1 | 0 | 0 | (0) | (17) | (0) | (0) |
| | | (29) | (6) | (12) | (0) | (20) | (15) | (0) | (0) | (0) | (33) | (8) | (0) | (0) | (17) | (0) | (0) | | | | |
| {Circulatory system} | | | | | | | | | | | | | | | | | | | | | |
| heart | | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | thrombus | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | (0) | (0) | (0) | (0) |
| | | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 5

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|--------------------------|---------------------------------------|------|------|------|-------|------|------|------|-------|-------|------|------|-------|------|------|------|-------|------|------|------|
| | | Grade | | | | 17 | | | | 20 | | | | 12 | | | | 6 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Circulatory system} | | | | | | | | | | | | | | | | | | | | | |
| heart | necrosis:focal | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | mineralization | | | | | | | | | | | | | | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | myocardial fibrosis | | | | | | | | | | | | | | | | | | | | |
| | | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (6) | (6) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (17) | (0) | (0) | (17) | (0) | (0) | (0) | (17) | (0) | (0) | (0) |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| tooth | dysplasia | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | | 5 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (29) | (0) | (0) | (0) | (15) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| salivary gl | lymphocytic infiltration | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | | 2 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (12) | (0) | (0) | (0) | (15) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (17) | (0) | (0) | (0) |
| stomach | ulcer:forestomach | <16> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (17) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 6

| Organ | Findings | Group Name No. of Animals on Study Grade | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|-------------------------------|--|--------|--------|-------|--------|--------|-------|-------|--------|--------|-------|-------|--------|--------|-------|-------|--------|--------|-------|-------|
| | | 17 | | | | 20 | | | | 12 | | | | 6 | | | | | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| stomach | | <16> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | hyperplasia:forestomach | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (13) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | erosion:glandular stomach | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyperplasia:glandular stomach | 6 | 7 | 3 | 0 | 6 | 9 | 1 | 0 | 5 | 5 | 0 | 0 | 2 | 2 | 0 | 0 | 2 | 2 | 0 | 0 |
| | | (38) | (44) | (19) | (0) | (30) | (45) | (5) | (0) | (42) | (42) | (0) | (0) | (33) | (33) | (0) | (0) | (33) | (33) | (0) | (0) |
| liver | | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | angiectasis | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | necrosis:central | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (6) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | necrosis:focal | 0 | 2 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (12) | (6) | (0) | (5) | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (17) | (0) | (0) | (0) | (17) | (0) | (0) | (0) |
| | inflammatory infiltration | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | basophilic cell focus | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 7

| Organ | Findings | Group Name No. of Animals on Study Grade | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|--------------------------|--|-----------|-----------|------------|-----------|------------|-----------|------------|-----------|-----------|-----------|------------|-----------|-----------|------------|------------|----------|
| | | | 17 | | | | 20 | | | | 12 | | | | 6 | | | |
| | | | 1 (%) | 2 (%) | 3 (%) | 4 (%) | 1 (%) | 2 (%) | 3 (%) | 4 (%) | 1 (%) | 2 (%) | 3 (%) | 4 (%) | 1 (%) | 2 (%) | 3 (%) | 4 (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | | |
| liver | biliary cyst | | <17> | | | | <20> | | | | <12> | | | | < 6> | | | |
| | | 1 (6) | 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 | hyaline droplet | | <17> | | | | <20> | | | | <12> | | | | < 6> | | | |
| | | 0 (0) | 1 (6) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (8) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| | hyaline cast | | 1 (6) | 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) | |
| | lymphocytic infiltration | | 1 (6) | 0 (0) | 0 (0) | 0 (0) | 3 (15) | 0 (0) | 0 (0) | 0 (0) | 1 (8) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| | inflammatory polyp | | 0 (0) | 1 (6) | 1 (6) | 0 (0) | 0 (0) | 1 (5) | 6 (30) | 0 (0) | 0 (0) | 0 (0) | 1 (8) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| | hydronephrosis | | 0 (0) | 0 (0) | 5 (29) | 1 (6) | 0 (0) | 1 (5) | 8 (40) | 0 (0) | 0 (0) | 1 (8) | 2 (17) | 0 (0) | 0 (0) | 1 (17) | 3 (50) | |
| | tubular necrosis | | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (8) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 8

| | | Group Name | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|---|-------------------------|------|------|------|------|------|-------|------|------|------|------|------|------|-------|-------|-------|------|
| | | No. of Animals on Study | 17 | | | | 20 | | | | 12 | | | | 6 | | | |
| Organ | Findings | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Urinary system} | | | | | | | | | | | | | | | | | | |
| kidney | | | <17> | | | | <20> | | | | <12> | | | | < 6> | | | |
| | mineralization:cortico-medullary junction | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | mineralization:cortex | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | dilatation:tubular lumen | | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (15) | (0) | (0) | (8) | (8) | (0) | (0) | (0) | (17) | (0) | (0) |
| | glomerulosclerosis | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (17) | (0) |
| urin bladd | | | | | | | | | | | | | | | | | | |
| | inflammation | | <17> | | | | <20> | | | | <12> | | | | < 6> | | | |
| | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Endocrine system} | | | | | | | | | | | | | | | | | | |
| pituitary | | | <16> | | | | <20> | | | | <12> | | | | < 6> | | | |
| | hyperplasia | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 9

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|-----------------------|---------------------------|---------------------------------------|------|------|------|-------|------|------|------|-------|------|------|------|-------|------|------|------|-------|------|------|------|
| | | Grade | | | | 17 | | | | 20 | | | | 12 | | | | 6 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Endocrine system} | | | | | | | | | | | | | | | | | | | | | |
| pituitary | Rathke pouch | <16> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (13) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| adrenal | spindle-cell hyperplasia | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | | 6 | 0 | 0 | 0 | 8 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (35) | (0) | (0) | (0) | (40) | (0) | (0) | (0) | (42) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyperplasia:cortical cell | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (12) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Reproductive system} | | | | | | | | | | | | | | | | | | | | | |
| testis | mineralization | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | | 8 | 1 | 0 | 0 | 7 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (47) | (6) | (0) | (0) | (35) | (0) | (0) | (0) | (33) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| epididymis | hemorrhage | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| prep/cli gl | duct ectasia | <17> | | | | <20> | | | | <12> | | | | < 6> | | | | | | | |
| | | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 10

| | | Group Name | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------------------|--------------------------|-------------------------|-------|------|------|------|-------|------|------|------|------|------|------|------|-------|------|-------|------|
| | | No. of Animals on Study | 17 | | | | 20 | | | | 12 | | | | 6 | | | |
| Organ | Findings | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Nervous system} | | | | | | | | | | | | | | | | | | |
| brain | | | <17> | | | | <20> | | | | <12> | | | | < 6> | | | |
| | hemorrhage | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| | mineralization | | 5 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (29) | (0) | (0) | (0) | (25) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| | gliosis | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | (17) | (0) |
| {Special sense organs/appendage} | | | | | | | | | | | | | | | | | | |
| Harder gl | | | <17> | | | | <20> | | | | <12> | | | | < 6> | | | |
| | lymphocytic infiltration | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| {Musculoskeletal system} | | | | | | | | | | | | | | | | | | |
| muscle | | | <17> | | | | <20> | | | | <12> | | | | < 6> | | | |
| | mineralization | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

APPENDIX J 3

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY,
MOUSE: MALE: SACRIFICED ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 1

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------------------|---|---------------------------------------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|--------|--------|--------|-------|--------|--------|--------|-------|
| | | Grade | | | | 33 | | | | 30 | | | | 38 | | | | 43 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Integumentary system/appandage} | | | | | | | | | | | | | | | | | | | | | |
| skin/app | inflammation | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (2) | (0) | (0) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | exudate | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | 18 | 6 | 0 | 0 | 18 | 6 | 0 |
| | | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (5) | (42) | (14) | (0) | (5) | (42) | (14) | (0) |
| | hyperplasia:gland | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 18 | 0 | 0 | 0 | 18 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (42) | (0) | (0) | (0) | (42) | (0) | (0) | (0) |
| | eosinophilic change:olfactory epithelium | 16 | 3 | 0 | 0 | 7 | 0 | 0 | 0 * | 11 | 1 | 0 | 0 | 15 | 5 | 0 | 0 | 15 | 5 | 0 | 0 |
| | | (48) | (9) | (0) | (0) | (23) | (0) | (0) | (0) | (29) | (3) | (0) | (0) | (35) | (12) | (0) | (0) | (35) | (12) | (0) | (0) |
| | eosinophilic change:respiratory epithelium | 5 | 2 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 4 | 2 | 1 | 0 | 4 | 2 | 1 | 0 |
| | | (15) | (6) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (3) | (0) | (0) | (9) | (5) | (2) | (0) | (9) | (5) | (2) | (0) |
| | inflammation:respiratory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 5 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (12) | (0) | (0) | (0) | (12) | (0) | (0) | (0) |
| | respiratory metaplasia:olfactory epithelium | 15 | 1 | 0 | 0 | 12 | 0 | 0 | 0 | 7 | 1 | 0 | 0 * | 15 | 26 | 1 | 0 ** | 15 | 26 | 1 | 0 ** |
| | | (45) | (3) | (0) | (0) | (40) | (0) | (0) | (0) | (18) | (3) | (0) | (0) | (35) | (60) | (2) | (0) | (35) | (60) | (2) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 2

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|---|---------------------------------------|-----------|-----------|-----------|------------|------------|-----------|-----------|------------|------------|-----------|-----------|-------------|-------------|-----------|-----------|-------|-----|-----|-----|
| | | Grade | | | | 33 | | | | 30 | | | | 38 | | | | 43 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | respiratory metaplasia:gland | 11 (33) | 2 (6) | 0 (0) | 0 (0) | 5 (17) | 5 (17) | 0 (0) | 0 (0) | 8 (21) | 2 (5) | 0 (0) | 0 (0) | 15 (35) | 23 (53) | 0 (0) | 0 (0) | | | | |
| | squamous cell metaplasia: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) | 16 (37) | 13 (30) | 0 (0) | 0 (0) | | | | |
| | cuboidal change:respiratory epithelium | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 4 (11) | 7 (18) | 0 (0) | 0 (0) | 13 (30) | 13 (30) | 0 (0) | 0 (0) | | | | |
| | atrophy:olfactory 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) | 27 (63) | 10 (23) | 0 (0) | 0 (0) | | | | |
| | atrophy: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) | 8 (19) | 2 (5) | 0 (0) | 0 (0) | | | | |
| | necrosis:olfactory 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) | 2 (5) | 1 (2) | 0 (0) | 0 (0) | | | | |
| | edema:lamina propria | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 16 (37) | 0 (0) | 0 (0) | 0 (0) | | | | |
| | necrosis: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) | 10 (23) | 3 (7) | 0 (0) | 0 (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) —
 SACRIFICED ANIMALS (105W)

PAGE : 3

| Organ | Findings | Group Name No. of Animals on Study Grade | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|------------------------------------|--|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | 33 | | | | 30 | | | | 38 | | | | 43 | | | | | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | hyperplasia:respiratory epithelium | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| nasopharynx | eosinophilic change | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| trachea | necrosis:epithelium | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) |
| lung | hemorrhage | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory infiltration | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | fibrosis | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | accumulation of foamy cells | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (3) | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 4

| Organ | Findings | Group Name No. of Animals on Study Grade | 0ppm | | | | 30ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------------|---------------------------------------|--|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | | 33 | | | | 30 | | | | 38 | | | | 43 | | | |
| | | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | |
| lung | | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | bronchiolar cell hyperplasia | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | bronchiolar-alveolar cell hyperplasia | | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | |
| bone marrow | | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | myelofibrosis | | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (6) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | erythropoiesis:increased | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | granulopoiesis:increased | | 1 | 0 | 0 | 0 | 2 | 1 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (3) | (0) | (0) | (0) | (7) | (3) | (0) | (0) | (5) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| lymph node | | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | lymphadenitis | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 5

| Organ_____ | Findings_____ | Group Name No. of Animals on Study Grade | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------------|------------------------------|--|-----------|------------|-----------|-----------|-----------|-----------|-----------|-----------|------------|-----------|-----------|------------|-----------|-----------|-----------|-----------|
| | | | 33 | | | | 30 | | | | 38 | | | | 43 | | | |
| | | | 1 (%) | 2 (%) | 3 (%) | 4 (%) | 1 (%) | 2 (%) | 3 (%) | 4 (%) | 1 (%) | 2 (%) | 3 (%) | 4 (%) | 1 (%) | 2 (%) | 3 (%) | 4 (%) |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | |
| thymus | cyst | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | 3 (9) | 0 (0) | 0 (0) | 0 (0) | 1 (3) | 0 (0) | 0 (0) | 0 (0) | 3 (8) | 0 (0) | 0 (0) | 0 (0) | 5 (12) | 0 (0) | 0 (0) | 0 (0) | |
| spleen | deposit of melanin | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | 1 (3) | 0 (0) | 0 (0) | 0 (0) | 1 (3) | 0 (0) | 0 (0) | 0 (0) | 1 (3) | 0 (0) | 0 (0) | 0 (0) | 4 (9) | 0 (0) | 0 (0) | 0 (0) | |
| | extramedullary hematopoiesis | | 2 (6) | 0 (0) | 0 (0) | 0 (0) | 2 (7) | 2 (7) | 0 (0) | 0 (0) | 4 (11) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | | follicular hyperplasia | | 4 (12) | 2 (6) | 0 (0) | 0 (0) | 2 (7) | 1 (3) | 0 (0) | 0 (0) | 3 (8) | 1 (3) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| {Circulatory system} | | | | | | | | | | | | | | | | | | |
| heart | myocardial fibrosis | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | 2 (6) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (3) | 0 (0) | 0 (0) | 2 (5) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| | arteritis | | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (3) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 6

| Organ | Findings | Group Name No. of Animals on Study Grade | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|---------------------------|--|--------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|
| | | | 33 | | | | 30 | | | | 38 | | | | 43 | | | |
| | | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Circulatory system} | | | | | | | | | | | | | | | | | | |
| heart | endocardial hyperplasia | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Digestive system} | | | | | | | | | | | | | | | | | | |
| tooth | dysplasia | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | | 20 | 1 | 0 | 0 | 15 | 0 | 0 | 0 | 18 | 0 | 0 | 0 | 23 | 0 | 0 | 0 |
| | | | (61) | (3) | (0) | (0) | (50) | (0) | (0) | (0) | (47) | (0) | (0) | (0) | (53) | (0) | (0) | (0) |
| tongue | arteritis | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (5) | (0) | (0) |
| salivary gl | lymphocytic infiltration | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | | 12 | 0 | 0 | 0 | 15 | 0 | 0 | 0 | 24 | 0 | 0 | 0 * | 12 | 0 | 0 | 0 |
| | | | (36) | (0) | (0) | (0) | (50) | (0) | (0) | (0) | (63) | (0) | (0) | (0) | (28) | (0) | (0) | (0) |
| stomach | inflammatory infiltration | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | erosion:forestomach | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 7

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|-------------------------------|---------------------------------------|--------|--------|-------|--------|--------|--------|-------|--------|--------|--------|-------|--------|--------|-------|-------|-------|-----|-----|-----|
| | | Grade | | | | 33 | | | | 30 | | | | 38 | | | | 43 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| stomach | | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | hyperplasia:forestomach | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | | | | |
| | erosion:glandular stomach | 0 | 1 | 0 | 0 | 4 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | | | | |
| | | (0) | (3) | (0) | (0) | (13) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | | | | |
| | hyperplasia:glandular stomach | 5 | 20 | 4 | 0 | 5 | 18 | 4 | 0 | 14 | 14 | 7 | 0 | 23 | 17 | 1 | 0 ** | | | | |
| | | (15) | (61) | (12) | (0) | (17) | (60) | (13) | (0) | (37) | (37) | (18) | (0) | (53) | (40) | (2) | (0) | | | | |
| small intes | | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | lymphadenitis | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |
| liver | | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | angiectasis | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (2) | (0) | (0) | | | | |
| | necrosis:central | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |
| | necrosis:focal | 0 | 0 | 0 | 0 | 2 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (7) | (3) | (0) | (0) | (3) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 8

| Organ | Findings | Group Name No. of Animals on Study Grade | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|------------------------------|--|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|-------|-------|-------|-------|
| | | 33 | | | | 30 | | | | 38 | | | | 43 | | | | | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | | | | |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| liver | | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | fatty change | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory infiltration | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory cell nest | 20 | 0 | 0 | 0 | 19 | 0 | 0 | 0 | 25 | 1 | 0 | 0 | 28 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (61) | (0) | (0) | (0) | (63) | (0) | (0) | (0) | (66) | (3) | (0) | (0) | (65) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | clear cell focus | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (3) | (3) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | basophilic cell focus | 4 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (12) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | mobilization of Kuppfer cell | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | biliary cyst | 1 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (3) | (0) | (3) | (0) | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| pancreas | | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | atrophy | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) :
SACRIFICED ANIMALS (105W)

PAGE : 9

| Organ | Findings | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------|--------------------------|--------|-------|--------|-------|--------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|
| | | 33 | | | | 30 | | | | 38 | | | | 43 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Urinary system} | | | | | | | | | | | | | | | | | |
| kidney | | | | | | | | | | | | | | | | | |
| | infarct | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | cyst | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) |
| | hyaline droplet | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | basophilic change | 15 | 0 | 0 | 0 | 9 | 0 | 0 | 0 | 18 | 0 | 0 | 0 | 10 | 0 | 0 | 0 |
| | | (45) | (0) | (0) | (0) | (30) | (0) | (0) | (0) | (47) | (0) | (0) | (0) | (23) | (0) | (0) | (0) |
| | hyaline cast | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | lymphocytic infiltration | 16 | 0 | 0 | 0 | 8 | 0 | 0 | 0 | 11 | 1 | 0 | 0 | 7 | 0 | 0 | 0 ** |
| | | (48) | (0) | (0) | (0) | (27) | (0) | (0) | (0) | (29) | (3) | (0) | (0) | (16) | (0) | (0) | (0) |
| | inflammatory polyp | 1 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 |
| | | (3) | (0) | (6) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (2) | (0) |
| | hydronephrosis | 0 | 0 | 4 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 3 | 0 |
| | | (0) | (0) | (12) | (0) | (0) | (3) | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (7) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 10

| Organ | Findings | Group Name | | No. of Animals on Study | | 0ppm | | 3ppm | | 6ppm | | 12ppm | | | | | |
|--------------------|--------------------------|------------|-------|-------------------------|-------|-------|-------|-------|-------|--------|-------|-------|-------|-------|-------|-------|-------|
| | | 33 | | 30 | | 38 | | 43 | | | | | | | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | | | |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Urinary system} | | | | | | | | | | | | | | | | | |
| kidney | mineralization:pelvis | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | mineralization:cortex | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| urin bladd | inflammation | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) |
| | lymphocytic infiltration | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (9) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (13) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | xanthogranuloma | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Endocrine system} | | | | | | | | | | | | | | | | | |
| pituitary | hyperplasia | <32> | | | | <30> | | | | <38> | | | | <42> | | | |
| | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 11

| Organ | Findings | Group Name No. of Animals on Study | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|---------------------------|---------------------------------------|-------|-------|-------|--------|-------|-------|-------|--------|--------|-------|-------|--------|-------|-------|-------|-------|-----|-----|-----|
| | | Grade | | | | 33 | | | | 30 | | | | 38 | | | | 43 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Endocrine system} | | | | | | | | | | | | | | | | | | | | | |
| pituitary | | <32> | | | | <30> | | | | <38> | | | | <42> | | | | | | | |
| | Rathke pouch | 3 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | | | | |
| | | (9) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (16) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | | | | |
| thyroid | | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | arteritis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | | | | |
| parathyroid | | <15> | | | | <13> | | | | <21> | | | | <24> | | | | | | | |
| | cyst | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (13) | (0) | (0) | (0) | | | | |
| adrenal | | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | deposit of melanin | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |
| | spindle-cell hyperplasia | 19 | 1 | 0 | 0 | 18 | 1 | 0 | 0 | 21 | 0 | 0 | 0 | 30 | 2 | 0 | 0 | | | | |
| | | (58) | (3) | (0) | (0) | (60) | (3) | (0) | (0) | (55) | (0) | (0) | (0) | (70) | (5) | (0) | (0) | | | | |
| | hyperplasia:cortical cell | 5 | 2 | 0 | 0 | 7 | 2 | 0 | 0 | 13 | 5 | 0 | 0 | 4 | 3 | 0 | 0 | | | | |
| | | (15) | (6) | (0) | (0) | (23) | (7) | (0) | (0) | (34) | (13) | (0) | (0) | (9) | (7) | (0) | (0) | | | | |
| | focal fatty change:cortex | 4 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | | | | |
| | | (12) | (0) | (0) | (0) | (3) | (3) | (0) | (0) | (5) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 12

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|-----------------------|-------------------------|---------------------------------------|-------|------|------|-------|-------|------|------|-------|-------|------|------|-------|------|------|------|-------|------|------|-----|
| | | Grade | | | | 33 | | | | 30 | | | | 38 | | | | 43 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Reproductive system} | | | | | | | | | | | | | | | | | | | | | |
| testis | mineralization | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | | 22 | 5 | 0 | 0 | 18 | 5 | 0 | 0 | 23 | 4 | 0 | 0 | 27 | 0 | 0 | 0 | 0 | 0 | 0 | * |
| | | (67) | (15) | (0) | (0) | (60) | (17) | (0) | (0) | (61) | (11) | (0) | (0) | (63) | (0) | (0) | (0) | (0) | (0) | (0) | |
| epididymis | inflammation | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | (3) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | |
| | spermatogenic granuloma | 1 | 3 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | (3) | (9) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | |
| prep/cli gl | xanthogranuloma | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | |
| | duct ectasia | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | (0) | (6) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (11) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | |
| {Nervous system} | | | | | | | | | | | | | | | | | | | | | |
| brain | mineralization | <33> | | | | <30> | | | | <38> | | | | <43> | | | | | | | |
| | | 19 | 0 | 0 | 0 | 19 | 0 | 0 | 0 | 13 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | ** |
| | | (58) | (0) | (0) | (0) | (63) | (0) | (0) | (0) | (34) | (0) | (0) | (0) | (12) | (0) | (0) | (0) | (0) | (0) | (0) | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 13

| Organ | Findings | Group Name No. of Animals on Study Grade | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------------------|--------------------------|--|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | | 33 | | | | 30 | | | | 38 | | | | 43 | | | |
| | | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Nervous system} | | | | | | | | | | | | | | | | | | |
| brain | gliosis | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Special sense organs/appendage} | | | | | | | | | | | | | | | | | | |
| eye | keratitis | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| Harder gl | lymphocytic infiltration | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (6) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyperplasia | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (3) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Musculoskeletal system} | | | | | | | | | | | | | | | | | | |
| bone | hyperplasia | | <33> | | | | <30> | | | | <38> | | | | <43> | | | |
| | | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

APPENDIX J 4

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY,
MOUSE: FEMALE: ALL ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 17

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------------------|-----------------------|---------------------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|--------|--------|-------|-------|-------|-------|-------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Integumentary system/appandage} | | | | | | | | | | | | | | | | | | | | | |
| skin/app | mastcell hyperplasia | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyperplasia:epidermis | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| subcutis | congestion | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | exudate | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 30 | 14 | 0 | 0 | 0 | 0 | ** |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (2) | (60) | (28) | (0) | (0) | (0) | (0) | (0) |
| | mineralization | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyperplasia:gland | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

(HPT150)

BAIS3

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 18

| Organ | Findings | Group Name No. of Animals on Study | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|---|---------------------------------------|-------------|-----------|-----------|-------------|-------------|-----------|--------------|-------------|-------------|-----------|--------------|-------------|-------------|-----------|--------------|-------|-----|-----|-----|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | | <50> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | eosinophilic change:olfactory epithelium | 19 (38) | 2 (4) | 1 (2) | 0 (0) | 8 (16) | 5 (10) | 0 (0) | 0 * (0) | 3 (6) | 0 (0) | 0 (0) | 0 ** (0) | 9 (18) | 5 (10) | 0 (0) | 0 (0) | | | | |
| | eosinophilic change:respiratory epithelium | 29 (58) | 10 (20) | 0 (0) | 0 (0) | 13 (26) | 33 (66) | 1 (2) | 0 ** (0) | 14 (28) | 12 (24) | 0 (0) | 0 ** (0) | 23 (46) | 4 (8) | 0 (0) | 0 * (0) | | | | |
| | inflammation: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) | 11 (22) | 1 (2) | 0 (0) | 0 ** (0) | | | | |
| | inflammation:olfactory 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) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | | | | |
| | respiratory metaplasia:olfactory epithelium | 8 (16) | 0 (0) | 0 (0) | 0 (0) | 10 (20) | 0 (0) | 0 (0) | 0 (0) | 5 (10) | 0 (0) | 0 (0) | 0 (0) | 5 (10) | 43 (86) | 1 (2) | 0 ** (0) | | | | |
| | respiratory metaplasia:gland | 4 (8) | 0 (0) | 0 (0) | 0 (0) | 6 (12) | 0 (0) | 0 (0) | 0 (0) | 8 (16) | 3 (6) | 0 (0) | 0 (0) | 16 (32) | 14 (28) | 0 (0) | 0 ** (0) | | | | |
| | squamous cell metaplasia: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) | 14 (28) | 16 (32) | 0 (0) | 0 ** (0) | | | | |
| | cuboidal change:respiratory epithelium | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 3 (6) | 3 (6) | 0 (0) | 0 * (0) | 12 (24) | 21 (42) | 3 (6) | 0 ** (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDf1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 19

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|------------------------------------|---------------------------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-------------|-------------|-----------|--------------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | | <50> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | atrophy:olfactory epithelium | 1 (2) | 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) | 35 (70) | 10 (20) | 0 (0) | 0 ** (0) |
| | atrophy: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) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 7 (14) | 2 (4) | 0 (0) | 0 ** (0) |
| | necrosis:olfactory 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) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 4 (8) | 0 (0) | 0 (0) | 0 (0) |
| | edema:lamina propria | 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) | 3 (6) | 0 (0) | 0 (0) | 0 (0) |
| | necrosis:respiratory epithelium | 1 (2) | 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) | 14 (28) | 5 (10) | 0 (0) | 0 ** (0) |
| | hyperplasia: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) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 6 (12) | 0 (0) | 0 (0) | 0 * (0) |
| nasopharynx | | <50> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | eosinophilic change | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 4 (8) | 0 (0) | 0 (0) | 0 (0) | 2 (4) | 0 (0) | 0 (0) | 0 (0) | 4 (8) | 0 (0) | 0 (0) | 0 (0) | 4 (8) | 0 (0) | 0 (0) | 0 (0) |
| trachea | | <50> | | | | <50> | | | | <49> | | | | <50> | | | | <50> | | | |
| | eosinophilic 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) | 0 (0) | 1 (2) | 0 (0) | 0 (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 20

| Organ | Findings | Group Name No. of Animals on Study | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|---------------------------|---------------------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-------|------|------|------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| trachea | necrosis:epithelium | <50> | | | | <50> | | | | <49> | | | | <50> | | | | | | | |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| lung | congestion | <50> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | 0 | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (6) | (0) | (0) | (0) | (2) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hemorrhage | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) |
| | edema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (2) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) |
| | thrombus | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) |
| | inflammatory infiltration | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 2 | 1 | 0 | 0 |
| | | (8) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (4) | (2) | (0) | (0) |
| | perivascular inflammation | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (2) | (2) | (0) | (0) | (2) | (0) | (0) | (0) |
| | fibrosis | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 21

| Organ | Findings | Group Name No. of Animals on Study Grade | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------------|---------------------------------------|--|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|-------------|------------|------------|------------|
| | | | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | |
| lung | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | accumulation of foamy cells | | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 2 (4) | 1 (2) | 0 (0) | 0 (0) |
| | bronchiolar cell hyperplasia | | 1 (2) | 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) |
| | bronchiolar-alveolar cell hyperplasia | | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | hyaline membrane | | 1 (2) | 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 (2) | 0 (0) |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | |
| bone marrow | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | myelofibrosis | | 3 (6) | 1 (2) | 0 (0) | 0 (0) | 2 (4) | 3 (6) | 0 (0) | 0 (0) | 2 (4) | 1 (2) | 0 (0) | 0 (0) | 5 (10) | 4 (8) | 0 (0) | 0 (0) |
| | erythropoiesis:increased | | 2 (4) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | erythropoiesis:decreased | | 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 (2) | 0 (0) | 0 (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDf1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 22

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------------|--------------------------|---------------------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | | | | |
| bone marrow | granulopoiesis:increased | <50> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | 1 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (4) | (0) | (0) | (0) |
| lymph node | mastcell hyperplasia | <50> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | lymphadenitis | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 2 | 2 | 0 | 0 |
| | | (0) | (2) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (2) | (2) | (0) | (0) |
| thymus | cyst | <50> | | | | <50> | | | | <49> | | | | <50> | | | | <50> | | | |
| | | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hemorrhage | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| spleen | thrombus | <50> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 23

| Organ | Findings | Group Name No. of Animals on Study Grade | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------------|------------------------------|--|--------|--------|--------|-------|--------|--------|-------|-------|--------|-------|-------|-------|-------|--------|-------|-------|
| | | | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | |
| spleen | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | deposit of melanin | | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 3 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (6) | (0) | (0) | (0) |
| | extramedullary hematopoiesis | | 6 | 8 | 5 | 0 | 7 | 5 | 4 | 0 | 5 | 1 | 3 | 0 | 2 | 5 | 4 | 0 |
| | | | (12) | (16) | (10) | (0) | (14) | (10) | (8) | (0) | (10) | (2) | (6) | (0) | (4) | (10) | (8) | (0) |
| | follicular hyperplasia | | 5 | 3 | 1 | 0 | 1 | 4 | 0 | 0 | 2 | 1 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | | (10) | (6) | (2) | (0) | (2) | (8) | (0) | (0) | (4) | (2) | (0) | (0) | (4) | (0) | (0) | (0) |
| {Circulatory system} | | | | | | | | | | | | | | | | | | |
| heart | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | thrombus | | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (2) | (0) | (0) |
| | mineralization | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | (0) |
| | myocardial fibrosis | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) |
| | pericarditis | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 24

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|--------------------------|---------------------------------------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Circulatory system} | | | | | | | | | | | | | | | | | | | | | |
| heart | arteritis | <50> | | | | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| artery/aort | arteritis | <50> | | | | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| tooth | inflammation | <50> | | | | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | dysplasia | 13 | 0 | 0 | 0 | 13 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 7 | 0 | 0 | 0 | 13 | 0 | 0 | 0 |
| | | (26) | (0) | (0) | (0) | (26) | (0) | (0) | (0) | (12) | (0) | (0) | (0) | (14) | (0) | (0) | (0) | (26) | (0) | (0) | (0) |
| tongue | arteritis | <50> | | | | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) |
| salivary gl | lymphocytic infiltration | <50> | | | | 20 | 0 | 0 | 0 | 17 | 0 | 0 | 0 | 21 | 0 | 0 | 0 | 13 | 0 | 0 | 0 |
| | | (40) | (0) | (0) | (0) | (40) | (0) | (0) | (0) | (34) | (0) | (0) | (0) | (42) | (0) | (0) | (0) | (26) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 25

| Organ | Findings | Group Name No. of Animals on Study | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|-------------------------------|---------------------------------------|-------|------|------|-------|-------|------|------|-------|-------|-------|------|-------|-------|------|------|-------|-------|------|------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| stomach | | | | | | | | | | | | | | | | | | | | | |
| | inflammatory infiltration | <50> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | erosion:forestomach | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyperplasia:forestomach | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | erosion:glandular stomach | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyperplasia:glandular stomach | 17 | 31 | 1 | 0 | 11 | 32 | 3 | 0 | 10 | 30 | 8 | 0 | 25 | 11 | 2 | 0 | 25 | 11 | 2 | 0 ** |
| | | (34) | (62) | (2) | (0) | (22) | (64) | (6) | (0) | (20) | (60) | (16) | (0) | (50) | (22) | (4) | (0) | (50) | (22) | (4) | (0) |
| small intes | | | | | | | | | | | | | | | | | | | | | |
| | inflammation | <50> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) |
| large intes | | | | | | | | | | | | | | | | | | | | | |
| | thrombus | <50> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 26

| Organ | Findings | Group Name No. of Animals on Study Grade | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|---------------------------|--|-------------|------------|-----------|-----------|-------------|-----------|-----------|-----------|-------------|-----------|-----------|-----------|-------------|-----------|-----------|-----------|
| | | | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | | 1 (%) | 2 (%) | 3 (%) | 4 (%) | 1 (%) | 2 (%) | 3 (%) | 4 (%) | 1 (%) | 2 (%) | 3 (%) | 4 (%) | 1 (%) | 2 (%) | 3 (%) | 4 (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | | |
| liver | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | angiectasis | | 2 (4) | 1 (2) | 0 (0) | 0 (0) | 1 (2) | 1 (2) | 0 (0) | 0 (0) | 2 (4) | 4 (8) | 0 (0) | 0 (0) | 3 (6) | 0 (0) | 0 (0) | 0 (0) |
| | necrosis:central | | 0 (0) | 2 (4) | 0 (0) | 0 (0) | 2 (4) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | necrosis:focal | | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 1 (2) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | inflammatory infiltration | | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 2 (4) | 3 (6) | 0 (0) | 0 (0) | 2 (4) | 0 (0) | 0 (0) | 0 (0) |
| | granulation | | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | inflammatory cell nest | | 19 (38) | 6 (12) | 0 (0) | 0 (0) | 17 (34) | 1 (2) | 0 (0) | 0 (0) | 19 (38) | 4 (8) | 0 (0) | 0 (0) | 25 (50) | 3 (6) | 0 (0) | 0 (0) |
| | perivascular inflammation | | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 2 (4) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | clear cell focus | | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 27

| | | Group Name | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|------------------------------------|-------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | No. of Animals on Study | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| Organ | Findings | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | | |
| liver | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | acidophilic cell focus | | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (2) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | basophilic cell focus | | 1 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (2) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | biliary cyst | | 1 | 1 | 1 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (2) | (2) | (2) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hepatocellular hypertrophy:central | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) |
| gall bladd | | | <49> | | | | <50> | | | | <50> | | | | <50> | | | |
| | dilatation | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | erosion | | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| pancreas | | | <50> | | | | <49> | | | | <50> | | | | <50> | | | |
| | atrophy | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 28

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------|--------------------------|---------------------------------------|-------|-------|-------|--------|--------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Urinary system} | | | | | | | | | | | | | | | | | | | | | |
| kidney | | | | | | | | | | | | | | | | | | | | | |
| | infarct | <50> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | 1 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 |
| | | (2) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) |
| | cyst | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyaline droplet | 1 | 4 | 2 | 0 | 1 | 5 | 1 | 0 | 0 | 3 | 0 | 0 | 0 | 3 | 0 | 0 | 2 | 2 | 4 | 0 |
| | | (2) | (8) | (4) | (0) | (2) | (10) | (2) | (0) | (0) | (6) | (0) | (0) | (0) | (6) | (0) | (0) | (4) | (4) | (8) | (0) |
| | basophilic change | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (4) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | deposit of hemosiderin | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | hyaline cast | 1 | 1 | 0 | 0 | 10 | 1 | 0 | 0 * | 9 | 0 | 0 | 0 * | 9 | 0 | 0 | 0 * | 2 | 1 | 0 | 0 |
| | | (2) | (2) | (0) | (0) | (20) | (2) | (0) | (0) | (18) | (0) | (0) | (0) | (18) | (0) | (0) | (0) | (4) | (2) | (0) | (0) |
| | lymphocytic infiltration | 15 | 3 | 0 | 0 | 15 | 1 | 0 | 0 | 18 | 1 | 0 | 0 | 18 | 1 | 0 | 0 | 11 | 1 | 0 | 0 |
| | | (30) | (6) | (0) | (0) | (30) | (2) | (0) | (0) | (36) | (2) | (0) | (0) | (36) | (2) | (0) | (0) | (22) | (2) | (0) | (0) |
| | inflammatory polyp | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 2 | 0 | 0 |
| | | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (4) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) —
ALL ANIMALS (0-105W)

PAGE : 29

| Organ | Findings | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|--------------------------|-------------------------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|
| | | Group Name | | | | 50 | | | | 50 | | | | 50 | | | |
| | | No. of Animals on Study | | | | Grade | | | | Grade | | | | Grade | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Urinary system} | | | | | | | | | | | | | | | | | |
| kidney | | | | | | | | | | | | | | | | | |
| | hydronephrosis | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | 3 | 0 | 0 | 0 | 0 | 0 | 4 | 0 * | 1 | 1 | 0 | 1 | 0 | 1 | 4 | 0 * |
| | | (6) | (0) | (0) | (0) | (0) | (0) | (8) | (0) | (2) | (2) | (0) | (2) | (0) | (2) | (8) | (0) |
| | tubular necrosis | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) |
| | glomerulosclerosis | 0 | 0 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (2) | (0) | (0) | (2) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| urin bladd | | | | | | | | | | | | | | | | | |
| | lymphocytic infiltration | <49> | | | | <49> | | | | <49> | | | | <50> | | | |
| | | 13 | 0 | 0 | 0 | 7 | 1 | 0 | 0 | 13 | 0 | 0 | 0 | 10 | 1 | 0 | 0 |
| | | (27) | (0) | (0) | (0) | (14) | (2) | (0) | (0) | (27) | (0) | (0) | (0) | (20) | (2) | (0) | (0) |
| {Endocrine system} | | | | | | | | | | | | | | | | | |
| pituitary | | | | | | | | | | | | | | | | | |
| | angiectasis | <50> | | | | <50> | | | | <48> | | | | <50> | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) |
| | cyst | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 30

| Organ | Findings | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|------------------------------|---------------------------------------|---------------------------|-----------|---------------------------|-----------|---------------------------|-----------|---------------------------|---------|-----|-----|-----|---------|-----|-----|-----|
| | | Group Name No. of Animals on Study | | | | 50 | | | | 50 | | | | 50 | | | |
| | | Grade | | | | 1 2 3 4 | | | | 1 2 3 4 | | | | 1 2 3 4 | | | |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Endocrine system} | | | | | | | | | | | | | | | | | |
| pituitary | hyperplasia | <50> | | | | <50> | | | | <48> | | | | <50> | | | |
| | | 1 4 1 0 | (2) (8) (2) (0) | 0 2 1 0 | (0) (4) (2) (0) | 0 4 0 0 | (0) (8) (0) (0) | 1 2 1 0 | (2) (4) (2) (0) | | | | | | | | |
| | Rathke pouch | <50> | | | | <50> | | | | <49> | | | | <50> | | | |
| | | 0 0 0 0 | (0) (0) (0) (0) | 1 0 0 0 | (2) (0) (0) (0) | 2 0 0 0 | (4) (0) (0) (0) | 2 0 0 0 | (4) (0) (0) (0) | | | | | | | | |
| thyroid | arteritis | <50> | | | | <50> | | | | <49> | | | | <50> | | | |
| | | 0 0 0 0 | (0) (0) (0) (0) | 0 1 0 0 | (0) (2) (0) (0) | 0 0 0 0 | (0) (0) (0) (0) | 0 0 0 0 | (0) (0) (0) (0) | | | | | | | | |
| adrenal | hemorrhage | <50> | | | | <50> | | | | <49> | | | | <50> | | | |
| | | 0 1 0 0 | (0) (2) (0) (0) | 0 0 0 0 | (0) (0) (0) (0) | 0 1 0 0 | (0) (2) (0) (0) | 0 0 0 0 | (0) (0) (0) (0) | | | | | | | | |
| | deposit of hemosiderin | <50> | | | | <50> | | | | <49> | | | | <50> | | | |
| | | 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 0 0 0 | (2) (0) (0) (0) | | | | | | | | |
| | extramedullary hematopoiesis | <50> | | | | <50> | | | | <49> | | | | <50> | | | |
| | | 1 0 0 0 | (2) (0) (0) (0) | 1 0 0 0 | (2) (0) (0) (0) | 0 0 0 0 | (0) (0) (0) (0) | 0 0 0 0 | (0) (0) (0) (0) | | | | | | | | |
| | spindle-cell hyperplasia | <50> | | | | <50> | | | | <49> | | | | <50> | | | |
| | | 21 29 0 0 | (42) (58) (0) (0) | 18 30 1 0 | (36) (60) (2) (0) | 22 26 0 0 | (45) (53) (0) (0) | 15 32 2 0 | (30) (64) (4) (0) | | | | | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 31

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|-----------------------|---------------------------|---------------------------------------|------|------|------|-------|------|------|------|-------|------|------|------|-------|-------|------|------|-------|-------|------|------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Endocrine system} | | | | | | | | | | | | | | | | | | | | | |
| adrenal | hyperplasia:medulla | <50> | | | | <50> | | | | <49> | | | | <50> | | | | | | | |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | focal fatty change:cortex | | | | | | | | | | | | | | | | | | | | |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) |
| {Reproductive system} | | | | | | | | | | | | | | | | | | | | | |
| ovary | hemorrhage | <50> | | | | <50> | | | | <49> | | | | <50> | | | | | | | |
| | | 1 | 2 | 0 | 0 | 0 | 0 | 1 | 0 | 2 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 1 | 0 | 0 |
| | | (2) | (4) | (0) | (0) | (0) | (0) | (2) | (0) | (4) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (2) | (2) | (0) | (0) |
| | cyst | | | | | | | | | | | | | | | | | | | | |
| | | 12 | 3 | 0 | 0 | 7 | 2 | 0 | 0 | 13 | 4 | 0 | 0 | 14 | 7 | 1 | 0 | 14 | 7 | 1 | 0 |
| | | (24) | (6) | (0) | (0) | (14) | (4) | (0) | (0) | (27) | (8) | (0) | (0) | (28) | (14) | (2) | (0) | (28) | (14) | (2) | (0) |
| | mastcell hyperplasia | | | | | | | | | | | | | | | | | | | | |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| uterus | thrombus | <49> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 32

| Organ | Findings | Group Name No. of Animals on Study | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|-----------------------|--------------------------------|---------------------------------------|-------|------|------|-------|-------|------|------|-------|-------|------|------|-------|-------|------|------|-------|-------|------|------|
| | | Grade | | | | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Reproductive system} | | | | | | | | | | | | | | | | | | | | | |
| uterus | | <49> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | cystic endometrial hyperplasia | 24 | 8 | 0 | 0 | 23 | 10 | 0 | 0 | 22 | 18 | 0 | 0 | 20 | 10 | 0 | 0 | 20 | 10 | 0 | 0 |
| | | (49) | (16) | (0) | (0) | (46) | (20) | (0) | (0) | (44) | (36) | (0) | (0) | (40) | (20) | (0) | (0) | (40) | (20) | (0) | (0) |
| mammary gl | | <50> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | hyperplasia | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | atypical hyperplasia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | galactoceles | 1 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 3 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (6) | (0) | (0) | (0) |
| prep/cli gl | | <50> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | duct ectasia | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Nervous system} | | | | | | | | | | | | | | | | | | | | | |
| brain | | <50> | | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | mineralization | 18 | 0 | 0 | 0 | 17 | 0 | 0 | 0 | 11 | 0 | 0 | 0 | 14 | 0 | 0 | 0 | 14 | 0 | 0 | 0 |
| | | (36) | (0) | (0) | (0) | (34) | (0) | (0) | (0) | (22) | (0) | (0) | (0) | (28) | (0) | (0) | (0) | (28) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 33

| Organ | Findings | Group Name No. of Animals on Study Grade | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------------------|---------------------------|--|-------|-------|-------|-------|-------|-------|-------|-------|--------|-------|-------|-------|-------|-------|-------|-------|
| | | | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Nervous system} | | | | | | | | | | | | | | | | | | |
| brain | perivascular inflammation | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| spinal cord | necrosis:focal | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | perivascular inflammation | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Special sense organs/appendage} | | | | | | | | | | | | | | | | | | |
| Harder gl | thrombus | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | lymphocytic infiltration | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 3 | 0 | 0 | 0 |
| | | | (6) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (6) | (0) | (0) | (0) |
| {Musculoskeletal system} | | | | | | | | | | | | | | | | | | |
| muscle | mineralization | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 34

| Organ | Findings | Group Name No. of Animals on Study Grade | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|-----------------|--------------|--|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Body cavities} | | | | | | | | | | | | | | | | | | |
| pleura | | | | | | | | | | | | | | | | | | |
| | inflammation | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| peritoneum | | | | | | | | | | | | | | | | | | |
| | inflammation | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

(HPT150)

BAIS3

APPENDIX J 5

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY,
MOUSE: FEMALE: DEAD AND MORIBUND ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 11

| Organ | Findings | Group Name No. of Animals on Study | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------------------|--|---------------------------------------|-------|-------|-------|--------|-------|-------|-------|-------|-------|-------|-------|-------|--------|--------|-------|-------|-------|-------|-------|
| | | Grade | | | | 20 | | | | 25 | | | | 20 | | | | 16 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Integumentary system/appandage} | | | | | | | | | | | | | | | | | | | | | |
| skin/app | mastcell hyperplasia | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyperplasia:epidermis | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| subcutis | congestion | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | exudate | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 12 | 3 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (5) | (0) | (0) | (0) | (75) | (19) | (0) | (0) | (0) | (0) | (0) |
| | mineralization | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | eosinophilic change:olfactory epithelium | 5 | 1 | 1 | 0 | 3 | 2 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (25) | (5) | (5) | (0) | (12) | (8) | (0) | (0) | (5) | (0) | (0) | (0) | (6) | (6) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) —
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 12

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|---|---------------------------------------|------------|-----------|-----------|------------|-------------|-----------|-------------|------------|------------|-----------|-------------|-------------|-------------|-----------|--------------|-------|-----|-----|-----|
| | | Grade | | | | 20 | | | | 25 | | | | 20 | | | | 16 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | eosinophilic change:respiratory epithelium | 11 (55) | 4 (20) | 0 (0) | 0 (0) | 7 (28) | 16 (64) | 1 (4) | 0 * (0) | 3 (15) | 3 (15) | 0 (0) | 0 * (0) | 5 (31) | 0 (0) | 0 (0) | 0 * (0) | | | | |
| | inflammation: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) | 4 (25) | 1 (6) | 0 (0) | 0 * (0) | | | | |
| | inflammation:olfactory 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) | 0 (0) | 1 (6) | 0 (0) | 0 (0) | | | | |
| | respiratory metaplasia:olfactory epithelium | 3 (15) | 0 (0) | 0 (0) | 0 (0) | 6 (24) | 0 (0) | 0 (0) | 0 (0) | 2 (10) | 0 (0) | 0 (0) | 0 (0) | 1 (6) | 13 (81) | 1 (6) | 0 ** (0) | | | | |
| | respiratory metaplasia:gland | 1 (5) | 0 (0) | 0 (0) | 0 (0) | 3 (12) | 0 (0) | 0 (0) | 0 (0) | 1 (5) | 0 (0) | 0 (0) | 0 (0) | 4 (25) | 1 (6) | 0 (0) | 0 (0) | | | | |
| | squamous cell metaplasia: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 (19) | 7 (44) | 0 (0) | 0 ** (0) | | | | |
| | cuboidal change:respiratory epithelium | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (5) | 1 (5) | 0 (0) | 0 (0) | 4 (25) | 10 (63) | 1 (6) | 0 ** (0) | | | | |
| | atrophy:olfactory epithelium | 1 (5) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 10 (63) | 5 (31) | 0 (0) | 0 ** (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 13

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|------------------------------------|---------------------------------------|-------|-------|-------|-------|-------|-------|-------|--------|-------|-------|-------|--------|--------|-------|-------|-------|-----|-----|-----|
| | | Grade | | | | 20 | | | | 25 | | | | 20 | | | | 16 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | atrophy:respiratory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 1 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (19) | (6) | (0) | (0) | | | | |
| | necrosis:olfactory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (13) | (0) | (0) | (0) | | | | |
| | edema:lamina propria | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (13) | (0) | (0) | (0) | | | | |
| | necrosis:respiratory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 5 | 0 | 0 ** | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (31) | (31) | (0) | (0) | | | | |
| | hyperplasia:respiratory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (19) | (0) | (0) | (0) | | | | |
| nasopharynx | | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | eosinophilic change | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |
| trachea | | <20> | | | | <25> | | | | <19> | | | | <16> | | | | | | | |
| | eosinophilic change | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 14

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|-----------------------------|---------------------------------------|-------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-------|------|------|------|
| | | Grade | | | | 20 | | | | 25 | | | | 20 | | | | 16 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| trachea | necrosis:epithelium | <20> | | | | <25> | | | | <19> | | | | <16> | | | | | | | |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| lung | congestion | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | | 0 | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (15) | (0) | (0) | (0) | (4) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hemorrhage | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | edema | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (5) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | thrombus | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (5) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory infiltration | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) |
| | fibrosis | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | accumulation of foamy cells | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 15

| Organ | Findings | Group Name No. of Animals on Study | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------------|---------------------------------------|---------------------------------------|------|------|------|------|------|------|------|-------|------|------|------|-------|------|------|------|-------|------|------|------|
| | | Grade | | | | 20 | | | | 25 | | | | 20 | | | | 16 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| lung | | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | bronchiolar cell hyperplasia | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | bronchiolar-alveolar cell hyperplasia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyaline membrane | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | | | |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | | | | |
| bone marrow | | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | myelofibrosis | 3 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | | | | |
| | | (15) | (0) | (0) | (0) | (4) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (13) | (0) | (0) | (0) | | | | |
| | erythropoiesis:increased | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | |
| | | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | | | | |
| | erythropoiesis:decreased | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | | | | |
| | granulopoiesis:increased | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | |
| | | (5) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) —
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 16

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------------|------------------------------|---------------------------------------|--------|--------|-------|--------|--------|--------|-------|--------|-------|--------|-------|-------|--------|--------|-------|-------|-------|-------|-------|
| | | Grade | | | | 20 | | | | 25 | | | | 20 | | | | 16 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | | | | |
| lymph node | | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | mastcell hyperplasia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | lymphadenitis | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (6) | (0) | (0) | | | | |
| thymus | | <20> | | | | <25> | | | | <19> | | | | <16> | | | | | | | |
| | cyst | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| spleen | | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | hemorrhage | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | thrombus | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | | | | |
| | extramedullary hematopoiesis | 3 | 7 | 3 | 0 | 3 | 4 | 4 | 0 | 4 | 1 | 3 | 0 | 1 | 4 | 4 | 0 | | | | |
| | | (15) | (35) | (15) | (0) | (12) | (16) | (16) | (0) | (20) | (5) | (15) | (0) | (6) | (25) | (25) | (0) | | | | |
| | follicular hyperplasia | 2 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (10) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) -
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 17

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|---------------------|---------------------------------------|-------|-------|-------|--------|-------|-------|-------|-------|-------|-------|-------|-------|--------|-------|-------|--------|-------|-------|-------|
| | | Grade | | | | 20 | | | | 25 | | | | 20 | | | | 16 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Circulatory system} | | | | | | | | | | | | | | | | | | | | | |
| heart | thrombus | <20> | | | | 0 | 0 | 0 | 0 | <25> | | | | 0 | 0 | 1 | 0 | <16> | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (4) | (4) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (6) | (0) | (0) |
| | mineralization | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (13) | (0) | (0) | (0) |
| | myocardial fibrosis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (0) | (0) | (0) |
| | arteritis | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (5) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| artery/aort | arteritis | <20> | | | | 0 | 0 | 0 | 0 | <25> | | | | 0 | 0 | 0 | 0 | <16> | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| tooth | dysplasia | <20> | | | | 4 | 0 | 0 | 0 | <25> | | | | 1 | 0 | 0 | 0 | <20> | | | |
| | | (20) | (0) | (0) | (0) | (20) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (25) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 18

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|-------------------------------|---------------------------------------|--------|-------|-------|--------|--------|-------|-------|--------|--------|--------|-------|--------|--------|-------|-------|-------|-------|-------|-------|
| | | Grade | | | | 20 | | | | 25 | | | | 20 | | | | 16 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| tongue | | <20> | | | | <25> | | | | <19> | | | | <16> | | | | | | | |
| | arteritis | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| salivary gl | | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | lymphocytic infiltration | 3 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (15) | (0) | (0) | (0) | (20) | (0) | (0) | (0) | (15) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| stomach | | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | erosion:glandular stomach | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyperplasia:glandular stomach | 9 | 11 | 0 | 0 | 7 | 14 | 0 | 0 | 7 | 9 | 3 | 0 | 8 | 2 | 0 | 0 | 0 | 0 | 0 | ** |
| | | (45) | (55) | (0) | (0) | (28) | (56) | (0) | (0) | (35) | (45) | (15) | (0) | (50) | (13) | (0) | (0) | (0) | (0) | (0) | (0) |
| large intes | | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | thrombus | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| liver | | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | angiectasis | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (5) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | necrosis:central | 0 | 2 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (10) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 19

| Organ | Findings | Group Name No. of Animals on Study Grade | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|---------------------------|--|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | 20 | | | | 25 | | | | 20 | | | | 16 | | | | | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| liver | | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | necrosis:focal | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (5) | (5) | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory infiltration | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | granulation | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory cell nest | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | perivascular inflammation | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | acidophilic cell focus | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (5) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | basophilic cell focus | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | biliary cyst | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 20

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|------------------------|---------------------------------------|--------|--------|-------|--------|--------|-------|-------|--------|--------|-------|-------|-------|--------|--------|-------|-------|-------|-------|-------|
| | | Grade | | | | 20 | | | | 25 | | | | 20 | | | | 16 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| gall bladd | dilatation | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Urinary system} | | | | | | | | | | | | | | | | | | | | | |
| kidney | infarct | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) |
| | cyst | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyaline droplet | 1 | 3 | 2 | 0 | 1 | 5 | 1 | 0 | 0 | 3 | 0 | 0 | 1 | 2 | 3 | 0 | | | | |
| | | (5) | (15) | (10) | (0) | (4) | (20) | (4) | (0) | (0) | (15) | (0) | (0) | (6) | (13) | (19) | (0) | | | | |
| | basophilic change | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | deposit of hemosiderin | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | | | | |
| | hyaline cast | 1 | 1 | 0 | 0 | 4 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | | | | |
| | | (5) | (5) | (0) | (0) | (16) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 21

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|--------------------------|---------------------------------------|------|------|------|------|------|------|------|-------|------|------|------|------|------|-------|------|-------|------|------|------|
| | | Grade | | | | 20 | | | | 25 | | | | 20 | | | | 16 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Urinary system} | | | | | | | | | | | | | | | | | | | | | |
| kidney | | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | lymphocytic infiltration | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (10) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (15) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory polyp | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) |
| | hydronephrosis | 1 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 1 | 1 | 0 | 1 | 0 | 1 | 2 | 0 | 0 | 0 | 0 | 0 |
| | | (5) | (0) | (0) | (0) | (0) | (0) | (8) | (0) | (5) | (5) | (0) | (5) | (0) | (6) | (13) | (0) | (0) | (0) | (0) | (0) |
| | tubular necrosis | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | glomerulosclerosis | 0 | 0 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (5) | (0) | (0) | (4) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| urin bladd | | <19> | | | | <24> | | | | <19> | | | | <16> | | | | | | | |
| | lymphocytic infiltration | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (16) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Endocrine system} | | | | | | | | | | | | | | | | | | | | | |
| pituitary | | <20> | | | | <25> | | | | <18> | | | | <16> | | | | | | | |
| | angiectasis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 22

| | | Group Name | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|---------------------------|------------------------------|-------------------------|--------|--------|-------|--------|--------|-------|-------|--------|--------|-------|-------|--------|--------|-------|-------|-------|
| | | No. of Animals on Study | 20 | | | | 25 | | | | 20 | | | | 16 | | | |
| Organ | Findings | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | | | | | | | | | | | | | | | | |
| {Endocrine system} | | | | | | | | | | | | | | | | | | |
| pituitary | Rathke pouch | | <20> | | | | <25> | | | | <18> | | | | <16> | | | |
| | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| thyroid | arteritis | | <20> | | | | <25> | | | | <19> | | | | <16> | | | |
| | | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| adrenal | hemorrhage | | <20> | | | | <25> | | | | <20> | | | | <16> | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) |
| | extramedullary hematopoiesis | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | spindle-cell hyperplasia | | 10 | 10 | 0 | 0 | 14 | 10 | 0 | 0 | 11 | 8 | 0 | 0 | 11 | 5 | 0 | 0 |
| | | (50) | (50) | (0) | (0) | (56) | (40) | (0) | (0) | (55) | (40) | (0) | (0) | (69) | (31) | (0) | (0) | |
| focal fatty change:cortex | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | |
| {Reproductive system} | | | | | | | | | | | | | | | | | | |
| ovary | hemorrhage | | <20> | | | | <25> | | | | <19> | | | | <16> | | | |
| | | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 23

| Organ | Findings | Group Name No. of Animals on Study Grade | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------------------|--------------------------------|--|-------|------|------|-------|-------|------|------|-------|-------|------|------|-------|------|------|------|-------|-----|-----|-----|
| | | 20 | | | | 25 | | | | 20 | | | | 16 | | | | | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Reproductive system} | | | | | | | | | | | | | | | | | | | | | |
| ovary | cyst | <20> | | | | <25> | | | | <19> | | | | <16> | | | | | | | |
| | | 2 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 4 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | | | | |
| | | (10) | (5) | (0) | (0) | (4) | (0) | (0) | (0) | (21) | (5) | (0) | (0) | (6) | (6) | (0) | (0) | | | | |
| uterus | cystic endometrial hyperplasia | <19> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | | 3 | 2 | 0 | 0 | 9 | 4 | 0 | 0 | 10 | 2 | 0 | 0 | 3 | 1 | 0 | 0 | | | | |
| | | (16) | (11) | (0) | (0) | (36) | (16) | (0) | (0) | (50) | (10) | (0) | (0) | (19) | (6) | (0) | (0) | | | | |
| mammary gl | galactoceles | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (13) | (0) | (0) | (0) | | | | |
| {Nervous system} | | | | | | | | | | | | | | | | | | | | | |
| brain | mineralization | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | | 7 | 0 | 0 | 0 | 8 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | | | | |
| | | (35) | (0) | (0) | (0) | (32) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (19) | (0) | (0) | (0) | | | | |
| spinal cord | necrosis:focal | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |
| {Special sense organs/appendage} | | | | | | | | | | | | | | | | | | | | | |
| Harder gl | thrombus | <20> | | | | <25> | | | | <20> | | | | <16> | | | | | | | |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 24

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|-------|----------|---------------------------------------|-----|-----|-----|------|-----|-----|-----|------|-----|-----|-----|------|-----|-----|-----|-------|-----|-----|-----|
| | | Grade | | | | 20 | | | | 25 | | | | 20 | | | | 16 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |

{Special sense organs/appendage}

| | | | | | | | | | | | | | | | | | |
|-----------|--------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| Harder gl | lymphocytic infiltration | <20> | | | | <25> | | | | <20> | | | | <16> | | | |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

{Musculoskeletal system}

| | | | | | | | | | | | | | | | | | |
|--------|----------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| muscle | mineralization | <20> | | | | <25> | | | | <20> | | | | <16> | | | |
| | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

{Body cavities}

| | | | | | | | | | | | | | | | | | |
|--------|--------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| pleura | inflammation | <20> | | | | <25> | | | | <20> | | | | <16> | | | |
| | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

(HPT150)

BAIS3

APPENDIX J 6

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY,
MOUSE: FEMALE: SACRIFICED ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 14

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|---|---------------------------------------|--------|-------|-------|--------|--------|-------|-------|--------|--------|-------|-------|--------|--------|--------|-------|-------|-----|-----|-----|
| | | Grade | | | | 30 | | | | 25 | | | | 30 | | | | 34 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | exudate | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 18 | 11 | 0 | ** | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (53) | (32) | (0) | | | | |
| | hyperplasia:gland | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | | | | |
| | eosinophilic change:olfactory epithelium | 14 | 1 | 0 | 0 | 5 | 3 | 0 | 0 | 2 | 0 | 0 | 0 | 8 | 4 | 0 | 0 | | | | |
| | | (47) | (3) | (0) | (0) | (20) | (12) | (0) | (0) | (7) | (0) | (0) | (0) | (24) | (12) | (0) | (0) | | | | |
| | eosinophilic change:respiratory epithelium | 18 | 6 | 0 | 0 | 6 | 17 | 0 | 0 | 11 | 9 | 0 | 0 | 18 | 4 | 0 | 0 | | | | |
| | | (60) | (20) | (0) | (0) | (24) | (68) | (0) | (0) | (37) | (30) | (0) | (0) | (53) | (12) | (0) | (0) | | | | |
| | inflammation:respiratory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 7 | 0 | 0 | 0 | * | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (21) | (0) | (0) | (0) | | | | |
| | respiratory metaplasia:olfactory epithelium | 5 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 4 | 30 | 0 | 0 | ** | | | |
| | | (17) | (0) | (0) | (0) | (16) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (12) | (88) | (0) | (0) | | | | |
| | respiratory metaplasia:gland | 3 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 7 | 3 | 0 | 0 | 12 | 13 | 0 | 0 | ** | | | |
| | | (10) | (0) | (0) | (0) | (12) | (0) | (0) | (0) | (23) | (10) | (0) | (0) | (35) | (38) | (0) | (0) | | | | |
| | squamous cell metaplasia:respiratory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 11 | 9 | 0 | 0 | ** | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (32) | (26) | (0) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 15

| Organ | Findings | Group Name No. of Animals on Study Grade | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------|--|--|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|--------|--------|-------|-------|-------|-----|-----|-----|
| | | 30 | | | | 25 | | | | 30 | | | | 34 | | | | | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| nasal cavit | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | cuboidal change:respiratory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 0 | 0 | 8 | 11 | 2 | 0 | ** | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (7) | (7) | (0) | (0) | (24) | (32) | (6) | (0) | | | | |
| | atrophy:olfactory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 25 | 5 | 0 | 0 | ** | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (74) | (15) | (0) | (0) | | | | |
| | atrophy:respiratory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 1 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (12) | (3) | (0) | (0) | | | | |
| | necrosis:olfactory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | | | | |
| | edema:lamina propria | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | | | | |
| | necrosis:respiratory epithelium | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 9 | 0 | 0 | 0 | * | | | |
| | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (26) | (0) | (0) | (0) | | | | |
| | hyperplasia:respiratory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | | | | |
| nasopharynx | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | eosinophilic change | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | | | | |
| | | (3) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (12) | (0) | (0) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 16

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------------|---------------------------------------|---------------------------------------|-------|-------|-------|-------|-------|-------|-------|--------|-------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|
| | | Grade | | | | 30 | | | | 25 | | | | 30 | | | | 34 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | | | | |
| lung | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | hemorrhage | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory infiltration | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (6) | (0) | (0) | (0) |
| | perivascular inflammation | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (3) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) |
| | fibrosis | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | accumulation of foamy cells | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (0) | (3) | (0) | (0) | (4) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (6) | (0) | (0) | (0) |
| | bronchiolar-alveolar cell hyperplasia | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) |
| | hyaline membrane | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | | | | |
| bone marrow | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | myelofibrosis | 0 | 1 | 0 | 0 | 1 | 2 | 0 | 0 | 2 | 1 | 0 | 0 | 3 | 4 | 0 | 0 | 3 | 4 | 0 | 0 |
| | | (0) | (3) | (0) | (0) | (4) | (8) | (0) | (0) | (7) | (3) | (0) | (0) | (9) | (12) | (0) | (0) | (9) | (12) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) -
SACRIFICED ANIMALS (105W)

PAGE : 17

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------------|--------------------------|---------------------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | Grade | | | | 30 | | | | 25 | | | | 30 | | | | 34 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | | | | |
| bone marrow | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | erythropoiesis:increased | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | granulopoiesis:increased | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) |
| lymph node | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | mastcell hyperplasia | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | lymphadenitis | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | follicular hyperplasia | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (3) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) |
| thymus | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | cyst | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| spleen | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | deposit of melanin | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 3 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (9) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 18

| Organ_____ | Findings_____ | Group Name No. of Animals on Study | | | | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------------|------------------------------|---------------------------------------|------------|-----------|-----------|------------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-------|--|--|--|
| | | Grade | | | | 30 | | | | 25 | | | | 30 | | | | 34 | | | |
| | | 1 (%) | 2 (%) | 3 (%) | 4 (%) | 1 (%) | 2 (%) | 3 (%) | 4 (%) | 1 (%) | 2 (%) | 3 (%) | 4 (%) | 1 (%) | 2 (%) | 3 (%) | 4 (%) | | | | |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | | | | |
| spleen | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | extramedullary hematopoiesis | 3 (10) | 1 (3) | 2 (7) | 0 (0) | 4 (16) | 1 (4) | 0 (0) | 0 (0) | 1 (3) | 0 (0) | 0 (0) | 0 (0) | 1 (3) | 1 (3) | 0 (0) | 0 (0) | | | | |
| | follicular hyperplasia | 3 (10) | 3 (10) | 1 (3) | 0 (0) | 1 (4) | 3 (12) | 0 (0) | 0 (0) | 2 (7) | 1 (3) | 0 (0) | 0 (0) | 2 (6) | 0 (0) | 0 (0) | 0 (0) | | | | |
| {Circulatory system} | | | | | | | | | | | | | | | | | | | | | |
| heart | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | mineralization | 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 (3) | 0 (0) | 0 (0) | 0 (0) | | | | |
| | pericarditis | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (4) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | | | |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| tooth | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | inflammation | 0 (0) | 1 (3) | 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) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 19

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|---------------------------|---------------------------------------|------|------|------|-------|------|------|------|-------|------|------|------|-------|------|------|------|-------|-----|-----|-----|
| | | Grade | | | | 30 | | | | 25 | | | | 30 | | | | 34 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| tooth | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | dysplasia | 9 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 9 | 0 | 0 | 0 | | | | |
| | | (30) | (0) | (0) | (0) | (20) | (0) | (0) | (0) | (20) | (0) | (0) | (0) | (26) | (0) | (0) | (0) | | | | |
| tongue | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | arteritis | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | | | | |
| | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | | | | |
| salivary gl | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | lymphocytic infiltration | 17 | 0 | 0 | 0 | 12 | 0 | 0 | 0 | 18 | 0 | 0 | 0 | 12 | 0 | 0 | 0 | | | | |
| | | (57) | (0) | (0) | (0) | (48) | (0) | (0) | (0) | (60) | (0) | (0) | (0) | (35) | (0) | (0) | (0) | | | | |
| stomach | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | inflammatory infiltration | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |
| | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | erosion:forestomach | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |
| | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | hyperplasia:forestomach | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | | | | |
| | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | erosion:glandular stomach | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (4) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 20

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|-------------------------------|---------------------------------------|--------|-------|-------|--------|--------|--------|-------|--------|--------|--------|-------|--------|--------|-------|-------|-------|-------|-------|-------|
| | | Grade | | | | 30 | | | | 25 | | | | 30 | | | | 34 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| stomach | hyperplasia:glandular stomach | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | | 8 | 20 | 1 | 0 | 4 | 18 | 3 | 0 | 3 | 21 | 5 | 0 | 17 | 9 | 2 | 0 * | | | | |
| | | (27) | (67) | (3) | (0) | (16) | (72) | (12) | (0) | (10) | (70) | (17) | (0) | (50) | (26) | (6) | (0) | | | | |
| small intes | inflammation | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| liver | angiectasis | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | | 2 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 3 | 0 | 0 | 3 | 0 | 0 | 0 | | | | |
| | | (7) | (3) | (0) | (0) | (4) | (0) | (0) | (0) | (3) | (10) | (0) | (0) | (9) | (0) | (0) | (0) | | | | |
| | necrosis:central | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |
| | inflammatory infiltration | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 2 | 0 | 0 | 2 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (3) | (0) | (4) | (0) | (0) | (0) | (3) | (7) | (0) | (0) | (6) | (0) | (0) | (0) | | | | |
| | inflammatory cell nest | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | | 17 | 6 | 0 | 0 | 17 | 1 | 0 | 0 | 18 | 4 | 0 | 0 | 25 | 3 | 0 | 0 | | | | |
| | | (57) | (20) | (0) | (0) | (68) | (4) | (0) | (0) | (60) | (13) | (0) | (0) | (74) | (9) | (0) | (0) | | | | |
| | perivascular inflammation | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 21

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|------------------------------------|---------------------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-------|------|------|------|
| | | Grade | | | | 30 | | | | 25 | | | | 30 | | | | 34 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| liver | clear cell focus | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | acidophilic cell focus | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | basophilic cell focus | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | biliary cyst | 1 | 1 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (3) | (3) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hepatocellular hypertrophy:central | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| gall bladd | erosion | <29> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| pancreas | atrophy | <30> | | | | <24> | | | | <30> | | | | <34> | | | | | | | |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 22

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------|--------------------------|---------------------------------------|--------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|--------|-------|-------|-------|-------|-----|-----|-----|
| | | Grade | | | | 30 | | | | 25 | | | | 30 | | | | 34 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Urinary system} | | | | | | | | | | | | | | | | | | | | | |
| kidney | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | infarct | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | |
| | | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | | | | |
| | hyaline droplet | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | | | | |
| | | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (3) | (0) | | | | |
| | basophilic change | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (3) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |
| | hyaline cast | 0 | 0 | 0 | 0 | 6 | 1 | 0 | 0 ** | 7 | 0 | 0 | 0 * | 2 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (24) | (4) | (0) | (0) | (23) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | | | | |
| | lymphocytic infiltration | 13 | 3 | 0 | 0 | 13 | 1 | 0 | 0 | 15 | 1 | 0 | 0 | 11 | 1 | 0 | 0 | | | | |
| | | (43) | (10) | (0) | (0) | (52) | (4) | (0) | (0) | (50) | (3) | (0) | (0) | (32) | (3) | (0) | (0) | | | | |
| | inflammatory polyp | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | | | | |
| | | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | | | | |
| | hydronephrosis | 2 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | | | | |
| | | (7) | (0) | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (6) | (0) | | | | |
| urin bladd | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | lymphocytic infiltration | 10 | 0 | 0 | 0 | 7 | 1 | 0 | 0 | 12 | 0 | 0 | 0 | 10 | 1 | 0 | 0 | | | | |
| | | (33) | (0) | (0) | (0) | (28) | (4) | (0) | (0) | (40) | (0) | (0) | (0) | (29) | (3) | (0) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 23

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|--------------------|------------------------------|---------------------------------------|--------|-------|-------|--------|--------|-------|-------|--------|--------|-------|-------|--------|--------|-------|-------|-------|-----|-----|-----|
| | | Grade | | | | 30 | | | | 25 | | | | 30 | | | | 34 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Endocrine system} | | | | | | | | | | | | | | | | | | | | | |
| pituitary | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | angiectasis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | | | | |
| | cyst | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | | | | |
| | hyperplasia | 1 | 4 | 1 | 0 | 0 | 2 | 1 | 0 | 0 | 4 | 0 | 0 | 1 | 2 | 1 | 0 | | | | |
| | | (3) | (13) | (3) | (0) | (0) | (8) | (4) | (0) | (0) | (13) | (0) | (0) | (3) | (6) | (3) | (0) | | | | |
| | Rathke pouch | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | | | | |
| adrenal | | <30> | | | | <25> | | | | <29> | | | | <34> | | | | | | | |
| | hemorrhage | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |
| | deposit of hemosiderin | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | | | | |
| | extramedullary hematopoiesis | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |
| | spindle-cell hyperplasia | 11 | 19 | 0 | 0 | 4 | 20 | 1 | 0 | 11 | 18 | 0 | 0 | 4 | 27 | 2 | 0 | | | | |
| | | (37) | (63) | (0) | (0) | (16) | (80) | (4) | (0) | (38) | (62) | (0) | (0) | (12) | (79) | (6) | (0) | | | | |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 24

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|-----------------------|---------------------------|---------------------------------------|------------|------------|------------|-------------|------------|------------|------------|-------------|-------------|------------|------------|--------------|-------------|------------|------------|------------|-------------|------------|------------|
| | | Grade | | | | 30 | | | | 25 | | | | 30 | | | | 34 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Endocrine system} | | | | | | | | | | | | | | | | | | | | | |
| adrenal | | <30> | | | | <25> | | | | <29> | | | | <34> | | | | | | | |
| | hyperplasia:medulla | 1 (3) | 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) | 0 (0) | 0 (0) | 0 (0) |
| | focal fatty change:cortex | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (3) | 0 (0) | 0 (0) | 0 (0) | 1 (3) | 0 (0) | 0 (0) | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| {Reproductive system} | | | | | | | | | | | | | | | | | | | | | |
| ovary | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | hemorrhage | 1 (3) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (4) | 0 (0) | 2 (7) | 0 (0) | 0 (0) | 0 (0) | 1 (3) | 1 (3) | 0 (0) | 0 (0) | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| | cyst | 10 (33) | 2 (7) | 0 (0) | 0 (0) | 6 (24) | 2 (8) | 0 (0) | 0 (0) | 9 (30) | 3 (10) | 0 (0) | 0 (0) | 13 (38) | 6 (18) | 1 (3) | 0 (0) | 0 (0) | 6 (18) | 1 (3) | 0 (0) |
| | mastcell hyperplasia | 1 (3) | 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) | 0 (0) | 0 (0) | 0 (0) |
| uterus | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | thrombus | 0 (0) | 0 (0) | 1 (3) | 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) | 0 (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 25

| Organ | Findings | Group Name No. of Animals on Study Grade | 0ppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|-----------------------|--------------------------------|--|-------------|------------|-----------|-----------|-------------|------------|-----------|-----------|-------------|-------------|-----------|-------------|-------------|------------|-----------|-----------|
| | | | 30 | | | | 25 | | | | 30 | | | | 34 | | | |
| | | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Reproductive system} | | | | | | | | | | | | | | | | | | |
| uterus | | | <30> | | | | <25> | | | | <30> | | | | <34> | | | |
| | cystic endometrial hyperplasia | | 21 (70) | 6 (20) | 0 (0) | 0 (0) | 14 (56) | 6 (24) | 0 (0) | 0 (0) | 12 (40) | 16 (53) | 0 (0) | 0 * (0) | 17 (50) | 9 (26) | 0 (0) | 0 (0) |
| mammary gl | | | <30> | | | | <25> | | | | <30> | | | | <34> | | | |
| | hyperplasia | | 1 (3) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (3) | 0 (0) | 0 (0) | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| | atypical hyperplasia | | 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 (3) | 0 (0) | 0 (0) | 0 (0) |
| | galactoceles | | 1 (3) | 0 (0) | 0 (0) | 0 (0) | 2 (8) | 0 (0) | 0 (0) | 0 (0) | 2 (7) | 0 (0) | 0 (0) | 0 (0) | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| prep/cli gl | | | <30> | | | | <25> | | | | <30> | | | | <34> | | | |
| | duct ectasia | | 0 (0) | 1 (3) | 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) |
| {Nervous system} | | | | | | | | | | | | | | | | | | |
| brain | | | <30> | | | | <25> | | | | <30> | | | | <34> | | | |
| | mineralization | | 11 (37) | 0 (0) | 0 (0) | 0 (0) | 9 (36) | 0 (0) | 0 (0) | 0 (0) | 9 (30) | 0 (0) | 0 (0) | 0 (0) | 11 (32) | 0 (0) | 0 (0) | 0 (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 26

| Organ | Findings | Group Name No. of Animals on Study | | | | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------------------|---------------------------|---------------------------------------|-------|-------|-------|-------|-------|-------|-------|--------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | Grade | | | | 30 | | | | 25 | | | | 30 | | | | 34 | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Nervous system} | | | | | | | | | | | | | | | | | | | | | |
| brain | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | perivascular inflammation | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| spinal cord | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | perivascular inflammation | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Special sense organs/appendage} | | | | | | | | | | | | | | | | | | | | | |
| Harder gl | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | lymphocytic infiltration | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (7) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Body cavities} | | | | | | | | | | | | | | | | | | | | | |
| peritoneum | | <30> | | | | <25> | | | | <30> | | | | <34> | | | | | | | |
| | inflammation | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

APPENDIX K 1

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS-TIME RELATED
MOUSE: MALE
(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

PAGE : 1

| Time-related Weeks | Items | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|-----------------------|-------------------------------------|------------|------|------|------|-------|
| 0 - 52 | NO. OF EXAMINED ANIMALS | | 3 | 5 | 1 | 2 |
| | NO. OF ANIMALS WITH TUMORS | | 1 | 1 | 0 | 0 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 1 | 1 | 0 | 0 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 0 | 0 | 0 | 0 |
| | NO. OF BENIGN TUMORS | | 0 | 1 | 0 | 0 |
| | NO. OF MALIGNANT TUMORS | | 1 | 0 | 0 | 0 |
| | NO. OF TOTAL TUMORS | | 1 | 1 | 0 | 0 |
| 53 - 78 | NO. OF EXAMINED ANIMALS | | 0 | 4 | 5 | 2 |
| | NO. OF ANIMALS WITH TUMORS | | 0 | 2 | 2 | 0 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 0 | 2 | 2 | 0 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 0 | 0 | 0 | 0 |
| | NO. OF BENIGN TUMORS | | 0 | 1 | 0 | 0 |
| | NO. OF MALIGNANT TUMORS | | 0 | 1 | 2 | 0 |
| | NO. OF TOTAL TUMORS | | 0 | 2 | 2 | 0 |
| 79 - 104 | NO. OF EXAMINED ANIMALS | | 14 | 11 | 6 | 2 |
| | NO. OF ANIMALS WITH TUMORS | | 12 | 10 | 5 | 1 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 9 | 5 | 4 | 1 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 3 | 5 | 1 | 0 |
| | NO. OF BENIGN TUMORS | | 4 | 12 | 1 | 0 |
| | NO. OF MALIGNANT TUMORS | | 12 | 7 | 5 | 1 |
| | NO. OF TOTAL TUMORS | | 16 | 19 | 6 | 1 |
| 105 - 105 | NO. OF EXAMINED ANIMALS | | 27 | 24 | 30 | 35 |
| | NO. OF ANIMALS WITH TUMORS | | 21 | 19 | 20 | 10 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 12 | 9 | 12 | 9 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 9 | 10 | 8 | 1 |
| | NO. OF BENIGN TUMORS | | 15 | 16 | 16 | 5 |
| | NO. OF MALIGNANT TUMORS | | 19 | 19 | 17 | 6 |
| | NO. OF TOTAL TUMORS | | 34 | 35 | 33 | 11 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

PAGE : 2

| Time-related Weeks | Items | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|-----------------------|-------------------------------------|------------|------|------|------|-------|
| 0 - 105 | NO. OF EXAMINED ANIMALS | | 50 | 50 | 50 | 49 |
| | NO. OF ANIMALS WITH TUMORS | | 34 | 32 | 27 | 11 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 22 | 17 | 18 | 10 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 12 | 15 | 9 | 1 |
| | NO. OF BENIGN TUMORS | | 19 | 30 | 17 | 5 |
| | NO. OF MALIGNANT TUMORS | | 32 | 27 | 24 | 7 |
| | NO. OF TOTAL TUMORS | | 51 | 57 | 41 | 12 |

(HPT070)

BAIS3

APPENDIX K 2

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS-TIME RELATED
MOUSE: FEMALE
(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

PAGE : 3

| Time-related Weeks | Items | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|-----------------------|-------------------------------------|------------|------|------|------|-------|
| 0 - 52 | NO. OF EXAMINED ANIMALS | | 0 | 1 | 0 | 1 |
| | NO. OF ANIMALS WITH TUMORS | | 0 | 0 | 0 | 0 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 0 | 0 | 0 | 0 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 0 | 0 | 0 | 0 |
| | NO. OF BENIGN TUMORS | | 0 | 0 | 0 | 0 |
| | NO. OF MALIGNANT TUMORS | | 0 | 0 | 0 | 0 |
| | NO. OF TOTAL TUMORS | | 0 | 0 | 0 | 0 |
| 53 - 78 | NO. OF EXAMINED ANIMALS | | 5 | 5 | 3 | 3 |
| | NO. OF ANIMALS WITH TUMORS | | 5 | 5 | 2 | 3 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 5 | 5 | 2 | 2 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 0 | 0 | 0 | 1 |
| | NO. OF BENIGN TUMORS | | 0 | 0 | 0 | 1 |
| | NO. OF MALIGNANT TUMORS | | 5 | 5 | 2 | 3 |
| | NO. OF TOTAL TUMORS | | 5 | 5 | 2 | 4 |
| 79 - 104 | NO. OF EXAMINED ANIMALS | | 15 | 19 | 17 | 12 |
| | NO. OF ANIMALS WITH TUMORS | | 13 | 17 | 17 | 12 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 6 | 10 | 12 | 9 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 7 | 7 | 5 | 3 |
| | NO. OF BENIGN TUMORS | | 7 | 8 | 5 | 5 |
| | NO. OF MALIGNANT TUMORS | | 15 | 17 | 19 | 10 |
| | NO. OF TOTAL TUMORS | | 22 | 25 | 24 | 15 |
| 105 - 105 | NO. OF EXAMINED ANIMALS | | 23 | 20 | 25 | 27 |
| | NO. OF ANIMALS WITH TUMORS | | 19 | 12 | 18 | 16 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 11 | 6 | 18 | 13 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 8 | 6 | 0 | 3 |
| | NO. OF BENIGN TUMORS | | 13 | 11 | 7 | 6 |
| | NO. OF MALIGNANT TUMORS | | 17 | 11 | 11 | 13 |
| | NO. OF TOTAL TUMORS | | 30 | 22 | 18 | 19 |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

PAGE : 4

| Time-related Weeks | Items | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|-----------------------|-------------------------------------|------------|------|------|------|-------|
| 0 - 105 | NO. OF EXAMINED ANIMALS | | 50 | 50 | 50 | 50 |
| | NO. OF ANIMALS WITH TUMORS | | 37 | 34 | 37 | 31 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 22 | 21 | 32 | 24 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 15 | 13 | 5 | 7 |
| | NO. OF BENIGN TUMORS | | 20 | 19 | 12 | 12 |
| | NO. OF MALIGNANT TUMORS | | 37 | 33 | 32 | 26 |
| | NO. OF TOTAL TUMORS | | 57 | 52 | 44 | 38 |

(HPT070)

BAIS3

APPENDIX L 1

HISTOLOGICAL FINDINGS: NEOPLASTIC LESIONS: SUMMARY,
MOUSE: MALE: ALL ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 1

| Organ | Findings | Group Name No. of animals on Study | 0ppm 50 | 3ppm 50 | 6ppm 50 | 12ppm 49 |
|---|--------------------------------|---------------------------------------|-----------------|------------------|------------------|-----------------|
| {Integumentary system/appandage} | | | | | | |
| subcutis | lipoma | | <50> 1 (2%) | <50> 0 (0%) | <50> 0 (0%) | <49> 0 (0%) |
| | hemangioma | | 0 (0%) | 1 (2%) | 0 (0%) | 0 (0%) |
| | histiocytic sarcoma | | 0 (0%) | 2 (4%) | 0 (0%) | 0 (0%) |
| {Respiratory system} | | | | | | |
| lung | bronchiolar-alveolar adenoma | | <50> 2 (4%) | <50> 5 (10%) | <50> 5 (10%) | <49> 0 (0%) |
| | bronchiolar-alveolar carcinoma | | 10 (20%) | 8 (16%) | 9 (18%) | 0 (0%) |
| {Hematopoietic system} | | | | | | |
| lymph node | hemangioma | | <50> 0 (0%) | <50> 1 (2%) | <50> 0 (0%) | <49> 0 (0%) |
| | malignant lymphoma | | 11 (22%) | 6 (12%) | 9 (18%) | 3 (6%) |
| spleen | hemangioma | | <50> 0 (0%) | <50> 3 (6%) | <50> 1 (2%) | <49> 1 (2%) |
| | malignant lymphoma | | 0 (0%) | 1 (2%) | 1 (2%) | 0 (0%) |
| | hemangiosarcoma | | 1 (2%) | 0 (0%) | 1 (2%) | 1 (2%) |
| {Circulatory system} | | | | | | |
| heart | hemangioma | | <50> 0 (0%) | <50> 1 (2%) | <50> 0 (0%) | <49> 0 (0%) |
| < a > a : Number of animals examined at the site b (c) b : Number of animals with neoplasm c : b / a * 100 | | | | | | |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 2

| Organ | Findings | Group Name No. of animals on Study | 0ppm 50 | 3ppm 50 | 6ppm 50 | 12ppm 49 |
|--------------------|-----------------------------|---------------------------------------|------------------|------------------|-----------------|-----------------|
| {Digestive system} | | | | | | |
| stomach | squamous cell papilloma | | <49> 0 (0%) | <50> 0 (0%) | <50> 1 (2%) | <49> 0 (0%) |
| liver | hemangioma | | <50> 5 (10%) | <50> 9 (18%) | <50> 4 (8%) | <49> 0 (0%) |
| | hepatocellular adenoma | | 9 (18%) | 11 (22%) | 9 (18%) | 5 (10%) |
| | histiocytic sarcoma | | 1 (2%) | 1 (2%) | 1 (2%) | 0 (0%) |
| | hemangiosarcoma | | 0 (0%) | 1 (2%) | 0 (0%) | 0 (0%) |
| | hepatocellular carcinoma | | 6 (12%) | 6 (12%) | 2 (4%) | 1 (2%) |
| gall bladd | papillary adenoma | | <48> 1 (2%) | <48> 0 (0%) | <50> 0 (0%) | <49> 0 (0%) |
| {Urinary system} | | | | | | |
| urin bladd | transitional cell papilloma | | <50> 0 (0%) | <50> 2 (4%) | <50> 0 (0%) | <49> 0 (0%) |
| | hemangioma | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |
| | histiocytic sarcoma | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |
| {Endocrine system} | | | | | | |
| pituitary | adenoma | | <48> 1 (2%) | <50> 1 (2%) | <50> 1 (2%) | <48> 0 (0%) |

< a > a : Number of animals examined at the site
 b (c) b : Number of animals with neoplasm c : b / a * 100

(HPT085)

BAIS3

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 3

| Organ | Findings | Group Name No. of animals on Study | 0ppm 50 | 3ppm 50 | 6ppm 50 | 12ppm 49 |
|----------------------------------|----------------------|---------------------------------------|-----------------|-----------------|------------------|-----------------|
| {Endocrine system} | | | | | | |
| parathyroid | adenoma | | <21> 0 (0%) | <23> 1 (4%) | <28> 0 (0%) | <28> 0 (0%) |
| adrenal | pheochromocytoma | | <50> 0 (0%) | <50> 0 (0%) | <50> 1 (2%) | <49> 0 (0%) |
| {Reproductive system} | | | | | | |
| epididymis | histiocytic sarcoma | | <50> 2 (4%) | <50> 3 (6%) | <50> 5 (10%) | <49> 3 (6%) |
| prep/cli gl | histiocytic sarcoma | | <50> 1 (2%) | <50> 0 (0%) | <50> 0 (0%) | <49> 0 (0%) |
| {Nervous system} | | | | | | |
| periph nerv | schwannoma:malignant | | <50> 0 (0%) | <50> 0 (0%) | <50> 0 (0%) | <49> 1 (2%) |
| | histiocytic sarcoma | | 0 (0%) | 2 (4%) | 0 (0%) | 0 (0%) |
| {Special sense organs/appendage} | | | | | | |
| Harder gl | adenoma | | <50> 3 (6%) | <50> 1 (2%) | <50> 2 (4%) | <49> 1 (2%) |
| {Musculoskeletal system} | | | | | | |
| bone | osteosarcoma | | <50> 0 (0%) | <50> 0 (0%) | <50> 0 (0%) | <49> 1 (2%) |
| {Body cavities} | | | | | | |
| peritoneum | hemangioma | | <50> 0 (0%) | <50> 0 (0%) | <50> 0 (0%) | <49> 1 (2%) |

< a > a : Number of animals examined at the site
b (c) b : Number of animals with neoplasm c : b / a * 100

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 4

| Organ | Findings | Group Name No. of animals on Study | 0ppm 50 | 3ppm 50 | 6ppm 50 | 12ppm 49 |
|-----------------|---------------------|---------------------------------------|-----------------|-----------------|-----------------|-----------------|
| {Body cavities} | | | | | | |
| peritoneum | histiocytic sarcoma | | <50> 1 (2%) | <50> 0 (0%) | <50> 0 (0%) | <49> 0 (0%) |
| mesenterium | histiocytic sarcoma | | <50> 1 (2%) | <50> 0 (0%) | <50> 0 (0%) | <49> 0 (0%) |

< a > a : Number of animals examined at the site
b (c) b : Number of animals with neoplasm c : b / a * 100

(HPT085)

BAIS3

APPENDIX L 2

HISTOLOGICAL FINDINGS: NEOPLASTIC LESIONS: SUMMARY,
MOUSE: FEMALE: ALL ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 5

| Organ | Findings | Group Name No. of animals on Study | 0ppm 50 | 3ppm 50 | 6ppm 50 | 12ppm 50 |
|----------------------------------|--------------------------------|---------------------------------------|------------|------------|------------|-------------|
| {Integumentary system/appandage} | | | | | | |
| skin/app | | | <50> | <50> | <50> | <50> |
| | squamous cell carcinoma | | 1 (2%) | 1 (2%) | 0 (0%) | 0 (0%) |
| subcutis | | | <50> | <50> | <50> | <50> |
| | schwannoma | | 0 (0%) | 0 (0%) | 0 (0%) | 1 (2%) |
| | hemangioma | | 0 (0%) | 0 (0%) | 0 (0%) | 1 (2%) |
| | malignant fibrous histiocyoma | | 0 (0%) | 1 (2%) | 0 (0%) | 0 (0%) |
| | histiocytic sarcoma | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |
| {Respiratory system} | | | | | | |
| lung | | | <50> | <50> | <50> | <50> |
| | bronchiolar-alveolar adenoma | | 2 (4%) | 1 (2%) | 2 (4%) | 0 (0%) |
| | bronchiolar-alveolar carcinoma | | 2 (4%) | 0 (0%) | 3 (6%) | 2 (4%) |
| {Hematopoietic system} | | | | | | |
| bone marrow | | | <50> | <50> | <50> | <50> |
| | hemangioma | | 0 (0%) | 0 (0%) | 0 (0%) | 1 (2%) |
| lymph node | | | <50> | <50> | <50> | <50> |
| | malignant lymphoma | | 17 (34%) | 17 (34%) | 21 (42%) | 6 (12%) |
| spleen | | | <50> | <50> | <50> | <50> |
| | hemangioma | | 1 (2%) | 1 (2%) | 0 (0%) | 0 (0%) |
| | malignant lymphoma | | 4 (8%) | 3 (6%) | 5 (10%) | 4 (8%) |

< a > a : Number of animals examined at the site
 b (c) b : Number of animals with neoplasm c : b / a * 100

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 6

| Organ | Findings | Group Name No. of animals on Study | 0ppm 50 | 3ppm 50 | 6ppm 50 | 12ppm 50 |
|------------------------|-------------------------------|---------------------------------------|------------------|-------------------|------------------|------------------|
| {Hematopoietic system} | | | | | | |
| spleen | hemangiosarcoma | | <50> 0 (0%) | <50> 0 (0%) | <50> 1 (2%) | <50> 1 (2%) |
| {Digestive system} | | | | | | |
| esophagus | squamous cell papilloma | | <50> 1 (2%) | <50> 0 (0%) | <49> 0 (0%) | <50> 0 (0%) |
| stomach | squamous cell papilloma | | <50> 1 (2%) | <50> 0 (0%) | <50> 0 (0%) | <50> 0 (0%) |
| small intes | malignant fibrous histiocyoma | | <50> 1 (2%) | <50> 0 (0%) | <50> 0 (0%) | <50> 0 (0%) |
| liver | hemangioma | | <50> 0 (0%) | <50> 1 (2%) | <50> 0 (0%) | <50> 0 (0%) |
| | hepatocellular adenoma | | 3 (6%) | 4 (8%) | 2 (4%) | 0 (0%) |
| | hemangiosarcoma | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |
| | hepatocellular carcinoma | | 1 (2%) | 1 (2%) | 0 (0%) | 0 (0%) |
| {Urinary system} | | | | | | |
| urin bladd | hemangiosarcoma | | <49> 0 (0%) | <49> 0 (0%) | <49> 0 (0%) | <50> 1 (2%) |
| {Endocrine system} | | | | | | |
| pituitary | adenoma | | <50> 7 (14%) | <50> 11 (22%) | <48> 8 (17%) | <50> 7 (14%) |

< a > a : Number of animals examined at the site
 b (c) b : Number of animals with neoplasm c : b / a * 100

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 7

| Organ | Findings | Group Name No. of animals on Study | 0ppm 50 | 3ppm 50 | 6ppm 50 | 12ppm 50 |
|-----------------------|-----------------------------|---------------------------------------|------------|------------|------------|-------------|
| {Endocrine system} | | | | | | |
| pituitary | | | <50> | <50> | <48> | <50> |
| | adenocarcinoma | | 1 (2%) | 3 (6%) | 0 (0%) | 0 (0%) |
| parathyroid | | | <15> | <22> | <17> | <13> |
| | adenoma | | 0 (0%) | 1 (5%) | 0 (0%) | 0 (0%) |
| adrenal | | | <50> | <50> | <49> | <50> |
| | A-B cell tumor | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| | pheochromocytoma:malignant | | 0 (0%) | 0 (0%) | 0 (0%) | 1 (2%) |
| {Reproductive system} | | | | | | |
| ovary | | | <50> | <50> | <49> | <50> |
| | cystadenoma | | 1 (2%) | 0 (0%) | 2 (4%) | 2 (4%) |
| uterus | | | <49> | <50> | <50> | <50> |
| | hemangioma | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |
| | endometrial stromal polyp | | 4 (8%) | 1 (2%) | 1 (2%) | 5 (10%) |
| | adenocarcinoma | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| | histiocytic sarcoma | | 8 (16%) | 10 (20%) | 3 (6%) | 12 (24%) |
| | endometrial stromal sarcoma | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |
| mammary gl | | | <50> | <50> | <50> | <50> |
| | adenoma | | 0 (0%) | 1 (2%) | 0 (0%) | 0 (0%) |
| | adenocarcinoma | | 4 (8%) | 0 (0%) | 1 (2%) | 1 (2%) |

< a > a : Number of animals examined at the site
 b (c) b : Number of animals with neoplasm c : b / a * 100

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 8

| Organ_____ | Findings_____ | Group Name No. of animals on Study | 0ppm 50 | 3ppm 50 | 6ppm 50 | 12ppm 50 |
|----------------------------------|---------------------|---------------------------------------|------------|------------|------------|-------------|
| <hr/> | | | | | | |
| {Nervous system} | | | | | | |
| periph nerv | | | <50> | <50> | <50> | <50> |
| | histiocytic sarcoma | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| {Special sense organs/appendage} | | | | | | |
| Harder gl | | | <50> | <50> | <50> | <50> |
| | adenoma | | 1 (2%) | 2 (4%) | 1 (2%) | 1 (2%) |

< a > a : Number of animals examined at the site
b (c) b : Number of animals with neoplasm c : b / a * 100

(HPT085)

BAIS3

APPENDIX M 1

NEOPLASTIC LESIONS - INCIDENCE AND STATISTICAL ANALYSIS, MOUSE: MALE

(2-YEAR STUDY)

STUDY No. : 0319
ANIMAL : MOUSE Crj:BDF1
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 1

| Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|--|--------------|--------------|--------------|--------------|
| SITE : lung TUMOR : bronchiolar-alveolar adenoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 2/50(4.0) | 5/50(10.0) | 5/50(10.0) | 0/49(0.0) |
| Adjusted rates(b) | 4.55 | 13.33 | 13.16 | 0.0 |
| Terminal rates(c) | 0/33(0.0) | 4/30(13.3) | 5/38(13.2) | 0/43(0.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.9137 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.2361 | | | |
| Fisher Exact test(e) | | P = 0.2180 | P = 0.2180 | P = 0.2525 |
| SITE : lung TUMOR : bronchiolar-alveolar carcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 10/50(20.0) | 8/50(16.0) | 9/50(18.0) | 0/49(0.0) |
| Adjusted rates(b) | 27.27 | 17.65 | 21.05 | 0.0 |
| Terminal rates(c) | 9/33(27.3) | 5/30(16.7) | 8/38(21.1) | 0/43(0.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.8626 | | | |
| Prevalence method(d) | P = 0.9996 | | | |
| Combined analysis(d) | P = 0.9998 | | | |
| Cochran-Armitage test(e) | P = 0.0033** | | | |
| Fisher Exact test(e) | | P = 0.3976 | P = 0.5000 | P = 0.0007** |
| SITE : lung TUMOR : bronchiolar-alveolar adenoma,bronchiolar-alveolar carcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 12/50(24.0) | 13/50(26.0) | 11/50(22.0) | 0/49(0.0) |
| Adjusted rates(b) | 29.41 | 30.00 | 26.32 | 0.0 |
| Terminal rates(c) | 9/33(27.3) | 9/30(30.0) | 10/38(26.3) | 0/43(0.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.8626 | | | |
| Prevalence method(d) | P = 0.9999 | | | |
| Combined analysis(d) | P = 1.0000 | | | |
| Cochran-Armitage test(e) | P = 0.0006** | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.5000 | P = 0.0001** |

STUDY No. : 0319
ANIMAL : MOUSE Crj:BDF1
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 2

| Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|---|--------------|-------------|-------------|-------------|
| SITE : Lymph node TUMOR : malignant Lymphoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 11/50(22.0) | 6/50(12.0) | 9/50(18.0) | 3/49(6.1) |
| Adjusted rates(b) | 11.43 | 15.63 | 15.79 | 6.98 |
| Terminal rates(c) | 3/33(9.1) | 4/30(13.3) | 6/38(15.8) | 3/43(7.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.9977 | | | |
| Prevalence method(d) | P = 0.7821 | | | |
| Combined analysis(d) | P = 0.9903 | | | |
| Cochran-Armitage test(e) | P = 0.0493* | | | |
| Fisher Exact test(e) | | P = 0.1434 | P = 0.4016 | P = 0.0223* |
| SITE : spleen TUMOR : hemangioma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 0/50(0.0) | 3/50(6.0) | 1/50(2.0) | 1/49(2.0) |
| Adjusted rates(b) | 0.0 | 8.33 | 2.63 | 2.33 |
| Terminal rates(c) | 0/33(0.0) | 1/30(3.3) | 1/38(2.6) | 1/43(2.3) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.5097 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.9250 | | | |
| Fisher Exact test(e) | | P = 0.1212 | P = 0.5000 | P = 0.4949 |
| SITE : spleen TUMOR : hemangioma,hemangiosarcoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 1/50(2.0) | 3/50(6.0) | 2/50(4.0) | 2/49(4.1) |
| Adjusted rates(b) | 0.0 | 8.33 | 2.63 | 4.65 |
| Terminal rates(c) | 0/33(0.0) | 1/30(3.3) | 1/38(2.6) | 2/43(4.7) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.7335 | | | |
| Prevalence method(d) | P = 0.2910 | | | |
| Combined analysis(d) | P = 0.4504 | | | |
| Cochran-Armitage test(e) | P = 0.7895 | | | |
| Fisher Exact test(e) | | P = 0.3087 | P = 0.5000 | P = 0.4923 |

STUDY No. : 0319
ANIMAL : MOUSE Grj:BDF1
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 3

| Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|--|-------------|--------------|-------------|-------------|
| SITE : Liver TUMOR : hemangioma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 5/50(10.0) | 9/50(18.0) | 4/50(8.0) | 0/49(0.0) |
| Adjusted rates(b) | 12.12 | 10.81 | 10.53 | 0.0 |
| Terminal rates(c) | 4/33(12.1) | 3/30(10.0) | 4/38(10.5) | 0/43(0.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.9038 | | | |
| Prevalence method(d) | P = 0.9876 | | | |
| Combined analysis(d) | P = 0.9957 | | | |
| Cochran-Armitage test(e) | P = 0.0165* | | | |
| Fisher Exact test(e) | | P = 0.1940 | P = 0.5000 | P = 0.0296* |
| SITE : Liver TUMOR : hepatocellular adenoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 9/50(18.0) | 11/50(22.0) | 9/50(18.0) | 5/49(10.2) |
| Adjusted rates(b) | 24.24 | 31.25 | 23.08 | 11.63 |
| Terminal rates(c) | 8/33(24.2) | 9/30(30.0) | 8/38(21.1) | 5/43(11.6) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.9636 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.1962 | | | |
| Fisher Exact test(e) | | P = 0.4016 | P = 0.3976 | P = 0.2053 |
| SITE : Liver TUMOR : hepatocellular carcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 6/50(12.0) | 6/50(12.0) | 2/50(4.0) | 1/49(2.0) |
| Adjusted rates(b) | 15.15 | 19.35 | 5.26 | 2.33 |
| Terminal rates(c) | 5/33(15.2) | 5/30(16.7) | 2/38(5.3) | 1/43(2.3) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.9946 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.0278* | | | |
| Fisher Exact test(e) | | P = 0.3798 | P = 0.1343 | P = 0.0590 |

STUDY No. : 0319
ANIMAL : MOUSE Grj:BDF1
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 4

| Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|---|--------------|--------------|--------------|-------------|
| SITE : liver TUMOR : hemangioma,hemangiosarcoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 5/50(10.0) | 10/50(20.0) | 4/50(8.0) | 0/49(0.0) |
| Adjusted rates(b) | 12.12 | 13.51 | 10.53 | 0.0 |
| Terminal rates(c) | 4/33(12.1) | 4/30(13.3) | 4/38(10.5) | 0/43(0.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.9038 | | | |
| Prevalence method(d) | P = 0.9906 | | | |
| Combined analysis(d) | P = 0.9967 | | | |
| Cochran-Armitage test(e) | P = 0.0139* | | | |
| Fisher Exact test(e) | | P = 0.1312 | P = 0.5000 | P = 0.0296* |
| SITE : liver TUMOR : hepatocellular adenoma,hepatocellular carcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 13/50(26.0) | 15/50(30.0) | 11/50(22.0) | 6/49(12.2) |
| Adjusted rates(b) | 33.33 | 43.75 | 28.21 | 13.85 |
| Terminal rates(c) | 11/33(33.3) | 12/30(40.0) | 10/38(26.3) | 6/43(14.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.9952 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.0475* | | | |
| Fisher Exact test(e) | | P = 0.4120 | P = 0.4076 | P = 0.0684 |
| SITE : epididymis TUMOR : histiocytic sarcoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 2/50(4.0) | 3/50(6.0) | 5/50(10.0) | 3/49(6.1) |
| Adjusted rates(b) | 6.06 | 10.00 | 13.16 | 6.98 |
| Terminal rates(c) | 2/33(6.1) | 3/30(10.0) | 5/38(13.2) | 3/43(7.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.5034 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.6409 | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.2180 | P = 0.4903 |

STUDY No. : 0319
ANIMAL : MOUSE Crj:BDF1
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 5

| Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|--------------------------|------------|------------|------------|------------|
| SITE : Harderian gland | | | | |
| TUMOR : adenoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 3/50(6.0) | 1/50(2.0) | 2/50(4.0) | 1/49(2.0) |
| Adjusted rates(b) | 9.09 | 3.33 | 5.26 | 2.33 |
| Terminal rates(c) | 3/33(9.1) | 1/30(3.3) | 2/38(5.3) | 1/43(2.3) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.8715 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.4078 | | | |
| Fisher Exact test(e) | | P = 0.3087 | P = 0.5000 | P = 0.3163 |

(HPT360A)

BAIS3

- (a): Number of tumor-bearing animals/number of animals examined at the site.
 (b): Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.
 (c): Observed tumor incidence at terminal kill.
 (d): Beneath the control incidence are the P-values associated with the trend test.
 Standard method : Death analysis
 Prevalence method : Incidental tumor test
 Combined analysis : Death analysis + Incidental tumor test
 (e): The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.
 ? : The conditional probabilities of the largest and smallest possible outcomes can not be estimated or this P-value is beyond the estimated P-value.
 ----- : There is no data which should be statistical analysis.
 Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

STUDY No. : 0319
 ANIMAL : MOUSE Gr-j:BDF1
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 1

| Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|--|-------------|--------------|-------------|------------|
| SITE : ALL SITE TUMOR : hemangioma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 6/50(12.0) | 11/50(22.0) | 4/50(8.0) | 2/49(4.1) |
| Adjusted rates(b) | 15.15 | 16.67 | 10.53 | 4.65 |
| Terminal rates(c) | 5/33(15.2) | 5/30(16.7) | 4/38(10.5) | 2/43(4.7) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.9038 | | | |
| Prevalence method(d) | P = 0.9661 | | | |
| Combined analysis(d) | P = 0.9881 | | | |
| Cochran-Armitage test(e) | P = 0.0507 | | | |
| Fisher Exact test(e) | | P = 0.1434 | P = 0.3703 | P = 0.1409 |
| SITE : ALL SITE TUMOR : histiocytic sarcoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 7/50(14.0) | 8/50(16.0) | 6/50(12.0) | 3/49(6.1) |
| Adjusted rates(b) | 15.15 | 20.00 | 13.16 | 6.98 |
| Terminal rates(c) | 5/33(15.2) | 6/30(20.0) | 5/38(13.2) | 3/43(7.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.9340 | | | |
| Prevalence method(d) | P = 0.9197 | | | |
| Combined analysis(d) | P = 0.9748 | | | |
| Cochran-Armitage test(e) | P = 0.1508 | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.5000 | P = 0.1672 |

(HPT360A)

BAIS3

STUDY No. : 0319
ANIMAL : MOUSE Crj:BDF1
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 2

| Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|----------------------------|--------------|-------------|--------------|-------------|
| SITE : ALL SITE | | | | |
| TUMOR : malignant lymphoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 11/50(22.0) | 7/50(14.0) | 10/50(20.0) | 3/49(6.1) |
| Adjusted rates(b) | 11.43 | 18.75 | 15.79 | 6.98 |
| Terminal rates(c) | 3/33(9.1) | 5/30(16.7) | 6/38(15.8) | 3/43(7.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.9957 | | | |
| Prevalence method(d) | P = 0.8174 | | | |
| Combined analysis(d) | P = 0.9905 | | | |
| Cochran-Armitage test(e) | P = 0.0482* | | | |
| Fisher Exact test(e) | | P = 0.2178 | P = 0.5000 | P = 0.0223* |

(HPT360A)

BAIS3

- (a): Number of tumor-bearing animals/number of animals examined at the site.
(b): Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.
(c): Observed tumor incidence at terminal kill.
(d): Beneath the control incidence are the P-values associated with the trend test.
Standard method : Death analysis
Prevalence method : Incidental tumor test
Combined analysis : Death analysis + Incidental tumor test
(e): The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.
? : The conditional probabilities of the largest and smallest possible outcomes can not be estimated or this P-value is beyond the estimated P-value.
—— : There is no data which should be statistically analyzed.
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

APPENDIX M 2

NEOPLASTIC LESIONS - INCIDENCE AND STATISTICAL ANALYSIS, MOUSE: FEMALE

(2-YEAR STUDY)

STUDY No. : 0319
ANIMAL : MOUSE Crj:BDF1
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 6

| Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|--|--------------|--------------|--------------|--------------|
| SITE : lung TUMOR : bronchiolar-alveolar carcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 2/50(4.0) | 0/50(0.0) | 3/50(6.0) | 2/50(4.0) |
| Adjusted rates(b) | 6.67 | 0.0 | 7.14 | 5.88 |
| Terminal rates(c) | 2/30(6.7) | 0/25(0.0) | 1/30(3.3) | 2/34(5.9) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.3637 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.6489 | | | |
| Fisher Exact test(e) | | P = 0.2475 | P = 0.5000 | P = 0.3087 |
| SITE : lung TUMOR : bronchiolar-alveolar adenoma,bronchiolar-alveolar carcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 4/50(8.0) | 1/50(2.0) | 5/50(10.0) | 2/50(4.0) |
| Adjusted rates(b) | 10.81 | 4.00 | 11.80 | 5.88 |
| Terminal rates(c) | 3/30(10.0) | 1/25(4.0) | 3/30(10.0) | 2/34(5.9) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.7050 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.6872 | | | |
| Fisher Exact test(e) | | P = 0.1811 | P = 0.5000 | P = 0.3389 |
| SITE : lymph node TUMOR : malignant lymphoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 17/50(34.0) | 17/50(34.0) | 21/50(42.0) | 6/50(12.0) |
| Adjusted rates(b) | 29.03 | 24.00 | 30.00 | 11.76 |
| Terminal rates(c) | 8/30(26.7) | 6/25(24.0) | 9/30(30.0) | 4/34(11.8) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.9823 | | | |
| Prevalence method(d) | P = 0.9531 | | | |
| Combined analysis(d) | P = 0.9965 | | | |
| Cochran-Armitage test(e) | P = 0.0137* | | | |
| Fisher Exact test(e) | | P = 0.4165 | P = 0.2684 | P = 0.0082** |

STUDY No. : 0319
ANIMAL : MOUSE Crj:BDF1
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 7

| Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|---|-------------|-------------|-------------|------------|
| SITE : spleen TUMOR : malignant lymphoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 4/50(8.0) | 3/50(6.0) | 5/50(10.0) | 4/50(8.0) |
| Adjusted rates(b) | 10.00 | 12.00 | 13.33 | 8.82 |
| Terminal rates(c) | 3/30(10.0) | 3/25(12.0) | 4/30(13.3) | 3/34(8.8) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.4049 | | | |
| Prevalence method(d) | P = 0.5809 | | | |
| Combined analysis(d) | P = 0.5350 | | | |
| Cochran-Armitage test(e) | P = 0.8601 | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.5000 | P = 0.3575 |
| SITE : liver TUMOR : hepatocellular adenoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 3/50(6.0) | 4/50(8.0) | 2/50(4.0) | 0/50(0.0) |
| Adjusted rates(b) | 10.00 | 12.00 | 4.35 | 0.0 |
| Terminal rates(c) | 3/30(10.0) | 3/25(12.0) | 1/30(3.3) | 0/34(0.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.9754 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.0739 | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.5000 | P = 0.1212 |
| SITE : Liver TUMOR : hepatocellular adenoma,hepatocellular carcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 4/50(8.0) | 5/50(10.0) | 2/50(4.0) | 0/50(0.0) |
| Adjusted rates(b) | 13.33 | 12.00 | 4.35 | 0.0 |
| Terminal rates(c) | 4/30(13.3) | 3/25(12.0) | 1/30(3.3) | 0/34(0.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.5991 | | | |
| Prevalence method(d) | P = 0.9898 | | | |
| Combined analysis(d) | P = 0.9913 | | | |
| Cochran-Armitage test(e) | P = 0.0316* | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.3389 | P = 0.0587 |

STUDY No. : 0319
ANIMAL : MOUSE Crj:BDF1
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 8

| Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|--|-------------|--------------|-------------|-------------|
| SITE : pituitary gland TUMOR : adenoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 7/50(14.0) | 11/50(22.0) | 8/48(16.7) | 7/50(14.0) |
| Adjusted rates(b) | 17.07 | 32.00 | 20.00 | 17.95 |
| Terminal rates(c) | 5/30(16.7) | 8/25(32.0) | 6/30(20.0) | 5/34(14.7) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.5995 | | | |
| Prevalence method(d) | P = 0.7349 | | | |
| Combined analysis(d) | P = 0.7567 | | | |
| Cochran-Armitage test(e) | P = 0.7322 | | | |
| Fisher Exact test(e) | | P = 0.2178 | P = 0.4654 | P = 0.3871 |
| SITE : pituitary gland TUMOR : adenocarcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 1/50(2.0) | 3/50(6.0) | 0/48(0.0) | 0/50(0.0) |
| Adjusted rates(b) | 0.0 | 4.00 | 0.0 | 0.0 |
| Terminal rates(c) | 0/30(0.0) | 1/25(4.0) | 0/30(0.0) | 0/34(0.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.9043 | | | |
| Prevalence method(d) | P = 0.6065 | | | |
| Combined analysis(d) | P = 0.9233 | | | |
| Cochran-Armitage test(e) | P = 0.1751 | | | |
| Fisher Exact test(e) | | P = 0.3087 | P = 0.4898 | P = 0.5000 |
| SITE : pituitary gland TUMOR : adenoma,adenocarcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 8/50(16.0) | 14/50(28.0) | 8/48(16.7) | 7/50(14.0) |
| Adjusted rates(b) | 17.07 | 36.00 | 20.00 | 17.95 |
| Terminal rates(c) | 5/30(16.7) | 9/25(36.0) | 6/30(20.0) | 5/34(14.7) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.8876 | | | |
| Prevalence method(d) | P = 0.7813 | | | |
| Combined analysis(d) | P = 0.8862 | | | |
| Cochran-Armitage test(e) | P = 0.4142 | | | |
| Fisher Exact test(e) | | P = 0.1135 | P = 0.4277 | P = 0.5000 |

STUDY No. : 0319
 ANIMAL : MOUSE Crj:BDF1
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 9

| Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|--|--------------|--------------|------------|--------------|
| SITE : uterus TUMOR : endometrial stromal polyp | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 4/49(8.2) | 1/50(2.0) | 1/50(2.0) | 5/50(10.0) |
| Adjusted rates(b) | 13.33 | 4.00 | 2.86 | 11.76 |
| Terminal rates(c) | 4/30(13.3) | 1/25(4.0) | 0/30(0.0) | 4/34(11.8) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.2933 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.4431 | | | |
| Fisher Exact test(e) | | P = 0.1748 | P = 0.1748 | P = 0.4870 |
| SITE : uterus TUMOR : histiocytic sarcoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 8/49(16.3) | 10/50(20.0) | 3/50(6.0) | 12/50(24.0) |
| Adjusted rates(b) | 6.82 | 15.38 | 0.0 | 14.71 |
| Terminal rates(c) | 1/30(3.3) | 3/25(12.0) | 0/30(0.0) | 5/34(14.7) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.3724 | | | |
| Prevalence method(d) | P = 0.3116 | | | |
| Combined analysis(d) | P = 0.2925 | | | |
| Cochran-Armitage test(e) | P = 0.4420 | | | |
| Fisher Exact test(e) | | P = 0.4161 | P = 0.0936 | P = 0.2423 |
| SITE : mammary gland TUMOR : adenocarcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 4/50(8.0) | 0/50(0.0) | 1/50(2.0) | 1/50(2.0) |
| Adjusted rates(b) | 10.00 | 0.0 | 0.0 | 0.0 |
| Terminal rates(c) | 3/30(10.0) | 0/25(0.0) | 0/30(0.0) | 0/34(0.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.4090 | | | |
| Prevalence method(d) | P = 0.9933 ? | | | |
| Combined analysis(d) | P = 0.9144 | | | |
| Cochran-Armitage test(e) | P = 0.2072 | | | |
| Fisher Exact test(e) | | P = 0.0587 | P = 0.1811 | P = 0.1811 |

STUDY No. : 0319
ANIMAL : MOUSE Crj:BDF1
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 10

| Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|--------------------------------|-------------|------------|------------|------------|
| SITE : mammary gland | | | | |
| TUMOR : adenoma,adenocarcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 4/50(8.0) | 1/50(2.0) | 1/50(2.0) | 1/50(2.0) |
| Adjusted rates(b) | 10.00 | 3.85 | 0.0 | 0.0 |
| Terminal rates(c) | 3/30(10.0) | 0/25(0.0) | 0/30(0.0) | 0/34(0.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.4090 | | | |
| Prevalence method(d) | P = 0.9908 | | | |
| Combined analysis(d) | P = 0.9321 | | | |
| Cochran-Armitage test(e) | P = 0.1720 | | | |
| Fisher Exact test(e) | | P = 0.1811 | P = 0.1811 | P = 0.1811 |

(HPT360A)

BAIS3

- (a): Number of tumor-bearing animals/number of animals examined at the site.
 (b): Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.
 (c): Observed tumor incidence at terminal kill.
 (d): Beneath the control incidence are the P-values associated with the trend test.
 Standard method : Death analysis
 Prevalence method : Incidental tumor test
 Combined analysis : Death analysis + Incidental tumor test
 (e): The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.
 ? : The conditional probabilities of the largest and smallest possible outcomes can not be estimated or this P-value is beyond the estimated P-value.
 ----- : There is no data which should be statistical analysis.
 Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

STUDY No. : 0319
ANIMAL : MOUSE Crj:BDF1
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 3

| Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|--|--------------|--------------|--------------|--------------|
| SITE : ALL SITE TUMOR : histiocytic sarcoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 9/50(18.0) | 10/50(20.0) | 4/50(8.0) | 12/50(24.0) |
| Adjusted rates(b) | 8.89 | 15.38 | 0.0 | 14.71 |
| Terminal rates(c) | 2/30(6.7) | 3/25(12.0) | 0/30(0.0) | 5/34(14.7) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.3534 | | | |
| Prevalence method(d) | P = 0.4471 | | | |
| Combined analysis(d) | P = 0.3542 | | | |
| Cochran-Armitage test(e) | P = 0.5501 | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.1168 | P = 0.3121 |
| SITE : ALL SITE TUMOR : malignant lymphoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 21/50(42.0) | 20/50(40.0) | 28/50(52.0) | 10/50(20.0) |
| Adjusted rates(b) | 38.71 | 36.00 | 43.33 | 20.59 |
| Terminal rates(c) | 11/30(36.7) | 9/25(36.0) | 13/30(43.3) | 7/34(20.6) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.9738 | | | |
| Prevalence method(d) | P = 0.9460 | | | |
| Combined analysis(d) | P = 0.9942 | | | |
| Cochran-Armitage test(e) | P = 0.0254* | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.2115 | P = 0.0149* |

(HPT360A)

BAIS3

- (a): Number of tumor-bearing animals/number of animals examined at the site.
(b): Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.
(c): Observed tumor incidence at terminal kill.
(d): Beneath the control incidence are the P-values associated with the trend test.
Standard method : Death analysis
Prevalence method : Incidental tumor test
Combined analysis : Death analysis + Incidental tumor test
(e): The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.
? : The conditional probabilities of the largest and smallest possible out comes can not estimated or this P-value is beyond the estimated P-value.
----- : There is no data which should be statistical analysis.
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

APPENDIX N 1

HISTOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY,
MOUSE: MALE: ALL ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 1

| | | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|---|-----------------------------------|-------------------------|-----------|-----------|-----------|-----------|
| Organ | Findings | No. of Animals on Study | 50 | 50 | 50 | 49 |
| {Integumentary system/appandage} | | | | | | |
| skin/app | leukemic cell infiltration | | <50> 3 | <50> 0 | <50> 0 | <49> 0 |
| {Respiratory system} | | | | | | |
| nasal cavit | leukemic cell infiltration | | <50> 3 | <50> 1 | <50> 0 | <49> 0 |
| | metastasis:peritoneum tumor | | 1 | 0 | 0 | 0 |
| | metastasis:subcutis tumor | | 0 | 1 | 0 | 0 |
| | metastasis:peripheral nerve tumor | | 0 | 1 | 0 | 0 |
| larynx | leukemic cell infiltration | | <50> 0 | <50> 1 | <50> 1 | <49> 0 |
| trachea | leukemic cell infiltration | | <50> 3 | <50> 0 | <50> 0 | <49> 0 |
| lung | leukemic cell infiltration | | <50> 6 | <50> 1 | <50> 3 | <49> 0 |
| | metastasis:liver tumor | | 1 | 0 | 0 | 0 |
| | metastasis:peritoneum tumor | | 1 | 0 | 0 | 0 |
| {Hematopoietic system} | | | | | | |
| bone marrow | leukemic cell infiltration | | <50> 4 | <50> 1 | <50> 2 | <49> 0 |
| | metastasis:subcutis tumor | | 0 | 1 | 0 | 0 |
| < a > a : Number of animals examined at the site b b : Number of animals with lesion | | | | | | |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 2

| Organ | Findings | Group Name | Oppm | 3ppm | 6ppm | 12ppm |
|------------------------|--|-------------------------|------|------|------|-------|
| | | No. of Animals on Study | 50 | 50 | 50 | 49 |
| | | | | | | |
| {Hematopoietic system} | | | | | | |
| lymph node | | | <50> | <50> | <50> | <49> |
| | leukemic cell infiltration | | 0 | 1 | 0 | 0 |
| | metastasis:peritoneum tumor | | 1 | 0 | 0 | 0 |
| thymus | | | <50> | <50> | <50> | <49> |
| | leukemic cell infiltration | | 1 | 0 | 0 | 0 |
| spleen | | | <50> | <50> | <50> | <49> |
| | leukemic cell infiltration | | 7 | 3 | 3 | 2 |
| | metastasis:peritoneum tumor | | 1 | 0 | 0 | 0 |
| {Circulatory system} | | | | | | |
| heart | | | <50> | <50> | <50> | <49> |
| | leukemic cell infiltration | | 6 | 0 | 1 | 0 |
| {Digestive system} | | | | | | |
| tongue | | | <50> | <50> | <50> | <49> |
| | leukemic cell infiltration | | 3 | 0 | 1 | 0 |
| salivary gl | | | <50> | <50> | <50> | <49> |
| | leukemic cell infiltration | | 5 | 1 | 2 | 0 |
| | metastasis:liver tumor | | 1 | 0 | 1 | 0 |
| | metastasis:peritoneum tumor | | 1 | 0 | 0 | 0 |
| stomach | | | <49> | <50> | <50> | <49> |
| | leukemic cell infiltration | | 5 | 1 | 2 | 0 |
| | metastasis:peritoneum tumor | | 1 | 0 | 0 | 0 |
| < a > | a : Number of animals examined at the site | | | | | |
| b | b : Number of animals with lesion | | | | | |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 3

| Organ | Findings | Group Name | Oppm | 3ppm | 6ppm | 12ppm |
|--------------------|--|-------------------------|------|------|------|-------|
| | | No. of Animals on Study | 50 | 50 | 50 | 49 |
| {Digestive system} | | | | | | |
| small intes | | <50> | <50> | <50> | <49> | |
| | leukemic cell infiltration | 1 | 2 | 0 | 0 | |
| | metastasis:peritoneum tumor | 1 | 0 | 0 | 0 | |
| | metastasis:subcutis tumor | 0 | 1 | 0 | 0 | |
| large intes | | <50> | <50> | <50> | <49> | |
| | leukemic cell infiltration | 1 | 0 | 0 | 0 | |
| | metastasis:peritoneum tumor | 1 | 0 | 0 | 0 | |
| liver | | <50> | <50> | <50> | <49> | |
| | leukemic cell infiltration | 7 | 2 | 4 | 0 | |
| | metastasis:subcutis tumor | 0 | 1 | 0 | 0 | |
| pancreas | | <50> | <50> | <50> | <49> | |
| | leukemic cell infiltration | 4 | 2 | 2 | 0 | |
| | metastasis:peritoneum tumor | 1 | 0 | 0 | 0 | |
| {Urinary system} | | | | | | |
| kidney | | <50> | <50> | <50> | <49> | |
| | leukemic cell infiltration | 6 | 1 | 3 | 0 | |
| | metastasis:peritoneum tumor | 1 | 0 | 0 | 0 | |
| | metastasis:subcutis tumor | 0 | 1 | 0 | 0 | |
| urin bladd | | <50> | <50> | <50> | <49> | |
| | leukemic cell infiltration | 5 | 1 | 2 | 0 | |
| | metastasis:peritoneum tumor | 1 | 0 | 0 | 0 | |
| < a > | a : Number of animals examined at the site | | | | | |
| b | b : Number of animals with lesion | | | | | |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 4

| Organ | Findings | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|-----------------------|------------------------------|-------------------------|------|------|------|-------|
| | | No. of Animals on Study | 50 | 50 | 50 | 49 |
| {Urinary system} | | | | | | |
| urin bladd | | | <50> | <50> | <50> | <49> |
| | metastasis:subcutis tumor | | 0 | 1 | 0 | 0 |
| {Endocrine system} | | | | | | |
| thyroid | | | <50> | <50> | <50> | <49> |
| | leukemic cell infiltration | | 2 | 1 | 1 | 0 |
| adrenal | | | <50> | <50> | <50> | <49> |
| | leukemic cell infiltration | | 1 | 0 | 1 | 0 |
| {Reproductive system} | | | | | | |
| testis | | | <50> | <50> | <50> | <49> |
| | metastasis:subcutis tumor | | 0 | 1 | 0 | 0 |
| epididymis | | | <50> | <50> | <50> | <49> |
| | leukemic cell infiltration | | 4 | 1 | 2 | 0 |
| | metastasis:peritoneum tumor | | 1 | 0 | 0 | 0 |
| | metastasis:subcutis tumor | | 0 | 1 | 0 | 0 |
| semin ves | | | <50> | <50> | <50> | <49> |
| | leukemic cell infiltration | | 3 | 1 | 0 | 0 |
| | metastasis:subcutis tumor | | 0 | 1 | 0 | 0 |
| | metastasis:mesenterium tumor | | 1 | 0 | 0 | 0 |
| prostate | | | <50> | <50> | <50> | <49> |
| | leukemic cell infiltration | | 7 | 2 | 0 | 0 |
| {Nervous system} | | | | | | |
| brain | | | <50> | <50> | <50> | <49> |
| | leukemic cell infiltration | | 1 | 0 | 0 | 0 |

< a > a : Number of animals examined at the site
 b b : Number of animals with lesion

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 5

| | | Group Name | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|----------------------------------|--|-------------------------|------|--|------|--|------|--|-------|--|
| Organ | Findings | No. of Animals on Study | 50 | | 50 | | 50 | | 49 | |
| | | | | | | | | | | |
| {Nervous system} | | | | | | | | | | |
| brain | | | <50> | | <50> | | <50> | | <49> | |
| | metastasis:peripheral nerve tumor | | 0 | | 1 | | 0 | | 1 | |
| spinal cord | | | <50> | | <50> | | <50> | | <49> | |
| | leukemic cell infiltration | | 1 | | 0 | | 0 | | 0 | |
| {Special sense organs/appendage} | | | | | | | | | | |
| eye | | | <50> | | <50> | | <50> | | <49> | |
| | leukemic cell infiltration | | 2 | | 0 | | 0 | | 0 | |
| Harder gl | | | <50> | | <50> | | <50> | | <49> | |
| | leukemic cell infiltration | | 3 | | 1 | | 2 | | 0 | |
| | metastasis:liver tumor | | 0 | | 1 | | 0 | | 0 | |
| {Musculoskeletal system} | | | | | | | | | | |
| muscle | | | <50> | | <50> | | <50> | | <49> | |
| | leukemic cell infiltration | | 3 | | 0 | | 1 | | 0 | |
| bone | | | <50> | | <50> | | <50> | | <49> | |
| | metastasis:peripheral nerve tumor | | 0 | | 0 | | 0 | | 1 | |
| | | | | | | | | | | |
| < a > | a : Number of animals examined at the site | | | | | | | | | |
| b | b : Number of animals with lesion | | | | | | | | | |

(JPT150)

BAIS3

APPENDIX N 2

HISTOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY,
MOUSE: MALE: DEAD AND MORIBUND ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 1

| | | Group Name No. of Animals on Study | 0ppm 17 | 3ppm 20 | 6ppm 12 | 12ppm 6 |
|----------------------------------|--|---------------------------------------|------------|------------|------------|------------|
| Organ | Findings | | | | | |
| {Integumentary system/appandage} | | | | | | |
| skin/app | leukemic cell infiltration | | <17> 2 | <20> 0 | <12> 0 | < 6> 0 |
| {Respiratory system} | | | | | | |
| nasal cavit | leukemic cell infiltration | | <17> 2 | <20> 0 | <12> 0 | < 6> 0 |
| | metastasis:peritoneum tumor | | 1 | 0 | 0 | 0 |
| | metastasis:peripheral nerve tumor | | 0 | 1 | 0 | 0 |
| larynx | leukemic cell infiltration | | <17> 0 | <20> 0 | <12> 1 | < 6> 0 |
| trachea | leukemic cell infiltration | | <17> 2 | <20> 0 | <12> 0 | < 6> 0 |
| lung | leukemic cell infiltration | | <17> 4 | <20> 0 | <12> 3 | < 6> 0 |
| | metastasis:liver tumor | | 1 | 0 | 0 | 0 |
| | metastasis:peritoneum tumor | | 1 | 0 | 0 | 0 |
| {Hematopoietic system} | | | | | | |
| bone marrow | leukemic cell infiltration | | <17> 2 | <20> 0 | <12> 1 | < 6> 0 |
| lymph node | metastasis:peritoneum tumor | | <17> 1 | <20> 0 | <12> 0 | < 6> 0 |
| thymus | leukemic cell infiltration | | <17> 1 | <20> 0 | <12> 0 | < 6> 0 |
| < a > | a : Number of animals examined at the site | | | | | |
| b | b : Number of animals with lesion | | | | | |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 2

| | | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|------------------------|--|-------------------------|------|------|------|-------|
| Organ | Findings | No. of Animals on Study | 17 | 20 | 12 | 6 |
| | | | | | | |
| {Hematopoietic system} | | | | | | |
| spleen | | | <17> | <20> | <12> | < 6> |
| | leukemic cell infiltration | | 5 | 1 | 2 | 0 |
| | metastasis:peritoneum tumor | | 1 | 0 | 0 | 0 |
| {Circulatory system} | | | | | | |
| heart | | | <17> | <20> | <12> | < 6> |
| | leukemic cell infiltration | | 4 | 0 | 1 | 0 |
| {Digestive system} | | | | | | |
| tongue | | | <17> | <20> | <12> | < 6> |
| | leukemic cell infiltration | | 2 | 0 | 1 | 0 |
| salivary gl | | | <17> | <20> | <12> | < 6> |
| | leukemic cell infiltration | | 4 | 0 | 2 | 0 |
| | metastasis:liver tumor | | 1 | 0 | 1 | 0 |
| | metastasis:peritoneum tumor | | 1 | 0 | 0 | 0 |
| stomach | | | <16> | <20> | <12> | < 6> |
| | leukemic cell infiltration | | 4 | 0 | 2 | 0 |
| | metastasis:peritoneum tumor | | 1 | 0 | 0 | 0 |
| small intes | | | <17> | <20> | <12> | < 6> |
| | metastasis:peritoneum tumor | | 1 | 0 | 0 | 0 |
| large intes | | | <17> | <20> | <12> | < 6> |
| | metastasis:peritoneum tumor | | 1 | 0 | 0 | 0 |
| liver | | | <17> | <20> | <12> | < 6> |
| | leukemic cell infiltration | | 5 | 0 | 3 | 0 |
| | | | | | | |
| < a > | a : Number of animals examined at the site | | | | | |
| b | b : Number of animals with lesion | | | | | |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 3

| | | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|-----------------------|-----------------------------|-------------------------|------|------|------|-------|
| Organ | Findings | No. of Animals on Study | 17 | 20 | 12 | 6 |
| | | | | | | |
| {Digestive system} | | | | | | |
| pancreas | | <17> | | <20> | <12> | < 6> |
| | leukemic cell infiltration | 3 | | 1 | 2 | 0 |
| | metastasis:peritoneum tumor | 1 | | 0 | 0 | 0 |
| {Urinary system} | | | | | | |
| kidney | | <17> | | <20> | <12> | < 6> |
| | leukemic cell infiltration | 4 | | 0 | 2 | 0 |
| | metastasis:peritoneum tumor | 1 | | 0 | 0 | 0 |
| urin bladd | | <17> | | <20> | <12> | < 6> |
| | leukemic cell infiltration | 3 | | 0 | 2 | 0 |
| | metastasis:peritoneum tumor | 1 | | 0 | 0 | 0 |
| {Endocrine system} | | | | | | |
| thyroid | | <17> | | <20> | <12> | < 6> |
| | leukemic cell infiltration | 1 | | 0 | 1 | 0 |
| adrenal | | <17> | | <20> | <12> | < 6> |
| | leukemic cell infiltration | 1 | | 0 | 1 | 0 |
| {Reproductive system} | | | | | | |
| epididymis | | <17> | | <20> | <12> | < 6> |
| | leukemic cell infiltration | 3 | | 0 | 2 | 0 |
| | metastasis:peritoneum tumor | 1 | | 0 | 0 | 0 |
| semin ves | | <17> | | <20> | <12> | < 6> |
| | leukemic cell infiltration | 3 | | 0 | 0 | 0 |

< a > a : Number of animals examined at the site
 b b : Number of animals with lesion

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 4

| | | Group Name | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|----------------------------------|--|-------------------------|------|------|------|------|-------|--|-------|--|
| Organ | Findings | No. of Animals on Study | 17 | 20 | 12 | 6 | 12ppm | | | |
| {Reproductive system} | | | | | | | | | | |
| prostate | | | <17> | <20> | <12> | < 6> | | | | |
| | leukemic cell infiltration | | 5 | 1 | 0 | 0 | | | | |
| {Nervous system} | | | | | | | | | | |
| brain | | | <17> | <20> | <12> | < 6> | | | | |
| | leukemic cell infiltration | | 1 | 0 | 0 | 0 | | | | |
| | metastasis:peripheral nerve tumor | | 0 | 1 | 0 | 1 | | | | |
| spinal cord | | | <17> | <20> | <12> | < 6> | | | | |
| | leukemic cell infiltration | | 1 | 0 | 0 | 0 | | | | |
| {Special sense organs/appendage} | | | | | | | | | | |
| eye | | | <17> | <20> | <12> | < 6> | | | | |
| | leukemic cell infiltration | | 1 | 0 | 0 | 0 | | | | |
| Harder gl | | | <17> | <20> | <12> | < 6> | | | | |
| | leukemic cell infiltration | | 2 | 0 | 2 | 0 | | | | |
| | metastasis:liver tumor | | 0 | 1 | 0 | 0 | | | | |
| {Musculoskeletal system} | | | | | | | | | | |
| muscle | | | <17> | <20> | <12> | < 6> | | | | |
| | leukemic cell infiltration | | 2 | 0 | 1 | 0 | | | | |
| bone | | | <17> | <20> | <12> | < 6> | | | | |
| | metastasis:peripheral nerve tumor | | 0 | 0 | 0 | 1 | | | | |
| < a > | a : Number of animals examined at the site | | | | | | | | | |
| b | b : Number of animals with lesion | | | | | | | | | |

< a > a : Number of animals examined at the site
 b b : Number of animals with lesion

APPENDIX N 3

HISTOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY,
MOUSE: MALE: SACRIFICED ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 1

| | | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|----------------------------------|--|-------------------------|------|------|------|-------|
| | | No. of Animals on Study | 33 | 30 | 38 | 43 |
| Organ | Findings | | | | | |
| {Integumentary system/appandage} | | | | | | |
| skin/app | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 1 | 0 | 0 | 0 |
| {Respiratory system} | | | | | | |
| nasal cavit | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 1 | 1 | 0 | 0 |
| | metastasis:subcutis tumor | | 0 | 1 | 0 | 0 |
| larynx | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 0 | 1 | 0 | 0 |
| trachea | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 1 | 0 | 0 | 0 |
| lung | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 2 | 1 | 0 | 0 |
| {Hematopoietic system} | | | | | | |
| bone marrow | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 2 | 1 | 1 | 0 |
| | metastasis:subcutis tumor | | 0 | 1 | 0 | 0 |
| lymph node | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 0 | 1 | 0 | 0 |
| spleen | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 2 | 2 | 1 | 2 |
| {Circulatory system} | | | | | | |
| heart | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 2 | 0 | 0 | 0 |
| < a > | a : Number of animals examined at the site | | | | | |
| b | b : Number of animals with lesion | | | | | |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 2

| | | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|--------------------|--|-------------------------|------|------|------|-------|
| Organ | Findings | No. of Animals on Study | 33 | 30 | 38 | 43 |
| {Digestive system} | | | | | | |
| tongue | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 1 | 0 | 0 | 0 |
| salivary gl | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 1 | 1 | 0 | 0 |
| stomach | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 1 | 1 | 0 | 0 |
| small intes | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 1 | 2 | 0 | 0 |
| | metastasis:subcutis tumor | | 0 | 1 | 0 | 0 |
| large intes | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 1 | 0 | 0 | 0 |
| liver | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 2 | 2 | 1 | 0 |
| | metastasis:subcutis tumor | | 0 | 1 | 0 | 0 |
| pancreas | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 1 | 1 | 0 | 0 |
| {Urinary system} | | | | | | |
| kidney | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 2 | 1 | 1 | 0 |
| | metastasis:subcutis tumor | | 0 | 1 | 0 | 0 |
| urin bladd | | | <33> | <30> | <38> | <43> |
| | leukemic cell infiltration | | 2 | 1 | 0 | 0 |
| < a > | a : Number of animals examined at the site | | | | | |
| b | b : Number of animals with lesion | | | | | |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 3

| | | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|----------------------------------|--|-------------------------|-----------|-----------|-----------|-----------|
| Organ | Findings | No. of Animals on Study | 33 | 30 | 38 | 43 |
| {Urinary system} | | | | | | |
| urin bladd | metastasis:subcutis tumor | | <33> 0 | <30> 1 | <38> 0 | <43> 0 |
| {Endocrine system} | | | | | | |
| thyroid | leukemic cell infiltration | | <33> 1 | <30> 1 | <38> 0 | <43> 0 |
| {Reproductive system} | | | | | | |
| testis | metastasis:subcutis tumor | | <33> 0 | <30> 1 | <38> 0 | <43> 0 |
| epididymis | leukemic cell infiltration | | <33> 1 | <30> 1 | <38> 0 | <43> 0 |
| | metastasis:subcutis tumor | | 0 | 1 | 0 | 0 |
| semin ves | leukemic cell infiltration | | <33> 0 | <30> 1 | <38> 0 | <43> 0 |
| | metastasis:subcutis tumor | | 0 | 1 | 0 | 0 |
| | metastasis:mesenterium tumor | | 1 | 0 | 0 | 0 |
| prostate | leukemic cell infiltration | | <33> 2 | <30> 1 | <38> 0 | <43> 0 |
| {Special sense organs/appendage} | | | | | | |
| eye | leukemic cell infiltration | | <33> 1 | <30> 0 | <38> 0 | <43> 0 |
| < a > | a : Number of animals examined at the site | | | | | |
| b | b : Number of animals with lesion | | | | | |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 4

| | | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|----------------------------------|----------------------------|-------------------------|-----------|-----------|-----------|-----------|
| | | No. of Animals on Study | 33 | 30 | 38 | 43 |
| Organ | Findings | | | | | |
| {Special sense organs/appendage} | | | | | | |
| Harder gl | leukemic cell infiltration | | <33> 1 | <30> 1 | <38> 0 | <43> 0 |
| {Musculoskeletal system} | | | | | | |
| muscle | leukemic cell infiltration | | <33> 1 | <30> 0 | <38> 0 | <43> 0 |

< a > a : Number of animals examined at the site
b b : Number of animals with lesion

(JPT150)

BAIS3

APPENDIX N 4

HISTOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY,
MOUSE: FEMALE: ALL ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 6

| Organ_____ | Findings_____ | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|----------------------------------|--|-------------------------|------|------|------|-------|
| | | No. of Animals on Study | 50 | 50 | 50 | 50 |
| <hr/> | | | | | | |
| {Integumentary system/appandage} | | | | | | |
| skin/app | | <50> | <50> | <50> | <50> | |
| | leukemic cell infiltration | 1 | 3 | 4 | 0 | |
| subcutis | | <50> | <50> | <50> | <50> | |
| | leukemic cell infiltration | 0 | 2 | 2 | 0 | |
| {Respiratory system} | | | | | | |
| nasal cavit | | <50> | <50> | <50> | <50> | |
| | leukemic cell infiltration | 0 | 0 | 2 | 0 | |
| | metastasis:uterus tumor | 0 | 0 | 0 | 1 | |
| larynx | | <50> | <50> | <50> | <50> | |
| | leukemic cell infiltration | 0 | 1 | 0 | 1 | |
| trachea | | <50> | <50> | <50> | <50> | |
| | leukemic cell infiltration | 0 | 0 | 3 | 1 | |
| | metastasis:uterus tumor | 0 | 0 | 1 | 0 | |
| lung | | <50> | <50> | <50> | <50> | |
| | leukemic cell infiltration | 9 | 10 | 16 | 4 | |
| | metastasis:liver tumor | 1 | 0 | 0 | 0 | |
| | metastasis:uterus tumor | 5 | 3 | 2 | 3 | |
| | metastasis:adrenal tumor | 0 | 0 | 0 | 1 | |
| | metastasis:subcutis tumor | 0 | 1 | 0 | 0 | |
| {Hematopoietic system} | | | | | | |
| bone marrow | | <50> | <50> | <50> | <50> | |
| | leukemic cell infiltration | 5 | 5 | 10 | 4 | |
| <hr/> | | | | | | |
| < a > | a : Number of animals examined at the site | | | | | |
| b | b : Number of animals with lesion | | | | | |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 7

| | | Group Name | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|------------------------|----------------------------------|-------------------------|------|----|------|----|------|----|-------|----|
| Organ_____ | Findings_____ | No. of Animals on Study | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| <hr/> | | | | | | | | | | |
| {Hematopoietic system} | | | | | | | | | | |
| bone marrow | | | <50> | | <50> | | <50> | | <50> | |
| | metastasis:uterus tumor | | 1 | | 4 | | 1 | | 1 | |
| lymph node | | | <50> | | <50> | | <50> | | <50> | |
| | leukemic cell infiltration | | 1 | | 0 | | 0 | | 1 | |
| | metastasis:uterus tumor | | 0 | | 1 | | 0 | | 0 | |
| | metastasis:subcutis tumor | | 0 | | 1 | | 0 | | 0 | |
| | metastasis:small intestine tumor | | 1 | | 0 | | 0 | | 0 | |
| thymus | | | <50> | | <50> | | <50> | | <50> | |
| | leukemic cell infiltration | | 2 | | 4 | | 1 | | 1 | |
| spleen | | | <50> | | <50> | | <50> | | <50> | |
| | leukemic cell infiltration | | 8 | | 11 | | 15 | | 3 | |
| {Circulatory system} | | | | | | | | | | |
| heart | | | <50> | | <50> | | <50> | | <50> | |
| | leukemic cell infiltration | | 2 | | 5 | | 6 | | 2 | |
| | metastasis:uterus tumor | | 1 | | 0 | | 0 | | 0 | |
| {Digestive system} | | | | | | | | | | |
| tongue | | | <50> | | <50> | | <50> | | <50> | |
| | leukemic cell infiltration | | 2 | | 4 | | 2 | | 2 | |
| salivary gl | | | <50> | | <50> | | <50> | | <50> | |
| | leukemic cell infiltration | | 6 | | 7 | | 8 | | 2 | |
| esophagus | | | <50> | | <50> | | <50> | | <50> | |
| | leukemic cell infiltration | | 0 | | 1 | | 1 | | 0 | |

< a > a : Number of animals examined at the site
 b b : Number of animals with lesion

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 8

| | | Group Name | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|--------------------|--|-------------------------|------|----|------|----|------|----|-------|----|
| Organ | Findings | No. of Animals on Study | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| {Digestive system} | | | | | | | | | | |
| stomach | | | <50> | | <50> | | <50> | | <50> | |
| | leukemic cell infiltration | | 7 | | 10 | | 13 | | 2 | |
| | metastasis:uterus tumor | | 1 | | 1 | | 2 | | 2 | |
| small intes | | | <50> | | <50> | | <50> | | <50> | |
| | leukemic cell infiltration | | 1 | | 3 | | 0 | | 0 | |
| | metastasis:uterus tumor | | 0 | | 0 | | 2 | | 2 | |
| large intes | | | <50> | | <50> | | <50> | | <50> | |
| | leukemic cell infiltration | | 1 | | 1 | | 0 | | 0 | |
| liver | | | <50> | | <50> | | <50> | | <50> | |
| | leukemic cell infiltration | | 10 | | 10 | | 17 | | 8 | |
| | metastasis:uterus tumor | | 6 | | 6 | | 4 | | 9 | |
| | metastasis:spleen tumor | | 0 | | 0 | | 0 | | 1 | |
| gall bladd | | | <50> | | <50> | | <50> | | <50> | |
| | leukemic cell infiltration | | 1 | | 0 | | 1 | | 1 | |
| | metastasis:uterus tumor | | 1 | | 0 | | 0 | | 0 | |
| pancreas | | | <50> | | <50> | | <50> | | <50> | |
| | leukemic cell infiltration | | 3 | | 7 | | 8 | | 1 | |
| | metastasis:uterus tumor | | 1 | | 1 | | 0 | | 1 | |
| {Urinary system} | | | | | | | | | | |
| kidney | | | <50> | | <50> | | <50> | | <50> | |
| | leukemic cell infiltration | | 8 | | 6 | | 13 | | 4 | |
| < a > | a : Number of animals examined at the site | | | | | | | | | |
| b | b : Number of animals with lesion | | | | | | | | | |

STUDY NO. : 0319
 ANIMAL : MOUSE CrJ:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 9

| | | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|-----------------------|--|-------------------------|------|------|------|-------|
| Organ | Findings | No. of Animals on Study | 50 | 50 | 50 | 50 |
| | | | | | | |
| {Urinary system} | | | | | | |
| kidney | | <50> | <50> | <50> | <50> | |
| | metastasis:uterus tumor | 2 | 2 | 1 | 3 | |
| urin bladd | | <50> | <50> | <50> | <50> | |
| | leukemic cell infiltration | 3 | 8 | 7 | 4 | |
| | metastasis:uterus tumor | 0 | 1 | 0 | 1 | |
| {Endocrine system} | | | | | | |
| pituitary | | <50> | <50> | <50> | <50> | |
| | metastasis:peripheral nerve tumor | 0 | 0 | 1 | 0 | |
| thyroid | | <50> | <50> | <50> | <50> | |
| | leukemic cell infiltration | 0 | 0 | 2 | 2 | |
| adrenal | | <50> | <50> | <50> | <50> | |
| | leukemic cell infiltration | 2 | 2 | 2 | 0 | |
| | metastasis:uterus tumor | 0 | 0 | 0 | 1 | |
| {Reproductive system} | | | | | | |
| ovary | | <50> | <50> | <50> | <50> | |
| | leukemic cell infiltration | 6 | 9 | 11 | 2 | |
| | metastasis:uterus tumor | 4 | 5 | 4 | 7 | |
| uterus | | <50> | <50> | <50> | <50> | |
| | leukemic cell infiltration | 7 | 7 | 10 | 1 | |
| vagina | | <50> | <50> | <50> | <50> | |
| | leukemic cell infiltration | 1 | 6 | 5 | 2 | |
| | | | | | | |
| < a > | a : Number of animals examined at the site | | | | | |
| b | b : Number of animals with lesion | | | | | |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 10

| Organ | Findings | Group Name | 0ppm | | 3ppm | | 6ppm | | 12ppm | | |
|----------------------------------|-----------------------------------|-------------------------|------|--|------|------|------|--|-------|--|------|
| | | No. of Animals on Study | 50 | | 50 | | 50 | | 50 | | |
| {Reproductive system} | | | | | | | | | | | |
| vagina | | | <50> | | | <50> | | | <50> | | <50> |
| | metastasis:uterus tumor | | 1 | | | 1 | | | 3 | | 3 |
| | metastasis:urinary bladder tumor | | 0 | | | 0 | | | 0 | | 1 |
| {Nervous system} | | | | | | | | | | | |
| brain | | | <50> | | | <50> | | | <50> | | <50> |
| | leukemic cell infiltration | | 1 | | | 1 | | | 2 | | 1 |
| | metastasis:pituitary tumor | | 1 | | | 3 | | | 0 | | 0 |
| spinal cord | | | <50> | | | <50> | | | <50> | | <50> |
| | leukemic cell infiltration | | 2 | | | 0 | | | 2 | | 1 |
| | metastasis:peripheral nerve tumor | | 0 | | | 0 | | | 1 | | 0 |
| {Special sense organs/appendage} | | | | | | | | | | | |
| eye | | | <50> | | | <50> | | | <50> | | <50> |
| | leukemic cell infiltration | | 0 | | | 1 | | | 3 | | 0 |
| Harder gl | | | <50> | | | <50> | | | <50> | | <50> |
| | leukemic cell infiltration | | 1 | | | 3 | | | 4 | | 2 |
| {Musculoskeletal system} | | | | | | | | | | | |
| muscle | | | <50> | | | <50> | | | <50> | | <50> |
| | leukemic cell infiltration | | 2 | | | 1 | | | 5 | | 0 |
| | metastasis:uterus tumor | | 0 | | | 0 | | | 0 | | 1 |
| {Body cavities} | | | | | | | | | | | |
| mediastinum | | | <50> | | | <50> | | | <50> | | <50> |
| | leukemic cell infiltration | | 1 | | | 0 | | | 1 | | 0 |

< a > a : Number of animals examined at the site
 b b : Number of animals with lesion

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 11

| Organ_____ | Findings_____ | Group Name | 0ppm | | 3ppm | | 6ppm | | 12ppm | | |
|-----------------|--|-------------------------|------|----|------|----|------|--|-------|--|--|
| | | No. of Animals on Study | 50 | 50 | 50 | 50 | 50 | | | | |
| <hr/> | | | | | | | | | | | |
| {Body cavities} | | | | | | | | | | | |
| mediastinum | | | <50> | | <50> | | <50> | | <50> | | |
| | metastasis:uterus tumor | | 0 | | 0 | | 0 | | 1 | | |
| peritoneum | | | <50> | | <50> | | <50> | | <50> | | |
| | leukemic cell infiltration | | 1 | | 0 | | 0 | | 0 | | |
| | metastasis:uterus tumor | | 1 | | 0 | | 0 | | 0 | | |
| retroperit | | | <50> | | <50> | | <50> | | <50> | | |
| | metastasis:uterus tumor | | 0 | | 0 | | 0 | | 1 | | |
| mesenterium | | | <50> | | <50> | | <50> | | <50> | | |
| | metastasis:uterus tumor | | 0 | | 0 | | 1 | | 0 | | |
| <hr/> | | | | | | | | | | | |
| < a > | a : Number of animals examined at the site | | | | | | | | | | |
| b | b : Number of animals with lesion | | | | | | | | | | |

(JPT150)

BAIS3

APPENDIX N 5

HISTOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY,
MOUSE: FEMALE: DEAD AND MORIBUND ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 5

| Organ_____ | Findings_____ | Group Name | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|----------------------------------|--|-------------------------|------|--|--|--|------|--|--|--|------|--|--|--|-------|--|--|--|
| | | No. of Animals on Study | 20 | | | | 25 | | | | 20 | | | | 16 | | | |
| | | | | | | | | | | | | | | | | | | |
| {Integumentary system/appandage} | | | | | | | | | | | | | | | | | | |
| skin/app | | | <20> | | | | <25> | | | | <20> | | | | <16> | | | |
| | leukemic cell infiltration | | 0 | | | | 3 | | | | 3 | | | | 0 | | | |
| subcutis | | | <20> | | | | <25> | | | | <20> | | | | <16> | | | |
| | leukemic cell infiltration | | 0 | | | | 1 | | | | 2 | | | | 0 | | | |
| {Respiratory system} | | | | | | | | | | | | | | | | | | |
| nasal cavit | | | <20> | | | | <25> | | | | <20> | | | | <16> | | | |
| | leukemic cell infiltration | | 0 | | | | 0 | | | | 2 | | | | 0 | | | |
| | metastasis:uterus tumor | | 0 | | | | 0 | | | | 0 | | | | 1 | | | |
| larynx | | | <20> | | | | <25> | | | | <20> | | | | <16> | | | |
| | leukemic cell infiltration | | 0 | | | | 1 | | | | 0 | | | | 0 | | | |
| trachea | | | <20> | | | | <25> | | | | <20> | | | | <16> | | | |
| | leukemic cell infiltration | | 0 | | | | 0 | | | | 2 | | | | 1 | | | |
| | metastasis:uterus tumor | | 0 | | | | 0 | | | | 1 | | | | 0 | | | |
| lung | | | <20> | | | | <25> | | | | <20> | | | | <16> | | | |
| | leukemic cell infiltration | | 5 | | | | 8 | | | | 10 | | | | 2 | | | |
| | metastasis:liver tumor | | 1 | | | | 0 | | | | 0 | | | | 0 | | | |
| | metastasis:uterus tumor | | 4 | | | | 3 | | | | 2 | | | | 3 | | | |
| | metastasis:subcutis tumor | | 0 | | | | 1 | | | | 0 | | | | 0 | | | |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | |
| bone marrow | | | <20> | | | | <25> | | | | <20> | | | | <16> | | | |
| | leukemic cell infiltration | | 1 | | | | 3 | | | | 3 | | | | 0 | | | |
| < a > | a : Number of animals examined at the site | | | | | | | | | | | | | | | | | |
| b | b : Number of animals with lesion | | | | | | | | | | | | | | | | | |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 6

| Organ | Findings | Group Name | Oppm | | | | 3ppm | | | | 6ppm | | | | 12ppm | | | |
|------------------------|--|-------------------------|------|----|------|----|------|------|----|----|------|----|----|------|-------|----|------|----|
| | | No. of Animals on Study | 20 | 25 | 30 | 40 | 20 | 25 | 30 | 40 | 20 | 25 | 30 | 40 | 20 | 25 | 30 | 40 |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | |
| bone marrow | | | <20> | | <25> | | | <20> | | | <25> | | | <20> | | | <16> | |
| | metastasis:uterus tumor | | 0 | | 4 | | | 1 | | | 1 | | | 1 | | | 1 | |
| lymph node | | | <20> | | <25> | | | <20> | | | <20> | | | <20> | | | <16> | |
| | metastasis:uterus tumor | | 0 | | 1 | | | 0 | | | 0 | | | 0 | | | 0 | |
| | metastasis:subcutis tumor | | 0 | | 1 | | | 0 | | | 0 | | | 0 | | | 0 | |
| thymus | | | <20> | | <25> | | | <20> | | | <20> | | | <20> | | | <16> | |
| | leukemic cell infiltration | | 1 | | 3 | | | 0 | | | 0 | | | 0 | | | 0 | |
| spleen | | | <20> | | <25> | | | <20> | | | <20> | | | <20> | | | <16> | |
| | leukemic cell infiltration | | 4 | | 8 | | | 9 | | | 9 | | | 9 | | | 1 | |
| {Circulatory system} | | | | | | | | | | | | | | | | | | |
| heart | | | <20> | | <25> | | | <20> | | | <20> | | | <20> | | | <16> | |
| | leukemic cell infiltration | | 1 | | 5 | | | 5 | | | 5 | | | 5 | | | 1 | |
| | metastasis:uterus tumor | | 1 | | 0 | | | 0 | | | 0 | | | 0 | | | 0 | |
| {Digestive system} | | | | | | | | | | | | | | | | | | |
| tongue | | | <20> | | <25> | | | <20> | | | <20> | | | <20> | | | <16> | |
| | leukemic cell infiltration | | 1 | | 4 | | | 1 | | | 1 | | | 1 | | | 1 | |
| salivary gl | | | <20> | | <25> | | | <20> | | | <20> | | | <20> | | | <16> | |
| | leukemic cell infiltration | | 3 | | 6 | | | 5 | | | 5 | | | 5 | | | 1 | |
| esophagus | | | <20> | | <25> | | | <20> | | | <20> | | | <20> | | | <16> | |
| | leukemic cell infiltration | | 0 | | 1 | | | 0 | | | 0 | | | 0 | | | 0 | |
| stomach | | | <20> | | <25> | | | <20> | | | <20> | | | <20> | | | <16> | |
| | leukemic cell infiltration | | 3 | | 7 | | | 9 | | | 9 | | | 9 | | | 1 | |
| < a > | a : Number of animals examined at the site | | | | | | | | | | | | | | | | | |
| b | b : Number of animals with lesion | | | | | | | | | | | | | | | | | |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 7

| Organ | Findings | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|--------------------|--|-------------------------|------|------|------|-------|
| | | No. of Animals on Study | 20 | 25 | 20 | 16 |
| {Digestive system} | | | | | | |
| stomach | | | <20> | <25> | <20> | <16> |
| | metastasis:uterus tumor | | 1 | 1 | 2 | 2 |
| small intes | | | <20> | <25> | <20> | <16> |
| | leukemic cell infiltration | | 1 | 1 | 0 | 0 |
| | metastasis:uterus tumor | | 0 | 0 | 2 | 2 |
| large intes | | | <20> | <25> | <20> | <16> |
| | leukemic cell infiltration | | 1 | 1 | 0 | 0 |
| liver | | | <20> | <25> | <20> | <16> |
| | leukemic cell infiltration | | 6 | 9 | 8 | 3 |
| | metastasis:uterus tumor | | 5 | 6 | 4 | 6 |
| | metastasis:spleen tumor | | 0 | 0 | 0 | 1 |
| gall bladd | | | <20> | <25> | <20> | <16> |
| | leukemic cell infiltration | | 1 | 0 | 1 | 1 |
| | metastasis:uterus tumor | | 1 | 0 | 0 | 0 |
| pancreas | | | <20> | <25> | <20> | <16> |
| | leukemic cell infiltration | | 3 | 6 | 5 | 1 |
| | metastasis:uterus tumor | | 1 | 1 | 0 | 0 |
| {Urinary system} | | | | | | |
| kidney | | | <20> | <25> | <20> | <16> |
| | leukemic cell infiltration | | 4 | 4 | 7 | 2 |
| | metastasis:uterus tumor | | 2 | 2 | 1 | 2 |
| < a > | a : Number of animals examined at the site | | | | | |
| b | b : Number of animals with lesion | | | | | |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 8

| Organ_____ | Findings_____ | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|-----------------------|--|-------------------------|------|------|------|-------|
| | | No. of Animals on Study | 20 | 25 | 20 | 16 |
| <hr/> | | | | | | |
| {Urinary system} | | | | | | |
| urin bladd | | <20> | <25> | <20> | <16> | |
| | leukemic cell infiltration | 1 | 5 | 3 | 1 | |
| | metastasis:uterus tumor | 0 | 1 | 0 | 1 | |
| {Endocrine system} | | | | | | |
| pituitary | | <20> | <25> | <20> | <16> | |
| | metastasis:peripheral nerve tumor | 0 | 0 | 1 | 0 | |
| thyroid | | <20> | <25> | <20> | <16> | |
| | leukemic cell infiltration | 0 | 0 | 1 | 1 | |
| adrenal | | <20> | <25> | <20> | <16> | |
| | leukemic cell infiltration | 1 | 2 | 1 | 0 | |
| | metastasis:uterus tumor | 0 | 0 | 0 | 1 | |
| {Reproductive system} | | | | | | |
| ovary | | <20> | <25> | <20> | <16> | |
| | leukemic cell infiltration | 4 | 6 | 7 | 1 | |
| | metastasis:uterus tumor | 3 | 5 | 4 | 6 | |
| uterus | | <20> | <25> | <20> | <16> | |
| | leukemic cell infiltration | 4 | 5 | 7 | 1 | |
| vagina | | <20> | <25> | <20> | <16> | |
| | leukemic cell infiltration | 1 | 5 | 4 | 1 | |
| | metastasis:uterus tumor | 1 | 1 | 3 | 2 | |
| | metastasis:urinary bladder tumor | 0 | 0 | 0 | 1 | |
| <hr/> | | | | | | |
| < a > | a : Number of animals examined at the site | | | | | |
| b | b : Number of animals with lesion | | | | | |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 9

| | | Group Name | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|----------------------------------|-----------------------------------|--|-----------|-----------|------|----|-----------|----|-----------|----|
| Organ | Findings | No. of Animals on Study | 20 | 25 | 20 | 25 | 20 | 25 | 16 | 20 |
| {Nervous system} | | | | | | | | | | |
| brain | leukemic cell infiltration | | <20> 1 | <25> 1 | | | <20> 2 | | <16> 0 | |
| | metastasis:pituitary tumor | | 1 | 2 | | | 0 | | 0 | |
| spinal cord | leukemic cell infiltration | | <20> 1 | <25> 0 | | | <20> 1 | | <16> 0 | |
| | metastasis:peripheral nerve tumor | | 0 | 0 | | | 1 | | 0 | |
| {Special sense organs/appendage} | | | | | | | | | | |
| eye | leukemic cell infiltration | | <20> 0 | <25> 1 | | | <20> 3 | | <16> 0 | |
| | Harder gl | | <20> 0 | <25> 3 | | | <20> 3 | | <16> 1 | |
| {Musculoskeletal system} | | | | | | | | | | |
| muscle | leukemic cell infiltration | | <20> 1 | <25> 1 | | | <20> 4 | | <16> 0 | |
| | metastasis:uterus tumor | | 0 | 0 | | | 0 | | 1 | |
| {Body cavities} | | | | | | | | | | |
| mediastinum | leukemic cell infiltration | | <20> 0 | <25> 0 | | | <20> 1 | | <16> 0 | |
| | metastasis:uterus tumor | | 0 | 0 | | | 0 | | 1 | |
| peritoneum | leukemic cell infiltration | | <20> 1 | <25> 0 | | | <20> 0 | | <16> 0 | |
| | | | | | | | | | | |
| < a > | | a : Number of animals examined at the site | | | | | | | | |
| b | | b : Number of animals with lesion | | | | | | | | |

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

PAGE : 10

| Organ | Findings | Group Name | 0ppm | 3ppm | 6ppm | 12ppm |
|-----------------|-------------------------|-------------------------|------|------|------|-------|
| | | No. of Animals on Study | 20 | 25 | 20 | 16 |
| {Body cavities} | | | | | | |
| peritoneum | | | <20> | <25> | <20> | <16> |
| | metastasis:uterus tumor | | 1 | 0 | 0 | 0 |
| retroperit | | | <20> | <25> | <20> | <16> |
| | metastasis:uterus tumor | | 0 | 0 | 0 | 1 |
| mesenterium | | | <20> | <25> | <20> | <16> |
| | metastasis:uterus tumor | | 0 | 0 | 1 | 0 |

< a > a : Number of animals examined at the site
b b : Number of animals with lesion

(JPT150)

BAIS3

APPENDIX N 6

HISTOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY,
MOUSE: FEMALE: SACRIFICED ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0319
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 5

| | | Group Name | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|----------------------------------|----------------------------------|-------------------------|------|------|------|------|------|------|-------|--|
| Organ_____ | Findings_____ | No. of Animals on Study | 30 | 25 | 30 | 34 | | | | |
| | | | | | | | | | | |
| {Integumentary system/appandage} | | | | | | | | | | |
| skin/app | | <30> | | <25> | | <30> | | <34> | | |
| | leukemic cell infiltration | 1 | | 0 | | 1 | | 0 | | |
| subcutis | | <30> | | <25> | | <30> | | <34> | | |
| | leukemic cell infiltration | 0 | | 1 | | 0 | | 0 | | |
| | | | | | | | | | | |
| {Respiratory system} | | | | | | | | | | |
| larynx | | <30> | | <25> | | <30> | | <34> | | |
| | leukemic cell infiltration | 0 | | 0 | | 0 | | 1 | | |
| trachea | | <30> | | <25> | | <30> | | <34> | | |
| | leukemic cell infiltration | 0 | | 0 | | 1 | | 0 | | |
| lung | | <30> | | <25> | | <30> | | <34> | | |
| | leukemic cell infiltration | 4 | | 2 | | 6 | | 2 | | |
| | metastasis:uterus tumor | 1 | | 0 | | 0 | | 0 | | |
| | metastasis:adrenal tumor | 0 | | 0 | | 0 | | 1 | | |
| | | | | | | | | | | |
| {Hematopoietic system} | | | | | | | | | | |
| bone marrow | | <30> | | <25> | | <30> | | <34> | | |
| | leukemic cell infiltration | 4 | | 2 | | 7 | | 4 | | |
| | metastasis:uterus tumor | 1 | | 0 | | 0 | | 0 | | |
| lymph node | | <30> | | <25> | | <30> | | <34> | | |
| | leukemic cell infiltration | 1 | | 0 | | 0 | | 1 | | |
| | metastasis:small intestine tumor | 1 | | 0 | | 0 | | 0 | | |
| thymus | | <30> | | <25> | | <30> | | <34> | | |
| | leukemic cell infiltration | 1 | | 1 | | 1 | | 1 | | |

< a > a : Number of animals examined at the site
b b : Number of animals with lesion

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 6

| | | Group Name | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|------------------------|----------------------------|-------------------------|-----------|-----------|------|----|-----------|----|-----------|----|
| Organ | Findings | No. of Animals on Study | 30 | 25 | 30 | 25 | 30 | 25 | 34 | 25 |
| | | | | | | | | | | |
| {Hematopoietic system} | | | | | | | | | | |
| spleen | leukemic cell infiltration | | <30> 4 | <25> 3 | | | <30> 6 | | <34> 2 | |
| {Circulatory system} | | | | | | | | | | |
| heart | leukemic cell infiltration | | <30> 1 | <25> 0 | | | <30> 1 | | <34> 1 | |
| {Digestive system} | | | | | | | | | | |
| tongue | leukemic cell infiltration | | <30> 1 | <25> 0 | | | <30> 1 | | <34> 1 | |
| salivary gl | leukemic cell infiltration | | <30> 3 | <25> 1 | | | <30> 3 | | <34> 1 | |
| esophagus | leukemic cell infiltration | | <30> 0 | <25> 0 | | | <30> 1 | | <34> 0 | |
| stomach | leukemic cell infiltration | | <30> 4 | <25> 3 | | | <30> 4 | | <34> 1 | |
| small intes | leukemic cell infiltration | | <30> 0 | <25> 2 | | | <30> 0 | | <34> 0 | |
| liver | leukemic cell infiltration | | <30> 4 | <25> 1 | | | <30> 9 | | <34> 5 | |
| | metastasis:uterus tumor | | 1 | 0 | | | 0 | | 3 | |
| pancreas | leukemic cell infiltration | | <30> 0 | <25> 1 | | | <30> 3 | | <34> 0 | |
| | metastasis:uterus tumor | | 0 | 0 | | | 0 | | 1 | |

< a > a : Number of animals examined at the site
 b b : Number of animals with lesion

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 7

| | | Group Name | 0ppm | | 3ppm | | 6ppm | | 12ppm | |
|-----------------------|--|-------------------------|------|------|------|------|------|--|-------|--|
| Organ | Findings | No. of Animals on Study | 30 | 25 | 30 | 34 | | | | |
| {Urinary system} | | | | | | | | | | |
| kidney | | | <30> | <25> | <30> | <34> | | | | |
| | leukemic cell infiltration | | 4 | 2 | 6 | 2 | | | | |
| | metastasis:uterus tumor | | 0 | 0 | 0 | 1 | | | | |
| urin bladd | | | <30> | <25> | <30> | <34> | | | | |
| | leukemic cell infiltration | | 2 | 3 | 4 | 3 | | | | |
| {Endocrine system} | | | | | | | | | | |
| thyroid | | | <30> | <25> | <30> | <34> | | | | |
| | leukemic cell infiltration | | 0 | 0 | 1 | 1 | | | | |
| adrenal | | | <30> | <25> | <30> | <34> | | | | |
| | leukemic cell infiltration | | 1 | 0 | 1 | 0 | | | | |
| {Reproductive system} | | | | | | | | | | |
| ovary | | | <30> | <25> | <30> | <34> | | | | |
| | leukemic cell infiltration | | 2 | 3 | 4 | 1 | | | | |
| | metastasis:uterus tumor | | 1 | 0 | 0 | 1 | | | | |
| uterus | | | <30> | <25> | <30> | <34> | | | | |
| | leukemic cell infiltration | | 3 | 2 | 3 | 0 | | | | |
| vagina | | | <30> | <25> | <30> | <34> | | | | |
| | leukemic cell infiltration | | 0 | 1 | 1 | 1 | | | | |
| | metastasis:uterus tumor | | 0 | 0 | 0 | 1 | | | | |
| {Nervous system} | | | | | | | | | | |
| brain | | | <30> | <25> | <30> | <34> | | | | |
| | leukemic cell infiltration | | 0 | 0 | 0 | 1 | | | | |
| < a > | a : Number of animals examined at the site | | | | | | | | | |
| b | b : Number of animals with lesion | | | | | | | | | |

STUDY NO. : 0319
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 8

| | | Group Name | Oppm | | | | 12ppm | |
|---|----------------------------|-------------------------|-----------|-----------|-----------|------|-----------|--|
| | | No. of Animals on Study | 30 | 25 | 30 | 6ppm | 34 | |
| Organ | Findings | | | | | | | |
| {Nervous system} | | | | | | | | |
| brain | metastasis:pituitary tumor | | <30> 0 | <25> 1 | <30> 0 | | <34> 0 | |
| spinal cord | leukemic cell infiltration | | <30> 1 | <25> 0 | <30> 1 | | <34> 1 | |
| {Special sense organs/appendage} | | | | | | | | |
| Harder gl | leukemic cell infiltration | | <30> 1 | <25> 0 | <30> 1 | | <34> 1 | |
| {Musculoskeletal system} | | | | | | | | |
| muscle | leukemic cell infiltration | | <30> 1 | <25> 0 | <30> 1 | | <34> 0 | |
| {Body cavities} | | | | | | | | |
| mediastinum | leukemic cell infiltration | | <30> 1 | <25> 0 | <30> 0 | | <34> 0 | |
| < a > a : Number of animals examined at the site b b : Number of animals with lesion | | | | | | | | |

(JPT150)

BAIS3

APPENDIX O 1

IDENTITY AND IMPURITY OF CROTONALDEHYDE IN THE 2-YEAR INHALATION STUDY

IDENTITY AND IMPURITY OF CROTONALDEHYDE IN THE 2-YEAR INHALATION STUDY

Test Substance : Crotonaldehyde (Wako Pure Chemical Industries, Ltd.)

A. Lot No. : SKJ4743

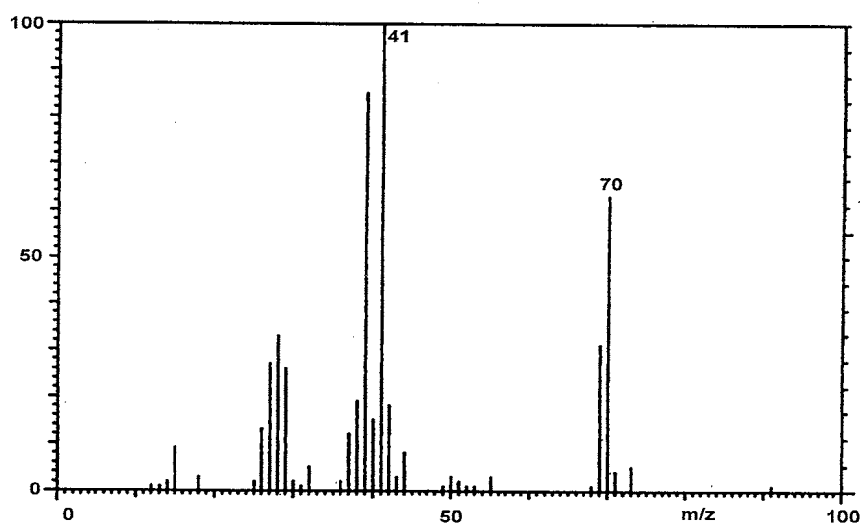
1. Spectral data

Mass Spectrometry

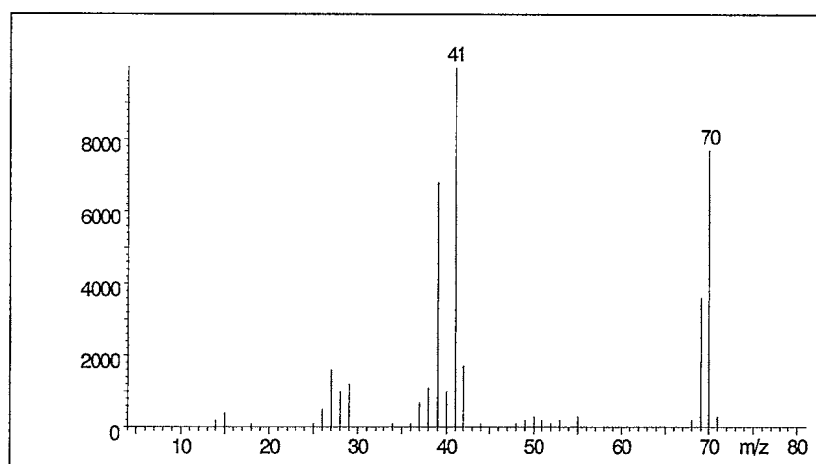
Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance



Mass Spectrum of Literature Data*

Results: The mass spectrum was consistent with literature spectrum.

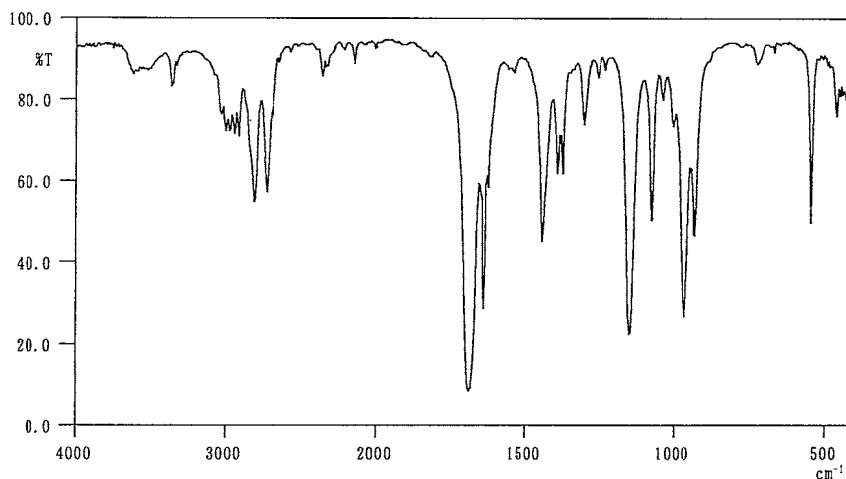
(*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition.
John Wiley and Sons, Inc. (U.S.), Entry Number 1111)

Infrared Spectrometry

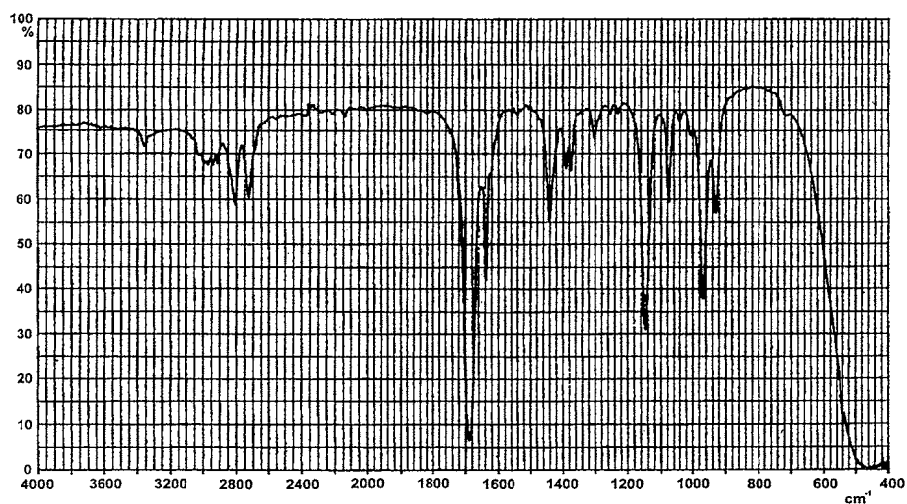
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 4 cm^{-1}



Infrared Spectrum of Test Substance



Infrared Spectrum of Literature Data*

Results: The infrared spectrum was consistent with literature spectrum.
(*Performed by the Wako Pure Chemical Industries, Ltd.)

2. Impurity

Instrument : Hewlett Packard 5890A Gas Chromatograph
Column : FALM (2 mm ϕ \times 2 m)
Column Temperature: 60° C \rightarrow (10° C/min) \rightarrow 150°
Flow Rate : 25 mL/min
Detector : FID (Flame Ionization Detector)
Injection Volume : 1 μ L

| Sample Name | Peak No. | Area (%) | Peak Name |
|----------------|----------|----------|----------------|
| Test Substance | 1 | 99.89 | Crotonaldehyde |
| | 2 | 0.07 | N.I.M.* |
| | 3 | 0.04 | Crotonic Acid |

* Not Identified Material

Results: Gas chromatography indicated one major peak (peak No.1) and two impurities. It was identified only by comparing its gas chromatograph with that of crotonic acid (peak No.3) in the crotonaldehyde, the amounts in the test substance were 99.89% and 0.04%. However, peak No.2 cannot be identified, the amount of the peak was 0.07%.

3. Conclusions: The test substance was identified as crotonaldehyde, by the mass spectrum and the infrared spectrum. Gas chromatography indicated one major peak (crotonaldehyde) and two impurities.

B. Lot No. : LEL4703

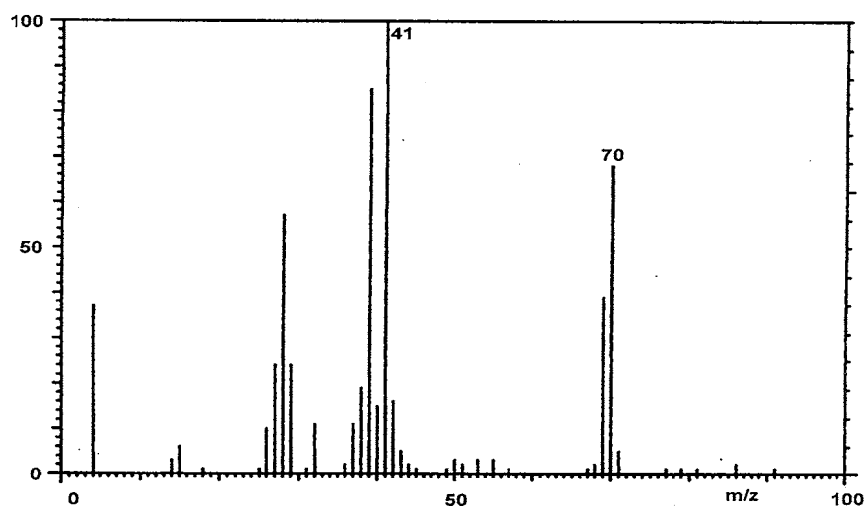
1. Spectral data

Mass Spectrometry

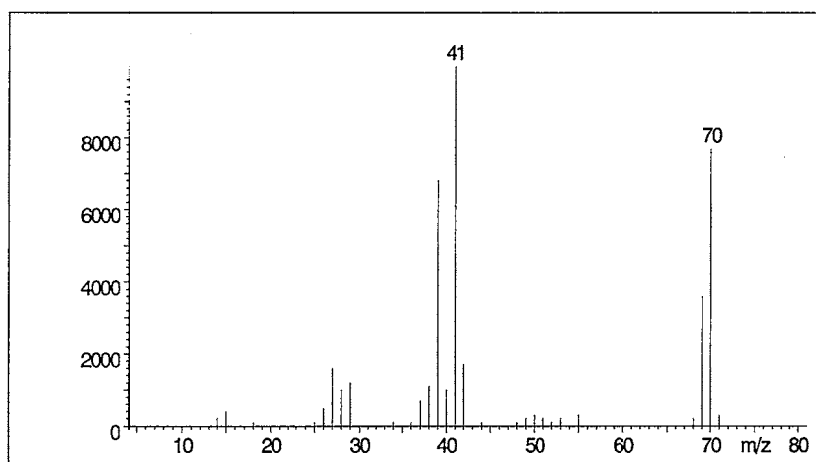
Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance



Mass Spectrum of Literature Data*

Results: The mass spectrum was consistent with literature spectrum.

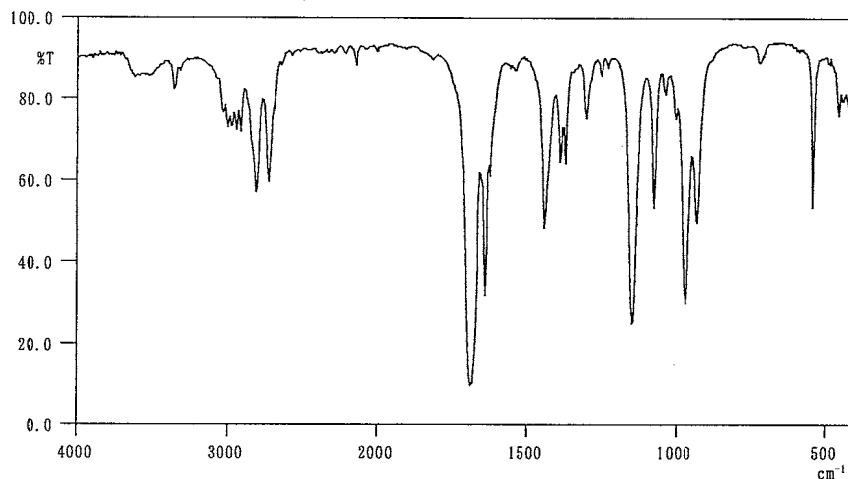
(*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition.
John Wiley and Sons, Inc. (U.S.), Entry Number 1111)

Infrared Spectrometry

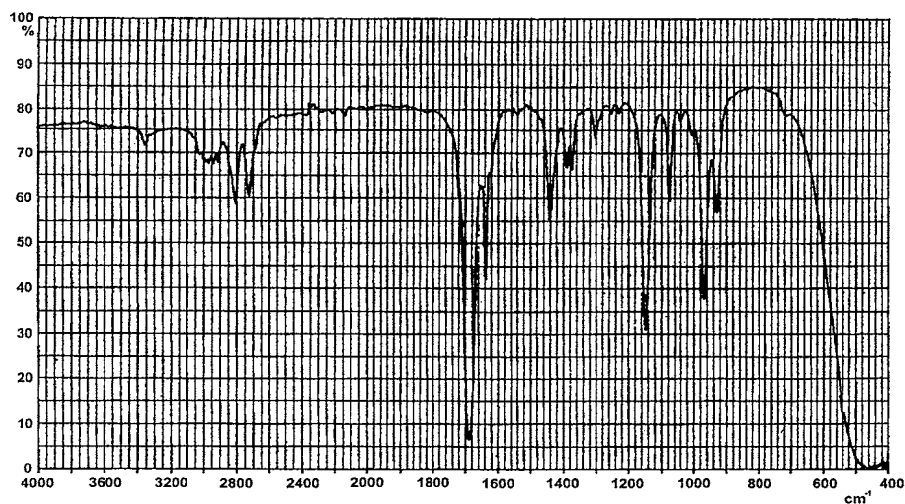
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 4 cm^{-1}



Infrared Spectrum of Test Substance



Infrared Spectrum of Literature Data*

Results: The infrared spectrum was consistent with literature spectrum.
(*Performed by the Wako Pure Chemical Industries, Ltd.)

2. Impurity

Instrument : Hewlett Packard 5890A Gas Chromatograph
Column : FALM (2 mm ϕ \times 2 m)
Column Temperature: 60° C \rightarrow (10° C/min) \rightarrow 150°
Flow Rate : 25 mL/min
Detector : FID (Flame Ionization Detector)
Injection Volume : 1 μ L

| Sample Name | Peak No. | Area (%) | Peak Name |
|----------------|----------|----------|----------------|
| Test Substance | 1 | 99.86 | Crotonaldehyde |
| | 2 | 0.07 | N.I.M.* |
| | 3 | 0.07 | Crotonic Acid |

* Not Identified Material

Results: Gas chromatography indicated one major peak (peak No.1) and two impurities. It was identified only by comparing its gas chromatograph with that of crotonic acid (peak No.3) in the crotonaldehyde, the amounts in the test substance were 99.86% and 0.07%. However, peak No.2 cannot be identified, the amount of the peak was 0.07%.

3. Conclusions: The test substance was identified as crotonaldehyde, by the mass spectrum and the infrared spectrum. Gas chromatography indicated one major peak (crotonaldehyde) and two impurities.

C. Lot No. : LEH5371

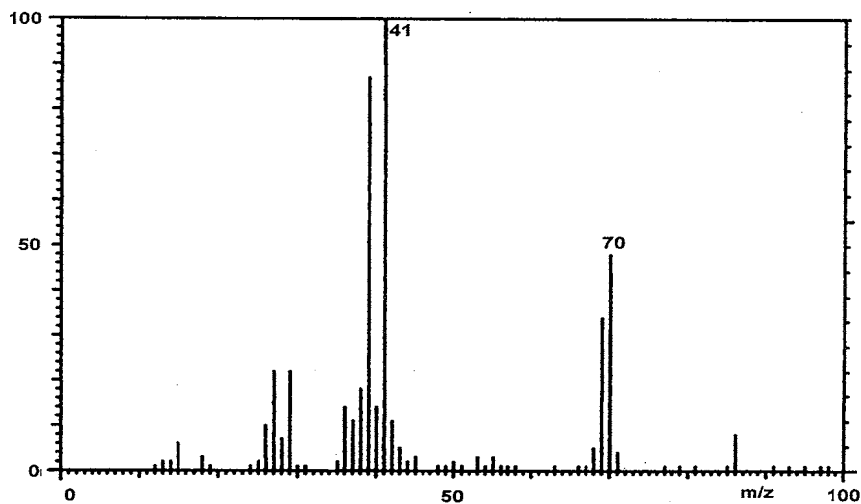
1. Spectral data

Mass Spectrometry

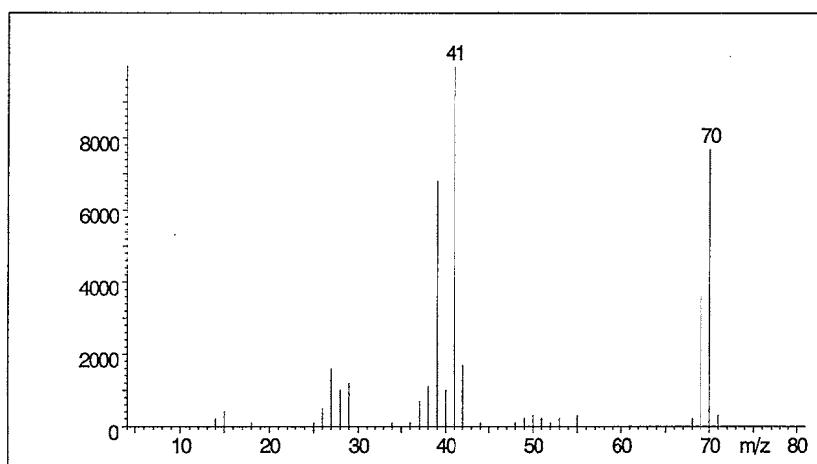
Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance



Mass Spectrum of Literature Data*

Results: The mass spectrum was consistent with literature spectrum.

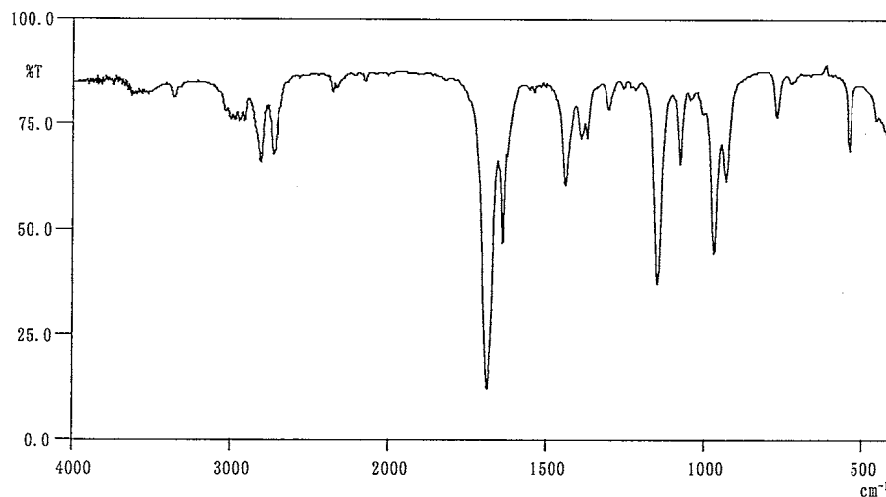
(*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition.
John Wiley and Sons, Inc. (U.S.), Entry Number 1111)

Infrared Spectrometry

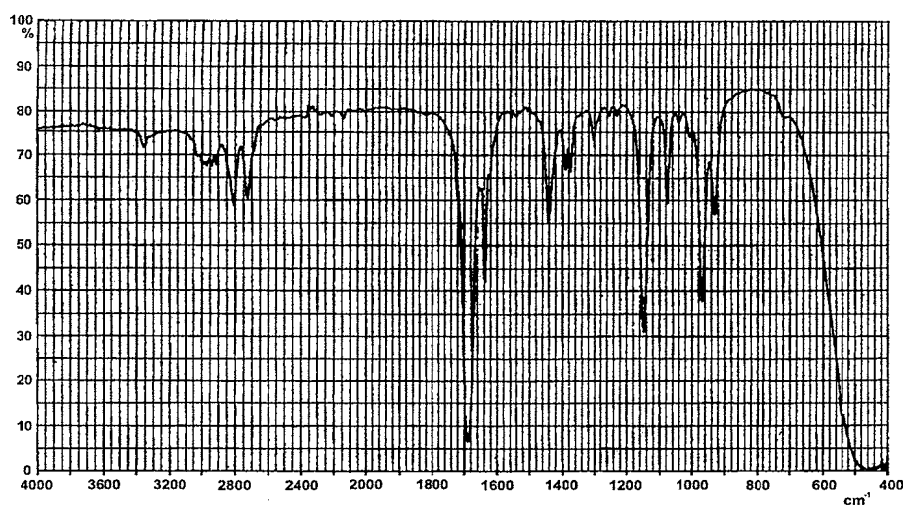
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 4 cm^{-1}



Infrared Spectrum of Test Substance



Infrared Spectrum of Literature Data*

Results: The infrared spectrum was consistent with literature spectrum.
(*Performed by the Wako Pure Chemical Industries, Ltd.)

2. Impurity

Instrument : Hewlett Packard 5890A Gas Chromatograph
Column : FALM (2 mm ϕ \times 2 m)
Column Temperature: 60° C \rightarrow (10° C/min) \rightarrow 150°
Flow Rate : 25 mL/min
Detector : FID (Flame Ionization Detector)
Injection Volume : 1 μ L

| Sample Name | Peak No. | Area (%) | Peak Name |
|----------------|----------|----------|----------------|
| Test Substance | 1 | 99.86 | Crotonaldehyde |
| | 2 | 0.05 | N.I.M.* |
| | 3 | 0.09 | Crotonic Acid |

* Not Identified Material

Results: Gas chromatography indicated one major peak (peak No.1) and two impurities. It was identified only by comparing its gas chromatograph with that of crotonic acid (peak No.3) in the crotonaldehyde, the amounts in the test substance were 99.86% and 0.09%. However, peak No.2 cannot be identified, the amount of the peak was 0.05%.

3. Conclusions: The test substance was identified as crotonaldehyde, by the mass spectrum and the infrared spectrum. Gas chromatography indicated one major peak (crotonaldehyde) and two impurities.

D. Lot No. : WTK5303

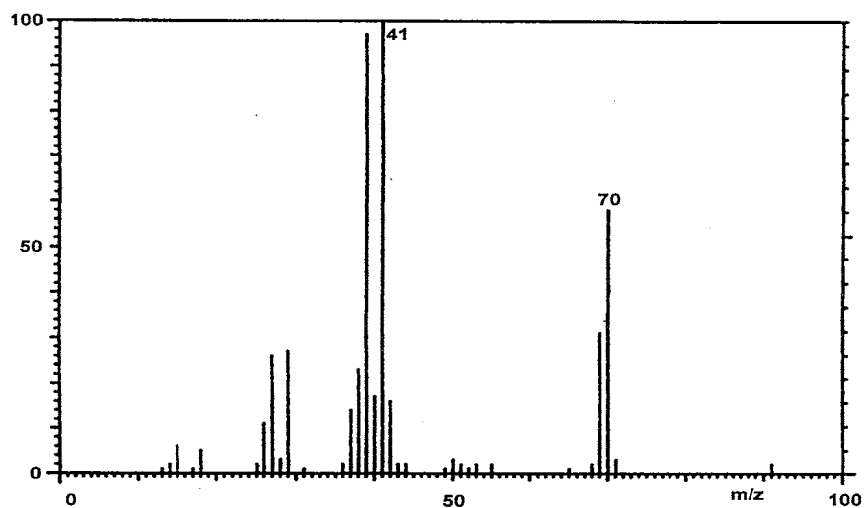
1. Spectral data

Mass Spectrometry

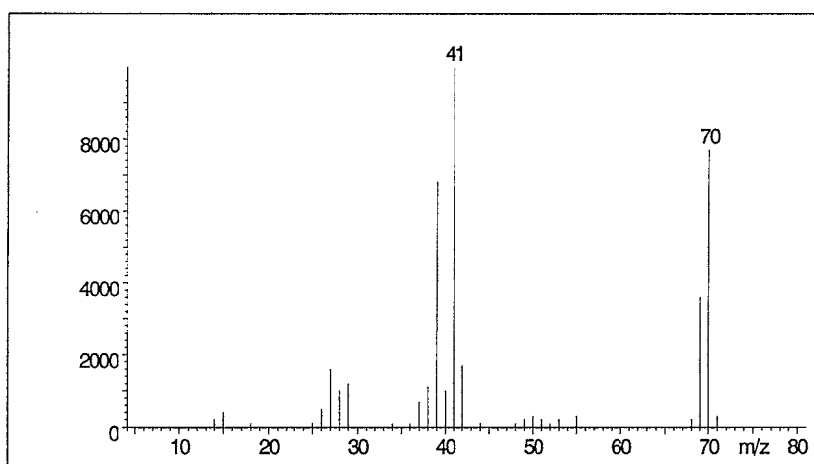
Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance



Mass Spectrum of Literature Data*

Results: The mass spectrum was consistent with literature spectrum.

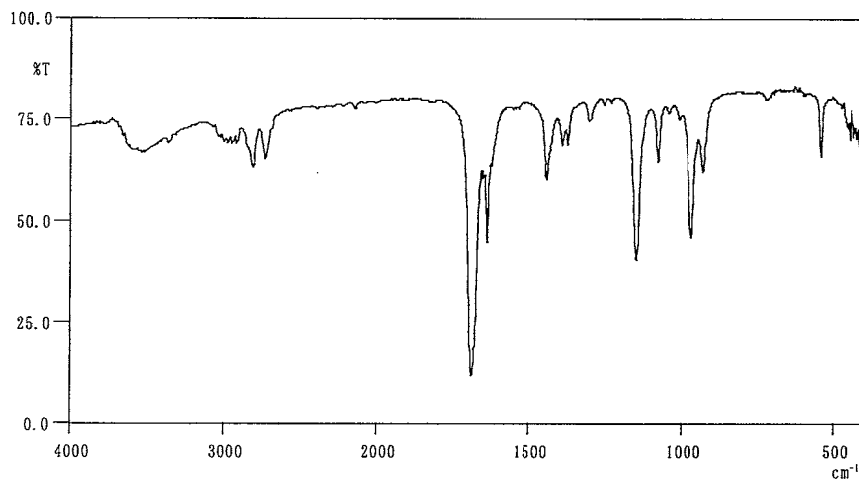
(*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition.
John Wiley and Sons, Inc. (U.S.), Entry Number 1111)

Infrared Spectrometry

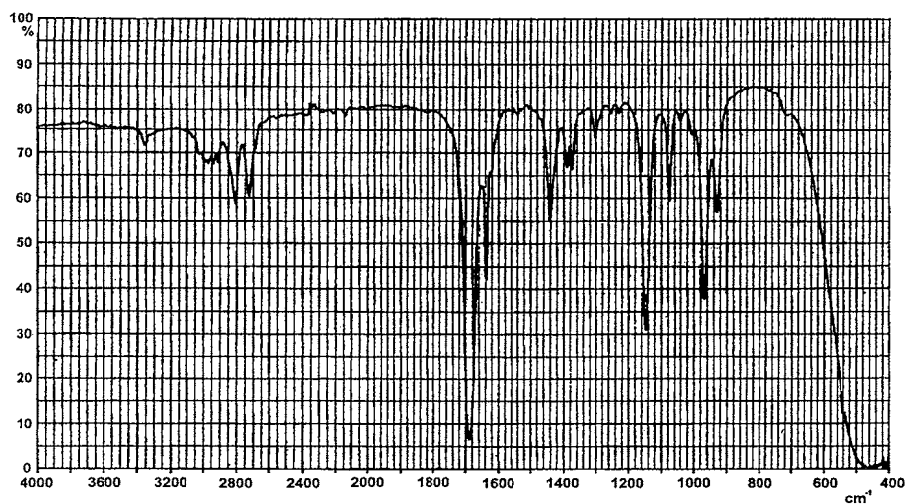
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 4 cm^{-1}



Infrared Spectrum of Test Substance



Infrared Spectrum of Literature Data*

Results: The infrared spectrum was consistent with literature spectrum.
(*Performed by the Wako Pure Chemical Industries, Ltd.)

2. Impurity

Instrument : Hewlett Packard 5890A Gas Chromatograph
Column : FALM (2 mm ϕ \times 2 m)
Column Temperature: 60° C \rightarrow (10° C/min) \rightarrow 150°
Flow Rate : 25 mL/min
Detector : FID (Flame Ionization Detector)
Injection Volume : 1 μ L

| Sample Name | Peak No. | Area (%) | Peak Name |
|----------------|----------|----------|----------------|
| Test Substance | 1 | 99.85 | Crotonaldehyde |
| | 2 | 0.04 | N.I.M.* |
| | 3 | 0.11 | Crotonic Acid |

* Not Identified Material

Results: Gas chromatography indicated one major peak (peak No.1) and two impurities. It was identified only by comparing its gas chromatograph with that of crotonic acid (peak No.3) in the crotonaldehyde, the amounts in the test substance were 99.85% and 0.11%. However, peak No.2 cannot be identified, the amount of the peak was 0.04%.

3. Conclusions: The test substance was identified as crotonaldehyde, by the mass spectrum and the infrared spectrum. Gas chromatography indicated one major peak (crotonaldehyde) and two impurities.

E. Lot No. : WTE4391

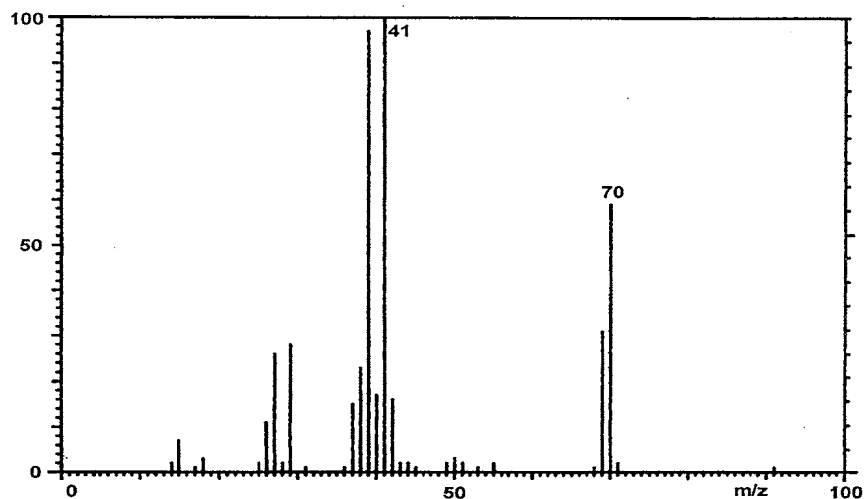
1. Spectral data

Mass Spectrometry

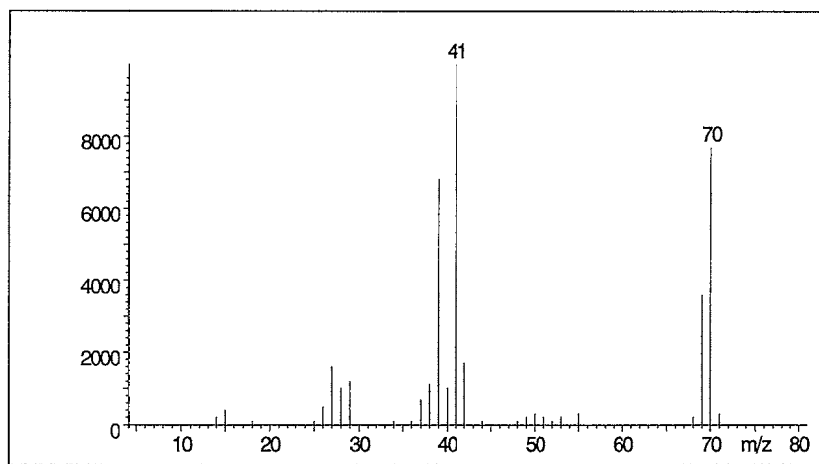
Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance



Mass Spectrum of Literature Data*

Results: The mass spectrum was consistent with literature spectrum.

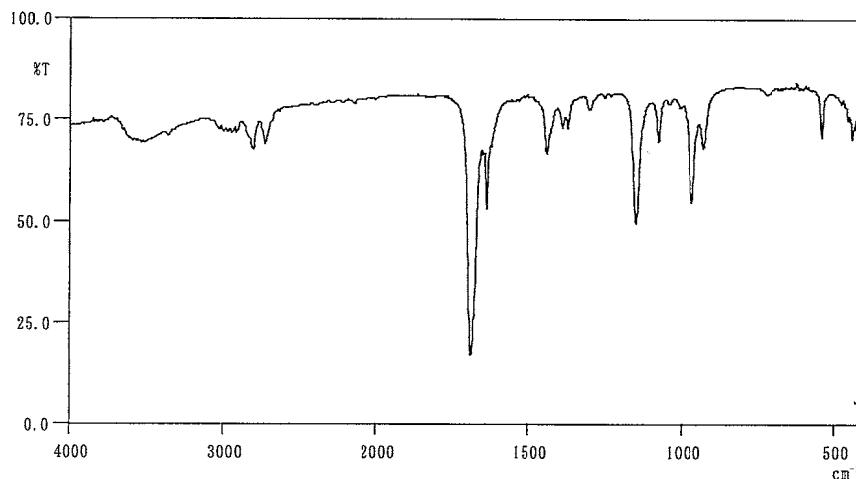
(*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition.
John Wiley and Sons, Inc. (U.S.), Entry Number 1111)

Infrared Spectrometry

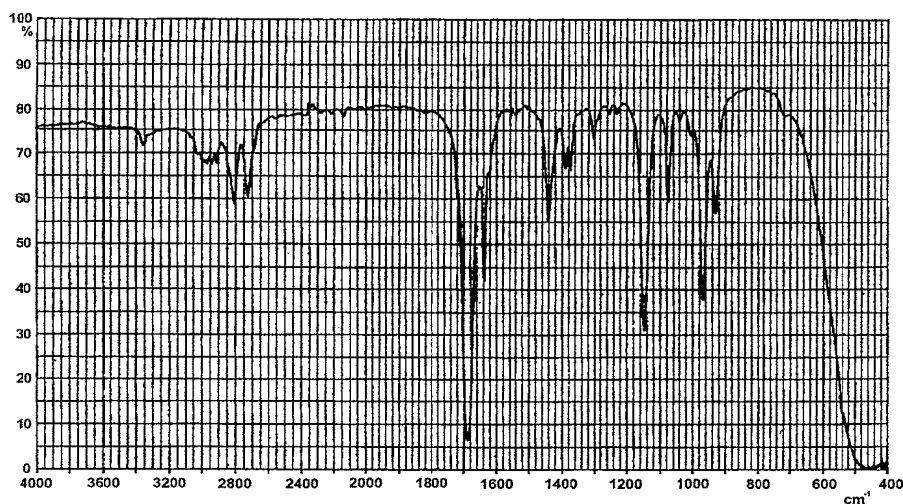
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 4 cm^{-1}



Infrared Spectrum of Test Substance



Infrared Spectrum of Literature Data*

Results: The infrared spectrum was consistent with literature spectrum.
(*Performed by the Wako Pure Chemical Industries, Ltd.)

2. Impurity

Instrument : Hewlett Packard 5890A Gas Chromatograph
 Column : FALM (2 mm ϕ \times 2 m)
 Column Temperature: 60° C \rightarrow (10° C/min) \rightarrow 150°
 Flow Rate : 25 mL/min
 Detector : FID (Flame Ionization Detector)
 Injection Volume : 1 μ L

| Sample Name | Peak No. | Area (%) | Peak Name |
|----------------|----------|----------|----------------|
| Test Substance | 1 | 99.85 | Crotonaldehyde |
| | 2 | 0.04 | N.I.M.* |
| | 3 | 0.11 | Crotonic Acid |

* Not Identified Material

Results: Gas chromatography indicated one major peak (peak No.1) and two impurities. It was identified only by comparing its gas chromatograph with that of crotonic acid (peak No.3) in the crotonaldehyde, the amounts in the test substance were 99.85% and 0.11%. However, peak No.2 cannot be identified, the amount of the peak was 0.04%.

3. Conclusions: The test substance was identified as crotonaldehyde, by the mass spectrum and the infrared spectrum. Gas chromatography indicated one major peak (crotonaldehyde) and two impurities.

APPENDIX O 2
STABILITY OF CROTONALDEHYDE IN THE 2-YEAR
INHALATION STUDY

STABILITY OF CROTONALDEHYDE IN THE 2-YEAR INHALATION STUDY

Test Substance : Crotonaldehyde (Wako Pure Chemical Industries, Ltd.)

A. Lot No. : SKJ4743

1. Sample : This lot was used from 1996.11.22 to 1997.4.1. Test substance was stored at room temperature.

2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : FALM (2 mm ϕ \times 2 m)

Column Temperature: 60° C \rightarrow (10° C/min) \rightarrow 150°

Flow Rate : 25 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

| Date (date analyzed) | Peak No. | Retention Time (min) | Area (%) |
|-------------------------|----------|-------------------------|-------------|
| 1996.10.21 | 1 | 2.058 | 99.89 |
| | 2 | 4.828 | 0.07 |
| | 3 | 10.235 | 0.04 |
| 1997.04.03 | 1 | 2.048 | 99.88 |
| | 2 | 4.824 | 0.07 |
| | 3 | 10.224 | 0.05 |

Results: Gas chromatography indicated one major peak (peak No.1) and two impurities (peaks No.2 and 3 < 0.2% of total area) analyzed at 1996.10.21 and one major peak (peak No.1) and two impurities (peaks No.2 and 3 < 0.2% of total area) analyzed at 1997.4.3. No new trace impurity peak in the test substance analyzed at 1997.4.3 was detected.

3. Conclusions: The test substance was stable for about 6 months at room temperature.

B. Lot No. : LEL4703

1. Sample : This lot was used from 1997.4.2 to 1997.8.25. Test substance was stored at room temperature.

2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : FALM (2 mm ϕ \times 2 m)

Column Temperature: 60° C \rightarrow (10° C/min) \rightarrow 150°

Flow Rate : 25 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

| Date (date analyzed) | Peak No. | Retention Time (min) | Area (%) |
|-------------------------|----------|-------------------------|-------------|
| 1997.04.01 | 1 | 2.056 | 99.86 |
| | 2 | 4.823 | 0.07 |
| | 3 | 10.219 | 0.07 |
| 1997.08.26 | 1 | 2.060 | 99.85 |
| | 2 | 4.822 | 0.07 |
| | 3 | 10.217 | 0.08 |

Results: Gas chromatography indicated one major peak (peak No.1) and two impurities (peaks No.2 and 3 < 0.2% of total area) analyzed at 1997.4.1 and one major peak (peak No.1) and two impurities (peaks No.2 and 3 < 0.2% of total area) analyzed at 1997.8.26. No new trace impurity peak in the test substance analyzed at 1997.8.26 was detected.

3. Conclusions: The test substance was stable for about 5 months at room temperature.

C. Lot No. : LEH5371

1. Sample : This lot was used from 1997.8.26 to 1998.1.6. Test substance was stored at room temperature.

2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : FALM (2 mm ϕ \times 2 m)

Column Temperature: 60° C \rightarrow (10° C/min) \rightarrow 150°

Flow Rate : 25 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

| Date (date analyzed) | Peak No. | Retention Time (min) | Area (%) |
|-------------------------|----------|-------------------------|-------------|
| 1997.08.25 | 1 | 2.050 | 99.86 |
| | 2 | 4.821 | 0.05 |
| | 3 | 10.213 | 0.09 |
| 1998.01.07 | 1 | 2.057 | 99.90 |
| | 2 | 5.009 | 0.05 |
| | 3 | 10.329 | 0.05 |

Results: Gas chromatography indicated one major peak (peak No.1) and two impurities (peaks No.2 and 3 < 0.2% of total area) analyzed at 1997.8.25 and one major peak (peak No.1) and two impurities (peaks No.2 and 3 < 0.2% of total area) analyzed at 1998.1.7. No new trace impurity peak in the test substance analyzed at 1998.1.7 was detected.

3. Conclusions: The test substance was stable for about 5 months at room temperature.

D. Lot No. : WTK5303

1. Sample : This lot was used from 1998.1.7 to 1998.7.21. Test substance was stored at room temperature.

2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : FALM (2 mm ϕ \times 2 m)

Column Temperature: 60° C \rightarrow (10° C/min) \rightarrow 150°

Flow Rate : 25 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

| Date (date analyzed) | Peak No. | Retention Time (min) | Area (%) |
|-------------------------|----------|-------------------------|-------------|
| 1998.01.05 | 1 | 2.059 | 99.85 |
| | 2 | 5.010 | 0.04 |
| | 3 | 10.300 | 0.11 |
| 1998.07.22 | 1 | 2.056 | 99.83 |
| | 2 | 5.007 | 0.05 |
| | 3 | 10.288 | 0.12 |

Results: Gas chromatography indicated one major peak (peak No.1) and two impurities (peaks No.2 and 3 < 0.2% of total area) analyzed at 1998.1.5 and one major peak (peak No.1) and two impurities (peaks No.2 and 3 < 0.2% of total area) analyzed at 1998.7.22. No new trace impurity peak in the test substance analyzed at 1998.7.22 was detected.

3. Conclusions: The test substance was stable for about 7 months at room temperature.

E. Lot No. : WTE4391

1. Sample : This lot was used from 1998.7.22 to 1998.11.19. Test substance was stored at room temperature.

2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : FALM (2 mm ϕ \times 2 m)

Column Temperature: 60° C \rightarrow (10° C/min) \rightarrow 150°

Flow Rate : 25 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

| Date (date analyzed) | Peak No. | Retention Time (min) | Area (%) |
|-------------------------|----------|-------------------------|-------------|
| 1998.07.21 | 1 | 2.055 | 99.85 |
| | 2 | 5.005 | 0.04 |
| | 3 | 10.290 | 0.11 |
| 1998.11.30 | 1 | 2.053 | 99.81 |
| | 2 | 5.004 | 0.04 |
| | 3 | 10.274 | 0.15 |

Results: Gas chromatography indicated one major peak (peak No.1) and two impurities (peaks No.2 and 3 < 0.2% of total area) analyzed at 1998.7.21 and one major peak (peak No.1) and two impurities (peaks No.2 and 3 < 0.2% of total area) analyzed at 1998.11.30. No new trace impurity peak in the test substance analyzed at 1998.11.30 was detected.

3. Conclusions: The test substance was stable for about 6 months at room temperature.

APPENDIX P 1

CONCENTRATION OF CROTONALDEHYDE IN THE INHALATION CHAMBER
OF THE 2-YEAR INHALATION STUDY

CONCENTRATION OF CROTONALDEHYDE IN THE INHALATION CHAMBER
OF THE 2-YEAR INHALATION STUDY

| Group Name | Concentration (ppm) |
|------------|---------------------|
| | Mean \pm S.D. |
| 0 ppm | 0.0 \pm 0.0 |
| 3 ppm | 3.0 \pm 0.0 |
| 6 ppm | 6.0 \pm 0.0 |
| 12 ppm | 12.0 \pm 0.1 |

APPENDIX P 2

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER
IN THE 2-YEAR INHALATION STUDY OF CROTONALDEHYDE

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-YEAR INHALATION STUDY OF CROTONALDEHYDE

| Group Name | Temperature(°C) Mean ± S.D. | Humidity(%) Mean ± S.D. | Ventilation Rate(L/min) Mean ± S.D. | Air Changes(time/h) Mean |
|------------|--------------------------------|----------------------------|--|-----------------------------|
| 0 ppm | 22.1 ± 0.1 | 53.3 ± 1.7 | 744.2 ± 5.3 | 12.1 |
| 3 ppm | 22.1 ± 0.2 | 54.1 ± 2.2 | 744.7 ± 5.0 | 12.1 |
| 6 ppm | 22.1 ± 0.2 | 55.1 ± 1.9 | 745.8 ± 4.7 | 12.1 |
| 12 ppm | 22.1 ± 0.1 | 54.6 ± 2.2 | 740.4 ± 5.4 | 12.0 |

APPENDIX Q 1

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS IN THE 2-YEAR INHALATION STUDY OF CROTONALDEHYDE

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS
IN THE 2-YEAR INHALATION STUDY OF CROTONALDEHYDE

| Item | Method |
|---|---|
| Hematology | |
| Red blood cell (RBC) | Light scattering method ¹⁾ |
| Hemoglobin (Hgb) | Cyanmethemoglobin method ¹⁾ |
| Hematocrit (Hct) | Calculated as $RBC \times MCV / 10$ ¹⁾ |
| Mean corpuscular volume (MCV) | Light scattering method ¹⁾ |
| Mean corpuscular hemoglobin (MCH) | Calculated as $Hgb / RBC \times 10$ ¹⁾ |
| Mean corpuscular hemoglobin concentration (MCHC) | Calculated as $Hgb / Hct \times 100$ ¹⁾ |
| Platelet | Light scattering method ¹⁾ |
| White blood cell (WBC) | Light scattering method ¹⁾ |
| Differential WBC | Pattern recognition method ²⁾ (Wright staining) |
| Biochemistry | |
| Total protein (TP) | Biuret method ³⁾ |
| Albumin (Alb) | BCG method ³⁾ |
| A/G ratio | Calculated as $Alb / (TP - Alb)$ ³⁾ |
| T-bilirubin | Alkaline azobilirubin method ³⁾ |
| Glucose | GlcK·G-6-PDH method ³⁾ |
| T-cholesterol | CE·COD·POD method ³⁾ |
| Triglyceride | LPL·GK·GPO·POD method ³⁾ |
| Phospholipid | PLD·ChOD·POD method ³⁾ |
| Glutamic oxaloacetic transaminase (GOT) | JSCC method ³⁾ |
| Glutamic pyruvic transaminase (GPT) | JSCC method ³⁾ |
| Lactate dehydrogenase (LDH) | SFBC method ³⁾ |
| Alkaline phosphatase (ALP) | GSCC method ³⁾ |
| γ -Glutamyl transpeptidase (γ -GTP) | L- γ -Glutamyl-p-nitroanilide method ³⁾ |
| Creatine phosphokinase (CPK) | JSCC method ³⁾ |
| Urea nitrogen | Urease·GLDH method ³⁾ |
| Sodium | Ion selective electrode method ³⁾ |
| Potassium | Ion selective electrode method ³⁾ |
| Chloride | Ion selective electrode method ³⁾ |
| Calcium | OCPC method ³⁾ |
| Inorganic phosphorus | PNP·XOD·POD method ³⁾ |
| Urinalysis | |
| pH, Protein, Glucose, Ketone body, Occult blood, Urobilinogen | Urinalysis reagent paper method ⁴⁾ |

1) Automatic blood cell analyzer (Technicon H·1 : Bayer Corporation)

2) Automatic blood cell differential analyzer (MICROX HEG-120NA : OMRON Corporation)

3) Automatic analyzer (Hitachi 7070 : Hitachi, Ltd.)

4) Ames reagent strips for urinalysis (Multistix : Bayer Corporation)

APPENDIX Q 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY
IN THE 2-YEAR INHALATION STUDY OF CROTONALDEHYDE

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY
IN THE 2-YEAR INHALATION STUDY OF CROTONALDEHYDE

| Item | Unit | Decimal Place |
|--|-----------------------------|---------------|
| Hematology | | |
| Red blood cell (RBC) | $\times 10^6 / \mu\text{L}$ | 2 |
| Hemoglobin | g/dL | 1 |
| Hematocrit | % | 1 |
| Mean corpuscular volume (MCV) | fL | 1 |
| Mean corpuscular hemoglobin (MCH) | pg | 1 |
| Mean corpuscular hemoglobin concentration (MCHC) | g/dL | 1 |
| Platelet | $\times 10^3 / \mu\text{L}$ | 0 |
| White blood cell (WBC) | $\times 10^3 / \mu\text{L}$ | 2 |
| Differential WBC | % | 0 |
| Biochemistry | | |
| Total protein | g/dL | 1 |
| Albumin | g/dL | 1 |
| A/G ratio | — | 1 |
| T-bilirubin | mg/dL | 2 |
| Glucose | mg/dL | 0 |
| T-cholesterol | mg/dL | 0 |
| Triglyceride | mg/dL | 0 |
| Glutamic oxaloacetic transaminase (GOT) | IU/L | 0 |
| Glutamic pyruvic transaminase (GPT) | IU/L | 0 |
| Lactate dehydrogenase (LDH) | IU/L | 0 |
| Alkaline phosphatase (ALP) | IU/L | 0 |
| Creatine phosphokinase (CPK) | IU/L | 0 |
| Urea nitrogen | mg/dL | 1 |
| Sodium | mEq/L | 0 |
| Potassium | mEq/L | 1 |
| Chloride | mEq/L | 0 |
| Calcium | mg/dL | 1 |
| Inorganic phosphorus | mg/dL | 1 |