

テトラクロロエチレンのラット及びマウスを用いた  
吸入によるがん原性試験報告書

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TABLE 1 EXPERIMENTAL DESIGN AND MATERIALS AND METHODS IN THE INHALATION STUDIES OF TETRACHLOROETHYLENE

| Two-Week Studies   | Thirteen-Week Studies  | Two-Year Studies   |
|--|--|--|
| <Number of Groups><br>Male 6, Female 6   | Male 6, Female 6   | Male 4, Female 4   |
| <Size of Study Groups><br>10 males and 10 females<br>of each groups  | 10-males and 10 females<br>of each groups  | 50 males and 50 females<br>of each groups  |
| <Animals><br>Strain and Species<br>F344/DuCrj(Fischer)rat<br>Crj:BDF <sub>1</sub> mouse<br>Animal Source<br>Charles River Japan, Inc.<br>During of Time Held Before Study<br>2 wk<br>Age When Placed on Study<br>6 wk<br>Age When Killed<br>8 wk   | F344/DuCrj(Fischer)rat<br>Crj:BDF <sub>1</sub> mouse<br>Charles River Japan, Inc.<br>2 wk<br>6 wk<br>19 wk   | F344/DuCrj(Fischer)rat<br>Crj:BDF <sub>1</sub> mouse<br>Charles River Japan, Inc.<br>2 wk<br>6 wk<br>110 wk~111 wk   |
| <Chamber Concentration><br>Rat--0, 200, 400, 800, 1600, or<br>3200ppm tetrachloroethylene<br>by inhalation; mouse--0, 200,<br>400, 800, 1600 or 3200ppm  | Rat--0, 50, 115, 265, 609, or<br>1400ppm tetrachloroethylene<br>by inhalation; mouse--0, 50,<br>115, 265, 609, or 1400ppm  | Rat--0, 50, 200, or 600ppm<br>tetrachloroethylene by<br>inhalation; mouse--0, 10<br>50, or 250ppm  |
| <Date of First Exposure><br>Rat:2/18/87; mouse:3/4/87  | Rat:5/7/87; mouse:5/15/87  | Rat:7/21/88; mouse:8/12/88   |
| <Date of Last Exposuure><br>Rat:3/3/87; mouse:3/17/87  | Rat:8/5/87; mouse:8/13/87  | Rat:7/18/90; mouse:8/9/90  |
| <Duration of Exposure><br>6h/d, 5d/wk for 2wk  | 6h/d, 5d/wk for 13wk   | 6h/d, 5d/wk for 104wk  |
| <Animal Maintenance><br>Feed<br>CRF-1<br>(Oriental Yeast Co., Ltd.)<br>Sterilized by $\gamma$ -ray<br>Available ad libitum<br>Water<br>Sterilized by<br>ultraviolet rays<br>Automatic watering system<br>Available ad libitum<br>Animals per Cage<br>Single<br>(stainless steel wire)<br>Animal Room Environment<br>Barrier system<br>Temperature:24 $\pm$ 2 $^{\circ}$ C<br>Humidity :55 $\pm$ 10%<br>Fluorescent light 12h/d<br>15-17 room air changes /h<br>Chamber Environment<br>Temperature:23~26 $^{\circ}$ C<br>Humidity :45~70%<br>Fluorescent light 12h/d<br>15 chamber air changes /h | Same as two-week studies<br>Same as two-week studies<br>Same as two-week studies<br>Same as two-week studies<br>Single<br>(stainless steel wire)<br>Same as two-week studies<br>Same as two-week studies | Same as two-week studies<br>Same as two-week studies<br>Single<br>(stainless steel wire)<br>Barrier system<br>Temperature:22~26 $^{\circ}$ C<br>Humidity :45~55%<br>Fluorescent light 12h/d<br>7.5~10 room air changes /h<br>Temperature:24 $\pm$ 1 $^{\circ}$ C<br>Humidity :55 $\pm$ 10%<br>Flouresent light 12h/d<br>12~15 chamber air changes /h |
| <Type and Frequency of Observation><br>Clinical Sign<br>Observed 1 $\times$ d<br>Body Weight<br>Weighed 0-0, 1-1, 1-2,<br>1-3, 1-7, 2-3, and 2-7(wk-d)   | Observed 1 $\times$ d<br>Weighed 1 $\times$ wk for 13wk  | Observed 1 $\times$ d<br>Weighed 1 $\times$ wk for 14wk<br>Weighed 1 $\times$ 2wk thereafter   |
| <Food Consumption><br>Weighed 1 $\times$ wk for 2wk  | Weighed 1 $\times$ wk for 13wk   | Weighed 1 $\times$ wk for 14wk<br>Weighed 1 $\times$ 4wk thereafter  |

TABLE 1 EXPERIMENTAL DESIGN AND MATERIALS AND METHODS IN THE INHALATION STUDIES OF TETRACHLOROETHYLENE  
(Continued)

| Two-Week Studies  | Thirteen-Week Studies   | Two-Year Studies  |
|---|---|---|
| <p>&lt;Hematology&gt;</p> <p>Red blood cell(RBC),<br/>Hemoglobin, Hematocrit,<br/>Mean corpuscular volume(MCV),<br/>Mean corpuscular hemoglobin(MCH),<br/>Mean corpuscular hemoglobin concentration(MCHC)<br/>Platelete, White blood cell(WBC),<br/>Differential WBC</p>  | <p>Same as two-week studies</p>   | <p>Same as two-week studies</p>   |
| <p>&lt;Blood Biochemistry&gt;</p> <p>Total protein, Albumin, T-bilirubin,<br/>Glucose, T-cholesterol,<br/>Glutamic oxaloacetic<br/>transaminase(GOT),<br/>Glutamic pyruvic transaminase(GPT),<br/>Lactate dehydrogenase(LDH),<br/>Creatine phosphokinase(CPK),<br/>Urea nitrgen, Creatinine&lt;rat only&gt;,<br/>Sodium, Potassium, Chloride,<br/>Calcium, Inorganic phosphrus.</p> | <p>Total protein, Albumin, A/G ratio,<br/>T-bilirubin, Glucose, T-cholesterol,<br/>Triglyceride Phospholipid&lt;rat only&gt;,<br/>Glutamic oxaloacetic<br/>transaminase(GOT),<br/>Glutamic pyruvic<br/>transaminase(GPT),<br/>Lactate dehydrogenase(LDH),<br/>Alkaline phosphatase(ALP),<br/>Leucine aminopeptidase(LAP)&lt;rat only&gt;,<br/><math>\gamma</math>-Glutamyl transpeptitase(G-GTP)<br/>&lt;rat only&gt;,<br/>Creatine phosphokinase(CPK),<br/>Urea nitrogen, Creatinine&lt;rat only&gt;,<br/>Sodium, Potassium, Chloride,<br/>Calcium<br/>Inorganic phosphorus.</p> | <p>Total protein, Albumin,<br/>A/G ratio, T-bilirubin, Glucose,<br/>T-cholesterol, Triglyceride,<br/>Phospholipid&lt;rat only&gt;,<br/>Glutamic oxaloacetic<br/>transaminase(GOT),<br/>Glutamic pyruvic<br/>transaminase(GPT),<br/>Lactate dehydrogenase(LDH),<br/>Alkaline phosphatase(ALP)<br/>&lt;rat only&gt;,<br/><math>\gamma</math>-Glutamyl transpeptidase<br/>(G-GTP) &lt;rat only&gt;,<br/>Creatine phosphokinase(CPK),<br/>Urea nitrogen, Creatinine<br/>&lt;rat only&gt;,<br/>Sodium, Potassium, Chloride,<br/>Calcium, Inorganic phosphorus.</p> |
| <p>&lt;Urinalysis&gt;</p> <p>None</p>   | <p>pH, Protein, Glucose,<br/>Ketone body, Bilirubin &lt;rat only&gt;,<br/>Occult blood, Urobilinogen.</p>   | <p>Same as thirteen-week studies</p>  |
| <p>&lt;Necropsy&gt;</p> <p>Necropsy performed<br/>on all animals.</p>   | <p>Same as two-week studies</p>   | <p>Same as two-week studies</p>   |
| <p>&lt;Organ Weight&gt;</p> <p>None</p>   | <p>Organ weight measurement performed<br/>on schedule sacrificed animals.<br/>The following organs were weighed<br/>:brain, lung, liver, spleen, heart,<br/>kidney, adrenal, testis, ovary, thymus.</p>   | <p>Same as thirteen-week studies</p> <p>The following organs were weighed<br/>:brain, lung, liver, spleen, heart,<br/>kidney, adrenal, testis, ovary.</p>   |
| <p>&lt;Histopathologic Examination&gt;</p> <p>Histopathologic examination<br/>performed on at least two<br/>animals per sex per group.</p>  | <p>Histopathologic examination<br/>performed on all animals.</p>  | <p>Same as thirteen-week studies</p>  |
| <p>The following organs were<br/>examined: nasal cavit,<br/>nasopharynx, larynx, trachea,<br/>lung, bone marrow, lymph node,<br/>thymus, spleen, heart, stomach,<br/>small intes, large intes,<br/>liver, pancreas, kidney,<br/>pituitary, adrenal,<br/>testis, ovary, brain.</p>   | <p>The following organs were examined<br/>:skin, nasal cavit, nasopharynx,<br/>larynx, trachea, lung, bone marrow,<br/>lymph node, thymus, spleen, heart,<br/>tongue, salivary gl, esophagus,<br/>stomach, small intes, large intes,<br/>liver, pancreas, kidney, urin bladd,<br/>pituitary, thyroid, adrenal, testis,<br/>epidymis, semin ves, prostate, ovary,<br/>uterus, vagina, mammary gl, brain,<br/>spinal cord, periph nerv, eye,<br/>Harder gl, muscle, bone.</p>   | <p>Same as thirteen-week studies</p>  |

TABLE 2 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN MALE RAT (TWO-WEEK STUDIES)

| Week-Day<br>on Study  | Control  |                          | 200 ppm  |                       |                  | 400 ppm  |                       |                  | 800 ppm  |                       |                  | 1600 ppm |                       |                  | 3200 ppm |                       |                  |
|---|----------|--------------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|
|   | Au.Wt.   | No.of<br>Surviv.<br><10> | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 0-0   | 125 (10) | 10/10                    | 125 (10) | 100                   | 10/10            | 125 (10) | 100                   | 10/10            | 125 (10) | 100                   | 10/10            | 125 (10) | 100                   | 10/10            | 125 (10) | 100                   | 10/10            |
| 1-1   | 128 (10) | 10/10                    | 128 (10) | 100                   | 10/10            | 129 (10) | 101                   | 10/10            | 128 (10) | 100                   | 10/10            | 125 (10) | 98                    | 10/10            | 119 (10) | 93                    | 10/10            |
| 1-2   | 131 (10) | 10/10                    | 132 (10) | 101                   | 10/10            | 133 (10) | 102                   | 10/10            | 130 (10) | 99                    | 10/10            | 124 (10) | 95                    | 10/10            | 115 (10) | 88                    | 10/10            |
| 1-3   | 135 (10) | 10/10                    | 135 (10) | 100                   | 10/10            | 136 (10) | 101                   | 10/10            | 135 (10) | 100                   | 10/10            | 125 (10) | 93                    | 10/10            | 112 (10) | 83                    | 10/10            |
| 1-7   | 150 (10) | 10/10                    | 151 (10) | 101                   | 10/10            | 152 (10) | 101                   | 10/10            | 150 (10) | 100                   | 10/10            | 138 (10) | 92                    | 10/10            | 117 (10) | 78                    | 10/10            |
| 2-3   | 163 (10) | 10/10                    | 165 (10) | 101                   | 10/10            | 165 (10) | 101                   | 10/10            | 163 (10) | 100                   | 10/10            | 149 (10) | 91                    | 10/10            | 116 ( 8) | 71                    | 7/10             |
| 2-7   | 181 (10) | 10/10                    | 182 (10) | 101                   | 10/10            | 180 (10) | 99                    | 10/10            | 180 (10) | 99                    | 10/10            | 166 (10) | 92                    | 10/10            | 125 ( 6) | 69                    | 5/10             |
| < >:No.of effective animals,( ):No.of measured animals                      Au.Wt.: g |          |                          |          |                       |                  |          |                       |                  |          |                       |                  |          |                       |                  |          |                       |                  |

&lt; &gt;:No.of effective animals,( ):No.of measured animals Au.Wt.: g

TABLE 3 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN FEMALE RAT (TWO-WEEK STUDIES)

| Week-Day<br>on Study | Control  |                          | 200 ppm  |                       | 400 ppm          |          | 800 ppm               |                  | 1600 ppm |                       | 3200 ppm         |          |                       |                  |          |                       |                  |
|----------------------|----------|--------------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|
|                      | Au.Wt.   | No.of<br>Surviv.<br><10> | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 0-0                  | 102 (10) | 10/10                    | 102 (10) | 100                   | 10/10            | 102 (10) | 100                   | 10/10            | 102 (10) | 100                   | 10/10            | 102 (10) | 100                   | 10/10            | 102 (10) | 100                   | 10/10            |
| 1-1                  | 105 (10) | 10/10                    | 105 (10) | 100                   | 10/10            | 105 (10) | 100                   | 10/10            | 104 (10) | 99                    | 10/10            | 103 (10) | 98                    | 10/10            | 98 (10)  | 93                    | 10/10            |
| 1-2                  | 105 (10) | 10/10                    | 106 (10) | 101                   | 10/10            | 106 (10) | 101                   | 10/10            | 105 (10) | 100                   | 10/10            | 102 (10) | 97                    | 10/10            | 96 (10)  | 91                    | 10/10            |
| 1-3                  | 107 (10) | 10/10                    | 108 (10) | 101                   | 10/10            | 107 (10) | 100                   | 10/10            | 107 (10) | 100                   | 10/10            | 103 (10) | 96                    | 10/10            | 93 (10)  | 87                    | 10/10            |
| 1-7                  | 114 (10) | 10/10                    | 114 (10) | 100                   | 10/10            | 115 (10) | 101                   | 10/10            | 115 (10) | 101                   | 10/10            | 111 (10) | 97                    | 10/10            | 94 ( 9)  | 82                    | 8/10             |
| 2-3                  | 120 (10) | 10/10                    | 121 (10) | 101                   | 10/10            | 122 (10) | 102                   | 10/10            | 122 (10) | 102                   | 10/10            | 118 (10) | 98                    | 10/10            | 93 ( 7)  | 78                    | 7/10             |
| 2-7                  | 128 (10) | 10/10                    | 130 (10) | 102                   | 10/10            | 129 (10) | 101                   | 10/10            | 129 (10) | 101                   | 10/10            | 127 (10) | 99                    | 10/10            | 102 ( 3) | 80                    | 3/10             |

&lt; &gt;:No.of effective animals,( ):No.of measured animals Au.Wt.: g



TABLE 4 FOOD CONSUMPTION IN MALE RAT (TWO-WEEK STUDIES)

| Week-Day<br>on Study | Control   |                          | 200 ppm   |                       |                  | 400 ppm   |                       |                  | 800 ppm   |                       |                  | 1600 ppm  |                       |                  | 3200 ppm  |                       |                  |
|----------------------|-----------|--------------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|
|                      | Au.FC.    | No.of<br>Surviv.<br><10> | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 1-7                  | 14.4 (10) | 10/10                    | 14.0 (10) | 97                    | 10/10            | 14.5 (10) | 101                   | 10/10            | 13.8 (10) | 96                    | 10/10            | 11.5 (10) | 80                    | 10/10            | 8.6 (10)  | 60                    | 10/10            |
| 2-7                  | 15.5 (10) | 10/10                    | 15.0 (10) | 97                    | 10/10            | 15.9 (10) | 103                   | 10/10            | 15.5 (10) | 100                   | 10/10            | 14.1 (10) | 91                    | 10/10            | 10.5 ( 6) | 68                    | 5/10             |

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

TABLE 5 FOOD CONSUMPTION IN FEMALE RAT (TWO-WEEK STUDIES)

| Week-Day<br>on Study | Control   |                          | 200 ppm   |                       |                  | 400 ppm   |                       |                  | 800 ppm   |                       |                  | 1600 ppm  |                       |                  | 3200 ppm |                       |                  |
|----------------------|-----------|--------------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|----------|-----------------------|------------------|
|                      | Au.FC.    | No.of<br>Surviv.<br><10> | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 1-7                  | 11.3 (10) | 10/10                    | 11.0 (10) | 97                    | 10/10            | 11.3 (10) | 100                   | 10/10            | 10.7 (10) | 95                    | 10/10            | 10.1 (10) | 89                    | 10/10            | 6.8 ( 9) | 60                    | 8/10             |
| 2-7                  | 10.9 (10) | 10/10                    | 11.1 (10) | 102                   | 10/10            | 11.1 (10) | 102                   | 10/10            | 11.1 (10) | 102                   | 10/10            | 11.5 (10) | 106                   | 10/10            | 8.9 ( 3) | 82                    | 3/10             |

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

TABLE 6 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN MALE RAT (THIRTEEN-WEEK STUDIES)

| Week<br>on Study | Control  |                          |  | 50 ppm   |                       |                  | 115 ppm  |                       |                  | 265 ppm  |                       |                  | 609 ppm  |                       |                  | 1400 ppm |                       |                  |
|------------------|----------|--------------------------|--|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|
|                  | Au.Wt.   | No.of<br>Surviv.<br><10> |  | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 0                | 131 (10) | 10/10                    |  | 131 (10) | 100                   | 10/10            | 131 (10) | 100                   | 10/10            | 131 (10) | 100                   | 10/10            | 131 (10) | 100                   | 10/10            | 131 (10) | 100                   | 10/10            |
| 1                | 164 (10) | 10/10                    |  | 159 (10) | 97                    | 10/10            | 162 (10) | 99                    | 10/10            | 162 (10) | 99                    | 10/10            | 160 (10) | 98                    | 10/10            | 150 (10) | 91                    | 10/10            |
| 2                | 200 (10) | 10/10                    |  | 192 (10) | 96                    | 10/10            | 194 (10) | 97                    | 10/10            | 195 (10) | 98                    | 10/10            | 195 (10) | 98                    | 10/10            | 181 (10) | 91                    | 10/10            |
| 3                | 227 (10) | 10/10                    |  | 219 (10) | 96                    | 10/10            | 221 (10) | 97                    | 10/10            | 222 (10) | 98                    | 10/10            | 221 (10) | 97                    | 10/10            | 207 (10) | 91                    | 10/10            |
| 4                | 252 (10) | 10/10                    |  | 243 (10) | 96                    | 10/10            | 244 (10) | 97                    | 10/10            | 246 (10) | 98                    | 10/10            | 246 (10) | 98                    | 10/10            | 231 (10) | 92                    | 10/10            |
| 5                | 272 (10) | 10/10                    |  | 262 (10) | 96                    | 10/10            | 263 (10) | 97                    | 10/10            | 267 (10) | 98                    | 10/10            | 265 (10) | 97                    | 10/10            | 250 (10) | 92                    | 10/10            |
| 6                | 288 (10) | 10/10                    |  | 278 (10) | 97                    | 10/10            | 278 (10) | 97                    | 10/10            | 283 (10) | 98                    | 10/10            | 281 (10) | 98                    | 10/10            | 265 (10) | 92                    | 10/10            |
| 7                | 305 (10) | 10/10                    |  | 295 (10) | 97                    | 10/10            | 294 (10) | 96                    | 10/10            | 298 (10) | 98                    | 10/10            | 298 (10) | 98                    | 10/10            | 280 (10) | 92                    | 10/10            |
| 8                | 320 (10) | 10/10                    |  | 308 (10) | 96                    | 10/10            | 309 (10) | 97                    | 10/10            | 314 (10) | 98                    | 10/10            | 314 (10) | 98                    | 10/10            | 294 (10) | 92                    | 10/10            |
| 9                | 335 (10) | 10/10                    |  | 321 (10) | 96                    | 10/10            | 321 (10) | 96                    | 10/10            | 330 (10) | 99                    | 10/10            | 328 (10) | 98                    | 10/10            | 307 (10) | 92                    | 10/10            |
| 10               | 345 (10) | 10/10                    |  | 331 (10) | 96                    | 10/10            | 330 (10) | 96                    | 10/10            | 339 (10) | 98                    | 10/10            | 337 (10) | 98                    | 10/10            | 316 (10) | 92                    | 10/10            |
| 11               | 355 (10) | 10/10                    |  | 340 (10) | 96                    | 10/10            | 339 (10) | 95                    | 10/10            | 349 (10) | 98                    | 10/10            | 346 (10) | 97                    | 10/10            | 327 (10) | 92                    | 10/10            |
| 12               | 361 (10) | 10/10                    |  | 348 (10) | 96                    | 10/10            | 349 (10) | 97                    | 10/10            | 357 (10) | 99                    | 10/10            | 357 (10) | 99                    | 10/10            | 337 (10) | 93                    | 10/10            |
| 13               | 368 (10) | 10/10                    |  | 355 (10) | 96                    | 10/10            | 357 (10) | 97                    | 10/10            | 367 (10) | 100                   | 10/10            | 366 (10) | 99                    | 10/10            | 345 (10) | 94                    | 10/10            |

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

TABLE 7 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN FEMALE RAT (THIRTEEN-WEEK STUDIES)

| Week<br>on Study | Control   |                          |  | 50 ppm    |                       |                  | 115 ppm   |                       |                  | 265 ppm   |                       |                  | 609 ppm   |                       |                  | 1400 ppm  |                       |                  |
|------------------|-----------|--------------------------|--|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|
|                  | Au.FC.    | No.of<br>Surviv.<br><10> |  | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 1                | 11.9 (10) | 10/10                    |  | 11.6 (10) | 97                    | 10/10            | 11.6 (10) | 97                    | 10/10            | 11.1 (10) | 93                    | 10/10            | 11.2 (10) | 94                    | 10/10            | 10.6 (10) | 89                    | 10/10            |
| 2                | 12.0 (10) | 10/10                    |  | 11.7 (10) | 98                    | 10/10            | 12.0 (10) | 100                   | 10/10            | 11.5 (10) | 96                    | 10/10            | 11.7 (10) | 98                    | 10/10            | 11.6 (10) | 97                    | 10/10            |
| 3                | 12.2 (10) | 10/10                    |  | 11.9 (10) | 98                    | 10/10            | 11.7 (10) | 96                    | 10/10            | 11.6 (10) | 95                    | 10/10            | 11.7 (10) | 96                    | 10/10            | 12.1 (10) | 99                    | 10/10            |
| 4                | 12.1 (10) | 10/10                    |  | 11.7 (10) | 97                    | 10/10            | 11.7 (10) | 97                    | 10/10            | 11.4 (10) | 94                    | 10/10            | 11.5 (10) | 95                    | 10/10            | 12.3 (10) | 102                   | 10/10            |
| 5                | 11.8 (10) | 10/10                    |  | 11.6 (10) | 98                    | 10/10            | 11.2 (10) | 95                    | 10/10            | 10.9 (10) | 92                    | 10/10            | 11.5 (10) | 97                    | 10/10            | 11.8 (10) | 100                   | 10/10            |
| 6                | 11.5 (10) | 10/10                    |  | 11.5 (10) | 100                   | 10/10            | 11.1 (10) | 97                    | 10/10            | 10.7 (10) | 93                    | 10/10            | 11.3 (10) | 98                    | 10/10            | 12.1 (10) | 105                   | 10/10            |
| 7                | 11.5 (10) | 10/10                    |  | 11.2 (10) | 97                    | 10/10            | 11.3 (10) | 98                    | 10/10            | 11.2 (10) | 97                    | 10/10            | 11.4 (10) | 99                    | 10/10            | 12.0 (10) | 104                   | 10/10            |
| 8                | 12.0 (10) | 10/10                    |  | 10.9 (10) | 91                    | 10/10            | 10.9 (10) | 91                    | 10/10            | 11.0 (10) | 92                    | 10/10            | 11.4 (10) | 95                    | 10/10            | 11.8 (10) | 98                    | 10/10            |
| 9                | 12.2 (10) | 10/10                    |  | 11.8 (10) | 97                    | 10/10            | 11.1 (10) | 91                    | 10/10            | 11.2 (10) | 92                    | 10/10            | 11.7 (10) | 96                    | 10/10            | 12.2 (10) | 100                   | 10/10            |
| 10               | 11.6 (10) | 10/10                    |  | 11.3 (10) | 97                    | 10/10            | 11.3 (10) | 97                    | 10/10            | 10.7 (10) | 92                    | 10/10            | 11.5 (10) | 99                    | 10/10            | 11.8 (10) | 102                   | 10/10            |
| 11               | 11.5 (10) | 10/10                    |  | 11.3 (10) | 98                    | 10/10            | 11.0 (10) | 96                    | 10/10            | 11.0 (10) | 96                    | 10/10            | 11.7 (10) | 102                   | 10/10            | 12.1 (10) | 105                   | 10/10            |
| 12               | 11.5 (10) | 10/10                    |  | 11.1 (10) | 97                    | 10/10            | 11.2 (10) | 97                    | 10/10            | 10.7 (10) | 93                    | 10/10            | 12.1 (10) | 105                   | 10/10            | 12.3 (10) | 107                   | 10/10            |
| 13               | 11.1 (10) | 10/10                    |  | 11.1 (10) | 100                   | 10/10            | 10.4 (10) | 94                    | 10/10            | 10.2 (10) | 92                    | 10/10            | 11.5 (10) | 104                   | 10/10            | 11.7 (10) | 105                   | 10/10            |

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

TABLE 8 FOOD CONSUMPTION IN MALE RAT (THIRTEEN-WEEK STUDIES)

| Week<br>on Study | Control   |                          |  | 50 ppm    |                       |                  | 115 ppm   |                       |                  | 265 ppm   |                       |                  | 609 ppm   |                       |                  | 1400 ppm  |                       |                  |
|------------------|-----------|--------------------------|--|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|
|                  | Au.FC.    | No.of<br>Surviv.<br><10> |  | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 1                | 15.5 (10) | 10/10                    |  | 15.1 (10) | 97                    | 10/10            | 14.9 (10) | 96                    | 10/10            | 15.2 (10) | 98                    | 10/10            | 14.5 (10) | 94                    | 10/10            | 12.6 (10) | 81                    | 10/10            |
| 2                | 17.0 (10) | 10/10                    |  | 16.9 (10) | 99                    | 10/10            | 16.6 (10) | 98                    | 10/10            | 16.6 (10) | 98                    | 10/10            | 16.3 (10) | 96                    | 10/10            | 15.6 (10) | 92                    | 10/10            |
| 3                | 17.6 (10) | 10/10                    |  | 17.9 (10) | 102                   | 10/10            | 18.1 (10) | 103                   | 10/10            | 17.7 (10) | 101                   | 10/10            | 16.9 (10) | 96                    | 10/10            | 16.3 (10) | 93                    | 10/10            |
| 4                | 18.1 (10) | 10/10                    |  | 18.2 (10) | 101                   | 10/10            | 18.2 (10) | 101                   | 10/10            | 18.0 (10) | 99                    | 10/10            | 17.6 (10) | 97                    | 10/10            | 17.3 (10) | 96                    | 10/10            |
| 5                | 17.9 (10) | 10/10                    |  | 17.9 (10) | 100                   | 10/10            | 17.8 (10) | 99                    | 10/10            | 18.4 (10) | 103                   | 10/10            | 17.3 (10) | 97                    | 10/10            | 17.3 (10) | 97                    | 10/10            |
| 6                | 17.8 (10) | 10/10                    |  | 17.3 (10) | 97                    | 10/10            | 17.0 (10) | 96                    | 10/10            | 18.0 (10) | 101                   | 10/10            | 17.4 (10) | 98                    | 10/10            | 16.9 (10) | 95                    | 10/10            |
| 7                | 18.2 (10) | 10/10                    |  | 17.3 (10) | 95                    | 10/10            | 16.9 (10) | 93                    | 10/10            | 18.3 (10) | 101                   | 10/10            | 17.8 (10) | 98                    | 10/10            | 17.2 (10) | 95                    | 10/10            |
| 8                | 18.1 (10) | 10/10                    |  | 17.4 (10) | 96                    | 10/10            | 17.0 (10) | 94                    | 10/10            | 18.0 (10) | 99                    | 10/10            | 17.4 (10) | 96                    | 10/10            | 17.3 (10) | 96                    | 10/10            |
| 9                | 18.6 (10) | 10/10                    |  | 17.4 (10) | 94                    | 10/10            | 17.4 (10) | 94                    | 10/10            | 18.4 (10) | 99                    | 10/10            | 17.9 (10) | 96                    | 10/10            | 17.4 (10) | 94                    | 10/10            |
| 10               | 17.6 (10) | 10/10                    |  | 16.4 (10) | 93                    | 10/10            | 16.4 (10) | 93                    | 10/10            | 17.2 (10) | 98                    | 10/10            | 17.2 (10) | 98                    | 10/10            | 16.8 (10) | 95                    | 10/10            |
| 11               | 17.2 (10) | 10/10                    |  | 16.6 (10) | 97                    | 10/10            | 16.7 (10) | 97                    | 10/10            | 17.7 (10) | 103                   | 10/10            | 17.3 (10) | 101                   | 10/10            | 17.2 (10) | 100                   | 10/10            |
| 12               | 16.9 (10) | 10/10                    |  | 16.3 (10) | 96                    | 10/10            | 16.7 (10) | 99                    | 10/10            | 16.8 (10) | 99                    | 10/10            | 17.2 (10) | 102                   | 10/10            | 17.6 (10) | 104                   | 10/10            |
| 13               | 17.0 (10) | 10/10                    |  | 16.3 (10) | 96                    | 10/10            | 16.6 (10) | 98                    | 10/10            | 17.0 (10) | 100                   | 10/10            | 17.0 (10) | 100                   | 10/10            | 17.2 (10) | 101                   | 10/10            |

&lt; &gt;:No.of effective animals,( ):No.of measured animals Au.FC.: g

TABLE 9 FOOD CONSUMPTION IN FEMALE RAT (THIRTEEN-WEEK STUDIES)

| Week<br>on Study | Control  |                          |  | 50 ppm   |                       |                  | 115 ppm  |                       |                  | 265 ppm  |                       |                  | 609 ppm  |                       |                  | 1400 ppm |                       |                  |
|------------------|----------|--------------------------|--|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|
|                  | Au.Wt.   | No.of<br>Surviv.<br><10> |  | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 0                | 104 (10) | 10/10                    |  | 104 (10) | 100                   | 10/10            | 104 (10) | 100                   | 10/10            | 104 (10) | 100                   | 10/10            | 104 (10) | 100                   | 10/10            | 104 (10) | 100                   | 10/10            |
| 1                | 120 (10) | 10/10                    |  | 119 (10) | 99                    | 10/10            | 118 (10) | 98                    | 10/10            | 118 (10) | 98                    | 10/10            | 118 (10) | 98                    | 10/10            | 114 (10) | 95                    | 10/10            |
| 2                | 136 (10) | 10/10                    |  | 134 (10) | 99                    | 10/10            | 132 (10) | 97                    | 10/10            | 132 (10) | 97                    | 10/10            | 132 (10) | 97                    | 10/10            | 131 (10) | 96                    | 10/10            |
| 3                | 147 (10) | 10/10                    |  | 146 (10) | 99                    | 10/10            | 143 (10) | 97                    | 10/10            | 144 (10) | 98                    | 10/10            | 144 (10) | 98                    | 10/10            | 144 (10) | 98                    | 10/10            |
| 4                | 157 (10) | 10/10                    |  | 155 (10) | 99                    | 10/10            | 153 (10) | 97                    | 10/10            | 152 (10) | 97                    | 10/10            | 152 (10) | 97                    | 10/10            | 155 (10) | 99                    | 10/10            |
| 5                | 167 (10) | 10/10                    |  | 164 (10) | 98                    | 10/10            | 160 (10) | 96                    | 10/10            | 160 (10) | 96                    | 10/10            | 161 (10) | 96                    | 10/10            | 164 (10) | 98                    | 10/10            |
| 6                | 171 (10) | 10/10                    |  | 171 (10) | 100                   | 10/10            | 166 (10) | 97                    | 10/10            | 166 (10) | 97                    | 10/10            | 168 (10) | 98                    | 10/10            | 171 (10) | 100                   | 10/10            |
| 7                | 179 (10) | 10/10                    |  | 177 (10) | 99                    | 10/10            | 172 (10) | 96                    | 10/10            | 173 (10) | 97                    | 10/10            | 173 (10) | 97                    | 10/10            | 178 (10) | 99                    | 10/10            |
| 8                | 186 (10) | 10/10                    |  | 181 (10) | 97                    | 10/10            | 178 (10) | 96                    | 10/10            | 181 (10) | 97                    | 10/10            | 181 (10) | 97                    | 10/10            | 184 (10) | 99                    | 10/10            |
| 9                | 192 (10) | 10/10                    |  | 189 (10) | 98                    | 10/10            | 183 (10) | 95                    | 10/10            | 186 (10) | 97                    | 10/10            | 186 (10) | 97                    | 10/10            | 190 (10) | 99                    | 10/10            |
| 10               | 199 (10) | 10/10                    |  | 194 (10) | 97                    | 10/10            | 189 (10) | 95                    | 10/10            | 189 (10) | 95                    | 10/10            | 193 (10) | 97                    | 10/10            | 196 (10) | 98                    | 10/10            |
| 11               | 203 (10) | 10/10                    |  | 198 (10) | 98                    | 10/10            | 193 (10) | 95                    | 10/10            | 194 (10) | 96                    | 10/10            | 199 (10) | 98                    | 10/10            | 200 (10) | 99                    | 10/10            |
| 12               | 208 (10) | 10/10                    |  | 202 (10) | 97                    | 10/10            | 198 (10) | 95                    | 10/10            | 197 (10) | 95                    | 10/10            | 204 (10) | 98                    | 10/10            | 206 (10) | 99                    | 10/10            |
| 13               | 210 (10) | 10/10                    |  | 204 (10) | 97                    | 10/10            | 199 (10) | 95                    | 10/10            | 199 (10) | 95                    | 10/10            | 208 (10) | 99                    | 10/10            | 207 (10) | 99                    | 10/10            |

&lt; &gt;:No.of effective animals,( ):No.of measured animals Au.Wt.: g

TABLE 10 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN MALE RAT

(TWO-YEAR STUDIES)

| Week<br>on Study | Control  |                          | 50 ppm   |                       | 200 ppm          |          | 600 ppm               |                  |          |                       |                  |
|------------------|----------|--------------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|
|                  | Au.Wt.   | No.of<br>Surviv.<br><50> | Au.Wt.   | % of<br>cont.<br><50> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><50> | No.of<br>Surviv. | Au.Wt.   | % of<br>cont.<br><50> | No.of<br>Surviv. |
| 0                | 127 (50) | 50/50                    | 127 (50) | 100                   | 50/50            | 127 (50) | 100                   | 50/50            | 127 (50) | 100                   | 50/50            |
| 1                | 160 (50) | 50/50                    | 160 (50) | 100                   | 50/50            | 159 (50) | 99                    | 50/50            | 158 (50) | 99                    | 50/50            |
| 2                | 196 (50) | 50/50                    | 193 (50) | 98                    | 50/50            | 193 (50) | 98                    | 50/50            | 193 (50) | 98                    | 50/50            |
| 3                | 223 (50) | 50/50                    | 221 (50) | 99                    | 50/50            | 219 (50) | 98                    | 50/50            | 220 (50) | 99                    | 50/50            |
| 4                | 247 (50) | 50/50                    | 244 (50) | 99                    | 50/50            | 242 (50) | 98                    | 50/50            | 243 (50) | 98                    | 50/50            |
| 5                | 266 (50) | 50/50                    | 263 (50) | 99                    | 50/50            | 261 (50) | 98                    | 50/50            | 262 (50) | 98                    | 50/50            |
| 6                | 282 (50) | 50/50                    | 279 (50) | 99                    | 50/50            | 275 (50) | 98                    | 50/50            | 277 (50) | 98                    | 50/50            |
| 7                | 299 (50) | 50/50                    | 296 (50) | 99                    | 50/50            | 293 (50) | 98                    | 50/50            | 292 (50) | 98                    | 50/50            |
| 8                | 314 (50) | 50/50                    | 311 (50) | 99                    | 50/50            | 307 (50) | 98                    | 50/50            | 305 (50) | 97                    | 50/50            |
| 9                | 328 (50) | 50/50                    | 325 (50) | 99                    | 50/50            | 318 (50) | 97                    | 50/50            | 318 (50) | 97                    | 50/50            |
| 10               | 338 (50) | 50/50                    | 335 (50) | 99                    | 50/50            | 329 (50) | 97                    | 50/50            | 328 (50) | 97                    | 50/50            |
| 11               | 346 (50) | 50/50                    | 344 (50) | 99                    | 50/50            | 337 (50) | 97                    | 50/50            | 338 (50) | 98                    | 50/50            |
| 12               | 355 (50) | 50/50                    | 353 (50) | 99                    | 50/50            | 348 (50) | 98                    | 50/50            | 347 (50) | 98                    | 50/50            |
| 13               | 364 (50) | 50/50                    | 362 (50) | 99                    | 50/50            | 357 (50) | 98                    | 50/50            | 355 (50) | 98                    | 50/50            |
| 14               | 371 (50) | 50/50                    | 368 (50) | 99                    | 50/50            | 364 (50) | 98                    | 50/50            | 361 (50) | 97                    | 50/50            |
| 16               | 382 (50) | 50/50                    | 381 (50) | 100                   | 50/50            | 379 (50) | 99                    | 50/50            | 375 (50) | 98                    | 50/50            |
| 18               | 393 (50) | 50/50                    | 393 (50) | 100                   | 50/50            | 390 (50) | 99                    | 50/50            | 386 (50) | 98                    | 50/50            |
| 20               | 405 (50) | 50/50                    | 404 (50) | 100                   | 50/50            | 400 (50) | 99                    | 50/50            | 392 (50) | 97                    | 50/50            |
| 22               | 417 (50) | 50/50                    | 414 (50) | 99                    | 50/50            | 411 (50) | 99                    | 50/50            | 403 (50) | 97                    | 50/50            |
| 24               | 425 (50) | 50/50                    | 422 (50) | 99                    | 50/50            | 419 (50) | 99                    | 50/50            | 413 (50) | 97                    | 50/50            |
| 26               | 432 (50) | 50/50                    | 431 (50) | 100                   | 50/50            | 425 (50) | 99                    | 50/50            | 418 (50) | 97                    | 50/50            |
| 28               | 437 (50) | 50/50                    | 437 (50) | 100                   | 50/50            | 431 (50) | 99                    | 50/50            | 420 (50) | 96                    | 50/50            |
| 30               | 447 (50) | 50/50                    | 445 (50) | 100                   | 50/50            | 438 (50) | 98                    | 50/50            | 427 (50) | 96                    | 50/50            |
| 32               | 455 (50) | 50/50                    | 455 (50) | 100                   | 50/50            | 447 (50) | 98                    | 50/50            | 437 (50) | 96                    | 50/50            |
| 34               | 460 (50) | 50/50                    | 461 (50) | 100                   | 50/50            | 452 (50) | 98                    | 50/50            | 442 (50) | 96                    | 50/50            |
| 36               | 465 (50) | 50/50                    | 466 (50) | 100                   | 50/50            | 458 (50) | 98                    | 50/50            | 449 (50) | 97                    | 50/50            |
| 38               | 471 (50) | 50/50                    | 472 (50) | 100                   | 50/50            | 461 (50) | 98                    | 50/50            | 454 (50) | 96                    | 50/50            |
| 40               | 475 (50) | 50/50                    | 477 (50) | 100                   | 50/50            | 465 (50) | 98                    | 50/50            | 457 (50) | 96                    | 50/50            |
| 42               | 480 (50) | 50/50                    | 480 (50) | 100                   | 50/50            | 469 (50) | 98                    | 50/50            | 462 (50) | 96                    | 50/50            |
| 44               | 488 (50) | 50/50                    | 485 (50) | 99                    | 50/50            | 475 (50) | 97                    | 50/50            | 467 (50) | 96                    | 50/50            |
| 46               | 487 (50) | 50/50                    | 486 (50) | 100                   | 50/50            | 476 (50) | 98                    | 50/50            | 467 (50) | 96                    | 50/50            |
| 48               | 484 (50) | 50/50                    | 484 (50) | 100                   | 50/50            | 477 (50) | 99                    | 50/50            | 468 (50) | 97                    | 50/50            |
| 50               | 490 (50) | 50/50                    | 489 (50) | 100                   | 50/50            | 480 (50) | 98                    | 50/50            | 471 (50) | 96                    | 50/50            |
| 52               | 490 (50) | 50/50                    | 487 (50) | 99                    | 50/50            | 479 (50) | 98                    | 50/50            | 471 (50) | 96                    | 50/50            |
| 54               | 491 (50) | 50/50                    | 487 (50) | 99                    | 50/50            | 481 (50) | 98                    | 50/50            | 475 (50) | 97                    | 50/50            |
| 56               | 496 (50) | 50/50                    | 492 (50) | 99                    | 50/50            | 485 (50) | 98                    | 50/50            | 475 (50) | 96                    | 50/50            |
| 58               | 500 (50) | 50/50                    | 495 (50) | 99                    | 50/50            | 488 (50) | 98                    | 50/50            | 478 (50) | 96                    | 50/50            |
| 60               | 503 (50) | 50/50                    | 499 (50) | 99                    | 50/50            | 490 (50) | 97                    | 50/50            | 479 (50) | 95                    | 50/50            |
| 62               | 505 (50) | 50/50                    | 503 (50) | 100                   | 50/50            | 493 (50) | 98                    | 50/50            | 480 (50) | 95                    | 50/50            |
| 64               | 507 (50) | 50/50                    | 502 (50) | 99                    | 50/50            | 494 (50) | 97                    | 50/50            | 481 (49) | 95                    | 49/50            |
| 66               | 509 (50) | 50/50                    | 505 (49) | 99                    | 49/50            | 496 (50) | 97                    | 50/50            | 482 (49) | 95                    | 49/50            |
| 68               | 509 (50) | 50/50                    | 507 (48) | 100                   | 48/50            | 497 (50) | 98                    | 50/50            | 482 (49) | 95                    | 49/50            |
| 70               | 510 (50) | 50/50                    | 507 (48) | 99                    | 48/50            | 499 (49) | 98                    | 49/50            | 484 (49) | 95                    | 49/50            |
| 72               | 509 (50) | 50/50                    | 507 (48) | 100                   | 48/50            | 498 (49) | 98                    | 49/50            | 484 (49) | 95                    | 49/50            |
| 74               | 508 (50) | 50/50                    | 506 (48) | 100                   | 48/50            | 501 (48) | 99                    | 48/50            | 483 (49) | 95                    | 49/50            |
| 76               | 507 (50) | 50/50                    | 507 (48) | 100                   | 48/50            | 506 (48) | 100                   | 48/50            | 486 (49) | 96                    | 49/50            |
| 78               | 499 (50) | 50/50                    | 501 (48) | 100                   | 48/50            | 488 (47) | 98                    | 47/50            | 476 (49) | 95                    | 49/50            |
| 80               | 495 (50) | 50/50                    | 497 (48) | 100                   | 48/50            | 487 (46) | 98                    | 46/50            | 469 (49) | 95                    | 49/50            |
| 82               | 491 (50) | 50/50                    | 491 (47) | 100                   | 47/50            | 484 (46) | 99                    | 46/50            | 467 (46) | 95                    | 46/50            |
| 84               | 494 (48) | 48/50                    | 488 (47) | 99                    | 47/50            | 481 (46) | 97                    | 46/50            | 467 (45) | 95                    | 45/50            |
| 86               | 493 (47) | 47/50                    | 485 (47) | 98                    | 47/50            | 479 (45) | 97                    | 45/50            | 461 (45) | 94                    | 44/50            |
| 88               | 489 (46) | 46/50                    | 483 (47) | 99                    | 47/50            | 479 (45) | 98                    | 45/50            | 462 (44) | 94                    | 44/50            |
| 90               | 487 (45) | 45/50                    | 482 (46) | 99                    | 46/50            | 472 (45) | 97                    | 45/50            | 461 (43) | 95                    | 43/50            |
| 92               | 479 (44) | 43/50                    | 480 (44) | 100                   | 44/50            | 467 (44) | 97                    | 44/50            | 459 (42) | 96                    | 42/50            |
| 94               | 481 (41) | 41/50                    | 477 (44) | 99                    | 44/50            | 457 (44) | 95                    | 44/50            | 446 (42) | 93                    | 42/50            |
| 96               | 477 (41) | 41/50                    | 474 (44) | 99                    | 44/50            | 453 (42) | 95                    | 41/50            | 443 (39) | 93                    | 39/50            |
| 98               | 478 (40) | 40/50                    | 468 (43) | 98                    | 43/50            | 453 (40) | 95                    | 40/50            | 438 (37) | 92                    | 36/50            |
| 100              | 474 (40) | 40/50                    | 461 (42) | 97                    | 41/50            | 445 (38) | 94                    | 37/50            | 434 (34) | 92                    | 33/50            |
| 102              | 467 (40) | 40/50                    | 454 (37) | 97                    | 37/50            | 456 (33) | 98                    | 33/50            | 433 (32) | 93                    | 32/50            |
| 104              | 459 (38) | 37/50                    | 445 (35) | 97                    | 34/50            | 454 (32) | 99                    | 30/50            | 425 (28) | 95                    | 28/50            |

&lt; &gt;:No.of effective animals,( ):No.of measured animals

Au.Wt.: g

TABLE 11 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN FEMALE RAT

(TWO-YEAR STUDIES)

| Week<br>on Study | Control  |                          | 50 ppm   |                       | No.of<br>Surviv. | 200 ppm  |                       | No.of<br>Surviv. | 600 ppm  |                       | No.of<br>Surviv. |
|------------------|----------|--------------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|
|                  | Au.Wt.   | No.of<br>Surviv.<br><50> | Au.Wt.   | % of<br>cont.<br><50> |                  | Au.Wt.   | % of<br>cont.<br><50> |                  | Au.Wt.   | % of<br>cont.<br><50> |                  |
| 0                | 101 (50) | 50/50                    | 101 (50) | 100                   | 50/50            | 101 (50) | 100                   | 50/50            | 101 (50) | 100                   | 50/50            |
| 1                | 116 (50) | 50/50                    | 116 (50) | 100                   | 50/50            | 115 (50) | 99                    | 50/50            | 114 (50) | 98                    | 50/50            |
| 2                | 131 (50) | 50/50                    | 130 (50) | 99                    | 50/50            | 130 (50) | 99                    | 50/50            | 129 (50) | 98                    | 50/50            |
| 3                | 143 (50) | 50/50                    | 142 (50) | 99                    | 50/50            | 140 (50) | 98                    | 50/50            | 140 (50) | 98                    | 50/50            |
| 4                | 153 (50) | 50/50                    | 150 (50) | 98                    | 50/50            | 148 (50) | 97                    | 50/50            | 149 (50) | 97                    | 50/50            |
| 5                | 161 (50) | 50/50                    | 158 (50) | 98                    | 50/50            | 157 (50) | 98                    | 50/50            | 158 (50) | 98                    | 50/50            |
| 6                | 168 (50) | 50/50                    | 165 (50) | 98                    | 50/50            | 163 (50) | 97                    | 50/50            | 164 (50) | 98                    | 50/50            |
| 7                | 174 (50) | 50/50                    | 172 (50) | 99                    | 50/50            | 169 (50) | 97                    | 50/50            | 171 (50) | 98                    | 50/50            |
| 8                | 179 (50) | 50/50                    | 177 (50) | 99                    | 50/50            | 174 (50) | 97                    | 50/50            | 176 (50) | 98                    | 50/50            |
| 9                | 184 (50) | 50/50                    | 184 (50) | 100                   | 50/50            | 179 (50) | 97                    | 50/50            | 181 (50) | 98                    | 50/50            |
| 10               | 189 (50) | 50/50                    | 188 (50) | 99                    | 50/50            | 184 (50) | 97                    | 50/50            | 185 (50) | 98                    | 50/50            |
| 11               | 192 (50) | 50/50                    | 191 (50) | 99                    | 50/50            | 186 (50) | 97                    | 50/50            | 189 (50) | 98                    | 50/50            |
| 12               | 196 (50) | 50/50                    | 196 (50) | 100                   | 50/50            | 192 (50) | 98                    | 50/50            | 193 (50) | 98                    | 50/50            |
| 13               | 199 (50) | 50/50                    | 200 (50) | 101                   | 50/50            | 195 (50) | 98                    | 50/50            | 196 (50) | 98                    | 50/50            |
| 14               | 202 (50) | 50/50                    | 202 (50) | 100                   | 50/50            | 198 (50) | 98                    | 50/50            | 198 (50) | 98                    | 50/50            |
| 16               | 207 (50) | 50/50                    | 207 (50) | 100                   | 50/50            | 203 (50) | 98                    | 50/50            | 204 (50) | 99                    | 50/50            |
| 18               | 211 (50) | 50/50                    | 212 (50) | 100                   | 50/50            | 207 (50) | 98                    | 50/50            | 210 (50) | 100                   | 50/50            |
| 20               | 216 (50) | 50/50                    | 218 (50) | 101                   | 50/50            | 212 (50) | 98                    | 50/50            | 212 (50) | 98                    | 50/50            |
| 22               | 222 (50) | 50/50                    | 224 (50) | 101                   | 50/50            | 218 (50) | 98                    | 50/50            | 218 (50) | 98                    | 50/50            |
| 24               | 226 (50) | 50/50                    | 228 (50) | 101                   | 50/50            | 222 (50) | 98                    | 50/50            | 225 (50) | 100                   | 50/50            |
| 26               | 230 (50) | 50/50                    | 233 (50) | 101                   | 50/50            | 225 (50) | 98                    | 50/50            | 226 (50) | 98                    | 50/50            |
| 28               | 232 (50) | 50/50                    | 233 (50) | 100                   | 50/50            | 226 (50) | 97                    | 50/50            | 227 (50) | 98                    | 50/50            |
| 30               | 236 (50) | 50/50                    | 237 (50) | 100                   | 50/50            | 230 (50) | 97                    | 50/50            | 231 (50) | 98                    | 50/50            |
| 32               | 241 (50) | 50/50                    | 241 (50) | 100                   | 50/50            | 233 (50) | 97                    | 50/50            | 235 (50) | 98                    | 50/50            |
| 34               | 245 (50) | 50/50                    | 246 (50) | 100                   | 50/50            | 237 (50) | 97                    | 50/50            | 237 (50) | 97                    | 50/50            |
| 36               | 249 (50) | 50/50                    | 250 (50) | 100                   | 50/50            | 240 (50) | 96                    | 50/50            | 241 (50) | 97                    | 50/50            |
| 38               | 252 (50) | 50/50                    | 254 (50) | 101                   | 50/50            | 243 (50) | 96                    | 50/50            | 244 (50) | 97                    | 50/50            |
| 40               | 255 (50) | 50/50                    | 256 (50) | 100                   | 50/50            | 245 (50) | 96                    | 50/50            | 246 (50) | 96                    | 50/50            |
| 42               | 257 (50) | 50/50                    | 259 (50) | 101                   | 50/50            | 246 (50) | 96                    | 50/50            | 248 (50) | 96                    | 50/50            |
| 44               | 261 (50) | 50/50                    | 262 (50) | 100                   | 50/50            | 249 (50) | 95                    | 50/50            | 252 (50) | 97                    | 50/50            |
| 46               | 263 (50) | 50/50                    | 265 (50) | 101                   | 50/50            | 252 (50) | 96                    | 50/50            | 253 (50) | 96                    | 50/50            |
| 48               | 261 (50) | 50/50                    | 263 (50) | 101                   | 50/50            | 252 (50) | 97                    | 50/50            | 254 (50) | 97                    | 50/50            |
| 50               | 267 (50) | 50/50                    | 268 (50) | 100                   | 50/50            | 255 (50) | 96                    | 50/50            | 255 (50) | 96                    | 50/50            |
| 52               | 271 (50) | 50/50                    | 272 (50) | 100                   | 50/50            | 259 (50) | 96                    | 50/50            | 259 (50) | 96                    | 50/50            |
| 54               | 274 (50) | 50/50                    | 273 (50) | 100                   | 50/50            | 263 (50) | 96                    | 50/50            | 262 (50) | 96                    | 50/50            |
| 56               | 279 (50) | 50/50                    | 278 (50) | 100                   | 50/50            | 266 (50) | 95                    | 50/50            | 264 (50) | 95                    | 50/50            |
| 58               | 282 (50) | 50/50                    | 283 (50) | 100                   | 50/50            | 270 (50) | 96                    | 50/50            | 267 (50) | 95                    | 50/50            |
| 60               | 286 (50) | 50/50                    | 285 (50) | 100                   | 50/50            | 271 (50) | 95                    | 50/50            | 269 (50) | 94                    | 50/50            |
| 62               | 289 (50) | 50/50                    | 289 (50) | 100                   | 50/50            | 274 (50) | 95                    | 50/50            | 271 (50) | 94                    | 50/50            |
| 64               | 291 (50) | 50/50                    | 289 (50) | 99                    | 50/50            | 275 (50) | 95                    | 50/50            | 273 (50) | 94                    | 50/50            |
| 66               | 295 (50) | 50/50                    | 295 (49) | 100                   | 49/50            | 279 (50) | 95                    | 50/50            | 277 (50) | 94                    | 50/50            |
| 68               | 298 (50) | 50/50                    | 298 (49) | 100                   | 49/50            | 281 (50) | 94                    | 50/50            | 278 (50) | 93                    | 50/50            |
| 70               | 303 (50) | 50/50                    | 302 (48) | 100                   | 48/50            | 285 (48) | 94                    | 48/50            | 283 (49) | 93                    | 49/50            |
| 72               | 304 (50) | 50/50                    | 304 (48) | 100                   | 48/50            | 285 (48) | 94                    | 48/50            | 285 (49) | 94                    | 49/50            |
| 74               | 307 (50) | 50/50                    | 306 (47) | 100                   | 47/50            | 289 (47) | 94                    | 47/50            | 284 (49) | 93                    | 49/50            |
| 76               | 308 (50) | 50/50                    | 307 (47) | 100                   | 47/50            | 286 (47) | 93                    | 47/50            | 287 (49) | 93                    | 49/50            |
| 78               | 303 (50) | 50/50                    | 302 (47) | 100                   | 47/50            | 281 (47) | 93                    | 47/50            | 277 (49) | 91                    | 49/50            |
| 80               | 301 (50) | 50/50                    | 304 (46) | 101                   | 46/50            | 276 (46) | 92                    | 46/50            | 274 (48) | 91                    | 48/50            |
| 82               | 299 (49) | 49/50                    | 300 (46) | 100                   | 46/50            | 276 (46) | 92                    | 46/50            | 272 (47) | 91                    | 47/50            |
| 84               | 299 (49) | 49/50                    | 300 (46) | 100                   | 46/50            | 275 (45) | 92                    | 45/50            | 273 (46) | 91                    | 46/50            |
| 86               | 301 (49) | 49/50                    | 298 (46) | 99                    | 46/50            | 277 (45) | 92                    | 45/50            | 272 (46) | 90                    | 45/50            |
| 88               | 311 (49) | 49/50                    | 303 (45) | 97                    | 45/50            | 283 (45) | 91                    | 45/50            | 288 (45) | 93                    | 45/50            |
| 90               | 317 (49) | 49/50                    | 314 (42) | 99                    | 42/50            | 292 (42) | 92                    | 42/50            | 295 (45) | 93                    | 45/50            |
| 92               | 319 (49) | 49/50                    | 318 (42) | 100                   | 42/50            | 294 (41) | 92                    | 40/50            | 298 (44) | 93                    | 44/50            |
| 94               | 322 (48) | 48/50                    | 319 (41) | 99                    | 41/50            | 296 (40) | 92                    | 40/50            | 291 (42) | 90                    | 42/50            |
| 96               | 323 (48) | 48/50                    | 317 (41) | 98                    | 40/50            | 298 (39) | 92                    | 38/50            | 290 (42) | 90                    | 42/50            |
| 98               | 322 (48) | 48/50                    | 319 (37) | 99                    | 37/50            | 301 (38) | 93                    | 38/50            | 288 (41) | 89                    | 41/50            |
| 100              | 328 (46) | 46/50                    | 317 (37) | 97                    | 37/50            | 302 (37) | 92                    | 38/50            | 294 (38) | 90                    | 38/50            |
| 102              | 328 (45) | 45/50                    | 314 (37) | 96                    | 37/50            | 305 (36) | 93                    | 36/50            | 296 (36) | 90                    | 36/50            |
| 104              | 326 (43) | 42/50                    | 321 (34) | 98                    | 34/50            | 303 (35) | 93                    | 34/50            | 299 (34) | 92                    | 34/50            |

&lt; &gt;:No.of effective animals,( ):No.of measured animals

Au.Wt.: g

TABLE 12 INCIDENCE AND TIME OF MASS OCCURRENCE(CLINICAL OBSERVATION) :RAT :MALE

|                         |         | Dosing week   |       |       |       |       |       |       |        |        |
|-------------------------|---------|---|-------|-------|-------|-------|-------|-------|--------|--------|
| Time of mass occurrence |         | 0~13  | 14~26 | 27~39 | 40~52 | 53~65 | 66~78 | 79~91 | 92~104 | 0~104  |
| The kind of mass        |         | No. of animals with mass (No. of dead and moribund animals with mass) |       |       |       |       |       |       |        |        |
| Internal mass           |         |   |       |       |       |       |       |       |        |        |
|                         | Control | 0   | 0     | 0     | 0     | 0     | 0     | 0     | 3      | 3 (1)  |
|                         | 50 ppm  | 0   | 0     | 0     | 0     | 0     | 0     | 3     | 2      | 5 (4)  |
|                         | 200 ppm | 0   | 0     | 0     | 0     | 1     | 0     | 1     | 6      | 7 (6)  |
|                         | 600 ppm | 0   | 0     | 0     | 0     | 0     | 1     | 4     | 10     | 13(11) |
| External mass           |         |   |       |       |       |       |       |       |        |        |
|                         | Control | 0   | 0     | 0     | 0     | 10    | 13    | 11    | 13     | 27 (8) |
|                         | 50 ppm  | 0   | 0     | 0     | 0     | 7     | 10    | 12    | 17     | 30(15) |
|                         | 200 ppm | 0   | 0     | 0     | 0     | 14    | 23    | 18    | 20     | 36(13) |
|                         | 600 ppm | 0   | 0     | 0     | 0     | 4     | 9     | 19    | 23     | 29(11) |

TABLE 13 INCIDENCE AND TIME OF MASS OCCURRENCE(CLINICAL OBSERVATION) :RAT :FEMALE

|                         |         | Dosing week   |       |       |       |       |       |       |        |       |
|-------------------------|---------|---|-------|-------|-------|-------|-------|-------|--------|-------|
| Time of mass occurrence |         | 0~13  | 14~26 | 27~39 | 40~52 | 53~65 | 66~78 | 79~91 | 92~104 | 0~104 |
| The kind of mass        |         | No. of animals with mass (No. of dead and moribund animals with mass) |       |       |       |       |       |       |        |       |
| Internal mass           |         |   |       |       |       |       |       |       |        |       |
|                         | Control | 0   | 0     | 0     | 0     | 0     | 0     | 1     | 3      | 4(3)  |
|                         | 50 ppm  | 0   | 0     | 0     | 0     | 1     | 0     | 5     | 4      | 10(8) |
|                         | 200 ppm | 0   | 0     | 0     | 0     | 0     | 1     | 4     | 5      | 8(6)  |
|                         | 600 ppm | 0   | 0     | 0     | 0     | 0     | 1     | 2     | 6      | 8(7)  |
| External mass           |         |   |       |       |       |       |       |       |        |       |
|                         | Control | 0   | 0     | 0     | 0     | 0     | 0     | 3     | 5      | 5(1)  |
|                         | 50 ppm  | 0   | 0     | 0     | 0     | 1     | 4     | 8     | 12     | 14(5) |
|                         | 200 ppm | 0   | 0     | 0     | 0     | 2     | 1     | 5     | 6      | 8(2)  |
|                         | 600 ppm | 0   | 0     | 0     | 0     | 2     | 5     | 4     | 2      | 8(5)  |

(Study No. 0104, 0105)

TABLE 14 FOOD CONSUMPTION IN MALE RAT (TWO-YEAR STUDIES)

| Week<br>on Study | Control   |                           | 50 ppm    |                       | No. of<br>Surviv. | 200 ppm   |                       | No. of<br>Surviv. | 600 ppm   |                       | No. of<br>Surviv. |
|------------------|-----------|---------------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|-----------|-----------------------|-------------------|
|                  | Au.FC.    | No. of<br>Surviv.<br><50> | Au.FC.    | % of<br>cont.<br><50> |                   | Au.FC.    | % of<br>cont.<br><50> |                   | Au.FC.    | % of<br>cont.<br><50> |                   |
| 1                | 15.1 (50) | 50/50                     | 14.8 (50) | 98                    | 50/50             | 14.5 (50) | 96                    | 50/50             | 14.3 (50) | 95                    | 50/50             |
| 2                | 17.3 (50) | 50/50                     | 16.9 (50) | 98                    | 50/50             | 16.6 (50) | 96                    | 50/50             | 16.9 (49) | 98                    | 50/50             |
| 3                | 18.1 (50) | 50/50                     | 17.8 (50) | 98                    | 50/50             | 17.1 (50) | 94                    | 50/50             | 17.4 (50) | 96                    | 50/50             |
| 4                | 18.5 (50) | 50/50                     | 18.4 (50) | 99                    | 50/50             | 17.7 (50) | 96                    | 50/50             | 18.3 (50) | 99                    | 50/50             |
| 5                | 18.9 (50) | 50/50                     | 18.6 (50) | 98                    | 50/50             | 18.1 (50) | 96                    | 50/50             | 18.6 (50) | 98                    | 50/50             |
| 6                | 18.5 (50) | 50/50                     | 18.3 (50) | 99                    | 50/50             | 18.0 (50) | 97                    | 50/50             | 18.4 (50) | 99                    | 50/50             |
| 7                | 18.9 (50) | 50/50                     | 18.6 (50) | 98                    | 50/50             | 18.0 (50) | 95                    | 50/50             | 18.3 (50) | 97                    | 50/50             |
| 8                | 18.9 (50) | 50/50                     | 18.4 (50) | 97                    | 50/50             | 18.1 (50) | 96                    | 50/50             | 18.5 (50) | 98                    | 50/50             |
| 9                | 19.0 (50) | 50/50                     | 18.5 (50) | 97                    | 50/50             | 18.0 (50) | 95                    | 50/50             | 18.2 (50) | 96                    | 50/50             |
| 10               | 18.8 (50) | 50/50                     | 18.5 (50) | 98                    | 50/50             | 17.9 (50) | 95                    | 50/50             | 18.5 (50) | 98                    | 50/50             |
| 11               | 18.4 (50) | 50/50                     | 17.9 (50) | 97                    | 50/50             | 17.9 (50) | 97                    | 50/50             | 18.5 (50) | 101                   | 50/50             |
| 12               | 18.4 (50) | 50/50                     | 18.3 (50) | 99                    | 50/50             | 18.2 (50) | 99                    | 50/50             | 18.7 (50) | 102                   | 50/50             |
| 13               | 18.8 (50) | 50/50                     | 18.2 (50) | 97                    | 50/50             | 18.1 (50) | 96                    | 50/50             | 18.2 (50) | 97                    | 50/50             |
| 14               | 17.9 (50) | 50/50                     | 17.6 (50) | 98                    | 50/50             | 17.7 (50) | 99                    | 50/50             | 17.9 (50) | 100                   | 50/50             |
| 18               | 18.6 (50) | 50/50                     | 18.2 (50) | 98                    | 50/50             | 18.0 (50) | 97                    | 50/50             | 18.5 (50) | 99                    | 50/50             |
| 22               | 19.1 (50) | 50/50                     | 18.6 (50) | 97                    | 50/50             | 18.2 (50) | 95                    | 50/50             | 18.3 (50) | 96                    | 50/50             |
| 26               | 19.0 (50) | 50/50                     | 18.8 (50) | 99                    | 50/50             | 18.6 (50) | 98                    | 50/50             | 18.6 (50) | 98                    | 50/50             |
| 30               | 19.4 (50) | 50/50                     | 19.1 (50) | 98                    | 50/50             | 19.0 (50) | 98                    | 50/50             | 18.7 (50) | 96                    | 50/50             |
| 34               | 19.1 (50) | 50/50                     | 18.8 (50) | 98                    | 50/50             | 19.0 (50) | 99                    | 50/50             | 19.0 (50) | 99                    | 50/50             |
| 38               | 18.7 (50) | 50/50                     | 18.6 (50) | 99                    | 50/50             | 18.0 (50) | 96                    | 50/50             | 18.5 (50) | 99                    | 50/50             |
| 42               | 19.3 (50) | 50/50                     | 18.8 (50) | 97                    | 50/50             | 18.8 (50) | 97                    | 50/50             | 19.0 (50) | 98                    | 50/50             |
| 46               | 18.1 (50) | 50/50                     | 18.0 (50) | 99                    | 50/50             | 18.1 (50) | 100                   | 50/50             | 18.1 (50) | 100                   | 50/50             |
| 50               | 18.4 (50) | 50/50                     | 18.5 (50) | 101                   | 50/50             | 18.3 (50) | 99                    | 50/50             | 18.0 (50) | 98                    | 50/50             |
| 52               | 17.9 (50) | 50/50                     | 17.5 (50) | 98                    | 50/50             | 17.9 (50) | 100                   | 50/50             | 18.0 (50) | 101                   | 50/50             |
| 54               | 17.8 (50) | 50/50                     | 17.6 (50) | 99                    | 50/50             | 18.0 (50) | 101                   | 50/50             | 18.1 (50) | 102                   | 50/50             |
| 58               | 18.5 (50) | 50/50                     | 18.5 (50) | 100                   | 50/50             | 18.5 (50) | 100                   | 50/50             | 18.0 (50) | 97                    | 50/50             |
| 62               | 19.0 (50) | 50/50                     | 18.8 (50) | 99                    | 50/50             | 18.7 (50) | 98                    | 50/50             | 18.2 (50) | 96                    | 50/50             |
| 66               | 19.0 (50) | 50/50                     | 18.8 (49) | 99                    | 49/50             | 18.7 (50) | 98                    | 50/50             | 18.3 (49) | 96                    | 49/50             |
| 70               | 18.7 (50) | 50/50                     | 18.7 (48) | 100                   | 48/50             | 18.4 (49) | 98                    | 49/50             | 18.5 (49) | 99                    | 49/50             |
| 74               | 18.7 (50) | 50/50                     | 18.5 (48) | 99                    | 48/50             | 18.6 (48) | 99                    | 48/50             | 18.8 (49) | 101                   | 49/50             |
| 78               | 17.8 (50) | 50/50                     | 17.6 (48) | 99                    | 48/50             | 17.7 (46) | 99                    | 47/50             | 17.6 (49) | 99                    | 49/50             |
| 82               | 17.5 (50) | 50/50                     | 17.7 (47) | 101                   | 47/50             | 17.9 (46) | 102                   | 46/50             | 16.9 (48) | 97                    | 46/50             |
| 86               | 17.4 (48) | 47/50                     | 17.5 (47) | 101                   | 47/50             | 17.7 (46) | 102                   | 45/50             | 17.4 (45) | 100                   | 44/50             |
| 90               | 18.6 (46) | 45/50                     | 18.3 (46) | 98                    | 46/50             | 17.8 (45) | 96                    | 45/50             | 18.2 (43) | 98                    | 43/50             |
| 94               | 16.9 (42) | 41/50                     | 18.0 (44) | 107                   | 44/50             | 17.0 (44) | 101                   | 44/50             | 17.2 (42) | 102                   | 42/50             |
| 98               | 17.8 (40) | 40/50                     | 16.8 (43) | 94                    | 43/50             | 17.3 (40) | 97                    | 40/50             | 17.1 (37) | 96                    | 36/50             |
| 102              | 17.2 (40) | 40/50                     | 16.7 (39) | 97                    | 37/50             | 17.5 (33) | 102                   | 33/50             | 17.4 (32) | 101                   | 32/50             |
| 104              | 16.4 (39) | 37/50                     | 17.5 (35) | 107                   | 34/50             | 17.7 (32) | 108                   | 30/50             | 17.4 (29) | 106                   | 28/50             |

&lt; &gt;:No. of effective animals, ( ):No. of measured animals

Au.FC.: g

TABLE 15 FOOD CONSUMPTION IN FEMALE RAT (TWO-YEAR STUDIES)

| Week<br>on Study | Control   |                          |  | 50 ppm    |                       |                  | 200 ppm   |                       |                  | 600 ppm   |                       |                  |
|------------------|-----------|--------------------------|--|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|
|                  | Au.FC.    | No.of<br>Surviv.<br><50> |  | Au.FC.    | % of<br>cont.<br><50> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><50> | No.of<br>Surviv. | Au.FC.    | % of<br>cont.<br><50> | No.of<br>Surviv. |
| 1                | 11.3 (50) | 50/50                    |  | 11.0 (50) | 97                    | 50/50            | 10.9 (50) | 96                    | 50/50            | 10.7 (50) | 95                    | 50/50            |
| 2                | 11.7 (50) | 50/50                    |  | 11.5 (50) | 98                    | 50/50            | 11.3 (50) | 97                    | 50/50            | 11.5 (50) | 98                    | 50/50            |
| 3                | 11.7 (50) | 50/50                    |  | 11.5 (50) | 98                    | 50/50            | 11.2 (50) | 96                    | 50/50            | 11.3 (50) | 97                    | 50/50            |
| 4                | 11.9 (50) | 50/50                    |  | 11.6 (50) | 97                    | 50/50            | 11.4 (50) | 96                    | 50/50            | 11.9 (50) | 100                   | 50/50            |
| 5                | 11.8 (49) | 50/50                    |  | 11.7 (50) | 99                    | 50/50            | 11.5 (49) | 97                    | 50/50            | 11.7 (50) | 99                    | 50/50            |
| 6                | 12.0 (50) | 50/50                    |  | 11.5 (50) | 96                    | 50/50            | 11.6 (50) | 97                    | 50/50            | 11.6 (50) | 97                    | 50/50            |
| 7                | 12.0 (50) | 50/50                    |  | 11.8 (50) | 98                    | 50/50            | 11.4 (50) | 95                    | 50/50            | 11.6 (49) | 97                    | 50/50            |
| 8                | 11.8 (50) | 50/50                    |  | 11.8 (50) | 98                    | 50/50            | 11.4 (50) | 97                    | 50/50            | 11.7 (50) | 99                    | 50/50            |
| 9                | 11.8 (50) | 50/50                    |  | 12.2 (50) | 103                   | 50/50            | 11.6 (50) | 98                    | 50/50            | 11.8 (50) | 100                   | 50/50            |
| 10               | 11.9 (50) | 50/50                    |  | 11.9 (50) | 100                   | 50/50            | 11.4 (49) | 96                    | 50/50            | 11.7 (50) | 98                    | 50/50            |
| 11               | 11.2 (50) | 50/50                    |  | 11.3 (50) | 101                   | 50/50            | 11.0 (50) | 98                    | 50/50            | 11.3 (50) | 101                   | 50/50            |
| 12               | 12.0 (50) | 50/50                    |  | 12.3 (50) | 103                   | 50/50            | 11.8 (50) | 98                    | 50/50            | 12.2 (50) | 102                   | 50/50            |
| 13               | 12.0 (50) | 50/50                    |  | 12.3 (50) | 103                   | 50/50            | 12.1 (50) | 101                   | 50/50            | 11.9 (50) | 99                    | 50/50            |
| 14               | 12.0 (50) | 50/50                    |  | 11.6 (50) | 97                    | 50/50            | 11.7 (50) | 98                    | 50/50            | 11.6 (50) | 97                    | 50/50            |
| 18               | 12.0 (50) | 50/50                    |  | 12.3 (50) | 103                   | 50/50            | 12.0 (50) | 100                   | 50/50            | 12.3 (50) | 103                   | 50/50            |
| 22               | 12.5 (50) | 50/50                    |  | 12.6 (50) | 101                   | 50/50            | 12.1 (50) | 97                    | 50/50            | 12.4 (50) | 99                    | 50/50            |
| 26               | 12.8 (50) | 50/50                    |  | 13.2 (50) | 103                   | 50/50            | 12.2 (50) | 95                    | 50/50            | 12.5 (50) | 98                    | 50/50            |
| 30               | 12.5 (50) | 50/50                    |  | 12.6 (50) | 101                   | 50/50            | 12.5 (50) | 100                   | 50/50            | 12.4 (50) | 99                    | 50/50            |
| 34               | 12.8 (50) | 50/50                    |  | 13.0 (50) | 102                   | 50/50            | 12.9 (50) | 101                   | 50/50            | 12.4 (50) | 97                    | 50/50            |
| 38               | 12.7 (50) | 50/50                    |  | 13.0 (50) | 102                   | 50/50            | 12.2 (49) | 96                    | 50/50            | 12.3 (50) | 97                    | 50/50            |
| 42               | 12.5 (50) | 50/50                    |  | 12.5 (50) | 100                   | 50/50            | 12.0 (50) | 96                    | 50/50            | 12.6 (50) | 101                   | 50/50            |
| 46               | 12.5 (50) | 50/50                    |  | 12.7 (49) | 102                   | 50/50            | 12.3 (50) | 98                    | 50/50            | 12.2 (50) | 98                    | 50/50            |
| 50               | 13.0 (50) | 50/50                    |  | 13.5 (50) | 104                   | 50/50            | 12.8 (50) | 98                    | 50/50            | 12.3 (50) | 95                    | 50/50            |
| 52               | 12.6 (50) | 50/50                    |  | 12.6 (50) | 100                   | 50/50            | 12.4 (50) | 98                    | 50/50            | 12.5 (50) | 99                    | 50/50            |
| 54               | 12.1 (50) | 50/50                    |  | 12.2 (50) | 101                   | 50/50            | 12.4 (50) | 102                   | 50/50            | 12.4 (49) | 102                   | 50/50            |
| 58               | 12.6 (50) | 50/50                    |  | 12.9 (50) | 102                   | 50/50            | 12.9 (50) | 102                   | 50/50            | 12.7 (50) | 101                   | 50/50            |
| 62               | 13.0 (50) | 50/50                    |  | 13.3 (50) | 102                   | 50/50            | 13.0 (50) | 100                   | 50/50            | 13.0 (50) | 100                   | 50/50            |
| 66               | 13.2 (50) | 50/50                    |  | 13.2 (50) | 100                   | 49/50            | 13.2 (50) | 100                   | 50/50            | 13.4 (50) | 102                   | 50/50            |
| 70               | 13.7 (50) | 50/50                    |  | 13.6 (49) | 99                    | 48/50            | 12.9 (49) | 94                    | 48/50            | 13.6 (50) | 99                    | 49/50            |
| 74               | 13.3 (49) | 50/50                    |  | 13.5 (47) | 102                   | 47/50            | 13.5 (47) | 102                   | 47/50            | 13.4 (49) | 101                   | 49/50            |
| 78               | 11.9 (50) | 50/50                    |  | 11.9 (46) | 100                   | 47/50            | 11.7 (47) | 98                    | 47/50            | 11.5 (49) | 97                    | 49/50            |
| 82               | 12.4 (49) | 49/50                    |  | 12.8 (46) | 103                   | 46/50            | 12.4 (46) | 100                   | 46/50            | 12.5 (43) | 101                   | 47/50            |
| 86               | 12.9 (49) | 49/50                    |  | 12.5 (46) | 97                    | 46/50            | 12.7 (44) | 98                    | 45/50            | 12.7 (46) | 98                    | 45/50            |
| 90               | 14.8 (49) | 49/50                    |  | 14.5 (43) | 98                    | 42/50            | 14.0 (43) | 95                    | 42/50            | 14.8 (45) | 100                   | 45/50            |
| 94               | 14.3 (48) | 48/50                    |  | 14.5 (40) | 101                   | 41/50            | 14.0 (40) | 98                    | 40/50            | 14.4 (42) | 101                   | 42/50            |
| 98               | 13.6 (48) | 48/50                    |  | 14.5 (36) | 107                   | 37/50            | 14.2 (38) | 104                   | 38/50            | 13.7 (41) | 101                   | 41/50            |
| 102              | 13.3 (46) | 45/50                    |  | 13.7 (36) | 103                   | 37/50            | 13.9 (36) | 105                   | 36/50            | 13.5 (37) | 102                   | 36/50            |
| 104              | 12.9 (44) | 42/50                    |  | 14.6 (35) | 113                   | 34/50            | 14.3 (35) | 111                   | 34/50            | 14.2 (33) | 110                   | 34/50            |

&lt; &gt;:No.of effective animals,( ):No.of measured animals

Au.FC.: g

(Study No. 0104, 0105)



TABLE 16 NEOPLASTIC LESIONS (SPLEEN) INCIDENCE AND STATISTICAL ANALYSIS : RAT : MALE

| Group Name                         | Control      | 50 ppm       | 200 ppm      | 600 ppm      |
|------------------------------------|--------------|--------------|--------------|--------------|
| SITE : spleen                      |              |              |              |              |
| TUMOUR : mononuclear cell leukemia |              |              |              |              |
| Overall Rates(a)                   | 11/50 (22.0) | 14/50 (28.0) | 22/50 (44.0) | 27/50 (54.0) |
| Adjusted Rates(b)                  | 24.32        | 17.65        | 40.00        | 42.86        |
| Terminal Rates(c)                  | 9/37 (24.3)  | 6/34 (17.6)  | 12/30 (40.0) | 12/28 (42.9) |
| Standard Rates(d)                  | P=0.0022**   |              |              |              |
| Prevalence Rates(d)                | P=0.0104*    |              |              |              |
| Combind analysis(d)                | P=0.0001**   |              |              |              |
| Cochran-Armitage Test(e)           | P=0.0005**   |              |              |              |
| Fisher Exact Test(e)               |              | P=0.3777     | P=0.0707     | P=0.0201*    |

TABLE 17 NEOPLASTIC LESIONS (SPLEEN) INCIDENCE AND STATISTICAL ANALYSIS : RAT : FEMALE

| Group Name                    | Control      | 10 ppm       | 50 ppm       | 250 ppm      |
|-------------------------------|--------------|--------------|--------------|--------------|
| SITE : spleen                 |              |              |              |              |
| TUMOUR : hemangioendothelioma |              |              |              |              |
| Overall Rates(a)              | 10/50 (20.0) | 17/50 (34.0) | 16/50 (32.0) | 19/50 (38.0) |
| Adjusted Rates(b)             | 14.29        | 20.59        | 22.50        | 20.59        |
| Terminal Rates(c)             | 6/42 (14.3)  | 7/34 (20.6)  | 7/34 (20.6)  | 7/34 (20.6)  |
| Standard Rates(d)             | P=0.0486*    |              |              |              |
| Prevalence Rates(d)           | P=0.3153     |              |              |              |
| Combind analysis(d)           | P=0.0571     |              |              |              |
| Cochran-Armitage Test(e)      | P=0.1397     |              |              |              |
| Fisher Exact Test(e)          |              | P=0.1636     | P=0.2039     | P=0.1027     |

(a):Number of tumor-bearing animals/number of animals examined at the site.

(b):Kaplan-Meire estimate tumor incidence at the end of study after adjusting for intercurrent mortality.

(c):Observed tumor incidence at terminal kill.

(d):Beneath the control incidence are the P-values associated with the trend test.

Standard method : Death analysis

Prevalence method : Incidental tumor test

Combind analysis : Death analysis + Incidental tumor test

(e):The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates.

? :The conditional probabilities of the largest and smallest possible out comes can not estimated or this P-value beyond the estimated P-value.

-----:There is no data which should be statistic analysis.

TABLE 18 NUMBER OF RAT WITH SELECTED LIVER LESIONS

| Group                       | Male    |       |        |        | Female  |       |        |        |
|-----------------------------|---------|-------|--------|--------|---------|-------|--------|--------|
|                             | Control | 50ppm | 200ppm | 600ppm | Control | 50ppm | 200ppm | 600ppm |
| Number of examined          | 50      | 50    | 50     | 50     | 50      | 50    | 50     | 50     |
| Spongiosis hepatitis        | 5       | 4     | 10     | 16     | 0       | 0     | 0      | 0      |
| Hyperplasia                 | 4       | 2     | 5      | 13     | 2       | 1     | 5      | 1      |
| Clear cell focus            | 3       | 1     | 0      | 1      | 1       | 0     | 0      | 1      |
| Acidphilic cell focus       | 1       | 0     | 1      | 0      | 0       | 0     | 0      | 0      |
| Basophilic cell focus       | 4       | 3     | 0      | 4      | 1       | 1     | 2      | 0      |
| Vacuolic cell focus         | 0       | 2     | 1      | 1      | 0       | 0     | 0      | 2      |
| Mixed cell focus            | 4       | 3     | 1      | 1      | 0       | 0     | 0      | 2      |
| Hepatocellular adenoma      | 3       | 0     | 0      | 2      | 0       | 0     | 1      | 0      |
| Cholangiocellular adenoma   | 1       | 0     | 0      | 0      | 1       | 0     | 0      | 0      |
| Cholangiocellular carcinoma | 1       | 0     | 1      | 0      | 0       | 0     | 0      | 0      |

TABLE 19 NUMBER OF RAT WITH SELECTED KIDNEY LESIONS

| Group                      | Male    |       |        |        | Female  |       |        |        |
|----------------------------|---------|-------|--------|--------|---------|-------|--------|--------|
|                            | Control | 50ppm | 200ppm | 600ppm | Control | 50ppm | 200ppm | 600ppm |
| Number of examined         | 50      | 50    | 50     | 50     | 50      | 50    | 50     | 50     |
| Nuclear enlargement:       |         |       |        |        |         |       |        |        |
| proximal tubule            | 0       | 0     | 23     | 48     | 0       | 0     | 1      | 18     |
| Atypical tubular dilation: |         |       |        |        |         |       |        |        |
| proximal tubule            | 0       | 0     | 0      | 24     | 0       | 0     | 0      | 6      |
| Liposarcoma                | 0       | 0     | 0      | 1      | 0       | 0     | 0      | 0      |
| Renal cell adenoma         | 1       | 2     | 1      | 2      | 1       | 0     | 0      | 0      |
| Renal cell carcinoma       | 0       | 0     | 0      | 0      | 0       | 0     | 0      | 1      |

TABLE 20 CAUSE OF DEATH :RAT

| Group                          | Male    |       |        |        | Female  |       |        |        |
|--------------------------------|---------|-------|--------|--------|---------|-------|--------|--------|
|                                | Control | 50ppm | 200ppm | 600ppm | Control | 50ppm | 200ppm | 600ppm |
| Number of dead/moriboud animal | 13      | 16    | 20     | 22     | 8       | 16    | 16     | 16     |
| Renal lesion                   | 1       | 0     | 2      | 0      | 0       | 0     | 1      | 0      |
| Chronic nephropathy            | 0       | 0     | 0      | 1      | 0       | 0     | 0      | 0      |
| Tumor death : leukemia         | 3       | 8     | 9      | 14     | 4       | 10    | 7      | 12     |
| : subcutis                     | 0       | 1     | 2      | 1      | 0       | 0     | 0      | 1      |
| : spleen                       | 0       | 0     | 0      | 0      | 1       | 0     | 0      | 0      |
| : small intestine              | 0       | 0     | 0      | 1      | 0       | 0     | 1      | 0      |
| : kidney                       | 0       | 0     | 0      | 2      | 0       | 0     | 0      | 0      |
| : pituitary gland              | 4       | 2     | 4      | 1      | 3       | 1     | 2      | 3      |
| : thyroid                      | 0       | 0     | 0      | 0      | 0       | 1     | 0      | 0      |
| : adrenal                      | 1       | 1     | 0      | 1      | 0       | 1     | 0      | 0      |
| : uterus                       | 0       | 0     | 0      | 0      | 0       | 1     | 3      | 0      |
| : mammary gland                | 1       | 0     | 0      | 0      | 0       | 1     | 0      | 0      |
| : prep./cli. gland             | 0       | 0     | 1      | 0      | 0       | 1     | 1      | 0      |
| : brain                        | 1       | 0     | 0      | 0      | 0       | 0     | 1      | 0      |
| : Zymbal gland                 | 0       | 1     | 1      | 0      | 8       | 8     | 8      | 9      |
| : muscle                       | 1       | 0     | 0      | 0      | 0       | 0     | 1      | 0      |
| : bone                         | 0       | 1     | 1      | 1      | 5       | 2     | 2      | 2      |
| : pleura                       | 1       | 0     | 0      | 0      | 1       | 0     | 0      | 0      |
| : mediastinum                  | 0       | 1     | 0      | 0      | 1       | 2     | 2      | 1      |
| : peritoneum                   | 0       | 1     | 0      | 0      | 0       | 0     | 0      | 0      |

TABLE 21 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN MALE MOUSE (TWO-WEEK STUDIES)

| Week-Day<br>on Study | Control        |                          | 200 ppm   |                       |                  | 400 ppm   |                       |                  | 800 ppm   |                       |                  | 1600 ppm  |                       |                  | 3200 ppm  |                       |                  |
|----------------------|----------------|--------------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|
|                      | Au.Wt.<br><10> | No.of<br>Surviv.<br><10> | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 0-0                  | 23.1 (10)      | 10/10                    | 23.1 (10) | 100                   | 10/10            | 23.1 (10) | 100                   | 10/10            | 23.1 (10) | 100                   | 10/10            | 23.1 (10) | 100                   | 10/10            | 23.1 (10) | 100                   | 10/10            |
| 1-1                  | 22.4 (10)      | 10/10                    | 22.6 (10) | 101                   | 10/10            | 22.7 (10) | 101                   | 10/10            | 22.5 (10) | 100                   | 10/10            | 22.2 (10) | 99                    | 10/10            | 21.8 (10) | 97                    | 9/10             |
| 1-2                  | 22.7 (10)      | 10/10                    | 23.4 (10) | 103                   | 10/10            | 23.2 (10) | 102                   | 10/10            | 22.8 (10) | 100                   | 10/10            | 21.9 (10) | 96                    | 10/10            | 21.1 ( 9) | 93                    | 5/10             |
| 1-3                  | 23.1 (10)      | 10/10                    | 23.5 (10) | 102                   | 10/10            | 23.6 (10) | 102                   | 10/10            | 23.4 (10) | 101                   | 10/10            | 22.1 (10) | 96                    | 10/10            | 21.2 ( 5) | 92                    | 5/10             |
| 1-7                  | 23.7 (10)      | 10/10                    | 24.3 (10) | 103                   | 10/10            | 24.4 (10) | 103                   | 10/10            | 24.4 (10) | 103                   | 10/10            | 23.1 (10) | 97                    | 10/10            | 22.1 ( 1) | 93                    | 1/10             |
| 2-3                  | 23.9 (10)      | 10/10                    | 24.9 (10) | 104                   | 10/10            | 24.9 (10) | 104                   | 10/10            | 25.0 (10) | 105                   | 10/10            | 23.5 (10) | 98                    | 10/10            | 22.3 ( 1) | 93                    | 1/10             |
| 2-7                  | 24.5 (10)      | 10/10                    | 25.2 (10) | 103                   | 10/10            | 25.3 (10) | 103                   | 10/10            | 25.3 (10) | 103                   | 10/10            | 24.0 (10) | 98                    | 10/10            | 23.3 ( 1) | 95                    | 1/10             |

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

TABLE 22 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN FEMALE MOUSE (TWO-WEEK STUDIES)

| Week-Day<br>on Study | Control        |                          | 200 ppm   |                       |                  | 400 ppm   |                       |                  | 800 ppm   |                       |                  | 1600 ppm  |                       |                  | 3200 ppm  |                       |                  |
|----------------------|----------------|--------------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|
|                      | Au.Wt.<br><10> | No.of<br>Surviv.<br><10> | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 0-0                  | 19.2 (10)      | 10/10                    | 19.2 (10) | 100                   | 10/10            | 19.2 (10) | 100                   | 10/10            | 19.2 (10) | 100                   | 10/10            | 19.2 (10) | 100                   | 10/10            | 19.2 (10) | 100                   | 10/10            |
| 1-1                  | 18.4 (10)      | 10/10                    | 18.2 (10) | 99                    | 10/10            | 18.4 (10) | 100                   | 10/10            | 18.4 (10) | 100                   | 10/10            | 18.3 (10) | 99                    | 10/10            | 18.0 (10) | 98                    | 7/10             |
| 1-2                  | 18.3 (10)      | 10/10                    | 18.5 (10) | 101                   | 10/10            | 18.7 (10) | 102                   | 10/10            | 18.4 (10) | 101                   | 10/10            | 18.1 (10) | 99                    | 10/10            | 17.2 ( 7) | 94                    | 5/10             |
| 1-3                  | 18.6 (10)      | 10/10                    | 18.7 (10) | 101                   | 10/10            | 19.0 (10) | 102                   | 10/10            | 19.1 (10) | 103                   | 10/10            | 18.5 (10) | 99                    | 10/10            | 16.7 ( 5) | 90                    | 5/10             |
| 1-7                  | 18.8 (10)      | 10/10                    | 19.2 (10) | 102                   | 10/10            | 19.9 (10) | 106                   | 10/10            | 20.0 (10) | 106                   | 10/10            | 19.4 (10) | 103                   | 10/10            | 17.5 ( 5) | 93                    | 5/10             |
| 2-3                  | 19.7 (10)      | 10/10                    | 20.5 (10) | 104                   | 10/10            | 20.5 (10) | 104                   | 10/10            | 20.8 (10) | 106                   | 10/10            | 20.8 (10) | 106                   | 10/10            | 18.8 ( 3) | 95                    | 3/10             |
| 2-7                  | 20.1 (10)      | 10/10                    | 21.1 (10) | 105                   | 10/10            | 20.9 (10) | 104                   | 10/10            | 21.1 (10) | 105                   | 10/10            | 21.0 (10) | 104                   | 10/10            | 19.1 ( 3) | 95                    | 3/10             |

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

TABLE 23 FOOD CONSUMPTION IN MALE MOUSE (TWO-WEEK STUDIES)

| Week-Day<br>on Study | Control  |                          | 200 ppm  |                       |                  | 400 ppm  |                       |                  | 800 ppm  |                       |                  | 1600 ppm |                       |                  | 3200 ppm |                       |                  |
|----------------------|----------|--------------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|
|                      | Au.FC.   | No.of<br>Surviv.<br><10> | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 1-7                  | 3.7 (10) | 10/10                    | 3.7 (10) | 100                   | 10/10            | 3.8 (10) | 103                   | 10/10            | 3.8 (10) | 103                   | 10/10            | 3.4 (10) | 92                    | 10/10            | 2.7 ( 1) | 73                    | 1/10             |
| 2-7                  | 3.6 ( 9) | 10/10                    | 3.8 (10) | 106                   | 10/10            | 3.9 (10) | 108                   | 10/10            | 4.4 (10) | 122                   | 10/10            | 4.6 (10) | 128                   | 10/10            | 3.9 ( 1) | 108                   | 1/10             |

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

TABLE 24 FOOD CONSUMPTION IN FEMALE MOUSE (TWO-WEEK STUDIES)

| Week-Day<br>on Study | Control  |                          | 200 ppm  |                       |                  | 400 ppm  |                       |                  | 800 ppm  |                       |                  | 1600 ppm |                       |                  | 3200 ppm |                       |                  |
|----------------------|----------|--------------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|
|                      | Au.FC.   | No.of<br>Surviv.<br><10> | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 1-7                  | 2.9 (10) | 10/10                    | 3.0 (10) | 103                   | 10/10            | 3.3 (10) | 114                   | 10/10            | 3.4 (10) | 117                   | 10/10            | 3.3 (10) | 114                   | 10/10            | 2.3 ( 5) | 79                    | 5/10             |
| 2-7                  | 3.0 (10) | 10/10                    | 3.4 (10) | 113                   | 10/10            | 3.4 (10) | 113                   | 10/10            | 3.5 (10) | 117                   | 10/10            | 3.9 (10) | 130                   | 10/10            | 3.8 ( 3) | 127                   | 3/10             |

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

TABLE 25 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN MALE MOUSE (THIRTEEN-WEEK STUDIES)

| Week<br>on Study | Control   |                          |  | 50 ppm    |                       |                  | 115 ppm   |                       |                  | 265 ppm   |                       |                  | 609 ppm   |                       |                  | 1400 ppm  |                       |                  |
|------------------|-----------|--------------------------|--|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|
|                  | Au.Wt.    | No.of<br>Surviv.<br><10> |  | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 0                | 22.7 (10) | 10/10                    |  | 22.7 (10) | 100                   | 10/10            | 22.7 (10) | 100                   | 10/10            | 22.7 (10) | 100                   | 10/10            | 22.7 (10) | 100                   | 10/10            | 22.7 (10) | 100                   | 10/10            |
| 1                | 24.3 (10) | 10/10                    |  | 24.4 (10) | 100                   | 10/10            | 24.3 (10) | 100                   | 10/10            | 23.9 (10) | 98                    | 10/10            | 24.6 (10) | 101                   | 10/10            | 22.8 (10) | 94                    | 10/10            |
| 2                | 25.5 (10) | 10/10                    |  | 26.0 (10) | 102                   | 10/10            | 25.8 (10) | 101                   | 10/10            | 25.4 (10) | 100                   | 10/10            | 26.0 (10) | 102                   | 10/10            | 22.2 (10) | 87                    | 10/10            |
| 3                | 26.7 (10) | 10/10                    |  | 27.1 (10) | 101                   | 10/10            | 26.9 (10) | 101                   | 10/10            | 26.6 (10) | 100                   | 10/10            | 26.8 (10) | 100                   | 10/10            | 23.7 (10) | 89                    | 10/10            |
| 4                | 27.5 (10) | 10/10                    |  | 28.1 (10) | 102                   | 10/10            | 27.9 (10) | 101                   | 10/10            | 27.4 (10) | 100                   | 10/10            | 26.8 (10) | 97                    | 10/10            | 24.5 (10) | 89                    | 10/10            |
| 5                | 28.9 (10) | 10/10                    |  | 29.1 (10) | 101                   | 10/10            | 29.1 (10) | 101                   | 10/10            | 28.4 (10) | 98                    | 10/10            | 27.3 (10) | 94                    | 10/10            | 24.5 (10) | 85                    | 10/10            |
| 6                | 29.8 (10) | 10/10                    |  | 29.9 (10) | 100                   | 10/10            | 29.6 (10) | 99                    | 10/10            | 29.2 (10) | 98                    | 10/10            | 27.1 (10) | 91                    | 10/10            | 24.9 (10) | 84                    | 10/10            |
| 7                | 30.7 (10) | 10/10                    |  | 31.1 (10) | 101                   | 10/10            | 30.9 (10) | 101                   | 10/10            | 29.7 (10) | 97                    | 10/10            | 27.6 (10) | 90                    | 10/10            | 25.7 (10) | 84                    | 10/10            |
| 8                | 31.4 (10) | 10/10                    |  | 32.1 (10) | 102                   | 10/10            | 31.9 (10) | 102                   | 10/10            | 30.6 (10) | 97                    | 10/10            | 27.8 (10) | 89                    | 10/10            | 26.2 (10) | 83                    | 10/10            |
| 9                | 32.8 (10) | 10/10                    |  | 32.9 (10) | 100                   | 10/10            | 32.8 (10) | 100                   | 10/10            | 31.3 (10) | 95                    | 10/10            | 28.3 (10) | 86                    | 10/10            | 26.5 (10) | 81                    | 10/10            |
| 10               | 33.5 (10) | 10/10                    |  | 33.7 (10) | 101                   | 10/10            | 33.6 (10) | 100                   | 10/10            | 32.0 (10) | 96                    | 10/10            | 29.2 (10) | 87                    | 10/10            | 28.0 (10) | 84                    | 10/10            |
| 11               | 34.3 (10) | 10/10                    |  | 34.7 (10) | 101                   | 10/10            | 34.4 (10) | 100                   | 10/10            | 32.5 (10) | 95                    | 10/10            | 28.9 (10) | 84                    | 10/10            | 26.5 (10) | 77                    | 10/10            |
| 12               | 35.0 (10) | 10/10                    |  | 35.3 (10) | 101                   | 10/10            | 35.2 (10) | 101                   | 10/10            | 33.0 (10) | 94                    | 10/10            | 28.9 (10) | 83                    | 10/10            | 27.6 (10) | 79                    | 10/10            |
| 13               | 35.9 (10) | 10/10                    |  | 36.1 (10) | 101                   | 10/10            | 35.9 (10) | 100                   | 10/10            | 33.1 (10) | 92                    | 10/10            | 29.1 (10) | 81                    | 10/10            | 27.7 (10) | 77                    | 10/10            |

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

TABLE 26 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN FEMALE MOUSE (THIRTEEN-WEEK STUDIES)

| Week<br>on Study | Control   |                          |  | 50 ppm    |                       |                  | 115 ppm   |                       |                  | 265 ppm   |                       |                  | 609 ppm   |                       |                  | 1400 ppm  |                       |                  |
|------------------|-----------|--------------------------|--|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|
|                  | Au.Wt.    | No.of<br>Surviv.<br><10> |  | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 0                | 19.0 (10) | 10/10                    |  | 19.0 (10) | 100                   | 10/10            | 19.0 (10) | 100                   | 10/10            | 19.0 (10) | 100                   | 10/10            | 19.0 (10) | 100                   | 10/10            | 19.0 (10) | 100                   | 10/10            |
| 1                | 20.1 (10) | 10/10                    |  | 19.9 (10) | 99                    | 10/10            | 19.8 (10) | 99                    | 10/10            | 20.2 (10) | 100                   | 10/10            | 20.1 (10) | 100                   | 10/10            | 19.3 (10) | 96                    | 10/10            |
| 2                | 20.7 (10) | 10/10                    |  | 20.6 (10) | 100                   | 10/10            | 20.5 (10) | 99                    | 10/10            | 21.2 (10) | 102                   | 10/10            | 20.8 (10) | 100                   | 10/10            | 20.3 (10) | 98                    | 10/10            |
| 3                | 21.5 (10) | 10/10                    |  | 21.5 (10) | 100                   | 10/10            | 21.4 (10) | 100                   | 10/10            | 21.9 (10) | 102                   | 10/10            | 21.6 (10) | 100                   | 10/10            | 21.2 (10) | 99                    | 10/10            |
| 4                | 22.1 (10) | 10/10                    |  | 22.2 (10) | 100                   | 10/10            | 22.5 (10) | 102                   | 10/10            | 22.3 (10) | 101                   | 10/10            | 22.3 (10) | 101                   | 10/10            | 22.1 (10) | 100                   | 10/10            |
| 5                | 22.8 (10) | 10/10                    |  | 23.1 (10) | 101                   | 10/10            | 23.1 (10) | 101                   | 10/10            | 22.9 (10) | 100                   | 10/10            | 22.9 (10) | 100                   | 10/10            | 22.4 (10) | 98                    | 10/10            |
| 6                | 23.8 (10) | 10/10                    |  | 23.9 (10) | 100                   | 10/10            | 23.6 (10) | 99                    | 10/10            | 23.4 (10) | 98                    | 10/10            | 23.6 (10) | 99                    | 10/10            | 22.9 (10) | 96                    | 10/10            |
| 7                | 24.5 (10) | 10/10                    |  | 24.8 (10) | 101                   | 10/10            | 24.7 (10) | 101                   | 10/10            | 24.2 (10) | 99                    | 10/10            | 24.1 (10) | 98                    | 10/10            | 23.4 (10) | 96                    | 10/10            |
| 8                | 25.3 (10) | 10/10                    |  | 25.5 (10) | 101                   | 10/10            | 25.2 (10) | 100                   | 10/10            | 25.3 (10) | 100                   | 10/10            | 24.5 (10) | 97                    | 10/10            | 23.5 (10) | 93                    | 10/10            |
| 9                | 25.9 (10) | 10/10                    |  | 26.2 (10) | 101                   | 10/10            | 25.2 (10) | 97                    | 10/10            | 25.4 (10) | 98                    | 10/10            | 25.0 (10) | 97                    | 10/10            | 24.4 (10) | 94                    | 10/10            |
| 10               | 26.7 (10) | 10/10                    |  | 26.5 (10) | 99                    | 10/10            | 26.4 (10) | 99                    | 10/10            | 25.7 (10) | 96                    | 10/10            | 25.6 (10) | 96                    | 10/10            | 25.2 (10) | 94                    | 10/10            |
| 11               | 27.4 (10) | 10/10                    |  | 26.6 (10) | 97                    | 10/10            | 26.4 (10) | 96                    | 10/10            | 26.2 (10) | 96                    | 10/10            | 25.2 (10) | 92                    | 10/10            | 24.3 (10) | 89                    | 10/10            |
| 12               | 27.3 (10) | 10/10                    |  | 27.5 (10) | 101                   | 10/10            | 27.0 (10) | 99                    | 10/10            | 26.8 (10) | 98                    | 10/10            | 25.6 (10) | 94                    | 10/10            | 25.1 (10) | 92                    | 10/10            |
| 13               | 28.0 (10) | 10/10                    |  | 28.0 (10) | 100                   | 10/10            | 27.3 (10) | 98                    | 10/10            | 27.6 (10) | 99                    | 10/10            | 26.0 (10) | 93                    | 10/10            | 25.3 (10) | 90                    | 10/10            |

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

TABLE 27 FOOD CONSUMPTION IN MALE MOUSE (THIRTEEN-WEEK STUDIES)

| Week<br>on Study | Control  |                          |  | 50 ppm   |                       |                  | 115 ppm  |                       |                  | 265 ppm  |                       |                  | 609 ppm  |                       |                  | 1400 ppm |                       |                  |
|------------------|----------|--------------------------|--|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|
|                  | Au.FC.   | No.of<br>Surviv.<br><10> |  | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 1                | 3.7 (10) | 10/10                    |  | 3.8 (10) | 103                   | 10/10            | 3.9 (10) | 105                   | 10/10            | 3.8 (10) | 103                   | 10/10            | 4.0 (10) | 108                   | 10/10            | 3.9 (10) | 105                   | 10/10            |
| 2                | 3.7 (10) | 10/10                    |  | 3.8 (10) | 103                   | 10/10            | 3.8 (10) | 103                   | 10/10            | 3.8 (10) | 103                   | 10/10            | 4.1 (10) | 111                   | 10/10            | 4.0 (10) | 108                   | 10/10            |
| 3                | 3.7 (10) | 10/10                    |  | 3.7 (10) | 100                   | 10/10            | 3.8 (10) | 103                   | 10/10            | 3.8 (10) | 103                   | 10/10            | 4.2 (10) | 114                   | 10/10            | 4.1 (10) | 111                   | 10/10            |
| 4                | 3.8 (10) | 10/10                    |  | 3.8 (10) | 100                   | 10/10            | 3.9 (10) | 103                   | 10/10            | 3.8 (10) | 100                   | 10/10            | 4.4 (10) | 116                   | 10/10            | 4.4 (10) | 116                   | 10/10            |
| 5                | 4.0 (10) | 10/10                    |  | 3.9 (10) | 98                    | 10/10            | 4.1 (10) | 103                   | 10/10            | 4.0 (10) | 100                   | 10/10            | 4.5 (10) | 113                   | 10/10            | 4.3 (10) | 108                   | 10/10            |
| 6                | 4.1 (10) | 10/10                    |  | 4.0 (10) | 98                    | 10/10            | 4.1 (10) | 100                   | 10/10            | 4.1 (10) | 100                   | 10/10            | 4.4 (10) | 107                   | 10/10            | 4.1 (10) | 100                   | 10/10            |
| 7                | 4.0 (10) | 10/10                    |  | 4.1 (10) | 103                   | 10/10            | 4.0 (10) | 100                   | 10/10            | 4.0 (10) | 100                   | 10/10            | 4.3 (10) | 108                   | 10/10            | 4.2 (10) | 105                   | 10/10            |
| 8                | 4.0 (10) | 10/10                    |  | 4.1 (10) | 103                   | 10/10            | 4.1 (10) | 103                   | 10/10            | 4.0 (10) | 100                   | 10/10            | 4.0 (10) | 100                   | 10/10            | 4.0 (10) | 100                   | 10/10            |
| 9                | 4.0 (10) | 10/10                    |  | 4.1 (10) | 103                   | 10/10            | 4.1 (10) | 103                   | 10/10            | 4.0 (10) | 100                   | 10/10            | 3.9 (10) | 98                    | 10/10            | 3.8 (10) | 95                    | 10/10            |
| 10               | 4.0 (10) | 10/10                    |  | 4.0 (10) | 100                   | 10/10            | 4.1 (10) | 103                   | 10/10            | 4.0 (10) | 100                   | 10/10            | 4.0 (10) | 100                   | 10/10            | 3.9 (10) | 98                    | 10/10            |
| 11               | 4.0 (10) | 10/10                    |  | 4.0 (10) | 100                   | 10/10            | 4.1 (10) | 103                   | 10/10            | 3.9 (10) | 98                    | 10/10            | 3.5 (10) | 88                    | 10/10            | 3.4 (10) | 85                    | 10/10            |
| 12               | 4.0 (10) | 10/10                    |  | 4.0 (10) | 100                   | 10/10            | 4.2 (10) | 105                   | 10/10            | 3.9 (10) | 98                    | 10/10            | 3.8 (10) | 95                    | 10/10            | 3.9 (10) | 98                    | 10/10            |
| 13               | 4.0 (10) | 10/10                    |  | 4.0 (10) | 100                   | 10/10            | 4.1 (10) | 103                   | 10/10            | 4.0 (10) | 100                   | 10/10            | 3.7 (10) | 93                    | 10/10            | 3.8 (10) | 95                    | 10/10            |

&lt; &gt;:No.of effective animals,( ):No.of measured animals

Au.FC.:g

TABLE 28 FOOD CONSUMPTION IN FEMALE MOUSE (THIRTEEN-WEEK STUDIES)

| Week<br>on Study | Control  |                          |  | 50 ppm   |                       |                  | 115 ppm  |                       |                  | 265 ppm  |                       |                  | 609 ppm  |                       |                  | 1400 ppm |                       |                  |
|------------------|----------|--------------------------|--|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|
|                  | Au.FC.   | No.of<br>Surviv.<br><10> |  | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><10> | No.of<br>Surviv. |
| 1                | 3.3 (10) | 10/10                    |  | 3.2 (10) | 97                    | 10/10            | 3.2 (10) | 97                    | 10/10            | 3.4 (10) | 103                   | 10/10            | 3.3 (10) | 100                   | 10/10            | 3.1 (10) | 94                    | 10/10            |
| 2                | 3.2 (10) | 10/10                    |  | 3.2 (10) | 100                   | 10/10            | 3.3 (10) | 103                   | 10/10            | 3.4 (10) | 106                   | 10/10            | 3.3 (10) | 103                   | 10/10            | 3.7 (10) | 116                   | 10/10            |
| 3                | 3.2 (10) | 10/10                    |  | 3.4 (10) | 106                   | 10/10            | 3.5 (10) | 109                   | 10/10            | 3.3 (10) | 103                   | 10/10            | 3.3 (10) | 103                   | 10/10            | 4.0 (10) | 125                   | 10/10            |
| 4                | 3.3 (10) | 10/10                    |  | 3.5 (10) | 106                   | 10/10            | 3.6 (10) | 109                   | 10/10            | 3.4 (10) | 103                   | 10/10            | 3.5 (10) | 106                   | 10/10            | 4.0 (10) | 121                   | 10/10            |
| 5                | 3.7 (10) | 10/10                    |  | 3.9 (10) | 105                   | 10/10            | 3.8 (10) | 103                   | 10/10            | 3.8 (10) | 103                   | 10/10            | 3.7 (10) | 100                   | 10/10            | 3.9 (10) | 105                   | 10/10            |
| 6                | 3.9 ( 9) | 10/10                    |  | 3.9 (10) | 100                   | 10/10            | 4.0 (10) | 103                   | 10/10            | 3.9 (10) | 100                   | 10/10            | 3.9 (10) | 100                   | 10/10            | 4.0 (10) | 103                   | 10/10            |
| 7                | 3.9 (10) | 10/10                    |  | 4.1 (10) | 105                   | 10/10            | 4.0 (10) | 103                   | 10/10            | 3.8 (10) | 97                    | 10/10            | 3.9 (10) | 100                   | 10/10            | 3.9 (10) | 100                   | 10/10            |
| 8                | 4.0 (10) | 10/10                    |  | 4.0 (10) | 100                   | 10/10            | 4.1 (10) | 103                   | 10/10            | 4.0 (10) | 100                   | 10/10            | 3.9 (10) | 98                    | 10/10            | 3.8 (10) | 95                    | 10/10            |
| 9                | 3.9 (10) | 10/10                    |  | 4.1 (10) | 105                   | 10/10            | 4.0 (10) | 103                   | 10/10            | 3.9 (10) | 100                   | 10/10            | 3.8 (10) | 97                    | 10/10            | 3.8 (10) | 97                    | 10/10            |
| 10               | 3.9 (10) | 10/10                    |  | 3.9 (10) | 100                   | 10/10            | 4.2 (10) | 108                   | 10/10            | 3.7 (10) | 95                    | 10/10            | 3.8 (10) | 97                    | 10/10            | 3.9 (10) | 100                   | 10/10            |
| 11               | 3.8 (10) | 10/10                    |  | 3.7 (10) | 97                    | 10/10            | 3.9 (10) | 103                   | 10/10            | 3.7 (10) | 97                    | 10/10            | 3.6 (10) | 95                    | 10/10            | 3.6 (10) | 95                    | 10/10            |
| 12               | 3.7 (10) | 10/10                    |  | 3.8 (10) | 103                   | 10/10            | 4.0 (10) | 108                   | 10/10            | 3.7 (10) | 100                   | 10/10            | 3.7 (10) | 100                   | 10/10            | 3.9 (10) | 105                   | 10/10            |
| 13               | 3.8 (10) | 10/10                    |  | 3.9 (10) | 103                   | 10/10            | 4.0 (10) | 105                   | 10/10            | 3.9 (10) | 103                   | 10/10            | 3.7 (10) | 97                    | 10/10            | 3.8 (10) | 100                   | 10/10            |

&lt; &gt;:No.of effective animals,( ):No.of measured animals

Au.FC.:g

(Study No.0104,0105)

TABLE 29 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN MALE MOUSE

(TWO-YEAR STUDIES)

| Week<br>on Study | Control   |                          | 10 ppm    |                       |                  | 50 ppm    |                       |                  | 250 ppm   |                       |                  |
|------------------|-----------|--------------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|
|                  | Au.Wt.    | No.of<br>Surviv.<br><50> | Au.Wt.    | % of<br>cont.<br><50> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><50> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><50> | No.of<br>Surviv. |
| 0                | 22.7 (50) | 50/50                    | 22.7 (50) | 100                   | 50/50            | 22.7 (50) | 100                   | 50/50            | 22.7 (50) | 100                   | 50/50            |
| 1                | 24.6 (50) | 50/50                    | 24.4 (50) | 99                    | 50/50            | 24.4 (50) | 99                    | 50/50            | 24.4 (50) | 99                    | 50/50            |
| 2                | 25.3 (50) | 50/50                    | 24.8 (50) | 98                    | 50/50            | 25.3 (50) | 100                   | 50/50            | 25.3 (50) | 100                   | 50/50            |
| 3                | 26.3 (50) | 50/50                    | 25.8 (50) | 98                    | 50/50            | 26.0 (50) | 99                    | 50/50            | 25.9 (49) | 98                    | 50/50            |
| 4                | 27.0 (50) | 50/50                    | 26.4 (50) | 98                    | 50/50            | 26.6 (50) | 99                    | 50/50            | 26.4 (50) | 98                    | 50/50            |
| 5                | 27.8 (50) | 50/50                    | 27.4 (50) | 99                    | 50/50            | 27.7 (50) | 100                   | 50/50            | 27.2 (50) | 98                    | 50/50            |
| 6                | 28.5 (50) | 50/50                    | 27.8 (50) | 98                    | 50/50            | 28.3 (50) | 99                    | 50/50            | 27.6 (50) | 97                    | 50/50            |
| 7                | 29.0 (50) | 50/50                    | 28.0 (50) | 97                    | 50/50            | 28.8 (50) | 99                    | 50/50            | 28.2 (50) | 97                    | 50/50            |
| 8                | 29.8 (50) | 50/50                    | 28.6 (50) | 96                    | 50/50            | 29.6 (50) | 99                    | 50/50            | 28.5 (50) | 96                    | 50/50            |
| 9                | 30.2 (50) | 50/50                    | 29.0 (50) | 96                    | 50/50            | 30.2 (50) | 100                   | 50/50            | 29.0 (50) | 96                    | 50/50            |
| 10               | 30.7 (50) | 50/50                    | 29.6 (50) | 96                    | 50/50            | 30.9 (50) | 101                   | 50/50            | 29.4 (50) | 96                    | 50/50            |
| 11               | 31.5 (50) | 50/50                    | 30.5 (50) | 97                    | 50/50            | 31.4 (50) | 100                   | 50/50            | 30.0 (50) | 95                    | 50/50            |
| 12               | 32.2 (50) | 50/50                    | 30.9 (50) | 96                    | 50/50            | 31.8 (50) | 99                    | 50/50            | 30.3 (50) | 94                    | 50/50            |
| 13               | 32.9 (50) | 50/50                    | 31.8 (50) | 97                    | 50/50            | 32.5 (50) | 99                    | 50/50            | 30.6 (50) | 93                    | 50/50            |
| 14               | 33.4 (50) | 50/50                    | 32.4 (50) | 97                    | 50/50            | 33.2 (50) | 99                    | 50/50            | 31.2 (50) | 93                    | 50/50            |
| 16               | 34.9 (50) | 50/50                    | 33.9 (50) | 97                    | 50/50            | 34.5 (50) | 99                    | 50/50            | 32.7 (50) | 94                    | 50/50            |
| 18               | 36.3 (50) | 50/50                    | 35.5 (50) | 98                    | 50/50            | 36.1 (50) | 99                    | 50/50            | 33.9 (50) | 93                    | 50/50            |
| 20               | 37.2 (50) | 50/50                    | 36.6 (50) | 98                    | 50/50            | 37.1 (50) | 100                   | 50/50            | 35.5 (50) | 95                    | 50/50            |
| 22               | 37.5 (50) | 50/50                    | 37.2 (50) | 99                    | 50/50            | 38.0 (50) | 101                   | 50/50            | 35.7 (50) | 95                    | 50/50            |
| 24               | 38.2 (50) | 50/50                    | 38.2 (50) | 100                   | 50/50            | 38.8 (50) | 102                   | 50/50            | 36.1 (50) | 95                    | 50/50            |
| 26               | 39.3 (50) | 50/50                    | 39.3 (50) | 100                   | 50/50            | 39.8 (50) | 101                   | 50/50            | 36.7 (50) | 93                    | 50/50            |
| 28               | 39.9 (50) | 49/50                    | 40.7 (50) | 102                   | 50/50            | 40.9 (50) | 103                   | 50/50            | 38.0 (50) | 95                    | 50/50            |
| 30               | 41.5 (49) | 49/50                    | 41.1 (50) | 99                    | 50/50            | 41.7 (50) | 100                   | 50/50            | 38.0 (50) | 92                    | 50/50            |
| 32               | 41.9 (49) | 49/50                    | 42.1 (50) | 100                   | 50/50            | 42.4 (50) | 101                   | 50/50            | 39.0 (49) | 93                    | 49/50            |
| 34               | 43.0 (49) | 49/50                    | 42.7 (50) | 99                    | 50/50            | 43.3 (50) | 101                   | 50/50            | 39.4 (49) | 92                    | 49/50            |
| 36               | 43.3 (49) | 49/50                    | 43.2 (50) | 100                   | 50/50            | 43.9 (50) | 101                   | 50/50            | 39.8 (49) | 92                    | 49/50            |
| 38               | 44.3 (49) | 49/50                    | 44.0 (50) | 99                    | 50/50            | 44.5 (50) | 100                   | 50/50            | 41.5 (49) | 94                    | 49/50            |
| 40               | 44.9 (49) | 49/50                    | 45.1 (49) | 100                   | 49/50            | 44.9 (50) | 100                   | 50/50            | 41.6 (49) | 93                    | 49/50            |
| 42               | 45.9 (48) | 48/50                    | 46.0 (49) | 100                   | 49/50            | 46.4 (49) | 101                   | 49/50            | 42.2 (49) | 92                    | 49/50            |
| 44               | 46.4 (48) | 48/50                    | 46.9 (49) | 101                   | 49/50            | 46.8 (49) | 101                   | 49/50            | 42.9 (49) | 92                    | 49/50            |
| 46               | 46.6 (48) | 48/50                    | 47.3 (49) | 102                   | 49/50            | 47.2 (49) | 101                   | 49/50            | 43.1 (49) | 92                    | 49/50            |
| 48               | 47.6 (47) | 47/50                    | 47.9 (49) | 101                   | 49/50            | 47.6 (49) | 100                   | 49/50            | 43.5 (49) | 91                    | 49/50            |
| 50               | 48.0 (46) | 46/50                    | 48.4 (49) | 101                   | 49/50            | 48.0 (49) | 100                   | 49/50            | 43.6 (49) | 91                    | 49/50            |
| 52               | 48.6 (46) | 46/50                    | 49.0 (49) | 101                   | 49/50            | 48.4 (48) | 100                   | 48/50            | 44.4 (49) | 91                    | 49/50            |
| 54               | 48.4 (46) | 46/50                    | 48.9 (49) | 101                   | 49/50            | 48.3 (48) | 100                   | 48/50            | 44.4 (49) | 92                    | 49/50            |
| 56               | 48.4 (46) | 46/50                    | 49.0 (48) | 101                   | 48/50            | 48.5 (48) | 100                   | 48/50            | 44.5 (49) | 92                    | 49/50            |
| 58               | 48.6 (46) | 46/50                    | 49.2 (48) | 101                   | 48/50            | 48.7 (48) | 100                   | 48/50            | 44.3 (49) | 91                    | 49/50            |
| 60               | 48.6 (46) | 46/50                    | 48.6 (48) | 100                   | 48/50            | 48.3 (48) | 99                    | 48/50            | 43.9 (49) | 90                    | 49/50            |
| 62               | 48.5 (46) | 46/50                    | 48.4 (48) | 100                   | 48/50            | 48.2 (48) | 99                    | 48/50            | 44.0 (49) | 91                    | 49/50            |
| 64               | 48.9 (46) | 46/50                    | 48.9 (47) | 100                   | 47/50            | 48.6 (47) | 99                    | 47/50            | 44.0 (49) | 90                    | 49/50            |
| 66               | 49.1 (46) | 46/50                    | 48.9 (47) | 100                   | 47/50            | 48.4 (47) | 99                    | 47/50            | 43.7 (48) | 89                    | 48/50            |
| 68               | 49.7 (46) | 46/50                    | 49.2 (47) | 99                    | 47/50            | 48.8 (47) | 98                    | 46/50            | 43.5 (48) | 88                    | 48/50            |
| 70               | 50.2 (46) | 46/50                    | 49.7 (47) | 99                    | 47/50            | 48.7 (46) | 97                    | 46/50            | 43.4 (47) | 86                    | 47/50            |
| 72               | 50.3 (46) | 46/50                    | 50.7 (47) | 101                   | 47/50            | 48.3 (46) | 96                    | 46/50            | 43.9 (47) | 87                    | 47/50            |
| 74               | 49.6 (46) | 46/50                    | 50.5 (47) | 102                   | 47/50            | 48.6 (45) | 98                    | 44/50            | 43.3 (47) | 87                    | 47/50            |
| 76               | 50.3 (45) | 45/50                    | 50.7 (47) | 101                   | 47/50            | 49.2 (43) | 98                    | 43/50            | 43.7 (46) | 87                    | 46/50            |
| 78               | 51.1 (44) | 44/50                    | 51.5 (47) | 101                   | 47/50            | 49.4 (43) | 97                    | 43/50            | 43.3 (46) | 85                    | 46/50            |
| 80               | 51.2 (44) | 44/50                    | 51.1 (47) | 100                   | 47/50            | 49.7 (42) | 97                    | 42/50            | 43.3 (45) | 85                    | 45/50            |
| 82               | 51.1 (44) | 44/50                    | 51.4 (47) | 101                   | 47/50            | 50.3 (41) | 98                    | 41/50            | 42.7 (44) | 84                    | 44/50            |
| 84               | 51.9 (42) | 42/50                    | 50.6 (47) | 97                    | 47/50            | 50.4 (41) | 97                    | 41/50            | 42.2 (44) | 81                    | 44/50            |
| 86               | 51.9 (42) | 42/50                    | 50.7 (46) | 98                    | 46/50            | 50.0 (41) | 96                    | 41/50            | 42.6 (40) | 82                    | 40/50            |
| 88               | 52.1 (42) | 42/50                    | 50.6 (46) | 97                    | 46/50            | 50.1 (39) | 96                    | 39/50            | 41.7 (39) | 80                    | 39/50            |
| 90               | 51.8 (42) | 42/50                    | 50.7 (46) | 98                    | 46/50            | 49.4 (38) | 95                    | 38/50            | 40.9 (39) | 79                    | 39/50            |
| 92               | 51.7 (41) | 41/50                    | 50.4 (45) | 97                    | 45/50            | 49.1 (37) | 95                    | 36/50            | 40.1 (37) | 78                    | 37/50            |
| 94               | 51.4 (41) | 41/50                    | 50.1 (44) | 97                    | 44/50            | 48.5 (35) | 94                    | 34/50            | 39.5 (35) | 77                    | 35/50            |
| 96               | 51.4 (38) | 38/50                    | 49.4 (44) | 96                    | 43/50            | 47.8 (32) | 93                    | 32/50            | 38.5 (34) | 75                    | 34/50            |
| 98               | 51.4 (36) | 36/50                    | 49.3 (41) | 96                    | 40/50            | 47.1 (31) | 92                    | 31/50            | 38.3 (31) | 75                    | 31/50            |
| 100              | 50.2 (36) | 36/50                    | 49.3 (39) | 98                    | 38/50            | 46.5 (30) | 93                    | 30/50            | 37.8 (27) | 75                    | 27/50            |
| 102              | 50.0 (35) | 34/50                    | 49.3 (37) | 99                    | 37/50            | 45.8 (30) | 92                    | 30/50            | 36.8 (25) | 74                    | 25/50            |
| 104              | 50.3 (31) | 31/50                    | 49.2 (35) | 98                    | 35/50            | 45.3 (28) | 90                    | 28/50            | 36.4 (23) | 72                    | 22/50            |

&lt; &gt;:No.of effective animals,( ):No.of measured animals

Au.Wt.: g



(Study No.0104,0105)

TABLE 30 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN FEMALE MOUSE

(TWO-YEAR STUDIES)

| Week<br>on Study | Control   |                          |  | 10 ppm    |                       |                  | 50 ppm    |                       |                  | 250 ppm   |                       |                  |
|------------------|-----------|--------------------------|--|-----------|-----------------------|------------------|-----------|-----------------------|------------------|-----------|-----------------------|------------------|
|                  | Au.Wt.    | No.of<br>Surviv.<br><50> |  | Au.Wt.    | % of<br>cont.<br><47> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><49> | No.of<br>Surviv. | Au.Wt.    | % of<br>cont.<br><50> | No.of<br>Surviv. |
| 0                | 18.6 (50) | 50/50                    |  | 18.5 (47) | 99                    | 50/50            | 18.5 (49) | 99                    | 50/50            | 18.6 (50) | 100                   | 50/50            |
| 1                | 20.0 (50) | 50/50                    |  | 19.9 (47) | 100                   | 50/50            | 19.5 (49) | 98                    | 50/50            | 19.7 (50) | 99                    | 50/50            |
| 2                | 20.5 (50) | 50/50                    |  | 20.5 (47) | 100                   | 50/50            | 20.2 (49) | 99                    | 50/50            | 20.4 (50) | 100                   | 50/50            |
| 3                | 21.2 (50) | 50/50                    |  | 21.0 (47) | 99                    | 50/50            | 20.9 (49) | 99                    | 50/50            | 21.3 (50) | 100                   | 50/50            |
| 4                | 22.0 (50) | 50/50                    |  | 21.7 (47) | 99                    | 50/50            | 21.6 (49) | 98                    | 50/50            | 22.1 (50) | 100                   | 50/50            |
| 5                | 22.4 (50) | 50/50                    |  | 22.4 (47) | 100                   | 50/50            | 22.2 (49) | 99                    | 50/50            | 23.1 (50) | 103                   | 50/50            |
| 6                | 23.0 (50) | 50/50                    |  | 22.8 (47) | 99                    | 50/50            | 22.8 (49) | 99                    | 50/50            | 23.1 (50) | 100                   | 50/50            |
| 7                | 23.4 (50) | 50/50                    |  | 23.1 (47) | 99                    | 49/49            | 23.1 (49) | 99                    | 50/50            | 23.7 (50) | 101                   | 50/50            |
| 8                | 24.1 (50) | 50/50                    |  | 23.5 (47) | 98                    | 49/49            | 23.9 (49) | 99                    | 50/50            | 24.1 (50) | 100                   | 50/50            |
| 9                | 23.9 (50) | 50/50                    |  | 23.6 (47) | 99                    | 49/49            | 23.9 (49) | 100                   | 50/50            | 24.4 (50) | 102                   | 50/50            |
| 10               | 24.4 (50) | 50/50                    |  | 23.8 (47) | 98                    | 49/49            | 24.0 (49) | 98                    | 50/50            | 24.6 (50) | 101                   | 50/50            |
| 11               | 24.9 (50) | 50/50                    |  | 24.2 (47) | 97                    | 49/49            | 24.2 (49) | 97                    | 50/50            | 24.6 (50) | 99                    | 50/50            |
| 12               | 24.9 (50) | 50/50                    |  | 24.5 (47) | 98                    | 49/49            | 24.6 (49) | 99                    | 50/50            | 24.8 (50) | 100                   | 50/50            |
| 13               | 24.9 (50) | 50/50                    |  | 24.9 (47) | 100                   | 49/49            | 24.7 (49) | 99                    | 50/50            | 25.2 (50) | 101                   | 50/50            |
| 14               | 25.2 (50) | 50/50                    |  | 25.1 (47) | 100                   | 49/49            | 25.1 (49) | 100                   | 50/50            | 25.1 (50) | 100                   | 50/50            |
| 16               | 26.1 (50) | 50/50                    |  | 25.6 (47) | 98                    | 49/49            | 25.6 (49) | 98                    | 50/50            | 26.0 (50) | 100                   | 50/50            |
| 18               | 27.0 (50) | 50/50                    |  | 26.6 (47) | 99                    | 49/49            | 26.2 (49) | 97                    | 50/50            | 26.8 (50) | 99                    | 50/50            |
| 20               | 27.5 (50) | 50/50                    |  | 27.1 (47) | 99                    | 49/49            | 27.1 (49) | 99                    | 50/50            | 27.3 (50) | 99                    | 50/50            |
| 22               | 27.4 (50) | 50/50                    |  | 27.2 (47) | 99                    | 49/49            | 27.1 (49) | 99                    | 50/50            | 27.7 (50) | 101                   | 50/50            |
| 24               | 27.2 (50) | 50/50                    |  | 27.5 (47) | 101                   | 49/49            | 27.1 (49) | 100                   | 49/49            | 27.5 (50) | 101                   | 50/50            |
| 26               | 28.3 (50) | 50/50                    |  | 27.9 (47) | 99                    | 49/49            | 27.5 (49) | 97                    | 49/49            | 28.8 (50) | 102                   | 50/50            |
| 28               | 28.3 (50) | 50/50                    |  | 29.0 (47) | 102                   | 49/49            | 27.9 (49) | 99                    | 49/49            | 28.7 (50) | 101                   | 50/50            |
| 30               | 29.7 (50) | 50/50                    |  | 29.2 (47) | 98                    | 49/49            | 28.8 (49) | 97                    | 49/49            | 29.2 (50) | 98                    | 50/50            |
| 32               | 29.4 (50) | 50/50                    |  | 29.6 (47) | 101                   | 49/49            | 28.5 (49) | 97                    | 49/49            | 29.0 (50) | 99                    | 50/50            |
| 34               | 30.3 (50) | 50/50                    |  | 29.9 (47) | 99                    | 49/49            | 29.1 (49) | 96                    | 49/49            | 29.9 (50) | 99                    | 50/50            |
| 36               | 29.7 (50) | 50/50                    |  | 30.3 (47) | 102                   | 49/49            | 29.9 (49) | 101                   | 49/49            | 30.0 (50) | 101                   | 50/50            |
| 38               | 30.3 (50) | 50/50                    |  | 31.2 (47) | 103                   | 49/49            | 30.2 (49) | 100                   | 49/49            | 31.1 (50) | 103                   | 50/50            |
| 40               | 31.0 (50) | 50/50                    |  | 31.8 (47) | 103                   | 49/49            | 31.1 (48) | 100                   | 48/49            | 31.0 (50) | 100                   | 50/50            |
| 42               | 32.4 (50) | 50/50                    |  | 32.3 (47) | 100                   | 49/49            | 32.1 (48) | 99                    | 48/49            | 31.8 (50) | 98                    | 50/50            |
| 44               | 32.7 (50) | 50/50                    |  | 33.5 (47) | 102                   | 49/49            | 32.1 (48) | 98                    | 48/49            | 32.7 (50) | 100                   | 50/50            |
| 46               | 33.1 (50) | 50/50                    |  | 33.6 (47) | 102                   | 49/49            | 32.3 (48) | 98                    | 48/49            | 32.9 (50) | 99                    | 50/50            |
| 48               | 33.9 (50) | 50/50                    |  | 34.1 (47) | 101                   | 49/49            | 33.3 (48) | 98                    | 48/49            | 33.6 (50) | 99                    | 50/50            |
| 50               | 33.9 (50) | 50/50                    |  | 34.6 (47) | 102                   | 49/49            | 33.6 (48) | 99                    | 48/49            | 33.5 (50) | 99                    | 50/50            |
| 52               | 34.9 (50) | 50/50                    |  | 35.3 (47) | 101                   | 49/49            | 34.6 (48) | 99                    | 48/49            | 34.3 (50) | 98                    | 50/50            |
| 54               | 34.6 (50) | 50/50                    |  | 34.8 (47) | 101                   | 48/48            | 34.4 (48) | 99                    | 47/49            | 34.9 (50) | 101                   | 50/50            |
| 56               | 35.4 (50) | 50/50                    |  | 35.8 (47) | 101                   | 48/48            | 34.5 (47) | 97                    | 47/49            | 34.2 (50) | 97                    | 50/50            |
| 58               | 35.7 (50) | 50/50                    |  | 35.8 (47) | 100                   | 48/48            | 34.7 (47) | 97                    | 47/49            | 34.7 (50) | 97                    | 50/50            |
| 60               | 35.0 (50) | 50/50                    |  | 35.5 (47) | 101                   | 48/48            | 34.0 (47) | 97                    | 47/49            | 33.7 (50) | 96                    | 50/50            |
| 62               | 35.2 (50) | 50/50                    |  | 35.2 (47) | 100                   | 48/48            | 34.0 (47) | 97                    | 47/49            | 33.9 (50) | 96                    | 50/50            |
| 64               | 35.6 (50) | 50/50                    |  | 35.2 (45) | 99                    | 46/48            | 34.7 (47) | 97                    | 47/49            | 34.3 (50) | 96                    | 50/50            |
| 66               | 35.6 (50) | 50/50                    |  | 35.2 (45) | 99                    | 46/48            | 34.2 (47) | 96                    | 47/49            | 34.1 (50) | 96                    | 50/50            |
| 68               | 36.0 (49) | 49/50                    |  | 35.5 (44) | 99                    | 45/48            | 35.5 (47) | 99                    | 47/49            | 34.6 (50) | 96                    | 50/50            |
| 70               | 36.6 (49) | 49/50                    |  | 36.5 (44) | 100                   | 45/48            | 35.5 (47) | 97                    | 47/49            | 34.8 (50) | 95                    | 50/50            |
| 72               | 36.9 (48) | 48/50                    |  | 36.4 (44) | 99                    | 45/48            | 35.7 (46) | 97                    | 46/49            | 35.2 (50) | 95                    | 50/50            |
| 74               | 37.0 (46) | 46/50                    |  | 36.4 (44) | 98                    | 45/48            | 36.2 (46) | 98                    | 46/49            | 34.7 (50) | 94                    | 50/50            |
| 76               | 37.1 (46) | 46/50                    |  | 37.1 (42) | 100                   | 43/48            | 36.0 (45) | 97                    | 44/49            | 35.6 (49) | 96                    | 49/50            |
| 78               | 38.3 (46) | 46/50                    |  | 38.0 (42) | 99                    | 43/48            | 37.8 (44) | 99                    | 44/49            | 35.7 (49) | 93                    | 49/50            |
| 80               | 39.0 (46) | 46/50                    |  | 37.8 (42) | 97                    | 43/48            | 37.2 (42) | 95                    | 42/49            | 36.1 (49) | 93                    | 49/50            |
| 82               | 38.9 (44) | 44/50                    |  | 39.0 (41) | 100                   | 42/48            | 37.6 (41) | 97                    | 40/49            | 35.9 (47) | 92                    | 47/50            |
| 84               | 38.9 (43) | 43/50                    |  | 37.8 (41) | 97                    | 42/48            | 37.9 (40) | 97                    | 39/49            | 35.7 (43) | 92                    | 43/50            |
| 86               | 39.3 (43) | 43/50                    |  | 38.4 (40) | 98                    | 41/48            | 38.0 (37) | 97                    | 37/49            | 36.4 (41) | 93                    | 41/50            |
| 88               | 39.2 (43) | 43/50                    |  | 38.0 (39) | 97                    | 41/48            | 38.0 (37) | 97                    | 37/49            | 35.3 (41) | 90                    | 41/50            |
| 90               | 39.6 (43) | 43/50                    |  | 38.5 (39) | 97                    | 40/48            | 38.2 (34) | 96                    | 34/49            | 34.9 (40) | 88                    | 40/50            |
| 92               | 39.3 (41) | 41/50                    |  | 37.8 (39) | 96                    | 40/48            | 37.7 (34) | 96                    | 34/49            | 34.9 (35) | 89                    | 35/50            |
| 94               | 39.5 (41) | 41/50                    |  | 37.5 (38) | 95                    | 38/47            | 37.5 (33) | 95                    | 33/49            | 34.0 (33) | 86                    | 33/50            |
| 96               | 38.8 (41) | 41/50                    |  | 37.2 (35) | 96                    | 34/47            | 37.2 (32) | 96                    | 32/49            | 33.8 (31) | 87                    | 31/50            |
| 98               | 38.6 (39) | 39/50                    |  | 37.8 (32) | 98                    | 32/47            | 36.8 (32) | 95                    | 32/49            | 33.7 (29) | 87                    | 29/50            |
| 100              | 38.1 (38) | 38/50                    |  | 37.6 (30) | 99                    | 30/47            | 36.5 (27) | 96                    | 27/49            | 31.6 (27) | 83                    | 27/50            |
| 102              | 38.5 (37) | 37/50                    |  | 37.9 (29) | 98                    | 28/47            | 35.6 (25) | 92                    | 25/49            | 31.6 (24) | 82                    | 24/50            |
| 104              | 37.3 (34) | 32/50                    |  | 37.3 (27) | 100                   | 27/47            | 35.5 (23) | 95                    | 22/49            | 31.1 (17) | 83                    | 17/50            |

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

Au.Wt.: g

TABLE 31 INCIDENCE AND TIME OF MASS OCCURRENCE(CLINICAL OBSERVATION) :MOUSE :MALE

|                         |         | Dosing week   |       |       |       |       |       |       |        |
|-------------------------|---------|---|-------|-------|-------|-------|-------|-------|--------|
| Time of mass occurrence |         | 0~13  | 14~26 | 27~39 | 40~52 | 53~65 | 66~78 | 79~91 | 92~104 |
| The kind of mass        |         | No. of animals with mass (No. of dead and moribund animals with mass) |       |       |       |       |       |       |        |
| Internal mass           |         |   |       |       |       |       |       |       |        |
|                         | Control | 0   | 0     | 0     | 1     | 3     | 8     | 10    | 11     |
|                         | 10 ppm  | 0   | 0     | 0     | 0     | 3     | 14    | 9     | 16     |
|                         | 50 ppm  | 0   | 0     | 0     | 1     | 3     | 17    | 18    | 20     |
|                         | 250 ppm | 0   | 0     | 0     | 1     | 4     | 11    | 12    | 20     |
| External mass           |         |   |       |       |       |       |       |       |        |
|                         | Control | 0   | 0     | 0     | 0     | 0     | 0     | 4     | 3      |
|                         | 10 ppm  | 0   | 0     | 0     | 0     | 0     | 2     | 2     | 4      |
|                         | 50 ppm  | 0   | 0     | 0     | 0     | 2     | 1     | 5     | 5      |
|                         | 250 ppm | 0   | 0     | 0     | 0     | 1     | 2     | 7     | 10     |

TABLE 32 INCIDENCE AND TIME OF MASS OCCURRENCE(CLINICAL OBSERVATION) :MOUSE :FEMALE

|                         |         | Dosing week   |       |       |       |       |       |       |        |
|-------------------------|---------|---|-------|-------|-------|-------|-------|-------|--------|
| Time of mass occurrence |         | 0~13  | 14~26 | 27~39 | 40~52 | 53~65 | 66~78 | 79~91 | 92~104 |
| The kind of mass        |         | No. of animals with mass (No. of dead and moribund animals with mass) |       |       |       |       |       |       |        |
| Internal mass           |         |   |       |       |       |       |       |       |        |
|                         | Control | 0   | 0     | 0     | 1     | 3     | 7     | 7     | 8      |
|                         | 10 ppm  | 0   | 0     | 0     | 1     | 2     | 7     | 7     | 8      |
|                         | 50 ppm  | 0   | 0     | 0     | 2     | 9     | 9     | 8     | 7      |
|                         | 250 ppm | 0   | 0     | 0     | 1     | 1     | 7     | 9     | 13     |
| External mass           |         |   |       |       |       |       |       |       |        |
|                         | Control | 0   | 0     | 0     | 0     | 0     | 2     | 4     | 4      |
|                         | 10 ppm  | 0   | 0     | 0     | 0     | 0     | 1     | 1     | 4      |
|                         | 50 ppm  | 0   | 0     | 0     | 0     | 2     | 1     | 5     | 6      |
|                         | 250 ppm | 0   | 0     | 0     | 0     | 1     | 2     | 3     | 3      |

(Study No. 0104, 0105)

TABLE 33 FOOD CONSUMPTION IN MALE MOUSE (TWO-YEAR STUDIES)

| Week<br>on Study | Control  |                          |  | 10 ppm   |                       |                  | 50 ppm   |                       |                  | 250 ppm  |                       |                  |
|------------------|----------|--------------------------|--|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|
|                  | Au.FC.   | No.of<br>Surviv.<br><50> |  | Au.FC.   | % of<br>cont.<br><50> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><50> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><50> | No.of<br>Surviv. |
| 1                | 3.8 (50) | 50/50                    |  | 3.8 (50) | 100                   | 50/50            | 3.8 (50) | 100                   | 50/50            | 3.8 (50) | 100                   | 50/50            |
| 2                | 3.8 (50) | 50/50                    |  | 3.6 (50) | 95                    | 50/50            | 3.7 (50) | 97                    | 50/50            | 3.8 (50) | 100                   | 50/50            |
| 3                | 3.9 (50) | 50/50                    |  | 3.7 (50) | 95                    | 50/50            | 3.7 (50) | 95                    | 50/50            | 3.8 (50) | 97                    | 50/50            |
| 4                | 4.0 (50) | 50/50                    |  | 3.9 (50) | 98                    | 50/50            | 3.9 (50) | 98                    | 50/50            | 3.9 (50) | 98                    | 50/50            |
| 5                | 4.0 (50) | 50/50                    |  | 3.9 (50) | 98                    | 50/50            | 4.0 (50) | 100                   | 50/50            | 3.9 (50) | 98                    | 50/50            |
| 6                | 4.1 (50) | 50/50                    |  | 3.9 (50) | 95                    | 50/50            | 3.9 (50) | 95                    | 50/50            | 3.9 (50) | 95                    | 50/50            |
| 7                | 4.1 (50) | 50/50                    |  | 3.8 (50) | 93                    | 50/50            | 4.0 (50) | 98                    | 50/50            | 3.9 (50) | 95                    | 50/50            |
| 8                | 4.1 (50) | 50/50                    |  | 4.0 (50) | 98                    | 50/50            | 4.1 (50) | 100                   | 50/50            | 4.0 (50) | 98                    | 50/50            |
| 9                | 4.2 (50) | 50/50                    |  | 4.1 (50) | 98                    | 50/50            | 4.1 (50) | 98                    | 50/50            | 4.1 (50) | 98                    | 50/50            |
| 10               | 4.1 (50) | 50/50                    |  | 4.1 (50) | 100                   | 50/50            | 4.1 (50) | 100                   | 50/50            | 4.0 (50) | 98                    | 50/50            |
| 11               | 4.2 (50) | 50/50                    |  | 4.1 (50) | 98                    | 50/50            | 4.1 (50) | 98                    | 50/50            | 4.1 (50) | 98                    | 50/50            |
| 12               | 4.3 (50) | 50/50                    |  | 4.1 (50) | 95                    | 50/50            | 4.2 (50) | 98                    | 50/50            | 4.2 (50) | 98                    | 50/50            |
| 13               | 4.2 (50) | 50/50                    |  | 4.1 (50) | 98                    | 50/50            | 4.1 (50) | 98                    | 50/50            | 4.0 (50) | 95                    | 50/50            |
| 14               | 4.2 (50) | 50/50                    |  | 4.2 (50) | 100                   | 50/50            | 4.2 (50) | 100                   | 50/50            | 4.2 (50) | 100                   | 50/50            |
| 18               | 4.4 (50) | 50/50                    |  | 4.2 (50) | 95                    | 50/50            | 4.4 (50) | 100                   | 50/50            | 4.3 (50) | 98                    | 50/50            |
| 22               | 4.4 (50) | 50/50                    |  | 4.4 (50) | 100                   | 50/50            | 4.4 (50) | 100                   | 50/50            | 4.1 (50) | 93                    | 50/50            |
| 26               | 4.6 (50) | 50/50                    |  | 4.5 (50) | 98                    | 50/50            | 4.6 (50) | 100                   | 50/50            | 4.4 (50) | 96                    | 50/50            |
| 30               | 4.6 (49) | 49/50                    |  | 4.5 (50) | 98                    | 50/50            | 4.6 (50) | 100                   | 50/50            | 4.4 (50) | 96                    | 50/50            |
| 34               | 4.6 (49) | 49/50                    |  | 4.5 (50) | 98                    | 50/50            | 4.6 (50) | 100                   | 50/50            | 4.5 (49) | 98                    | 49/50            |
| 38               | 4.8 (49) | 49/50                    |  | 4.6 (50) | 96                    | 50/50            | 4.7 (50) | 98                    | 50/50            | 4.7 (49) | 98                    | 49/50            |
| 42               | 4.7 (48) | 48/50                    |  | 4.6 (49) | 98                    | 49/50            | 4.6 (49) | 98                    | 49/50            | 4.5 (49) | 96                    | 49/50            |
| 46               | 4.6 (48) | 48/50                    |  | 4.7 (49) | 102                   | 49/50            | 4.6 (49) | 100                   | 49/50            | 4.5 (49) | 98                    | 49/50            |
| 50               | 4.7 (46) | 46/50                    |  | 4.6 (49) | 98                    | 49/50            | 4.7 (49) | 100                   | 49/50            | 4.6 (49) | 98                    | 49/50            |
| 52               | 4.7 (46) | 46/50                    |  | 4.6 (49) | 98                    | 49/50            | 4.8 (48) | 102                   | 48/50            | 4.5 (49) | 96                    | 49/50            |
| 54               | 4.7 (46) | 46/50                    |  | 4.5 (49) | 96                    | 49/50            | 4.8 (48) | 102                   | 48/50            | 4.6 (49) | 98                    | 49/50            |
| 58               | 5.0 (46) | 46/50                    |  | 4.8 (48) | 96                    | 48/50            | 5.1 (48) | 102                   | 48/50            | 4.8 (49) | 96                    | 49/50            |
| 62               | 4.7 (46) | 46/50                    |  | 4.7 (48) | 100                   | 48/50            | 4.9 (48) | 104                   | 48/50            | 4.6 (49) | 98                    | 49/50            |
| 66               | 4.8 (46) | 46/50                    |  | 4.7 (47) | 98                    | 47/50            | 4.9 (47) | 102                   | 47/50            | 4.7 (49) | 98                    | 48/50            |
| 70               | 4.8 (46) | 46/50                    |  | 4.7 (47) | 98                    | 47/50            | 4.8 (46) | 100                   | 46/50            | 4.7 (48) | 98                    | 47/50            |
| 74               | 4.8 (46) | 46/50                    |  | 4.9 (47) | 102                   | 47/50            | 4.7 (46) | 98                    | 44/50            | 4.4 (47) | 92                    | 47/50            |
| 78               | 5.1 (44) | 44/50                    |  | 5.0 (47) | 98                    | 47/50            | 5.1 (43) | 100                   | 43/50            | 5.0 (46) | 98                    | 46/50            |
| 82               | 5.2 (44) | 44/50                    |  | 5.0 (47) | 96                    | 47/50            | 5.2 (42) | 100                   | 41/50            | 4.9 (44) | 94                    | 44/50            |
| 86               | 5.2 (42) | 42/50                    |  | 5.0 (46) | 96                    | 46/50            | 5.1 (41) | 98                    | 41/50            | 4.6 (41) | 88                    | 40/50            |
| 90               | 5.2 (42) | 42/50                    |  | 5.0 (46) | 96                    | 46/50            | 5.1 (39) | 98                    | 38/50            | 4.8 (39) | 92                    | 39/50            |
| 94               | 5.0 (41) | 41/50                    |  | 4.9 (44) | 98                    | 44/50            | 4.9 (36) | 98                    | 34/50            | 4.6 (36) | 92                    | 35/50            |
| 98               | 5.0 (36) | 36/50                    |  | 5.0 (41) | 100                   | 40/50            | 5.1 (31) | 102                   | 31/50            | 4.6 (33) | 92                    | 31/50            |
| 102              | 4.9 (36) | 34/50                    |  | 4.8 (37) | 98                    | 37/50            | 4.9 (30) | 100                   | 30/50            | 4.4 (25) | 90                    | 25/50            |
| 104              | 5.1 (32) | 31/50                    |  | 4.8 (35) | 94                    | 35/50            | 4.7 (28) | 92                    | 28/50            | 4.5 (24) | 88                    | 22/50            |

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

Au.FC.: g

(Study No. 0104, 0105)

TABLE 34 FOOD CONSUMPTION IN FEMALE MOUSE (TWO-YEAR STUDIES)

| Week<br>on Study | Control  |                          | 10 ppm   |                       |                  | 50 ppm   |                       |                  | 250 ppm  |                       |                  |
|------------------|----------|--------------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|----------|-----------------------|------------------|
|                  | Au.FC.   | No.of<br>Surviv.<br><50> | Au.FC.   | % of<br>cont.<br><47> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><49> | No.of<br>Surviv. | Au.FC.   | % of<br>cont.<br><50> | No.of<br>Surviv. |
| 1                | 3.2 (50) | 50/50                    | 3.3 (47) | 103                   | 50/50            | 3.1 (49) | 97                    | 50/50            | 3.2 (50) | 100                   | 50/50            |
| 2                | 3.1 (50) | 50/50                    | 3.1 (47) | 100                   | 50/50            | 3.2 (49) | 103                   | 50/50            | 3.2 (50) | 103                   | 50/50            |
| 3                | 3.4 (50) | 50/50                    | 3.2 (47) | 94                    | 50/50            | 3.4 (49) | 100                   | 50/50            | 3.5 (50) | 103                   | 50/50            |
| 4                | 3.6 (50) | 50/50                    | 3.5 (47) | 97                    | 50/50            | 3.6 (49) | 100                   | 50/50            | 3.7 (50) | 103                   | 50/50            |
| 5                | 3.7 (50) | 50/50                    | 3.6 (47) | 97                    | 50/50            | 3.7 (49) | 100                   | 50/50            | 3.8 (50) | 103                   | 50/50            |
| 6                | 3.9 (50) | 50/50                    | 3.7 (47) | 95                    | 50/50            | 3.8 (49) | 97                    | 50/50            | 3.7 (50) | 95                    | 50/50            |
| 7                | 3.9 (50) | 50/50                    | 3.8 (47) | 97                    | 49/49            | 3.9 (49) | 100                   | 50/50            | 3.8 (50) | 97                    | 50/50            |
| 8                | 4.0 (50) | 50/50                    | 3.9 (47) | 98                    | 49/49            | 4.0 (49) | 100                   | 50/50            | 3.9 (50) | 98                    | 50/50            |
| 9                | 4.0 (50) | 50/50                    | 3.9 (47) | 98                    | 49/49            | 3.9 (49) | 98                    | 50/50            | 4.0 (50) | 100                   | 50/50            |
| 10               | 4.0 (50) | 50/50                    | 3.9 (47) | 98                    | 49/49            | 3.8 (49) | 95                    | 50/50            | 3.9 (50) | 98                    | 50/50            |
| 11               | 4.0 (50) | 50/50                    | 3.9 (47) | 98                    | 49/49            | 3.9 (49) | 98                    | 50/50            | 3.9 (50) | 98                    | 50/50            |
| 12               | 3.9 (50) | 50/50                    | 3.9 (47) | 100                   | 49/49            | 4.0 (49) | 103                   | 50/50            | 4.0 (50) | 103                   | 50/50            |
| 13               | 3.9 (50) | 50/50                    | 3.8 (47) | 97                    | 49/49            | 3.9 (49) | 100                   | 50/50            | 3.9 (50) | 100                   | 50/50            |
| 14               | 3.9 (50) | 50/50                    | 3.9 (47) | 100                   | 49/49            | 4.0 (49) | 103                   | 50/50            | 4.0 (50) | 103                   | 50/50            |
| 18               | 4.2 (50) | 50/50                    | 4.1 (47) | 98                    | 49/49            | 4.1 (49) | 98                    | 50/50            | 4.3 (50) | 102                   | 50/50            |
| 22               | 4.3 (50) | 50/50                    | 4.1 (47) | 95                    | 49/49            | 4.1 (49) | 95                    | 50/50            | 4.1 (50) | 95                    | 50/50            |
| 26               | 4.5 (50) | 50/50                    | 4.4 (47) | 98                    | 49/49            | 4.4 (49) | 98                    | 49/49            | 4.5 (50) | 100                   | 50/50            |
| 30               | 4.5 (50) | 50/50                    | 4.4 (47) | 98                    | 49/49            | 4.5 (49) | 100                   | 49/49            | 4.4 (50) | 98                    | 50/50            |
| 34               | 4.7 (50) | 50/50                    | 4.5 (47) | 96                    | 49/49            | 4.5 (49) | 96                    | 49/49            | 4.5 (50) | 96                    | 50/50            |
| 38               | 4.6 (50) | 50/50                    | 4.6 (47) | 100                   | 49/49            | 4.6 (49) | 100                   | 49/49            | 4.7 (50) | 102                   | 50/50            |
| 42               | 4.6 (50) | 50/50                    | 4.4 (47) | 96                    | 49/49            | 4.6 (48) | 100                   | 48/49            | 4.5 (50) | 98                    | 50/50            |
| 46               | 4.4 (50) | 50/50                    | 4.4 (47) | 100                   | 49/49            | 4.3 (48) | 98                    | 48/49            | 4.5 (50) | 102                   | 50/50            |
| 50               | 4.4 (50) | 50/50                    | 4.4 (47) | 100                   | 49/49            | 4.4 (48) | 100                   | 48/49            | 4.5 (50) | 102                   | 50/50            |
| 52               | 4.7 (50) | 50/50                    | 4.5 (47) | 96                    | 49/49            | 4.6 (48) | 98                    | 48/49            | 4.5 (50) | 96                    | 50/50            |
| 54               | 4.5 (50) | 50/50                    | 4.3 (47) | 96                    | 48/48            | 4.4 (48) | 98                    | 47/49            | 4.7 (50) | 104                   | 50/50            |
| 58               | 4.9 (50) | 50/50                    | 4.7 (44) | 96                    | 48/48            | 4.7 (47) | 96                    | 47/49            | 4.7 (50) | 96                    | 50/50            |
| 62               | 4.5 (50) | 50/50                    | 4.4 (47) | 98                    | 48/48            | 4.4 (47) | 98                    | 47/49            | 4.4 (50) | 98                    | 50/50            |
| 66               | 4.5 (49) | 50/50                    | 4.5 (45) | 100                   | 46/48            | 4.4 (47) | 98                    | 47/49            | 4.4 (50) | 98                    | 50/50            |
| 70               | 4.6 (49) | 49/50                    | 4.6 (44) | 100                   | 45/48            | 4.4 (47) | 96                    | 47/49            | 4.6 (50) | 100                   | 50/50            |
| 74               | 4.4 (48) | 46/50                    | 4.7 (44) | 107                   | 45/48            | 4.4 (46) | 100                   | 46/49            | 4.3 (50) | 98                    | 50/50            |
| 78               | 4.8 (46) | 46/50                    | 4.7 (42) | 98                    | 43/48            | 5.0 (44) | 104                   | 44/49            | 4.9 (49) | 102                   | 49/50            |
| 82               | 4.9 (45) | 44/50                    | 4.9 (42) | 100                   | 42/48            | 4.9 (41) | 100                   | 40/49            | 4.7 (48) | 96                    | 47/50            |
| 86               | 5.0 (43) | 43/50                    | 4.9 (40) | 98                    | 41/48            | 4.8 (38) | 96                    | 37/49            | 4.8 (41) | 96                    | 41/50            |
| 90               | 4.8 (43) | 43/50                    | 5.0 (39) | 104                   | 40/48            | 4.8 (35) | 100                   | 34/49            | 4.7 (41) | 98                    | 40/50            |
| 94               | 4.9 (41) | 41/50                    | 4.7 (38) | 96                    | 38/47            | 4.6 (34) | 94                    | 33/49            | 4.6 (35) | 94                    | 33/50            |
| 98               | 4.8 (40) | 39/50                    | 4.5 (34) | 94                    | 32/47            | 4.6 (31) | 96                    | 32/49            | 4.8 (30) | 100                   | 29/50            |
| 102              | 4.6 (38) | 37/50                    | 4.6 (29) | 100                   | 28/47            | 4.3 (27) | 93                    | 25/49            | 4.3 (24) | 93                    | 24/50            |
| 104              | 4.1 (37) | 32/50                    | 4.4 (28) | 107                   | 27/47            | 4.7 (24) | 115                   | 22/49            | 4.0 (18) | 98                    | 17/50            |

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

Au.FC.: g

TABLE 35                      NEOPLASTIC LESIONS (SPLEEN) INCIDENCE AND STATISTICAL ANALYSIS : MOUSE:MALE

| Group Name   | Control     | 10 ppm      | 50 ppm      | 250 ppm     |
|--|-------------|-------------|-------------|-------------|
| SITE : spleen  |             |             |             |             |
| TUMOUR : hemangioendothelioma                              |             |             |             |             |
| Overall Rates(a)   | 1/50 ( 2.0) | 1/50 ( 2.0) | 3/50 ( 6.0) | 5/50 (10.0) |
| Adjusted Rates(b)  | 3.23        | 0.0         | 6.38        | 12.00       |
| Terminal Rates(c)  | 1/31 ( 3.2) | 0/35 ( 0.0) | 0/28 ( 0.0) | 2/22 ( 9.1) |
| Standard Rates(d)  | P=0.5167    |             |             |             |
| Prevalence Rates(d)  | P=0.0177*   |             |             |             |
| Combind analysis(d)  | P=0.0340*   |             |             |             |
| Cochran-Armitage Test(e)                                   | P=0.0420*   |             |             |             |
| Fisher Exact Test(e)                                       |             | P=0.2475    | P=0.3235    | P=0.1210    |
| SITE : spleen  |             |             |             |             |
| TUMOUR : hemangioendothelioma:benign, hemangioendothelioma |             |             |             |             |
| Overall Rates(a)   | 2/50 ( 4.0) | 2/50 ( 4.0) | 3/50 ( 6.0) | 6/50 (12.0) |
| Adjusted Rates(b)  | 6.45        | 2.86        | 6.38        | 12.90       |
| Terminal Rates(c)  | 2/31 ( 6.5) | 1/35 ( 2.9) | 0/28 ( 0.0) | 2/22 ( 9.1) |
| Standard Rates(d)  | P=0.5167    |             |             |             |
| Prevalence Rates(d)  | P=0.0276*   |             |             |             |
| Combind analysis(d)  | P=0.0458*   |             |             |             |
| Cochran-Armitage Test(e)                                   | P=0.0608    |             |             |             |
| Fisher Exact Test(e)                                       |             | P=0.3088    | P=0.4909    | P=0.1606    |

(a):Number of tumor-bearing animals/number of animals examined at the site.

(b):Kaplan-Meire estimate tumor incidence at the end of study after adjusting for intercurrent mortality.

(c):Observed tumor incidence at terminal kill.

(d):Beneth the control incidence are the P-values associated with the trend test.

Standard method : Death analysis

Prevalence method : Incidental tumor test

Combind analysis : Death analysis + Incidental tumor test

(e):The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates.

? :The conditional probabilities of the largest and smallest possible out comes can not estimated or this P-value beyond the estimated P-value.

-----:There is no data which should be statistic analysis.

TABLE 36 NEOPLASTIC LESIONS (LIVER) INCIDENCE AND STATISTICAL ANALYSIS : MOUSE:MALE

| Group Name  | Control      | 10 ppm       | 50 ppm       | 250 ppm      |
|---|--------------|--------------|--------------|--------------|
| SITE : liver<br>TUMOUR : hepatocellular adenoma                           |              |              |              |              |
| Overall Rates(a)  | 7/50 (14.0)  | 13/50 (26.0) | 8/50 (16.0)  | 26/50 (52.0) |
| Adjusted Rates(b)   | 15.22        | 34.29        | 20.59        | 77.27        |
| Terminal Rates(c)   | 4/31 (12.9)  | 12/35 (34.3) | 5/28 (17.9)  | 17/22 (77.3) |
| Standard Rates(d)   | P=1.0000 ?   |              |              |              |
| Prevalence Rates(d)   | P<0.0001**   |              |              |              |
| Combind analysis(d)   | P<0.0001**   |              |              |              |
| Cochran-Armitage Test(e)  | P<0.0001**   |              |              |              |
| Fisher Exact Test(e)  |              | P=0.1634     | P=0.4854     | P=0.0029**   |
| SITE : liver<br>TUMOUR : hemangioendothelioma                             |              |              |              |              |
| Overall Rates(a)  | 1/50 ( 2.0)  | 1/50 ( 2.0)  | 5/50 (10.0)  | 5/50 (10.0)  |
| Adjusted Rates(b)   | 0.0          | 2.17         | 3.57         | 13.64        |
| Terminal Rates(c)   | 0/31 ( 0.0)  | 0/35 ( 0.0)  | 1/28 ( 3.6)  | 3/22 (13.6)  |
| Standard Rates(d)   | P=0.2158     |              |              |              |
| Prevalence Rates(d)   | P=0.0270*    |              |              |              |
| Combind analysis(d)   | P=0.0332*    |              |              |              |
| Cochran-Armitage Test(e)  | P=0.0883     |              |              |              |
| Fisher Exact Test(e)  |              | P=0.2475     | P=0.1210     | P=0.1210     |
| SITE : liver<br>TUMOUR : hepatocellular carcinoma                         |              |              |              |              |
| Overall Rates(a)  | 7/50 (14.0)  | 8/50 (16.0)  | 12/50 (24.0) | 25/50 (50.0) |
| Adjusted Rates(b)   | 16.13        | 16.67        | 25.00        | 45.45        |
| Terminal Rates(c)   | 5/31 (16.1)  | 5/35 (14.3)  | 7/28 (25.0)  | 10/22 (45.5) |
| Standard Rates(d)   | P=0.0010**   |              |              |              |
| Prevalence Rates(d)   | P=0.0002**   |              |              |              |
| Combind analysis(d)   | P<0.0001**   |              |              |              |
| Cochran-Armitage Test(e)  | P<0.0001**   |              |              |              |
| Fisher Exact Test(e)  |              | P=0.4854     | P=0.2119     | P=0.0041**   |
| SITE : liver<br>TUMOUR : hepatocellular adenoma, hepatocellular carcinoma |              |              |              |              |
| Overall Rates(a)  | 13/50 (26.0) | 21/50 (42.0) | 19/50 (38.0) | 40/50 (80.0) |
| Adjusted Rates(b)   | 26.47        | 50.00        | 39.39        | 90.91        |
| Terminal Rates(c)   | 8/31 (25.8)  | 17/35 (48.6) | 11/28 (39.3) | 20/22 (90.9) |
| Standard Rates(d)   | P=0.0020**   |              |              |              |
| Prevalence Rates(d)   | P<0.0001**   |              |              |              |
| Combind analysis(d)   | P<0.0001**   |              |              |              |
| Cochran-Armitage Test(e)  | P<0.0001**   |              |              |              |
| Fisher Exact Test(e)  |              | P=0.1615     | P=0.2359     | P=0.0018**   |

(a):Number of tumor-bearing animals/number of animals examined at the site.

(b):Kaplan-Meire estimate tumor incidence at the end of study after adjusting for intercurrent mortality.

(c):Observed tumor incidence at terminal kill.

(d):Beneath the control incidence are the P-values associated with the trend test.

Standard method : Death analysis

Prevalence method : Incidental tumor test

Combind analysis : Death analysis + Incidental tumor test

(e):The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates.

? :The conditional probabilities of the largest and smallest possible out comes can not estimated or this P-value beyond the estimated P-value.

-----:There is no data which should be statistic analysis.

TABLE 37 NEOPLASTIC LESIONS (LIVER) INCIDENCE AND STATISTICAL ANALYSIS : MOUSE:FEMALE

| Group Name  | Control     | 10 ppm      | 50 ppm      | 250 ppm      |
|---|-------------|-------------|-------------|--------------|
| SITE : liver<br>TUMOUR : hepatocellular adenoma                           |             |             |             |              |
| Overall Rates(a)  | 3/50 ( 6.0) | 3/47 ( 6.4) | 7/49 (14.3) | 26/49 (53.1) |
| Adjusted Rates(b)   | 9.38        | 11.11       | 30.43       | 64.00        |
| Terminal Rates(c)   | 3/32 ( 9.4) | 3/27 (11.1) | 6/22 (27.3) | 9/17 (52.9)  |
| Standard Rates(d)   | P=-----     |             |             |              |
| Prevalence Rates(d)   | P<0.0001**? |             |             |              |
| Combind analysis(d)   | P=-----     |             |             |              |
| Cochran-Armitage Test(e)  | P<0.0001**  |             |             |              |
| Fisher Exact Test(e)  |             | P=0.3673    | P=0.1836    | P=0.0001**   |
| SITE : liver<br>TUMOUR : hepatocellular carcinoma                         |             |             |             |              |
| Overall Rates(a)  | 0/50 ( 0.0) | 0/47 ( 0.0) | 0/49 ( 0.0) | 14/49 (28.6) |
| Adjusted Rates(b)   | 0.0         | 0.0         | 0.0         | 23.33        |
| Terminal Rates(c)   | 0/32 ( 0.0) | 0/27 ( 0.0) | 0/22 ( 0.0) | 3/17 (17.6)  |
| Standard Rates(d)   | P<0.0001**? |             |             |              |
| Prevalence Rates(d)   | P<0.0001**? |             |             |              |
| Combind analysis(d)   | P<0.0001**? |             |             |              |
| Cochran-Armitage Test(e)  | P<0.0001**? |             |             |              |
| Fisher Exact Test(e)  |             | P=0.5000    | P=0.5000    | P=0.0001**   |
| SITE : liver<br>TUMOUR : hepatocellular adenoma, hepatocellular carcinoma |             |             |             |              |
| Overall Rates(a)  | 3/50 ( 6.0) | 3/47 ( 6.4) | 7/49 (14.3) | 33/49 (67.3) |
| Adjusted Rates(b)   | 9.38        | 11.11       | 30.43       | 69.70        |
| Terminal Rates(c)   | 3/32 ( 9.4) | 3/27 (11.1) | 6/22 (27.3) | 10/17 (58.8) |
| Standard Rates(d)   | P<0.0001**? |             |             |              |
| Prevalence Rates(d)   | P<0.0001**? |             |             |              |
| Combind analysis(d)   | P<0.0001**? |             |             |              |
| Cochran-Armitage Test(e)  | P<0.0001**? |             |             |              |
| Fisher Exact Test(e)  |             | P=0.3673    | P=0.1836    | P<0.0001**   |

(a):Number of tumor-bearing animals/number of animals examined at the site.

(b):Kaplan-Meire estimate tumor incidence at the end of study after adjusting for intercurrent mortality.

(c):Observed tumor incidence at terminal kill.

(d):Beneth the control incidence are the P-values associated with the trend test.

Standard method : Death analysis

Prevalence method : Incidental tumor test

Combind analysis : Death analysis + Incidental tumor test

(e):The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates.

? :The conditional probabilities of the largest and smallest possible out comes can not estimated or this P-value beyond the estimated P-value.

-----:There is no data which should be statistic analysis.

TABLE 38 NUMBER OF MOUSE WITH SELECTED LIVER LESIONS

| Group                     | Male    |       |       |        | Female  |       |       |        |
|---------------------------|---------|-------|-------|--------|---------|-------|-------|--------|
|                           | Control | 10ppm | 50ppm | 250ppm | Control | 10ppm | 50ppm | 250ppm |
| Number of examined        | 50      | 50    | 50    | 50     | 50      | 47    | 49    | 50     |
| Anigectasis               | 1       | 3     | 12    | 30     | 6       | 9     | 8     | 26     |
| Degeneration:central      | 1       | 1     | 4     | 37     | 0       | 1     | 2     | 30     |
| Necrosis:central          | 0       | 0     | 2     | 3      | 1       | 1     | 1     | 0      |
| Necrosis:focal            | 3       | 4     | 8     | 13     | 1       | 1     | 1     | 0      |
| Hyperplasia               | 1       | 0     | 3     | 3      | 0       | 1     | 0     | 0      |
| Clear cell focus          | 2       | 2     | 3     | 5      | 1       | 1     | 0     | 4      |
| Acidophilic cell focus    | 1       | 1     | 0     | 0      | 0       | 0     | 0     | 1      |
| Basophilic cell focus     | 2       | 3     | 4     | 5      | 0       | 0     | 0     | 1      |
| Vacuolic cell focus       | 0       | 0     | 0     | 0      | 1       | 0     | 0     | 1      |
| Mixed cell focus          | 0       | 0     | 0     | 0      | 2       | 1     | 1     | 0      |
| Hepatocellular adenoma    | 7       | 13    | 8     | 26     | 3       | 3     | 7     | 26     |
| Cholangiocellular adenoma | 0       | 0     | 0     | 0      | 0       | 1     | 0     | 0      |
| Histiocytic sarcoma       | 2       | 0     | 1     | 1      | 1       | 1     | 1     | 0      |
| Hemangioendothelioma      | 1       | 1     | 5     | 5      | 0       | 0     | 0     | 1      |
| Hepatocellular carcinoma  | 7       | 8     | 12    | 25     | 0       | 0     | 0     | 14     |

TABLE 39 NUMBER OF MOUSE WITH SELECTED KIDNEY LESIONS

| Group                      | Male    |       |       |        | Female  |       |       |        |
|----------------------------|---------|-------|-------|--------|---------|-------|-------|--------|
|                            | Control | 10ppm | 50ppm | 250ppm | Control | 10ppm | 50ppm | 250ppm |
| Number of examined         | 50      | 50    | 50    | 50     | 50      | 47    | 49    | 50     |
| Nuclear enlargement:       |         |       |       |        |         |       |       |        |
| proximal tubule            | 0       | 0     | 6     | 38     | 0       | 0     | 1     | 49     |
| Atypical tubular dilation: |         |       |       |        |         |       |       |        |
| proximal tubule            | 0       | 0     | 0     | 1      | 0       | 0     | 0     | 6      |
| Renal cell adenoma         | 0       | 1     | 0     | 0      | 0       | 0     | 0     | 0      |
| Renal cell carcinoma       | 0       | 0     | 1     | 0      | 0       | 0     | 0     | 0      |



TABLE 40 NEOPLASTIC LESIONS (HARDERIAN GLAND) INCIDENCE AND STATISTICAL ANALYSIS : MOUSE:MALE

| Group Name                                      | Control     | 10 ppm      | 50 ppm      | 250 ppm     |
|---|-------------|-------------|-------------|-------------|
| SITE : mammary gland<br>TUMOUR : adenocarcinoma |             |             |             |             |
| Overall Rates(a)                                | 2/50 ( 2.0) | 2/50 ( 4.0) | 2/50 ( 4.0) | 8/50 (16.0) |
| Adjusted Rates(b)                               | 6.45        | 5.26        | 6.45        | 23.08       |
| Terminal Rates(c)                               | 2/31 ( 6.5) | 1/35 ( 2.9) | 0/28 ( 0.0) | 4/22 (18.2) |
| Standard Rates(d)                               | P=-----     |             |             |             |
| Prevalence Rates(d)                             | P=0.0024**  |             |             |             |
| Combind analysis(d)                             | P=-----     |             |             |             |
| Cochran-Armitage Test(e)                        | P=0.0046**  |             |             |             |
| Fisher Exact Test(e)                            |             | P=0.3088    | P=0.3088    | P=0.0671    |

TABLE 41 NEOPLASTIC LESIONS (PITUITARY GLAND) INCIDENCE AND STATISTICAL ANALYSIS : MOUSE:FEMALE

| Group Name                                 | Control     | 10 ppm       | 50 ppm      | 250 ppm     |
|--|-------------|--------------|-------------|-------------|
| SITE : pituitary gland<br>TUMOUR : adenoma |             |              |             |             |
| Overall Rates(a)                           | 9/49 (18.4) | 11/47 (23.4) | 4/48 ( 8.3) | 9/50 (18.0) |
| Adjusted Rates(b)                          | 23.08       | 31.03        | 13.64       | 27.78       |
| Terminal Rates(c)                          | 7/32 (21.9) | 8/27 (29.6)  | 3/22 (13.6) | 4/17 (23.5) |
| Standard Rates(d)                          | P=0.0154*   |              |             |             |
| Prevalence Rates(d)                        | P=0.6810    |              |             |             |
| Combind analysis(d)                        | P=0.2327    |              |             |             |
| Cochran-Armitage Test(e)                   | P=0.9190    |              |             |             |
| Fisher Exact Test(e)                       |             | P=0.4032     | P=0.1655    | P=0.3839    |

(a):Number of tumor-bearing animals/number of animals examined at the site.

(b):Kaplan-Meire estimate tumor incidence at the end of study after adjusting for intercurrent mortality.

(c):Observed tumor incidence at terminal kill.

(d):Beneth the control incidence are the P-values associated with the trend test.

Standard method : Death analysis

Prevalence method : Incidental tumor test

Combind analysis : Death analysis + Incidental tumor test

(e):The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates.

? :The conditional probabilities of the largest and smallest possible out comes can not estimated or this P-value beyond the estimated P-value.

-----:There is no data which should be statistic analysis.

TABLE 42 CAUSE OF DEATH :MOUSE

| Group                          | Male    |       |       |        | Female  |       |       |        |
|--------------------------------|---------|-------|-------|--------|---------|-------|-------|--------|
|                                | Control | 10ppm | 50ppm | 250ppm | Control | 10ppm | 50ppm | 250ppm |
| Number of dead/moriboud animal | 19      | 15    | 22    | 28     | 18      | 20    | 27    | 33     |
| No microscopical confirmation  | 2       | 2     | 1     | 0      | 0       | 1     | 2     | 0      |
| Cardiovascular lesion          | 0       | 0     | 0     | 0      | 0       | 1     | 2     | 0      |
| Respiratory sy. lesion         | 1       | 0     | 0     | 1      | 0       | 0     | 0     | 0      |
| Hepatic lesion                 | 0       | 1     | 1     | 4      | 0       | 0     | 0     | 1      |
| Urinary sy. lesion             | 0       | 0     | 0     | 1      | 0       | 0     | 0     | 0      |
| Renal lesion                   | 3       | 1     | 4     | 1      | 1       | 2     | 0     | 1      |
| Urinary retention              | 1       | 3     | 2     | 0      | 0       | 0     | 0     | 0      |
| Amyloidosis                    | 0       | 1     | 0     | 0      | 0       | 0     | 0     | 0      |
| Arteritis                      | 2       | 0     | 1     | 0      | 0       | 0     | 0     | 0      |
| Tumor death : leukemia         | 4       | 3     | 3     | 4      | 6       | 4     | 13    | 10     |
| : subcutis                     | 0       | 0     | 0     | 1      | 0       | 2     | 0     | 1      |
| : stomach                      | 0       | 0     | 0     | 0      | 1       | 0     | 0     | 0      |
| : lung                         | 1       | 0     | 1     | 0      | 0       | 0     | 0     | 0      |
| : lymph node                   | 0       | 0     | 0     | 1      | 0       | 0     | 0     | 0      |
| : spleen                       | 0       | 1     | 0     | 0      | 0       | 0     | 0     | 0      |
| : liver                        | 4       | 3     | 8     | 13     | 0       | 1     | 1     | 7      |
| : pituitary gland              | 0       | 0     | 0     | 0      | 1       | 2     | 2     | 4      |
| : ovary                        | 0       | 0     | 0     | 0      | 0       | 0     | 0     | 1      |
| : uterus                       | 0       | 0     | 0     | 0      | 8       | 8     | 8     | 9      |
| : mammary gland                | 0       | 0     | 0     | 0      | 0       | 0     | 1     | 0      |
| : epididymis                   | 0       | 0     | 0     | 1      | 5       | 2     | 2     | 2      |
| : seminal vesicle              | 1       | 0     | 0     | 1      | 1       | 0     | 0     | 0      |
| : bone                         | 0       | 0     | 1     | 0      | 1       | 2     | 2     | 1      |