

アクリル酸メチルのラットを用いた吸入による13週間毒性試験報告書

試験番号：0803

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TABLE A

**CONCENTRATIONS OF METHYL ACRYLATE
IN THE INHALATION CHAMBER
OF THE 13-WEEK INHALATION STUDY**

CONCENTRATIONS OF METHYL ACRYLATE IN THE INHALATION
CHAMBER OF THE 13-WEEK INHALATION STUDY

| Group Name | Concentration(ppm) Mean \pm S.D. |
|------------|---------------------------------------|
| Control | 0.00 \pm 0.00 |
| 12.5 ppm | 12.51 \pm 0.12 |
| 25 ppm | 24.99 \pm 0.28 |
| 50 ppm | 50.04 \pm 0.53 |
| 100 ppm | 100.01 \pm 0.70 |
| 200 ppm | 199.86 \pm 1.74 |

TABLE B1

SURVIVAL ANIMAL NUMBERS : MALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]
 REPORT TYPE : A1 13
 SEX : MALE

SURVIVAL ANIMAL NUMBERS

| Group Name | Animals At start | Administration (Weeks) | | | | | | | | | | | | | |
|------------|---------------------|---|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| | | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| Control | 10 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 |
| 12.5ppm | 10 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 |
| 25ppm | 10 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 |
| 50ppm | 10 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 |
| 100ppm | 10 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 |
| 200ppm | 10 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 |
| | | Number of survival/ Number of effective animals Survival rate(%) | | | | | | | | | | | | | |

TABLE B2

SURVIVAL ANIMAL NUMBERS : FEMALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]
 REPORT TYPE : A1 13
 SEX : FEMALE

SURVIVAL ANIMAL NUMBERS

| Group Name | Animals At start | Administration (Weeks) | | | | | | | | | | | | | |
|------------|---------------------|---|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| | | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| Control | 10 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 |
| 12.5ppm | 10 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 |
| 25ppm | 10 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 |
| 50ppm | 10 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 |
| 100ppm | 10 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 |
| 200ppm | 10 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 | 10/10 100.0 |
| | | Number of survival/ Number of effective animals Survival rate(%) | | | | | | | | | | | | | |

TABLE C1

CLINICAL OBSERVATION : MALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]
 REPORT TYPE : A1 13

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 |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12.5ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 25ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 50ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 100ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 200ppm | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| NON REMARKABLE | Control | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| | 12.5ppm | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| | 25ppm | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| | 50ppm | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| | 100ppm | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| | 200ppm | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |

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TABLE C2

CLINICAL OBSERVATION : FEMALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

| Clinical sign | Group Name | Administration Week-day | | | 4-7 | 5-7 | 6-7 | 7-7 | 8-7 | 9-7 | 10-7 | 11-7 | 12-7 | 13-7 |
|-----------------|------------|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|
| | | 1-7 | 2-7 | 3-7 | | | | | | | | | | |
| CORNEAL OPACITY | Control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 12.5ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 25ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 50ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 100ppm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 200ppm | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NON REMARKABLE | Control | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| | 12.5ppm | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| | 25ppm | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| | 50ppm | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| | 100ppm | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| | 200ppm | 8 | 9 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |

TABLE D1

**BODY WEIGHT CHANGES AND SURVIVAL ANIMAL
NUMBERS : MALE**

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

MEAN BODY WEIGHTS AND SURVIVAL

| Week on Study | Control | | 12.5ppm | | | 25ppm | | | 50ppm | | | 100ppm | | | 200ppm | | |
|---------------|----------|---------------------|----------|-----------------|----------------|----------|-----------------|----------------|----------|-----------------|----------------|----------|-----------------|----------------|----------|-----------------|----------------|
| | Av. Wt. | No. of Surviv. <10> | Av. Wt. | % of cont. <10> | No. of Surviv. | Av. Wt. | % of cont. <10> | No. of Surviv. | Av. Wt. | % of cont. <10> | No. of Surviv. | Av. Wt. | % of cont. <10> | No. of Surviv. | Av. Wt. | % of cont. <10> | No. of Surviv. |
| 0 | 119 (10) | 10/10 | 119 (10) | 100 | 10/10 | 119 (10) | 100 | 10/10 | 119 (10) | 100 | 10/10 | 119 (10) | 100 | 10/10 | 119 (10) | 100 | 10/10 |
| 1 | 152 (10) | 10/10 | 153 (10) | 101 | 10/10 | 153 (10) | 101 | 10/10 | 151 (10) | 99 | 10/10 | 147 (10) | 97 | 10/10 | 136 (10) | 89 | 10/10 |
| 2 | 186 (10) | 10/10 | 186 (10) | 100 | 10/10 | 186 (10) | 100 | 10/10 | 185 (10) | 99 | 10/10 | 179 (10) | 96 | 10/10 | 161 (10) | 87 | 10/10 |
| 3 | 211 (10) | 10/10 | 214 (10) | 101 | 10/10 | 213 (10) | 101 | 10/10 | 210 (10) | 100 | 10/10 | 205 (10) | 97 | 10/10 | 179 (10) | 85 | 10/10 |
| 4 | 226 (10) | 10/10 | 226 (10) | 100 | 10/10 | 228 (10) | 101 | 10/10 | 226 (10) | 100 | 10/10 | 220 (10) | 97 | 10/10 | 189 (10) | 84 | 10/10 |
| 5 | 246 (10) | 10/10 | 247 (10) | 100 | 10/10 | 250 (10) | 102 | 10/10 | 248 (10) | 101 | 10/10 | 239 (10) | 97 | 10/10 | 208 (10) | 85 | 10/10 |
| 6 | 259 (10) | 10/10 | 259 (10) | 100 | 10/10 | 263 (10) | 102 | 10/10 | 261 (10) | 101 | 10/10 | 253 (10) | 98 | 10/10 | 219 (10) | 85 | 10/10 |
| 7 | 270 (10) | 10/10 | 271 (10) | 100 | 10/10 | 277 (10) | 103 | 10/10 | 274 (10) | 101 | 10/10 | 265 (10) | 98 | 10/10 | 227 (10) | 84 | 10/10 |
| 8 | 282 (10) | 10/10 | 281 (10) | 100 | 10/10 | 290 (10) | 103 | 10/10 | 284 (10) | 101 | 10/10 | 273 (10) | 97 | 10/10 | 238 (10) | 84 | 10/10 |
| 9 | 292 (10) | 10/10 | 290 (10) | 99 | 10/10 | 300 (10) | 103 | 10/10 | 293 (10) | 100 | 10/10 | 282 (10) | 97 | 10/10 | 246 (10) | 84 | 10/10 |
| 10 | 295 (10) | 10/10 | 293 (10) | 99 | 10/10 | 303 (10) | 103 | 10/10 | 298 (10) | 101 | 10/10 | 287 (10) | 97 | 10/10 | 251 (10) | 85 | 10/10 |
| 11 | 302 (10) | 10/10 | 301 (10) | 100 | 10/10 | 309 (10) | 102 | 10/10 | 304 (10) | 101 | 10/10 | 292 (10) | 97 | 10/10 | 259 (10) | 86 | 10/10 |
| 12 | 309 (10) | 10/10 | 306 (10) | 99 | 10/10 | 318 (10) | 103 | 10/10 | 312 (10) | 101 | 10/10 | 297 (10) | 96 | 10/10 | 260 (10) | 84 | 10/10 |
| 13 | 315 (10) | 10/10 | 310 (10) | 98 | 10/10 | 321 (10) | 102 | 10/10 | 318 (10) | 101 | 10/10 | 304 (10) | 97 | 10/10 | 267 (10) | 85 | 10/10 |

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

TABLE D2

**BODY WEIGHT CHANGES AND SURVIVAL ANIMAL
NUMBERS : FEMALE**

STUDY NO. : 0803
ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

MEAN BODY WEIGHTS AND SURVIVAL

| Week on Study | Control | | 12.5ppm | | 25ppm | | 50ppm | | 100ppm | | 200ppm | | | | | | |
|------------------|----------|---------------------------|----------|-----------------------|-------------------|----------|-----------------------|-------------------|----------|-----------------------|-------------------|----------|-----------------------|-------------------|----------|-----|-------|
| | Av. Wt. | No. of Surviv. <10> | Av. Wt. | % of cont. <10> | No. of Surviv. | Av. Wt. | % of cont. <10> | No. of Surviv. | Av. Wt. | % of cont. <10> | No. of Surviv. | Av. Wt. | % of cont. <10> | No. of Surviv. | | | |
| 0 | 94 (10) | 10/10 | 94 (10) | 100 | 10/10 | 94 (10) | 100 | 10/10 | 94 (10) | 100 | 10/10 | 94 (10) | 100 | 10/10 | 94 (10) | 100 | 10/10 |
| 1 | 110 (10) | 10/10 | 112 (10) | 102 | 10/10 | 111 (10) | 101 | 10/10 | 109 (10) | 99 | 10/10 | 108 (10) | 98 | 10/10 | 102 (10) | 93 | 10/10 |
| 2 | 125 (10) | 10/10 | 126 (10) | 101 | 10/10 | 125 (10) | 100 | 10/10 | 123 (10) | 98 | 10/10 | 121 (10) | 97 | 10/10 | 113 (10) | 90 | 10/10 |
| 3 | 136 (10) | 10/10 | 135 (10) | 99 | 10/10 | 135 (10) | 99 | 10/10 | 132 (10) | 97 | 10/10 | 131 (10) | 96 | 10/10 | 121 (10) | 89 | 10/10 |
| 4 | 139 (10) | 10/10 | 136 (10) | 98 | 10/10 | 139 (10) | 100 | 10/10 | 137 (10) | 99 | 10/10 | 134 (10) | 96 | 10/10 | 124 (10) | 89 | 10/10 |
| 5 | 151 (10) | 10/10 | 147 (10) | 97 | 10/10 | 149 (10) | 99 | 10/10 | 148 (10) | 98 | 10/10 | 145 (10) | 96 | 10/10 | 133 (10) | 88 | 10/10 |
| 6 | 157 (10) | 10/10 | 150 (10) | 96 | 10/10 | 154 (10) | 98 | 10/10 | 151 (10) | 96 | 10/10 | 149 (10) | 95 | 10/10 | 138 (10) | 88 | 10/10 |
| 7 | 160 (10) | 10/10 | 157 (10) | 98 | 10/10 | 159 (10) | 99 | 10/10 | 157 (10) | 98 | 10/10 | 153 (10) | 96 | 10/10 | 142 (10) | 89 | 10/10 |
| 8 | 164 (10) | 10/10 | 159 (10) | 97 | 10/10 | 163 (10) | 99 | 10/10 | 160 (10) | 98 | 10/10 | 157 (10) | 96 | 10/10 | 147 (10) | 90 | 10/10 |
| 9 | 167 (10) | 10/10 | 162 (10) | 97 | 10/10 | 166 (10) | 99 | 10/10 | 164 (10) | 98 | 10/10 | 163 (10) | 98 | 10/10 | 149 (10) | 89 | 10/10 |
| 10 | 169 (10) | 10/10 | 164 (10) | 97 | 10/10 | 169 (10) | 100 | 10/10 | 166 (10) | 98 | 10/10 | 164 (10) | 97 | 10/10 | 153 (10) | 91 | 10/10 |
| 11 | 173 (10) | 10/10 | 166 (10) | 96 | 10/10 | 173 (10) | 100 | 10/10 | 168 (10) | 97 | 10/10 | 168 (10) | 97 | 10/10 | 156 (10) | 90 | 10/10 |
| 12 | 175 (10) | 10/10 | 169 (10) | 97 | 10/10 | 177 (10) | 101 | 10/10 | 172 (10) | 98 | 10/10 | 170 (10) | 97 | 10/10 | 159 (10) | 91 | 10/10 |
| 13 | 177 (10) | 10/10 | 171 (10) | 97 | 10/10 | 179 (10) | 101 | 10/10 | 172 (10) | 97 | 10/10 | 175 (10) | 99 | 10/10 | 162 (10) | 92 | 10/10 |

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

TABLE D3

BODY WEIGHT CHANGES : MALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

| Group Name | Administration week | | 1 | | 2 | | 3 | | 4 | | 5 | | 6 | |
|------------|---------------------|--|-----------|--|-----------|--|-----------|--|-----------|--|-----------|--|-----------|--|
| | 0 | | | | | | | | | | | | | |
| Control | 119 ± 4 | | 152 ± 5 | | 186 ± 5 | | 211 ± 7 | | 226 ± 7 | | 246 ± 8 | | 259 ± 9 | |
| 12.5ppm | 119 ± 4 | | 153 ± 5 | | 186 ± 5 | | 214 ± 5 | | 226 ± 6 | | 247 ± 6 | | 259 ± 7 | |
| 25ppm | 119 ± 4 | | 153 ± 5 | | 186 ± 4 | | 213 ± 5 | | 228 ± 6 | | 250 ± 5 | | 263 ± 7 | |
| 50ppm | 119 ± 4 | | 151 ± 5 | | 185 ± 7 | | 210 ± 7 | | 226 ± 9 | | 248 ± 9 | | 261 ± 12 | |
| 100ppm | 119 ± 4 | | 147 ± 6 | | 179 ± 5* | | 205 ± 7 | | 220 ± 7 | | 239 ± 7 | | 253 ± 8 | |
| 200ppm | 119 ± 4 | | 136 ± 6** | | 161 ± 6** | | 179 ± 8** | | 189 ± 7** | | 208 ± 8** | | 219 ± 7** | |

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

Test of Dunnett

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrjCrj [F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

| Group Name | Administration week | | 7 | | 8 | | 9 | | 10 | | 11 | | 12 | | 13 | |
|------------|---------------------|-----|------------|-----|------------|-----|------------|------|------------|-----|------------|------|------------|------|------------|---|
| | Weight (g) | n | Weight (g) | n | Weight (g) | n | Weight (g) | n | Weight (g) | n | Weight (g) | n | Weight (g) | n | Weight (g) | n |
| Control | 270 ± | 8 | 282 ± | 9 | 292 ± | 8 | 295 ± | 8 | 302 ± | 7 | 309 ± | 7 | 315 ± | 10 | | |
| 12.5ppm | 271 ± | 8 | 281 ± | 9 | 290 ± | 10 | 293 ± | 10 | 301 ± | 13 | 306 ± | 12 | 310 ± | 12 | | |
| 25ppm | 277 ± | 6 | 290 ± | 8 | 300 ± | 11 | 303 ± | 10 | 309 ± | 10 | 318 ± | 12 | 321 ± | 12 | | |
| 50ppm | 274 ± | 13 | 284 ± | 13 | 293 ± | 14 | 298 ± | 14 | 304 ± | 15 | 312 ± | 15 | 318 ± | 17 | | |
| 100ppm | 265 ± | 9 | 273 ± | 6 | 282 ± | 7 | 287 ± | 9 | 292 ± | 9 | 297 ± | 9 | 304 ± | 9 | | |
| 200ppm | 227 ± | 8** | 238 ± | 9** | 246 ± | 9** | 251 ± | 10** | 259 ± | 9** | 260 ± | 10** | 267 ± | 10** | | |

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

Test of Dunnett

TABLE D4

BODY WEIGHT CHANGES : FEMALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

| Group Name | Administration week | | 1 | | 2 | | 3 | | 4 | | 5 | | 6 | |
|------------|---------------------|--|-----------|--|-----------|--|-----------|--|-----------|--|-----------|--|-----------|--|
| | 0 | | | | | | | | | | | | | |
| Control | 94 ± 4 | | 110 ± 5 | | 125 ± 6 | | 136 ± 6 | | 139 ± 8 | | 151 ± 8 | | 157 ± 9 | |
| 12.5ppm | 94 ± 4 | | 112 ± 5 | | 126 ± 6 | | 135 ± 7 | | 136 ± 7 | | 147 ± 6 | | 150 ± 8 | |
| 25ppm | 94 ± 4 | | 111 ± 3 | | 125 ± 3 | | 135 ± 3 | | 139 ± 3 | | 149 ± 4 | | 154 ± 4 | |
| 50ppm | 94 ± 4 | | 109 ± 3 | | 123 ± 2 | | 132 ± 2 | | 137 ± 3 | | 148 ± 3 | | 151 ± 3 | |
| 100ppm | 94 ± 4 | | 108 ± 4 | | 121 ± 3 | | 131 ± 5 | | 134 ± 5 | | 145 ± 7 | | 149 ± 7 | |
| 200ppm | 94 ± 4 | | 102 ± 4** | | 113 ± 4** | | 121 ± 5** | | 124 ± 5** | | 133 ± 6** | | 138 ± 5** | |

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

Test of Dunnett

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrIj [F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

| Group Name | Administration week | | 7 | | 8 | | 9 | | 10 | | 11 | | 12 | | 13 | |
|------------|---------------------|-----|-------|-----|-------|-----|-------|-----|-------|-----|-------|-----|-------|-----|----|--|
| | | | | | | | | | | | | | | | | |
| Control | 160 ± | 11 | 164 ± | 10 | 167 ± | 12 | 169 ± | 11 | 173 ± | 10 | 175 ± | 11 | 177 ± | 11 | | |
| 12.5ppm | 157 ± | 8 | 159 ± | 8 | 162 ± | 9 | 164 ± | 9 | 166 ± | 9 | 169 ± | 9 | 171 ± | 9 | | |
| 25ppm | 159 ± | 5 | 163 ± | 5 | 166 ± | 6 | 169 ± | 7 | 173 ± | 7 | 177 ± | 6 | 179 ± | 7 | | |
| 50ppm | 157 ± | 4 | 160 ± | 3 | 164 ± | 5 | 166 ± | 4 | 168 ± | 5 | 172 ± | 5 | 172 ± | 5 | | |
| 100ppm | 153 ± | 7 | 157 ± | 8 | 163 ± | 10 | 164 ± | 10 | 168 ± | 9 | 170 ± | 9 | 175 ± | 10 | | |
| 200ppm | 142 ± | 6** | 147 ± | 7** | 149 ± | 6** | 153 ± | 6** | 156 ± | 6** | 159 ± | 7** | 162 ± | 6** | | |

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

Test of Dunnett

TABLE E1

**FOOD CONSUMPTION CHANGES AND SURVIVAL ANIMAL
NUMBERS : MALE**

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrIj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

MEAN FOOD CONSUMPTION (FC) AND SURVIVAL

| Week on Study | Control | | 12.5ppm | | | 25ppm | | | 50ppm | | | 100ppm | | | 200ppm | | |
|------------------|-----------|---------------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|
| | Av. FC. | No. of Surviv. <10> | Av. FC. | % of cont. <10> | No. of Surviv. | Av. FC. | % of cont. <10> | No. of Surviv. | Av. FC. | % of cont. <10> | No. of Surviv. | Av. FC. | % of cont. <10> | No. of Surviv. | Av. FC. | % of cont. <10> | No. of Surviv. |
| 1 | 14.7 (10) | 10/10 | 14.9 (10) | 101 | 10/10 | 15.0 (10) | 102 | 10/10 | 14.3 (10) | 97 | 10/10 | 13.3 (10) | 90 | 10/10 | 11.4 (10) | 78 | 10/10 |
| 2 | 16.7 (10) | 10/10 | 16.6 (10) | 99 | 10/10 | 16.5 (10) | 99 | 10/10 | 16.6 (10) | 99 | 10/10 | 15.2 (10) | 91 | 10/10 | 13.6 (10) | 81 | 10/10 |
| 3 | 17.1 (10) | 10/10 | 17.4 (10) | 102 | 10/10 | 17.0 (10) | 99 | 10/10 | 16.8 (10) | 98 | 10/10 | 16.1 (10) | 94 | 10/10 | 13.5 (10) | 79 | 10/10 |
| 4 | 17.4 (10) | 10/10 | 17.5 (10) | 101 | 10/10 | 16.7 (10) | 96 | 10/10 | 17.1 (10) | 98 | 10/10 | 16.2 (10) | 93 | 10/10 | 14.3 (10) | 82 | 10/10 |
| 5 | 17.0 (10) | 10/10 | 16.9 (10) | 99 | 10/10 | 17.0 (10) | 100 | 10/10 | 17.4 (10) | 102 | 10/10 | 16.4 (10) | 96 | 10/10 | 14.8 (10) | 87 | 10/10 |
| 6 | 16.7 (10) | 10/10 | 16.7 (10) | 100 | 10/10 | 16.8 (10) | 101 | 10/10 | 17.0 (10) | 102 | 10/10 | 16.0 (10) | 96 | 10/10 | 14.5 (10) | 87 | 10/10 |
| 7 | 16.7 (10) | 10/10 | 17.1 (10) | 102 | 10/10 | 16.9 (10) | 101 | 10/10 | 17.0 (10) | 102 | 10/10 | 16.3 (10) | 98 | 10/10 | 14.8 (10) | 89 | 10/10 |
| 8 | 17.2 (10) | 10/10 | 16.7 (10) | 97 | 10/10 | 16.9 (10) | 98 | 10/10 | 17.2 (10) | 100 | 10/10 | 16.1 (10) | 94 | 10/10 | 14.6 (10) | 85 | 10/10 |
| 9 | 17.0 (10) | 10/10 | 16.4 (10) | 96 | 10/10 | 16.8 (10) | 99 | 10/10 | 16.8 (10) | 99 | 10/10 | 15.9 (10) | 94 | 10/10 | 14.7 (10) | 86 | 10/10 |
| 10 | 16.3 (10) | 10/10 | 16.0 (10) | 98 | 10/10 | 16.5 (10) | 101 | 10/10 | 16.6 (10) | 102 | 10/10 | 15.7 (10) | 96 | 10/10 | 15.0 (10) | 92 | 10/10 |
| 11 | 16.4 (10) | 10/10 | 16.3 (10) | 99 | 10/10 | 16.3 (10) | 99 | 10/10 | 16.4 (10) | 100 | 10/10 | 16.0 (10) | 98 | 10/10 | 15.3 (10) | 93 | 10/10 |
| 12 | 16.1 (10) | 10/10 | 15.5 (10) | 96 | 10/10 | 15.9 (10) | 99 | 10/10 | 16.0 (10) | 99 | 10/10 | 15.2 (10) | 94 | 10/10 | 14.4 (10) | 89 | 10/10 |
| 13 | 15.5 (10) | 10/10 | 15.5 (10) | 100 | 10/10 | 15.8 (10) | 102 | 10/10 | 16.0 (10) | 103 | 10/10 | 15.0 (10) | 97 | 10/10 | 13.9 (10) | 90 | 10/10 |

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

TABLE E2

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

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

MEAN FOOD CONSUMPTION (FC) AND SURVIVAL

| Week on Study | Control | | 12.5ppm | | | 25ppm | | | 50ppm | | | 100ppm | | | 200ppm | | |
|------------------|-----------|---------------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|
| | Av. FC. | No. of Surviv. <10> | Av. FC. | % of cont. <10> | No. of Surviv. | Av. FC. | % of cont. <10> | No. of Surviv. | Av. FC. | % of cont. <10> | No. of Surviv. | Av. FC. | % of cont. <10> | No. of Surviv. | Av. FC. | % of cont. <10> | No. of Surviv. |
| 1 | 11.3 (10) | 10/10 | 11.4 (10) | 101 | 10/10 | 11.1 (10) | 98 | 10/10 | 10.8 (10) | 96 | 10/10 | 10.3 (10) | 91 | 10/10 | 9.2 (10) | 81 | 10/10 |
| 2 | 11.7 (10) | 10/10 | 12.0 (10) | 103 | 10/10 | 11.5 (10) | 98 | 10/10 | 11.4 (10) | 97 | 10/10 | 11.1 (10) | 95 | 10/10 | 10.3 (10) | 88 | 10/10 |
| 3 | 11.6 (10) | 10/10 | 11.4 (10) | 98 | 10/10 | 11.1 (10) | 96 | 10/10 | 10.8 (10) | 93 | 10/10 | 10.9 (10) | 94 | 10/10 | 9.5 (10) | 82 | 10/10 |
| 4 | 11.3 (10) | 10/10 | 10.9 (10) | 96 | 10/10 | 10.9 (10) | 96 | 10/10 | 10.7 (10) | 95 | 10/10 | 10.6 (10) | 94 | 10/10 | 9.8 (10) | 87 | 10/10 |
| 5 | 11.4 (10) | 10/10 | 11.0 (10) | 96 | 10/10 | 11.4 (10) | 100 | 10/10 | 11.2 (10) | 98 | 10/10 | 10.8 (10) | 95 | 10/10 | 10.1 (10) | 89 | 10/10 |
| 6 | 11.0 (10) | 10/10 | 10.9 (10) | 99 | 10/10 | 11.2 (10) | 102 | 10/10 | 10.8 (10) | 98 | 10/10 | 10.5 (10) | 95 | 10/10 | 9.6 (10) | 87 | 10/10 |
| 7 | 11.2 (10) | 10/10 | 11.0 (10) | 98 | 10/10 | 11.0 (10) | 98 | 10/10 | 10.8 (10) | 96 | 10/10 | 10.4 (10) | 93 | 10/10 | 10.1 (10) | 90 | 10/10 |
| 8 | 10.9 (10) | 10/10 | 10.7 (10) | 98 | 10/10 | 11.1 (10) | 102 | 10/10 | 10.5 (10) | 96 | 10/10 | 10.2 (10) | 94 | 10/10 | 9.7 (10) | 89 | 10/10 |
| 9 | 10.9 (10) | 10/10 | 10.8 (10) | 99 | 10/10 | 11.0 (10) | 101 | 10/10 | 10.9 (10) | 100 | 10/10 | 10.9 (10) | 100 | 10/10 | 10.1 (10) | 93 | 10/10 |
| 10 | 10.9 (10) | 10/10 | 10.5 (10) | 96 | 10/10 | 11.1 (10) | 102 | 10/10 | 10.5 (10) | 96 | 10/10 | 10.7 (10) | 98 | 10/10 | 10.3 (10) | 94 | 10/10 |
| 11 | 10.7 (10) | 10/10 | 10.1 (10) | 94 | 10/10 | 10.9 (10) | 102 | 10/10 | 10.3 (10) | 96 | 10/10 | 10.6 (10) | 99 | 10/10 | 10.5 (10) | 98 | 10/10 |
| 12 | 10.8 (10) | 10/10 | 10.7 (10) | 99 | 10/10 | 11.1 (10) | 103 | 10/10 | 10.8 (10) | 100 | 10/10 | 10.6 (10) | 98 | 10/10 | 10.4 (10) | 96 | 10/10 |
| 13 | 10.5 (10) | 10/10 | 10.4 (10) | 99 | 10/10 | 10.6 (10) | 101 | 10/10 | 10.1 (10) | 96 | 10/10 | 10.3 (10) | 98 | 10/10 | 10.2 (10) | 97 | 10/10 |

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

TABLE E3

FOOD CONSUMPTION CHANGES : MALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

| Group Name | Administration week | | | | | | |
|------------|---------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Control | 14.7± 0.6 | 16.7± 0.9 | 17.1± 0.7 | 17.4± 0.9 | 17.0± 0.8 | 16.7± 1.0 | 16.7± 1.1 |
| 12.5ppm | 14.9± 0.6 | 16.6± 0.6 | 17.4± 0.6 | 17.5± 0.9 | 16.9± 1.0 | 16.7± 0.9 | 17.1± 1.1 |
| 25ppm | 15.0± 1.0 | 16.5± 0.8 | 17.0± 1.0 | 16.7± 0.5 | 17.0± 0.5 | 16.8± 0.7 | 16.9± 0.7 |
| 50ppm | 14.3± 0.6 | 16.6± 0.8 | 16.8± 0.8 | 17.1± 0.8 | 17.4± 0.8 | 17.0± 0.9 | 17.0± 1.0 |
| 100ppm | 13.3± 0.6** | 15.2± 0.6** | 16.1± 0.4* | 16.2± 0.6** | 16.4± 0.7 | 16.0± 0.7 | 16.3± 0.5 |
| 200ppm | 11.4± 0.7** | 13.6± 0.9** | 13.5± 0.9** | 14.3± 1.0** | 14.8± 0.6** | 14.5± 0.7** | 14.8± 0.7** |

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

Test of Dunnett

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

| Group Name | Administration week | | | | | |
|------------|---------------------|-------------|-------------|-------------|-------------|-------------|
| | 8 | 9 | 10 | 11 | 12 | 13 |
| Control | 17.2± 0.9 | 17.0± 0.5 | 16.3± 0.5 | 16.4± 0.6 | 16.1± 0.6 | 15.5± 0.5 |
| 12.5ppm | 16.7± 1.4 | 16.4± 1.4 | 16.0± 1.1 | 16.3± 1.0 | 15.5± 1.1 | 15.5± 1.1 |
| 25ppm | 16.9± 0.6 | 16.8± 0.5 | 16.5± 0.5 | 16.3± 0.5 | 15.9± 0.6 | 15.8± 0.4 |
| 50ppm | 17.2± 1.2 | 16.8± 1.1 | 16.6± 1.0 | 16.4± 0.9 | 16.0± 0.8 | 16.0± 0.8 |
| 100ppm | 16.1± 0.5** | 15.9± 0.5** | 15.7± 0.5 | 16.0± 0.7 | 15.2± 0.7 | 15.0± 0.7 |
| 200ppm | 14.6± 0.5** | 14.7± 0.7** | 15.0± 0.4** | 15.3± 0.5** | 14.4± 0.6** | 13.9± 0.7** |

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

Test of Dunnett

TABLE E4

FOOD CONSUMPTION CHANGES : FEMALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

| Group Name | Administration week | | | | | | |
|------------|---------------------|--------------|-------------|--------------|--------------|-------------|--------------|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Control | 11.3 ± 0.6 | 11.7 ± 0.5 | 11.6 ± 0.7 | 11.3 ± 0.6 | 11.4 ± 0.5 | 11.0 ± 0.6 | 11.2 ± 1.0 |
| 12.5ppm | 11.4 ± 0.7 | 12.0 ± 0.6 | 11.4 ± 1.1 | 10.9 ± 0.5 | 11.0 ± 0.8 | 10.9 ± 1.0 | 11.0 ± 1.0 |
| 25ppm | 11.1 ± 0.4 | 11.5 ± 0.5 | 11.1 ± 0.4 | 10.9 ± 0.5 | 11.4 ± 0.5 | 11.2 ± 0.6 | 11.0 ± 0.9 |
| 50ppm | 10.8 ± 0.4 | 11.4 ± 0.3 | 10.8 ± 0.5* | 10.7 ± 0.4* | 11.2 ± 0.4 | 10.8 ± 0.4 | 10.8 ± 0.3 |
| 100ppm | 10.3 ± 0.5** | 11.1 ± 0.5* | 10.9 ± 0.7 | 10.6 ± 0.5** | 10.8 ± 0.7 | 10.5 ± 0.5 | 10.4 ± 0.3 |
| 200ppm | 9.2 ± 0.6** | 10.3 ± 0.6** | 9.5 ± 0.4** | 9.8 ± 0.6** | 10.1 ± 0.5** | 9.6 ± 0.4** | 10.1 ± 0.5** |

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

Test of Dunnett

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

| Group Name | Administration week | | | | | |
|------------|---------------------|------------|------------|------------|------------|------------|
| | 8 | 9 | 10 | 11 | 12 | 13 |
| Control | 10.9 ± 0.9 | 10.9 ± 0.8 | 10.9 ± 1.0 | 10.7 ± 0.3 | 10.8 ± 0.6 | 10.5 ± 0.7 |
| 12.5ppm | 10.7 ± 0.8 | 10.8 ± 0.9 | 10.5 ± 0.8 | 10.1 ± 0.6 | 10.7 ± 0.7 | 10.4 ± 0.6 |
| 25ppm | 11.1 ± 0.7 | 11.0 ± 0.8 | 11.1 ± 0.9 | 10.9 ± 0.7 | 11.1 ± 0.6 | 10.6 ± 0.8 |
| 50ppm | 10.5 ± 0.4 | 10.9 ± 0.5 | 10.5 ± 0.4 | 10.3 ± 0.8 | 10.8 ± 0.7 | 10.1 ± 0.5 |
| 100ppm | 10.2 ± 0.6 | 10.9 ± 0.7 | 10.7 ± 0.6 | 10.6 ± 0.6 | 10.6 ± 0.8 | 10.3 ± 0.7 |
| 200ppm | 9.7 ± 0.5** | 10.1 ± 0.7 | 10.3 ± 0.5 | 10.5 ± 0.6 | 10.4 ± 0.6 | 10.2 ± 0.7 |

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

Test of Dunnett

TABLE F1

HEMATOLOGY : MALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 MEASURE TIME : 1
 SEX : MALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

| Group Name | NO. of Animals | RED BLOOD CELL 10 ⁶ /μl | | HEMOGLOBIN g/dl | | HEMATOCRIT % | | MCV fl | | MCH pg | | MCHC g/dl | | PLATELET 10 ⁹ /μl | |
|------------|----------------|---------------------------------------|------|--------------------|-------|-----------------|------|-----------|-------|-----------|-----|--------------|-----|---------------------------------|----|
| Control | 10 | 9.67± | 0.22 | 15.3± | 0.2 | 45.7± | 0.8 | 47.2± | 0.5 | 15.8± | 0.3 | 33.4± | 0.4 | 799± | 32 |
| 12.5ppm | 10 | 9.75± | 0.21 | 15.2± | 0.2 | 45.8± | 0.8 | 46.9± | 0.6 | 15.5± | 0.4 | 33.1± | 0.7 | 775± | 68 |
| 25ppm | 10 | 9.69± | 0.22 | 15.3± | 0.3 | 45.5± | 1.2 | 46.9± | 0.3 | 15.7± | 0.2 | 33.5± | 0.5 | 803± | 45 |
| 50ppm | 10 | 9.79± | 0.18 | 15.3± | 0.4 | 46.0± | 0.9 | 46.9± | 0.5 | 15.7± | 0.3 | 33.4± | 0.4 | 802± | 35 |
| 100ppm | 10 | 9.71± | 0.16 | 15.3± | 0.2 | 45.6± | 0.4 | 47.0± | 0.6 | 15.7± | 0.2 | 33.5± | 0.3 | 776± | 81 |
| 200ppm | 10 | 9.72± | 0.19 | 15.7± | 0.2** | 46.7± | 0.6* | 48.1± | 0.5** | 16.1± | 0.3 | 33.5± | 0.3 | 778± | 43 |

Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01

Test of Dunnett

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 MEASURE TIME : 1
 SEX : MALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 2

| Group Name | NO. of Animals | RETICULOCYTE % | | PROTHROMBIN TIME sec | | APTT sec | |
|------------|----------------|----------------|------|----------------------|-----|----------|-----|
| Control | 10 | 1.8± | 0.2 | 13.6± | 1.4 | 20.9± | 2.3 |
| 12.5ppm | 10 | 1.7± | 0.2 | 14.7± | 1.4 | 22.0± | 1.6 |
| 25ppm | 10 | 1.8± | 0.2 | 13.9± | 1.3 | 21.1± | 2.0 |
| 50ppm | 10 | 1.8± | 0.2 | 14.1± | 2.7 | 20.5± | 2.6 |
| 100ppm | 10 | 1.8± | 0.1 | 14.7± | 2.3 | 21.8± | 1.7 |
| 200ppm | 10 | 1.6± | 0.1* | 13.7± | 2.1 | 20.4± | 1.6 |

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

Test of Dunnett

(HCL070)

BAIS5

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 MEASURE TIME : 1
 SEX : MALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

| Group Name | NO. of Animals | WBC | | Differential | | WBC (%) | | MONO | EOSINO | BASO | OTHER | | |
|------------|----------------|---------------------|--|--------------|--|---------|--|-------|--------|-------|-------|--|--|
| | | 10 ³ /μℓ | | NEUTRO | | LYMPHO | | | | | | | |
| Control | 10 | 5.32 ± 1.19 | | 25 ± 4 | | 70 ± 4 | | 2 ± 1 | 1 ± 0 | 0 ± 0 | 2 ± 1 | | |
| 12.5ppm | 10 | 5.02 ± 1.43 | | 26 ± 5 | | 69 ± 5 | | 2 ± 0 | 1 ± 1 | 0 ± 0 | 2 ± 1 | | |
| 25ppm | 10 | 4.99 ± 1.20 | | 25 ± 5 | | 70 ± 5 | | 2 ± 1 | 1 ± 0 | 0 ± 0 | 2 ± 1 | | |
| 50ppm | 10 | 5.32 ± 1.09 | | 25 ± 5 | | 71 ± 4 | | 1 ± 1 | 1 ± 0 | 0 ± 0 | 2 ± 1 | | |
| 100ppm | 10 | 5.41 ± 1.41 | | 26 ± 4 | | 69 ± 4 | | 2 ± 0 | 1 ± 0 | 0 ± 0 | 2 ± 1 | | |
| 200ppm | 10 | 5.21 ± 1.00 | | 27 ± 4 | | 69 ± 4 | | 2 ± 1 | 1 ± 1 | 0 ± 0 | 2 ± 1 | | |

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

TABLE F2

HEMATOLOGY : FEMALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrj [F344/DuCrj]
 MEASURE TIME : 1
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

| Group Name | NO. of Animals | RED BLOOD CELL 10 ⁶ /μl | HEMOGLOBIN g/dl | HEMATOCRIT % | MCV fl | MCH pg | MCHC g/dl | PLATELET 10 ⁹ /μl |
|------------|----------------|---------------------------------------|--------------------|-----------------|------------|------------|--------------|---------------------------------|
| Control | 10 | 8.98 ± 0.13 | 15.3 ± 0.3 | 45.0 ± 0.6 | 50.1 ± 0.1 | 17.1 ± 0.4 | 34.1 ± 0.6 | 871 ± 46 |
| 12.5ppm | 10 | 8.95 ± 0.19 | 15.3 ± 0.5 | 45.0 ± 0.9 | 50.4 ± 0.3 | 17.1 ± 0.2 | 34.1 ± 0.4 | 879 ± 50 |
| 25ppm | 10 | 9.04 ± 0.18 | 15.4 ± 0.4 | 45.3 ± 0.9 | 50.2 ± 0.6 | 17.1 ± 0.4 | 34.0 ± 0.5 | 841 ± 43 |
| 50ppm | 10 | 9.04 ± 0.17 | 15.5 ± 0.5 | 45.5 ± 0.9 | 50.4 ± 0.3 | 17.2 ± 0.4 | 34.1 ± 0.6 | 886 ± 47 |
| 100ppm | 10 | 9.03 ± 0.15 | 15.4 ± 0.3 | 45.4 ± 0.7 | 50.2 ± 0.3 | 17.1 ± 0.4 | 34.0 ± 0.7 | 873 ± 27 |
| 200ppm | 10 | 9.19 ± 0.17* | 15.7 ± 0.3 | 46.3 ± 0.9** | 50.4 ± 0.3 | 17.1 ± 0.4 | 34.0 ± 0.8 | 822 ± 41 |

Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01

Test of Dunnett

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]
 MEASURE TIME : 1
 SEX : FEMALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

| Group Name | NO. of Animals | RETICULOCYTE % | | PROTHROMBIN TIME sec | | APTT sec | |
|------------|----------------|----------------|-----|----------------------|-----|----------|-----|
| Control | 10 | 1.7± | 0.2 | 11.8± | 0.4 | 14.2± | 0.5 |
| 12.5ppm | 10 | 1.7± | 0.2 | 11.8± | 0.3 | 13.9± | 1.0 |
| 25ppm | 10 | 1.6± | 0.1 | 11.6± | 0.4 | 14.1± | 1.0 |
| 50ppm | 10 | 1.6± | 0.3 | 11.6± | 0.5 | 13.9± | 0.9 |
| 100ppm | 10 | 1.7± | 0.2 | 12.0± | 0.3 | 14.0± | 0.7 |
| 200ppm | 10 | 1.8± | 0.2 | 12.1± | 0.3 | 13.7± | 0.8 |

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

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrIj]
 MEASURE TIME : 1
 SEX : FEMALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

| Group Name | NO. of Animals | WBC | | Differential | | WBC (%) | | MONO | EOSINO | BASO | OTHER | | | | |
|------------|-------------------|----------------|------|--------------|---|---------|---|------|--------|------|-------|----|---|----|---|
| | | $10^9/\mu\ell$ | | NEUTRO | | LYMPHO | | | | | | | | | |
| Control | 10 | 3.39± | 1.05 | 25± | 4 | 71± | 4 | 2± | 1 | 1± | 0 | 0± | 0 | 2± | 1 |
| 12.5ppm | 10 | 2.83± | 0.62 | 23± | 4 | 72± | 4 | 2± | 1 | 1± | 0 | 0± | 0 | 2± | 1 |
| 25ppm | 10 | 3.19± | 1.31 | 26± | 8 | 69± | 8 | 2± | 0 | 1± | 0 | 0± | 0 | 2± | 1 |
| 50ppm | 10 | 3.53± | 1.07 | 22± | 6 | 73± | 5 | 2± | 0 | 1± | 0 | 0± | 0 | 1± | 1 |
| 100ppm | 10 | 3.78± | 1.32 | 23± | 4 | 72± | 4 | 2± | 0 | 1± | 0 | 0± | 0 | 2± | 1 |
| 200ppm | 10 | 3.83± | 0.73 | 26± | 5 | 69± | 5 | 1± | 1 | 1± | 1 | 0± | 0 | 1± | 1 |

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

TABLE G1

BIOCHEMISTRY : MALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 MEASURE TIME : 1
 SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

| 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 | 10 | 6.5± | 0.2 | 3.8± | 0.1 | 1.4± | 0.1 | 0.04± | 0.01 | 184± | 13 | 65± | 6 | 48± | 18 |
| 12.5ppm | 10 | 6.4± | 0.2 | 3.7± | 0.1 | 1.4± | 0.0 | 0.04± | 0.01 | 185± | 7 | 65± | 6 | 40± | 9 |
| 25ppm | 10 | 6.5± | 0.1 | 3.7± | 0.1 | 1.3± | 0.1 | 0.04± | 0.01 | 184± | 6 | 64± | 3 | 40± | 15 |
| 50ppm | 10 | 6.6± | 0.2 | 3.8± | 0.1 | 1.4± | 0.1 | 0.04± | 0.00 | 188± | 11 | 64± | 4 | 40± | 14 |
| 100ppm | 10 | 6.3± | 0.2 | 3.6± | 0.1 | 1.3± | 0.1 | 0.04± | 0.01 | 184± | 8 | 60± | 5 | 41± | 11 |
| 200ppm | 10 | 6.2± | 0.2** | 3.6± | 0.1* | 1.4± | 0.1 | 0.04± | 0.01 | 185± | 9 | 54± | 3** | 27± | 8** |

Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01

Test of Dunnett

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 MEASURE. TIME : 1
 SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

| Group Name | NO. of Animals | PHOSPHOLIPID mg/dl | | AST U/L | | ALT U/L | | LDH U/L | | ALP U/L | | G-GTP U/L | | CK U/L | |
|------------|----------------|--------------------|-----|---------|----|---------|----|---------|----|---------|-----|-----------|-----|--------|----|
| Control | 10 | 118± | 10 | 105± | 29 | 59± | 11 | 117± | 27 | 388± | 33 | 0.4± | 0.2 | 102± | 22 |
| 12.5ppm | 10 | 115± | 8 | 105± | 35 | 58± | 13 | 125± | 33 | 367± | 22 | 0.4± | 0.2 | 102± | 20 |
| 25ppm | 10 | 114± | 3 | 103± | 31 | 52± | 9 | 127± | 35 | 375± | 23 | 0.4± | 0.2 | 104± | 16 |
| 50ppm | 10 | 116± | 8 | 91± | 24 | 50± | 6 | 106± | 34 | 388± | 25 | 0.3± | 0.2 | 98± | 18 |
| 100ppm | 10 | 111± | 7 | 113± | 49 | 55± | 16 | 116± | 63 | 391± | 33 | 0.4± | 0.2 | 97± | 7 |
| 200ppm | 10 | 104± | 7** | 86± | 20 | 44± | 8 | 91± | 35 | 426± | 36* | 0.5± | 0.2 | 106± | 10 |

Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01

Test of Dunnett

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrIj [F344/DuCrj]
 MEASURE. TIME : 1
 SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

| 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 | 10 | 17.7± | 1.3 | 0.30± | 0.03 | 144± | 2 | 3.4± | 0.1 | 107± | 2 | 10.2± | 0.3 | 5.7± | 0.6 |
| 12.5ppm | 10 | 18.2± | 1.1 | 0.29± | 0.02 | 144± | 2 | 3.5± | 0.3 | 107± | 2 | 10.1± | 0.2 | 5.3± | 1.0 |
| 25ppm | 10 | 18.3± | 1.4 | 0.31± | 0.02 | 144± | 2 | 3.5± | 0.2 | 107± | 2 | 10.2± | 0.1 | 5.8± | 0.9 |
| 50ppm | 10 | 18.2± | 1.3 | 0.29± | 0.02 | 144± | 2 | 3.4± | 0.3 | 107± | 1 | 10.3± | 0.2 | 5.5± | 1.0 |
| 100ppm | 10 | 18.4± | 1.1 | 0.29± | 0.02 | 144± | 2 | 3.5± | 0.3 | 108± | 2 | 10.1± | 0.1 | 5.7± | 0.9 |
| 200ppm | 10 | 18.1± | 1.3 | 0.28± | 0.03 | 144± | 2 | 3.6± | 0.3 | 108± | 2 | 9.9± | 0.2* | 5.9± | 0.8 |

Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01

Test of Dunnett

TABLE G2

BIOCHEMISTRY : FEMALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrIcRij [F344/DuCrj]
 MEASURE TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

| 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 | 10 | 6.3± | 0.2 | 3.7± | 0.1 | 1.4± | 0.1 | 0.05± | 0.00 | 149± | 7 | 73± | 7 | 11± | 3 |
| 12.5ppm | 10 | 6.2± | 0.2 | 3.7± | 0.1 | 1.5± | 0.1 | 0.05± | 0.01 | 142± | 19 | 73± | 7 | 9± | 3 |
| 25ppm | 10 | 6.3± | 0.2 | 3.7± | 0.1 | 1.4± | 0.1 | 0.05± | 0.01 | 144± | 21 | 71± | 7 | 9± | 3 |
| 50ppm | 10 | 6.3± | 0.1 | 3.7± | 0.1 | 1.4± | 0.1 | 0.05± | 0.00 | 149± | 14 | 70± | 6 | 10± | 3 |
| 100ppm | 10 | 6.3± | 0.1 | 3.7± | 0.1 | 1.4± | 0.1 | 0.05± | 0.01 | 149± | 12 | 74± | 6 | 12± | 4 |
| 200ppm | 10 | 6.1± | 0.2 | 3.6± | 0.1 | 1.4± | 0.1 | 0.05± | 0.01 | 140± | 11 | 64± | 7* | 9± | 2 |

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

Test of Dunnett

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 MEASURE TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

| Group Name | NO. of Animals | PHOSPHOLIPID mg/dl | | AST U/L | | ALT U/L | | LDH U/L | | ALP U/L | | G-GTP U/L | | CK U/L | |
|------------|----------------|--------------------|-----|---------|----|---------|----|---------|----|---------|------|-----------|-----|--------|----|
| Control | 10 | 137± | 12 | 72± | 6 | 35± | 8 | 104± | 39 | 322± | 25 | 1.0± | 0.2 | 101± | 18 |
| 12.5ppm | 10 | 132± | 12 | 74± | 9 | 37± | 9 | 106± | 45 | 321± | 36 | 1.1± | 0.3 | 104± | 27 |
| 25ppm | 10 | 131± | 10 | 83± | 17 | 46± | 23 | 104± | 39 | 330± | 27 | 1.2± | 0.4 | 106± | 24 |
| 50ppm | 10 | 129± | 9 | 75± | 9 | 35± | 4 | 122± | 71 | 315± | 19 | 1.0± | 0.2 | 119± | 35 |
| 100ppm | 10 | 139± | 9 | 82± | 18 | 42± | 14 | 112± | 48 | 319± | 33 | 1.2± | 0.2 | 109± | 27 |
| 200ppm | 10 | 123± | 12* | 77± | 4 | 36± | 5 | 118± | 49 | 381± | 21** | 1.3± | 0.3 | 127± | 35 |

Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01

Test of Dunnett

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrIj [F344/DuCrj]
 MEASURE TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

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 | 10 | 18.8± | 2.0 | 0.33± | 0.03 | 144± | 2 | 3.3± | 0.3 | 109± | 3 | 9.8± | 0.2 | 4.8± | 1.2 |
| 12.5ppm | 10 | 17.8± | 2.3 | 0.33± | 0.03 | 144± | 3 | 3.4± | 0.2 | 110± | 3 | 9.7± | 0.3 | 4.6± | 1.1 |
| 25ppm | 10 | 19.2± | 2.6 | 0.34± | 0.02 | 144± | 2 | 3.3± | 0.3 | 110± | 2 | 10.0± | 0.3 | 5.2± | 1.0 |
| 50ppm | 10 | 17.6± | 1.6 | 0.33± | 0.02 | 144± | 2 | 3.3± | 0.2 | 110± | 2 | 9.9± | 0.2 | 4.6± | 1.2 |
| 100ppm | 10 | 18.9± | 1.3 | 0.33± | 0.03 | 143± | 2 | 3.5± | 0.3 | 109± | 3 | 9.9± | 0.2 | 4.8± | 1.0 |
| 200ppm | 10 | 17.4± | 1.3 | 0.31± | 0.02 | 144± | 2 | 3.7± | 0.2** | 110± | 2 | 9.8± | 0.2 | 5.3± | 1.2 |

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

Test of Dunnett

TABLE H1

URINALYSIS : MALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 MEASURE TIME : 1
 SEX : MALE REPORT TYPE : A1

URINALYSIS

| Group Name | NO. of Animals | pH | | | | | | | CHI | Protein | | | | | CHI | Glucose | | | | | CHI | Ketone body | | | | | CHI | Bilirubin | | | CHI | | | |
|------------|----------------|-----|-----|-----|-----|-----|-----|-----|-----|---------|---|---|----|----|-----|---------|----|---|---|----|-----|-------------|----|----|---|---|-----|-----------|----|----|-----|---|---|----|
| | | 5.0 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | | - | ± | + | 2+ | 3+ | | 4+ | - | ± | + | 2+ | | 3+ | 4+ | - | ± | + | | 2+ | 3+ | 4+ | | - | + | 2+ |
| Control | 10 | 0 | 0 | 0 | 0 | 1 | 5 | 4 | | 4 | 6 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 |
| 12.5ppm | 10 | 0 | 0 | 0 | 0 | 0 | 1 | 9 | | 2 | 4 | 4 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 9 | 0 | 1 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 |
| 25ppm | 10 | 0 | 0 | 0 | 1 | 3 | 2 | 4 | | 4 | 4 | 1 | 1 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 8 | 1 | 0 | 1 | 0 | 0 | | 10 | 0 | 0 | 0 |
| 50ppm | 10 | 0 | 0 | 0 | 0 | 6 | 3 | 1 | | 5 | 3 | 2 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 |
| 100ppm | 10 | 0 | 0 | 0 | 0 | 3 | 2 | 5 | | 1 | 6 | 1 | 2 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 7 | 2 | 1 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 |
| 200ppm | 10 | 0 | 0 | 1 | 1 | 3 | 4 | 1 | | 5 | 2 | 1 | 2 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 0 | | 8 | 1 | 1 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 |

Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01

Test of CHI SQUARE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 MEASURE TIME : 1
 SEX : MALE

URINALYSIS

REPORT TYPE : A1

| Group Name | NO. of Animals | Occult blood | | | | CHI | Urobilinogen | | | | CHI |
|------------|----------------|--------------|---|----|----|-----|--------------|---|----|----|-----|
| | | - | ± | 2+ | 3+ | | ± | + | 2+ | 3+ | |
| Control | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |
| 12.5ppm | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |
| 25ppm | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |
| 50ppm | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |
| 100ppm | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |
| 200ppm | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |

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

Test of CHI SQUARE

TABLE H2

URINALYSIS : FEMALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 MEASURE TIME : 1
 SEX : FEMALE REPORT TYPE : A1

URINALYSIS

| 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+ | - | |
| Control | 10 | 0 | 0 | 0 | 0 | 0 | 8 | 2 | 9 | 0 | 1 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | | |
| 12.5ppm | 10 | 0 | 0 | 0 | 1 | 1 | 5 | 3 | 6 | 3 | 1 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | | |
| 25ppm | 10 | 0 | 0 | 0 | 0 | 0 | 6 | 4 | 4 | 5 | 1 | 0 | 0 | 0 | * | 10 | 0 | 0 | 0 | 0 | 9 | 1 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | | |
| 50ppm | 10 | 0 | 0 | 0 | 0 | 3 | 6 | 1 | 7 | 2 | 1 | 0 | 0 | 0 | * | 10 | 0 | 0 | 0 | 0 | 9 | 1 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | | |
| 100ppm | 10 | 0 | 0 | 0 | 0 | 0 | 8 | 2 | 5 | 5 | 0 | 0 | 0 | 0 | * | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | | |
| 200ppm | 10 | 0 | 0 | 0 | 0 | 2 | 6 | 2 | 8 | 2 | 0 | 0 | 0 | 0 | | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | | |

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

Test of CHI SQUARE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 MEASURE. TIME : 1
 SEX : FEMALE REPORT TYPE : A1

URINALYSIS

| Group Name | NO. of Animals | Occult blood | | | | CHI | Urobilinogen | | | | CHI |
|------------|----------------|--------------|---|----|----|-----|--------------|---|----|----|-----|
| | | - | ± | 2+ | 3+ | | ± | + | 2+ | 3+ | |
| Control | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |
| 12.5ppm | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |
| 25ppm | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |
| 50ppm | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |
| 100ppm | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |
| 200ppm | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 |

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

Test of CHI SQUARE

TABLE I 1

GROSS FINDINGS : MALE

STUDY NO. : 0803
ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

| Organ | Findings | Group Name NO. of Animals | Control | | 12.5ppm | | 25ppm | | 50ppm | |
|-------|------------|------------------------------|---------|-------|---------|-------|-------|------|-------|-------|
| | | | 10 | (%) | 10 | (%) | 10 | (%) | 10 | (%) |
| liver | herniation | | 1 | (10) | 1 | (10) | 0 | (0) | 2 | (20) |
| eye | turbid | | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) |

STUDY NO. : 0803
ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

| Organ | Findings | Group Name NO. of Animals | 100ppm | | 200ppm | |
|-------|------------|------------------------------|--------|-------|--------|-------|
| | | | 10 | (%) | 10 | (%) |
| liver | herniation | | 1 | (10) | 1 | (10) |
| eye | turbid | | 0 | (0) | 1 | (10) |

TABLE I 2

GROSS FINDINGS : FEMALE

STUDY NO. : 0803
ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

| Organ | Findings | Group Name NO. of Animals | Control | | 12.5ppm | | 25ppm | | 50ppm | |
|--------|------------|------------------------------|---------|-------|---------|-------|-------|-------|-------|------|
| | | | 10 | (%) | 10 | (%) | 10 | (%) | 10 | (%) |
| liver | herniation | | 1 | (10) | 1 | (10) | 1 | (10) | 0 | (0) |
| uterus | absence | | 1 | (10) | 0 | (0) | 0 | (0) | 0 | (0) |

STUDY NO. : 0803
ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 4

| Organ | Findings | Group Name NO. of Animals | 100ppm | | 200ppm | |
|--------|------------|------------------------------|--------|-------|--------|-------|
| | | | 10 | (%) | 10 | (%) |
| liver | herniation | | 3 | (30) | 1 | (10) |
| uterus | absence | | 0 | (0) | 0 | (0) |

(HPT080)

BAIS 5

TABLE J1

ORGAN WEIGHT, ABSOLUTE : MALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Crlj [F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

ORGAN WEIGHT: ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (14W)

PAGE : 1

| Group Name | NO. of Animals | Body Weight | THYMUS | ADRENALS | TESTES | HEART | LUNGS |
|------------|----------------|-------------|-----------------|---------------|---------------|-----------------|---------------|
| Control | 10 | 294 ± 8 | 0.262 ± 0.025 | 0.062 ± 0.010 | 3.080 ± 0.096 | 0.876 ± 0.032 | 0.924 ± 0.051 |
| 12.5ppm | 10 | 289 ± 12 | 0.253 ± 0.030 | 0.064 ± 0.013 | 3.099 ± 0.121 | 0.889 ± 0.064 | 0.933 ± 0.047 |
| 25ppm | 10 | 301 ± 11 | 0.246 ± 0.026 | 0.061 ± 0.018 | 3.090 ± 0.062 | 0.894 ± 0.047 | 0.950 ± 0.053 |
| 50ppm | 10 | 296 ± 16 | 0.252 ± 0.054 | 0.055 ± 0.007 | 3.070 ± 0.127 | 0.883 ± 0.063 | 0.949 ± 0.053 |
| 100ppm | 10 | 281 ± 10 | 0.243 ± 0.027 | 0.063 ± 0.008 | 3.073 ± 0.099 | 0.873 ± 0.031 | 0.939 ± 0.033 |
| 200ppm | 10 | 242 ± 8** | 0.189 ± 0.028** | 0.060 ± 0.014 | 2.978 ± 0.080 | 0.806 ± 0.042** | 0.870 ± 0.041 |

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

Test of Dunnett

(HCL040)

BAIS 5

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (14W)

| Group Name | NO. of Animals | KIDNEYS | | SPLEEN | | LIVER | | BRAIN | |
|------------|----------------|---------|---------|--------|---------|--------|---------|--------|-------|
| Control | 10 | 1.754± | 0.067 | 0.534± | 0.029 | 6.976± | 0.318 | 1.891± | 0.057 |
| 12.5ppm | 10 | 1.786± | 0.096 | 0.521± | 0.022 | 6.938± | 0.323 | 1.893± | 0.049 |
| 25ppm | 10 | 1.818± | 0.090 | 0.571± | 0.068 | 7.169± | 0.425 | 1.914± | 0.035 |
| 50ppm | 10 | 1.825± | 0.115 | 0.542± | 0.031 | 7.224± | 0.551 | 1.934± | 0.055 |
| 100ppm | 10 | 1.743± | 0.066 | 0.529± | 0.036 | 6.801± | 0.317 | 1.892± | 0.061 |
| 200ppm | 10 | 1.584± | 0.074** | 0.464± | 0.062** | 5.757± | 0.216** | 1.863± | 0.046 |

Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01

Test of Dunnett

TABLE J2

ORGAN WEIGHT, ABSOLUTE : FEMALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCr1j]
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (14W)

PAGE : 3

| Group Name | NO. of Animals | Body Weight | THYMUS | ADRENALS | OVARIES | HEART | LUNGS |
|------------|----------------|-------------|-----------------|---------------|---------------|---------------|----------------|
| Control | 10 | 162 ± 9 | 0.210 ± 0.021 | 0.063 ± 0.011 | 0.097 ± 0.007 | 0.578 ± 0.041 | 0.694 ± 0.045 |
| 12.5ppm | 10 | 158 ± 8 | 0.185 ± 0.036 | 0.065 ± 0.009 | 0.098 ± 0.010 | 0.571 ± 0.023 | 0.687 ± 0.033 |
| 25ppm | 10 | 162 ± 5 | 0.189 ± 0.019 | 0.063 ± 0.008 | 0.102 ± 0.014 | 0.600 ± 0.050 | 0.711 ± 0.038 |
| 50ppm | 10 | 158 ± 5 | 0.196 ± 0.023 | 0.065 ± 0.009 | 0.103 ± 0.009 | 0.592 ± 0.027 | 0.704 ± 0.028 |
| 100ppm | 10 | 158 ± 10 | 0.190 ± 0.024 | 0.060 ± 0.007 | 0.096 ± 0.006 | 0.576 ± 0.034 | 0.686 ± 0.043 |
| 200ppm | 10 | 145 ± 5** | 0.163 ± 0.018** | 0.064 ± 0.007 | 0.094 ± 0.015 | 0.552 ± 0.034 | 0.645 ± 0.035* |

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

Test of Dunnett

(HCL040)

BAIS 5

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (14W)

| Group Name | NO. of Animals | KIDNEYS | | SPLEEN | | LIVER | | BRAIN | |
|------------|----------------|---------|-------|--------|---------|--------|--------|--------|--------|
| Control | 10 | 1.073± | 0.062 | 0.354± | 0.016 | 3.738± | 0.291 | 1.769± | 0.038 |
| 12.5ppm | 10 | 1.064± | 0.050 | 0.345± | 0.025 | 3.677± | 0.141 | 1.774± | 0.028 |
| 25ppm | 10 | 1.088± | 0.044 | 0.356± | 0.018 | 3.780± | 0.201 | 1.765± | 0.045 |
| 50ppm | 10 | 1.073± | 0.031 | 0.356± | 0.017 | 3.721± | 0.161 | 1.768± | 0.043 |
| 100ppm | 10 | 1.043± | 0.059 | 0.352± | 0.026 | 3.644± | 0.205 | 1.769± | 0.049 |
| 200ppm | 10 | 1.037± | 0.044 | 0.323± | 0.014** | 3.485± | 0.184* | 1.717± | 0.030* |

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

Test of Dunnett

TABLE K1

ORGAN WEIGHT, RELATIVE : MALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Crij [F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE
 UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
 SURVIVAL ANIMALS (14W)

PAGE : 1

| Group Name | NO. of Animals | Body Weight (g) | THYMUS | ADRENALS | TESTES | HEART | LUNGS |
|------------|----------------|-----------------|--------------|--------------|----------------|----------------|----------------|
| Control | 10 | 294± 8 | 0.089± 0.007 | 0.021± 0.003 | 1.050± 0.040 | 0.299± 0.012 | 0.315± 0.015 |
| 12.5ppm | 10 | 289± 12 | 0.088± 0.010 | 0.022± 0.005 | 1.075± 0.033 | 0.308± 0.013 | 0.323± 0.009 |
| 25ppm | 10 | 301± 11 | 0.082± 0.009 | 0.020± 0.006 | 1.028± 0.040 | 0.297± 0.014 | 0.316± 0.016 |
| 50ppm | 10 | 296± 16 | 0.085± 0.014 | 0.019± 0.002 | 1.040± 0.066 | 0.298± 0.009 | 0.321± 0.014 |
| 100ppm | 10 | 281± 10 | 0.087± 0.010 | 0.022± 0.003 | 1.095± 0.050 | 0.311± 0.015 | 0.334± 0.012* |
| 200ppm | 10 | 242± 8** | 0.078± 0.012 | 0.025± 0.006 | 1.229± 0.024** | 0.333± 0.019** | 0.359± 0.019** |

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

Test of Dunnett

STUDY NO. : 0803
ANIMAL : RAT F344/DuCrIj [F344/DuCrj]
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (14W)

PAGE : 2

| Group Name | NO. of Animals | KIDNEYS | SPLEEN | LIVER | BRAIN |
|------------|----------------|-----------------|---------------|---------------|-----------------|
| Control | 10 | 0.598 ± 0.025 | 0.182 ± 0.009 | 2.376 ± 0.058 | 0.645 ± 0.025 |
| 12.5ppm | 10 | 0.619 ± 0.015 | 0.181 ± 0.005 | 2.405 ± 0.061 | 0.657 ± 0.019 |
| 25ppm | 10 | 0.604 ± 0.026 | 0.190 ± 0.025 | 2.382 ± 0.069 | 0.637 ± 0.019 |
| 50ppm | 10 | 0.617 ± 0.016 | 0.184 ± 0.009 | 2.439 ± 0.066 | 0.655 ± 0.035 |
| 100ppm | 10 | 0.621 ± 0.019 | 0.188 ± 0.009 | 2.420 ± 0.062 | 0.674 ± 0.027 |
| 200ppm | 10 | 0.654 ± 0.017** | 0.192 ± 0.024 | 2.376 ± 0.050 | 0.769 ± 0.025** |

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

Test of Dunnett

TABLE K2

ORGAN WEIGHT, RELATIVE : FEMALE

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT : %

ORGAN WEIGHT:RELATIVE (SUMMARY)
 SURVIVAL ANIMALS (14W)

| Group Name | NO. of Animals | Body Weight (g) | THYMUS | ADRENALS | OVARIES | HEART | LUNGS |
|------------|----------------|-----------------|---------------|---------------|---------------|---------------|---------------|
| Control | 10 | 162 ± 9 | 0.130 ± 0.009 | 0.039 ± 0.005 | 0.060 ± 0.004 | 0.358 ± 0.017 | 0.430 ± 0.023 |
| 12.5ppm | 10 | 158 ± 8 | 0.117 ± 0.020 | 0.041 ± 0.006 | 0.062 ± 0.006 | 0.363 ± 0.020 | 0.437 ± 0.022 |
| 25ppm | 10 | 162 ± 5 | 0.117 ± 0.011 | 0.039 ± 0.004 | 0.063 ± 0.007 | 0.370 ± 0.023 | 0.439 ± 0.022 |
| 50ppm | 10 | 158 ± 5 | 0.124 ± 0.014 | 0.041 ± 0.006 | 0.065 ± 0.006 | 0.375 ± 0.017 | 0.445 ± 0.021 |
| 100ppm | 10 | 158 ± 10 | 0.120 ± 0.013 | 0.038 ± 0.004 | 0.061 ± 0.005 | 0.365 ± 0.014 | 0.435 ± 0.022 |
| 200ppm | 10 | 145 ± 5** | 0.113 ± 0.011 | 0.044 ± 0.005 | 0.065 ± 0.009 | 0.382 ± 0.025 | 0.446 ± 0.017 |

Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01

Test of Dunnett

STUDY NO. : 0803
ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (14W)

PAGE : 4

| Group Name | NO. of Animals | KIDNEYS | SPLEEN | LIVER | BRAIN |
|------------|----------------|-----------------|---------------|---------------|-----------------|
| Control | 10 | 0.664 ± 0.010 | 0.220 ± 0.009 | 2.313 ± 0.089 | 1.097 ± 0.047 |
| 12.5ppm | 10 | 0.677 ± 0.034 | 0.220 ± 0.017 | 2.337 ± 0.091 | 1.129 ± 0.053 |
| 25ppm | 10 | 0.671 ± 0.020 | 0.220 ± 0.013 | 2.331 ± 0.083 | 1.090 ± 0.040 |
| 50ppm | 10 | 0.679 ± 0.020 | 0.225 ± 0.011 | 2.354 ± 0.086 | 1.119 ± 0.039 |
| 100ppm | 10 | 0.661 ± 0.012 | 0.224 ± 0.020 | 2.310 ± 0.084 | 1.123 ± 0.057 |
| 200ppm | 10 | 0.718 ± 0.030** | 0.223 ± 0.007 | 2.411 ± 0.070 | 1.189 ± 0.051** |

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

Test of Dunnett

(HCL042)

BAIS 5

TABLE L1

**HISTOPATHOLOGICAL FINDINGS :
NON-NEOPLASTIC LESIONS : MALE**

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrIj [F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Group Name No. of Animals on Study Grade | Control | | | | 12.5ppm | | | | 25ppm | | | | 50ppm | | | | |
|----------------------|--|--|---------|-------|-------|-------|---------|-------|-------|-------|-------|-------|-------|-------|--------|-------|-------|-------|-------|
| | | | 10 | | | | 10 | | | | 10 | | | | 10 | | | | |
| | | | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | |
| (Respiratory system) | | | | | | | | | | | | | | | | | | | |
| nasal cavit | | | <10> | | | | <10> | | | | <10> | | | | <10> | | | | |
| | goblet cell hyperplasia | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 0 * |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (60) | (0) | (0) | (0) | (0) |
| | eosinophilic change:olfactory epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | respiratory metaplasia:olfactory epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | desquamation:olfactory epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | ulcer:olfactory epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | hyperplasia:transitional epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory infiltration:respiratory epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory infiltration:olfactory epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (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. : 0803
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | 100ppm | | | | 200ppm | | | |
|----------------------|--|-------------|----------|----------|-------------|-------------|-----------|----------|-------------|
| | | 10 | | | | 10 | | | |
| | | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Respiratory system) | | | | | | | | | |
| nasal cavit | | <10> | | | | <10> | | | |
| | goblet cell hyperplasia | 10 (100) | 0 (0) | 0 (0) | 0 ** (0) | 2 (20) | 0 (0) | 0 (0) | 0 (0) |
| | eosinophilic change:olfactory epithelium | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 0 (0) | 0 (0) | 0 (0) |
| | respiratory metaplasia:olfactory epithelium | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | desquamation:olfactory epithelium | 5 (50) | 0 (0) | 0 (0) | 0 * (0) | 2 (20) | 8 (80) | 0 (0) | 0 ** (0) |
| | ulcer:olfactory epithelium | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 5 (50) | 0 (0) | 0 (0) | 0 * (0) |
| | hyperplasia:transitional epithelium | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 8 (80) | 2 (20) | 0 (0) | 0 ** (0) |
| | inflammatory infiltration:respiratory epithelium | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 10 (100) | 0 (0) | 0 (0) | 0 ** (0) |
| | inflammatory infiltration:olfactory epithelium | 5 (50) | 0 (0) | 0 (0) | 0 * (0) | 10 (100) | 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. : 0803
 ANIMAL : RAT F344/DuCrI:CrIj [F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Control | | | | 12.5ppm | | | | 25ppm | | | | 50ppm | | | |
|--|----------|-------------------------|------|------|------|-------------------------|------|------|------|-------------------------|------|------|------|-------------------------|-------|------|------|
| | | 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+ |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Respiratory system) | | | | | | | | | | | | | | | | | |
| nasal cavit | | | | | | | | | | | | | | | | | |
| | | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| squamous cell metaplasia:transitional epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| regeneration:respiratory epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 8 | 0 | 0 | 0 ** |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (80) | (0) | (0) | (0) |
| regeneration:olfactory epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 8 | 1 | 0 | 0 ** |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (80) | (10) | (0) | (0) |
| atrophy:olfactory 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) | (10) | (0) | (0) | (0) |
| necrosis:olfactory epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| adhesion:turbinat | | 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) |
| larynx | | | | | | | | | | | | | | | | | |
| inflammatory infiltration | | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (10) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (30) | (0) | (0) | (0) | (10) | (0) | (0) | (0) |
| regeneration:epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (30) | (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. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Group Name No. of Animals on Study | | | | 100ppm | | | | 200ppm | | | | |
|-------------------------------|--|---------------------------------------|------|------|-------|--------|------|------|------|--------|------|------|------|------|
| | | Grade | | | | 10 | | | | 10 | | | | |
| | | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | |
| {Respiratory system} | | | | | | | | | | | | | | |
| nasal cavit | squamous cell metaplasia:transitional epithelium | <10> | | | | <10> | | | | | | | | |
| | | 1 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (10) | (0) | (0) | (0) | (100) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | regeneration:respiratory epithelium | 9 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (90) | (0) | (0) | (0) | (100) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | regeneration:olfactory epithelium | 0 | 10 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | (0) | (100) | (0) | (0) | (0) | (100) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | |
| atrophy:olfactory epithelium | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | (100) | (0) | (0) | (0) | (0) | (100) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | |
| necrosis:olfactory epithelium | 0 | 10 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | (0) | (100) | (0) | (0) | (0) | (100) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | |
| adhesion:turbinat | 0 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | (0) | (0) | (0) | (0) | (60) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | |
| larynx | inflammatory infiltration | <10> | | | | <10> | | | | | | | | |
| | | 7 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | (70) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | |
| regeneration:epithelium | 8 | 0 | 0 | 0 | 5 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | (80) | (0) | (0) | (0) | (50) | (50) | (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. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Group Name No. of Animals on Study Grade | Control | | | | 12.5ppm | | | | 25ppm | | | | 50ppm | | | |
|----------------------|---------------------------|--|---------|------|------|------|---------|------|------|------|-------|------|------|------|-------|------|------|------|
| | | | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | |
| [Respiratory system] | | | | | | | | | | | | | | | | | | |
| trachea | ulcer | | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory infiltration | | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 3 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (20) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (30) | (0) | (0) | (0) |
| | regeneration:epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 5 | 0 | 0 | 0 * |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (50) | (0) | (0) | (0) |
| | atrophy:epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| [Digestive system] | | | | | | | | | | | | | | | | | | |
| liver | herniation | | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | | (10) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (20) | (0) | (0) | (0) |
| | hemorrhage | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| | inflammatory infiltration | | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (20) | (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. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Group Name | | 100ppm | | | | 200ppm | | | |
|----------------------|---------------------------|-------------------------|-------|--------|------|------|-------|--------|------|------|--|
| | | No. of Animals on Study | | 10 | | | | 10 | | | |
| | | Grade | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | |
| [Respiratory system] | | | | | | | | | | | |
| trachea | ulcer | | <10> | | | | <10> | | | | |
| | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | |
| | inflammatory infiltration | | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | |
| | | | (20) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | |
| | regeneration:epithelium | | 6 | 0 | 0 | 0 * | 7 | 0 | 0 | 0 ** | |
| | | | (60) | (0) | (0) | (0) | (70) | (0) | (0) | (0) | |
| | atrophy:epithelium | | 0 | 0 | 0 | 0 | 6 | 0 | 0 | 0 * | |
| | | | (0) | (0) | (0) | (0) | (60) | (0) | (0) | (0) | |
| [Digestive system] | | | | | | | | | | | |
| liver | herniation | | <10> | | | | <10> | | | | |
| | | | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | |
| | | | (10) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | |
| | hemorrhage | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | |
| | | | (0) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | |
| | inflammatory infiltration | | 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. : 0803
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrIj]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Control | | | | 12.5ppm | | | | 25ppm | | | | 50ppm | | | |
|----------------------------------|---------------------------|-------------------------|------|------|------|-------------------------|------|------|------|-------------------------|------|------|------|-------------------------|------|------|------|
| | | 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+ |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Urinary system) | | | | | | | | | | | | | | | | | |
| kidney | eosinophilic body | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | 10 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 10 | 0 | 0 | 0 |
| | | (100) | (0) | (0) | (0) | (100) | (0) | (0) | (0) | (100) | (0) | (0) | (0) | (100) | (0) | (0) | (0) |
| (Endocrine system) | | | | | | | | | | | | | | | | | |
| pituitary | Rathke pouch | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | 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) |
| (Reproductive system) | | | | | | | | | | | | | | | | | |
| prostate | inflammatory infiltration | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| (Special sense organs/appendage) | | | | | | | | | | | | | | | | | |
| eye | cataract | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | 0 | 0 | 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) |

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. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Group Name No. of Animals on Study | 100ppm | | | | 200ppm | | | |
|----------------------------------|---------------------------|---------------------------------------|--------|------|------|------|--------|------|------|------|
| | | | Grade | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Urinary system) | | | | | | | | | | |
| kidney | eosinophilic body | | <10> | | | | <10> | | | |
| | | 10 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 0 |
| | | (100) | (0) | (0) | (0) | (0) | (100) | (0) | (0) | (0) |
| (Endocrine system) | | | | | | | | | | |
| pituitary | Rathke pouch | | <10> | | | | <10> | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| (Reproductive system) | | | | | | | | | | |
| prostate | inflammatory infiltration | | <10> | | | | <10> | | | |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| (Special sense organs/appendage) | | | | | | | | | | |
| eye | cataract | | <10> | | | | <10> | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |

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

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Control | | | | 12.5ppm | | | | 25ppm | | | | 50ppm | | | |
|----------------------------------|--------------------------|-------------------------|------|------|------|-------------------------|------|------|------|-------------------------|------|------|------|-------------------------|------|------|------|
| | | 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+ |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Special sense organs/appendage) | | | | | | | | | | | | | | | | | |
| eye | retinal atrophy | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | 0 | 0 | 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) |
| | keratitis | 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) |
| Harder gl | lymphocytic infiltration | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (20) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| (Musculoskeletal system) | | | | | | | | | | | | | | | | | |
| bone | osteosclerosis | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (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. : 0803
 ANIMAL : RAT F344/DuCr|Cr|j [F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Group Name | | 100ppm | | | | 200ppm | | | |
|----------------------------------|--------------------------|-------------------------|-------|--------|------|------|-------|--------|------|------|--|
| | | No. of Animals on Study | | 10 | | | | 10 | | | |
| | | Grade | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | |
| (Special sense organs/appendage) | | | | | | | | | | | |
| eye | retinal atrophy | | <10> | | | | <10> | | | | |
| | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | |
| | keratitis | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | |
| | | | (0) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | |
| Harder gl | lymphocytic infiltration | | <10> | | | | <10> | | | | |
| | | | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | | (20) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | |
| (Musculoskeletal system) | | | | | | | | | | | |
| bone | osteosclerosis | | <10> | | | | <10> | | | | |
| | | | 0 | 0 | 0 | 0 | 1 | 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 : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

TABLE L2

**HISTOPATHOLOGICAL FINDINGS :
NON-NEOPLASTIC LESIONS : FEMALE**

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Control | | | | 12.5ppm | | | | 25ppm | | | | 50ppm | | | |
|--|----------|-------------------------|------|------|------|-------------------------|------|------|------|-------------------------|-------|------|------|-------------------------|------|------|------|
| | | 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+ |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | | | | | | | | | |
| nasal cavit | | | | | | | | | | | | | | | | | |
| | | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| goblet cell hyperplasia | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| respiratory metaplasia:gland | | 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) |
| desquamation:olfactory epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| hyperplasia:transitional epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| inflammatory infiltration:respiratory epithelium | | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 1 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (30) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (20) | (10) | (0) | (0) | (20) | (0) | (0) | (0) |
| inflammatory infiltration:olfactory epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| squamous cell metaplasia:transitional epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| regeneration:respiratory epithelium | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (20) | (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. : 0803
 ANIMAL : RAT F344/DuCr|Cr|j [F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | 100ppm | | | | 200ppm | | | |
|----------------------|--|------------|------------|-----------|--------------|-------------|------------|-----------|--------------|
| | | 10 | | | | 10 | | | |
| | | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Respiratory system) | | | | | | | | | |
| nasal cavit | | <10> | | | | <10> | | | |
| | goblet cell hyperplasia | 5 (50) | 0 (0) | 0 (0) | 0 * (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | respiratory metaplasia:gland | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 3 (30) | 0 (0) | 0 (0) | 0 (0) |
| | desquamation:olfactory epithelium | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 1 (10) | 9 (90) | 0 (0) | 0 ** (0) |
| | hyperplasia:transitional epithelium | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 10 (100) | 0 (0) | 0 (0) | 0 ** (0) |
| | inflammtry infiltration:respiratory epithelium | 1 (10) | 1 (10) | 0 (0) | 0 (0) | 10 (100) | 0 (0) | 0 (0) | 0 ** (0) |
| | inflammatory infiltration:olfactory epithelium | 3 (30) | 0 (0) | 0 (0) | 0 (0) | 10 (100) | 0 (0) | 0 (0) | 0 ** (0) |
| | squamous cell metaplasia:transitional epithelium | 1 (10) | 0 (0) | 0 (0) | 0 (0) | 10 (100) | 0 (0) | 0 (0) | 0 ** (0) |
| | regeneration:respiratory epithelium | 9 (90) | 0 (0) | 0 (0) | 0 ** (0) | 10 (100) | 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. : 0803
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Control | | | | 12.5ppm | | | | 25ppm | | | | 50ppm | | | | |
|----------------------|-----------------------------------|-------------------------|------|------|------|---------|------|------|-------|-------|------|------|-------|-------|------|------|------|------|
| | | No. of Animals on Study | | | | 10 | | | | 10 | | | | 10 | | | | |
| | | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | |
| (Respiratory system) | | | | | | | | | | | | | | | | | | |
| nasal cavit | regeneration:olfactory epithelium | <10> | | | | <10> | | | | <10> | | | | <10> | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | * |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (50) | (0) | (0) | (0) | (0) |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (20) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (0) | |
| | necrosis:olfactory epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | |
| | adhesion:turbinate | 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) | |
| larynx | inflammatory infiltration | <10> | | | | <10> | | | | <10> | | | | <10> | | | | |
| | | 3 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 8 | 0 | 0 | 0 | |
| | | (30) | (0) | (0) | (0) | (30) | (0) | (0) | (0) | (60) | (0) | (0) | (0) | (80) | (0) | (0) | (0) | |
| | regeneration:epithelium | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | * |
| | | (0) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (60) | (0) | (0) | (0) | (0) |
| trachea | ulcer | <10> | | | | <10> | | | | <10> | | | | <10> | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (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. : 0803
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | 100ppm | | | | 200ppm | | | |
|---------------------------------------|-----------------------------------|--------|-------|------|------|--------|-------|------|------|
| | | 10 | | | | 10 | | | |
| Group Name No. of Animals on Study | | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ |
| Grade | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Respiratory system} | | | | | | | | | |
| nasal cavit | regeneration:olfactory epithelium | <10> | | | | <10> | | | |
| | | 0 | 10 | 0 | 0 ** | 0 | 10 | 0 | 0 ** |
| | | (0) | (100) | (0) | (0) | (0) | (100) | (0) | (0) |
| | | | | | | | | | |
| | atrophy:olfactory epithelium | 10 | 0 | 0 | 0 ** | 0 | 10 | 0 | 0 ** |
| | | (100) | (0) | (0) | (0) | (0) | (100) | (0) | (0) |
| | | | | | | | | | |
| | | | | | | | | | |
| | necrosis:olfactory epithelium | 10 | 0 | 0 | 0 ** | 10 | 0 | 0 | 0 ** |
| | | (100) | (0) | (0) | (0) | (100) | (0) | (0) | (0) |
| | | | | | | | | | |
| | | | | | | | | | |
| | adhesion:turbinate | 0 | 0 | 0 | 0 | 7 | 0 | 0 | 0 ** |
| | | (0) | (0) | (0) | (0) | (70) | (0) | (0) | (0) |
| | | | | | | | | | |
| | | | | | | | | | |
| larynx | inflammatory infiltration | <10> | | | | <10> | | | |
| | | 8 | 0 | 0 | 0 | 6 | 0 | 0 | 0 |
| | | (80) | (0) | (0) | (0) | (60) | (0) | (0) | (0) |
| | | | | | | | | | |
| | regeneration:epithelium | 4 | 0 | 0 | 0 | 6 | 0 | 0 | 0 * |
| | | (40) | (0) | (0) | (0) | (60) | (0) | (0) | (0) |
| | | | | | | | | | |
| | | | | | | | | | |
| trachea | ulcer | <10> | | | | <10> | | | |
| | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (10) | (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. : 0803
 ANIMAL : RAT F344/DuCrj [F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Control | | | | 12.5ppm | | | | 25ppm | | | | 50ppm | | | |
|------------------------|-----------------------------|-------------------------|------|------|------|-------------------------|------|------|------|-------------------------|------|------|------|-------------------------|------|------|------|
| | | No. of Animals on Study | | | | No. of Animals on Study | | | | No. of Animals on Study | | | | No. of Animals on Study | | | |
| Grade | | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Respiratory system) | | | | | | | | | | | | | | | | | |
| trachea | inflammatory infiltration | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 3 | 0 | 0 | 0 |
| | | (10) | (0) | (0) | (0) | (20) | (0) | (0) | (0) | (30) | (0) | (0) | (0) | (30) | (0) | (0) | (0) |
| | regeneration:epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (20) | (0) | (0) | (0) | (20) | (0) | (0) | (0) |
| | atrophy:epithelium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| lung | inflammatory infiltration | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | 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) |
| | accumulation of foamy cells | 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) |
| (Hematopoietic system) | | | | | | | | | | | | | | | | | |
| bone marrow | granulation | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | (10) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (10) | (0) | (0) | (0) |

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

STUDY NO. : 0803
 ANIMAL : RAT F344/DuCrI CrI j [F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Group Name No. of Animals on Study | | | | 100ppm | | | | 200ppm | | | |
|------------------------|-----------------------------|---------------------------------------|------|------|------|--------|------|------|------|--------|-----|-----|-----|
| | | Grade | | | | 10 | | | | 10 | | | |
| | | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ |
| | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Respiratory system) | | | | | | | | | | | | | |
| trachea | | <10> | | | | <10> | | | | | | | |
| | inflammatory infiltration | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | |
| | | (30) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | | | | |
| | regeneration:epithelium | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | |
| | | (10) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | | | | |
| | atrophy:epithelium | 0 | 0 | 0 | 0 | 5 | 0 | 0 | 0 * | | | | |
| | | (0) | (0) | (0) | (0) | (50) | (0) | (0) | (0) | | | | |
| lung | | <10> | | | | <10> | | | | | | | |
| | inflammatory infiltration | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | | | | |
| | accumulation of foamy cells | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | |
| | | (0) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | | | | |
| (Hematopoietic system) | | | | | | | | | | | | | |
| bone marrow | | <10> | | | | <10> | | | | | | | |
| | granulation | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | | (10) | (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. : 0803
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Group Name No. of Animals on Study | Control | | | | 12.5ppm | | | | 25ppm | | | | 50ppm | | | |
|-----------------------|---|---------------------------------------|---------|------|------|------|---------|------|------|-------|-------|------|------|-------|-------|------|------|------|
| | | | Grade | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ |
| (Digestive system) | | | | | | | | | | | | | | | | | | |
| liver | herniation | | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (10) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| (Urinary system) | | | | | | | | | | | | | | | | | | |
| kidney | mineralization:cortico-medullary junction | | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (0) |
| (Endocrine system) | | | | | | | | | | | | | | | | | | |
| thyroid | ultimobranhial body remanet | | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | | 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) |
| (Reproductive system) | | | | | | | | | | | | | | | | | | |
| ovary | cyst | | <10> | | | | <10> | | | | <10> | | | | <10> | | | |
| | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (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. : 0803
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Group Name No. of Animals on Study | 100ppm | | | | 200ppm | | | | | | |
|-----------------------|---|---------------------------------------|--------|-------|------|------|--------|-------|------|------|------|------|------|
| | | | Grade | 1+ | 2+ | 3+ | 4+ | Grade | 1+ | 2+ | 3+ | 4+ | |
| | | | | <10> | | | | | | <10> | | | |
| | | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| (Digestive system) | | | | | | | | | | | | | |
| liver | herniation | | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | |
| | | | | (30) | (0) | (0) | (0) | (10) | (0) | (0) | (0) | (0) | (0) |
| (Urinary system) | | | | | | | | | | | | | |
| kidney | mineralization:cortico-medullary junction | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| (Endocrine system) | | | | | | | | | | | | | |
| thyroid | ultimobranchial body remanet | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| (Reproductive system) | | | | | | | | | | | | | |
| ovary | cyst | | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | | | |
| | | | | (0) | (0) | (0) | (0) | (20) | (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. : 0803
 ANIMAL : RAT F344/DuCr1Cr1j [F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Group Name No. of Animals on Study | Control | | | | 12.5ppm | | | | 25ppm | | | | 50ppm | | | | |
|----------------------------------|--------------------------|---------------------------------------|---------|------|------|------|---------|------|------|------|-------|------|------|------|-------|------|------|------|------|
| | | | Grade | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ |
| (Reproductive system) | | | | | | | | | | | | | | | | | | | |
| uterus | malformation | | <10> | | | | <10> | | | | <10> | | | | <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) | (0) |
| (Special sense organs/appendage) | | | | | | | | | | | | | | | | | | | |
| eye | retinal atrophy | | <10> | | | | <10> | | | | <10> | | | | <10> | | | | |
| | | | 0 | 0 | 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) |
| Harder gl | lymphocytic infiltration | | <10> | | | | <10> | | | | <10> | | | | <10> | | | | |
| | | | 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) | (30) | (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. : 0803
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

| Organ | Findings | Group Name No. of Animals on Study | 100ppm | | | | 200ppm | | | |
|----------------------------------|--------------------------|---------------------------------------|--------|------|------|------|--------|------|------|------|
| | | | 10 | | | | 10 | | | |
| | | Grade | 1+ | 2+ | 3+ | 4+ | 1+ | 2+ | 3+ | 4+ |
| | | | (%) | (%) | (%) | (%) | (%) | (%) | (%) | (%) |
| {Reproductive system} | | | | | | | | | | |
| uterus | malformation | | <10> | | | | <10> | | | |
| | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| {Special sense organs/appendage} | | | | | | | | | | |
| eye | retinal atrophy | | <10> | | | | <10> | | | |
| | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (0) | (0) | (0) | (0) | (0) | (0) | (0) | (0) |
| Harder gl | lymphocytic infiltration | | <10> | | | | <10> | | | |
| | | | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | (40) | (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