

2-メチル-1-プロパノールのラットを用いた
経口投与によるがん原性試験（混水試験）報告書

試験番号：0612

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TABLE A 1

SURVIVAL ANIMAL NUMBERS: MALE

STUDY NO. : 0612

SURVIVAL ANIMAL NUMBERS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 104

SEX : MALE

PAGE : 1

| Group Name | Animals At start | Administration (Weeks) | | | | | | | | | | | | | |
|---|---------------------|------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| Control | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 3300 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 10000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 30000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| Number of survival/ Number of effective animals | | | | | | | | | | | | | | | |
| Survival rate(%) | | | | | | | | | | | | | | | |

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STUDY NO. : 0612

SURVIVAL ANIMAL NUMBERS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 104

SEX : MALE

PAGE : 2

| Group Name | Animals At start | Administration (Weeks) | | | | | | | | | | | | | |
|---|---------------------|------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 |
| Control | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 3300 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 |
| 10000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 30000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| Number of survival/ Number of effective animals | | | | | | | | | | | | | | | |
| Survival rate(%) | | | | | | | | | | | | | | | |

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STUDY NO. : 0612

SURVIVAL ANIMAL NUMBERS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 104

SEX : MALE

PAGE : 3

| Group Name | Animals At start | Administration (Weeks) | | | | | | | | | | | | | |
|---|---------------------|------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 |
| Control | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 3300 ppm | 50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 |
| | | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 |
| 10000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 30000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| Number of survival/ Number of effective animals Survival rate(%) | | | | | | | | | | | | | | | |

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STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1 104
 SEX : MALE

SURVIVAL ANIMAL NUMBERS

PAGE : 4

| Group Name | Animals At start | Administration (Weeks) | | | | | | | | | | | | | |
|---|---------------------|------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | 42 | 43 | 44 | 45 | 46 | 47 | 48 | 49 | 50 | 51 | 52 | 53 | 54 | 55 |
| Control | 50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 |
| | | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 |
| 3300 ppm | 50 | 49/50 | 48/50 | 48/50 | 48/50 | 48/50 | 48/50 | 48/50 | 48/50 | 48/50 | 48/50 | 48/50 | 47/50 | 47/50 | 47/50 |
| | | 98.0 | 96.0 | 96.0 | 96.0 | 96.0 | 96.0 | 96.0 | 96.0 | 96.0 | 96.0 | 96.0 | 94.0 | 94.0 | 94.0 |
| 10000 ppm | 50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 |
| | | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 |
| 30000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| Number of survival/ Number of effective animals | | | | | | | | | | | | | | | |
| Survival rate(%) | | | | | | | | | | | | | | | |

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STUDY NO. : 0612

SURVIVAL ANIMAL NUMBERS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 104

SEX : MALE

PAGE : 5

| Group Name. | Animals At start | Administration (Weeks) | | | | | | | | | | | | | |
|---|---------------------|------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | 56 | 57 | 58 | 59 | 60 | 61 | 62 | 63 | 64 | 65 | 66 | 67 | 68 | 69 |
| Control | 50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 |
| | | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 |
| 3300 ppm | 50 | 47/50 | 47/50 | 47/50 | 47/50 | 47/50 | 46/50 | 46/50 | 46/50 | 46/50 | 46/50 | 46/50 | 46/50 | 45/50 | 45/50 |
| | | 94.0 | 94.0 | 94.0 | 94.0 | 94.0 | 92.0 | 92.0 | 92.0 | 92.0 | 92.0 | 92.0 | 92.0 | 90.0 | 90.0 |
| 10000 ppm | 50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 |
| | | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 |
| 30000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| Number of survival/ Number of effective animals Survival rate(%) | | | | | | | | | | | | | | | |

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STUDY NO. : 0612

SURVIVAL ANIMAL NUMBERS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 104

SEX : MALE

PAGE : 6

| Group Name | Animals At start | Administration (Weeks) | | | | | | | | | | | | | |
|---|---------------------|------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | 70 | 71 | 72 | 73 | 74 | 75 | 76 | 77 | 78 | 79 | 80 | 81 | 82 | 83 |
| Control | 50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 48/50 |
| | | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 96.0 |
| 3300 ppm | 50 | 45/50 | 45/50 | 44/50 | 43/50 | 43/50 | 42/50 | 42/50 | 42/50 | 42/50 | 41/50 | 40/50 | 40/50 | 40/50 | 40/50 |
| | | 90.0 | 90.0 | 88.0 | 86.0 | 86.0 | 84.0 | 84.0 | 84.0 | 84.0 | 82.0 | 80.0 | 80.0 | 80.0 | 80.0 |
| 10000 ppm | 50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 48/50 | 48/50 | 48/50 | 48/50 | 48/50 | 48/50 | 48/50 |
| | | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 96.0 | 96.0 | 96.0 | 96.0 | 96.0 | 96.0 | 96.0 |
| 30000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| Number of survival/ Number of effective animals Survival rate(%) | | | | | | | | | | | | | | | |

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STUDY NO. : 0612

SURVIVAL ANIMAL NUMBERS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 104

SEX : MALE

PAGE : 7

| Group Name | Animals At start | Administration (Weeks) | | | | | | | | | | | | | |
|---|---------------------|------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | 84 | 85 | 86 | 87 | 88 | 89 | 90 | 91 | 92 | 93 | 94 | 95 | 96 | 97 |
| Control | 50 | 48/50 | 48/50 | 48/50 | 48/50 | 48/50 | 47/50 | 47/50 | 47/50 | 47/50 | 47/50 | 46/50 | 46/50 | 45/50 | 45/50 |
| | | 96.0 | 96.0 | 96.0 | 96.0 | 96.0 | 94.0 | 94.0 | 94.0 | 94.0 | 94.0 | 92.0 | 92.0 | 90.0 | 90.0 |
| 3300 ppm | 50 | 40/50 | 40/50 | 40/50 | 40/50 | 40/50 | 40/50 | 40/50 | 39/50 | 39/50 | 39/50 | 38/50 | 37/50 | 37/50 | 37/50 |
| | | 80.0 | 80.0 | 80.0 | 80.0 | 80.0 | 80.0 | 80.0 | 78.0 | 78.0 | 78.0 | 76.0 | 74.0 | 74.0 | 74.0 |
| 10000 ppm | 50 | 48/50 | 48/50 | 48/50 | 47/50 | 47/50 | 47/50 | 47/50 | 47/50 | 47/50 | 46/50 | 45/50 | 44/50 | 44/50 | 44/50 |
| | | 96.0 | 96.0 | 96.0 | 94.0 | 94.0 | 94.0 | 94.0 | 94.0 | 94.0 | 92.0 | 90.0 | 88.0 | 88.0 | 88.0 |
| 30000 ppm | 50 | 50/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 48/50 | 48/50 | 48/50 | 47/50 | 46/50 | 45/50 | 45/50 | 43/50 |
| | | 100.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 96.0 | 96.0 | 96.0 | 94.0 | 92.0 | 90.0 | 90.0 | 86.0 |
| Number of survival/ Number of effective animals Survival rate(%) | | | | | | | | | | | | | | | |

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STUDY NO. : 0612

SURVIVAL ANIMAL NUMBERS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 104

SEX : MALE

PAGE : 8

| Group Name | Animals At start | Administration (Weeks) | | | | | | |
|---|---------------------|------------------------|-------|-------|-------|-------|-------|-------|
| | | 98 | 99 | 100 | 101 | 102 | 103 | 104 |
| Control | 50 | 43/50 | 43/50 | 42/50 | 41/50 | 40/50 | 40/50 | 40/50 |
| | | 86.0 | 86.0 | 84.0 | 82.0 | 80.0 | 80.0 | 80.0 |
| 3300 ppm | 50 | 36/50 | 36/50 | 36/50 | 36/50 | 35/50 | 35/50 | 35/50 |
| | | 72.0 | 72.0 | 72.0 | 72.0 | 70.0 | 70.0 | 70.0 |
| 10000 ppm | 50 | 44/50 | 42/50 | 42/50 | 41/50 | 40/50 | 40/50 | 39/50 |
| | | 88.0 | 84.0 | 84.0 | 82.0 | 80.0 | 80.0 | 78.0 |
| 30000 ppm | 50 | 43/50 | 43/50 | 43/50 | 43/50 | 43/50 | 41/50 | 40/50 |
| | | 86.0 | 86.0 | 86.0 | 86.0 | 86.0 | 82.0 | 80.0 |
| Number of survival/ Number of effective animals Survival rate(%) | | | | | | | | |

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TABLE A 2

SURVIVAL ANIMAL NUMBERS: FEMALE

STUDY NO. : 0612

SURVIVAL ANIMAL NUMBERS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 104

SEX : FEMALE

PAGE : 9

| Group Name | Animals | Administration (Weeks) | | | | | | | | | | | | | |
|---|----------|------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | At start | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| Control | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 3300 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 10000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 30000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| Number of survival/ Number of effective animals | | | | | | | | | | | | | | | |
| Survival rate(%) | | | | | | | | | | | | | | | |

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STUDY NO. : 0612

SURVIVAL ANIMAL NUMBERS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 104

SEX : FEMALE

PAGE : 10

| Group Name | Animals At start | Administration (Weeks) | | | | | | | | | | | | | |
|---|---------------------|------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 |
| Control | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 3300 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 10000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 30000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| Number of survival/ Number of effective animals | | | | | | | | | | | | | | | |
| Survival rate(%) | | | | | | | | | | | | | | | |

(HAN360)

BAIS4

STUDY NO. : 0612

SURVIVAL ANIMAL NUMBERS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 104

SEX : FEMALE

PAGE : 11

| Group Name | Animals At start | Administration (Weeks) | | | | | | | | | | | | | |
|---|---------------------|------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 |
| Control | 50 | 50/50 | 50/50 | 50/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 |
| | | 100.0 | 100.0 | 100.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 |
| 3300 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 10000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 30000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| Number of survival/ Number of effective animals | | | | | | | | | | | | | | | |
| Survival rate(%) | | | | | | | | | | | | | | | |

(HAN360)

BAIS4

STUDY NO. : 0612

SURVIVAL ANIMAL NUMBERS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 104

SEX : FEMALE

PAGE : 12

| Group Name | Animals At start | Administration (Weeks) | | | | | | | | | | | | | |
|---|---------------------|------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | 42 | 43 | 44 | 45 | 46 | 47 | 48 | 49 | 50 | 51 | 52 | 53 | 54 | 55 |
| Control | 50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 48/50 | 48/50 | 47/50 | 47/50 | 47/50 | 47/50 |
| | | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 96.0 | 96.0 | 94.0 | 94.0 | 94.0 | 94.0 |
| 3300 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 10000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 30000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| Number of survival/ Number of effective animals | | Survival rate(%) | | | | | | | | | | | | | |

(HAN360)

BAIS4

STUDY NO. : 0612

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 104

SEX : FEMALE

SURVIVAL ANIMAL NUMBERS

PAGE : 13

| Group Name | Animals At start | Administration (Weeks) | | | | | | | | | | | | | |
|---|---------------------|------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | 56 | 57 | 58 | 59 | 60 | 61 | 62 | 63 | 64 | 65 | 66 | 67 | 68 | 69 |
| Control | 50 | 47/50 | 47/50 | 47/50 | 47/50 | 47/50 | 47/50 | 47/50 | 47/50 | 47/50 | 47/50 | 47/50 | 47/50 | 46/50 | 46/50 |
| | | 94.0 | 94.0 | 94.0 | 94.0 | 94.0 | 94.0 | 94.0 | 94.0 | 94.0 | 94.0 | 94.0 | 94.0 | 92.0 | 92.0 |
| 3300 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 |
| 10000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 30000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 49/50 | 49/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 98.0 | 98.0 |
| Number of survival/ Number of effective animals Survival rate(%) | | | | | | | | | | | | | | | |

(HAN360)

BATS4

STUDY NO. : 0612

SURVIVAL ANIMAL NUMBERS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 104

SEX : FEMALE

PAGE : 14

| Group Name | Animals At start | Administration (Weeks) | | | | | | | | | | | | | |
|---|---------------------|------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | 70 | 71 | 72 | 73 | 74 | 75 | 76 | 77 | 78 | 79 | 80 | 81 | 82 | 83 |
| Control | 50 | 46/50 | 46/50 | 46/50 | 46/50 | 46/50 | 45/50 | 45/50 | 45/50 | 45/50 | 45/50 | 45/50 | 44/50 | 43/50 | 42/50 |
| | | 92.0 | 92.0 | 92.0 | 92.0 | 92.0 | 90.0 | 90.0 | 90.0 | 90.0 | 90.0 | 90.0 | 88.0 | 86.0 | 84.0 |
| 3300 ppm | 50 | 49/50 | 49/50 | 49/50 | 48/50 | 48/50 | 48/50 | 48/50 | 47/50 | 47/50 | 47/50 | 47/50 | 45/50 | 45/50 | 45/50 |
| | | 98.0 | 98.0 | 98.0 | 96.0 | 96.0 | 96.0 | 96.0 | 94.0 | 94.0 | 94.0 | 94.0 | 90.0 | 90.0 | 90.0 |
| 10000 ppm | 50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 50/50 | 49/50 | 49/50 | 49/50 | 49/50 | 49/50 |
| | | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 98.0 | 98.0 | 98.0 | 98.0 | 98.0 |
| 30000 ppm | 50 | 48/50 | 48/50 | 47/50 | 47/50 | 47/50 | 46/50 | 46/50 | 46/50 | 46/50 | 46/50 | 46/50 | 46/50 | 46/50 | 46/50 |
| | | 96.0 | 96.0 | 94.0 | 94.0 | 94.0 | 92.0 | 92.0 | 92.0 | 92.0 | 92.0 | 92.0 | 92.0 | 92.0 | 92.0 |
| Number of survival/ Number of effective animals Survival rate(%) | | | | | | | | | | | | | | | |

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BAIS4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1 104
 SEX : FEMALE

SURVIVAL ANIMAL NUMBERS

PAGE : 15

| Group Name | Animals At start | Administration (Weeks) | | | | | | | | | | | | | |
|---|---------------------|------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | 84 | 85 | 86 | 87 | 88 | 89 | 90 | 91 | 92 | 93 | 94 | 95 | 96 | 97 |
| Control | 50 | 42/50 | 41/50 | 40/50 | 40/50 | 40/50 | 39/50 | 38/50 | 38/50 | 38/50 | 38/50 | 38/50 | 38/50 | 38/50 | 38/50 |
| | | 84.0 | 82.0 | 80.0 | 80.0 | 80.0 | 78.0 | 76.0 | 76.0 | 76.0 | 76.0 | 76.0 | 76.0 | 76.0 | 76.0 |
| 3300 ppm | 50 | 45/50 | 45/50 | 45/50 | 45/50 | 45/50 | 45/50 | 44/50 | 44/50 | 44/50 | 44/50 | 43/50 | 43/50 | 43/50 | 43/50 |
| | | 90.0 | 90.0 | 90.0 | 90.0 | 90.0 | 90.0 | 88.0 | 88.0 | 88.0 | 88.0 | 86.0 | 86.0 | 86.0 | 86.0 |
| 10000 ppm | 50 | 49/50 | 49/50 | 49/50 | 49/50 | 48/50 | 48/50 | 48/50 | 48/50 | 48/50 | 48/50 | 47/50 | 46/50 | 46/50 | 46/50 |
| | | 98.0 | 98.0 | 98.0 | 98.0 | 96.0 | 96.0 | 96.0 | 96.0 | 96.0 | 96.0 | 94.0 | 92.0 | 92.0 | 92.0 |
| 30000 ppm | 50 | 46/50 | 45/50 | 45/50 | 45/50 | 44/50 | 44/50 | 44/50 | 44/50 | 44/50 | 44/50 | 44/50 | 44/50 | 44/50 | 44/50 |
| | | 92.0 | 90.0 | 90.0 | 90.0 | 88.0 | 88.0 | 88.0 | 88.0 | 88.0 | 88.0 | 88.0 | 88.0 | 88.0 | 88.0 |
| Number of survival/ Number of effective animals | | | | | | | | | | | | | | | |
| Survival rate(%) | | | | | | | | | | | | | | | |

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BAIS4

STUDY NO. : 0612

SURVIVAL ANIMAL NUMBERS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 104

SEX : FEMALE

PAGE : 16

| Group Name | Animals At start | Administration (Weeks) | | | | | | |
|---|---------------------|------------------------|-------|-------|-------|-------|-------|-------|
| | | 98 | 99 | 100 | 101 | 102 | 103 | 104 |
| Control | 50 | 38/50 | 37/50 | 36/50 | 36/50 | 35/50 | 35/50 | 35/50 |
| | | 76.0 | 74.0 | 72.0 | 72.0 | 70.0 | 70.0 | 70.0 |
| 3300 ppm | 50 | 43/50 | 42/50 | 42/50 | 41/50 | 40/50 | 39/50 | 39/50 |
| | | 86.0 | 84.0 | 84.0 | 82.0 | 80.0 | 78.0 | 78.0 |
| 10000 ppm | 50 | 45/50 | 45/50 | 44/50 | 44/50 | 44/50 | 44/50 | 44/50 |
| | | 90.0 | 90.0 | 88.0 | 88.0 | 88.0 | 88.0 | 88.0 |
| 30000 ppm | 50 | 43/50 | 43/50 | 43/50 | 43/50 | 40/50 | 39/50 | 39/50 |
| | | 86.0 | 86.0 | 86.0 | 86.0 | 80.0 | 78.0 | 78.0 |
| Number of survival/ Number of effective animals Survival rate(%) | | | | | | | | |

(HAN360)

BAIS4

TABLE B 1

CLINICAL OBSERVATION: MALE

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 1

| 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 | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MORIBUND SACRIFICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERT-GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 2

| 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 | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MORIBUND SACRIFICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERI-GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 3

| 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 | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MORIBUND SACRIFICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERI-GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 104

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 | Control | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 2 | 2 | 2 | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MORIBUND SACRIFICE | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERI-GENITALIA | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 2 | 2 | 2 | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 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 |
| DEATH | Control | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MORIBUND SACRIFICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERI-GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 | Control | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 |
| | 3300 ppm | 4 | 4 | 4 | 4 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MORIBUND SACRIFICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERI-GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | Control | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 | Control | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 5 |
| | 3300 ppm | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 8 | 9 | 9 | 9 | 9 |
| | 10000 ppm | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 4 | 4 | 4 | 4 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 5 | 5 |
| MORIBUND SACRIFICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 2 |
| | 3300 ppm | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 2 | 2 | 2 | 2 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 |
| SOILED PERI-GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXOPHTHALMOS | Control | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 | Control | 5 | 5 | 6 | 7 | 7 | 7 |
| | 3300 ppm | 9 | 9 | 9 | 9 | 9 | 9 |
| | 10000 ppm | 4 | 4 | 4 | 5 | 5 | 6 |
| | 30000 ppm | 5 | 5 | 5 | 5 | 6 | 7 |
| MORIBUND SACRIFICE | Control | 2 | 3 | 3 | 3 | 3 | 3 |
| | 3300 ppm | 5 | 5 | 5 | 6 | 6 | 6 |
| | 10000 ppm | 4 | 4 | 5 | 5 | 5 | 5 |
| | 30000 ppm | 2 | 2 | 2 | 2 | 3 | 3 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | 1 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 1 | 1 | 0 |
| PARALYTIC GAIT | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 1 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | 0 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 1 | 0 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERI-GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 1 | 0 |
| EXOPHTHALMOS | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| CATARACT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NOSE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HEAD | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

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| Clinical sign | Group Name | Administration Week-day | | | | 18-7 | 19-7 | 20-7 | 21-7 | 22-7 | 23-7 | 24-7 | 25-7 | 26-7 | 27-7 | 28-7 |
|-----------------|------------|-------------------------|------|------|---|------|------|------|------|------|------|------|------|------|------|------|
| | | 15-7 | 16-7 | 17-7 | | | | | | | | | | | | |
| CATARACT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NOSE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HEAD | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| CATARACT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NOSE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HEAD | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| CATARACT | Control | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NOSE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HEAD | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
|-----------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 57-7 | 58-7 | 59-7 | 60-7 | | | | | | | | | | | | | | |
| CATARACT | Control | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NOSE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HEAD | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 |
| CATARACT | Control | 3 | 5 | 5 | 5 | 5 | 5 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| | 3300 ppm | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 30000 ppm | 0 | 0 | 0 | 1 | 1 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 |
| | 3300 ppm | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 10000 ppm | 3 | 3 | 3 | 4 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 5 | 4 | 6 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 3 |
| INTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NOSE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HEAD | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| CATARACT | Control | 7 | 8 | 8 | 8 | 8 | 8 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 8 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 10000 ppm | 2 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 4 |
| | 30000 ppm | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 4 | 5 | 5 | 5 | 6 | 7 | 7 | 9 | 9 | 9 | 9 | 8 | 8 | 8 |
| | 3300 ppm | 2 | 2 | 3 | 2 | 3 | 3 | 4 | 4 | 4 | 3 | 2 | 2 | 2 | 5 |
| | 10000 ppm | 6 | 6 | 6 | 7 | 7 | 7 | 8 | 8 | 7 | 8 | 8 | 8 | 8 | 9 |
| | 30000 ppm | 3 | 4 | 4 | 3 | 3 | 3 | 3 | 4 | 4 | 3 | 3 | 4 | 3 | 3 |
| INTERNAL MASS | Control | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 1 | 1 | 1 | 2 | 2 | 2 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NOSE | Control | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 2 | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HEAD | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 |
| CATARACT | Control | 8 | 8 | 7 | 8 | 8 | 10 |
| | 3300 ppm | 2 | 2 | 2 | 2 | 2 | 4 |
| | 10000 ppm | 5 | 6 | 6 | 6 | 6 | 7 |
| | 30000 ppm | 2 | 2 | 2 | 2 | 1 | 2 |
| CORNEAL OPACITY | Control | 0 | 0 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 7 | 8 | 6 | 9 | 9 | 9 |
| | 3300 ppm | 6 | 8 | 7 | 7 | 7 | 7 |
| | 10000 ppm | 10 | 11 | 8 | 10 | 10 | 9 |
| | 30000 ppm | 3 | 3 | 4 | 5 | 4 | 4 |
| INTERNAL MASS | Control | 1 | 1 | 1 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 2 | 2 | 2 | 2 | 2 | 2 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NOSE | Control | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 1 | 1 | 1 | 1 |
| M. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 1 | 1 | 1 | 1 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HEAD | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 1 | 1 | 1 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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. NECK | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HINDLIMB | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. TAIL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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. NECK | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HINDLIMB | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. TAIL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | 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 | 31-7 | | | | | | | | | | | | |
| M. NECK | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HINDLIMB | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. TAIL | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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. NECK | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HINDLIMB | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. TAIL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 57-7 | 58-7 | 59-7 | | | | | | | | | | | | | | |
| M. NECK | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HINDLIMB | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. TAIL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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. NECK | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| M. BREAST | Control | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| M. ABDOMEN | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HINDLIMB | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. TAIL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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. NECK | Control | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| M. BREAST | Control | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 3300 ppm | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| M. ABDOMEN | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 10000 ppm | 1 | 1 | 1 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 1 | 1 | 1 | 1 | 1 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 1 |
| | 10000 ppm | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 |
| M. HINDLIMB | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. TAIL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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. NECK | Control | 1 | 1 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| M. BREAST | Control | 2 | 2 | 2 | 4 | 4 | 4 |
| | 3300 ppm | 1 | 1 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 0 | 0 |
| M. ABDOMEN | Control | 0 | 0 | 0 | 1 | 1 | 1 |
| | 3300 ppm | 1 | 1 | 1 | 2 | 2 | 2 |
| | 10000 ppm | 3 | 3 | 1 | 2 | 2 | 2 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 2 | 2 | 1 | 2 | 2 | 2 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 2 | 3 | 2 | 2 | 2 | 2 |
| | 3300 ppm | 1 | 2 | 2 | 2 | 2 | 2 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. HINDLIMB | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. TAIL | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| ANEMIA | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 1 | 1 | 1 |
| | 10000 ppm | 1 | 1 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 1 | 1 | 1 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr-j]
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 |
| JAUNDICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ULCER | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TORTICOLLIS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| RESPIRATORY SOUND ABNOR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| RED URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| YELLOW URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

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| Clinical sign | Group Name | Administration Week-day | | | | 18-7 | 19-7 | 20-7 | 21-7 | 22-7 | 23-7 | 24-7 | 25-7 | 26-7 | 27-7 | 28-7 |
|-------------------------|------------|-------------------------|------|------|---|------|------|------|------|------|------|------|------|------|------|------|
| | | 15-7 | 16-7 | 17-7 | | | | | | | | | | | | |
| JAUNDICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ULCER | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TORTICOLLIS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| RESPIRATORY SOUND ABNOR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| RED URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| YELLOW URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| JAUNDICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ULCER | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TORTICOLLIS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| RESPIRATORY SOUND ABNOR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| RED URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| YELLOW URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| JAUNDICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ULCER | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TORTICOLLIS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| RESPIRATORY SOUND ABNOR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| RED URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| YELLOW URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr-j]
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 |
| JAUNDICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ULCER | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TORTICOLLIS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| RESPIRATORY SOUND ABNOR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| RED URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| YELLOW URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 |
| JAUNDICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ULCER | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TORTICOLLIS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | 3300 ppm | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| RESPIRATORY SOUND ABNOR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| RED URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| YELLOW URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| JAUNDICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ULCER | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TORTICOLLIS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 0 | 0 |
| RESPIRATORY SOUND ABNOR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| RED URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| YELLOW URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 |
| JAUNDICE | Control | 0 | 0 | 1 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| ULCER | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| TORTICOLLIS | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 0 | 0 | 0 | 1 | 1 | 3 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 1 | 2 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 1 | 1 | 1 | 1 | 0 |
| RESPIRATORY SOUND ABNOR | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| DEEP BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| RED URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| YELLOW URINE | Control | 1 | 1 | 1 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| SMALL STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| OLIGO-STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| | 3300 ppm | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| | 10000 ppm | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| | 30000 ppm | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |

(HAN190)

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STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 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 |
| SMALL STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| OLIGO-STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| | 3300 ppm | 50 | 50 | 50 | 50 | 50 | 49 | 49 | 49 | 49 | 49 | 49 | 49 | 49 | 49 |
| | 10000 ppm | 49 | 49 | 49 | 49 | 49 | 49 | 48 | 48 | 48 | 48 | 48 | 48 | 48 | 47 |
| | 30000 ppm | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |

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STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 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 |
| SMALL STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| OLIGO-STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 49 |
| | 3300 ppm | 49 | 49 | 49 | 49 | 49 | 49 | 48 | 48 | 48 | 48 | 48 | 47 | 47 | 47 |
| | 10000 ppm | 47 | 47 | 47 | 47 | 47 | 46 | 46 | 46 | 46 | 45 | 45 | 45 | 46 | 46 |
| | 30000 ppm | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |

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STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 104

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 | | | | | | | | | | | |
| SMALL STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| OLIGO-STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 49 | 49 | 49 | 49 | 49 | 48 | 48 | 48 | 48 | 48 | 48 | 48 | 48 | 47 |
| | 3300 ppm | 47 | 47 | 47 | 47 | 47 | 47 | 47 | 47 | 47 | 47 | 46 | 46 | 46 | 46 |
| | 10000 ppm | 46 | 46 | 46 | 46 | 46 | 46 | 46 | 46 | 46 | 46 | 46 | 46 | 46 | 45 |
| | 30000 ppm | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |

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STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
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 |
| SMALL STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| OLIGO-STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 47 | 47 | 47 | 47 | 47 | 47 | 47 | 46 | 46 | 46 | 46 | 45 | 45 | 45 |
| | 3300 ppm | 46 | 46 | 45 | 45 | 45 | 45 | 45 | 45 | 45 | 45 | 45 | 43 | 44 | 43 |
| | 10000 ppm | 46 | 46 | 46 | 46 | 46 | 45 | 45 | 44 | 45 | 45 | 45 | 44 | 44 | 44 |
| | 30000 ppm | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |

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STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
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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 |
| SMALL STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 2 | 1 | 1 |
| | 3300 ppm | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 2 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| OLIGO-STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 |
| | 3300 ppm | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUBNORMAL TEMP | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 45 | 43 | 43 | 43 | 43 | 43 | 42 | 41 | 41 | 39 | 39 | 38 | 38 | 38 |
| | 3300 ppm | 42 | 42 | 42 | 41 | 40 | 40 | 39 | 37 | 36 | 36 | 37 | 37 | 37 | 37 |
| | 10000 ppm | 44 | 44 | 44 | 43 | 42 | 42 | 41 | 42 | 42 | 41 | 41 | 39 | 40 | 38 |
| | 30000 ppm | 50 | 50 | 50 | 49 | 49 | 47 | 47 | 47 | 46 | 46 | 45 | 45 | 45 | 44 |

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BATS 4

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| SMALL STOOL | Control | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 2 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 0 |
| | 10000 ppm | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 2 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 2 | 1 | 0 | 1 | 0 | 0 |
| OLIGO-STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | 1 | 1 | 1 | 1 | 0 |
| | 10000 ppm | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 2 | 1 | 3 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 2 | 0 | 0 | 1 | 2 | 1 | 0 | 1 | 0 | 2 |
| SUBNORMAL TEMP | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 37 | 36 | 35 | 35 | 35 | 35 | 33 | 31 | 30 | 29 | 30 | 30 | 30 | 29 |
| | 3300 ppm | 37 | 37 | 36 | 37 | 34 | 33 | 32 | 32 | 31 | 32 | 32 | 32 | 32 | 29 |
| | 10000 ppm | 38 | 36 | 37 | 37 | 37 | 37 | 35 | 34 | 34 | 31 | 31 | 31 | 31 | 27 |
| | 30000 ppm | 43 | 42 | 42 | 42 | 42 | 42 | 42 | 41 | 40 | 40 | 40 | 38 | 38 | 37 |

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STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

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| Clinical sign | Group Name | Administration Week-day | | | | | |
|----------------|------------|-------------------------|-------|-------|-------|-------|-------|
| | | 99-7 | 100-7 | 101-7 | 102-7 | 103-7 | 104-7 |
| SMALL STOOL | Control | 0 | 0 | 0 | 1 | 2 | 2 |
| | 3300 ppm | 0 | 0 | 0 | 1 | 1 | 2 |
| | 10000 ppm | 0 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 2 | 1 | 3 | 2 | 1 |
| OLIGO-STOOL | Control | 0 | 0 | 0 | 1 | 1 | 2 |
| | 3300 ppm | 0 | 1 | 1 | 1 | 2 | 2 |
| | 10000 ppm | 1 | 1 | 1 | 0 | 0 | 0 |
| | 30000 ppm | 2 | 3 | 2 | 4 | 2 | 1 |
| SUBNORMAL TEMP | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 30 | 28 | 28 | 23 | 23 | 21 |
| | 3300 ppm | 28 | 25 | 25 | 24 | 24 | 23 |
| | 10000 ppm | 25 | 24 | 24 | 23 | 23 | 22 |
| | 30000 ppm | 37 | 37 | 36 | 34 | 34 | 33 |

(HAN190)

BAIS 4

TABLE B 2

CLINICAL OBSERVATION: FEMALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 |
| DEATH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MORIBUND SACRIFICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HUNCHBACK POSITION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| A LOT OF SPILLED FOOD | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 42

| 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 | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MORIBUND SACRIFICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HUNCHBACK POSITION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| A LOT OF SPILLED FOOD | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 43

| 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 | Control | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MORBUND SACRIFICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HUNCHBACK POSITION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | Control | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| A LOT OF SPILLED FOOD | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 44

| 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 | Control | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 2 | 2 | 3 | 3 | 3 | 3 | 3 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MORBUND SACRIFICE | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HUNCHBACK POSITION | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| A LOT OF SPILLED FOOD | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 45

| 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 | Control | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| MORIBUND SACRIFICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HUNCHBACK POSITION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| A LOT OF SPILLED FOOD | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 46

| 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 | Control | 4 | 4 | 4 | 4 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 7 | 8 | 8 |
| | 3300 ppm | 1 | 1 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 5 | 5 | 5 | 5 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 1 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| MORIBUND SACRIFICE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HUNCHBACK POSITION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| A LOT OF SPILLED FOOD | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 | Control | 8 | 9 | 9 | 9 | 10 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 |
| | 3300 ppm | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 3 |
| | 30000 ppm | 4 | 4 | 4 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 |
| MORIBUND SACRIFICE | Control | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HUNCHBACK POSITION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| A LOT OF SPILLED FOOD | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 | Control | 12 | 12 | 12 | 12 | 12 | 12 |
| | 3300 ppm | 7 | 7 | 8 | 9 | 10 | 10 |
| | 10000 ppm | 3 | 3 | 3 | 3 | 3 | 3 |
| | 30000 ppm | 6 | 6 | 6 | 8 | 9 | 9 |
| MORIBUND SACRIFICE | Control | 1 | 2 | 2 | 3 | 3 | 3 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 2 | 3 | 3 | 3 | 3 | 3 |
| | 30000 ppm | 1 | 1 | 1 | 2 | 2 | 2 |
| LOCOMOTOR MOVEMENT DECR | Control | 0 | 0 | 0 | 0 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 0 | 0 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 1 | 0 | 0 | 0 |
| HUNCHBACK POSITION | Control | 0 | 0 | 0 | 0 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| PARALYTIC GAIT | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| A LOT OF SPILLED FOOD | Control | 0 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| WASTING | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 1 | 1 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| PILOERECTION | Control | 1 | 1 | 2 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| LOSS OF HAIR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERI-GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CATARACT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MALOCCLUSION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EYE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| LOSS OF HAIR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERI-GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| CATARACT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MALOCCLUSION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EYE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 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 |
| LOSS OF HAIR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERI-GENITALIA | Control | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 30000 ppm | 2 | 3 | 3 | 2 | 2 | 2 | 2 | 1 | 1 | 2 | 2 | 2 | 2 | 5 |
| CATARACT | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MALOCCLUSION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | Control | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EYE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

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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 | | | | | | | | | | | | |
| LOSS OF HAIR | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERI-GENITALIA | Control | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 1 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| | 10000 ppm | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 1 |
| | 30000 ppm | 5 | 5 | 5 | | 5 | 5 | 5 | 5 | 5 | 5 | 9 | 9 | 10 | 10 | 9 |
| CATARACT | Control | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 2 | 2 | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 30000 ppm | 0 | 0 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MALOCCLUSION | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| INTERNAL MASS | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EYE | Control | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 |
|-----------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 57-7 | 58-7 | 59-7 | 60-7 | | | | | | | | | | | | | | |
| LOSS OF HAIR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERI-GENITALIA | Control | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 9 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 10 | 8 | 8 | 8 |
| CATARACT | Control | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MALOCCLUSION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 1 | 1 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 |
| INTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EYE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | 74-7 | 75-7 | 76-7 | 77-7 | 78-7 | 79-7 | 80-7 | 81-7 | 82-7 | 83-7 | 84-7 |
|-----------------------|------------|-------------------------|------|------|----|------|------|------|------|------|------|------|------|------|------|------|
| | | 71-7 | 72-7 | 73-7 | | | | | | | | | | | | |
| LOSS OF HAIR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERI-GENITALIA | Control | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 |
| | 3300 ppm | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 8 | 8 | 8 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 7 | 7 | 8 | 8 | 7 |
| CATARACT | Control | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 3 | 3 | 3 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 3 | 3 |
| | 10000 ppm | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MALOCCLUSION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| INTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| | 3300 ppm | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 |
| M. EYE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1j[F344/DuCrj]
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 |
| LOSS OF HAIR | Control | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERI-GENITALIA | Control | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 7 | 7 | 9 | 7 | 7 | 7 | 7 | 6 | 6 | 6 | 6 | 5 | 4 | 4 |
| CATARACT | Control | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 |
| | 3300 ppm | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 |
| | 10000 ppm | 3 | 3 | 4 | 4 | 4 | 4 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 |
| | 30000 ppm | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MALOCCLUSION | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 2 | 2 | 3 | 4 | 4 | 4 | 4 |
| | 10000 ppm | 0 | 0 | 1 | 0 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 4 | 4 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| INTERNAL MASS | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 2 | 1 |
| M. EYE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 |
| LOSS OF HAIR | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| FROG BELLY | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| SOILED PERI-GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 3 | 3 | 3 | 2 | 2 | 0 |
| CATARACT | Control | 3 | 3 | 4 | 4 | 4 | 4 |
| | 3300 ppm | 4 | 4 | 4 | 4 | 4 | 4 |
| | 10000 ppm | 6 | 6 | 7 | 7 | 7 | 7 |
| | 30000 ppm | 2 | 2 | 2 | 2 | 2 | 2 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| MALOCCLUSION | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| EXTERNAL MASS | Control | 1 | 1 | 1 | 3 | 4 | 5 |
| | 3300 ppm | 4 | 4 | 5 | 5 | 5 | 5 |
| | 10000 ppm | 4 | 3 | 3 | 5 | 6 | 6 |
| | 30000 ppm | 2 | 2 | 2 | 2 | 2 | 2 |
| INTERNAL MASS | Control | 1 | 1 | 1 | 0 | 1 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 1 | 3 |
| | 30000 ppm | 1 | 1 | 1 | 0 | 0 | 1 |
| M. EYE | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| M. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 |
| M. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
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 |
| M. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 |
| M. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
|---------------------|------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | 57-7 | 58-7 | 59-7 | 60-7 | | | | | | | | | | | | | | |
| M. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 |
| M. GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| M. GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | Control | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| M. GENITALIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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. PERI-MOUTH | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. EAR | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 1 | 1 | 1 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. PERI EAR | Control | 0 | 0 | 0 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. NECK | Control | 1 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. BREAST | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ABDOMEN | Control | 0 | 0 | 0 | 0 | 0 | 1 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. ANTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 2 | 1 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| M. POSTERIOR DORSUM | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 0 | 0 |
| | 10000 ppm | 1 | 2 | 2 | 2 | 2 | 2 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 1 |
| M. GENITALIA | Control | 0 | 0 | 0 | 1 | 2 | 2 |
| | 3300 ppm | 2 | 2 | 2 | 2 | 3 | 3 |
| | 10000 ppm | 0 | 0 | 0 | 1 | 2 | 2 |
| | 30000 ppm | 1 | 1 | 1 | 1 | 1 | 1 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| ANEMIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| YELLOW URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DIARRHEA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SMALL STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| OLIGO-STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| | 3300 ppm | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| | 10000 ppm | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| | 30000 ppm | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| ANEMIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| YELLOW URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DIARRHEA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SMALL STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| OLIGO-STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 48 |
| | 3300 ppm | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| | 10000 ppm | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 49 | 49 | 49 | 49 | 49 | 49 | 49 |
| | 30000 ppm | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 48 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

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| Clinical sign | Group Name | Administration Week-day | | | | 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 | 31-7 | | | | | | | | | | | | |
| ANEMIA | Control | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| YELLOW URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DIARRHEA | Control | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SMALL STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| OLIGO-STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 48 | 48 | 48 | 48 | 48 | 48 | 48 | 48 | 48 | 48 | 48 | 48 | 48 | 48 | 48 |
| | 3300 ppm | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| | 10000 ppm | 49 | 48 | 48 | 49 | 49 | 49 | 49 | 49 | 49 | 49 | 49 | 49 | 49 | 49 | 48 |
| | 30000 ppm | 48 | 47 | 47 | 48 | 48 | 48 | 48 | 49 | 49 | 49 | 48 | 48 | 48 | 48 | 45 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
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 |
| ANEMIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| YELLOW URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DIARRHEA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SMALL STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| OLIGO-STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 47 | 47 | 47 | 47 | 47 | 47 | 47 | 46 | 46 | 44 | 44 | 44 | 43 | 44 |
| | 3300 ppm | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 49 | 48 | 48 | 48 |
| | 10000 ppm | 48 | 47 | 47 | 47 | 46 | 47 | 47 | 47 | 47 | 47 | 47 | 46 | 46 | 47 |
| | 30000 ppm | 45 | 45 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 40 | 40 | 39 | 39 | 40 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 | | | | | | | | | | | | |
| ANEMIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| YELLOW URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DIARRHEA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SMALL STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| OLIGO-STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 43 | 42 | 42 | 42 | 42 |
| | 3300 ppm | 48 | 48 | 48 | 47 | 47 | 48 | 48 | 49 | 49 | 49 | 48 | 48 | 47 | 47 | 47 |
| | 10000 ppm | 47 | 47 | 47 | 47 | 47 | 47 | 47 | 48 | 48 | 48 | 48 | 48 | 48 | 48 | 48 |
| | 30000 ppm | 40 | 41 | 41 | 41 | 41 | 40 | 40 | 39 | 39 | 39 | 38 | 39 | 38 | 38 | 37 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| ANEMIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| YELLOW URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DIARRHEA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SMALL STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| | 3300 ppm | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 1 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 |
| OLIGO-STOOL | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 41 | 41 | 41 | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 38 | 37 | 37 |
| | 3300 ppm | 47 | 47 | 46 | 46 | 46 | 46 | 46 | 46 | 44 | 44 | 43 | 42 | 42 | 42 |
| | 10000 ppm | 48 | 48 | 48 | 48 | 47 | 47 | 47 | 47 | 46 | 46 | 46 | 46 | 46 | 46 |
| | 30000 ppm | 38 | 37 | 37 | 35 | 34 | 33 | 34 | 34 | 34 | 36 | 36 | 35 | 35 | 36 |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 |
| ANEMIA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| | 10000 ppm | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 1 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| YELLOW URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DIARRHEA | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SMALL STOOL | Control | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 2 | 2 |
| | 3300 ppm | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 1 | 1 | 2 | 2 |
| | 30000 ppm | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| OLIGO-STOOL | Control | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| NON REMARKABLE | Control | 37 | 36 | 36 | 37 | 37 | 35 | 35 | 34 | 33 | 34 | 33 | 33 | 32 | 32 |
| | 3300 ppm | 40 | 41 | 41 | 40 | 39 | 39 | 39 | 39 | 39 | 38 | 36 | 36 | 36 | 36 |
| | 10000 ppm | 45 | 44 | 42 | 43 | 42 | 41 | 40 | 40 | 39 | 39 | 38 | 38 | 36 | 35 |
| | 30000 ppm | 35 | 35 | 34 | 35 | 34 | 34 | 34 | 35 | 35 | 35 | 35 | 34 | 33 | 33 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 |
| ANEMIA | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 1 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 1 | 0 | 0 | 1 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 1 | 1 | 1 | 1 |
| CRUSTA | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 1 | 1 | 1 | 1 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| HEMORRHAGE | Control | 0 | 0 | 0 | 1 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 1 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| IRREGULAR BREATHING | Control | 0 | 2 | 2 | 1 | 2 | 2 |
| | 3300 ppm | 0 | 0 | 1 | 1 | 1 | 0 |
| | 10000 ppm | 1 | 0 | 0 | 0 | 1 | 1 |
| | 30000 ppm | 1 | 1 | 1 | 0 | 0 | 0 |
| YELLOW URINE | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 1 | 0 | 0 | 0 | 0 | 0 |
| DIARRHEA | Control | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3300 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 10000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| | 30000 ppm | 0 | 0 | 0 | 0 | 0 | 0 |
| SMALL STOOL | Control | 2 | 2 | 2 | 1 | 2 | 2 |
| | 3300 ppm | 0 | 0 | 2 | 1 | 2 | 2 |
| | 10000 ppm | 3 | 1 | 1 | 3 | 3 | 3 |
| | 30000 ppm | 2 | 2 | 3 | 1 | 1 | 1 |
| OLIGO-STOOL | Control | 0 | 1 | 1 | 1 | 1 | 1 |
| | 3300 ppm | 0 | 0 | 2 | 2 | 2 | 2 |
| | 10000 ppm | 1 | 0 | 0 | 1 | 0 | 0 |
| | 30000 ppm | 2 | 1 | 2 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 30 | 30 | 29 | 26 | 26 | 26 |
| | 3300 ppm | 35 | 34 | 32 | 31 | 29 | 29 |
| | 10000 ppm | 35 | 35 | 34 | 32 | 30 | 29 |
| | 30000 ppm | 34 | 34 | 33 | 33 | 32 | 34 |

TABLE C 1

BODY WEIGHT CHANGES AND
SURVIVAL ANIMAL NUMBERS: MALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

MEAN BODY WEIGHTS AND SURVIVAL

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| Week-Day on Study | Control | | | 3300 ppm | | | 10000 ppm | | | 30000 ppm | | |
|----------------------|----------|---------------------------|--|----------|-----------------------|-------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|
| | Av. Wt. | No. of Surviv. <50> | | Av. Wt. | % of cont. <50> | No. of Surviv. | Av. Wt. | % of cont. <50> | No. of Surviv. | Av. Wt. | % of cont. <50> | No. of Surviv. |
| 0-0 | 126 (50) | 50/50 | | 126 (50) | 100 | 50/50 | 126 (50) | 100 | 50/50 | 126 (50) | 100 | 50/50 |
| 1-7 | 157 (50) | 50/50 | | 156 (50) | 99 | 50/50 | 154 (50) | 98 | 50/50 | 151 (50) | 96 | 50/50 |
| 2-7 | 187 (50) | 50/50 | | 187 (50) | 100 | 50/50 | 184 (50) | 98 | 50/50 | 179 (50) | 96 | 50/50 |
| 3-7 | 211 (50) | 50/50 | | 211 (50) | 100 | 50/50 | 207 (50) | 98 | 50/50 | 202 (50) | 96 | 50/50 |
| 4-7 | 229 (50) | 50/50 | | 230 (50) | 100 | 50/50 | 225 (50) | 98 | 50/50 | 220 (50) | 96 | 50/50 |
| 5-7 | 242 (50) | 50/50 | | 244 (50) | 101 | 50/50 | 239 (50) | 99 | 50/50 | 233 (50) | 96 | 50/50 |
| 6-7 | 253 (50) | 50/50 | | 256 (50) | 101 | 50/50 | 251 (50) | 99 | 50/50 | 245 (50) | 97 | 50/50 |
| 7-7 | 264 (50) | 50/50 | | 265 (50) | 100 | 50/50 | 262 (50) | 99 | 50/50 | 254 (50) | 96 | 50/50 |
| 8-7 | 274 (50) | 50/50 | | 277 (50) | 101 | 50/50 | 273 (50) | 100 | 50/50 | 265 (50) | 97 | 50/50 |
| 9-7 | 282 (50) | 50/50 | | 283 (50) | 100 | 50/50 | 280 (50) | 99 | 50/50 | 272 (50) | 96 | 50/50 |
| 10-7 | 288 (50) | 50/50 | | 289 (50) | 100 | 50/50 | 285 (50) | 99 | 50/50 | 277 (50) | 96 | 50/50 |
| 11-7 | 293 (50) | 50/50 | | 294 (50) | 100 | 50/50 | 289 (50) | 99 | 50/50 | 281 (50) | 96 | 50/50 |
| 12-7 | 301 (50) | 50/50 | | 303 (50) | 101 | 50/50 | 297 (50) | 99 | 50/50 | 288 (50) | 96 | 50/50 |
| 13-7 | 307 (50) | 50/50 | | 310 (50) | 101 | 50/50 | 303 (50) | 99 | 50/50 | 294 (50) | 96 | 50/50 |
| 14-7 | 312 (50) | 50/50 | | 316 (50) | 101 | 50/50 | 309 (50) | 99 | 50/50 | 299 (50) | 96 | 50/50 |
| 18-7 | 330 (50) | 50/50 | | 333 (50) | 101 | 50/50 | 327 (50) | 99 | 50/50 | 316 (50) | 96 | 50/50 |
| 22-7 | 343 (50) | 50/50 | | 349 (49) | 102 | 49/50 | 340 (50) | 99 | 50/50 | 328 (50) | 96 | 50/50 |
| 26-7 | 355 (50) | 50/50 | | 359 (49) | 101 | 49/50 | 350 (50) | 99 | 50/50 | 338 (50) | 95 | 50/50 |
| 30-7 | 365 (50) | 50/50 | | 369 (49) | 101 | 49/50 | 359 (50) | 98 | 50/50 | 346 (50) | 95 | 50/50 |
| 34-7 | 373 (50) | 50/50 | | 377 (49) | 101 | 49/50 | 366 (50) | 98 | 50/50 | 353 (50) | 95 | 50/50 |
| 38-7 | 379 (50) | 50/50 | | 386 (49) | 102 | 49/50 | 373 (50) | 98 | 50/50 | 361 (50) | 95 | 50/50 |
| 42-7 | 388 (49) | 49/50 | | 392 (49) | 101 | 49/50 | 378 (49) | 97 | 49/50 | 366 (50) | 94 | 50/50 |
| 46-7 | 394 (49) | 49/50 | | 398 (48) | 101 | 48/50 | 383 (49) | 97 | 49/50 | 371 (50) | 94 | 50/50 |
| 50-7 | 401 (49) | 49/50 | | 404 (48) | 101 | 48/50 | 389 (49) | 97 | 49/50 | 376 (50) | 94 | 50/50 |
| 54-7 | 408 (49) | 49/50 | | 414 (47) | 101 | 47/50 | 396 (49) | 97 | 49/50 | 383 (50) | 94 | 50/50 |
| 58-7 | 414 (49) | 49/50 | | 419 (47) | 101 | 47/50 | 403 (49) | 97 | 49/50 | 386 (50) | 93 | 50/50 |
| 62-7 | 420 (49) | 49/50 | | 423 (46) | 101 | 46/50 | 407 (49) | 97 | 49/50 | 391 (50) | 93 | 50/50 |
| 66-7 | 418 (49) | 49/50 | | 422 (46) | 101 | 46/50 | 408 (49) | 98 | 49/50 | 391 (50) | 94 | 50/50 |
| 70-7 | 421 (49) | 49/50 | | 421 (45) | 100 | 45/50 | 408 (49) | 97 | 49/50 | 390 (50) | 93 | 50/50 |
| 74-7 | 424 (49) | 49/50 | | 429 (43) | 101 | 43/50 | 407 (49) | 96 | 49/50 | 393 (50) | 93 | 50/50 |
| 78-7 | 425 (49) | 49/50 | | 427 (42) | 100 | 42/50 | 414 (48) | 97 | 48/50 | 394 (50) | 93 | 50/50 |
| 82-7 | 420 (49) | 49/50 | | 427 (40) | 102 | 40/50 | 414 (48) | 99 | 48/50 | 391 (50) | 93 | 50/50 |
| 86-7 | 423 (48) | 48/50 | | 428 (40) | 101 | 40/50 | 416 (48) | 98 | 48/50 | 391 (49) | 92 | 49/50 |
| 90-7 | 423 (47) | 47/50 | | 423 (40) | 100 | 40/50 | 421 (47) | 100 | 47/50 | 386 (48) | 91 | 48/50 |
| 94-7 | 420 (46) | 46/50 | | 421 (38) | 100 | 38/50 | 408 (45) | 97 | 45/50 | 383 (46) | 91 | 46/50 |
| 98-7 | 411 (43) | 43/50 | | 419 (36) | 102 | 36/50 | 399 (44) | 97 | 44/50 | 384 (43) | 93 | 43/50 |
| 102-7 | 403 (40) | 40/50 | | 406 (35) | 101 | 35/50 | 397 (40) | 99 | 40/50 | 372 (43) | 92 | 43/50 |
| 104-7 | 398 (40) | 40/50 | | 398 (35) | 100 | 35/50 | 393 (39) | 99 | 39/50 | 370 (40) | 93 | 40/50 |

< >:No. of effective animals, () :No. of measured animals

Av. Wt. : g

TABLE C 2

BODY WEIGHT CHANGES AND
SURVIVAL ANIMAL NUMBERS: FEMALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

MEAN BODY WEIGHTS AND SURVIVAL

PAGE : 2

| Week-Day on Study | Control | | | 3300 ppm | | | 10000 ppm | | | 30000 ppm | | |
|----------------------|----------|---------------------------|--|----------|-----------------------|-------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|
| | Av. Wt. | No. of Surviv. <50> | | Av. Wt. | % of cont. <50> | No. of Surviv. | Av. Wt. | % of cont. <50> | No. of Surviv. | Av. Wt. | % of cont. <50> | No. of Surviv. |
| 0-0 | 99 (50) | 50/50 | | 99 (50) | 100 | 50/50 | 99 (50) | 100 | 50/50 | 99 (50) | 100 | 50/50 |
| 1-7 | 114 (50) | 50/50 | | 115 (50) | 101 | 50/50 | 113 (50) | 99 | 50/50 | 112 (50) | 98 | 50/50 |
| 2-7 | 125 (50) | 50/50 | | 126 (50) | 101 | 50/50 | 125 (50) | 100 | 50/50 | 125 (50) | 100 | 50/50 |
| 3-7 | 134 (50) | 50/50 | | 135 (50) | 101 | 50/50 | 133 (50) | 99 | 50/50 | 132 (50) | 99 | 50/50 |
| 4-7 | 140 (50) | 50/50 | | 142 (50) | 101 | 50/50 | 141 (50) | 101 | 50/50 | 139 (50) | 99 | 50/50 |
| 5-7 | 145 (50) | 50/50 | | 147 (50) | 101 | 50/50 | 146 (50) | 101 | 50/50 | 143 (50) | 99 | 50/50 |
| 6-7 | 151 (50) | 50/50 | | 152 (50) | 101 | 50/50 | 151 (50) | 100 | 50/50 | 148 (50) | 98 | 50/50 |
| 7-7 | 153 (50) | 50/50 | | 155 (50) | 101 | 50/50 | 153 (50) | 100 | 50/50 | 149 (50) | 97 | 50/50 |
| 8-7 | 156 (50) | 50/50 | | 158 (50) | 101 | 50/50 | 156 (50) | 100 | 50/50 | 152 (50) | 97 | 50/50 |
| 9-7 | 158 (50) | 50/50 | | 161 (50) | 102 | 50/50 | 158 (50) | 100 | 50/50 | 154 (50) | 97 | 50/50 |
| 10-7 | 161 (50) | 50/50 | | 163 (50) | 101 | 50/50 | 161 (50) | 100 | 50/50 | 157 (50) | 98 | 50/50 |
| 11-7 | 163 (50) | 50/50 | | 165 (50) | 101 | 50/50 | 163 (50) | 100 | 50/50 | 158 (50) | 97 | 50/50 |
| 12-7 | 166 (50) | 50/50 | | 168 (50) | 101 | 50/50 | 166 (50) | 100 | 50/50 | 161 (50) | 97 | 50/50 |
| 13-7 | 168 (50) | 50/50 | | 171 (50) | 102 | 50/50 | 167 (50) | 99 | 50/50 | 163 (50) | 97 | 50/50 |
| 14-7 | 169 (50) | 50/50 | | 171 (50) | 101 | 50/50 | 169 (50) | 100 | 50/50 | 163 (50) | 96 | 50/50 |
| 18-7 | 176 (50) | 50/50 | | 178 (50) | 101 | 50/50 | 176 (50) | 100 | 50/50 | 169 (50) | 96 | 50/50 |
| 22-7 | 182 (50) | 50/50 | | 183 (50) | 101 | 50/50 | 182 (50) | 100 | 50/50 | 174 (50) | 96 | 50/50 |
| 26-7 | 186 (50) | 50/50 | | 189 (50) | 102 | 50/50 | 186 (50) | 100 | 50/50 | 178 (50) | 96 | 50/50 |
| 30-7 | 190 (50) | 50/50 | | 193 (50) | 102 | 50/50 | 190 (50) | 100 | 50/50 | 181 (50) | 95 | 50/50 |
| 34-7 | 195 (49) | 49/50 | | 197 (50) | 101 | 50/50 | 195 (50) | 100 | 50/50 | 186 (50) | 95 | 50/50 |
| 38-7 | 199 (49) | 49/50 | | 201 (50) | 101 | 50/50 | 198 (50) | 99 | 50/50 | 189 (50) | 95 | 50/50 |
| 42-7 | 204 (49) | 49/50 | | 205 (50) | 100 | 50/50 | 203 (50) | 100 | 50/50 | 192 (50) | 94 | 50/50 |
| 46-7 | 206 (49) | 49/50 | | 208 (50) | 101 | 50/50 | 206 (50) | 100 | 50/50 | 194 (50) | 94 | 50/50 |
| 50-7 | 212 (48) | 48/50 | | 213 (50) | 100 | 50/50 | 210 (50) | 99 | 50/50 | 197 (50) | 93 | 50/50 |
| 54-7 | 218 (47) | 47/50 | | 219 (50) | 100 | 50/50 | 216 (50) | 99 | 50/50 | 201 (50) | 92 | 50/50 |
| 58-7 | 224 (47) | 47/50 | | 224 (50) | 100 | 50/50 | 221 (50) | 99 | 50/50 | 204 (50) | 91 | 50/50 |
| 62-7 | 228 (47) | 47/50 | | 229 (49) | 100 | 49/50 | 225 (50) | 99 | 50/50 | 209 (50) | 92 | 50/50 |
| 66-7 | 232 (47) | 47/50 | | 233 (49) | 100 | 49/50 | 230 (50) | 99 | 50/50 | 214 (50) | 92 | 50/50 |
| 70-7 | 235 (46) | 46/50 | | 239 (49) | 102 | 49/50 | 233 (50) | 99 | 50/50 | 216 (48) | 92 | 48/50 |
| 74-7 | 239 (46) | 46/50 | | 245 (48) | 103 | 48/50 | 238 (50) | 100 | 50/50 | 219 (47) | 92 | 47/50 |
| 78-7 | 245 (45) | 45/50 | | 249 (47) | 102 | 47/50 | 240 (50) | 98 | 50/50 | 224 (46) | 91 | 46/50 |
| 82-7 | 250 (43) | 43/50 | | 250 (45) | 100 | 45/50 | 244 (49) | 98 | 49/50 | 227 (46) | 91 | 46/50 |
| 86-7 | 256 (40) | 40/50 | | 258 (45) | 101 | 45/50 | 248 (49) | 97 | 49/50 | 231 (45) | 90 | 45/50 |
| 90-7 | 258 (38) | 38/50 | | 260 (44) | 101 | 44/50 | 250 (48) | 97 | 48/50 | 233 (44) | 90 | 44/50 |
| 94-7 | 260 (38) | 38/50 | | 262 (43) | 101 | 43/50 | 251 (47) | 97 | 47/50 | 234 (44) | 90 | 44/50 |
| 98-7 | 262 (38) | 38/50 | | 265 (43) | 101 | 43/50 | 251 (45) | 96 | 45/50 | 234 (43) | 89 | 43/50 |
| 102-7 | 263 (35) | 35/50 | | 269 (40) | 102 | 40/50 | 252 (44) | 96 | 44/50 | 234 (40) | 89 | 40/50 |
| 104-7 | 262 (35) | 35/50 | | 262 (39) | 100 | 39/50 | 252 (44) | 96 | 44/50 | 234 (39) | 89 | 39/50 |

< >:No. of effective animals, ():No. of measured animals Av. Wt. : g

TABLE C 3

BODY WEIGHT CHANGES: MALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 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 | |
| Control | 126± | 5 | 157± | 6 | 187± | 9 | 211± | 10 | 229± | 11 | 242± | 12 |
| 3300 ppm | 126± | 5 | 156± | 7 | 187± | 10 | 211± | 12 | 230± | 13 | 244± | 15 |
| 10000 ppm | 126± | 5 | 154± | 7* | 184± | 10 | 207± | 10 | 225± | 12 | 239± | 13 |
| 30000 ppm | 126± | 5 | 151± | 6** | 179± | 8** | 202± | 9** | 220± | 10** | 233± | 11** |

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 | | | |
| Control | 264± | 14 | 274± | 14 | 282± | 15 | 288± | 15 | 293± | 15 | 301± | 15 | 307± | 15 | | |
| 3300 ppm | 265± | 16 | 277± | 17 | 283± | 17 | 289± | 18 | 294± | 19 | 303± | 19 | 310± | 20 | | |
| 10000 ppm | 262± | 13 | 273± | 14 | 280± | 15 | 285± | 14 | 289± | 15 | 297± | 15 | 303± | 15 | | |
| 30000 ppm | 254± | 13** | 265± | 13** | 272± | 14** | 277± | 13** | 281± | 12** | 288± | 13** | 294± | 14** | | |

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 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 | |
| Control | 312± | 16 | 330± | 17 | 343± | 18 | 355± | 18 | 365± | 19 | 373± | 21 |
| 3300 ppm | 316± | 21 | 333± | 21 | 349± | 21 | 359± | 21 | 369± | 23 | 377± | 24 |
| 10000 ppm | 309± | 16 | 327± | 17 | 340± | 18 | 350± | 20 | 359± | 22 | 366± | 24 |
| 30000 ppm | 299± | 14** | 316± | 14** | 328± | 15** | 338± | 17** | 346± | 18** | 353± | 18** |

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 | |
| Control | 388± | 22 | 394± | 22 | 401± | 23 | 408± | 23 | 414± | 24 | 420± | 23 |
| 3300 ppm | 392± | 27 | 398± | 29 | 404± | 30 | 414± | 26 | 419± | 26 | 423± | 26 |
| 10000 ppm | 378± | 26 | 383± | 26 | 389± | 26 | 396± | 26* | 403± | 27 | 407± | 27* |
| 30000 ppm | 366± | 20** | 371± | 21** | 376± | 22** | 383± | 22** | 386± | 24** | 391± | 24** |

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 | |
| Control | 421± | 24 | 424± | 24 | 425± | 25 | 420± | 33 | 423± | 34 | 423± | 25 |
| 3300 ppm | 421± | 34 | 429± | 27 | 427± | 29 | 427± | 24 | 428± | 24 | 423± | 29 |
| 10000 ppm | 408± | 26* | 407± | 35* | 414± | 25 | 414± | 25 | 416± | 28 | 421± | 46 |
| 30000 ppm | 390± | 25** | 393± | 23** | 394± | 22** | 391± | 23** | 391± | 30** | 386± | 35** |

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]

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 | |
| Control | 411± | 28 | 403± | 34 | 398± | 40 |
| 3300 ppm | 419± | 26 | 406± | 33 | 398± | 40 |
| 10000 ppm | 399± | 35 | 397± | 35 | 393± | 40 |
| 30000 ppm | 384± | 28** | 372± | 37** | 370± | 31** |

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

Test of Dunnett

(HAN260)

BAIS 4

TABLE C 4

BODY WEIGHT CHANGES: FEMALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 UNIT : g
 REPORT TYPE : AI 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 | |
| Control | 99± | 3 | 114± | 4 | 125± | 5 | 134± | 6 | 140± | 7 | 145± | 8 |
| 3300 ppm | 99± | 3 | 115± | 5 | 126± | 5 | 135± | 6 | 142± | 6 | 147± | 7 |
| 10000 ppm | 99± | 3 | 113± | 4 | 125± | 5 | 133± | 6 | 141± | 7 | 146± | 7 |
| 30000 ppm | 99± | 3 | 112± | 4* | 125± | 4 | 132± | 5 | 139± | 6 | 143± | 6 |

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

(HAN260)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 | |
|------------|-------------------------|---|------|---|------|----|------|---|------|----|------|----|------|----|------|--|
| | | | | | | | | | | | | | | | | |
| Control | 153± | 8 | 156± | 8 | 158± | 9 | 161± | 9 | 163± | 10 | 166± | 10 | 168± | 10 | | |
| 3300 ppm | 155± | 8 | 158± | 8 | 161± | 9 | 163± | 9 | 165± | 9 | 168± | 9 | 171± | 9 | | |
| 10000 ppm | 153± | 8 | 156± | 8 | 158± | 8 | 161± | 9 | 163± | 9 | 166± | 9 | 167± | 10 | | |
| 30000 ppm | 149± | 7 | 152± | 8 | 154± | 8* | 157± | 9 | 158± | 9 | 161± | 9* | 163± | 9* | | |

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

Test of Dunnett

(HAN260)

BATS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 | | | |
| Control | 169± | 10 | 176± | 10 | 182± | 11 | 186± | 11 | 190± | 12 | 195± | 12 | 199± | 13 | | |
| 3300 ppm | 171± | 10 | 178± | 10 | 183± | 10 | 189± | 11 | 193± | 11 | 197± | 11 | 201± | 12 | | |
| 10000 ppm | 169± | 10 | 176± | 10 | 182± | 10 | 186± | 11 | 190± | 12 | 195± | 13 | 198± | 12 | | |
| 30000 ppm | 163± | 9** | 169± | 9** | 174± | 9** | 178± | 10** | 181± | 10** | 186± | 10** | 189± | 10** | | |

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 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 | |
| Control | 204± | 14 | 206± | 15 | 212± | 16 | 218± | 19 | 224± | 21 | 228± | 22 |
| 3300 ppm | 205± | 12 | 208± | 13 | 213± | 13 | 219± | 15 | 224± | 16 | 229± | 17 |
| 10000 ppm | 203± | 14 | 206± | 14 | 210± | 16 | 216± | 18 | 221± | 19 | 225± | 20 |
| 30000 ppm | 192± | 10** | 194± | 11** | 197± | 11** | 201± | 12** | 204± | 13** | 209± | 13** |

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 | |
| Control | 235± | 23 | 239± | 23 | 245± | 24 | 250± | 22 | 256± | 21 | 258± | 22 |
| 3300 ppm | 239± | 20 | 245± | 19 | 249± | 20 | 250± | 24 | 258± | 22 | 260± | 23 |
| 10000 ppm | 233± | 21 | 238± | 22 | 240± | 25 | 244± | 21 | 248± | 21 | 250± | 21 |
| 30000 ppm | 216± | 15** | 219± | 16** | 224± | 15** | 227± | 15** | 231± | 15** | 233± | 14** |

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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 | |
| Control | 262± | 24 | 263± | 25 | 262± | 28 |
| 3300 ppm | 265± | 32 | 269± | 50 | 262± | 34 |
| 10000 ppm | 251± | 27 | 252± | 27 | 252± | 27 |
| 30000 ppm | 234± | 17** | 234± | 17** | 234± | 18** |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 4

TABLE D 1

FOOD CONSUMPTION CHANGES AND
SURVIVAL ANIMAL NUMBERS: MALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

MEAN FOOD CONSUMPTION(FC) AND SURVIVAL

PAGE : 1

| Week-Day on Study | Control | | 3300 ppm | | | 10000 ppm | | | 30000 ppm | | |
|----------------------|-----------|---------------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|
| | Av. FC. | No. of Surviv. <50> | Av. FC. | % of cont. <50> | No. of Surviv. | Av. FC. | % of cont. <50> | No. of Surviv. | Av. FC. | % of cont. <50> | No. of Surviv. |
| 1-7 | 14.1 (50) | 50/50 | 14.0 (50) | 99 | 50/50 | 13.4 (50) | 95 | 50/50 | 11.8 (50) | 84 | 50/50 |
| 2-7 | 15.4 (50) | 50/50 | 15.3 (50) | 99 | 50/50 | 14.6 (50) | 95 | 50/50 | 13.2 (50) | 86 | 50/50 |
| 3-7 | 15.6 (50) | 50/50 | 15.6 (50) | 100 | 50/50 | 14.8 (50) | 95 | 50/50 | 13.5 (50) | 87 | 50/50 |
| 4-7 | 15.1 (50) | 50/50 | 15.3 (50) | 101 | 50/50 | 14.8 (50) | 98 | 50/50 | 13.4 (50) | 89 | 50/50 |
| 5-7 | 15.1 (50) | 50/50 | 15.0 (50) | 99 | 50/50 | 14.5 (50) | 96 | 50/50 | 13.2 (50) | 87 | 50/50 |
| 6-7 | 14.6 (50) | 50/50 | 14.7 (50) | 101 | 50/50 | 14.2 (50) | 97 | 50/50 | 12.9 (50) | 88 | 50/50 |
| 7-7 | 14.5 (50) | 50/50 | 14.4 (50) | 99 | 50/50 | 13.9 (50) | 96 | 50/50 | 12.7 (50) | 88 | 50/50 |
| 8-7 | 14.8 (50) | 50/50 | 14.7 (50) | 99 | 50/50 | 14.2 (50) | 96 | 50/50 | 12.9 (50) | 87 | 50/50 |
| 9-7 | 14.7 (50) | 50/50 | 14.5 (50) | 99 | 50/50 | 14.1 (50) | 96 | 50/50 | 12.8 (50) | 87 | 50/50 |
| 10-7 | 14.7 (25) | 50/50 | 14.6 (50) | 99 | 50/50 | 14.1 (50) | 96 | 50/50 | 12.8 (50) | 87 | 50/50 |
| 11-7 | 14.7 (50) | 50/50 | 14.7 (50) | 100 | 50/50 | 14.1 (50) | 96 | 50/50 | 12.9 (50) | 88 | 50/50 |
| 12-7 | 14.9 (50) | 50/50 | 14.8 (50) | 99 | 50/50 | 14.2 (50) | 95 | 50/50 | 12.9 (50) | 87 | 50/50 |
| 13-7 | 14.7 (50) | 50/50 | 14.5 (50) | 99 | 50/50 | 13.9 (50) | 95 | 50/50 | 12.6 (50) | 86 | 50/50 |
| 14-7 | 14.7 (50) | 50/50 | 14.7 (50) | 100 | 50/50 | 13.9 (50) | 95 | 50/50 | 12.8 (50) | 87 | 50/50 |
| 18-7 | 14.8 (50) | 50/50 | 14.9 (50) | 101 | 50/50 | 14.2 (50) | 96 | 50/50 | 13.0 (50) | 88 | 50/50 |
| 22-7 | 14.9 (50) | 50/50 | 14.9 (49) | 100 | 49/50 | 14.3 (50) | 96 | 50/50 | 13.1 (50) | 88 | 50/50 |
| 26-7 | 15.2 (50) | 50/50 | 15.2 (49) | 100 | 49/50 | 14.5 (50) | 95 | 50/50 | 13.3 (50) | 88 | 50/50 |
| 30-7 | 15.3 (50) | 50/50 | 15.3 (49) | 100 | 49/50 | 14.7 (50) | 96 | 50/50 | 13.6 (50) | 89 | 50/50 |
| 34-7 | 15.4 (50) | 50/50 | 15.5 (49) | 101 | 49/50 | 14.7 (50) | 95 | 50/50 | 13.6 (50) | 88 | 50/50 |
| 38-7 | 15.5 (50) | 50/50 | 15.7 (49) | 101 | 49/50 | 14.9 (50) | 96 | 50/50 | 13.9 (50) | 90 | 50/50 |
| 42-7 | 15.8 (49) | 49/50 | 15.6 (49) | 99 | 49/50 | 14.9 (49) | 94 | 49/50 | 13.9 (50) | 88 | 50/50 |
| 46-7 | 16.1 (49) | 49/50 | 16.0 (48) | 99 | 48/50 | 15.2 (49) | 94 | 49/50 | 14.1 (50) | 88 | 50/50 |
| 50-7 | 15.8 (49) | 49/50 | 15.7 (48) | 99 | 48/50 | 15.0 (49) | 95 | 49/50 | 13.9 (50) | 88 | 50/50 |
| 54-7 | 16.0 (49) | 49/50 | 15.9 (47) | 99 | 47/50 | 15.3 (49) | 96 | 49/50 | 14.2 (50) | 89 | 50/50 |
| 58-7 | 15.9 (49) | 49/50 | 15.8 (47) | 99 | 47/50 | 15.3 (49) | 96 | 49/50 | 14.1 (50) | 89 | 50/50 |
| 62-7 | 16.1 (49) | 49/50 | 16.0 (46) | 99 | 46/50 | 15.4 (49) | 96 | 49/50 | 14.2 (50) | 88 | 50/50 |
| 66-7 | 16.2 (49) | 49/50 | 16.0 (46) | 99 | 46/50 | 15.4 (49) | 95 | 49/50 | 14.6 (50) | 90 | 50/50 |
| 70-7 | 16.7 (49) | 49/50 | 16.4 (45) | 98 | 45/50 | 16.1 (49) | 96 | 49/50 | 15.0 (50) | 90 | 50/50 |
| 74-7 | 16.9 (49) | 49/50 | 17.0 (43) | 101 | 43/50 | 15.9 (49) | 94 | 49/50 | 15.5 (50) | 92 | 50/50 |
| 78-7 | 16.2 (49) | 49/50 | 15.9 (42) | 98 | 42/50 | 15.9 (48) | 98 | 48/50 | 14.9 (49) | 92 | 50/50 |
| 82-7 | 16.3 (49) | 49/50 | 16.7 (40) | 102 | 40/50 | 16.2 (48) | 99 | 48/50 | 14.9 (50) | 91 | 50/50 |
| 86-7 | 16.9 (47) | 48/50 | 16.6 (40) | 98 | 40/50 | 15.9 (48) | 94 | 48/50 | 14.7 (49) | 87 | 49/50 |
| 90-7 | 16.9 (46) | 47/50 | 16.7 (40) | 99 | 40/50 | 16.5 (46) | 98 | 47/50 | 14.9 (48) | 88 | 48/50 |
| 94-7 | 16.4 (45) | 46/50 | 16.5 (38) | 101 | 38/50 | 15.5 (45) | 95 | 45/50 | 14.6 (46) | 89 | 46/50 |
| 98-7 | 16.4 (43) | 43/50 | 16.4 (36) | 100 | 36/50 | 15.2 (44) | 93 | 44/50 | 14.7 (43) | 90 | 43/50 |
| 102-7 | 16.0 (40) | 40/50 | 15.1 (35) | 94 | 35/50 | 15.9 (40) | 99 | 40/50 | 14.0 (43) | 88 | 43/50 |
| 104-7 | 16.2 (40) | 40/50 | 15.4 (34) | 95 | 35/50 | 15.9 (39) | 98 | 39/50 | 14.3 (40) | 88 | 40/50 |

< >:No. of effective animals, () :No. of measured animals Av. FC. : g

TABLE D 2

FOOD CONSUMPTION CHANGES AND
SURVIVAL ANIMAL NUMBERS: FEMALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

MEAN FOOD CONSUMPTION(FC) AND SURVIVAL

PAGE : 2

| Week-Day on Study | Control | | 3300 ppm | | | 10000 ppm | | | 30000 ppm | | |
|----------------------|-----------|---------------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|
| | Av. FC. | No. of Surviv. <50> | Av. FC. | % of cont. <50> | No. of Surviv. | Av. FC. | % of cont. <50> | No. of Surviv. | Av. FC. | % of cont. <50> | No. of Surviv. |
| 1-7 | 10.8 (50) | 50/50 | 10.5 (50) | 97 | 50/50 | 10.0 (50) | 93 | 50/50 | 9.0 (50) | 83 | 50/50 |
| 2-7 | 10.8 (50) | 50/50 | 10.5 (50) | 97 | 50/50 | 10.3 (50) | 95 | 50/50 | 9.6 (50) | 89 | 50/50 |
| 3-7 | 10.4 (50) | 50/50 | 10.2 (50) | 98 | 50/50 | 9.9 (50) | 95 | 50/50 | 9.2 (50) | 88 | 50/50 |
| 4-7 | 10.1 (50) | 50/50 | 9.9 (50) | 98 | 50/50 | 9.8 (50) | 97 | 50/50 | 9.1 (50) | 90 | 50/50 |
| 5-7 | 9.8 (50) | 50/50 | 9.6 (50) | 98 | 50/50 | 9.3 (50) | 95 | 50/50 | 8.7 (50) | 89 | 50/50 |
| 6-7 | 9.8 (50) | 50/50 | 9.4 (50) | 96 | 50/50 | 9.0 (50) | 92 | 50/50 | 8.4 (50) | 86 | 50/50 |
| 7-7 | 9.4 (50) | 50/50 | 9.2 (50) | 98 | 50/50 | 8.8 (50) | 94 | 50/50 | 8.2 (50) | 87 | 50/50 |
| 8-7 | 9.4 (50) | 50/50 | 9.1 (50) | 97 | 50/50 | 8.8 (50) | 94 | 50/50 | 8.2 (50) | 87 | 50/50 |
| 9-7 | 9.4 (50) | 50/50 | 9.1 (50) | 97 | 50/50 | 8.7 (50) | 93 | 50/50 | 8.0 (50) | 85 | 50/50 |
| 10-7 | 9.6 (50) | 50/50 | 9.4 (50) | 98 | 50/50 | 9.0 (50) | 94 | 50/50 | 8.2 (50) | 85 | 50/50 |
| 11-7 | 9.7 (50) | 50/50 | 9.3 (50) | 96 | 50/50 | 9.0 (50) | 93 | 50/50 | 8.2 (50) | 85 | 50/50 |
| 12-7 | 9.8 (50) | 50/50 | 9.6 (50) | 98 | 50/50 | 9.2 (50) | 94 | 50/50 | 8.4 (50) | 86 | 50/50 |
| 13-7 | 9.6 (50) | 50/50 | 9.2 (50) | 96 | 50/50 | 8.9 (50) | 93 | 50/50 | 8.1 (50) | 84 | 50/50 |
| 14-7 | 9.6 (50) | 50/50 | 9.3 (50) | 97 | 50/50 | 9.0 (50) | 94 | 50/50 | 8.2 (50) | 85 | 50/50 |
| 18-7 | 9.9 (50) | 50/50 | 9.7 (50) | 98 | 50/50 | 9.3 (50) | 94 | 50/50 | 8.4 (50) | 85 | 50/50 |
| 22-7 | 9.9 (50) | 50/50 | 9.5 (50) | 96 | 50/50 | 9.4 (50) | 95 | 50/50 | 8.6 (50) | 87 | 50/50 |
| 26-7 | 10.1 (50) | 50/50 | 9.9 (50) | 98 | 50/50 | 9.6 (50) | 95 | 50/50 | 8.8 (50) | 87 | 50/50 |
| 30-7 | 10.2 (50) | 50/50 | 9.9 (50) | 97 | 50/50 | 9.7 (50) | 95 | 50/50 | 8.9 (50) | 87 | 50/50 |
| 34-7 | 10.2 (49) | 49/50 | 9.8 (50) | 96 | 50/50 | 9.9 (50) | 97 | 50/50 | 9.0 (50) | 88 | 50/50 |
| 38-7 | 10.4 (49) | 49/50 | 10.1 (50) | 97 | 50/50 | 10.0 (50) | 96 | 50/50 | 9.1 (50) | 88 | 50/50 |
| 42-7 | 10.5 (49) | 49/50 | 10.4 (50) | 99 | 50/50 | 10.2 (50) | 97 | 50/50 | 9.2 (50) | 88 | 50/50 |
| 46-7 | 10.8 (49) | 49/50 | 10.5 (50) | 97 | 50/50 | 10.3 (50) | 95 | 50/50 | 9.4 (50) | 87 | 50/50 |
| 50-7 | 10.7 (48) | 48/50 | 10.3 (50) | 96 | 50/50 | 10.1 (50) | 94 | 50/50 | 9.2 (50) | 86 | 50/50 |
| 54-7 | 11.0 (47) | 47/50 | 10.4 (50) | 95 | 50/50 | 10.2 (50) | 93 | 50/50 | 9.2 (50) | 84 | 50/50 |
| 58-7 | 10.9 (47) | 47/50 | 10.4 (50) | 95 | 50/50 | 10.3 (50) | 94 | 50/50 | 9.3 (50) | 85 | 50/50 |
| 62-7 | 11.0 (47) | 47/50 | 10.7 (49) | 97 | 49/50 | 10.4 (50) | 95 | 50/50 | 9.7 (50) | 88 | 50/50 |
| 66-7 | 11.0 (47) | 47/50 | 10.9 (49) | 99 | 49/50 | 10.5 (50) | 95 | 50/50 | 9.5 (50) | 86 | 50/50 |
| 70-7 | 11.3 (46) | 46/50 | 11.3 (49) | 100 | 49/50 | 10.7 (50) | 95 | 50/50 | 9.7 (48) | 86 | 48/50 |
| 74-7 | 11.5 (46) | 46/50 | 11.7 (48) | 102 | 48/50 | 11.2 (50) | 97 | 50/50 | 10.1 (47) | 88 | 47/50 |
| 78-7 | 11.6 (45) | 45/50 | 11.3 (47) | 97 | 47/50 | 10.9 (50) | 94 | 50/50 | 10.1 (46) | 87 | 46/50 |
| 82-7 | 11.5 (43) | 43/50 | 11.4 (45) | 99 | 45/50 | 10.9 (49) | 95 | 49/50 | 10.0 (46) | 87 | 46/50 |
| 86-7 | 11.9 (40) | 40/50 | 11.9 (45) | 100 | 45/50 | 11.0 (49) | 92 | 49/50 | 10.1 (45) | 85 | 45/50 |
| 90-7 | 12.0 (38) | 38/50 | 12.0 (44) | 100 | 44/50 | 11.2 (48) | 93 | 48/50 | 10.5 (44) | 88 | 44/50 |
| 94-7 | 11.9 (38) | 38/50 | 11.7 (43) | 98 | 43/50 | 11.1 (47) | 93 | 47/50 | 10.4 (44) | 87 | 44/50 |
| 98-7 | 12.1 (38) | 38/50 | 12.0 (43) | 99 | 43/50 | 11.5 (45) | 95 | 45/50 | 10.3 (43) | 85 | 43/50 |
| 102-7 | 12.2 (34) | 35/50 | 11.9 (39) | 98 | 40/50 | 11.2 (44) | 92 | 44/50 | 10.3 (40) | 84 | 40/50 |
| 104-7 | 12.3 (33) | 35/50 | 11.7 (39) | 95 | 39/50 | 11.3 (44) | 92 | 44/50 | 10.2 (39) | 83 | 39/50 |

< >:No. of effective animals, ():No. of measured animals Av. FC. : g

TABLE D 3

FOOD CONSUMPTION CHANGES: MALE

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
UNIT : g
REPORT TYPE : A1 104
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 1-7(7) | 2-7(7) | 3-7(7) | 4-7(7) | 5-7(7) | 6-7(7) | 7-7(7) |
| Control | 14.1± 0.7 | 15.4± 0.8 | 15.6± 0.8 | 15.1± 0.9 | 15.1± 0.8 | 14.6± 0.9 | 14.5± 0.9 |
| 3300 ppm | 14.0± 0.9 | 15.3± 1.1 | 15.6± 1.1 | 15.3± 1.1 | 15.0± 1.0 | 14.7± 1.1 | 14.4± 1.0 |
| 10000 ppm | 13.4± 0.8** | 14.6± 0.9** | 14.8± 0.9** | 14.8± 0.8 | 14.5± 0.8** | 14.2± 1.0 | 13.9± 0.6** |
| 30000 ppm | 11.8± 0.8** | 13.2± 0.8** | 13.5± 0.8** | 13.4± 0.8** | 13.2± 0.8** | 12.9± 0.8** | 12.7± 0.7** |

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

Test of Dunnett

(HAN260)

BATS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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) |
| Control | 14.8± 0.9 | 14.7± 0.9 | 14.7± 0.9 | 14.7± 0.9 | 14.9± 1.0 | 14.7± 0.8 | 14.7± 1.0 |
| 3300 ppm | 14.7± 1.0 | 14.5± 1.0 | 14.6± 1.0 | 14.7± 1.1 | 14.8± 1.0 | 14.5± 0.9 | 14.7± 1.0 |
| 10000 ppm | 14.2± 0.7** | 14.1± 0.7** | 14.1± 0.7* | 14.1± 0.8** | 14.2± 0.8** | 13.9± 0.7** | 13.9± 0.8** |
| 30000 ppm | 12.9± 0.8** | 12.8± 0.9** | 12.8± 0.8** | 12.9± 0.8** | 12.9± 0.9** | 12.6± 0.9** | 12.8± 0.8** |

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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) |
| Control | 14.8± 0.9 | 14.9± 1.1 | 15.2± 1.1 | 15.3± 1.0 | 15.4± 1.1 | 15.5± 1.1 | 15.8± 1.0 |
| 3300 ppm | 14.9± 1.0 | 14.9± 0.8 | 15.2± 1.0 | 15.3± 1.0 | 15.5± 0.9 | 15.7± 1.0 | 15.6± 1.5 |
| 10000 ppm | 14.2± 0.8** | 14.3± 0.8** | 14.5± 0.8** | 14.7± 0.7** | 14.7± 0.8** | 14.9± 0.8** | 14.9± 0.8** |
| 30000 ppm | 13.0± 0.8** | 13.1± 0.8** | 13.3± 0.8** | 13.6± 0.9** | 13.6± 0.9** | 13.9± 0.9** | 13.9± 0.8** |

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 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) |
| Control | 16.1± 1.0 | 15.8± 1.0 | 16.0± 1.0 | 15.9± 1.0 | 16.1± 0.8 | 16.2± 1.0 | 16.7± 1.1 |
| 3300 ppm | 16.0± 1.1 | 15.7± 1.2 | 15.9± 0.9 | 15.8± 1.1 | 16.0± 0.9 | 16.0± 1.0 | 16.4± 2.2 |
| 10000 ppm | 15.2± 0.8** | 15.0± 0.8** | 15.3± 0.7** | 15.3± 0.8** | 15.4± 0.8** | 15.4± 0.6** | 16.1± 0.8* |
| 30000 ppm | 14.1± 0.9** | 13.9± 0.9** | 14.2± 0.8** | 14.1± 0.9** | 14.2± 0.9** | 14.6± 0.9** | 15.0± 0.9** |

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

Test of Dunnett

(HAN260)

BATS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 UNIT : g
 REPORT TYPE : AI 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) |
| Control | 16.9± 1.0 | 16.2± 1.0 | 16.3± 1.9 | 16.9± 1.3 | 16.9± 1.3 | 16.4± 1.3 | 16.4± 1.3 |
| 3300 ppm | 17.0± 1.4 | 15.9± 2.3 | 16.7± 1.3 | 16.6± 1.0 | 16.7± 1.8 | 16.5± 1.3 | 16.4± 1.2 |
| 10000 ppm | 15.9± 2.3** | 15.9± 1.1 | 16.2± 0.9 | 15.9± 1.4** | 16.5± 1.0 | 15.5± 1.6* | 15.2± 2.1** |
| 30000 ppm | 15.5± 0.9** | 14.9± 0.8** | 14.9± 0.8** | 14.7± 1.2** | 14.9± 1.3** | 14.6± 1.3** | 14.7± 1.7** |

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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) |
| Control | 16.0± 1.6 | 16.2± 1.7 |
| 3300 ppm | 15.1± 2.9 | 15.4± 3.6 |
| 10000 ppm | 15.9± 1.7 | 15.9± 2.0 |
| 30000 ppm | 14.0± 2.2** | 14.3± 1.3** |

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

Test of Dunnett

(HAN260)

BAIS 4

TABLE D 4

FOOD CONSUMPTION CHANGES: FEMALE

STUDY NO. : 0612

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]

UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE : 7

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|-------------|------------|------------|------------|------------|------------|
| | 1-7(7) | 2-7(7) | 3-7(7) | 4-7(7) | 5-7(7) | 6-7(7) | 7-7(7) |
| Control | 10.8± 0.6 | 10.8± 0.7 | 10.4± 0.7 | 10.1± 0.7 | 9.8± 0.7 | 9.8± 0.7 | 9.4± 0.7 |
| 3300 ppm | 10.5± 0.6* | 10.5± 0.6 | 10.2± 0.6 | 9.9± 0.7 | 9.6± 0.6 | 9.4± 0.7* | 9.2± 0.7 |
| 10000 ppm | 10.0± 0.5** | 10.3± 0.6** | 9.9± 0.6** | 9.8± 0.6 | 9.3± 0.5** | 9.0± 0.5** | 8.8± 0.5** |
| 30000 ppm | 9.0± 0.5** | 9.6± 0.6** | 9.2± 0.6** | 9.1± 0.6** | 8.7± 0.7** | 8.4± 0.6** | 8.2± 0.6** |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

| Group Name | Administration 8-7(7) | week-day(effective) 9-7(7) | 10-7(7) | 11-7(7) | 12-7(7) | 13-7(7) | 14-7(7) |
|------------|--------------------------|-------------------------------|------------|------------|------------|------------|------------|
| Control | 9.4± 0.7 | 9.4± 0.6 | 9.6± 0.7 | 9.7± 0.7 | 9.8± 0.7 | 9.6± 0.7 | 9.6± 0.7 |
| 3300 ppm | 9.1± 0.6 | 9.1± 0.7* | 9.4± 0.6 | 9.3± 0.7* | 9.6± 0.6 | 9.2± 0.6 | 9.3± 0.7** |
| 10000 ppm | 8.8± 0.5** | 8.7± 0.6** | 9.0± 0.6** | 9.0± 0.7** | 9.2± 0.7** | 8.9± 0.7** | 9.0± 0.6** |
| 30000 ppm | 8.2± 0.6** | 8.0± 0.6** | 8.2± 0.6** | 8.2± 0.7** | 8.4± 0.6** | 8.1± 0.6** | 8.2± 0.6** |

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 9

| 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) |
| Control | 9.9± 0.7 | 9.9± 0.7 | 10.1± 0.7 | 10.2± 0.9 | 10.2± 0.7 | 10.4± 0.8 | 10.5± 0.9 |
| 3300 ppm | 9.7± 0.6 | 9.5± 0.6* | 9.9± 0.6 | 9.9± 0.6 | 9.8± 0.6* | 10.1± 0.7* | 10.4± 0.6 |
| 10000 ppm | 9.3± 0.7** | 9.4± 0.6** | 9.6± 0.6** | 9.7± 0.7** | 9.9± 0.7 | 10.0± 0.7** | 10.2± 0.7 |
| 30000 ppm | 8.4± 0.6** | 8.6± 0.6** | 8.8± 0.6** | 8.9± 0.5** | 9.0± 0.5** | 9.1± 0.5** | 9.2± 0.5** |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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) |
| Control | 10.8± 0.9 | 10.7± 0.9 | 11.0± 1.0 | 10.9± 1.0 | 11.0± 0.9 | 11.0± 1.1 | 11.3± 1.0 |
| 3300 ppm | 10.5± 0.9 | 10.3± 0.6 | 10.4± 0.8* | 10.4± 0.7* | 10.7± 0.8 | 10.9± 0.7 | 11.3± 0.8 |
| 10000 ppm | 10.3± 0.6** | 10.1± 0.8** | 10.2± 0.8** | 10.3± 0.8** | 10.4± 0.7** | 10.5± 0.9** | 10.7± 0.7** |
| 30000 ppm | 9.4± 0.6** | 9.2± 0.6** | 9.2± 0.6** | 9.3± 0.7** | 9.7± 0.9** | 9.5± 0.9** | 9.7± 0.8** |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr.j]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 11

| Group Name | Administration 74-7(7) | week-day(effective) 78-7(7) | 82-7(7) | 86-7(7) | 90-7(7) | 94-7(7) | 98-7(7) |
|------------|---------------------------|--------------------------------|-------------|-------------|-------------|-------------|-------------|
| Control | 11.5± 1.2 | 11.6± 1.1 | 11.5± 1.3 | 11.9± 1.2 | 12.0± 0.8 | 11.9± 1.6 | 12.1± 1.3 |
| 3300 ppm | 11.7± 0.9 | 11.3± 1.1 | 11.4± 0.8 | 11.9± 0.8 | 12.0± 0.7 | 11.7± 0.9 | 12.0± 1.3 |
| 10000 ppm | 11.2± 0.8 | 10.9± 1.3* | 10.9± 0.8** | 11.0± 1.7** | 11.2± 1.2** | 11.1± 1.7** | 11.5± 1.3 |
| 30000 ppm | 10.1± 0.8** | 10.1± 0.6** | 10.0± 0.9** | 10.1± 0.9** | 10.5± 0.8** | 10.4± 0.7** | 10.3± 0.9** |

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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) |
| Control | 12.2± 1.2 | 12.3± 1.1 |
| 3300 ppm | 11.9± 1.1 | 11.7± 1.7 |
| 10000 ppm | 11.2± 1.7** | 11.3± 1.3** |
| 30000 ppm | 10.3± 0.8** | 10.2± 1.0** |

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

Test of Dunnett

(HAN260)

BAIS 4

TABLE E 1

WATER CONSUMPTION CHANGES AND
SURVIVAL ANIMAL NUMBERS: MALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

MEAN WATER CONSUMPTION(WC) AND SURVIVAL

PAGE : 1

| Week-Day on Study | Control | | | 3300 ppm | | | 10000 ppm | | | 30000 ppm | | |
|----------------------|-----------|---------------------------|--|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|
| | Av. WC. | No. of Surviv. <50> | | Av. WC. | % of cont. <50> | No. of Surviv. | Av. WC. | % of cont. <50> | No. of Surviv. | Av. WC. | % of cont. <50> | No. of Surviv. |
| 1-7 | 16.9 (50) | 50/50 | | 17.6 (50) | 104 | 50/50 | 15.6 (50) | 92 | 50/50 | 13.9 (50) | 82 | 50/50 |
| 2-7 | 18.4 (50) | 50/50 | | 19.2 (50) | 104 | 50/50 | 16.4 (50) | 89 | 50/50 | 14.5 (50) | 79 | 50/50 |
| 3-7 | 19.1 (50) | 50/50 | | 19.3 (50) | 101 | 50/50 | 16.6 (50) | 87 | 50/50 | 14.6 (50) | 76 | 50/50 |
| 4-7 | 19.5 (50) | 50/50 | | 19.9 (49) | 102 | 50/50 | 17.3 (50) | 89 | 50/50 | 14.9 (50) | 76 | 50/50 |
| 5-7 | 19.0 (48) | 50/50 | | 19.6 (50) | 103 | 50/50 | 17.5 (50) | 92 | 50/50 | 15.4 (49) | 81 | 50/50 |
| 6-7 | 17.7 (50) | 50/50 | | 18.2 (50) | 103 | 50/50 | 16.6 (50) | 94 | 50/50 | 14.4 (50) | 81 | 50/50 |
| 7-7 | 17.9 (50) | 50/50 | | 18.2 (48) | 102 | 50/50 | 16.2 (50) | 91 | 50/50 | 14.3 (50) | 80 | 50/50 |
| 8-7 | 18.1 (49) | 50/50 | | 18.6 (50) | 103 | 50/50 | 16.3 (50) | 90 | 50/50 | 14.3 (50) | 79 | 50/50 |
| 9-7 | 17.5 (50) | 50/50 | | 18.8 (50) | 107 | 50/50 | 15.9 (50) | 91 | 50/50 | 13.9 (50) | 79 | 50/50 |
| 10-7 | 17.6 (50) | 50/50 | | 18.0 (49) | 102 | 50/50 | 15.5 (50) | 88 | 50/50 | 13.7 (50) | 78 | 50/50 |
| 11-7 | 17.8 (50) | 50/50 | | 18.0 (50) | 101 | 50/50 | 15.6 (50) | 88 | 50/50 | 13.6 (50) | 76 | 50/50 |
| 12-7 | 17.1 (50) | 50/50 | | 17.4 (50) | 102 | 50/50 | 15.3 (50) | 89 | 50/50 | 13.7 (50) | 80 | 50/50 |
| 13-7 | 17.4 (50) | 50/50 | | 17.2 (49) | 99 | 50/50 | 15.5 (50) | 89 | 50/50 | 13.7 (50) | 79 | 50/50 |
| 14-7 | 17.1 (49) | 50/50 | | 17.3 (50) | 101 | 50/50 | 15.1 (50) | 88 | 50/50 | 13.2 (50) | 77 | 50/50 |
| 18-7 | 16.5 (50) | 50/50 | | 16.1 (50) | 98 | 50/50 | 14.8 (50) | 90 | 50/50 | 12.8 (50) | 78 | 50/50 |
| 22-7 | 16.3 (49) | 50/50 | | 16.1 (49) | 99 | 49/50 | 14.7 (50) | 90 | 50/50 | 13.1 (50) | 80 | 50/50 |
| 26-7 | 16.4 (50) | 50/50 | | 16.3 (49) | 99 | 49/50 | 15.2 (50) | 93 | 50/50 | 13.4 (50) | 82 | 50/50 |
| 30-7 | 16.4 (50) | 50/50 | | 16.4 (49) | 100 | 49/50 | 14.9 (50) | 91 | 50/50 | 13.9 (50) | 85 | 50/50 |
| 34-7 | 16.0 (50) | 50/50 | | 16.2 (49) | 101 | 49/50 | 14.8 (50) | 93 | 50/50 | 13.5 (50) | 84 | 50/50 |
| 38-7 | 15.9 (50) | 50/50 | | 15.9 (49) | 100 | 49/50 | 14.7 (50) | 92 | 50/50 | 13.7 (50) | 86 | 50/50 |
| 42-7 | 16.1 (49) | 49/50 | | 15.6 (49) | 97 | 49/50 | 14.8 (49) | 92 | 49/50 | 13.6 (50) | 84 | 50/50 |
| 46-7 | 16.4 (49) | 49/50 | | 16.3 (48) | 99 | 48/50 | 15.0 (49) | 91 | 49/50 | 13.9 (50) | 85 | 50/50 |
| 50-7 | 16.6 (49) | 49/50 | | 16.3 (48) | 98 | 48/50 | 15.6 (49) | 94 | 49/50 | 14.5 (50) | 87 | 50/50 |
| 54-7 | 16.5 (49) | 49/50 | | 16.5 (47) | 100 | 47/50 | 15.9 (49) | 96 | 49/50 | 14.6 (50) | 88 | 50/50 |
| 58-7 | 17.2 (49) | 49/50 | | 17.1 (47) | 99 | 47/50 | 16.4 (49) | 95 | 49/50 | 15.3 (50) | 89 | 50/50 |
| 62-7 | 17.1 (49) | 49/50 | | 17.1 (46) | 100 | 46/50 | 16.0 (49) | 94 | 49/50 | 14.6 (50) | 85 | 50/50 |
| 66-7 | 17.0 (49) | 49/50 | | 16.6 (46) | 98 | 46/50 | 15.7 (49) | 92 | 49/50 | 14.4 (50) | 85 | 50/50 |
| 70-7 | 17.9 (49) | 49/50 | | 17.4 (44) | 97 | 45/50 | 16.7 (49) | 93 | 49/50 | 15.4 (50) | 86 | 50/50 |
| 74-7 | 18.0 (49) | 49/50 | | 18.5 (42) | 103 | 43/50 | 16.9 (48) | 94 | 49/50 | 15.7 (50) | 87 | 50/50 |
| 78-7 | 18.1 (48) | 49/50 | | 17.5 (42) | 97 | 42/50 | 17.4 (48) | 96 | 48/50 | 15.9 (50) | 88 | 50/50 |
| 82-7 | 18.4 (48) | 49/50 | | 18.2 (39) | 99 | 40/50 | 17.5 (48) | 95 | 48/50 | 15.6 (50) | 85 | 50/50 |
| 86-7 | 19.2 (46) | 48/50 | | 18.9 (39) | 98 | 40/50 | 17.5 (47) | 91 | 48/50 | 15.3 (49) | 80 | 49/50 |
| 90-7 | 19.7 (44) | 47/50 | | 19.1 (40) | 97 | 40/50 | 18.5 (46) | 94 | 47/50 | 16.1 (48) | 82 | 48/50 |
| 94-7 | 19.9 (42) | 46/50 | | 19.6 (37) | 98 | 38/50 | 18.1 (44) | 91 | 45/50 | 15.8 (44) | 79 | 46/50 |
| 98-7 | 19.7 (38) | 43/50 | | 19.4 (35) | 98 | 36/50 | 18.1 (42) | 92 | 44/50 | 16.5 (42) | 84 | 43/50 |
| 102-7 | 20.9 (36) | 40/50 | | 19.0 (33) | 91 | 35/50 | 19.4 (39) | 93 | 40/50 | 16.3 (40) | 78 | 43/50 |
| 104-7 | 21.0 (34) | 40/50 | | 18.7 (31) | 89 | 35/50 | 18.7 (36) | 89 | 39/50 | 16.2 (39) | 77 | 40/50 |

< >:No. of effective animals, ():No. of measured animals Av. WC. : g

TABLE E 2

**WATER CONSUMPTION CHANGES AND
SURVIVAL ANIMAL NUMBERS: FEMALE**

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

MEAN WATER CONSUMPTION(WC) AND SURVIVAL

PAGE : 2

| Week-Day on Study | Control | | | 3300 ppm | | | 10000 ppm | | | 30000 ppm | | |
|----------------------|-----------|---------------------------|--|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|
| | Av. WC. | No. of Surviv. <50> | | Av. WC. | % of cont. <50> | No. of Surviv. | Av. WC. | % of cont. <50> | No. of Surviv. | Av. WC. | % of cont. <50> | No. of Surviv. |
| 1-7 | 16.4 (50) | 50/50 | | 15.7 (50) | 96 | 50/50 | 13.2 (50) | 80 | 50/50 | 11.2 (50) | 68 | 50/50 |
| 2-7 | 17.4 (47) | 50/50 | | 16.8 (48) | 97 | 50/50 | 13.0 (50) | 75 | 50/50 | 11.4 (50) | 66 | 50/50 |
| 3-7 | 20.2 (48) | 50/50 | | 17.8 (49) | 88 | 50/50 | 12.9 (50) | 64 | 50/50 | 10.6 (50) | 52 | 50/50 |
| 4-7 | 18.4 (41) | 50/50 | | 17.8 (45) | 97 | 50/50 | 13.3 (50) | 72 | 50/50 | 10.7 (50) | 58 | 50/50 |
| 5-7 | 16.6 (33) | 50/50 | | 18.0 (47) | 108 | 50/50 | 13.0 (50) | 78 | 50/50 | 10.4 (50) | 63 | 50/50 |
| 6-7 | 17.7 (36) | 50/50 | | 17.7 (44) | 100 | 50/50 | 12.4 (50) | 70 | 50/50 | 9.9 (50) | 56 | 50/50 |
| 7-7 | 17.7 (41) | 50/50 | | 16.7 (43) | 94 | 50/50 | 12.1 (50) | 68 | 50/50 | 9.5 (50) | 54 | 50/50 |
| 8-7 | 17.4 (35) | 50/50 | | 18.0 (44) | 103 | 50/50 | 11.9 (50) | 68 | 50/50 | 9.3 (50) | 53 | 50/50 |
| 9-7 | 18.2 (41) | 50/50 | | 18.7 (45) | 103 | 50/50 | 11.7 (50) | 64 | 50/50 | 9.3 (50) | 51 | 50/50 |
| 10-7 | 18.5 (41) | 50/50 | | 17.1 (44) | 92 | 50/50 | 11.4 (50) | 62 | 50/50 | 9.2 (50) | 50 | 50/50 |
| 11-7 | 18.4 (41) | 50/50 | | 17.4 (43) | 95 | 50/50 | 11.7 (50) | 64 | 50/50 | 9.4 (50) | 51 | 50/50 |
| 12-7 | 17.0 (40) | 50/50 | | 16.7 (44) | 98 | 50/50 | 11.4 (50) | 67 | 50/50 | 9.1 (50) | 54 | 50/50 |
| 13-7 | 18.5 (40) | 50/50 | | 17.5 (44) | 95 | 50/50 | 11.7 (50) | 63 | 50/50 | 9.6 (50) | 52 | 50/50 |
| 14-7 | 17.9 (38) | 50/50 | | 17.3 (44) | 97 | 50/50 | 11.6 (50) | 65 | 50/50 | 8.9 (50) | 50 | 50/50 |
| 18-7 | 19.0 (37) | 50/50 | | 17.2 (44) | 91 | 50/50 | 12.1 (50) | 64 | 50/50 | 9.1 (50) | 48 | 50/50 |
| 22-7 | 18.0 (37) | 50/50 | | 17.9 (46) | 99 | 50/50 | 12.3 (50) | 68 | 50/50 | 9.3 (50) | 52 | 50/50 |
| 26-7 | 17.6 (38) | 50/50 | | 18.4 (45) | 105 | 50/50 | 12.0 (49) | 68 | 50/50 | 9.8 (49) | 56 | 50/50 |
| 30-7 | 18.1 (40) | 50/50 | | 17.8 (44) | 98 | 50/50 | 12.3 (50) | 68 | 50/50 | 9.3 (50) | 51 | 50/50 |
| 34-7 | 16.7 (36) | 49/50 | | 16.9 (47) | 101 | 50/50 | 12.5 (50) | 75 | 50/50 | 9.7 (49) | 58 | 50/50 |
| 38-7 | 17.0 (41) | 49/50 | | 16.9 (46) | 99 | 50/50 | 11.8 (50) | 69 | 50/50 | 9.4 (50) | 55 | 50/50 |
| 42-7 | 17.2 (38) | 49/50 | | 16.3 (45) | 95 | 50/50 | 12.3 (50) | 72 | 50/50 | 10.5 (50) | 61 | 50/50 |
| 46-7 | 16.7 (45) | 49/50 | | 16.6 (48) | 99 | 50/50 | 12.2 (50) | 73 | 50/50 | 10.1 (50) | 60 | 50/50 |
| 50-7 | 17.1 (43) | 48/50 | | 17.3 (46) | 101 | 50/50 | 12.4 (50) | 73 | 50/50 | 10.6 (50) | 62 | 50/50 |
| 54-7 | 16.2 (41) | 47/50 | | 16.4 (47) | 101 | 50/50 | 12.3 (50) | 76 | 50/50 | 10.7 (50) | 66 | 50/50 |
| 58-7 | 16.7 (44) | 47/50 | | 15.9 (49) | 95 | 50/50 | 12.8 (50) | 77 | 50/50 | 11.3 (50) | 68 | 50/50 |
| 62-7 | 16.8 (45) | 47/50 | | 15.6 (48) | 93 | 49/50 | 12.5 (50) | 74 | 50/50 | 11.4 (50) | 68 | 50/50 |
| 66-7 | 15.0 (46) | 47/50 | | 16.2 (48) | 108 | 49/50 | 11.8 (50) | 79 | 50/50 | 10.9 (50) | 73 | 50/50 |
| 70-7 | 15.6 (46) | 46/50 | | 16.8 (47) | 108 | 49/50 | 12.9 (50) | 83 | 50/50 | 11.7 (48) | 75 | 48/50 |
| 74-7 | 14.9 (44) | 46/50 | | 16.3 (48) | 109 | 48/50 | 12.6 (50) | 85 | 50/50 | 11.8 (47) | 79 | 47/50 |
| 78-7 | 15.0 (43) | 45/50 | | 16.0 (47) | 107 | 47/50 | 13.1 (50) | 87 | 50/50 | 12.0 (46) | 80 | 46/50 |
| 82-7 | 15.1 (43) | 43/50 | | 15.1 (43) | 100 | 45/50 | 12.5 (49) | 83 | 49/50 | 12.2 (46) | 81 | 46/50 |
| 86-7 | 15.2 (39) | 40/50 | | 16.4 (45) | 108 | 45/50 | 12.9 (49) | 85 | 49/50 | 12.2 (45) | 80 | 45/50 |
| 90-7 | 15.4 (38) | 38/50 | | 15.6 (43) | 101 | 44/50 | 13.2 (48) | 86 | 48/50 | 12.5 (44) | 81 | 44/50 |
| 94-7 | 16.1 (38) | 38/50 | | 15.7 (43) | 98 | 43/50 | 13.8 (47) | 86 | 47/50 | 12.8 (43) | 80 | 44/50 |
| 98-7 | 16.2 (37) | 38/50 | | 16.2 (43) | 100 | 43/50 | 14.3 (45) | 88 | 45/50 | 12.9 (43) | 80 | 43/50 |
| 102-7 | 17.4 (34) | 35/50 | | 16.6 (38) | 95 | 40/50 | 14.9 (44) | 86 | 44/50 | 13.7 (39) | 79 | 40/50 |
| 104-7 | 16.6 (35) | 35/50 | | 16.5 (39) | 99 | 39/50 | 14.6 (44) | 88 | 44/50 | 12.9 (39) | 78 | 39/50 |

< >:No. of effective animals, ():No. of measured animals Av. WC. : g

TABLE E 3

WATER CONSUMPTION CHANGES: MALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 1-7(3) | 2-7(3) | 3-7(3) | 4-7(3) | 5-7(3) | 6-7(3) | 7-7(3) |
| Control | 16.9± 0.9 | 18.4± 1.4 | 19.1± 2.2 | 19.5± 1.6 | 19.0± 1.6 | 17.7± 1.6 | 17.9± 1.8 |
| 3300 ppm | 17.6± 1.4* | 19.2± 2.0 | 19.3± 2.5 | 19.9± 2.4 | 19.6± 2.6 | 18.2± 2.0 | 18.2± 2.2 |
| 10000 ppm | 15.6± 1.4** | 16.4± 1.4** | 16.6± 1.9** | 17.3± 1.7** | 17.5± 1.8** | 16.6± 1.9** | 16.2± 1.7** |
| 30000 ppm | 13.9± 0.9** | 14.5± 0.8** | 14.6± 1.3** | 14.9± 0.9** | 15.4± 1.0** | 14.4± 1.2** | 14.3± 1.1** |

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

Test of Dunnett

(HAN260)

BATS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

| Group Name | Administration 8-7(3) | week-day(effective) 9-7(3) | 10-7(3) | 11-7(3) | 12-7(3) | 13-7(3) | 14-7(3) |
|------------|--------------------------|-------------------------------|-------------|-------------|-------------|-------------|-------------|
| Control | 18.1± 1.6 | 17.5± 1.6 | 17.6± 1.8 | 17.8± 1.8 | 17.1± 1.8 | 17.4± 1.6 | 17.1± 2.2 |
| 3300 ppm | 18.6± 2.3 | 18.8± 3.1 | 18.0± 2.0 | 18.0± 2.1 | 17.4± 2.2 | 17.2± 1.3 | 17.3± 2.4 |
| 10000 ppm | 16.3± 1.6** | 15.9± 1.6** | 15.5± 1.3** | 15.6± 1.4** | 15.3± 1.3** | 15.5± 2.0** | 15.1± 1.2** |
| 30000 ppm | 14.3± 1.1** | 13.9± 1.2** | 13.7± 1.7** | 13.6± 1.2** | 13.7± 1.0** | 13.7± 1.1** | 13.2± 1.0** |

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

(HAN260)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

| Group Name | Administration | | week-day(effective) | | | | | | | | | |
|------------|----------------|-------|---------------------|-------|---------|-------|---------|-------|---------|-------|---------|-------|
| | 18-7(3) | | 22-7(3) | | 26-7(3) | | 30-7(3) | | 34-7(3) | | 38-7(3) | |
| Control | 16.5± | 1.5 | 16.3± | 1.3 | 16.4± | 1.7 | 16.4± | 1.1 | 16.0± | 1.5 | 15.9± | 1.4 |
| 3300 ppm | 16.1± | 1.7 | 16.1± | 1.5 | 16.3± | 1.7 | 16.4± | 1.7 | 16.2± | 2.0 | 15.9± | 1.1 |
| 10000 ppm | 14.8± | 1.7** | 14.7± | 1.2** | 15.2± | 1.5** | 14.9± | 1.6** | 14.8± | 1.2** | 14.7± | 1.4** |
| 30000 ppm | 12.8± | 1.0** | 13.1± | 0.9** | 13.4± | 1.2** | 13.9± | 2.4** | 13.5± | 1.2** | 13.7± | 1.2** |

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

Test of Dunnett

(HAN260)

BATS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 46-7(3) | 50-7(3) | 54-7(3) | 58-7(3) | 62-7(3) | 66-7(3) | 70-7(3) |
| Control | 16.4± 1.1 | 16.6± 1.3 | 16.5± 1.4 | 17.2± 1.4 | 17.1± 1.4 | 17.0± 1.7 | 17.9± 2.2 |
| 3300 ppm | 16.3± 1.6 | 16.3± 1.7 | 16.5± 1.4 | 17.1± 1.6 | 17.1± 1.5 | 16.6± 1.5 | 17.4± 3.0 |
| 10000 ppm | 15.0± 1.3** | 15.6± 1.3** | 15.9± 1.5 | 16.4± 1.3* | 16.0± 1.3** | 15.7± 1.4** | 16.7± 1.6** |
| 30000 ppm | 13.9± 1.3** | 14.5± 1.7** | 14.6± 1.2** | 15.3± 1.5** | 14.6± 1.3** | 14.4± 1.2** | 15.4± 1.3** |

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

Test of Dunnett

(HAN260)

BATS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 UNIT : g
 REPORT TYPE : AI 104
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

| Group Name | Administration | | week-day(effective) | | | | | | | | | | | |
|------------|----------------|-------|---------------------|-------|----------|-------|----------|-------|----------|-------|----------|-------|----------|-------|
| | 74-7 (3) | | 78-7 (3) | | 82-7 (3) | | 86-7 (3) | | 90-7 (3) | | 94-7 (3) | | 98-7 (3) | |
| Control | 18.0± | 2.3 | 18.1± | 2.5 | 18.4± | 3.4 | 19.2± | 3.2 | 19.7± | 3.6 | 19.9± | 3.5 | 19.7± | 3.1 |
| 3300 ppm | 18.5± | 2.6 | 17.5± | 3.5 | 18.2± | 2.9 | 18.9± | 2.6 | 19.1± | 3.8 | 19.6± | 3.0 | 19.4± | 3.4 |
| 10000 ppm | 16.9± | 1.8* | 17.4± | 1.6 | 17.5± | 2.4 | 17.5± | 3.4** | 18.5± | 3.7 | 18.1± | 3.1* | 18.1± | 3.5 |
| 30000 ppm | 15.7± | 2.1** | 15.9± | 1.6** | 15.6± | 1.7** | 15.3± | 1.9** | 16.1± | 3.2** | 15.8± | 2.6** | 16.5± | 3.1** |

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 104
SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 6

| Group Name | Administration week-day(effective) | |
|------------|------------------------------------|-------------|
| | 102-7(3) | 104-7(3) |
| Control | 20.9± 4.2 | 21.0± 4.0 |
| 3300 ppm | 19.0± 4.1 | 18.7± 4.9 |
| 10000 ppm | 19.4± 4.2 | 18.7± 4.2 |
| 30000 ppm | 16.3± 3.7** | 16.2± 3.5** |

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

Test of Dunnett

(HAN260)

BAIS 4

TABLE E 4

WATER CONSUMPTION CHANGES: FEMALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 7

| Group Name | Administration | | week-day(effective) | | 3-7(3) | 4-7(3) | 5-7(3) | 6-7(3) | 7-7(3) |
|------------|----------------|--|---------------------|--|-------------|-------------|-------------|-------------|-------------|
| | 1-7(3) | | 2-7(3) | | | | | | |
| Control | 16.4± 3.4 | | 17.4± 4.8 | | 20.2± 8.1 | 18.4± 4.3 | 16.6± 3.1 | 17.7± 4.4 | 17.7± 5.4 |
| 3300 ppm | 15.7± 1.5 | | 16.8± 3.1 | | 17.8± 4.3 | 17.8± 3.7 | 18.0± 4.1 | 17.7± 3.9 | 16.7± 3.5 |
| 10000 ppm | 13.2± 3.0** | | 13.0± 2.1** | | 12.9± 1.8** | 13.3± 2.0** | 13.0± 2.0** | 12.4± 1.5** | 12.1± 1.8** |
| 30000 ppm | 11.2± 0.8** | | 11.4± 0.8** | | 10.6± 0.9** | 10.7± 0.9** | 10.4± 0.9** | 9.9± 1.2** | 9.5± 1.1** |

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

Test of Dunnett

(HAN260)

BATS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : AI 104
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

| Group Name | Administration week-day(effective) 8-7(3) | 9-7(3) | 10-7(3) | 11-7(3) | 12-7(3) | 13-7(3) | 14-7(3) |
|------------|--|-------------|-------------|-------------|-------------|-------------|-------------|
| Control | 17.4± 4.8 | 18.2± 5.2 | 18.5± 5.7 | 18.4± 5.0 | 17.0± 4.5 | 18.5± 4.9 | 17.9± 5.0 |
| 3300 ppm | 18.0± 4.5 | 18.7± 5.3 | 17.1± 4.1 | 17.4± 4.0 | 16.7± 4.0 | 17.5± 4.6 | 17.3± 4.2 |
| 10000 ppm | 11.9± 1.4** | 11.7± 1.7** | 11.4± 1.6** | 11.7± 1.8** | 11.4± 1.8** | 11.7± 1.5** | 11.6± 2.2** |
| 30000 ppm | 9.3± 1.0** | 9.3± 1.0** | 9.2± 1.8** | 9.4± 1.3** | 9.1± 0.8** | 9.6± 1.6** | 8.9± 0.7** |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 9

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 18-7(3) | 22-7(3) | 26-7(3) | 30-7(3) | 34-7(3) | 38-7(3) | 42-7(3) |
| Control | 19.0± 5.1 | 18.0± 4.7 | 17.6± 4.2 | 18.1± 4.3 | 16.7± 3.9 | 17.0± 4.1 | 17.2± 5.3 |
| 3300 ppm | 17.2± 4.6 | 17.9± 5.0 | 18.4± 5.0 | 17.8± 4.7 | 16.9± 4.4 | 16.9± 5.1 | 16.3± 4.1 |
| 10000 ppm | 12.1± 1.8** | 12.3± 3.2** | 12.0± 1.9** | 12.3± 2.4** | 12.5± 2.8** | 11.8± 1.7** | 12.3± 3.1** |
| 30000 ppm | 9.1± 1.6** | 9.3± 0.9** | 9.8± 2.5** | 9.3± 1.2** | 9.7± 2.7** | 9.4± 1.0** | 10.5± 3.2** |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BATS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 10

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 46-7(3) | 50-7(3) | 54-7(3) | 58-7(3) | 62-7(3) | 66-7(3) | 70-7(3) |
| Control | 16.7± 4.8 | 17.1± 4.8 | 16.2± 4.0 | 16.7± 4.2 | 16.8± 4.9 | 15.0± 3.5 | 15.6± 3.7 |
| 3300 ppm | 16.6± 4.6 | 17.3± 5.0 | 16.4± 4.6 | 15.9± 4.0 | 15.6± 3.6 | 16.2± 4.3 | 16.8± 4.3 |
| 10000 ppm | 12.2± 1.8** | 12.4± 1.8** | 12.3± 2.1** | 12.8± 1.7** | 12.5± 2.2** | 11.8± 1.4** | 12.9± 2.2** |
| 30000 ppm | 10.1± 1.0** | 10.6± 1.8** | 10.7± 1.3** | 11.3± 1.7** | 11.4± 2.0** | 10.9± 1.3** | 11.7± 1.5** |

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 11

| Group Name | Administration week-day(effective) | | | | | | |
|------------|------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 74-7(3) | 78-7(3) | 82-7(3) | 86-7(3) | 90-7(3) | 94-7(3) | 98-7(3) |
| Control | 14.9± 3.3 | 15.0± 3.0 | 15.1± 3.5 | 15.2± 3.3 | 15.4± 2.7 | 16.1± 3.0 | 16.2± 3.4 |
| 3300 ppm | 16.3± 3.5* | 16.0± 3.6 | 15.1± 2.7 | 16.4± 3.8 | 15.6± 2.9 | 15.7± 3.0 | 16.2± 3.4 |
| 10000 ppm | 12.6± 2.3** | 13.1± 2.3** | 12.5± 2.7** | 12.9± 2.2** | 13.2± 2.7** | 13.8± 3.1** | 14.3± 3.6** |
| 30000 ppm | 11.8± 2.2** | 12.0± 1.8** | 12.2± 3.2** | 12.2± 1.7** | 12.5± 1.6** | 12.8± 1.6** | 12.9± 2.0** |

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

Test of Dunnett

(HAN260)

BATS 4

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 12

| Group Name | Administration week-day(effective) | |
|------------|------------------------------------|-------------|
| | 102-7(3) | 104-7(3) |
| Control | 17.4± 4.7 | 16.6± 4.5 |
| 3300 ppm | 16.6± 3.4 | 16.5± 3.1 |
| 10000 ppm | 14.9± 4.0* | 14.6± 3.4* |
| 30000 ppm | 13.7± 2.8** | 12.9± 2.6** |

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

Test of Dunnett

(HAN260)

BAIS 4

TABLE F 1

CHEMICAL INTAKE CHANGES: MALE

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
UNIT : mg/kg/d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

| Group Name | Administration (weeks) | | | | | | | | | | | | | |
|------------|------------------------|-----------|-----------|----------|-----------|-----------|-----------|--|--|--|--|--|--|--|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | | | | | | | |
| Control | 0± 0 | 0± 0 | 0± 0 | 0± 0 | 0± 0 | 0± 0 | 0± 0 | | | | | | | |
| 3300 ppm | 372± 26 | 338± 27 | 302± 30 | 285± 29 | 265± 35 | 235± 24 | 227± 23 | | | | | | | |
| 10000 ppm | 1013± 63 | 894± 58 | 805± 77 | 772± 70 | 731± 70 | 661± 69 | 617± 53 | | | | | | | |
| 30000 ppm | 2779± 166 | 2435± 119 | 2158± 166 | 2031± 96 | 1984± 116 | 1764± 136 | 1683± 109 | | | | | | | |

(HAN300)

BAIS 4

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
UNIT : mg/kg/d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

| Group Name | Administration (weeks) | | | | | | | | | | | | | |
|------------|------------------------|-----|-------|-----|-------|-----|-------|-----|-------|----|-------|----|-------|----|
| | 8 | | 9 | | 10 | | 11 | | 12 | | 13 | | 14 | |
| Control | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 |
| 3300 ppm | 222± | 24 | 219± | 33 | 206± | 22 | 202± | 20 | 190± | 24 | 184± | 15 | 181± | 24 |
| 10000 ppm | 597± | 46 | 569± | 49 | 543± | 39 | 541± | 38 | 516± | 37 | 512± | 67 | 491± | 33 |
| 30000 ppm | 1618± | 115 | 1530± | 121 | 1489± | 178 | 1451± | 110 | 1422± | 83 | 1394± | 82 | 1329± | 92 |

(HAN300)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : mg/kg/day
 REPORT TYPE : A1 104
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

| Group Name | Administration (weeks) | | | | | | | | | | | | | |
|------------|------------------------|----|-------|----|-------|----|-------|-----|-------|----|-------|----|-------|-----|
| | 18 | | 22 | | 26 | | 30 | | 34 | | 38 | | 42 | |
| Control | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 |
| 3300 ppm | 160± | 16 | 152± | 14 | 150± | 15 | 147± | 14 | 142± | 21 | 136± | 8 | 131± | 21 |
| 10000 ppm | 452± | 60 | 433± | 40 | 436± | 52 | 417± | 55 | 404± | 31 | 397± | 46 | 392± | 40 |
| 30000 ppm | 1220± | 79 | 1202± | 69 | 1191± | 89 | 1207± | 203 | 1147± | 72 | 1140± | 86 | 1114± | 107 |

(HAN300)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : mg/kg/day
 REPORT TYPE : AI 104
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

| Group Name | Administration (weeks) | | | | | | | | | | | | | |
|------------|------------------------|----|-------|-----|-------|----|-------|-----|-------|----|-------|----|-------|----|
| | 46 | | 50 | | 54 | | 58 | | 62 | | 66 | | 70 | |
| Control | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 |
| 3300 ppm | 135± | 9 | 134± | 10 | 132± | 8 | 135± | 10 | 133± | 10 | 130± | 9 | 136± | 21 |
| 10000 ppm | 394± | 43 | 400± | 34 | 402± | 46 | 408± | 33 | 393± | 29 | 385± | 39 | 410± | 42 |
| 30000 ppm | 1123± | 79 | 1156± | 128 | 1147± | 93 | 1190± | 101 | 1119± | 82 | 1108± | 91 | 1182± | 89 |

(HAN300)

BATS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 104
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

| Group Name | Administration (weeks) | | | | | | | | | | | | | |
|------------|------------------------|-----|-------|-----|-------|-----|-------|-----|-------|-----|-------|-----|-------|-----|
| | 74 | | 78 | | 82 | | 86 | | 90 | | 94 | | 98 | |
| Control | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 |
| 3300 ppm | 142± | 17 | 134± | 24 | 140± | 19 | 146± | 18 | 148± | 27 | 154± | 24 | 153± | 24 |
| 10000 ppm | 413± | 48 | 420± | 45 | 424± | 65 | 420± | 83 | 446± | 96 | 445± | 74 | 450± | 87 |
| 30000 ppm | 1199± | 169 | 1208± | 121 | 1199± | 150 | 1182± | 192 | 1262± | 279 | 1267± | 308 | 1303± | 283 |

(HAN300)

BAIS 4

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
UNIT : mg/kg/d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 6

| Group Name | Administration (weeks) | | | |
|------------|------------------------|-----|-------|-----|
| | 102 | | 104 | |
| Control | 0± | 0 | 0± | 0 |
| 3300 ppm | 154± | 31 | 154± | 38 |
| 10000 ppm | 492± | 125 | 486± | 168 |
| 30000 ppm | 1314± | 366 | 1333± | 405 |

(HAN300)

BAIS 4

TABLE F 2

CHEMICAL INTAKE CHANGES: FEMALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 7

| Group Name | Administration (weeks) | | | | | | | | | | | | | |
|------------|------------------------|-----|-------|-----|-------|-----|-------|-----|-------|-----|-------|-----|-------|-----|
| | 1 | | 2 | | 3 | | 4 | | 5 | | 6 | | 7 | |
| Control | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 |
| 3300 ppm | 451± | 37 | 439± | 70 | 434± | 99 | 415± | 80 | 404± | 83 | 383± | 80 | 355± | 68 |
| 10000 ppm | 1169± | 256 | 1043± | 151 | 962± | 117 | 941± | 117 | 890± | 126 | 824± | 89 | 791± | 101 |
| 30000 ppm | 2989± | 173 | 2753± | 147 | 2400± | 173 | 2315± | 154 | 2170± | 151 | 2001± | 203 | 1903± | 166 |

(HAN300)

BATS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

| Group Name | Administration | | (weeks) | | | | | | | | | | | |
|------------|----------------|-----|---------|-----|-------|-----|-------|-----|-------|-----|-------|-----|-------|-----|
| | 8 | | 9 | | 10 | | 11 | | 12 | | 13 | | 14 | |
| Control | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 |
| 3300 ppm | 376± | 89 | 384± | 109 | 346± | 79 | 347± | 76 | 328± | 74 | 338± | 86 | 333± | 76 |
| 10000 ppm | 762± | 78 | 736± | 89 | 709± | 86 | 719± | 92 | 687± | 88 | 701± | 75 | 687± | 108 |
| 30000 ppm | 1832± | 156 | 1798± | 151 | 1756± | 291 | 1778± | 217 | 1702± | 127 | 1764± | 280 | 1638± | 115 |

(HAN300)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 9

| Group Name | Administration (weeks) | | | | | | | | | | | | | |
|------------|------------------------|-----------|-----------|-----------|-----------|-----------|-----------|--|--|--|--|--|--|--|
| | 18 | 22 | 26 | 30 | 34 | 38 | 42 | | | | | | | |
| Control | 0± 0 | 0± 0 | 0± 0 | 0± 0 | 0± 0 | 0± 0 | 0± 0 | | | | | | | |
| 3300 ppm | 320± 84 | 323± 86 | 322± 87 | 305± 76 | 282± 69 | 279± 86 | 261± 61 | | | | | | | |
| 10000 ppm | 688± 91 | 676± 154 | 644± 84 | 645± 108 | 636± 123 | 596± 75 | 605± 134 | | | | | | | |
| 30000 ppm | 1625± 299 | 1601± 128 | 1646± 423 | 1532± 174 | 1561± 376 | 1500± 141 | 1631± 492 | | | | | | | |

(HAN300)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 10

| Group Name | Administration (weeks) | | | | | | | | | | | | | |
|------------|------------------------|-----|-------|-----|-------|-----|-------|-----|-------|-----|-------|-----|-------|-----|
| | 46 | | 50 | | 54 | | 58 | | 62 | | 66 | | 70 | |
| Control | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 |
| 3300 ppm | 262± | 70 | 268± | 78 | 246± | 67 | 234± | 58 | 225± | 55 | 230± | 62 | 233± | 61 |
| 10000 ppm | 591± | 68 | 592± | 64 | 569± | 84 | 578± | 78 | 552± | 80 | 514± | 42 | 558± | 95 |
| 30000 ppm | 1557± | 127 | 1618± | 254 | 1602± | 179 | 1672± | 253 | 1644± | 293 | 1542± | 201 | 1627± | 203 |

(HAN300)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 11

| Group Name | Administration (weeks) | | | | | | | | | | | | | |
|------------|------------------------|-----|-------|-----|-------|-----|-------|-----|-------|-----|-------|-----|-------|-----|
| | 74 | | 78 | | 82 | | 86 | | 90 | | 94 | | 98 | |
| Control | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 | 0± | 0 |
| 3300 ppm | 222± | 53 | 213± | 53 | 199± | 36 | 211± | 55 | 200± | 48 | 198± | 42 | 204± | 46 |
| 10000 ppm | 529± | 86 | 544± | 82 | 510± | 94 | 522± | 80 | 529± | 108 | 551± | 121 | 573± | 147 |
| 30000 ppm | 1620± | 293 | 1608± | 273 | 1622± | 466 | 1593± | 249 | 1612± | 211 | 1646± | 245 | 1661± | 277 |

(HAN300)

BAIS 4

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
UNIT : mg/kg/d a y
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 12

| Group Name | Administration (weeks) | | | |
|------------|------------------------|-----|-------|-----|
| | 102 | | 104 | |
| Control | 0± | 0 | 0± | 0 |
| 3300 ppm | 208± | 52 | 210± | 53 |
| 10000 ppm | 592± | 173 | 585± | 152 |
| 30000 ppm | 1768± | 431 | 1666± | 382 |

(HAN300)

BAIS 4

TABLE G 1

HEMATOLOGY: MALE

STUDY NO. : 0612

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)

ALL ANIMALS (105W)

PAGE : 1

| Group Name | NO. of Animals | RED BLOOD CELL 10 ⁶ /μl | | HEMOGLOBIN g/dl | | HEMATOCRIT % | | MCV fl | | MCH pg | | MC1C g/dl | | PLATELET 10 ³ /μl | |
|------------|-------------------|---------------------------------------|------|--------------------|-----|-----------------|-----|-----------|-----|-----------|-----|--------------|-----|---------------------------------|-----|
| Control | 40 | 8.22± | 1.71 | 14.0± | 2.8 | 42.0± | 7.3 | 52.1± | 5.7 | 17.1± | 1.2 | 33.0± | 2.2 | 978± | 285 |
| 3300 ppm | 34 | 8.37± | 1.11 | 14.2± | 2.0 | 43.1± | 5.2 | 51.5± | 1.7 | 17.0± | 0.8 | 32.9± | 1.2 | 1018± | 279 |
| 10000 ppm | 39 | 8.32± | 1.33 | 14.1± | 2.4 | 42.4± | 6.2 | 51.1± | 2.4 | 17.0± | 1.2 | 33.2± | 1.6 | 1015± | 329 |
| 30000 ppm | 40 | 8.52± | 1.40 | 14.5± | 2.4 | 43.4± | 6.6 | 51.2± | 2.3 | 17.0± | 0.9 | 33.3± | 1.0 | 916± | 284 |

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

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
MEASURE. TIME : 1
SEX : MALE

HEMATOLOGY (SUMMARY)
ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 2

| Group Name | NO. of Animals | RETICULOCYTE % | |
|------------|-------------------|-------------------|-----|
| Control | 40 | 5.2± | 8.0 |
| 3300 ppm | 34 | 4.1± | 2.5 |
| 10000 ppm | 39 | 4.2± | 3.0 |
| 30000 ppm | 40 | 4.1± | 3.7 |

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

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : MALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 3

| Group Name | NO. of Animals | WBC 1 O ³ /μl | | Differential N-BAND | | WBC (%) N-SEG | | EOSINO | | BASO | | MONO | | LYMPHO | | OTHER | |
|------------|-------------------|-----------------------------|-------|------------------------|---|------------------|----|--------|---|------|---|------|---|--------|----|-------|----|
| Control | 40 | 10.65± | 28.46 | 1± | 1 | 46± | 12 | 2± | 1 | 0± | 0 | 5± | 2 | 42± | 11 | 4± | 16 |
| 3300 ppm | 34 | 5.40± | 1.17 | 0± | 1 | 49± | 9 | 2± | 1 | 0± | 0 | 5± | 1 | 43± | 9 | 0± | 1 |
| 10000 ppm | 39 | 5.87± | 2.94 | 1± | 1 | 51± | 13 | 1± | 1 | 0± | 0 | 5± | 1 | 41± | 13 | 1± | 5 |
| 30000 ppm | 40 | 5.41± | 1.80 | 1± | 1 | 51± | 9 | 2± | 1 | 0± | 0 | 5± | 2 | 40± | 9 | 1± | 2 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 4

TABLE G 2

HEMATOLOGY: FEMALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 4

| Group Name | NO. of Animals | RED BLOOD CELL 10 ⁶ /μl | | HEMOGLOBIN g/dl | | HEMATOCRIT % | | MCV fl | | MCH pg | | MCHC g/dl | | PLATELET 10 ³ /μl | |
|------------|-------------------|---------------------------------------|------|--------------------|-----|-----------------|-----|-----------|-----|-----------|-----|--------------|-----|---------------------------------|-----|
| Control | 34 | 8.40± | 0.46 | 15.2± | 0.8 | 44.4± | 2.0 | 52.9± | 1.7 | 18.1± | 0.7 | 34.3± | 0.7 | 730± | 113 |
| 3300 ppm | 38 | 8.47± | 0.38 | 15.4± | 0.6 | 44.7± | 1.7 | 52.9± | 1.2 | 18.2± | 0.5 | 34.5± | 0.5 | 698± | 88 |
| 10000 ppm | 44 | 8.10± | 1.11 | 14.8± | 1.7 | 43.2± | 4.0 | 53.9± | 4.4 | 18.4± | 1.0 | 34.3± | 1.1 | 728± | 155 |
| 30000 ppm | 39 | 8.22± | 0.82 | 14.8± | 1.7 | 43.2± | 4.5 | 52.5± | 1.7 | 17.9± | 0.9 | 34.2± | 1.2 | 704± | 141 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0612

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)

ALL ANIMALS (105W)

PAGE : 5

| Group Name | NO. of Animals | RETICULOCYTE % | |
|------------|-------------------|-------------------|-----|
| Control | 34 | 2.8± | 1.2 |
| 3300 ppm | 38 | 2.6± | 0.8 |
| 10000 ppm | 44 | 4.5± | 6.3 |
| 30000 ppm | 39 | 2.9± | 1.5 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0612

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)

ALL ANIMALS (105W)

PAGE : 6

| Group Name | NO. of Animals | WBC 1 O ³ /μ ² | | Differential N-BAND | | WBC (%) N-SEG | | EOSINO | | BASO | | MONO | | LYMPHO | | OTHER | |
|------------|-------------------|---|------|------------------------|---|------------------|----|--------|---|------|---|------|---|--------|----|-------|---|
| Control | 34 | 3.51± | 4.78 | 1± | 1 | 43± | 10 | 2± | 1 | 0± | 0 | 5± | 2 | 49± | 10 | 1± | 2 |
| 3300 ppm | 38 | 2.70± | 0.89 | 1± | 1 | 40± | 7 | 2± | 1 | 0± | 0 | 5± | 2 | 52± | 6 | 1± | 1 |
| 10000 ppm | 44 | 3.25± | 1.75 | 1± | 1 | 41± | 11 | 2± | 1 | 0± | 0 | 5± | 2 | 51± | 11 | 1± | 2 |
| 30000 ppm | 39 | 2.99± | 1.65 | 1± | 1 | 41± | 11 | 2± | 1 | 0± | 0 | 5± | 2 | 50± | 12 | 1± | 2 |

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

Test of Dunnett

(HCL070)

BAIS 4

TABLE H 1

BIOCHEMISTRY: MALE

STUDY NO. : 0612

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (105W)

PAGE : 1

| Group Name | NO. of Animals | TOTAL PROTEIN g /dl | | ALBUMIN g /dl | | A/G RATIO | | T-BILIRUBIN mg/dl | | GLUCOSE mg/dl | | T-CHOLESTEROL mg/dl | | TRIGLYCERIDE mg/dl | |
|------------|-------------------|------------------------|-------|------------------|-----|-----------|-----|----------------------|------|------------------|----|------------------------|----|-----------------------|-----|
| Control | 40 | 6.8± | 0.5 | 2.8± | 0.3 | 0.7± | 0.1 | 0.28± | 0.76 | 149± | 27 | 223± | 80 | 149± | 100 |
| 3300 ppm | 34 | 6.8± | 0.3 | 2.9± | 0.3 | 0.7± | 0.1 | 0.15± | 0.03 | 155± | 25 | 200± | 53 | 125± | 80 |
| 10000 ppm | 39 | 6.7± | 0.3 | 2.8± | 0.3 | 0.7± | 0.1 | 0.16± | 0.07 | 146± | 26 | 209± | 76 | 142± | 133 |
| 30000 ppm | 40 | 6.6± | 0.4** | 2.8± | 0.2 | 0.8± | 0.1 | 0.17± | 0.07 | 153± | 21 | 193± | 66 | 109± | 94 |

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

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0612

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (105W)

PAGE : 2

| Group Name | NO. of Animals | PHOSPHOLIPID mg/dl | | AST IU/l | | ALT IU/l | | LDH IU/l | | ALP IU/l | | G-GTP IU/l | | CK IU/l | |
|------------|-------------------|-----------------------|-----|-------------|-----|-------------|----|-------------|-----|-------------|-----|---------------|---|------------|-----|
| Control | 40 | 318± | 129 | 158± | 302 | 57± | 84 | 331± | 843 | 244± | 393 | 8± | 6 | 130± | 85 |
| 3300 ppm | 34 | 279± | 67 | 81± | 26 | 36± | 10 | 171± | 45 | 197± | 61 | 7± | 3 | 116± | 43 |
| 10000 ppm | 39 | 295± | 105 | 86± | 44 | 41± | 26 | 178± | 71 | 192± | 75 | 7± | 4 | 138± | 107 |
| 30000 ppm | 40 | 279± | 90 | 80± | 26 | 38± | 21 | 158± | 34 | 167± | 46 | 6± | 3 | 110± | 36 |

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

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 3

| Group Name | NO. of Animals | UREA NITROGEN mg/dl | | CREATININE mg/dl | | SODIUM mEq/l | | POTASSIUM mEq/l | | CHLORIDE mEq/l | | CALCIUM mg/dl | | INORGANIC PHOSPHORUS mg/dl | |
|------------|-------------------|------------------------|------|---------------------|-----|-----------------|---|--------------------|-----|-------------------|---|------------------|-----|-------------------------------|-----|
| Control | 40 | 24.0 ± | 10.7 | 0.7 ± | 0.2 | 143 ± | 1 | 3.6 ± | 0.3 | 106 ± | 2 | 10.8 ± | 0.5 | 4.4 ± | 0.9 |
| 3300 ppm | 34 | 24.2 ± | 24.0 | 0.8 ± | 1.1 | 142 ± | 2 | 3.6 ± | 0.3 | 105 ± | 2 | 10.7 ± | 0.7 | 4.6 ± | 2.4 |
| 10000 ppm | 39 | 27.2 ± | 36.7 | 0.7 ± | 0.7 | 142 ± | 2 | 3.7 ± | 0.4 | 105 ± | 2 | 10.7 ± | 0.7 | 4.8 ± | 3.7 |
| 30000 ppm | 40 | 22.8 ± | 15.8 | 0.6 ± | 0.2 | 142 ± | 2 | 3.8 ± | 0.3 | 105 ± | 1 | 10.5 ± | 0.6 | 4.2 ± | 1.3 |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 4

TABLE H 2

BIOCHEMISTRY: FEMALE

STUDY NO. : 0612

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (105W)

PAGE : 4

| Group Name | NO. of Animals | TOTAL PROTEIN g /dl | | ALBUMIN g /dl | | A/G RATIO | | T-BILIRUBIN mg/dl | | GLUCOSE mg/dl | | T-CHOLESTEROL mg/dl | | TRIGLYCERIDE mg/dl | |
|------------|-------------------|------------------------|------|------------------|-----|-----------|-----|----------------------|------|------------------|----|------------------------|----|-----------------------|----|
| Control | 34 | 7.0± | 0.3 | 3.5± | 0.3 | 1.0± | 0.1 | 0.14± | 0.03 | 142± | 14 | 141± | 29 | 64± | 64 |
| 3300 ppm | 38 | 7.0± | 0.4 | 3.6± | 0.3 | 1.1± | 0.1 | 0.14± | 0.03 | 147± | 11 | 141± | 28 | 64± | 55 |
| 10000 ppm | 44 | 6.9± | 0.4 | 3.5± | 0.4 | 1.0± | 0.2 | 0.17± | 0.12 | 141± | 14 | 136± | 29 | 63± | 34 |
| 30000 ppm | 39 | 6.7± | 0.4* | 3.5± | 0.2 | 1.1± | 0.1 | 0.14± | 0.03 | 149± | 21 | 131± | 20 | 50± | 19 |

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

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0612

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (105W)

PAGE : 5

| Group Name | NO. of Animals | PHOSPHOLIPID mg/dl | | AST IU/l | | ALT IU/l | | LDH IU/l | | ALP IU/l | | G-GTP IU/l | | CK IU/l | |
|------------|-------------------|-----------------------|----|-------------|----|-------------|----|-------------|-----|-------------|----|---------------|---|------------|----|
| Control | 34 | 244± | 49 | 116± | 46 | 46± | 17 | 206± | 72 | 121± | 69 | 3± | 2 | 99± | 22 |
| 3300 ppm | 38 | 247± | 44 | 128± | 93 | 53± | 44 | 212± | 104 | 116± | 36 | 2± | 1 | 103± | 37 |
| 10000 ppm | 44 | 240± | 48 | 129± | 81 | 46± | 19 | 240± | 262 | 115± | 46 | 3± | 1 | 103± | 29 |
| 30000 ppm | 39 | 233± | 31 | 117± | 93 | 44± | 26 | 205± | 145 | 120± | 36 | 3± | 1 | 100± | 51 |

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

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 MEASURE. TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 6

| Group Name | NO. of Animals | UREA NITROGEN mg/dl | | CREATININE mg/dl | | SODIUM mEq/l | | POTASSIUM mEq/l | | CHLORIDE mEq/l | | CALCIUM mg/dl | | INORGANIC PHOSPHORUS mg/dl | |
|------------|-------------------|------------------------|------|---------------------|-----|-----------------|---|--------------------|-------|-------------------|---|------------------|-----|-------------------------------|------|
| Control | 34 | 18.0± | 2.4 | 0.5± | 0.1 | 142± | 1 | 3.4± | 0.3 | 105± | 2 | 10.6± | 0.3 | 3.7± | 0.7 |
| 3300 ppm | 38 | 17.9± | 2.7 | 0.5± | 0.1 | 142± | 1 | 3.4± | 0.3 | 104± | 1 | 10.6± | 0.3 | 3.7± | 0.7 |
| 10000 ppm | 44 | 16.6± | 2.9 | 0.5± | 0.1 | 142± | 1 | 3.5± | 0.4 | 104± | 2 | 10.7± | 0.4 | 3.9± | 0.9 |
| 30000 ppm | 39 | 23.0± | 25.9 | 0.5± | 0.1 | 141± | 2 | 3.7± | 0.5** | 104± | 1 | 10.6± | 0.4 | 4.3± | 1.2* |

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 4

TABLE I 1

URINALYSIS: MALE

STUDY NO. : 0612

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

URINALYSIS

PAGE : 1

| Group Name | NO. of Animals | pH | | | | | | | CHI | Protein | | | | | CHI | Glucose | | | | | CHI | Ketone body | | | | | CHI | Bilirubin | | | | CHI | | |
|------------|-------------------|-----|-----|-----|-----|-----|-----|-----|-----|---------|---|---|----|----|-----|---------|----|---|---|----|-----|-------------|----|----|---|---|-----|-----------|----|----|----|-----|---|----|
| | | 5.0 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | | — | ± | + | 2+ | 3+ | | 4+ | — | ± | + | 2+ | | 3+ | 4+ | — | ± | + | | 2+ | 3+ | 4+ | — | | + | 2+ |
| Control | 40 | 0 | 1 | 8 | 9 | 19 | 3 | 0 | | 0 | 0 | 0 | 0 | 29 | 11 | | 40 | 0 | 0 | 0 | 0 | 0 | | 38 | 2 | 0 | 0 | 0 | 0 | | 40 | 0 | 0 | 0 |
| 3300 ppm | 35 | 0 | 0 | 4 | 10 | 19 | 2 | 0 | | 0 | 0 | 0 | 0 | 25 | 10 | | 35 | 0 | 0 | 0 | 0 | 0 | | 32 | 3 | 0 | 0 | 0 | 0 | | 35 | 0 | 0 | 0 |
| 10000 ppm | 40 | 0 | 3 | 4 | 11 | 17 | 5 | 0 | | 0 | 0 | 0 | 0 | 29 | 11 | | 40 | 0 | 0 | 0 | 0 | 0 | | 39 | 1 | 0 | 0 | 0 | 0 | | 40 | 0 | 0 | 0 |
| 30000 ppm | 42 | 1 | 2 | 5 | 10 | 22 | 2 | 0 | | 0 | 0 | 0 | 0 | 30 | 12 | | 42 | 0 | 0 | 0 | 0 | 0 | | 37 | 5 | 0 | 0 | 0 | 0 | | 42 | 0 | 0 | 0 |

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

Test of CHI SQUARE

(HCL101)

BATS 4

STUDY NO. : 0612

URINALYSIS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

PAGE : 2

| Group Name | NO. of Animals | Occult blood | | | | | Urobilinogen | | | | | | |
|------------|-------------------|--------------|---|---|----|----|--------------|----|---|----|----|----|-----|
| | | — | ± | + | 2+ | 3+ | CHI | ± | + | 2+ | 3+ | 4+ | CHI |
| Control | 40 | 38 | 1 | 0 | 0 | 1 | | 40 | 0 | 0 | 0 | 0 | |
| 3300 ppm | 35 | 34 | 0 | 1 | 0 | 0 | | 35 | 0 | 0 | 0 | 0 | |
| 10000 ppm | 40 | 40 | 0 | 0 | 0 | 0 | | 40 | 0 | 0 | 0 | 0 | |
| 30000 ppm | 42 | 40 | 0 | 1 | 1 | 0 | | 42 | 0 | 0 | 0 | 0 | |

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

Test of CHI SQUARE

(HCL101)

BAIS 4

TABLE I 2

URINALYSIS: FEMALE

STUDY NO. : 0612

URINALYSIS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

PAGE : 3

| Group Name | NO. of Animals | pH | | | | | | | CHI | Protein | | | | | CHI | Glucose | | | | | CHI | Ketone body | | | | | CHI | Bilirubin | | | | CHI | | |
|------------|-------------------|-----|-----|-----|-----|-----|-----|-----|-----|---------|---|----|----|----|-----|---------|----|---|---|----|-----|-------------|----|----|---|---|-----|-----------|----|----|----|-----|---|----|
| | | 5.0 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | | — | ± | + | 2+ | 3+ | | 4+ | — | ± | + | 2+ | | 3+ | 4+ | — | ± | + | | 2+ | 3+ | 4+ | — | | + | 2+ |
| Control | 35 | 0 | 1 | 5 | 4 | 10 | 9 | 6 | | 0 | 3 | 11 | 14 | 7 | 0 | | 35 | 0 | 0 | 0 | 0 | 0 | | 31 | 3 | 1 | 0 | 0 | 0 | | 35 | 0 | 0 | 0 |
| 3300 ppm | 39 | 0 | 0 | 0 | 11 | 13 | 11 | 4 | | 0 | 2 | 12 | 18 | 6 | 1 | | 39 | 0 | 0 | 0 | 0 | 0 | | 38 | 0 | 1 | 0 | 0 | 0 | | 39 | 0 | 0 | 0 |
| 10000 ppm | 43 | 0 | 3 | 2 | 12 | 16 | 3 | 7 | | 0 | 3 | 14 | 8 | 18 | 0 | | 43 | 0 | 0 | 0 | 0 | 0 | | 37 | 3 | 3 | 0 | 0 | 0 | | 43 | 0 | 0 | 0 |
| 30000 ppm | 40 | 0 | 4 | 4 | 9 | 6 | 6 | 11 | | 0 | 1 | 7 | 18 | 13 | 1 | | 40 | 0 | 0 | 0 | 0 | 0 | | 33 | 3 | 4 | 0 | 0 | 0 | | 39 | 1 | 0 | 0 |

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

Test of CHI SQUARE

(HCL101)

BAIS 4

STUDY NO. : 0612

URINALYSIS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

| Group Name | NO. of Animals | Occult blood | | | | | CHI | Urobilinogen | | | | | CHI |
|------------|-------------------|--------------|---|---|----|----|-----|--------------|---|----|----|----|-----|
| | | - | ± | + | 2+ | 3+ | | ± | + | 2+ | 3+ | 4+ | |
| Control | 35 | 34 | 0 | 0 | 0 | 0 | 1 | 35 | 0 | 0 | 0 | 0 | 0 |
| 3300 ppm | 39 | 39 | 0 | 0 | 0 | 0 | 0 | 39 | 0 | 0 | 0 | 0 | 0 |
| 10000 ppm | 43 | 42 | 0 | 0 | 0 | 1 | 0 | 43 | 0 | 0 | 0 | 0 | 0 |
| 30000 ppm | 40 | 26 | 1 | 3 | 1 | 9 | * | 40 | 0 | 0 | 0 | 0 | 0 |

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

Test of CHI SQUARE

(HCL101)

BAIS 4

TABLE J 1

GROSS FINDINGS: MALE: ALL ANIMALS

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

| Organ | Findings | Group Name NO. of Animals | Control 50 (%) | 3300 ppm 50 (%) | 10000 ppm 50 (%) | 30000 ppm 50 (%) |
|-------------|------------|------------------------------|-------------------|--------------------|---------------------|---------------------|
| skin/app | nodule | | 1 (2) | 2 (4) | 4 (8) | 1 (2) |
| subcutis | jaundice | | 1 (2) | 2 (4) | 1 (2) | 0 (0) |
| | mass | | 8 (16) | 4 (8) | 8 (16) | 6 (12) |
| lung | red | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | white zone | | 1 (2) | 1 (2) | 0 (0) | 0 (0) |
| | red zone | | 0 (0) | 0 (0) | 0 (0) | 1 (2) |
| | brown zone | | 1 (2) | 0 (0) | 0 (0) | 2 (4) |
| | nodule | | 1 (2) | 1 (2) | 3 (6) | 0 (0) |
| lymph node | enlarged | | 0 (0) | 0 (0) | 2 (4) | 0 (0) |
| spleen | enlarged | | 2 (4) | 4 (8) | 6 (12) | 3 (6) |
| | white zone | | 1 (2) | 0 (0) | 1 (2) | 0 (0) |
| | brown zone | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | deformed | | 1 (2) | 1 (2) | 1 (2) | 0 (0) |
| heart | white zone | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| oral cavity | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (2) |
| tongue | nodule | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| forestomach | red zone | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| | ulcer | | 1 (2) | 2 (4) | 0 (0) | 1 (2) |
| | erosion | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| gl stomach | erosion | | 0 (0) | 0 (0) | 1 (2) | 1 (2) |
| stomach | gas | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| small intes | white zone | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

| Organ | Findings | Group Name NO. of Animals | Control 50 (%) | 3300 ppm 50 (%) | 10000 ppm 50 (%) | 30000 ppm 50 (%) |
|-------------|------------------------|------------------------------|-------------------|--------------------|---------------------|---------------------|
| small intes | gas | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| large intes | white zone | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | nodule | | 0 (0) | 1 (2) | 1 (2) | 0 (0) |
| | gas | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| liver | pale | | 0 (0) | 0 (0) | 0 (0) | 1 (2) |
| | nodule | | 2 (4) | 0 (0) | 0 (0) | 3 (6) |
| | rough | | 1 (2) | 3 (6) | 2 (4) | 0 (0) |
| | herniation | | 7 (14) | 7 (14) | 5 (10) | 8 (16) |
| pancreas | nodule | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| kidney | white zone | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | black zone | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | cyst | | 0 (0) | 1 (2) | 0 (0) | 1 (2) |
| | granular | | 12 (24) | 8 (16) | 12 (24) | 11 (22) |
| urin bladd | nodule | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| | urine:marked retention | | 2 (4) | 0 (0) | 0 (0) | 0 (0) |
| pituitary | enlarged | | 13 (26) | 8 (16) | 5 (10) | 9 (18) |
| | red zone | | 7 (14) | 5 (10) | 10 (20) | 6 (12) |
| | brown zone | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| | nodule | | 5 (10) | 1 (2) | 4 (8) | 3 (6) |
| thyroid | enlarged | | 4 (8) | 0 (0) | 7 (14) | 4 (8) |
| | nodule | | 0 (0) | 0 (0) | 1 (2) | 5 (10) |
| adrenal | enlarged | | 1 (2) | 0 (0) | 0 (0) | 3 (6) |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 3

| Organ | Findings | Group Name NO. of Animals | Control 50 (%) | 3300 ppm 50 (%) | 10000 ppm 50 (%) | 30000 ppm 50 (%) |
|-------------|---------------|------------------------------|-------------------|--------------------|---------------------|---------------------|
| testis | nodule | | 24 (48) | 29 (58) | 30 (60) | 35 (70) |
| prostate | nodule | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| prep/cli gl | nodule | | 0 (0) | 1 (2) | 1 (2) | 0 (0) |
| brain | deformed | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| spinal cord | nodule | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| eye | turbid | | 1 (2) | 0 (0) | 1 (2) | 1 (2) |
| | white | | 12 (24) | 5 (10) | 7 (14) | 3 (6) |
| Zymbal gl | nodule | | 0 (0) | 0 (0) | 2 (4) | 0 (0) |
| bone | nodule | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| pleura | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (2) |
| mediastinum | mass | | 0 (0) | 0 (0) | 0 (0) | 1 (2) |
| peritoneum | nodule | | 1 (2) | 0 (0) | 1 (2) | 4 (8) |
| retroperit | mass | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| abdominal c | mass | | 0 (0) | 0 (0) | 2 (4) | 0 (0) |
| | ascites | | 0 (0) | 0 (0) | 3 (6) | 3 (6) |
| mesenterium | nodule | | 1 (2) | 0 (0) | 0 (0) | 1 (2) |
| thoracic ca | pleural fluid | | 1 (2) | 1 (2) | 1 (2) | 0 (0) |
| other | tail:nodule | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| | ear:nodule | | 1 (2) | 0 (0) | 1 (2) | 0 (0) |
| | nose:nodule | | 1 (2) | 1 (2) | 1 (2) | 1 (2) |
| whole body | anemic | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |

TABLE J 2

GROSS FINDINGS: MALE: DEAD AND MORIBUND ANIMALS

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

| Organ | Findings | Group Name NO. of Animals | Control 10 (%) | 3300 ppm 15 (%) | 10000 ppm 11 (%) | 30000 ppm 10 (%) |
|-------------|------------|------------------------------|-------------------|--------------------|---------------------|---------------------|
| skin/app | nodule | | 0 (0) | 1 (7) | 1 (9) | 0 (0) |
| subcutis | jaundice | | 1 (10) | 2 (13) | 1 (9) | 0 (0) |
| | mass | | 2 (20) | 1 (7) | 3 (27) | 3 (30) |
| lung | red | | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| | white zone | | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| | red zone | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |
| | nodule | | 0 (0) | 0 (0) | 1 (9) | 0 (0) |
| lymph node | enlarged | | 0 (0) | 0 (0) | 1 (9) | 0 (0) |
| spleen | enlarged | | 1 (10) | 2 (13) | 3 (27) | 2 (20) |
| | white zone | | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| heart | white zone | | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| tongue | nodule | | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| forestomach | red zone | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| | ulcer | | 1 (10) | 1 (7) | 0 (0) | 1 (10) |
| gl stomach | erosion | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |
| stomach | gas | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| small intes | white zone | | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| | gas | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| large intes | white zone | | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| | gas | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| liver | pale | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |
| | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

| Organ | Findings | Group Name NO. of Animals | Control 10 (%) | 3300 ppm 15 (%) | 10000 ppm 11 (%) | 30000 ppm 10 (%) |
|-------------|------------------------|------------------------------|-------------------|--------------------|---------------------|---------------------|
| liver | rough | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| | herniation | | 2 (20) | 2 (13) | 2 (18) | 0 (0) |
| kidney | white zone | | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| | granular | | 2 (20) | 1 (7) | 0 (0) | 1 (10) |
| urin bladd | nodule | | 0 (0) | 0 (0) | 1 (9) | 0 (0) |
| | urine marked retention | | 2 (20) | 0 (0) | 0 (0) | 0 (0) |
| pituitary | enlarged | | 6 (60) | 5 (33) | 3 (27) | 4 (40) |
| | red zone | | 0 (0) | 0 (0) | 1 (9) | 0 (0) |
| thyroid | enlarged | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |
| adrenal | enlarged | | 1 (10) | 0 (0) | 0 (0) | 2 (20) |
| testis | nodule | | 0 (0) | 4 (27) | 4 (36) | 4 (40) |
| brain | deformed | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| spinal cord | nodule | | 0 (0) | 0 (0) | 1 (9) | 0 (0) |
| eye | turbid | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |
| | white | | 2 (20) | 1 (7) | 0 (0) | 1 (10) |
| Zymbal gl | nodule | | 0 (0) | 0 (0) | 2 (18) | 0 (0) |
| bone | nodule | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| pleura | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |
| mediastinum | mass | | 0 (0) | 0 (0) | 0 (0) | 1 (10) |
| peritoneum | nodule | | 0 (0) | 0 (0) | 1 (9) | 1 (10) |
| abdominal c | mass | | 0 (0) | 0 (0) | 2 (18) | 0 (0) |
| | ascites | | 0 (0) | 0 (0) | 3 (27) | 1 (10) |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

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

PAGE : 3

| Organ | Findings | Group Name NO. of Animals | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|-------------|---------------|------------------------------|---------|----------|-----------|-----------|
| | | | 10 (%) | 15 (%) | 11 (%) | 10 (%) |
| mesenterium | nodule | | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| thoracic ca | pleural fluid | | 1 (10) | 0 (0) | 1 (9) | 0 (0) |
| other | tail:nodule | | 0 (0) | 1 (7) | 0 (0) | 0 (0) |
| whole body | anemic | | 0 (0) | 0 (0) | 1 (9) | 0 (0) |

(IPT080)

BATS 4

TABLE J 3

GROSS FINDINGS: MALE: SACRIFICED ANIMALS

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 1

| Organ | Findings | Group Name NO. of Animals | Control 40 (%) | 3300 ppm 35 (%) | 10000 ppm 39 (%) | 30000 ppm 40 (%) |
|-------------|------------|------------------------------|-------------------|--------------------|---------------------|---------------------|
| skin/app | nodule | | 1 (3) | 1 (3) | 3 (8) | 1 (3) |
| subcutis | mass | | 6 (15) | 3 (9) | 5 (13) | 3 (8) |
| lung | white zone | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| | brown zone | | 1 (3) | 0 (0) | 0 (0) | 2 (5) |
| | nodule | | 1 (3) | 1 (3) | 2 (5) | 0 (0) |
| lymph node | enlarged | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| spleen | enlarged | | 1 (3) | 2 (6) | 3 (8) | 1 (3) |
| | white zone | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| | brown zone | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| | deformed | | 1 (3) | 1 (3) | 1 (3) | 0 (0) |
| oral cavity | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| forestomach | ulcer | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| | erosion | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| gl stomach | erosion | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| large intes | nodule | | 0 (0) | 1 (3) | 1 (3) | 0 (0) |
| liver | nodule | | 2 (5) | 0 (0) | 0 (0) | 2 (5) |
| | rough | | 1 (3) | 2 (6) | 2 (5) | 0 (0) |
| | herniation | | 5 (13) | 5 (14) | 3 (8) | 8 (20) |
| pancreas | nodule | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| kidney | black zone | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| | cyst | | 0 (0) | 1 (3) | 0 (0) | 1 (3) |
| | granular | | 10 (25) | 7 (20) | 12 (31) | 10 (25) |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 2

| Organ | Findings | Group Name NO. of Animals | Control 40 (%) | 3300 ppm 35 (%) | 10000 ppm 39 (%) | 30000 ppm 40 (%) |
|-------------|---------------|------------------------------|-------------------|--------------------|---------------------|---------------------|
| pituitary | enlarged | | 7 (18) | 3 (9) | 2 (5) | 5 (13) |
| | red zone | | 7 (18) | 5 (14) | 9 (23) | 6 (15) |
| | brown zone | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| | nodule | | 5 (13) | 1 (3) | 4 (10) | 3 (8) |
| thyroid | enlarged | | 4 (10) | 0 (0) | 7 (18) | 3 (8) |
| | nodule | | 0 (0) | 0 (0) | 1 (3) | 5 (13) |
| adrenal | enlarged | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| testis | nodule | | 24 (60) | 25 (71) | 26 (67) | 31 (78) |
| prostate | nodule | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| prep/cli gl | nodule | | 0 (0) | 1 (3) | 1 (3) | 0 (0) |
| eye | turbid | | 1 (3) | 0 (0) | 1 (3) | 0 (0) |
| | white | | 10 (25) | 4 (11) | 7 (18) | 2 (5) |
| peritoneum | nodule | | 1 (3) | 0 (0) | 0 (0) | 3 (8) |
| retroperit | mass | | 0 (0) | 0 (0) | 1 (3) | 0 (0) |
| abdominal c | ascites | | 0 (0) | 0 (0) | 0 (0) | 2 (5) |
| mesenterium | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| thoracic ca | pleural fluid | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| other | ear:nodule | | 1 (3) | 0 (0) | 1 (3) | 0 (0) |
| | nose:nodule | | 1 (3) | 1 (3) | 1 (3) | 1 (3) |

TABLE J 4

GROSS FINDINGS: FEMALE: ALL ANIMALS

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 4

| Organ | Findings | Group Name NO. of Animals | Control 50 (%) | 3300 ppm 50 (%) | 10000 ppm 50 (%) | 30000 ppm 50 (%) |
|-------------|------------------------|------------------------------|-------------------|--------------------|---------------------|---------------------|
| skin/app | nodule | | 0 (0) | 0 (0) | 1 (2) | 2 (4) |
| subcutis | jaundice | | 0 (0) | 0 (0) | 2 (4) | 0 (0) |
| | mass | | 6 (12) | 6 (12) | 8 (16) | 3 (6) |
| lung | brown zone | | 0 (0) | 0 (0) | 0 (0) | 1 (2) |
| | nodule | | 1 (2) | 1 (2) | 0 (0) | 1 (2) |
| | voluminous | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| lymph node | enlarged | | 1 (2) | 0 (0) | 2 (4) | 0 (0) |
| thymus | red | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| spleen | enlarged | | 3 (6) | 3 (6) | 5 (10) | 2 (4) |
| heart | white zone | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| oral cavity | nodule | | 0 (0) | 0 (0) | 2 (4) | 1 (2) |
| tongue | nodule | | 1 (2) | 0 (0) | 1 (2) | 0 (0) |
| forestomach | ulcer | | 0 (0) | 0 (0) | 0 (0) | 1 (2) |
| large intes | nodule | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| liver | white zone | | 0 (0) | 0 (0) | 0 (0) | 1 (2) |
| | nodule | | 1 (2) | 0 (0) | 0 (0) | 3 (6) |
| | rough | | 0 (0) | 1 (2) | 2 (4) | 0 (0) |
| | herniation | | 7 (14) | 7 (14) | 9 (18) | 5 (10) |
| kidney | nodule | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | cyst | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| | granular | | 1 (2) | 0 (0) | 1 (2) | 0 (0) |
| urin bladd | urine marked retention | | 1 (2) | 0 (0) | 1 (2) | 0 (0) |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 5

| Organ | Findings | Group Name No. of Animals | Control 50 (%) | 3300 ppm 50 (%) | 10000 ppm 50 (%) | 30000 ppm 50 (%) |
|-------------|------------|------------------------------|-------------------|--------------------|---------------------|---------------------|
| pituitary | enlarged | | 8 (16) | 5 (10) | 6 (12) | 5 (10) |
| | red zone | | 3 (6) | 11 (22) | 15 (30) | 9 (18) |
| | nodule | | 2 (4) | 1 (2) | 1 (2) | 4 (8) |
| thyroid | enlarged | | 3 (6) | 0 (0) | 4 (8) | 1 (2) |
| | nodule | | 0 (0) | 2 (4) | 2 (4) | 1 (2) |
| adrenal | enlarged | | 1 (2) | 2 (4) | 1 (2) | 2 (4) |
| ovary | enlarged | | 0 (0) | 0 (0) | 2 (4) | 0 (0) |
| | nodule | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | cyst | | 1 (2) | 0 (0) | 2 (4) | 3 (6) |
| uterus | enlarged | | 0 (0) | 0 (0) | 0 (0) | 2 (4) |
| | red zone | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| | nodule | | 8 (16) | 9 (18) | 8 (16) | 7 (14) |
| vagina | nodule | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| prep/cli gl | nodule | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| spinal cord | red zone | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| eye | turbid | | 0 (0) | 2 (4) | 0 (0) | 0 (0) |
| | white | | 6 (12) | 4 (8) | 7 (14) | 2 (4) |
| Zymbal gl | nodule | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| peritoneum | nodule | | 0 (0) | 0 (0) | 2 (4) | 1 (2) |
| retroperit | mass | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| abdominal c | hemorrhage | | 0 (0) | 1 (2) | 0 (0) | 1 (2) |
| | ascites | | 0 (0) | 1 (2) | 2 (4) | 1 (2) |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 6

| Organ | Findings | Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|-------------|---------------|----------------|---------|----------|-----------|-----------|
| | | NO. of Animals | 50 (%) | 50 (%) | 50 (%) | 50 (%) |
| thoracic ca | pleural fluid | | 1 (2) | 0 (0) | 1 (2) | 2 (4) |
| other | nodule | | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| whole body | anemic | | 0 (0) | 1 (2) | 0 (0) | 0 (0) |

(HPT080)

BAIS 4

TABLE J 5

GROSS FINDINGS: FEMALE: DEAD AND MORIBUND ANIMALS

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 4

| Organ | Findings | Group Name NO. of Animals | Control 15 (%) | 3300 ppm 11 (%) | 10000 ppm 6 (%) | 30000 ppm 11 (%) |
|-------------|------------------------|------------------------------|-------------------|--------------------|--------------------|---------------------|
| subcutis | jaundice | | 0 (0) | 0 (0) | 2 (33) | 0 (0) |
| | mass | | 0 (0) | 3 (27) | 2 (33) | 2 (18) |
| lung | nodule | | 1 (7) | 0 (0) | 0 (0) | 1 (9) |
| | voluminus | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| lymph node | enlarged | | 1 (7) | 0 (0) | 1 (17) | 0 (0) |
| thymus | red | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| spleen | enlarged | | 3 (20) | 3 (27) | 3 (50) | 2 (18) |
| forestomach | ulcer | | 0 (0) | 0 (0) | 0 (0) | 1 (9) |
| large intes | nodule | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| liver | nodule | | 1 (7) | 0 (0) | 0 (0) | 2 (18) |
| | rough | | 0 (0) | 0 (0) | 1 (17) | 0 (0) |
| | herniation | | 1 (7) | 1 (9) | 2 (33) | 2 (18) |
| kidney | nodule | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| urin bladd | urine:marked retention | | 1 (7) | 0 (0) | 1 (17) | 0 (0) |
| pituitary | enlarged | | 3 (20) | 1 (9) | 0 (0) | 2 (18) |
| | red zone | | 1 (7) | 1 (9) | 2 (33) | 1 (9) |
| | nodule | | 1 (7) | 0 (0) | 0 (0) | 1 (9) |
| thyroid | enlarged | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| ovary | nodule | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| | cyst | | 0 (0) | 0 (0) | 0 (0) | 1 (9) |
| uterus | enlarged | | 0 (0) | 0 (0) | 0 (0) | 1 (9) |
| | nodule | | 5 (33) | 2 (18) | 1 (17) | 3 (27) |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 5

| Organ | Findings | Group Name NO. of Animals | Control 15 (%) | 3300 ppm 11 (%) | 10000 ppm 6 (%) | 30000 ppm 11 (%) |
|-------------|---------------|------------------------------|-------------------|--------------------|--------------------|---------------------|
| spinal cord | red zone | | 0 (0) | 1 (9) | 0 (0) | 0 (0) |
| eye | turbid | | 0 (0) | 1 (9) | 0 (0) | 0 (0) |
| | white | | 2 (13) | 0 (0) | 0 (0) | 0 (0) |
| peritoneum | nodule | | 0 (0) | 0 (0) | 1 (17) | 1 (9) |
| retroperit | mass | | 1 (7) | 0 (0) | 0 (0) | 0 (0) |
| abdominal c | hemorrhage | | 0 (0) | 1 (9) | 0 (0) | 1 (9) |
| | ascites | | 0 (0) | 1 (9) | 2 (33) | 1 (9) |
| thoracic ca | pleural fluid | | 1 (7) | 0 (0) | 1 (17) | 1 (9) |
| whole body | anemic | | 0 (0) | 1 (9) | 0 (0) | 0 (0) |

(HPT080)

BAIS 4

TABLE J 6

GROSS FINDINGS: FEMALE: SACRIFICED ANIMALS

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 3

| Organ | Findings | Group Name NO. of Animals | Control 35 (%) | 3300 ppm 39 (%) | 10000 ppm 44 (%) | 30000 ppm 39 (%) |
|-------------|------------|------------------------------|-------------------|--------------------|---------------------|---------------------|
| skin/app | nodule | | 0 (0) | 0 (0) | 1 (2) | 2 (5) |
| subcutis | mass | | 6 (17) | 3 (8) | 6 (14) | 1 (3) |
| lung | brown zone | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| | nodule | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| lymph node | enlarged | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| spleen | enlarged | | 0 (0) | 0 (0) | 2 (5) | 0 (0) |
| heart | white zone | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| oral cavity | nodule | | 0 (0) | 0 (0) | 2 (5) | 1 (3) |
| tongue | nodule | | 1 (3) | 0 (0) | 1 (2) | 0 (0) |
| liver | white zone | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| | nodule | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| | rough | | 0 (0) | 1 (3) | 1 (2) | 0 (0) |
| | herniation | | 6 (17) | 6 (15) | 7 (16) | 3 (8) |
| kidney | cyst | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| | granular | | 1 (3) | 0 (0) | 1 (2) | 0 (0) |
| pituitary | enlarged | | 5 (14) | 4 (10) | 6 (14) | 3 (8) |
| | red zone | | 2 (6) | 10 (26) | 13 (30) | 8 (21) |
| | nodule | | 1 (3) | 1 (3) | 1 (2) | 3 (8) |
| thyroid | enlarged | | 2 (6) | 0 (0) | 4 (9) | 1 (3) |
| | nodule | | 0 (0) | 2 (5) | 2 (5) | 1 (3) |
| adrenal | enlarged | | 1 (3) | 2 (5) | 1 (2) | 2 (5) |
| ovary | enlarged | | 0 (0) | 0 (0) | 2 (5) | 0 (0) |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 4

| Organ | Findings | Group Name NO. of Animals | Control 35 (%) | 3300 ppm 39 (%) | 10000 ppm 44 (%) | 30000 ppm 39 (%) |
|-------------|---------------|------------------------------|-------------------|--------------------|---------------------|---------------------|
| ovary | cyst | | 1 (3) | 0 (0) | 2 (5) | 2 (5) |
| uterus | enlarged | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| | red zone | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| | nodule | | 3 (9) | 7 (18) | 7 (16) | 4 (10) |
| vagina | nodule | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |
| prep/cli gl | nodule | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| eye | turbid | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| | white | | 4 (11) | 4 (10) | 7 (16) | 2 (5) |
| Zymbal gl | nodule | | 0 (0) | 1 (3) | 0 (0) | 0 (0) |
| peritoneum | nodule | | 0 (0) | 0 (0) | 1 (2) | 0 (0) |
| thoracic ca | pleural fluid | | 0 (0) | 0 (0) | 0 (0) | 1 (3) |
| other | nodule | | 1 (3) | 0 (0) | 0 (0) | 0 (0) |

(HPT080)

BAIS 4

TABLE K 1

ORGAN WEIGHT, ABSOLUTE: MALE

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
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 | |
|------------|-------------------|-------------|-----|----------|-------|--------|-------|--------|---------|--------|---------|---------|-------|
| Control | 40 | 370± | 42 | 0.075± | 0.013 | 2.556± | 1.156 | 1.197± | 0.110 | 1.405± | 0.256 | 2.741± | 0.390 |
| 3300 ppm | 34 | 376± | 33 | 0.074± | 0.013 | 2.668± | 0.993 | 1.215± | 0.082 | 1.350± | 0.096 | 2.717± | 0.399 |
| 10000 ppm | 39 | 367± | 41 | 0.077± | 0.016 | 2.636± | 1.204 | 1.208± | 0.101 | 1.368± | 0.164 | 2.883± | 0.485 |
| 30000 ppm | 40 | 347± | 30* | 0.146± | 0.472 | 3.129± | 1.331 | 1.128± | 0.086** | 1.293± | 0.065** | 2.808± | 0.414 |

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

Test of Dunnett

(HCL040)

BAIS 4

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

PAGE : 2

| Group Name | NO. of Animals | SPLEEN | | LIVER | | BRAIN | |
|------------|-------------------|--------|-------|---------|---------|--------|-------|
| Control | 40 | 1.186± | 1.205 | 11.475± | 2.481 | 2.088± | 0.048 |
| 3300 ppm | 34 | 0.934± | 0.222 | 10.801± | 1.055 | 2.106± | 0.077 |
| 10000 ppm | 39 | 1.135± | 0.965 | 10.879± | 1.681 | 2.090± | 0.049 |
| 30000 ppm | 40 | 1.016± | 0.762 | 10.290± | 1.223** | 2.071± | 0.039 |

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

Test of Dunnett

(HCL040)

BAIS 4

TABLE K 2

ORGAN WEIGHT, ABSOLUTE: FEMALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 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 |
|------------|-------------------|-------------|----------------|--------------|--------------|--------------|----------------|
| Control | 34 | 247± 24 | 0.074± 0.035 | 0.128± 0.022 | 0.846± 0.064 | 0.934± 0.069 | 1.691± 0.117 |
| 3300 ppm | 38 | 249± 28 | 0.090± 0.116 | 0.124± 0.021 | 0.830± 0.050 | 0.939± 0.069 | 1.691± 0.113 |
| 10000 ppm | 44 | 236± 27 | 0.077± 0.069 | 0.136± 0.042 | 0.850± 0.062 | 0.928± 0.068 | 1.845± 0.180** |
| 30000 ppm | 39 | 220± 19** | 0.157± 0.491** | 0.153± 0.118 | 0.815± 0.065 | 0.907± 0.066 | 1.842± 0.126** |

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

Test of Dunnett

(HCL040)

BAIS 4

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

PAGE : 4

| Group Name | NO. of Animals | SPLEEN | | LIVER | | BRAIN | |
|------------|-------------------|--------|-------|--------|---------|--------|-------|
| Control | 34 | 0.557± | 0.224 | 6.259± | 0.683 | 1.900± | 0.042 |
| 3300 ppm | 38 | 0.537± | 0.172 | 6.184± | 0.566 | 1.923± | 0.050 |
| 10000 ppm | 44 | 0.849± | 1.465 | 6.332± | 0.997 | 1.901± | 0.042 |
| 30000 ppm | 39 | 0.510± | 0.137 | 5.833± | 0.590** | 1.879± | 0.046 |

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

Test of Dunnett

(HCL040)

BAIS 4

TABLE L 1

ORGAN WEIGHT, RELATIVE: MALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 |
|------------|-------------------|--------------------|--------------|----------------|--------------|--------------|----------------|
| Control | 40 | 370± 42 | 0.021± 0.006 | 0.683± 0.287 | 0.327± 0.045 | 0.387± 0.112 | 0.752± 0.158 |
| 3300 ppm | 34 | 376± 33 | 0.020± 0.005 | 0.710± 0.265 | 0.326± 0.044 | 0.362± 0.050 | 0.734± 0.186 |
| 10000 ppm | 39 | 367± 41 | 0.022± 0.007 | 0.713± 0.315 | 0.333± 0.042 | 0.377± 0.057 | 0.810± 0.288 |
| 30000 ppm | 40 | 347± 30* | 0.042± 0.132 | 0.900± 0.368** | 0.326± 0.024 | 0.374± 0.030 | 0.822± 0.214** |

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

Test of Dunnett

(HCL042)

BAIS 4

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE : 2

| Group Name | NO. of Animals | SPLEEN | LIVER | BRAIN |
|------------|-------------------|--------------|--------------|--------------|
| Control | 40 | 0.337± 0.433 | 3.133± 0.812 | 0.572± 0.073 |
| 3300 ppm | 34 | 0.249± 0.059 | 2.889± 0.337 | 0.565± 0.059 |
| 10000 ppm | 39 | 0.304± 0.241 | 2.977± 0.411 | 0.577± 0.075 |
| 30000 ppm | 40 | 0.297± 0.241 | 2.988± 0.492 | 0.601± 0.058 |

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

(HCL042)

BAIS 4

TABLE L 2

ORGAN WEIGHT, RELATIVE: FEMALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 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 |
|------------|-------------------|--------------------|--------------|----------------|----------------|----------------|----------------|
| Control | 34 | 247± 24 | 0.030± 0.012 | 0.052± 0.010 | 0.345± 0.035 | 0.381± 0.044 | 0.691± 0.081 |
| 3300 ppm | 38 | 249± 28 | 0.041± 0.081 | 0.051± 0.009 | 0.339± 0.061 | 0.383± 0.054 | 0.688± 0.081 |
| 10000 ppm | 44 | 236± 27 | 0.033± 0.029 | 0.058± 0.018 | 0.364± 0.039* | 0.398± 0.047 | 0.795± 0.155** |
| 30000 ppm | 39 | 220± 19** | 0.073± 0.228 | 0.069± 0.052** | 0.372± 0.033** | 0.415± 0.046** | 0.842± 0.088** |

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

Test of Dunnett

(HCL042)

BAIS 4

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE : 4

| Group Name | NO. of Animals | SPLEEN | LIVER | BRAIN |
|------------|-------------------|--------------|----------------|----------------|
| Control | 34 | 0.228± 0.105 | 2.548± 0.298 | 0.777± 0.078 |
| 3300 ppm | 38 | 0.216± 0.065 | 2.501± 0.192 | 0.784± 0.101 |
| 10000 ppm | 44 | 0.359± 0.614 | 2.699± 0.411* | 0.816± 0.098 |
| 30000 ppm | 39 | 0.233± 0.064 | 2.654± 0.200** | 0.859± 0.071** |

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

Test of Dunnett

(HCL042)

BAIS 4

TABLE M 1

HISTOPATHOLOGICAL FINDINGS:

NON-NEOPLASTIC LESIONS:

MALE: ALL ANIMALS

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

| Organ | Findings | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|----------------------------------|--|-------------------------|--------|-------|-------|-------------------------|-------|-------|-------|-------------------------|--------|-------|-------|-------------------------|--------|-------|-------|
| | | No. of Animals on Study | | | | No. of Animals on Study | | | | No. of Animals on Study | | | | No. of Animals on Study | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Integumentary system/appandage) | | | | | | | | | | | | | | | | | |
| skin/app | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | abscess | 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) |
| | squamous cell hyperplasia | 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) |
| | epidermal cyst | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (0) | (0) | (0) |
| (Respiratory system) | | | | | | | | | | | | | | | | | |
| nasal cavit | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | thrombus | 0 | 0 | 0 | 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) |
| | eosinophilic change:olfactory epithelium | 30 | 7 | 0 | 0 | 29 | 3 | 0 | 0 | 30 | 5 | 0 | 0 | 28 | 9 | 2 | 0 |
| | | (60) | (14) | (0) | (0) | (58) | (6) | (0) | (0) | (60) | (10) | (0) | (0) | (56) | (18) | (4) | (0) |
| | eosinophilic change:respiratory epithelium | 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) |
| | inflammation:foreign body | 9 | 3 | 0 | 0 | 14 | 2 | 0 | 0 | 7 | 2 | 0 | 0 | 7 | 1 | 0 | 0 |
| | | (18) | (6) | (0) | (0) | (28) | (4) | (0) | (0) | (14) | (4) | (0) | (0) | (14) | (2) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 50 | | | | 10000 ppm 50 | | | | 30000 ppm 50 | | | |
|----------------------|---|---|-------|-------|-------|----------------|-------|-------|-------|-----------------|-------|-------|-------|-----------------|-------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Respiratory system) | | | | | | | | | | | | | | | | | |
| nasal cavit | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | inflammation:respiratory epithelium | 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) |
| | respiratory metaplasia:olfactory epithelium | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | respiratory metaplasia:gland | 3 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (6) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) |
| | inflammation:transitional epithelium | 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) |
| larynx | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | inflammation | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| lung | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | edema | 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) |
| | inflammation | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (2) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 3

| Organ | Findings | Group Name No. of Animals on Study Grade | Control 50 | | | | 3300 ppm 50 | | | | 10000 ppm 50 | | | | 30000 ppm 50 | | | |
|------------------------|---------------------------------------|--|---------------|-------|-------|-------|----------------|-------|-------|-------|-----------------|-------|-------|-------|-----------------|-------|-------|-------|
| | | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | | |
| lung | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | 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) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | accumulation of foamy cells | | 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) |
| | bronchiolar-alveolar cell hyperplasia | | 1 | 2 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 2 | 1 | 0 | 0 |
| | | | (2) | (4) | (0) | (0) | (4) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (4) | (2) | (0) | (0) |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | |
| bone marrow | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | congestion | | 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) |
| | granulation | | 1 | 0 | 0 | 0 | 2 | 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) |
| | increased hematopoiesis | | 4 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 8 | 0 | 0 | 0 | 4 | 0 | 0 | 0 |
| | | | (8) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (16) | (0) | (0) | (0) | (8) | (0) | (0) | (0) |
| lymph node | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | lymphadenitis | | 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 : 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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 4

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 50 | | | | 10000 ppm 50 | | | | 30000 ppm 50 | | | |
|------------------------|------------------------------|---|-------|-------|-------|----------------|-------|-------|-------|-----------------|-------|-------|-------|-----------------|-------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | |
| thymus | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | ectopic tissue | 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) |
| spleen | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | atrophy | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 1 | 1 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (2) | (2) | (0) | (0) |
| | congestion | 6 | 3 | 0 | 0 | 6 | 0 | 0 | 0 | 6 | 1 | 0 | 0 | 10 | 0 | 0 | 0 |
| | | (12) | (6) | (0) | (0) | (12) | (0) | (0) | (0) | (12) | (2) | (0) | (0) | (20) | (0) | (0) | (0) |
| | deposit of hemosiderin | 10 | 2 | 0 | 0 | 10 | 4 | 0 | 0 | 8 | 1 | 0 | 0 | 10 | 3 | 0 | 0 |
| | | (20) | (4) | (0) | (0) | (20) | (8) | (0) | (0) | (16) | (2) | (0) | (0) | (20) | (6) | (0) | (0) |
| | inflammation | 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) |
| | fibrosis | 0 | 0 | 0 | 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) |
| | fibrosis:focal | 0 | 2 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (4) | (0) | (0) | (2) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (2) | (0) | (0) | (0) |
| | extramedullary hematopoiesis | 4 | 1 | 0 | 0 | 2 | 0 | 0 | 0 | 4 | 1 | 1 | 0 | 5 | 1 | 1 | 0 |
| | | (8) | (2) | (0) | (0) | (4) | (0) | (0) | (0) | (8) | (2) | (2) | (0) | (10) | (2) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 5

| Organ | Findings | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|----------------------|------------------------|-------------------------|---------|------|------|------|----------|------|------|------|-----------|------|------|------|-----------|------|------|------|
| | | No. of Animals on Study | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Circulatory system) | | | | | | | | | | | | | | | | | | |
| heart | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | thrombus | | 2 | 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) |
| | mineralization | | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) |
| | inflammatory cell nest | | 1 | 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) | (2) | (0) | (0) | (0) |
| | myocardial fibrosis | | 18 | 0 | 0 | 0 | 15 | 1 | 0 | 0 | 14 | 0 | 0 | 0 | 14 | 0 | 0 | 0 |
| | | | (36) | (0) | (0) | (0) | (30) | (2) | (0) | (0) | (28) | (0) | (0) | (0) | (28) | (0) | (0) | (0) |
| (Digestive system) | | | | | | | | | | | | | | | | | | |
| stomach | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | hemorrhage | | 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) |
| | basal cell hyperplasia | | 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) | (0) | (0) | (0) | (0) |
| | 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) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 6

| Organ | Findings | Control No. of Animals on Study 50 Grade | | | | 3300 ppm 50 | | | | 10000 ppm 50 | | | | 30000 ppm 50 | | | |
|--------------------|----------------------------------|--|-------|-------|-------|----------------|-------|-------|-------|-----------------|-------|-------|-------|-----------------|-------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | |
| stomach | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | ulcer:forestomach | 1 | 1 | 0 | 0 | 2 | 3 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (2) | (2) | (0) | (0) | (4) | (6) | (0) | (0) | (4) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | hyperplasia:forestomach | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (2) | (0) | (0) |
| small intes | erosion:glandular stomach | 2 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (4) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | hyperplasia:glandular stomach | 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) |
| | mineralization:glandular stomach | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| large intes | | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (2) | (0) | (0) |
| | inflammatory infiltration | 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) |
| | inflammatory infiltration | 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) |

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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 7

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 50 | | | | 10000 ppm 50 | | | | 30000 ppm 50 | | | |
|--------------------|-------------------------|---|-----------|-----------|-----------|----------------|-----------|-----------|-----------|-----------------|-----------|-----------|-----------|-----------------|-----------|-----------|-----------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | |
| liver | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | herniation | 7 (14) | 0 (0) | 0 (0) | 0 (0) | 8 (16) | 0 (0) | 0 (0) | 0 (0) | 4 (8) | 0 (0) | 0 (0) | 0 (0) | 7 (14) | 0 (0) | 0 (0) | 0 (0) |
| | necrosis:central | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| | necrosis:focal | 1 (2) | 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) | 0 (0) |
| | fatty change | 0 (0) | 0 (0) | 1 (2) | 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) |
| | fatty change:central | 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) | 0 (0) | 0 (0) | 0 (0) |
| | fatty change:peripheral | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 1 (2) | 0 (0) | 0 (0) |
| | 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 (2) | 0 (0) | 0 (0) | 0 (0) |
| | granulation | 5 (10) | 0 (0) | 0 (0) | 0 (0) | 3 (6) | 0 (0) | 0 (0) | 0 (0) | 4 (8) | 1 (2) | 0 (0) | 0 (0) | 3 (6) | 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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 8

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 50 | | | | 10000 ppm 50 | | | | 30000 ppm 50 | | | |
|--------------------|------------------------|---|-------------|-----------|-----------|----------------|-------------|-----------|-------------|-----------------|-------------|-----------|-----------|-----------------|-------------|-----------|-----------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Digestive system) | | | | | | | | | | | | | | | | | |
| liver | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | clear cell focus | 12 (24) | 0 (0) | 0 (0) | 0 (0) | 6 (12) | 4 (8) | 0 (0) | 0 * (0) | 6 (12) | 3 (6) | 0 (0) | 0 (0) | 9 (18) | 1 (2) | 0 (0) | 0 (0) |
| | acidophilic cell focus | 4 (8) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 6 (12) | 0 (0) | 0 (0) | 0 (0) |
| | basophilic cell focus | 8 (16) | 1 (2) | 0 (0) | 0 (0) | 5 (10) | 1 (2) | 0 (0) | 0 (0) | 9 (18) | 2 (4) | 0 (0) | 0 (0) | 6 (12) | 1 (2) | 0 (0) | 0 (0) |
| | mixed cell focus | 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) | 1 (2) | 0 (0) | 0 (0) |
| | spongiosis hepatitis | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 2 (4) | 0 (0) | 0 (0) | 0 (0) | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| | bile duct hyperplasia | 6 (12) | 42 (84) | 0 (0) | 0 (0) | 3 (6) | 44 (88) | 0 (0) | 0 (0) | 1 (2) | 48 (96) | 0 (0) | 0 (0) | 4 (8) | 46 (92) | 0 (0) | 0 (0) |
| pancreas | biliary cyst | 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) |
| | atrophy | 15 (30) | 0 (0) | 0 (0) | 0 (0) | 12 (24) | 1 (2) | 0 (0) | 0 (0) | 12 (24) | 3 (6) | 0 (0) | 0 (0) | 11 (22) | 4 (8) | 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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 9

| | | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|--------------------|------------------------|-------------------------|---------|--------|--------|-------|----------|--------|--------|-------|-----------|--------|--------|-------|-----------|--------|--------|-------|
| | | 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} | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | |
| pancreas | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | arteritis | | 0 | 0 | 0 | 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) | (0) | (2) | (0) |
| | | | | | | | | | | | | | | | | | | |
| {Urinary system} | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | |
| kidney | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | cyst | | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | inflammatory cell nest | | 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) |
| | scar | | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | chronic nephropathy | | 12 | 16 | 15 | 4 | 15 | 19 | 10 | 1 | 15 | 21 | 9 | 2 | 17 | 21 | 9 | 2 |
| | | | (24) | (32) | (30) | (8) | (30) | (38) | (20) | (2) | (30) | (42) | (18) | (4) | (34) | (42) | (18) | (4) |
| | tubular necrosis | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (4) | (0) | (0) | (0) |
| | mineralization:pelvis | | 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) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 10

| | | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|--------------------|----------------------------------|-------------------------|---------|--------|-------|-------|----------|--------|-------|-------|-----------|-------|-------|-------|-----------|--------|-------|-------|
| | | 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 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| | | | | | | | | | | | | | | | | | | |
| {Urinary system} | | | | | | | | | | | | | | | | | | |
| kidney | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | mineralization:cortex | | 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) |
| | | | | | | | | | | | | | | | | | | |
| | urothelial hyperplasia: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) | (2) | (0) | (0) | (0) |
| | atypical tubule hyperplasia | | 2 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (4) | (2) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (0) | (0) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| {Endocrine system} | | | | | | | | | | | | | | | | | | |
| pituitary | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | angiectasis | | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | hyperplasia | | 6 | 8 | 0 | 0 | 10 | 12 | 0 | 0 | 6 | 4 | 0 | 0 | 3 | 7 | 0 | 0 |
| | | | (12) | (16) | (0) | (0) | (20) | (24) | (0) | (0) | (12) | (8) | (0) | (0) | (6) | (14) | (0) | (0) |
| | Rathke pouch | | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (2) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | aberrant craniopharyngeal tissue | | 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) |

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. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

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

PAGE : 11

| Organ_____ | Findings_____ | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|--------------------|---------------------------|-------------------------|---------|-------|-------|--------|----------|-------|-------|--------|-----------|-------|-------|--------|-----------|-------|-------|-----|
| | | No. of Animals on Study | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Endocrine system} | | | | | | | | | | | | | | | | | | |
| thyroid | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | follicular hyperplasia | 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) | |
| | C-cell hyperplasia | 12 | 2 | 0 | 0 | 14 | 4 | 0 | 0 | 9 | 6 | 0 | 0 | 5 | 2 | 0 | 0 | |
| | | (24) | (4) | (0) | (0) | (28) | (8) | (0) | (0) | (18) | (12) | (0) | (0) | (10) | (4) | (0) | (0) | |
| parathyroid | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | hyperplasia | 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) | |
| adrenal | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | congestion | 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) | |
| | hyperplasia:cortical cell | 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) | |
| | hyperplasia:medulla | 2 | 1 | 0 | 0 | 4 | 1 | 0 | 0 | 4 | 2 | 0 | 0 | 2 | 3 | 0 | 0 | |
| | | (4) | (2) | (0) | (0) | (8) | (2) | (0) | (0) | (8) | (4) | (0) | (0) | (4) | (6) | (0) | (0) | |
| | focal fatty change:cortex | 0 | 0 | 0 | 0 | 3 | 1 | 0 | 0 | 4 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | |
| | | (0) | (0) | (0) | (0) | (6) | (2) | (0) | (0) | (8) | (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 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. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

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

PAGE : 12

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 50 | | | | 10000 ppm 50 | | | | 30000 ppm 50 | | | |
|-----------------------|-------------------------------|---|-------|-------|-------|----------------|-------|-------|-------|-----------------|-------|-------|-------|-----------------|--------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Reproductive system} | | | | | | | | | | | | | | | | | |
| testis | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | mineralization | 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) |
| | arteritis | 8 | 3 | 0 | 0 | 2 | 1 | 0 | 0 | 3 | 2 | 0 | 0 | 2 | 1 | 0 | 0 |
| | | (16) | (6) | (0) | (0) | (4) | (2) | (0) | (0) | (6) | (4) | (0) | (0) | (4) | (2) | (0) | (0) |
| | interstitial cell hyperplasia | 17 | 3 | 0 | 0 | 17 | 0 | 0 | 0 | 15 | 2 | 0 | 0 | 10 | 8 | 0 | 0 |
| | | (34) | (6) | (0) | (0) | (34) | (0) | (0) | (0) | (30) | (4) | (0) | (0) | (20) | (16) | (0) | (0) |
| prostate | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | inflammation | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (4) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyperplasia | 8 | 2 | 0 | 0 | 9 | 1 | 0 | 0 | 3 | 2 | 0 | 0 | 4 | 0 | 0 | 0 |
| | | (16) | (4) | (0) | (0) | (18) | (2) | (0) | (0) | (6) | (4) | (0) | (0) | (8) | (0) | (0) | (0) |
| mammary gl | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | galactoceles | 0 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (4) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Nervous system} | | | | | | | | | | | | | | | | | |
| brain | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | hemorrhage | 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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 13

| Organ_____ | Findings_____ | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|----------------------------------|---------------------------------|-------------------------|---------|------|------|-------|----------|------|------|-------|-----------|------|------|-------|-----------|------|------|------|
| | | No. of Animals on Study | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| | | | | | | | | | | | | | | | | | | |
| {Nervous system} | | | | | | | | | | | | | | | | | | |
| brain | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | dilatation:cerebral ventricle | 1 | 0 | 0 | 0 | 1 | 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) |
| spinal cord | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | hemorrhage | 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) | (0) | (0) |
| | hematoma | 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) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| {Special sense organs/appendage} | | | | | | | | | | | | | | | | | | |
| eye | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | cataract | 12 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 7 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | * |
| | | (24) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (14) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (0) |
| | retinal atrophy | 25 | 12 | 4 | 0 | 19 | 14 | 3 | 0 | 26 | 14 | 3 | 0 | 23 | 17 | 3 | 0 | |
| | | (50) | (24) | (8) | (0) | (38) | (28) | (6) | (0) | (52) | (28) | (6) | (0) | (46) | (34) | (6) | (0) | |
| | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | squamous cell metaplasia:cornea | 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) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 14

| | | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|----------------------------------|---------------------------|-------------------------|---------|-------|-------|-------|----------|-------|-------|-------|-----------|-------|-------|-------|-----------|-------|-------|-------|
| | | 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 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Special sense organs/appendage} | | | | | | | | | | | | | | | | | | |
| Harder gl | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | inflammatory infiltration | | 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) |
| nasolacr d | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | inflammation | | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (4) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Musculoskeletal system} | | | | | | | | | | | | | | | | | | |
| muscle | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | atrophy | | 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) |
| bone | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | osteosclerosis | | 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) | (0) |
| {Body cavities} | | | | | | | | | | | | | | | | | | |
| peritoneum | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | inflammation | | 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) |

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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 15

| Organ | Findings | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|---|--------------|---|-------|-------|-------|-------------------------|-------|-------|-------|-------------------------|-------|-------|-------|-------------------------|-------|-------|-------|
| | | No. of Animals on Study | | | | No. of Animals on Study | | | | No. of Animals on Study | | | | No. of Animals on Study | | | |
| | | Grade | | | | Grade | | | | Grade | | | | Grade | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Body cavities} | | | | | | | | | | | | | | | | | |
| mesenterium | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | inflammation | 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) |
| | arteritis | 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) |
| 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 | | | | | | | | | | | | | | | |

(HPT150)

BAIS4

TABLE M 2

HISTOPATHOLOGICAL FINDINGS:

NON-NEOPLASTIC LESIONS:

MALE: DEAD AND MORIBUND ANIMALS

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

| Organ_____ | Findings_____ | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|----------------------------------|--|-------------------------|---------|--------|-------|-------|----------|-------|-------|-------|-----------|-------|-------|-------|-----------|-------|-------|-------|
| | | No. of Animals on Study | 10 | | | | 15 | | | | 11 | | | | 10 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Integumentary system/appandage) | | | | | | | | | | | | | | | | | | |
| skin/app | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | abscess | | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| (Respiratory system) | | | | | | | | | | | | | | | | | | |
| nasal cavit | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | thrombus | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (10) | (0) | (0) | (0) |
| | eosinophilic change:olfactory epithelium | | 4 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 7 | 0 | 0 | 0 | 5 | 0 | 0 | 0 |
| | | | (40) | (0) | (0) | (0) | (33) | (0) | (0) | (0) | (64) | (0) | (0) | (0) | (50) | (0) | (0) | (0) |
| | inflammation:foreign body | | 1 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (10) | (0) | (0) | (0) | (20) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | respiratory metaplasia:gland | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| larynx | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | inflammation | | 0 | 1 | 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) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

| | | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|------------------------|-----------------------------|-------------------------|---------|--------|-------|-------|----------|-------|-------|-------|-----------|--------|-------|-------|-----------|--------|-------|-------|
| | | No. of Animals on Study | 10 | | | | 15 | | | | 11 | | | | 10 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Organ_____ | Findings_____ | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| | | | | | | | | | | | | | | | | | | |
| {Respiratory system} | | | | | | | | | | | | | | | | | | |
| lung | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | edema | | 0 | 1 | 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) | (0) |
| | inflammation | | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (10) | (0) | (0) | (7) | (0) | (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) | (9) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | accumulation of foamy cells | | 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) | (9) | (0) | (0) | (0) | (0) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | |
| bone marrow | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | congestion | | 0 | 1 | 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) | (0) |
| | increased hematopoiesis | | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | | (20) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (36) | (0) | (0) | (0) | (20) | (0) | (0) | (0) |
| spleen | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | atrophy | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 1 | 1 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (18) | (0) | (0) | (10) | (10) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 3

| | | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|------------------------|------------------------------|-------------------------|---------|--------|-------|-------|----------|--------|-------|-------|-----------|-------|-------|-------|-----------|--------|--------|-------|
| | | No. of Animals on Study | 10 | | | | 15 | | | | 11 | | | | 10 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Organ_____ | Findings_____ | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| <hr/> | | | | | | | | | | | | | | | | | | |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | |
| spleen | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | congestion | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (10) | (0) | (0) | (0) |
| | deposit of hemosiderin | | 1 | 2 | 0 | 0 | 5 | 4 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 2 | 0 | 0 |
| | | | (10) | (20) | (0) | (0) | (33) | (27) | (0) | (0) | (18) | (0) | (0) | (0) | (20) | (20) | (0) | (0) |
| | inflammation | | 0 | 1 | 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) | (0) |
| | fibrosis:focal | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | extramedullary hematopoiesis | | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 1 | 1 | 0 | 0 | 1 | 1 | 0 |
| | | | (10) | (10) | (0) | (0) | (7) | (0) | (0) | (0) | (18) | (9) | (9) | (0) | (0) | (10) | (10) | (0) |
| <hr/> | | | | | | | | | | | | | | | | | | |
| {Circulatory system} | | | | | | | | | | | | | | | | | | |
| heart | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | thrombus | | 1 | 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) | (0) | (0) |
| | mineralization | | 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) | (10) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 4

| | | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|----------------------|---------------------------|-------------------------|---------|------|------|-------|----------|------|------|------|-----------|------|------|-------|-----------|-------|------|------|
| | | No. of Animals on Study | 10 | | | | 15 | | | | 11 | | | | 10 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Organ_____ | Findings_____ | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| <hr/> | | | | | | | | | | | | | | | | | | |
| {Circulatory system} | | | | | | | | | | | | | | | | | | |
| heart | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | inflammatory cell nest | | 1 | 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) | (0) | (0) | (0) |
| | myocardial fibrosis | | 6 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 5 | 0 | 0 | 0 |
| | | (60) | (0) | (0) | (0) | (0) | (27) | (0) | (0) | (0) | (27) | (0) | (0) | (0) | (50) | (0) | (0) | (0) |
| <hr/> | | | | | | | | | | | | | | | | | | |
| {Digestive system} | | | | | | | | | | | | | | | | | | |
| stomach | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | hemorrhage | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 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) |
| | 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) | (9) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | ulcer:forestomach | | 1 | 1 | 0 | 0 | 2 | 2 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (10) | (10) | (0) | (0) | (13) | (13) | (0) | (0) | (9) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (0) |
| | hyperplasia:forestomach | | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (13) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (0) | (0) | (10) | (0) | (0) |
| | erosion:glandular stomach | | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (10) | (0) | (0) | (0) | (13) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (10) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 5

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 15 | | | | 10000 ppm 11 | | | | 30000 ppm 10 | | | |
|--------------------|----------------------------------|---|--------|--------|-------|----------------|-------|-------|-------|-----------------|-------|-------|-------|-----------------|--------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | |
| stomach | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | hyperplasia:glandular stomach | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | mineralization:glandular stomach | 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) | (10) | (0) | (0) |
| small intes | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | inflammatory infiltration | 0 | 1 | 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) | (0) |
| large intes | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | inflammatory infiltration | 0 | 1 | 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) | (0) |
| liver | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | herniation | 2 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (20) | (0) | (0) | (0) | (20) | (0) | (0) | (0) | (18) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | necrosis:central | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (0) | (10) | (0) | (0) |
| | fatty change | 0 | 0 | 1 | 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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 6

| | | Group Name No. of Animals on Study | Control 10 | | | | 3300 ppm 15 | | | | 10000 ppm 11 | | | | 30000 ppm 10 | | | |
|--------------------|-------------------------|---------------------------------------|---------------|-------|------|------|----------------|-------|------|------|-----------------|-------|------|------|-----------------|-------|------|------|
| Organ | Findings | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Digestive system) | | | | | | | | | | | | | | | | | | |
| liver | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | fatty change: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) | (9) | (0) | (0) | (0) | (0) | (0) | (0) |
| | fatty change:peripheral | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (10) | (0) | (0) |
| | mineralization | | 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) | (10) | (0) | (0) | |
| | acidophilic cell focus | | 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) | (10) | (0) | (0) | (0) |
| | basophilic cell focus | | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (10) | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | bile duct hyperplasia | | 2 | 6 | 0 | 0 | 2 | 11 | 0 | 0 | 0 | 10 | 0 | 0 | 1 | 9 | 0 | 0 |
| | | | (20) | (60) | (0) | (0) | (13) | (73) | (0) | (0) | (0) | (91) | (0) | (0) | (10) | (90) | (0) | (0) |
| pancreas | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | atrophy | | 4 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 3 | 1 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (40) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (27) | (9) | (0) | (0) | (10) | (0) | (0) | (0) |
| (Urinary system) | | | | | | | | | | | | | | | | | | |
| kidney | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | inflammatory cell nest | | 0 | 1 | 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) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 7

| Organ | Findings | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|--------------------|----------------------------------|-------------------------|--------|--------|--------|-------------------------|--------|--------|-------|-------------------------|--------|-------|-------|-------------------------|--------|-------|--------|
| | | No. of Animals on Study | | | | No. of Animals on Study | | | | No. of Animals on Study | | | | No. of Animals on Study | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Urinary system) | | | | | | | | | | | | | | | | | |
| kidney | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | chronic nephropathy | 2 | 1 | 3 | 1 | 5 | 2 | 3 | 0 | 5 | 3 | 0 | 0 | 6 | 1 | 0 | 2 |
| | | (20) | (10) | (30) | (10) | (33) | (13) | (20) | (0) | (45) | (27) | (0) | (0) | (60) | (10) | (0) | (20) |
| | tubular necrosis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (18) | (0) | (0) | (20) | (0) | (0) | (0) |
| | mineralization:cortex | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| (Endocrine system) | | | | | | | | | | | | | | | | | |
| pituitary | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | hyperplasia | 0 | 1 | 0 | 0 | 2 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (10) | (0) | (0) | (13) | (7) | (0) | (0) | (0) | (18) | (0) | (0) | (0) | (0) | (0) | (0) |
| | Ratlike pouch | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | aberrant craniopharyngeal tissue | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| thyroid | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | C-cell hyperplasia | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (10) | (0) | (0) | (0) | (7) | (7) | (0) | (0) | (18) | (9) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 8

| Organ_____ | Findings_____ | Group Name No. of Animals on Study Grade | Control 10 | | | | 3300 ppm 15 | | | | 10000 ppm 11 | | | | 30000 ppm 10 | | | |
|-----------------------|-------------------------------|--|---------------|--------|-------|-------|----------------|-------|-------|-------|-----------------|-------|-------|-------|-----------------|--------|-------|-------|
| | | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| | | | | | | | | | | | | | | | | | | |
| {Endocrine system} | | | | | | | | | | | | | | | | | | |
| adrenal | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | congestion | | 0 | 1 | 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) | (0) |
| | hyperplasia:medulla | | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (10) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | focal fatty change:cortex | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (20) | (0) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| {Reproductive system} | | | | | | | | | | | | | | | | | | |
| testis | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | arteritis | | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (20) | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | interstitial cell hyperplasia | | 3 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 3 | 0 | 0 |
| | | | (30) | (0) | (0) | (0) | (20) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (10) | (30) | (0) | (0) |
| prostate | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | inflammation | | 0 | 1 | 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) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 9

| | | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|-----------------------|--------------------------------|-------------------------|---------|--------|--------|-------|----------|-------|-------|-------|-----------|-------|-------|-------|-----------|-------|-------|-------|
| | | No. of Animals on Study | 10 | | | | 15 | | | | 11 | | | | 10 | | | |
| Organ_____ | Findings_____ | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | | | | | | | | | | | | | | | | |
| {Reproductive system} | | | | | | | | | | | | | | | | | | |
| prostate | hyperplasia | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| mammary gl | galactoceles | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | | 0 | 0 | 1 | 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) |
| {Nervous system} | | | | | | | | | | | | | | | | | | |
| brain | hemorrhage | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | dilatation: cerebral ventricle | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| spinal cord | hemorrhage | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | | 1 | 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) | (0) | (0) |
| | hematoma | | 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) | (9) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 10

| | | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|----------------------------------|---------------------------|-------------------------|---------|-------|------|------|----------|------|------|------|-----------|------|------|------|-----------|-------|-------|------|
| | | No. of Animals on Study | 10 | | | | 15 | | | | 11 | | | | 10 | | | |
| Organ_____ | Findings_____ | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| <hr/> | | | | | | | | | | | | | | | | | | |
| {Special sense organs/appendage} | | | | | | | | | | | | | | | | | | |
| eye | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | cataract | | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (20) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (10) | (0) | (0) | (0) |
| | retinal atrophy | | 3 | 2 | 0 | 0 | 2 | 1 | 1 | 0 | 3 | 1 | 0 | 0 | 1 | 0 | 2 | 0 |
| | | | (30) | (20) | (0) | (0) | (13) | (7) | (7) | (0) | (27) | (9) | (0) | (0) | (10) | (0) | (20) | (0) |
| Harder gl | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | inflammatory infiltration | | 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) | (10) | (0) | (0) |
| <hr/> | | | | | | | | | | | | | | | | | | |
| {Musculoskeletal system} | | | | | | | | | | | | | | | | | | |
| muscle | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | atrophy | | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| <hr/> | | | | | | | | | | | | | | | | | | |
| {Body cavities} | | | | | | | | | | | | | | | | | | |
| peritoneum | | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | inflammation | | 0 | 1 | 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) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 11

| Organ_____ | Findings_____ | Group Name | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|------------|---------------|-------------------------|-----|-----|-----|----------|-----|-----|-----|-----------|-----|-----|-----|-----------|-----|-----|-----|
| | | Control | | | | | | | | | | | | | | | |
| | | No. of Animals on Study | | | | 15 | | | | 11 | | | | 10 | | | |
| | | Grade | | | | | | | | | | | | | | | |
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |

{Body cavities}

| | | | | | | | | | | | | | | | | | |
|-------------|--------------|--------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|--|
| mesenterium | | <10> | | | | <15> | | | | <11> | | | | <10> | | | |
| | inflammation | 1 | 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) | (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)

BAIS4

TABLE M 3

HISTOPATHOLOGICAL FINDINGS:

NON-NEOPLASTIC LESIONS:

MALE: SACRIFICED ANIMALS

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 35 | | | | 10000 ppm 39 | | | | 30000 ppm 40 | | | |
|----------------------------------|---|---|-------|------|------|----------------|------|------|------|-----------------|-------|------|------|-----------------|-------|------|------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Integumentary system/appandage} | | | | | | | | | | | | | | | | | |
| skin/app | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | squamous cell hyperplasia | 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) |
| | epidermal cyst | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (3) | (3) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Respiratory system} | | | | | | | | | | | | | | | | | |
| nasal cavit | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | eosinophilic change:olfactory epithelium | 26 | 7 | 0 | 0 | 24 | 3 | 0 | 0 | 23 | 5 | 0 | 0 | 23 | 9 | 2 | 0 |
| | | (65) | (18) | (0) | (0) | (69) | (9) | (0) | (0) | (59) | (13) | (0) | (0) | (58) | (23) | (5) | (0) |
| | eosinophilic change:respiratory epithelium | 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) |
| | inflammation:foreign body | 8 | 3 | 0 | 0 | 11 | 2 | 0 | 0 | 7 | 2 | 0 | 0 | 7 | 1 | 0 | 0 |
| | | (20) | (8) | (0) | (0) | (31) | (6) | (0) | (0) | (18) | (5) | (0) | (0) | (18) | (3) | (0) | (0) |
| | inflammation:respiratory epithelium | 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) |
| | respiratory metaplasia:olfactory epithelium | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

| Organ | Findings | Control No. of Animals on Study 40 Grade | | | | 3300 ppm 35 | | | | 10000 ppm 39 | | | | 30000 ppm 40 | | | |
|------------------------|---------------------------------------|--|-------|-------|-------|----------------|-------|-------|-------|-----------------|-------|-------|-------|-----------------|-------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Respiratory system) | | | | | | | | | | | | | | | | | |
| nasal cavit | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | respiratory metaplasia:gland | 3 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (8) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) |
| | inflammation:transitional epithelium | 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) |
| larynx | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | inflammation | 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) |
| lung | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | bronchiolar-alveolar cell hyperplasia | 1 | 2 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 2 | 1 | 0 | 0 |
| | | (3) | (5) | (0) | (0) | (6) | (0) | (0) | (0) | (3) | (3) | (0) | (0) | (5) | (3) | (0) | (0) |
| (Hematopoietic system) | | | | | | | | | | | | | | | | | |
| bone marrow | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | granulation | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (5) | (0) | (0) | (0) |
| | increased hematopoiesis | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (5) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (5) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 3

| Organ | Findings | Control No. of Animals on Study 40 Grade | | | | 3300 ppm 35 | | | | 10000 ppm 39 | | | | 30000 ppm 40 | | | |
|------------------------|------------------------------|--|-------|-------|-------|----------------|-------|-------|-------|-----------------|-------|-------|-------|-----------------|-------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Hematopoietic system) | | | | | | | | | | | | | | | | | |
| lymph node | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | lymphadenitis | 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) |
| thymus | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | ectopic tissue | 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) |
| spleen | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | congestion | 6 | 3 | 0 | 0 | 6 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 9 | 0 | 0 | 0 |
| | | (15) | (8) | (0) | (0) | (17) | (0) | (0) | (0) | (15) | (0) | (0) | (0) | (23) | (0) | (0) | (0) |
| | deposit of hemosiderin | 9 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 6 | 1 | 0 | 0 | 8 | 1 | 0 | 0 |
| | | (23) | (0) | (0) | (0) | (14) | (0) | (0) | (0) | (15) | (3) | (0) | (0) | (20) | (3) | (0) | (0) |
| | fibrosis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (3) | (0) | (0) |
| | fibrosis:focal | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (5) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (3) | (0) | (0) | (0) |
| | extramedullary hematopoiesis | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 5 | 0 | 0 | 0 |
| | | (8) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (13) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 4

| | | Group Name No. of Animals on Study Grade | Control 40 | | | | 3300 ppm 35 | | | | 10000 ppm 39 | | | | 30000 ppm 40 | | | |
|----------------------|---------------------------|--|---------------|------|------|------|----------------|------|------|------|-----------------|------|------|------|-----------------|------|------|------|
| Organ | Findings | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Circulatory system) | | | | | | | | | | | | | | | | | | |
| heart | | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | thrombus | | 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) |
| | mineralization | | 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) | (0) | (0) | (0) |
| | inflammatory cell nest | | 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) |
| | myocardial fibrosis | | 12 | 0 | 0 | 0 | 11 | 1 | 0 | 0 | 11 | 0 | 0 | 0 | 9 | 0 | 0 | 0 |
| | | | (30) | (0) | (0) | (0) | (31) | (3) | (0) | (0) | (28) | (0) | (0) | (0) | (23) | (0) | (0) | (0) |
| (Digestive system) | | | | | | | | | | | | | | | | | | |
| stomach | | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | basal cell hyperplasia | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (3) | (0) | (0) | (0) | (0) | (0) | (0) |
| | ulcer:forestomach | | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | erosion:glandular stomach | | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (3) | (0) | (0) | (0) | (6) | (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 ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 5

| Organ | Findings | Group Name No. of Animals on Study Grade | Control 40 | | | | 3300 ppm 35 | | | | 10000 ppm 39 | | | | 30000 ppm 40 | | | |
|--------------------|----------------------------------|--|---------------|-------|-------|-------|----------------|--------|-------|-------|-----------------|-------|-------|-------|-----------------|-------|-------|-------|
| | | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Digestive system) | | | | | | | | | | | | | | | | | | |
| stomach | mineralization:glandular stomach | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | | | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| liver | herniation | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | | | 5 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 7 | 0 | 0 | 0 |
| | | | (13) | (0) | (0) | (0) | (14) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (18) | (0) | (0) | (0) |
| | necrosis:focal | | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (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) | (3) | (0) | (0) | (0) | (0) | (0) | (0) |
| | fatty change:peripheral | | 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) |
| | granulation | | 5 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 4 | 1 | 0 | 0 | 3 | 1 | 0 | 0 |
| | | | (13) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (10) | (3) | (0) | (0) | (8) | (3) | (0) | (0) |
| | clear cell focus | | 12 | 0 | 0 | 0 | 6 | 4 | 0 | 0 | 6 | 3 | 0 | 0 | 9 | 1 | 0 | 0 |
| | | | (30) | (0) | (0) | (0) | (17) | (11) | (0) | (0) | (15) | (8) | (0) | (0) | (23) | (3) | (0) | (0) |
| | acidophilic cell focus | | 4 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 5 | 0 | 0 | 0 |
| | | | (10) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (13) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 6

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 35 | | | | 10000 ppm 39 | | | | 30000 ppm 40 | | | |
|--------------------|-----------------------|---|--------|-------|-------|----------------|--------|-------|-------|-----------------|--------|-------|-------|-----------------|--------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | |
| liver | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | basophilic cell focus | 7 | 0 | 0 | 0 | 5 | 1 | 0 | 0 | 9 | 2 | 0 | 0 | 6 | 1 | 0 | 0 |
| | | (18) | (0) | (0) | (0) | (14) | (3) | (0) | (0) | (23) | (5) | (0) | (0) | (15) | (3) | (0) | (0) |
| | mixed cell focus | 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) |
| | spongiosis hepatitis | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (3) | (0) | (0) | (0) |
| | bile duct hyperplasia | 4 | 36 | 0 | 0 | 1 | 33 | 0 | 0 | 1 | 38 | 0 | 0 | 3 | 37 | 0 | 0 |
| | | (10) | (90) | (0) | (0) | (3) | (94) | (0) | (0) | (3) | (97) | (0) | (0) | (8) | (93) | (0) | (0) |
| | biliary cyst | 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) |
| pancreas | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | atrophy | 11 | 0 | 0 | 0 | 11 | 1 | 0 | 0 | 9 | 2 | 0 | 0 | 10 | 4 | 0 | 0 |
| | | (28) | (0) | (0) | (0) | (31) | (3) | (0) | (0) | (23) | (5) | (0) | (0) | (25) | (10) | (0) | (0) |
| | arteritis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (3) | (0) | (0) |
| {Urinary system} | | | | | | | | | | | | | | | | | |
| kidney | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | cyst | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 7

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 35 | | | | 10000 ppm 39 | | | | 30000 ppm 40 | | | |
|--------------------|-------------------------------|---|--------|--------|-------|----------------|--------|--------|-------|-----------------|--------|--------|-------|-----------------|--------|--------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Urinary system) | | | | | | | | | | | | | | | | | |
| kidney | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | scar | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) |
| | chronic nephropathy | 10 | 15 | 12 | 3 | 10 | 17 | 7 | 1 | 10 | 18 | 9 | 2 | 11 | 20 | 9 | 0 |
| | | (25) | (38) | (30) | (8) | (29) | (49) | (20) | (3) | (26) | (46) | (23) | (5) | (28) | (50) | (23) | (0) |
| | mineralization:pelvis | 0 | 0 | 0 | 0 | 2 | 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) |
| | urothelial hyperplasia: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) | (3) | (0) | (0) | (0) |
| | atypical tubule hyperplasia | 2 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (5) | (3) | (0) | (0) | (3) | (0) | (0) | (0) | (3) | (3) | (0) | (0) | (0) | (0) | (0) | (0) |
| (Endocrine system) | | | | | | | | | | | | | | | | | |
| pituitary | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | angiectasis | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) |
| | hyperplasia | 6 | 7 | 0 | 0 | 8 | 11 | 0 | 0 | 6 | 2 | 0 | 0 | 3 | 7 | 0 | 0 |
| | | (15) | (18) | (0) | (0) | (23) | (31) | (0) | (0) | (15) | (5) | (0) | (0) | (8) | (18) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 8

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 35 | | | | 10000 ppm 39 | | | | 30000 ppm 40 | | | |
|--------------------|---------------------------|---|-------|-------|-------|----------------|-------|-------|-------|-----------------|--------|-------|-------|-----------------|-------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Endocrine system} | | | | | | | | | | | | | | | | | |
| pituitary | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | Rathke pouch | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) |
| thyroid | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | follicular hyperplasia | 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) |
| | C-cell hyperplasia | 11 | 2 | 0 | 0 | 13 | 3 | 0 | 0 | 7 | 5 | 0 | 0 | 5 | 2 | 0 | 0 |
| | | (28) | (5) | (0) | (0) | (37) | (9) | (0) | (0) | (18) | (13) | (0) | (0) | (13) | (5) | (0) | (0) |
| parathyroid | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | hyperplasia | 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) |
| adrenal | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | hyperplasia:cortical cell | 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) |
| | hyperplasia:medulla | 2 | 0 | 0 | 0 | 3 | 1 | 0 | 0 | 4 | 2 | 0 | 0 | 2 | 3 | 0 | 0 |
| | | (5) | (0) | (0) | (0) | (9) | (3) | (0) | (0) | (10) | (5) | (0) | (0) | (5) | (8) | (0) | (0) |
| | focal fatty change:cortex | 0 | 0 | 0 | 0 | 3 | 1 | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (9) | (3) | (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 : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 9

| | | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|-----------------------|-------------------------------|-------------------------|---------|-------|-------|-------|----------|-------|-------|-------|-----------|-------|-------|-------|-----------|--------|-------|-------|
| | | No. of Animals on Study | 40 | | | | 35 | | | | 39 | | | | 40 | | | |
| Organ_____ | Findings_____ | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| <hr/> | | | | | | | | | | | | | | | | | | |
| {Reproductive system} | | | | | | | | | | | | | | | | | | |
| testis | | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | mineralization | | 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) |
| | | | | | | | | | | | | | | | | | | |
| | arteritis | | 6 | 2 | 0 | 0 | 2 | 1 | 0 | 0 | 3 | 2 | 0 | 0 | 2 | 1 | 0 | 0 |
| | | | (15) | (5) | (0) | (0) | (6) | (3) | (0) | (0) | (8) | (5) | (0) | (0) | (5) | (3) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| | interstitial cell hyperplasia | | 14 | 3 | 0 | 0 | 14 | 0 | 0 | 0 | 15 | 1 | 0 | 0 | 9 | 5 | 0 | 0 |
| | | | (35) | (8) | (0) | (0) | (40) | (0) | (0) | (0) | (38) | (3) | (0) | (0) | (23) | (13) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| prostate | | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | inflammation | | 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) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| | hyperplasia | | 8 | 1 | 0 | 0 | 9 | 1 | 0 | 0 | 2 | 2 | 0 | 0 | 4 | 0 | 0 | 0 |
| | | | (20) | (3) | (0) | (0) | (26) | (3) | (0) | (0) | (5) | (5) | (0) | (0) | (10) | (0) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| mammary gl | | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | galactoceles | | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (5) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| <hr/> | | | | | | | | | | | | | | | | | | |
| {Nervous system} | | | | | | | | | | | | | | | | | | |
| brain | | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | dilatation:cerebral ventricle | | 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) |
| | | | | | | | | | | | | | | | | | | |

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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 10

| Organ | Findings | Group Name No. of Animals on Study Grade | Control 40 | | | | 3300 ppm 35 | | | | 10000 ppm 39 | | | | 30000 ppm 40 | | | |
|----------------------------------|---------------------------------|--|---------------|--------|--------|-------|----------------|--------|-------|-------|-----------------|--------|-------|-------|-----------------|--------|-------|-------|
| | | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Special sense organs/appendage) | | | | | | | | | | | | | | | | | | |
| eye | cataract | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | | | 10 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 7 | 0 | 0 | 0 | 2 | 0 | 0 | 0 * |
| | | | (25) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (18) | (0) | (0) | (0) | (5) | (0) | (0) | (0) |
| | retinal atrophy | | 22 | 10 | 4 | 0 | 17 | 13 | 2 | 0 | 23 | 13 | 3 | 0 | 22 | 17 | 1 | 0 |
| | | | (55) | (25) | (10) | (0) | (49) | (37) | (6) | (0) | (59) | (33) | (8) | (0) | (55) | (43) | (3) | (0) |
| | squamous cell metaplasia:cornea | | 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) |
| nasolacr d | inflammation | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | | | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (5) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| (Musculoskeletal system) | | | | | | | | | | | | | | | | | | |
| bone | osteosclerosis | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | | | 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) | (0) | (0) | (0) | (0) |
| {Body cavities} | | | | | | | | | | | | | | | | | | |
| mesenterium | arteritis | | <40> | | | | <35> | | | | <39> | | | | <40> | | | |
| | | | 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) | (3) | (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

TABLE M 4

HISTOPATHOLOGICAL FINDINGS:

NON-NEOPLASTIC LESIONS:

FEMALE: ALL ANIMALS

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 16

| Organ_____ | Findings_____ | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|----------------------|---|-------------------------|---------|-------|-------|------|----------|-------|-------|------|-----------|-------|-------|------|-----------|-------|-------|------|
| | | No. of Animals on Study | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Respiratory system) | | | | | | | | | | | | | | | | | | |
| nasal cavit | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | 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) | (2) | (0) | (0) | (0) |
| | eosinophilic change:olfactory epithelium | | 8 | 29 | 10 | 0 | 7 | 31 | 7 | 0 | 8 | 32 | 9 | 0 | 4 | 35 | 11 | 0 |
| | | | (16) | (58) | (20) | (0) | (14) | (62) | (14) | (0) | (16) | (64) | (18) | (0) | (8) | (70) | (22) | (0) |
| | eosinophilic change:respiratory epithelium | | 34 | 0 | 0 | 0 | 32 | 0 | 0 | 0 | 32 | 0 | 0 | 0 | 37 | 0 | 0 | 0 |
| | | | (68) | (0) | (0) | (0) | (64) | (0) | (0) | (0) | (64) | (0) | (0) | (0) | (74) | (0) | (0) | (0) |
| | inflammation:foreign body | | 1 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | | (2) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) |
| | inflammation:respiratory epithelium | | 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) |
| | inflammation:olfactory epithelium | | 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) |
| | respiratory metaplasia:olfactory epithelium | | 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) | (0) |
| | respiratory metaplasia:gland | | 7 | 0 | 0 | 0 | 7 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 4 | 0 | 0 | 0 |
| | | | (14) | (0) | (0) | (0) | (14) | (0) | (0) | (0) | (12) | (0) | (0) | (0) | (8) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 17

| Organ_____ | Findings_____ | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|----------------------|---|-------------------------|---------|------|------|------|----------|------|------|------|-----------|------|------|------|-----------|------|------|------|
| | | No. of Animals on Study | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Respiratory system) | | | | | | | | | | | | | | | | | | |
| nasal cavit | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | inflammation:transitional epithelium | | 1 | 0 | 0 | 0 | 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) |
| | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | squamous cell metaplasia:respiratory epithelium | | 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) |
| larynx | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | inflammation | | 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) |
| lung | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | congestion | | 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) | (2) | (0) | (0) | (0) | (0) | (2) | (0) |
| | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | edema | | 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) |
| | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | bronchiolar-alveolar cell hyperplasia | | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 1 | 0 | 0 |
| | | | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (4) | (2) | (0) | (0) |
| | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | emphysema | | 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) |

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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 18

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 50 | | | | 10000 ppm 50 | | | | 30000 ppm 50 | | | |
|------------------------|-------------------------|---|-------|-------|-------|----------------|-------|-------|-------|-----------------|-------|-------|-------|-----------------|-------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Hematopoietic system) | | | | | | | | | | | | | | | | | |
| bone marrow | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | granulation | 5 | 2 | 0 | 0 | 7 | 0 | 0 | 0 | 4 | 2 | 0 | 0 | 7 | 2 | 0 | 0 |
| | | (10) | (4) | (0) | (0) | (14) | (0) | (0) | (0) | (8) | (4) | (0) | (0) | (14) | (4) | (0) | (0) |
| | increased hematopoiesis | 5 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 5 | 0 | 0 | 0 |
| | | (10) | (0) | (0) | (0) | (12) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (10) | (0) | (0) | (0) |
| thymus | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | hemorrhage | 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) |
| spleen | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | atrophy | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) |
| | congestion | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (2) | (0) | (0) |
| | deposit of hemosiderin | 29 | 4 | 0 | 0 | 27 | 3 | 0 | 0 | 30 | 3 | 0 | 0 | 26 | 1 | 0 | 0 |
| | | (58) | (8) | (0) | (0) | (54) | (6) | (0) | (0) | (60) | (6) | (0) | (0) | (52) | (2) | (0) | (0) |
| | fibrosis | 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) |

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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 19

| Organ_____ | Findings_____ | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|------------------------|------------------------------|-------------------------|---------|-------|-------|-------|----------|-------|-------|-------|-----------|-------|-------|-------|-----------|-------|-------|-------|
| | | No. of Animals on Study | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| | | | | | | | | | | | | | | | | | | |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | | |
| spleen | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | extramedullary hematopoiesis | | 4 | 1 | 1 | 0 | 5 | 4 | 0 | 0 | 7 | 2 | 0 | 0 | 6 | 2 | 0 | 0 |
| | | | (8) | (2) | (2) | (0) | (10) | (8) | (0) | (0) | (14) | (4) | (0) | (0) | (12) | (4) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| {Circulatory system} | | | | | | | | | | | | | | | | | | |
| heart | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | thrombus | | 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) |
| | mineralization | | 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) |
| | myocardial fibrosis | | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (4) | (0) | (0) | (0) |
| | subendocardial fibrosis | | 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) |
| | | | | | | | | | | | | | | | | | | |
| {Digestive system} | | | | | | | | | | | | | | | | | | |
| oral cavity | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | squamous cell hyperplasia | | 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) |

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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 20

| Organ | Findings | Group Name No. of Animals on Study Grade | Control 50 | | | | 3300 ppm 50 | | | | 10000 ppm 50 | | | | 30000 ppm 50 | | | |
|--------------------|---------------------------|--|---------------|-------|-------|-------|----------------|-------|-------|-------|-----------------|-------|-------|-------|-----------------|-------|-------|-------|
| | | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Digestive system) | | | | | | | | | | | | | | | | | | |
| tongue | squamous cell hyperplasia | | <50> | | | | <50> | | | | <50> | | | | <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) |
| | arteritis | | 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) |
| salivary gl | atrophy | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | | 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) |
| stomach | ulcer:forestomach | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) |
| | hyperplasia: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) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | erosion:glandular stomach | | 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) |
| | ulcer:glandular stomach | | 1 | 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) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 21

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 50 | | | | 10000 ppm 50 | | | | 30000 ppm 50 | | | |
|--------------------|----------------------------------|---|------|------|------|----------------|------|------|------|-----------------|------|------|------|-----------------|------|------|------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | |
| stomach | mineralization:glandular stomach | <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) |
| large intes | cyst | <50> | | | | <50> | | | | <50> | | | | <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) |
| liver | herniation | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | | 7 | 0 | 0 | 0 | 7 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 5 | 0 | 0 | 0 |
| | | (14) | (0) | (0) | (0) | (14) | (0) | (0) | (0) | (20) | (0) | (0) | (0) | (10) | (0) | (0) | (0) |
| | necrosis:central | 0 | 0 | 0 | 0 | 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) |
| | necrosis:focal | 2 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (4) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (2) | (2) | (0) | (0) | (0) | (2) | (0) | (0) |
| | fatty change | 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) | (0) |
| | lymphocytic infiltration | 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) |

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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 22

| Organ_____ | Findings_____ | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | | | |
|--------------------|------------------------------|-------------------------|------------|------------|------------|------------|--------------|------------|------------|------------|------------|--------------|-------------|------------|------------|------------|--------------|-------------|------------|------------|
| | | No. of Animals on Study | 50 | | | | 50 | | | | 50 | | | | 50 | | | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | | |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | | |
| <hr/> | | | | | | | | | | | | | | | | | | | | |
| {Digestive system} | | | | | | | | | | | | | | | | | | | | |
| liver | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | | | |
| | granulation | 14 (28) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 11 (22) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 10 (20) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 15 (30) | 1 (2) | 0 (0) | 0 (0) |
| | inflammatory cell nest | 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) | |
| | extramedullary hematopoiesis | 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) | 0 (0) | 0 (0) | |
| | clear cell focus | 1 (2) | 1 (2) | 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) | 0 (0) | 0 (0) | |
| | basophilic cell focus | 27 (54) | 2 (4) | 0 (0) | 0 (0) | 0 (0) | 30 (60) | 2 (4) | 0 (0) | 0 (0) | 0 (0) | 32 (64) | 2 (4) | 0 (0) | 0 (0) | 0 (0) | 26 (52) | 2 (4) | 0 (0) | 0 (0) |
| | mixed cell focus | 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) | 0 (0) | 0 (0) | |
| | bile duct hyperplasia | 20 (40) | 1 (2) | 0 (0) | 0 (0) | 0 (0) | 16 (32) | 2 (4) | 0 (0) | 0 (0) | 0 (0) | 16 (32) | 5 (10) | 0 (0) | 0 (0) | 0 (0) | 14 (28) | 5 (10) | 0 (0) | 0 (0) |
| | biliary cyst | 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) | 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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 23

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 50 | | | | 10000 ppm 50 | | | | 30000 ppm 50 | | | |
|--------------------|--------------------------|---|-------|-------|-------|----------------|-------|-------|-------|-----------------|-------|-------|-------|-----------------|-------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Digestive system) | | | | | | | | | | | | | | | | | |
| pancreas | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | atrophy | 3 | 1 | 0 | 0 | 4 | 1 | 0 | 0 | 4 | 0 | 0 | 0 | 6 | 2 | 0 | 0 |
| | | (6) | (2) | (0) | (0) | (8) | (2) | (0) | (0) | (8) | (0) | (0) | (0) | (12) | (4) | (0) | (0) |
| | lymphocytic infiltration | 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) |
| | islet cell hyperplasia | 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) | (2) | (0) | (0) | (0) | (2) | (0) | (0) |
| (Urinary system) | | | | | | | | | | | | | | | | | |
| kidney | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | cyst | 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) |
| | hyaline droplet | 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) |
| | deposit of hemosiderin | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (2) | (0) | (0) | (0) |
| | scar | 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) |

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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 24

| Organ_____ | Findings_____ | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|------------------------------|---|-------------------------|---------|------|------|-------|----------|------|------|-------|-----------|------|-------|-------|-----------|------|------|-----|
| | | No. of Animals on Study | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Urinary system} | | | | | | | | | | | | | | | | | | |
| kidney | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | chronic nephropathy | 28 | 2 | 1 | 0 | 27 | 2 | 1 | 0 | 29 | 5 | 1 | 0 | 26 | 2 | 2 | 0 | |
| | | (56) | (4) | (2) | (0) | (54) | (4) | (2) | (0) | (58) | (10) | (2) | (0) | (52) | (4) | (4) | (0) | |
| | tubular necrosis | 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) | (4) | (0) | (0) | |
| | papillary necrosis | 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) | (12) | (0) | (0) | (0) | |
| | mineralization:cortico-medullary junction | 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) | | |
| mineralization:papilla | 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) | (12) | (0) | (0) | (0) | | |
| mineralization:pelvis | 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) | | |
| mineralization:cortex | 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) | | |
| regeneration:proximal tubule | 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) | | |

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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 25

| Organ | Findings | Control No. of Animals on Study 50 Grade | | | | 3300 ppm 50 | | | | 10000 ppm 50 | | | | 30000 ppm 50 | | | |
|--------------------|-------------------------------|--|-------|-------|-------|----------------|-------|-------|-------|-----------------|--------|-------|-------|-----------------|--------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Urinary system) | | | | | | | | | | | | | | | | | |
| kidney | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | urothelial hyperplasia:pelvis | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 5 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (10) | (0) | (0) | (0) |
| | atypical tubule hyperplasia | 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) |
| | dilated pelvis | 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) |
| (Endocrine system) | | | | | | | | | | | | | | | | | |
| pituitary | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | angiectasis | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 2 | 2 | 0 | 0 | 1 | 1 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (6) | (0) | (0) | (4) | (4) | (0) | (0) | (2) | (2) | (0) | (0) |
| | cyst | 5 | 1 | 0 | 0 | 3 | 3 | 0 | 0 | 4 | 1 | 0 | 0 | 5 | 0 | 0 | 0 |
| | | (10) | (2) | (0) | (0) | (6) | (6) | (0) | (0) | (8) | (2) | (0) | (0) | (10) | (0) | (0) | (0) |
| | hyperplasia | 7 | 2 | 0 | 0 | 4 | 4 | 0 | 0 | 6 | 7 | 0 | 0 | 10 | 5 | 0 | 0 |
| | | (14) | (4) | (0) | (0) | (8) | (8) | (0) | (0) | (12) | (14) | (0) | (0) | (20) | (10) | (0) | (0) |
| | Rathke pouch | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (4) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 26

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 50 | | | | 10000 ppm 50 | | | | 30000 ppm 50 | | | |
|-----------------------|------------------------------|---|-------|-------|-------|----------------|--------|-------|-------|-----------------|-------|-------|-------|-----------------|-------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Endocrine system} | | | | | | | | | | | | | | | | | |
| thyroid | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | ultimobranchial body remanet | 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) | (0) |
| | C-cell hyperplasia | 9 | 2 | 0 | 0 | 14 | 5 | 0 | 0 | 10 | 4 | 0 | 0 | 5 | 1 | 0 | 0 |
| | | (18) | (4) | (0) | (0) | (28) | (10) | (0) | (0) | (20) | (8) | (0) | (0) | (10) | (2) | (0) | (0) |
| adrenal | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | peliosis-like lesion | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (6) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | extramedullary hematopoiesis | 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) | (0) | (0) | (0) | (0) | (0) |
| | hyperplasia:cortical cell | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (0) | (2) | (0) | (0) |
| | hyperplasia:medulla | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (4) | (0) | (0) | (0) | (0) | (0) | (0) |
| | focal fatty change:cortex | 6 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 3 | 3 | 0 | 0 |
| | | (12) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (6) | (6) | (0) | (0) |
| {Reproductive system} | | | | | | | | | | | | | | | | | |
| ovary | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | cyst | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 1 | 0 | 0 |
| | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (4) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 27

| | | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|----------------------------------|---------------------------------|-------------------------|---------|--------|-------|-------|----------|--------|--------|-------|-----------|--------|--------|-------|-----------|--------|-------|-------|
| | | 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 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Reproductive system) | | | | | | | | | | | | | | | | | | |
| uterus | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | decidual change | | 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) | (0) | (0) |
| | cystic endometrial hyperplasia | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 4 | 2 | 0 | 0 |
| | | | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (8) | (4) | (0) | (0) |
| (Special sense organs/appendage) | | | | | | | | | | | | | | | | | | |
| eye | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | inflammatory infiltration | | 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) |
| | cataract | | 6 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | | (12) | (0) | (0) | (0) | (12) | (0) | (0) | (0) | (12) | (0) | (0) | (0) | (4) | (0) | (0) | (0) |
| | retinal atrophy | | 18 | 18 | 2 | 0 | 20 | 15 | 5 | 0 | 21 | 20 | 5 | 0 | 22 | 18 | 2 | 0 |
| | | | (36) | (36) | (4) | (0) | (40) | (30) | (10) | (0) | (42) | (40) | (10) | (0) | (44) | (36) | (4) | (0) |
| | squamous cell metaplasia:cornea | | 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) | (0) |
| Harder gl | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | degeneration | | 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 : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 28

| | | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|----------------------------------|--------------------------|-------------------------|---------|-------|-------|-------|----------|-------|-------|-------|-----------|-------|-------|-------|-----------|-------|-------|-------|
| | | No. of Animals on Study | 50 | | | | 50 | | | | 50 | | | | 50 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Organ_____ | Findings_____ | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| <hr/> | | | | | | | | | | | | | | | | | | |
| (Special sense organs/appendage) | | | | | | | | | | | | | | | | | | |
| Harder gl | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | lymphocytic infiltration | | 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) |
| nasolacr d | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | inflammation | | 7 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | | (14) | (0) | (0) | (0) | (6) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (4) | (0) | (0) | (0) |
| <hr/> | | | | | | | | | | | | | | | | | | |
| (Musculoskeletal system) | | | | | | | | | | | | | | | | | | |
| bone | | | <50> | | | | <50> | | | | <50> | | | | <50> | | | |
| | osteosclerosis | | 3 | 1 | 0 | 0 | 2 | 2 | 1 | 0 | 5 | 1 | 0 | 0 | 2 | 1 | 2 | 0 |
| | | | (6) | (2) | (0) | (0) | (4) | (4) | (2) | (0) | (10) | (2) | (0) | (0) | (4) | (2) | (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 ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

(HPT150)

BAIS4

TABLE M 5

HISTOPATHOLOGICAL FINDINGS:

NON-NEOPLASTIC LESIONS:

FEMALE: DEAD AND MORIBUND ANIMALS

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 12

| Organ | Findings | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|----------------------|--|-------------------------|---------|-------|------|------|----------|-------|------|------|-----------|-------|------|------|-----------|-------|------|------|
| | | No. of Animals on Study | 15 | | | | 11 | | | | 6 | | | | 11 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Respiratory system) | | | | | | | | | | | | | | | | | | |
| nasal cavit | | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | 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) | (9) | (0) | (0) | (0) |
| | eosinophilic change:olfactory epithelium | | 5 | 7 | 0 | 0 | 2 | 5 | 0 | 0 | 1 | 4 | 0 | 0 | 4 | 7 | 0 | 0 |
| | | | (33) | (47) | (0) | (0) | (18) | (45) | (0) | (0) | (17) | (67) | (0) | (0) | (36) | (64) | (0) | (0) |
| | eosinophilic change:respiratory epithelium | | 4 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 5 | 0 | 0 | 0 |
| | | | (27) | (0) | (0) | (0) | (36) | (0) | (0) | (0) | (33) | (0) | (0) | (0) | (45) | (0) | (0) | (0) |
| | respiratory metaplasia:gland | | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (27) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| larynx | | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | inflammation | | 1 | 0 | 0 | 0 | 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) |
| lung | | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | congestion | | 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) | (17) | (0) | (0) | (0) | (9) | (0) | (0) |
| | bronchiolar-alveolar cell hyperplasia | | 0 | 1 | 0 | 0 | 0 | 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) |

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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 13

| Organ_____ | Findings_____ | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|------------------------|-------------------------|-------------------------|---------|--------|-------|-------|----------|-------|-------|-------|-----------|-------|-------|-------|-----------|-------|-------|-------|
| | | No. of Animals on Study | 15 | | | | 11 | | | | 6 | | | | 11 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Respiratory system) | | | | | | | | | | | | | | | | | | |
| lung | | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | emphysema | | 0 | 1 | 0 | 0 | 0 | 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) |
| (Hematopoietic system) | | | | | | | | | | | | | | | | | | |
| bone marrow | | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | granulation | | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (13) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) |
| | increased hematopoiesis | | 3 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | 0 | 0 |
| | | | (20) | (0) | (0) | (0) | (55) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (45) | (0) | (0) | (0) |
| thymus | | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | hemorrhage | | 1 | 0 | 0 | 0 | 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) |
| spleen | | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | atrophy | | 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) | (9) | (0) | (0) |
| | deposit of hemosiderin | | 5 | 2 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 4 | 0 | 0 | 0 |
| | | | (33) | (13) | (0) | (0) | (18) | (0) | (0) | (0) | (33) | (0) | (0) | (0) | (36) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 14

| Organ | Findings | Control No. of Animals on Study 15 Grade | | | | 3300 ppm 11 | | | | 10000 ppm 6 | | | | 30000 ppm 11 | | | |
|------------------------|------------------------------|--|-------|-------|-------|----------------|--------|-------|-------|----------------|--------|-------|-------|-----------------|-------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Hematopoietic system) | | | | | | | | | | | | | | | | | |
| spleen | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | fibrosis | 0 | 1 | 0 | 0 | 0 | 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) |
| | extramedullary hematopoiesis | 1 | 1 | 1 | 0 | 1 | 4 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 1 | 0 | 0 |
| | | (7) | (7) | (7) | (0) | (9) | (36) | (0) | (0) | (17) | (0) | (0) | (0) | (18) | (9) | (0) | (0) |
| (Circulatory system) | | | | | | | | | | | | | | | | | |
| heart | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | thrombus | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| (Digestive system) | | | | | | | | | | | | | | | | | |
| salivary gl | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | atrophy | 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) | (17) | (0) | (0) | (0) | (0) | (0) | (0) |
| stomach | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | ulcer:forestomach | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (0) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 15

| Organ_____ | Findings_____ | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|------------|---------------|-------------------------|---------|-----|-----|-----|----------|-----|-----|-----|-----------|-----|-----|-----|-----------|-----|-----|-----|
| | | No. of Animals on Study | 15 | | | | 11 | | | | 6 | | | | 11 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |

| | | | | | | | | | | | | | | | | | | | | | |
|--------------------|---------------------------|-------|------|------|------|------|------|------|------|------|-------|-------|------|------|-------|------|------|------|------|--|--|
| {Digestive system} | | | | | | | | | | | | | | | | | | | | | |
| stomach | | <15> | | | | | <11> | | | | | < 6> | | | | | <11> | | | | |
| | erosion:glandular stomach | 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) | (17) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | |
| | ulcer:glandular stomach | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | |
| | | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | | |
| large intes | | <15> | | | | | <11> | | | | | < 6> | | | | | <11> | | | | |
| | cyst | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 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) | (0) | | |
| liver | | <15> | | | | | <11> | | | | | < 6> | | | | | <11> | | | | |
| | herniation | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | | |
| | | (7) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (33) | (0) | (0) | (0) | (18) | (0) | (0) | (0) | (0) | | |
| | necrosis:central | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (0) | | |
| | necrosis:focal | 2 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | |
| | | (13) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (17) | (17) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | | |
| | fatty change | 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) | (33) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 16

| | | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|--------------------|------------------------------|-------------------------|---------|------|------|------|----------|------|------|------|-----------|------|-------|------|-----------|------|------|------|
| | | No. of Animals on Study | 15 | | | | 11 | | | | 6 | | | | 11 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Organ_____ | Findings_____ | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| | | | | | | | | | | | | | | | | | | |
| {Digestive system} | | | | | | | | | | | | | | | | | | |
| liver | | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | granulation | | 3 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | | (20) | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (18) | (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) | (9) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | basophilic cell focus | | 3 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (20) | (0) | (0) | (0) | (27) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (9) | (0) | (0) | (0) |
| | bile duct hyperplasia | | 2 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 1 | 0 | 0 |
| | | | (13) | (0) | (0) | (0) | (36) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (18) | (9) | (0) | (0) |
| pancreas | | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | atrophy | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| {Urinary system} | | | | | | | | | | | | | | | | | | |
| kidney | | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | deposit of hemosiderin | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (17) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 17

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 11 | | | | 10000 ppm 6 | | | | 30000 ppm 11 | | | |
|--------------------|-------------------------------|---|-----------|-----------|-----------|----------------|-----------|-----------|-----------|----------------|------------|-----------|-----------|-----------------|------------|-----------|-----------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Urinary system} | | | | | | | | | | | | | | | | | |
| kidney | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | chronic nephropathy | 5 (33) | 1 (7) | 0 (0) | 0 (0) | 1 (9) | 0 (0) | 0 (0) | 0 (0) | 2 (33) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 2 (18) | 0 (0) | 0 (0) |
| | tubular necrosis | 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) | 2 (18) | 0 (0) | 0 (0) |
| | papillary necrosis | 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 (18) | 0 (0) | 0 (0) | 0 (0) |
| | urothelial hyperplasia:pelvis | 1 (7) | 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) |
| | dilated pelvis | 0 (0) | 1 (7) | 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) |
| {Endocrine system} | | | | | | | | | | | | | | | | | |
| pituitary | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | angiectasis | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (17) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | cyst | 1 (7) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (9) | 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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 18

| Organ | Findings | Group Name No. of Animals on Study Grade | Control 15 | | | | 3300 ppm 11 | | | | 10000 ppm 6 | | | | 30000 ppm 11 | | | |
|-----------------------|------------------------------|--|---------------|-------|-------|-------|----------------|--------|-------|-------|----------------|--------|-------|-------|-----------------|-------|-------|-------|
| | | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Endocrine system) | | | | | | | | | | | | | | | | | | |
| pituitary | | | | | | | | | | | | | | | | | | |
| | hyperplasia | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | | | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| | Rathke pouch | | 1 | 0 | 0 | 0 | 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) |
| thyroid | | | | | | | | | | | | | | | | | | |
| | C-cell hyperplasia | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | | | 1 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (7) | (0) | (0) | (0) | (0) | (18) | (0) | (0) | (17) | (0) | (0) | (0) | (9) | (0) | (0) | (0) |
| adrenal | | | | | | | | | | | | | | | | | | |
| | extramedullary hematopoiesis | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | | | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (18) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| | hyperplasia:medulla | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (7) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (0) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| | focal fatty change:cortex | | 2 | 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) |
| (Reproductive system) | | | | | | | | | | | | | | | | | | |
| ovary | | | | | | | | | | | | | | | | | | |
| | cyst | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | | | 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) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 19

| | | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|----------------------------------|---------------------------|-------------------------|---------|-------|------|------|----------|------|------|------|-----------|-------|------|------|-----------|-------|------|------|
| | | No. of Animals on Study | 15 | | | | 11 | | | | 6 | | | | 11 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Organ_____ | Findings_____ | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| | | | | | | | | | | | | | | | | | | |
| {Special sense organs/appendage} | | | | | | | | | | | | | | | | | | |
| eye | | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | inflammatory infiltration | | 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) | (17) | (0) | (0) | (0) | (0) | (0) | (0) |
| | cataract | | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (13) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | retinal atrophy | | 2 | 2 | 1 | 0 | 2 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 2 | 2 | 0 | 0 |
| | | | (13) | (13) | (7) | (0) | (18) | (0) | (0) | (0) | (17) | (17) | (0) | (0) | (18) | (18) | (0) | (0) |
| nasolacr d | | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | inflammation | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (17) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | | | | | | | | | | | | | | | | | | |
| {Musculoskeletal system} | | | | | | | | | | | | | | | | | | |
| bone | | | <15> | | | | <11> | | | | < 6> | | | | <11> | | | |
| | osteosclerosis | | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (7) | (0) | (0) | (0) | (0) | (0) | (9) | (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

TABLE M 6

HISTOPATHOLOGICAL FINDINGS:

NON-NEOPLASTIC LESIONS:

FEMALE: SACRIFICED ANIMALS

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 11

| Organ | Findings | Control No. of Animals on Study 35 Grade | | | | 3300 ppm 39 | | | | 10000 ppm 44 | | | | 30000 ppm 39 | | | |
|----------------------|---|--|--------|--------|-------|----------------|--------|--------|-------|-----------------|--------|--------|-------|-----------------|--------|--------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | |
| nasal cavit | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | eosinophilic change:olfactory epithelium | 3 | 22 | 10 | 0 | 5 | 26 | 7 | 0 | 7 | 28 | 9 | 0 | 0 | 28 | 11 | 0 |
| | | (9) | (63) | (29) | (0) | (13) | (67) | (18) | (0) | (16) | (64) | (20) | (0) | (0) | (72) | (28) | (0) |
| | eosinophilic change:respiratory epithelium | 30 | 0 | 0 | 0 | 28 | 0 | 0 | 0 | 30 | 0 | 0 | 0 | 32 | 0 | 0 | 0 |
| | | (86) | (0) | (0) | (0) | (72) | (0) | (0) | (0) | (68) | (0) | (0) | (0) | (82) | (0) | (0) | (0) |
| | inflammation:foreign body | 1 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (13) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) |
| | inflammation:respiratory epithelium | 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) |
| | inflammation:olfactory epithelium | 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) |
| | respiratory metaplasia:olfactory epithelium | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | respiratory metaplasia:gland | 7 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 4 | 0 | 0 | 0 |
| | | (20) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (11) | (0) | (0) | (0) | (10) | (0) | (0) | (0) |
| | inflammation:transitional epithelium | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (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. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 12

| Organ | Findings | Group Name No. of Animals on Study Grade | Control 35 | | | | 3300 ppm 39 | | | | 10000 ppm 44 | | | | 30000 ppm 39 | | | |
|------------------------|---|--|---------------|-------|-------|-------|----------------|-------|-------|-------|-----------------|-------|-------|-------|-----------------|-------|-------|-------|
| | | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Respiratory system) | | | | | | | | | | | | | | | | | | |
| nasal cavit | squamous cell metaplasia:respiratory epithelium | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | | | 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) |
| lung | edema | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | | | 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) |
| | bronchiolar-alveolar cell hyperplasia | | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 1 | 0 | 0 |
| | | | (0) | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (5) | (3) | (0) | (0) |
| (Hematopoietic system) | | | | | | | | | | | | | | | | | | |
| bone marrow | granulation | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | | | 3 | 2 | 0 | 0 | 7 | 0 | 0 | 0 | 4 | 2 | 0 | 0 | 6 | 2 | 0 | 0 |
| | | | (9) | (6) | (0) | (0) | (18) | (0) | (0) | (0) | (9) | (5) | (0) | (0) | (15) | (5) | (0) | (0) |
| | increased hematopoiesis | | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (6) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| spleen | atrophy | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | | | 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) |

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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 13

| Organ | Findings | Control No. of Animals on Study 35 Grade | | | | 3300 ppm 39 | | | | 10000 ppm 44 | | | | 30000 ppm 39 | | | |
|------------------------|------------------------------|--|------|------|------|----------------|------|------|------|-----------------|------|------|------|-----------------|------|------|------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Hematopoietic system} | | | | | | | | | | | | | | | | | |
| spleen | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | congestion | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (3) | (3) | (0) | (0) |
| | deposit of hemosiderin | 24 | 2 | 0 | 0 | 25 | 3 | 0 | 0 | 28 | 3 | 0 | 0 | 22 | 1 | 0 | 0 |
| | | (69) | (6) | (0) | (0) | (64) | (8) | (0) | (0) | (64) | (7) | (0) | (0) | (56) | (3) | (0) | (0) |
| | extramedullary hematopoiesis | 3 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 6 | 2 | 0 | 0 | 4 | 1 | 0 | 0 |
| | | (9) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (14) | (5) | (0) | (0) | (10) | (3) | (0) | (0) |
| {Circulatory system} | | | | | | | | | | | | | | | | | |
| heart | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | mineralization | 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) |
| | myocardial fibrosis | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (5) | (0) | (0) | (0) |
| | subendocardial fibrosis | 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) |
| {Digestive system} | | | | | | | | | | | | | | | | | |
| oral cavity | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | squamous cell hyperplasia | 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) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 14

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 39 | | | | 10000 ppm 44 | | | | 30000 ppm 39 | | | |
|--------------------|----------------------------------|---|-------|-------|-------|----------------|-------|-------|-------|-----------------|-------|-------|-------|-----------------|-------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | |
| tongue | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | squamous cell hyperplasia | 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) |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | arteritis | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| stomach | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | hyperplasia: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) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | mineralization:glandular stomach | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| liver | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | herniation | 6 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 8 | 0 | 0 | 0 | 3 | 0 | 0 | 0 |
| | | (17) | (0) | (0) | (0) | (15) | (0) | (0) | (0) | (18) | (0) | (0) | (0) | (8) | (0) | (0) | (0) |
| | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | necrosis:focal | (0) | (0) | (0) | (0) | (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 | 1 | 0 | 0 |
| | lymphocytic infiltration | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 15

| Organ | Findings | Control No. of Animals on Study 35 Grade | | | | 3300 ppm 39 | | | | 10000 ppm 44 | | | | 30000 ppm 39 | | | |
|--------------------|------------------------|--|------|------|------|----------------|------|------|------|-----------------|-------|------|------|-----------------|-------|------|------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Digestive system) | | | | | | | | | | | | | | | | | |
| liver | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | granulation | 11 | 0 | 0 | 0 | 11 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 13 | 1 | 0 | 0 |
| | | (31) | (0) | (0) | (0) | (28) | (0) | (0) | (0) | (23) | (0) | (0) | (0) | (33) | (3) | (0) | (0) |
| | inflammatory cell nest | 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) |
| | clear cell focus | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (3) | (3) | (0) | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | basophilic cell focus | 24 | 2 | 0 | 0 | 27 | 2 | 0 | 0 | 31 | 2 | 0 | 0 | 25 | 2 | 0 | 0 |
| | | (69) | (6) | (0) | (0) | (69) | (5) | (0) | (0) | (70) | (5) | (0) | (0) | (64) | (5) | (0) | (0) |
| | mixed cell focus | 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) |
| | bile duct hyperplasia | 18 | 1 | 0 | 0 | 12 | 2 | 0 | 0 | 15 | 5 | 0 | 0 | 12 | 4 | 0 | 0 |
| | | (51) | (3) | (0) | (0) | (31) | (5) | (0) | (0) | (34) | (11) | (0) | (0) | (31) | (10) | (0) | (0) |
| | biliary cyst | 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) |
| pancreas | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | atrophy | 2 | 1 | 0 | 0 | 4 | 1 | 0 | 0 | 4 | 0 | 0 | 0 | 6 | 1 | 0 | 0 |
| | | (6) | (3) | (0) | (0) | (10) | (3) | (0) | (0) | (9) | (0) | (0) | (0) | (15) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 16

| Organ | Findings | Control No. of Animals on Study Grade | | | | 3300 ppm 39 | | | | 10000 ppm 44 | | | | 30000 ppm 39 | | | |
|--------------------|--------------------------|---|-------|-------|-------|----------------|-------|-------|-------|-----------------|--------|-------|-------|-----------------|-------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Digestive system} | | | | | | | | | | | | | | | | | |
| pancreas | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | lymphocytic infiltration | 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) |
| | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | islet cell hyperplasia | 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) | (2) | (0) | (0) | (0) | (3) | (0) | (0) |
| {Urinary system} | | | | | | | | | | | | | | | | | |
| kidney | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | cyst | 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) |
| | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | hyaline droplet | 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) |
| | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | scar | 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) | (3) | (3) | (0) | (0) |
| | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | chronic nephropathy | 23 | 1 | 1 | 0 | 26 | 2 | 1 | 0 | 27 | 5 | 1 | 0 | 26 | 0 | 2 | 0 |
| | | (66) | (3) | (3) | (0) | (67) | (5) | (3) | (0) | (61) | (11) | (2) | (0) | (67) | (0) | (5) | (0) |
| | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | papillary necrosis | 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) | (10) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 17

| Organ_____ | Findings_____ | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|------------|---------------|-------------------------|---------|-----|-----|-----|----------|-----|-----|-----|-----------|-----|-----|-----|-----------|-----|-----|-----|
| | | No. of Animals on Study | 35 | | | | 39 | | | | 44 | | | | 39 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |

{Urinary system}

kidney

mineralization:cortico-medullary junction

0100

(0) (3) (0) (0)

0000

(0) (0) (0) (0)

0000

(0) (0) (0) (0)

0000

(0) (0) (0) (0)

mineralization:papilla

0000

(0) (0) (0) (0)

0000

(0) (0) (0) (0)

0000

(0) (0) (0) (0)

6000 *

(15) (0) (0) (0)

mineralization:pelvis

1000

(3) (0) (0) (0)

0000

(0) (0) (0) (0)

0000

(0) (0) (0) (0)

0000

(0) (0) (0) (0)

mineralization:cortex

0100

(0) (3) (0) (0)

0000

(0) (0) (0) (0)

0000

(0) (0) (0) (0)

0000

(0) (0) (0) (0)

regeneration:proximal tubule

0100

(0) (3) (0) (0)

0000

(0) (0) (0) (0)

0000

(0) (0) (0) (0)

0000

(0) (0) (0) (0)

urothelial hyperplasia:pelvis

0000

(0) (0) (0) (0)

0000

(0) (0) (0) (0)

1000

(2) (0) (0) (0)

5000

(13) (0) (0) (0)

atypical tubule hyperplasia

0000

(0) (0) (0) (0)

0000

(0) (0) (0) (0)

0000

(0) (0) (0) (0)

1000

(3) (0) (0) (0)

{Endocrine system}

| | | | | | | | | | | | | | | | | | |
|-----------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| pituitary | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | angiectasis | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 2 | 1 | 0 | 0 | 1 | 1 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (8) | (0) | (0) | (5) | (2) | (0) | (0) | (3) | (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. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 18

| Organ | Findings | Control No. of Animals on Study 35 Grade | | | | 3300 ppm 39 | | | | 10000 ppm 44 | | | | 30000 ppm 39 | | | |
|--------------------|------------------------------|--|------|------|------|----------------|------|------|------|-----------------|-------|------|------|-----------------|-------|------|------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Endocrine system} | | | | | | | | | | | | | | | | | |
| pituitary | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | cyst | 4 | 1 | 0 | 0 | 3 | 3 | 0 | 0 | 4 | 1 | 0 | 0 | 4 | 0 | 0 | 0 |
| | | (11) | (3) | (0) | (0) | (8) | (8) | (0) | (0) | (9) | (2) | (0) | (0) | (10) | (0) | (0) | (0) |
| | hyperplasia | 7 | 2 | 0 | 0 | 4 | 3 | 0 | 0 | 6 | 7 | 0 | 0 | 9 | 5 | 0 | 0 |
| | | (20) | (6) | (0) | (0) | (10) | (8) | (0) | (0) | (14) | (16) | (0) | (0) | (23) | (13) | (0) | (0) |
| | Rathke pouch | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (3) | (0) | (0) | (0) |
| thyroid | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | ultimobranchial body remanet | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | C-cell hyperplasia | 8 | 2 | 0 | 0 | 14 | 3 | 0 | 0 | 9 | 4 | 0 | 0 | 4 | 1 | 0 | 0 |
| | | (23) | (6) | (0) | (0) | (36) | (8) | (0) | (0) | (20) | (9) | (0) | (0) | (10) | (3) | (0) | (0) |
| adrenal | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | peliosis-like lesion | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (9) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyperplasia:cortical cell | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| | | (0) | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (0) | (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 ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 19

| Organ | Findings | Group Name No. of Animals on Study Control 35 Grade | | | | 3300 ppm 39 | | | | 10000 ppm 44 | | | | 30000 ppm 39 | | | |
|----------------------------------|--------------------------------|---|-------|-------|-------|----------------|-------|-------|-------|-----------------|-------|-------|-------|-----------------|-------|-------|-------|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Endocrine system} | | | | | | | | | | | | | | | | | |
| adrenal | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | hyperplasia:medulla | 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) | (0) | (0) | (0) | (0) |
| | focal fatty change:cortex | 4 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 3 | 3 | 0 | 0 |
| | | (11) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (8) | (8) | (0) | (0) |
| {Reproductive system} | | | | | | | | | | | | | | | | | |
| ovary | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | cyst | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 1 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (5) | (0) | (0) | (0) | (3) | (3) | (0) | (0) |
| uterus | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | decidual change | 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) | (0) | (0) |
| | cystic endometrial hyperplasia | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 4 | 2 | 0 | 0 |
| | | (3) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (2) | (2) | (0) | (0) | (10) | (5) | (0) | (0) |
| {Special sense organs/appendage} | | | | | | | | | | | | | | | | | |
| eye | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | cataract | 4 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (11) | (0) | (0) | (0) | (13) | (0) | (0) | (0) | (14) | (0) | (0) | (0) | (5) | (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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 20

| | | Group Name | Control | | | | 3300 ppm | | | | 10000 ppm | | | | 30000 ppm | | | |
|----------------------------------|---------------------------------|-------------------------|---------|-------|------|------|----------|-------|-------|------|-----------|-------|-------|------|-----------|-------|------|------|
| | | No. of Animals on Study | 35 | | | | 39 | | | | 44 | | | | 39 | | | |
| | | Grade | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Organ | Findings | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Special sense organs/appendage) | | | | | | | | | | | | | | | | | | |
| eye | | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | retinal atrophy | | 16 | 16 | 1 | 0 | 18 | 15 | 5 | 0 | 20 | 19 | 5 | 0 | 20 | 16 | 2 | 0 |
| | | | (46) | (46) | (3) | (0) | (46) | (38) | (13) | (0) | (45) | (43) | (11) | (0) | (51) | (41) | (5) | (0) |
| | squamous cell metaplasia:cornea | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (3) | (0) | (0) | (0) | (2) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| Harder gl | | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | degeneration | | 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) |
| | lymphocytic infiltration | | 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) |
| nasolacr d | | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | inflammation | | 7 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | | (20) | (0) | (0) | (0) | (8) | (0) | (0) | (0) | (9) | (0) | (0) | (0) | (5) | (0) | (0) | (0) |
| (Musculoskeletal system) | | | | | | | | | | | | | | | | | | |
| bone | | | <35> | | | | <39> | | | | <44> | | | | <39> | | | |
| | osteosclerosis | | 2 | 1 | 0 | 0 | 2 | 2 | 0 | 0 | 5 | 1 | 0 | 0 | 2 | 1 | 2 | 0 |
| | | | (6) | (3) | (0) | (0) | (5) | (5) | (0) | (0) | (11) | (2) | (0) | (0) | (5) | (3) | (5) | (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

TABLE N 1

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

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
REPORT TYPE : A1
SEX : MALE

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

PAGE : 1

| Time-related Weeks | Items | Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|-----------------------|-------------------------------------|------------|---------|----------|-----------|-----------|
| 0 - 52 | NO. OF EXAMINED ANIMALS | | 1 | 2 | 1 | 0 |
| | NO. OF ANIMALS WITH TUMORS | | 0 | 1 | 1 | 0 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 0 | 1 | 1 | 0 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 0 | 0 | 0 | 0 |
| | NO. OF BENIGN TUMORS | | 0 | 0 | 0 | 0 |
| | NO. OF MALIGNANT TUMORS | | 0 | 1 | 1 | 0 |
| | NO. OF TOTAL TUMORS | | 0 | 1 | 1 | 0 |
| 53 - 78 | NO. OF EXAMINED ANIMALS | | 0 | 6 | 1 | 0 |
| | NO. OF ANIMALS WITH TUMORS | | 0 | 2 | 1 | 0 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 0 | 1 | 1 | 0 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 0 | 1 | 0 | 0 |
| | NO. OF BENIGN TUMORS | | 0 | 1 | 0 | 0 |
| | NO. OF MALIGNANT TUMORS | | 0 | 2 | 1 | 0 |
| | NO. OF TOTAL TUMORS | | 0 | 3 | 1 | 0 |
| 79 - 104 | NO. OF EXAMINED ANIMALS | | 9 | 7 | 9 | 10 |
| | NO. OF ANIMALS WITH TUMORS | | 8 | 7 | 9 | 9 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 3 | 2 | 1 | 3 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 5 | 5 | 8 | 6 |
| | NO. OF BENIGN TUMORS | | 9 | 11 | 18 | 13 |
| | NO. OF MALIGNANT TUMORS | | 4 | 2 | 5 | 5 |
| | NO. OF TOTAL TUMORS | | 13 | 13 | 23 | 18 |
| 105 - 105 | NO. OF EXAMINED ANIMALS | | 40 | 35 | 39 | 40 |
| | NO. OF ANIMALS WITH TUMORS | | 39 | 34 | 39 | 38 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 13 | 18 | 9 | 15 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 26 | 16 | 30 | 23 |
| | NO. OF BENIGN TUMORS | | 73 | 52 | 68 | 68 |
| | NO. OF MALIGNANT TUMORS | | 5 | 7 | 16 | 11 |
| | NO. OF TOTAL TUMORS | | 78 | 59 | 84 | 79 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

| Time-related Weeks | Items | Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|-----------------------|-------------------------------------|------------|---------|----------|-----------|-----------|
| 0 - 105 | NO. OF EXAMINED ANIMALS | | 50 | 50 | 50 | 50 |
| | NO. OF ANIMALS WITH TUMORS | | 47 | 44 | 50 | 47 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 16 | 22 | 12 | 18 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 31 | 22 | 38 | 29 |
| | NO. OF BENIGN TUMORS | | 82 | 64 | 86 | 81 |
| | NO. OF MALIGNANT TUMORS | | 9 | 12 | 23 | 16 |
| | NO. OF TOTAL TUMORS | | 91 | 76 | 109 | 97 |

(HPT070)

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TABLE N 2

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

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 3

| Time-related Weeks | Items | Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|-----------------------|-------------------------------------|------------|---------|----------|-----------|-----------|
| 0 - 52 | NO. OF EXAMINED ANIMALS | | 3 | 0 | 0 | 0 |
| | NO. OF ANIMALS WITH TUMORS | | 2 | 0 | 0 | 0 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 1 | 0 | 0 | 0 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 1 | 0 | 0 | 0 |
| | NO. OF BENIGN TUMORS | | 1 | 0 | 0 | 0 |
| | NO. OF MALIGNANT TUMORS | | 2 | 0 | 0 | 0 |
| | NO. OF TOTAL TUMORS | | 3 | 0 | 0 | 0 |
| 53 - 78 | NO. OF EXAMINED ANIMALS | | 2 | 3 | 0 | 4 |
| | NO. OF ANIMALS WITH TUMORS | | 2 | 3 | 0 | 2 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 1 | 3 | 0 | 2 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 1 | 0 | 0 | 0 |
| | NO. OF BENIGN TUMORS | | 1 | 0 | 0 | 1 |
| | NO. OF MALIGNANT TUMORS | | 2 | 3 | 0 | 1 |
| | NO. OF TOTAL TUMORS | | 3 | 3 | 0 | 2 |
| 79 - 104 | NO. OF EXAMINED ANIMALS | | 10 | 8 | 6 | 7 |
| | NO. OF ANIMALS WITH TUMORS | | 9 | 5 | 5 | 7 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 6 | 4 | 3 | 3 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 3 | 1 | 2 | 4 |
| | NO. OF BENIGN TUMORS | | 8 | 2 | 2 | 6 |
| | NO. OF MALIGNANT TUMORS | | 4 | 4 | 5 | 6 |
| | NO. OF TOTAL TUMORS | | 12 | 6 | 7 | 12 |
| 105 - 105 | NO. OF EXAMINED ANIMALS | | 35 | 39 | 44 | 39 |
| | NO. OF ANIMALS WITH TUMORS | | 23 | 25 | 34 | 21 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 14 | 16 | 24 | 16 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 9 | 9 | 10 | 5 |
| | NO. OF BENIGN TUMORS | | 26 | 32 | 36 | 22 |
| | NO. OF MALIGNANT TUMORS | | 7 | 4 | 10 | 4 |
| | NO. OF TOTAL TUMORS | | 33 | 36 | 46 | 26 |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 4

| Time-related Weeks | Items | Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|-----------------------|-------------------------------------|------------|---------|----------|-----------|-----------|
| 0 - 105 | NO. OF EXAMINED ANIMALS | | 50 | 50 | 50 | 50 |
| | NO. OF ANIMALS WITH TUMORS | | 36 | 33 | 39 | 30 |
| | NO. OF ANIMALS WITH SINGLE TUMORS | | 22 | 23 | 27 | 21 |
| | NO. OF ANIMALS WITH MULTIPLE TUMORS | | 14 | 10 | 12 | 9 |
| | NO. OF BENIGN TUMORS | | 36 | 34 | 38 | 29 |
| | NO. OF MALIGNANT TUMORS | | 15 | 11 | 15 | 11 |
| | NO. OF TOTAL TUMORS | | 51 | 45 | 53 | 40 |

(HPT070)

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TABLE O 1

HISTOPATHOLOGICAL FINDINGS:
NEOPLASTIC LESIONS: MALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

| Organ | Findings | Group Name No. of animals on Study | Control 50 | 3300 ppm 50 | 10000 ppm 50 | 30000 ppm 50 |
|----------------------------------|--------------------------------|---------------------------------------|---------------|----------------|-----------------|-----------------|
| (Integumentary system/appandage) | | | | | | |
| skin/app | | | <50> | <50> | <50> | <50> |
| | squamous cell papilloma | | 0 (0%) | 1 (2%) | 1 (2%) | 1 (2%) |
| | trichoepithelioma | | 2 (4%) | 1 (2%) | 1 (2%) | 0 (0%) |
| | keratoacanthoma | | 1 (2%) | 1 (2%) | 2 (4%) | 0 (0%) |
| subcutis | | | <50> | <50> | <50> | <50> |
| | fibroma | | 2 (4%) | 1 (2%) | 5 (10%) | 2 (4%) |
| | lipoma | | 1 (2%) | 0 (0%) | 1 (2%) | 2 (4%) |
| | hemangioma | | 0 (0%) | 0 (0%) | 0 (0%) | 1 (2%) |
| | fibrosarcoma | | 1 (2%) | 0 (0%) | 1 (2%) | 0 (0%) |
| | leiomyosarcoma | | 0 (0%) | 1 (2%) | 0 (0%) | 0 (0%) |
| | schwannoma:malignant | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| (Respiratory system) | | | | | | |
| lung | | | <50> | <50> | <50> | <50> |
| | bronchiolar-alveolar adenoma | | 3 (6%) | 3 (6%) | 2 (4%) | 2 (4%) |
| | bronchiolar-alveolar carcinoma | | 1 (2%) | 1 (2%) | 3 (6%) | 1 (2%) |
| (Hematopoietic system) | | | | | | |
| spleen | | | <50> | <50> | <50> | <50> |
| | mononuclear cell leukemia | | 3 (6%) | 6 (12%) | 8 (16%) | 2 (4%) |

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

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

| Organ | Findings | Group Name No. of animals on Study | Control 50 | 3300 ppm 50 | 10000 ppm 50 | 30000 ppm 50 |
|--------------------|----------------------------------|---------------------------------------|---------------|----------------|-----------------|-----------------|
| (Digestive system) | | | | | | |
| oral cavity | | | <50> | <50> | <50> | <50> |
| | squamous cell papilloma | | 1 (2%) | 0 (0%) | 0 (0%) | 1 (2%) |
| tongue | | | <50> | <50> | <50> | <50> |
| | squamous cell papilloma | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |
| large intes | | | <50> | <50> | <50> | <50> |
| | adenoma | | 0 (0%) | 1 (2%) | 0 (0%) | 0 (0%) |
| | neuroendocrine cell tumor:benign | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| liver | | | <50> | <50> | <50> | <50> |
| | hepatocellular adenoma | | 2 (4%) | 1 (2%) | 0 (0%) | 1 (2%) |
| | hepatocellular carcinoma | | 1 (2%) | 0 (0%) | 0 (0%) | 2 (4%) |
| pancreas | | | <50> | <50> | <50> | <50> |
| | islet cell adenoma | | 1 (2%) | 1 (2%) | 0 (0%) | 0 (0%) |
| | mixed acinar-islet cell adenoma | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| | islet cell adenocarcinoma | | 0 (0%) | 3 (6%) | 2 (4%) | 1 (2%) |
| (Urinary system) | | | | | | |
| kidney | | | <50> | <50> | <50> | <50> |
| | renal cell adenoma | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| urin bladd | | | <50> | <50> | <50> | <50> |
| | transitional cell papilloma | | 1 (2%) | 0 (0%) | 1 (2%) | 1 (2%) |
| (Endocrine system) | | | | | | |
| pituitary | | | <50> | <50> | <50> | <50> |
| | adenoma | | 24 (48%) | 13 (26%) | 20 (40%) | 14 (28%) |

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

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 3

| Organ | Findings | Group Name No. of animals on Study | Control 50 | 3300 ppm 50 | 10000 ppm 50 | 30000 ppm 50 |
|-----------------------|----------------------------|---------------------------------------|---------------|----------------|-----------------|-----------------|
| {Endocrine system} | | | | | | |
| pituitary | | | <50> | <50> | <50> | <50> |
| | adenocarcinoma | | 1 (2%) | 0 (0%) | 0 (0%) | 1 (2%) |
| thyroid | | | <50> | <50> | <50> | <50> |
| | C-cell adenoma | | 8 (16%) | 3 (6%) | 6 (12%) | 10 (20%) |
| | follicular adenoma | | 1 (2%) | 0 (0%) | 1 (2%) | 2 (4%) |
| | C-cell carcinoma | | 0 (0%) | 0 (0%) | 2 (4%) | 0 (0%) |
| adrenal | | | <50> | <50> | <50> | <50> |
| | pheochromocytoma | | 4 (8%) | 5 (10%) | 5 (10%) | 6 (12%) |
| | cortical adenoma | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |
| | pheochromocytoma:malignant | | 0 (0%) | 0 (0%) | 0 (0%) | 2 (4%) |
| {Reproductive system} | | | | | | |
| testis | | | <50> | <50> | <50> | <50> |
| | interstitial cell tumor | | 28 (56%) | 30 (60%) | 34 (68%) | 36 (72%) |
| | hemangiosarcoma | | 0 (0%) | 0 (0%) | 0 (0%) | 1 (2%) |
| prostate | | | <50> | <50> | <50> | <50> |
| | adenoma | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |
| mammary gl | | | <50> | <50> | <50> | <50> |
| | adenoma | | 0 (0%) | 0 (0%) | 0 (0%) | 1 (2%) |
| | fibroadenoma | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |

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

(HPT085)

BAIS4

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 4

| Organ | Findings | Group Name No. of animals on Study | Control 50 | 3300 ppm 50 | 10000 ppm 50 | 30000 ppm 50 |
|----------------------------------|------------------------------|---------------------------------------|---------------|----------------|-----------------|-----------------|
| {Reproductive system} | | | | | | |
| prep/cli gl | | | <50> | <50> | <50> | <50> |
| | adenoma | | 0 (0%) | 1 (2%) | 1 (2%) | 1 (2%) |
| {Nervous system} | | | | | | |
| brain | | | <50> | <50> | <50> | <50> |
| | glioma | | 0 (0%) | 1 (2%) | 0 (0%) | 0 (0%) |
| periph nerv | | | <50> | <50> | <50> | <50> |
| | schwannoma:malignant | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |
| {Special sense organs/appendage} | | | | | | |
| Harder gl | | | <50> | <50> | <50> | <50> |
| | adenoma | | 0 (0%) | 1 (2%) | 0 (0%) | 0 (0%) |
| Zymbal gl | | | <50> | <50> | <50> | <50> |
| | Zymbal gland tumor:malignant | | 0 (0%) | 0 (0%) | 2 (4%) | 1 (2%) |
| {Musculoskeletal system} | | | | | | |
| bone | | | <50> | <50> | <50> | <50> |
| | osteoma | | 0 (0%) | 1 (2%) | 0 (0%) | 0 (0%) |
| | osteosarcoma | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| {Body cavities} | | | | | | |
| pleura | | | <50> | <50> | <50> | <50> |
| | mesothelioma | | 0 (0%) | 0 (0%) | 0 (0%) | 1 (2%) |
| peritoneum | | | <50> | <50> | <50> | <50> |
| | fibroma | | 0 (0%) | 0 (0%) | 1 (2%) | 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. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
REPORT TYPE : A1
SEX : MALE

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

PAGE : 5

| Organ_____ | Findings_____ | Group Name No. of animals on Study | Control 50 | 3300 ppm 50 | 10000 ppm 50 | 30000 ppm 50 |
|-----------------|--|---------------------------------------|---------------|----------------|-----------------|-----------------|
| (Body cavities) | | | | | | |
| peritoneum | | | <50> | <50> | <50> | <50> |
| | mesothelioma | | 1 (2%) | 0 (0%) | 2 (4%) | 4 (8%) |
| adipose | | | <50> | <50> | <50> | <50> |
| | lipoma | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| | liposarcoma | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| <hr/> | | | | | | |
| < a > | a : Number of animals examined at the site | | | | | |
| b (c) | b : Number of animals with neoplasm c : b / a * 100 | | | | | |

(HPT085)

BAIS4

TABLE O 2

HISTOPATHOLOGICAL FINDINGS:
NEOPLASTIC LESIONS: FEMALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 6

| Organ | Findings | Group Name No. of animals on Study | Control 50 | 3300 ppm 50 | 10000 ppm 50 | 30000 ppm 50 |
|----------------------------------|--------------------------------|---------------------------------------|---------------|----------------|-----------------|-----------------|
| (Integumentary system/appandage) | | | | | | |
| subcutis | | | <50> | <50> | <50> | <50> |
| | fibroma | | 0 (0%) | 1 (2%) | 0 (0%) | 0 (0%) |
| | lipoma | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| | fibrosarcoma | | 0 (0%) | 0 (0%) | 0 (0%) | 1 (2%) |
| | histiocytic sarcoma | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| (Respiratory system) | | | | | | |
| nasal cavit | | | <50> | <50> | <50> | <50> |
| | adenoma | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| lung | | | <50> | <50> | <50> | <50> |
| | bronchiolar-alveolar adenoma | | 1 (2%) | 2 (4%) | 0 (0%) | 1 (2%) |
| | bronchiolar-alveolar carcinoma | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |
| (Hematopoietic system) | | | | | | |
| spleen | | | <50> | <50> | <50> | <50> |
| | mononuclear cell leukemia | | 4 (8%) | 5 (10%) | 5 (10%) | 3 (6%) |
| (Digestive system) | | | | | | |
| oral cavity | | | <50> | <50> | <50> | <50> |
| | squamous cell papilloma | | 0 (0%) | 0 (0%) | 2 (4%) | 0 (0%) |
| | squamous cell carcinoma | | 0 (0%) | 0 (0%) | 1 (2%) | 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. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 7

| Organ | Findings | Group Name No. of animals on Study | Control 50 | 3300 ppm 50 | 10000 ppm 50 | 30000 ppm 50 |
|--------------------|---------------------------------|---------------------------------------|-------------------|------------------|------------------|-------------------|
| (Digestive system) | | | | | | |
| tongue | squamous cell papilloma | | <50> 0 (0%) | <50> 0 (0%) | <50> 1 (2%) | <50> 0 (0%) |
| liver | hepatocellular adenoma | | <50> 2 (4%) | <50> 0 (0%) | <50> 0 (0%) | <50> 1 (2%) |
| pancreas | islet cell adenoma | | <50> 1 (2%) | <50> 0 (0%) | <50> 0 (0%) | <50> 0 (0%) |
| | mixed acinar-islet cell adenoma | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |
| | islet cell adenocarcinoma | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |
| (Urinary system) | | | | | | |
| kidney | renal cell adenoma | | <50> 0 (0%) | <50> 1 (2%) | <50> 0 (0%) | <50> 0 (0%) |
| | nephroblastoma | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| urin bladd | transitional cell papilloma | | <50> 0 (0%) | <50> 0 (0%) | <50> 1 (2%) | <50> 0 (0%) |
| (Endocrine system) | | | | | | |
| pituitary | adenoma | | <50> 11 (22%) | <50> 7 (14%) | <50> 8 (16%) | <50> 11 (22%) |
| | adenocarcinoma | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| thyroid | C-cell adenoma | | <50> 4 (8%) | <50> 7 (14%) | <50> 6 (12%) | <50> 1 (2%) |

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

(HPT085)

BAIS4.

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 8

| Organ | Findings | Group Name No. of animals on Study | Control 50 | 3300 ppm 50 | 10000 ppm 50 | 30000 ppm 50 |
|-----------------------|-----------------------------|---------------------------------------|---------------|----------------|-----------------|-----------------|
| {Endocrine system} | | | | | | |
| thyroid | | | <50> | <50> | <50> | <50> |
| | follicular adenoma | | 0 (0%) | 0 (0%) | 0 (0%) | 1 (2%) |
| | C-cell carcinoma | | 1 (2%) | 0 (0%) | 2 (4%) | 0 (0%) |
| adrenal | | | <50> | <50> | <50> | <50> |
| | pheochromocytoma | | 2 (4%) | 3 (6%) | 2 (4%) | 0 (0%) |
| | pheochromocytoma:malignant | | 1 (2%) | 1 (2%) | 1 (2%) | 2 (4%) |
| {Reproductive system} | | | | | | |
| ovary | | | <50> | <50> | <50> | <50> |
| | granulosa-theca cell tumor | | 0 (0%) | 0 (0%) | 2 (4%) | 0 (0%) |
| | adenocarcinoma | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |
| uterus | | | <50> | <50> | <50> | <50> |
| | adenoma | | 1 (2%) | 1 (2%) | 0 (0%) | 0 (0%) |
| | leiomyoma | | 0 (0%) | 0 (0%) | 1 (2%) | 0 (0%) |
| | endometrial stromal polyp | | 8 (16%) | 7 (14%) | 7 (14%) | 9 (18%) |
| | adenocarcinoma | | 1 (2%) | 1 (2%) | 2 (4%) | 3 (6%) |
| | leiomyosarcoma | | 0 (0%) | 0 (0%) | 0 (0%) | 1 (2%) |
| | endometrial stromal sarcoma | | 2 (4%) | 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

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 9

| Organ | Findings | Group Name No. of animals on Study | Control 50 | 3300 ppm 50 | 10000 ppm 50 | 30000 ppm 50 |
|----------------------------------|------------------------------|---------------------------------------|---------------|----------------|-----------------|-----------------|
| (Reproductive system) | | | | | | |
| mammary gl | | | <50> | <50> | <50> | <50> |
| | adenoma | | 0 (0%) | 0 (0%) | 0 (0%) | 1 (2%) |
| | fibroadenoma | | 4 (8%) | 3 (6%) | 4 (8%) | 3 (6%) |
| | adenocarcinoma | | 1 (2%) | 2 (4%) | 0 (0%) | 0 (0%) |
| prep/cli gl | | | <50> | <50> | <50> | <50> |
| | adenoma | | 1 (2%) | 1 (2%) | 2 (4%) | 1 (2%) |
| (Special sense organs/appendage) | | | | | | |
| Zymbal gl | | | <50> | <50> | <50> | <50> |
| | Zymbal gland tumor:benign | | 0 (0%) | 1 (2%) | 0 (0%) | 0 (0%) |
| | Zymbal gland tumor:malignant | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |
| (Body cavities) | | | | | | |
| retroperit | | | <50> | <50> | <50> | <50> |
| | schwannoma:malignant | | 1 (2%) | 0 (0%) | 0 (0%) | 0 (0%) |

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

(HPT085)

BAIS4

TABLE P 1

NEOPLASTIC LESIONS-INCIDENCE AND
STATISTICAL ANALYSIS: MALE

STUDY No. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 1

| Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|---|------------|------------|-------------|------------|
| SITE : subcutis TUMOR : fibroma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 2/50(4.0) | 1/50(2.0) | 5/50(10.0) | 2/50(4.0) |
| Adjusted rates(b) | 5.00 | 2.86 | 9.52 | 2.17 |
| Terminal rates(c) | 2/40(5.0) | 1/35(2.9) | 3/39(7.7) | 0/40(0.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.1730 | | | |
| Prevalence method(d) | P = 0.6644 | | | |
| Combined analysis(d) | P = 0.4621 | | | |
| Cochran-Armitage test(e) | P = 0.8881 | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.2180 | P = 0.6913 |
| SITE : subcutis TUMOR : fibroma, fibrosarcoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 3/50(6.0) | 1/50(2.0) | 6/50(12.0) | 2/50(4.0) |
| Adjusted rates(b) | 5.00 | 2.86 | 11.90 | 2.17 |
| Terminal rates(c) | 2/40(5.0) | 1/35(2.9) | 4/39(10.3) | 0/40(0.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.3557 | | | |
| Prevalence method(d) | P = 0.6745 | | | |
| Combined analysis(d) | P = 0.5902 | | | |
| Cochran-Armitage test(e) | P = 0.8660 | | | |
| Fisher Exact test(e) | | P = 0.3087 | P = 0.2435 | P = 0.5000 |
| SITE : lung TUMOR : bronchiolar-alveolar adenoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 3/50(6.0) | 3/50(6.0) | 2/50(4.0) | 2/50(4.0) |
| Adjusted rates(b) | 7.50 | 8.57 | 4.88 | 5.00 |
| Terminal rates(c) | 3/40(7.5) | 3/35(8.6) | 1/39(2.6) | 2/40(5.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.7246 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.6091 | | | |
| Fisher Exact test(e) | | P = 0.6611 | P = 0.5000 | P = 0.5000 |

STUDY No. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 2

| Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|---|-------------|-------------|-------------|------------|
| SITE : lung TUMOR : bronchiolar-alveolar carcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 1/50(2.0) | 1/50(2.0) | 3/50(6.0) | 1/50(2.0) |
| Adjusted rates(b) | 2.50 | 2.86 | 7.69 | 2.50 |
| Terminal rates(c) | 1/40(2.5) | 1/35(2.9) | 3/39(7.7) | 1/40(2.5) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.5193 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.9532 | | | |
| Fisher Exact test(e) | | P = 0.7525 | P = 0.3087 | P = 0.7525 |
| SITE : lung TUMOR : bronchiolar-alveolar adenoma, bronchiolar-alveolar carcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 4/50(8.0) | 3/50(6.0) | 5/50(10.0) | 3/50(6.0) |
| Adjusted rates(b) | 10.00 | 8.57 | 12.20 | 7.50 |
| Terminal rates(c) | 4/40(10.0) | 3/35(8.6) | 4/39(10.3) | 3/40(7.5) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.6611 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.7736 | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.5000 | P = 0.5000 |
| SITE : spleen TUMOR : mononuclear cell leukemia | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 3/50(6.0) | 6/50(12.0) | 8/50(16.0) | 2/50(4.0) |
| Adjusted rates(b) | 5.00 | 10.00 | 15.38 | 2.50 |
| Terminal rates(c) | 2/40(5.0) | 3/35(8.6) | 6/39(15.4) | 1/40(2.5) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.6141 | | | |
| Prevalence method(d) | P = 0.8435 | | | |
| Combined analysis(d) | P = 0.8496 | | | |
| Cochran-Armitage test(e) | P = 0.3420 | | | |
| Fisher Exact test(e) | | P = 0.2435 | P = 0.0999 | P = 0.5000 |

STUDY No. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 3

| Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|--|------------|------------|------------|------------|
| SITE : liver | | | | |
| TUMOR : hepatocellular adenoma, hepatocellular carcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 3/50(6.0) | 1/50(2.0) | 0/50(0.0) | 3/50(6.0) |
| Adjusted rates(b) | 7.50 | 2.86 | 0.0 | 7.14 |
| Terminal rates(c) | 3/40(7.5) | 1/35(2.9) | 0/39(0.0) | 2/40(5.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.3145 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.5625 | | | |
| Fisher Exact test(e) | | P = 0.3087 | P = 0.1212 | P = 0.6611 |
| SITE : pancreas | | | | |
| TUMOR : islet cell adenocarcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 0/50(0.0) | 3/50(6.0) | 2/50(4.0) | 1/50(2.0) |
| Adjusted rates(b) | 0.0 | 5.71 | 5.13 | 2.50 |
| Terminal rates(c) | 0/40(0.0) | 2/35(5.7) | 2/39(5.1) | 1/40(2.5) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.5374 | | | |
| Prevalence method(d) | P = 0.4560 | | | |
| Combined analysis(d) | P = 0.5654 | | | |
| Cochran-Armitage test(e) | P = 0.8573 | | | |
| Fisher Exact test(e) | | P = 0.1212 | P = 0.2475 | P = 0.5000 |
| SITE : pancreas | | | | |
| TUMOR : islet cell adenoma, islet cell adenocarcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 1/50(2.0) | 4/50(8.0) | 2/50(4.0) | 1/50(2.0) |
| Adjusted rates(b) | 2.50 | 8.57 | 5.13 | 2.50 |
| Terminal rates(c) | 1/40(2.5) | 3/35(8.6) | 2/39(5.1) | 1/40(2.5) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.5374 | | | |
| Prevalence method(d) | P = 0.6995 | | | |
| Combined analysis(d) | P = 0.7700 | | | |
| Cochran-Armitage test(e) | P = 0.4683 | | | |
| Fisher Exact test(e) | | P = 0.1811 | P = 0.5000 | P = 0.7525 |

STUDY No. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 4

| Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|---|--------------|--------------|--------------|--------------|
| SITE : pituitary gland TUMOR : adenoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 24/50(48.0) | 13/50(26.0) | 20/50(40.0) | 14/50(28.0) |
| Adjusted rates(b) | 50.00 | 20.00 | 41.03 | 25.00 |
| Terminal rates(c) | 20/40(50.0) | 7/35(20.0) | 16/39(41.0) | 10/40(25.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.5012 | | | |
| Prevalence method(d) | P = 0.9579 | | | |
| Combined analysis(d) | P = 0.9300 | | | |
| Cochran-Armitage test(e) | P = 0.1798 | | | |
| Fisher Exact test(e) | | P = 0.0188* | P = 0.2729 | P = 0.0315* |
| SITE : pituitary gland TUMOR : adenoma, adenocarcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 25/50(50.0) | 13/50(26.0) | 20/50(40.0) | 15/50(30.0) |
| Adjusted rates(b) | 50.00 | 20.00 | 41.03 | 27.50 |
| Terminal rates(c) | 20/40(50.0) | 7/35(20.0) | 16/39(41.0) | 11/40(27.5) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.5948 | | | |
| Prevalence method(d) | P = 0.9279 | | | |
| Combined analysis(d) | P = 0.9154 | | | |
| Cochran-Armitage test(e) | P = 0.2195 | | | |
| Fisher Exact test(e) | | P = 0.0114* | P = 0.2108 | P = 0.0328* |
| SITE : thyroid TUMOR : C-cell adenoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 8/50(16.0) | 3/50(6.0) | 6/50(12.0) | 10/50(20.0) |
| Adjusted rates(b) | 17.78 | 8.57 | 13.95 | 22.50 |
| Terminal rates(c) | 6/40(15.0) | 3/35(8.6) | 4/39(10.3) | 9/40(22.5) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.1446 | | | |
| Prevalence method(d) | P = 0.1660 | | | |
| Combined analysis(d) | P = 0.1022 | | | |
| Cochran-Armitage test(e) | P = 0.1677 | | | |
| Fisher Exact test(e) | | P = 0.0999 | P = 0.3871 | P = 0.3976 |

STUDY No. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 5

| Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|--|-------------|-------------|-------------|--------------|
| SITE : thyroid TUMOR : C-cell adenoma, C-cell carcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 8/50(16.0) | 3/50(6.0) | 8/50(16.0) | 10/50(20.0) |
| Adjusted rates(b) | 17.78 | 8.57 | 18.60 | 22.50 |
| Terminal rates(c) | 6/40(15.0) | 3/35(8.6) | 6/39(15.4) | 9/40(22.5) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.1446 | | | |
| Prevalence method(d) | P = 0.1817 | | | |
| Combined analysis(d) | P = 0.1146 | | | |
| Cochran-Armitage test(e) | P = 0.1900 | | | |
| Fisher Exact test(e) | | P = 0.0999 | P = 0.6071 | P = 0.3976 |
| SITE : adrenal gland TUMOR : pheochromocytoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 4/50(8.0) | 5/50(10.0) | 5/50(10.0) | 6/50(12.0) |
| Adjusted rates(b) | 9.30 | 13.16 | 12.82 | 13.95 |
| Terminal rates(c) | 3/40(7.5) | 4/35(11.4) | 5/39(12.8) | 4/40(10.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.3182 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.5436 | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.5000 | P = 0.3703 |
| SITE : adrenal gland TUMOR : pheochromocytoma, pheochromocytoma:malignant | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 4/50(8.0) | 5/50(10.0) | 5/50(10.0) | 8/50(16.0) |
| Adjusted rates(b) | 9.30 | 13.16 | 12.82 | 16.28 |
| Terminal rates(c) | 3/40(7.5) | 4/35(11.4) | 5/39(12.8) | 5/40(12.5) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.1430 | | | |
| Prevalence method(d) | P = 0.1949 | | | |
| Combined analysis(d) | P = 0.1186 | | | |
| Cochran-Armitage test(e) | P = 0.1846 | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.5000 | P = 0.1783 |

STUDY No. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 6

| Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|--|--------------|--------------|--------------|--------------|
| SITE : testis TUMOR : interstitial cell tumor | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 28/50(56.0) | 30/50(60.0) | 34/50(68.0) | 36/50(72.0) |
| Adjusted rates(b) | 67.50 | 78.38 | 75.00 | 80.00 |
| Terminal rates(c) | 27/40(67.5) | 27/35(77.1) | 29/39(74.4) | 32/40(80.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.1199 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.0914 | | | |
| Fisher Exact test(e) | | P = 0.4198 | P = 0.1515 | P = 0.0721 |
| SITE : peritoneum TUMOR : mesothelioma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 1/50(2.0) | 0/50(0.0) | 2/50(4.0) | 4/50(8.0) |
| Adjusted rates(b) | 2.50 | 0.0 | 4.65 | 7.50 |
| Terminal rates(c) | 1/40(2.5) | 0/35(0.0) | 1/39(2.6) | 3/40(7.5) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.1465 | | | |
| Prevalence method(d) | P = 0.0751 | | | |
| Combined analysis(d) | P = 0.0293* | | | |
| Cochran-Armitage test(e) | P = 0.0338* | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.5000 | P = 0.1811 |

(HPT360A)

BAIS4

- (a): Number of tumor-bearing animals/number of animals examined at the site.
 (b): Kaplan-Meier 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 : * : $P \leq 0.05$ ** : $P \leq 0.01$
 N.C. : Statistical value cannot be calculated and was not significant.

TABLE P 2

NEOPLASTIC LESIONS-INCIDENCE AND
STATISTICAL ANALYSIS: FEMALE

STUDY No. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 7

| Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|--|--------------|-------------|-------------|--------------|
| SITE : spleen TUMOR : mononuclear cell leukemia | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 4/50(8.0) | 5/50(10.0) | 5/50(10.0) | 3/50(6.0) |
| Adjusted rates(b) | 2.86 | 5.13 | 4.55 | 0.0 |
| Terminal rates(c) | 1/35(2.9) | 2/39(5.1) | 2/44(4.5) | 0/39(0.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.5129 | | | |
| Prevalence method(d) | P = 0.8723 | | | |
| Combined analysis(d) | P = 0.7402 | | | |
| Cochran-Armitage test(e) | P = 0.5489 | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.5000 | P = 0.5000 |
| SITE : oral cavity TUMOR : squamous cell papilloma, squamous cell carcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 0/50(0.0) | 0/50(0.0) | 3/50(6.0) | 0/50(0.0) |
| Adjusted rates(b) | 0.0 | 0.0 | 4.55 | 0.0 |
| Terminal rates(c) | 0/35(0.0) | 0/39(0.0) | 2/44(4.5) | 0/39(0.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.3810 | | | |
| Prevalence method(d) | P = 0.4871 | | | |
| Combined analysis(d) | P = 0.5188 | | | |
| Cochran-Armitage test(e) | P = 0.9016 | | | |
| Fisher Exact test(e) | | P = N.C. | P = 0.1212 | P = N.C. |
| SITE : pituitary gland TUMOR : adenoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 11/50(22.0) | 7/50(14.0) | 8/50(16.0) | 11/50(22.0) |
| Adjusted rates(b) | 18.18 | 15.38 | 16.33 | 21.43 |
| Terminal rates(c) | 6/35(17.1) | 6/39(15.4) | 7/44(15.9) | 8/39(20.5) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.5218 | | | |
| Prevalence method(d) | P = 0.3383 | | | |
| Combined analysis(d) | P = 0.3722 | | | |
| Cochran-Armitage test(e) | P = 0.6104 | | | |
| Fisher Exact test(e) | | P = 0.2178 | P = 0.3055 | P = 0.5952 |

STUDY No. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr.j]
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 8

| Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|--|--------------|-------------|-------------|--------------|
| SITE : pituitary gland TUMOR : adenoma, adenocarcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 11/50(22.0) | 7/50(14.0) | 9/50(18.0) | 11/50(22.0) |
| Adjusted rates(b) | 18.18 | 15.38 | 18.37 | 21.43 |
| Terminal rates(c) | 6/35(17.1) | 6/39(15.4) | 8/44(18.2) | 8/39(20.5) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.5218 | | | |
| Prevalence method(d) | P = 0.3483 | | | |
| Combined analysis(d) | P = 0.3810 | | | |
| Cochran-Armitage test(e) | P = 0.6230 | | | |
| Fisher Exact test(e) | | P = 0.2178 | P = 0.4016 | P = 0.5952 |
| SITE : thyroid TUMOR : C-cell adenoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 4/50(8.0) | 7/50(14.0) | 6/50(12.0) | 1/50(2.0) |
| Adjusted rates(b) | 9.30 | 17.95 | 13.64 | 2.56 |
| Terminal rates(c) | 3/35(8.6) | 7/39(17.9) | 6/44(13.6) | 1/39(2.6) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.9737 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.0827 | | | |
| Fisher Exact test(e) | | P = 0.2623 | P = 0.3703 | P = 0.1811 |
| SITE : thyroid TUMOR : C-cell adenoma, C-cell carcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 5/50(10.0) | 7/50(14.0) | 8/50(16.0) | 1/50(2.0) |
| Adjusted rates(b) | 11.63 | 17.95 | 18.18 | 2.56 |
| Terminal rates(c) | 4/35(11.4) | 7/39(17.9) | 8/44(18.2) | 1/39(2.6) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.9820 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.0619 | | | |
| Fisher Exact test(e) | | P = 0.3798 | P = 0.2768 | P = 0.1022 |

STUDY No. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 9

| Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|--|--------------|-------------|-------------|-------------|
| SITE : adrenal gland TUMOR : pheochromocytoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 2/50(4.0) | 3/50(6.0) | 2/50(4.0) | 0/50(0.0) |
| Adjusted rates(b) | 5.71 | 7.69 | 4.55 | 0.0 |
| Terminal rates(c) | 2/35(5.7) | 3/39(7.7) | 2/44(4.5) | 0/39(0.0) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.9569 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.1295 | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.6913 | P = 0.2475 |
| SITE : adrenal gland TUMOR : pheochromocytoma, pheochromocytoma:malignant | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 3/50(6.0) | 4/50(8.0) | 3/50(6.0) | 2/50(4.0) |
| Adjusted rates(b) | 8.57 | 10.26 | 6.82 | 5.13 |
| Terminal rates(c) | 3/35(8.6) | 4/39(10.3) | 3/44(6.8) | 2/39(5.1) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.7727 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.4947 | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.6611 | P = 0.5000 |
| SITE : uterus TUMOR : endometrial stromal polyp | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 8/50(16.0) | 7/50(14.0) | 7/50(14.0) | 9/50(18.0) |
| Adjusted rates(b) | 14.89 | 17.95 | 15.91 | 20.00 |
| Terminal rates(c) | 4/35(11.4) | 7/39(17.9) | 7/44(15.9) | 7/39(17.9) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 1.0000 ? | | | |
| Prevalence method(d) | P = 0.2896 | | | |
| Combined analysis(d) | P = 0.3577 | | | |
| Cochran-Armitage test(e) | P = 0.6441 | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.5000 | P = 0.5000 |

STUDY No. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr.j]
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 10

| Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|--|-------------|------------|------------|------------|
| SITE : uterus TUMOR : adenocarcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 1/50(2.0) | 1/50(2.0) | 2/50(4.0) | 3/50(6.0) |
| Adjusted rates(b) | 2.86 | 2.56 | 2.27 | 5.13 |
| Terminal rates(c) | 1/35(2.9) | 1/39(2.6) | 1/44(2.3) | 2/39(5.1) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.1670 | | | |
| Prevalence method(d) | P = 0.2378 | | | |
| Combined analysis(d) | P = 0.1273 | | | |
| Cochran-Armitage test(e) | P = 0.2149 | | | |
| Fisher Exact test(e) | | P = 0.7525 | P = 0.5000 | P = 0.3087 |
| SITE : uterus TUMOR : adenoma, adenocarcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 2/50(4.0) | 2/50(4.0) | 2/50(4.0) | 3/50(6.0) |
| Adjusted rates(b) | 5.71 | 5.13 | 2.27 | 5.13 |
| Terminal rates(c) | 2/35(5.7) | 2/39(5.1) | 1/44(2.3) | 2/39(5.1) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.1670 | | | |
| Prevalence method(d) | P = 0.4899 | | | |
| Combined analysis(d) | P = 0.3031 | | | |
| Cochran-Armitage test(e) | P = 0.5743 | | | |
| Fisher Exact test(e) | | P = 0.6913 | P = 0.6913 | P = 0.5000 |
| SITE : mammary gland TUMOR : fibroadenoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 4/50(8.0) | 3/50(6.0) | 4/50(8.0) | 3/50(6.0) |
| Adjusted rates(b) | 11.43 | 7.69 | 8.89 | 7.14 |
| Terminal rates(c) | 4/35(11.4) | 3/39(7.7) | 3/44(6.8) | 2/39(5.1) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = ----- | | | |
| Prevalence method(d) | P = 0.6509 | | | |
| Combined analysis(d) | P = ----- | | | |
| Cochran-Armitage test(e) | P = 0.7815 | | | |
| Fisher Exact test(e) | | P = 0.5000 | P = 0.6425 | P = 0.5000 |

STUDY No. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 11

| Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|---|-------------|-------------|------------|------------|
| SITE : mammary gland | | | | |
| TUMOR : adenoma, fibroadenoma, adenocarcinoma | | | | |
| Tumor rate | | | | |
| Overall rates(a) | 5/50(10.0) | 5/50(10.0) | 4/50(8.0) | 4/50(8.0) |
| Adjusted rates(b) | 14.29 | 7.69 | 8.89 | 9.30 |
| Terminal rates(c) | 5/35(14.3) | 3/39(7.7) | 3/44(6.8) | 2/39(5.1) |
| Statistical analysis | | | | |
| Peto test | | | | |
| Standard method(d) | P = 0.7957 | | | |
| Prevalence method(d) | P = 0.5777 | | | |
| Combined analysis(d) | P = 0.6942 | | | |
| Cochran-Armitage test(e) | P = 0.6969 | | | |
| Fisher Exact test(e) | | P = 0.6297 | P = 0.5000 | P = 0.5000 |

(HPT360A)

BAIS4

- (a): Number of tumor-bearing animals/number of animals examined at the site.
 (b): Kaplan-Meier 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 : * : $P \leq 0.05$ ** : $P \leq 0.01$
 N.C. : Statistical value cannot be calculated and was not significant.

TABLE Q 1

HISTOPATHOLOGICAL FINDINGS:
METASTASIS OF TUMOR: MALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

| Group Name | | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|----------------------------------|--|---------|----------|-----------|-----------|
| No. of Animals on Study | | 50 | 50 | 50 | 50 |
| Organ | Findings | | | | |
| {Integumentary system/appandage} | | | | | |
| subcutis | | <50> | <50> | <50> | <50> |
| | metastasis:adrenal tumor | 0 | 0 | 0 | 1 |
| {Respiratory system} | | | | | |
| lung | | <50> | <50> | <50> | <50> |
| | leukemic cell infiltration | 3 | 3 | 3 | 1 |
| | metastasis:adrenal tumor | 0 | 0 | 0 | 1 |
| | metastasis:bone tumor | 0 | 0 | 1 | 0 |
| | metastasis:pleura tumor | 0 | 0 | 0 | 1 |
| {Hematopoietic system} | | | | | |
| bone marrow | | <50> | <50> | <50> | <50> |
| | leukemic cell infiltration | 1 | 2 | 2 | 0 |
| lymph node | | <50> | <50> | <50> | <50> |
| | leukemic cell infiltration | 0 | 0 | 1 | 0 |
| | metastasis:adrenal tumor | 0 | 0 | 0 | 1 |
| {Digestive system} | | | | | |
| salivary gl | | <50> | <50> | <50> | <50> |
| | metastasis:subcutis tumor | 1 | 0 | 0 | 0 |
| liver | | <50> | <50> | <50> | <50> |
| | leukemic cell infiltration | 3 | 3 | 3 | 1 |
| {Urinary system} | | | | | |
| kidney | | <50> | <50> | <50> | <50> |
| | leukemic cell infiltration | 0 | 2 | 2 | 0 |
| < a > | a : Number of animals examined at the site | | | | |
| b | b : Number of animals with lesion | | | | |

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

| | | Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|----------------------|--|-------------------------|---------|----------|-----------|-----------|
| | | No. of Animals on Study | 50 | 50 | 50 | 50 |
| Organ_____ | Findings_____ | | | | | |
| <hr/> | | | | | | |
| (Endocrine system) | | | | | | |
| pituitary | | <50> | <50> | <50> | <50> | |
| | metastasis:peripheral nerve tumor | 1 | 0 | 0 | 0 | |
| (Nervous system) | | | | | | |
| brain | | <50> | <50> | <50> | <50> | |
| | metastasis:pituitary tumor | 1 | 0 | 0 | 1 | |
| <hr/> | | | | | | |
| < a > | a : Number of animals examined at the site | | | | | |
| b | b : Number of animals with lesion | | | | | |

(JPT150)

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TABLE Q 2

HISTOPATHOLOGICAL FINDINGS:
METASTASIS OF TUMOR: FEMALE

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 3

| Group Name | | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|-------------------------|-------------------------------|-----------|-----------|-----------|-----------|
| No. of Animals on Study | | 50 | 50 | 50 | 50 |
| Organ | Findings | | | | |
| (Respiratory system) | | | | | |
| lung | leukemic cell infiltration | <50> 3 | <50> 2 | <50> 3 | <50> 3 |
| | metastasis:uterus tumor | 0 | 0 | 1 | 2 |
| | metastasis:adrenal tumor | 0 | 0 | 0 | 1 |
| | metastasis:zygmal gland tumor | 1 | 0 | 0 | 0 |
| (Hematopoietic system) | | | | | |
| bone marrow | leukemic cell infiltration | <50> 1 | <50> 2 | <50> 3 | <50> 2 |
| | | | | | |
| lymph node | leukemic cell infiltration | <50> 2 | <50> 0 | <50> 1 | <50> 0 |
| | metastasis:uterus tumor | 0 | 0 | 1 | 0 |
| | metastasis:subcutis tumor | 0 | 0 | 1 | 0 |
| spleen | metastasis:ovary tumor | <50> 1 | <50> 0 | <50> 0 | <50> 0 |
| | | | | | |
| (Digestive system) | | | | | |
| stomach | leukemic cell infiltration | <50> 1 | <50> 0 | <50> 0 | <50> 0 |
| | | | | | |
| liver | leukemic cell infiltration | <50> 4 | <50> 4 | <50> 4 | <50> 3 |
| | metastasis:uterus tumor | 0 | 0 | 0 | 2 |

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

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 4

| Group Name | | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|-------------------------|--|---------|----------|-----------|-----------|
| No. of Animals on Study | | 50 | 50 | 50 | 50 |
| Organ | Findings | | | | |
| (Digestive system) | | | | | |
| liver | | <50> | <50> | <50> | <50> |
| | metastasis:ovary tumor | 1 | 0 | 0 | 0 |
| pancreas | | <50> | <50> | <50> | <50> |
| | leukemic cell infiltration | 1 | 0 | 0 | 0 |
| | metastasis:uterus tumor | 0 | 0 | 1 | 1 |
| | metastasis:ovary tumor | 1 | 0 | 0 | 0 |
| (Urinary system) | | | | | |
| kidney | | <50> | <50> | <50> | <50> |
| | leukemic cell infiltration | 2 | 2 | 3 | 2 |
| urin bladd | | <50> | <50> | <50> | <50> |
| | leukemic cell infiltration | 1 | 0 | 0 | 0 |
| (Endocrine system) | | | | | |
| adrenal | | <50> | <50> | <50> | <50> |
| | leukemic cell infiltration | 0 | 0 | 0 | 1 |
| | metastasis:kidney tumor | 0 | 0 | 1 | 0 |
| (Reproductive system) | | | | | |
| uterus | | <50> | <50> | <50> | <50> |
| | leukemic cell infiltration | 1 | 0 | 0 | 0 |
| | metastasis:ovary tumor | 1 | 0 | 0 | 0 |
| (Nervous system) | | | | | |
| brain | | <50> | <50> | <50> | <50> |
| | metastasis:pituitary tumor | 0 | 0 | 1 | 0 |
| | | | | | |
| < a > | a : Number of animals examined at the site | | | | |
| b | b : Number of animals with lesion | | | | |

STUDY NO. : 0612
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 5

| Organ | Findings | Group Name No. of Animals on Study | Control 50 | 3300 ppm 50 | 10000 ppm 50 | 30000 ppm 50 |
|---|----------------------------|---------------------------------------|---------------|----------------|-----------------|-----------------|
| (Nervous system) | | | | | | |
| spinal cord | | | <50> | <50> | <50> | <50> |
| | leukemic cell infiltration | | 0 | 1 | 1 | 0 |
| (Musculoskeletal system) | | | | | | |
| muscle | | | <50> | <50> | <50> | <50> |
| | metastasis:subcutis tumor | | 0 | 0 | 1 | 0 |
| (Body cavities) | | | | | | |
| peritoneum | | | <50> | <50> | <50> | <50> |
| | metastasis:uterus tumor | | 0 | 0 | 1 | 1 |
| | metastasis:ovary tumor | | 1 | 0 | 0 | 0 |
| | metastasis:kidney tumor | | 0 | 0 | 1 | 0 |
| < a > a : Number of animals examined at the site b b : Number of animals with lesion | | | | | | |

(JPT150)

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TABLE R

HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC
LESIONS IN JAPAN BIOASSAY RESEARCH CENTER:
F344/DuCr1Cr1j MALE RATS

TABLE R HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC LESIONS
IN JAPAN BIOASSAY RESEARCH CENTER : F344/DuCr1Cr1j MALE RATS

| Organs Tumors | No. of animals examined | No. of animals bearing tumor | Incidence (%) | Min. - Max. (%) |
|----------------------------|----------------------------|---------------------------------|------------------|--------------------|
| Peritoneum Mesothelioma | 2399 | 63 | 2.6 | 0 - 8 |

48 carcinogenicity studies examined in Japan Bioassay Research Center were used.

Study No. : 0043, 0059, 0061, 0063, 0065, 0067, 0095, 0104, 0115, 0130, 0141, 0158, 0162, 0189,
0205, 0210, 0224, 0242, 0246, 0267, 0269, 0278, 0284, 0288, 0294, 0296, 0318, 0328,
0342, 0347, 0365, 0371, 0396, 0399, 0401, 0407, 0417, 0421, 0437, 0448, 0457, 0461,
0497, 0535, 0560, 0579, 0581, 0610

TABLE S 1

CAUSE OF DEATH: MALE

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
SEX : MALE

COUSE OF DEATH (SUMMARY)
(0-105W)

PAGE : 1

| Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|------------------------------------|---------|----------|-----------|-----------|
| Number of Dead and Moribund Animal | 10 | 15 | 11 | 10 |
| no microscop confirm | 1 | 5 | 0 | 1 |
| chronic nephropathy | 1 | 0 | 0 | 0 |
| peritonitis | 1 | 0 | 0 | 0 |
| tumor d:leukemia | 1 | 2 | 2 | 1 |
| tumor d:subcutis | 1 | 1 | 1 | 1 |
| tumor d:pancreas | 0 | 1 | 0 | 0 |
| tumor d:urin bladd | 0 | 0 | 1 | 0 |
| tumor d:pituitary | 4 | 5 | 3 | 3 |
| tumor d:thyroid | 0 | 0 | 0 | 1 |
| tumor d:adrenal | 0 | 0 | 0 | 1 |
| tumor d:periph nerv | 1 | 0 | 0 | 0 |
| tumor d:Zymbal gl | 0 | 0 | 2 | 0 |
| tumor d:bone | 0 | 1 | 0 | 0 |
| tumor d:pleura | 0 | 0 | 0 | 1 |
| tumor d:peritoneum | 0 | 0 | 1 | 1 |
| tumor d:adipose | 0 | 0 | 1 | 0 |

(BI0120)

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TABLE S 2

CAUSE OF DEATH: FEMALE

STUDY NO. : 0612
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
SEX : FEMALE

COUSE OF DEATH (SUMMARY)
(0-105W)

PAGE : 2

| Group Name | Control | 3300 ppm | 10000 ppm | 30000 ppm |
|------------------------------------|---------|----------|-----------|-----------|
| Number of Dead and Moribund Animal | 15 | 11 | 6 | 11 |
| no microscop confirm | 4 | 3 | 1 | 2 |
| tumor d:leukemia | 3 | 3 | 3 | 3 |
| tumor d:subcutis | 0 | 1 | 0 | 1 |
| tumor d:oral cavity | 0 | 0 | 1 | 0 |
| tumor d:pituitary | 3 | 0 | 0 | 2 |
| tumor d:ovary | 1 | 0 | 0 | 0 |
| tumor d:uterus | 3 | 2 | 1 | 3 |
| tumor d:mammary gl | 0 | 2 | 0 | 0 |
| tumor d:retroperit | 1 | 0 | 0 | 0 |

(B10120)

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