

ジフェニルアミンのマウスを用いた  
経口投与による2週間毒性試験（混餌試験）報告書

試験番号：0652

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TABLE 1 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF MALE MICE IN THE 2-WEEK FEED STUDY OF DIPHENYLAMINE

| Week-Day<br>on Study | Control  |                  | 1600 ppm |               |                  | 4000 ppm |               |                  | 7000 ppm |               |                  | 10000 ppm |               |                  | 25000 ppm |               |                  |
|----------------------|----------|------------------|----------|---------------|------------------|----------|---------------|------------------|----------|---------------|------------------|-----------|---------------|------------------|-----------|---------------|------------------|
|                      | Av.Wt.   | No.of<br>Surviv. | Av.Wt.   | % of<br>cont. | No.of<br>Surviv. | Av.Wt.   | % of<br>cont. | No.of<br>Surviv. | Av.Wt.   | % of<br>cont. | No.of<br>Surviv. | Av.Wt.    | % of<br>cont. | No.of<br>Surviv. | Av.Wt.    | % of<br>cont. | No.of<br>Surviv. |
|                      | < 5>     |                  | < 5>     |               |                  | < 5>     |               |                  | < 5>     |               |                  | < 5>      |               |                  | < 5>      |               |                  |
| 0-0                  | 23.0 (5) | 5/5              | 22.9 (5) | 100           | 5/5              | 22.9 (5) | 100           | 5/5              | 23.0 (5) | 100           | 5/5              | 22.7 (5)  | 99            | 5/5              | 22.9 (5)  | 100           | 5/5              |
| 1-4                  | 23.4 (5) | 5/5              | 23.3 (5) | 100           | 5/5              | 22.8 (5) | 97            | 5/5              | 21.9 (5) | 94            | 5/5              | 19.3 (5)  | 82            | 5/5              | 16.1 (5)  | 69            | 5/5              |
| 1-7                  | 24.3 (5) | 5/5              | 24.0 (5) | 99            | 5/5              | 23.0 (5) | 95            | 5/5              | 22.1 (5) | 91            | 5/5              | 20.0 (5)  | 82            | 5/5              | 15.0 (5)  | 62            | 5/5              |
| 2-4                  | 25.3 (5) | 5/5              | 24.9 (5) | 98            | 5/5              | 24.4 (5) | 96            | 5/5              | 24.1 (5) | 95            | 5/5              | 22.2 (5)  | 88            | 5/5              | 14.4 (4)  | 57            | 4/5              |
| 2-7                  | 25.5 (5) | 5/5              | 25.5 (5) | 100           | 5/5              | 25.1 (5) | 98            | 5/5              | 24.8 (5) | 97            | 5/5              | 22.8 (5)  | 89            | 5/5              | 14.3 (4)  | 56            | 4/5              |

< > : No. of effective animals, ( ) : No. of measured animals      Av.Wt. : Averaged body weight (Unit : g).

TABLE 2 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF FEMALE MICE IN THE 2-WEEK FEED STUDY OF DIPHENYLAMINE

| Week-Day<br>on Study | Control  |                  | 1600 ppm |               |                  | 4000 ppm |               |                  | 7000 ppm |               |                  | 10000 ppm |               |                  | 25000 ppm |               |                  |
|----------------------|----------|------------------|----------|---------------|------------------|----------|---------------|------------------|----------|---------------|------------------|-----------|---------------|------------------|-----------|---------------|------------------|
|                      | Av.Wt.   | No.of<br>Surviv. | Av.Wt.   | % of<br>cont. | No.of<br>Surviv. | Av.Wt.   | % of<br>cont. | No.of<br>Surviv. | Av.Wt.   | % of<br>cont. | No.of<br>Surviv. | Av.Wt.    | % of<br>cont. | No.of<br>Surviv. | Av.Wt.    | % of<br>cont. | No.of<br>Surviv. |
|                      | < 5>     |                  | < 5>     |               |                  | < 5>     |               |                  | < 5>     |               |                  | < 5>      |               |                  | < 5>      |               |                  |
| 0-0                  | 19.0 (5) | 5/5              | 19.1 (5) | 101           | 5/5              | 19.0 (5) | 100           | 5/5              | 19.0 (5) | 100           | 5/5              | 19.0 (5)  | 100           | 5/5              | 19.0 (5)  | 100           | 5/5              |
| 1-4                  | 19.8 (5) | 5/5              | 19.2 (5) | 97            | 5/5              | 18.5 (5) | 93            | 5/5              | 17.7 (5) | 89            | 5/5              | 16.5 (5)  | 83            | 5/5              | 13.7 (5)  | 69            | 5/5              |
| 1-7                  | 19.7 (5) | 5/5              | 19.4 (5) | 98            | 5/5              | 19.5 (5) | 99            | 5/5              | 18.4 (5) | 93            | 5/5              | 16.9 (5)  | 86            | 5/5              | 12.6 (5)  | 64            | 5/5              |
| 2-4                  | 20.3 (5) | 5/5              | 20.3 (5) | 100           | 5/5              | 20.3 (5) | 100           | 5/5              | 20.3 (5) | 100           | 5/5              | 18.8 (5)  | 93            | 5/5              | 12.0 (5)  | 59            | 5/5              |
| 2-7                  | 20.6 (5) | 5/5              | 20.9 (5) | 101           | 5/5              | 20.5 (5) | 100           | 5/5              | 20.4 (5) | 99            | 5/5              | 19.5 (5)  | 95            | 5/5              | 11.4 (5)  | 55            | 5/5              |

< > : No. of effective animals, ( ) : No. of measured animals      Av.Wt. : Averaged body weight (Unit : g).

TABLE 3 FOOD CONSUMPTION CHANGES OF MALE MICE IN THE 2-WEEK FEED STUDY OF DIPHENYLAMINE

| Week-Day<br>on Study | Control |                  | 1600 ppm |               |                  | 4000 ppm |               |                  | 7000 ppm |               |                  | 10000 ppm |               |                  | 25000 ppm |               |                  |
|----------------------|---------|------------------|----------|---------------|------------------|----------|---------------|------------------|----------|---------------|------------------|-----------|---------------|------------------|-----------|---------------|------------------|
|                      | Av.Fc.  | No.of<br>Surviv. | Av.Fc.   | % of<br>cont. | No.of<br>Surviv. | Av.Fc.   | % of<br>cont. | No.of<br>Surviv. | Av.Fc.   | % of<br>cont. | No.of<br>Surviv. | Av.Fc.    | % of<br>cont. | No.of<br>Surviv. | Av.Fc.    | % of<br>cont. | No.of<br>Surviv. |
|                      | < 5>    |                  | < 5>     |               |                  | < 5>     |               |                  | < 5>     |               |                  | < 5>      |               |                  | < 5>      |               |                  |
| 1-4                  | 3.9 (5) | 5/5              | 3.7 (5)  | 95            | 5/5              | 3.7 (5)  | 95            | 5/5              | 3.3 (5)  | 85            | 5/5              | 2.1 (5)   | 54            | 5/5              | 0.7 (5)   | 18            | 5/5              |
| 1-7                  | 4.5 (5) | 5/5              | 4.2 (5)  | 93            | 5/5              | 3.7 (5)  | 82            | 5/5              | 3.9 (5)  | 87            | 5/5              | 3.5 (5)   | 78            | 5/5              | 1.6 (5)   | 36            | 5/5              |
| 2-4                  | 4.0 (5) | 5/5              | 3.7 (5)  | 93            | 5/5              | 4.0 (5)  | 100           | 5/5              | 4.4 (5)  | 110           | 5/5              | 3.8 (5)   | 95            | 5/5              | 1.5 (4)   | 38            | 4/5              |
| 2-7                  | 3.9 (5) | 5/5              | 4.0 (5)  | 103           | 5/5              | 4.1 (5)  | 105           | 5/5              | 4.8 (5)  | 123           | 5/5              | 4.2 (5)   | 108           | 5/5              | 1.2 (4)   | 31            | 4/5              |

< > : No. of effective animals, ( ) : No. of measured animals      Av.Fc. : Averaged food consumption (Unit : g).

TABLE 4 FOOD CONSUMPTION CHANGES OF FEMALE MICE IN THE 2-WEEK FEED STUDY OF DIPHENYLAMINE

| Week-Day<br>on Study | Control |                  | 1600 ppm |               |                  | 4000 ppm |               |                  | 7000 ppm |               |                  | 10000 ppm |               |                  | 25000 ppm |               |                  |
|----------------------|---------|------------------|----------|---------------|------------------|----------|---------------|------------------|----------|---------------|------------------|-----------|---------------|------------------|-----------|---------------|------------------|
|                      | Av.Fc.  | No.of<br>Surviv. | Av.Fc.   | % of<br>cont. | No.of<br>Surviv. | Av.Fc.   | % of<br>cont. | No.of<br>Surviv. | Av.Fc.   | % of<br>cont. | No.of<br>Surviv. | Av.Fc.    | % of<br>cont. | No.of<br>Surviv. | Av.Fc.    | % of<br>cont. | No.of<br>Surviv. |
|                      | < 5>    |                  | < 5>     |               |                  | < 5>     |               |                  | < 5>     |               |                  | < 5>      |               |                  | < 5>      |               |                  |
| 1-4                  | 3.5 (5) | 5/5              | 3.3 (5)  | 94            | 5/5              | 3.5 (5)  | 100           | 5/5              | 2.7 (5)  | 77            | 5/5              | 1.9 (5)   | 54            | 5/5              | 0.8 (5)   | 23            | 5/5              |
| 1-7                  | 3.5 (5) | 5/5              | 3.3 (5)  | 94            | 5/5              | 3.6 (5)  | 103           | 5/5              | 3.4 (5)  | 97            | 5/5              | 2.8 (5)   | 80            | 5/5              | 1.5 (5)   | 43            | 5/5              |
| 2-4                  | 3.5 (5) | 5/5              | 3.3 (5)  | 94            | 5/5              | 3.5 (5)  | 100           | 5/5              | 3.8 (5)  | 109           | 5/5              | 3.2 (5)   | 91            | 5/5              | 1.5 (5)   | 43            | 5/5              |
| 2-7                  | 3.7 (5) | 5/5              | 3.8 (5)  | 103           | 5/5              | 3.8 (5)  | 103           | 5/5              | 3.4 (5)  | 92            | 5/5              | 4.4 (5)   | 119           | 5/5              | 1.2 (5)   | 32            | 5/5              |

< > : No. of effective animals, ( ) : No. of measured animals      Av.Fc. : Averaged food consumption (Unit : g).

TABLE 5 HEMATOLOGY OF MALE MICE IN THE 2-WEEK FEED STUDY OF DIPHENYLAMINE

| Group Name                            | Control          | 1600 ppm           | 4000 ppm           | 7000 ppm           | 10000 ppm          | 25000 ppm           |
|---------------------------------------|------------------|--------------------|--------------------|--------------------|--------------------|---------------------|
| No. of examined animals               | 5                | 5                  | 5                  | 5                  | 5                  | 4                   |
| RED BLOOD CELL ( $10^6/\mu\text{L}$ ) | 10.31 $\pm$ 0.27 | 8.19 $\pm$ 0.40 ** | 6.73 $\pm$ 0.10 ** | 5.97 $\pm$ 0.22 ** | 5.76 $\pm$ 0.21 ** | 2.49 $\pm$ 0.54 **  |
| HEMOGLOBIN (g/dL)                     | 15.9 $\pm$ 0.4   | 16.0 $\pm$ 1.0     | 13.4 $\pm$ 0.4 **  | 10.7 $\pm$ 0.3 **  | 10.0 $\pm$ 0.5 **  | 3.8 $\pm$ 0.8 **    |
| HEMATOCRIT (%)                        | 47.5 $\pm$ 1.7   | 40.6 $\pm$ 2.8 **  | 37.9 $\pm$ 1.3 **  | 39.6 $\pm$ 1.9 **  | 39.9 $\pm$ 1.3 **  | 14.8 $\pm$ 3.5 **   |
| MCV (fL)                              | 46.0 $\pm$ 0.7   | 49.5 $\pm$ 1.3 **  | 56.3 $\pm$ 1.5 **  | 66.4 $\pm$ 1.5 **  | 69.4 $\pm$ 1.8 **  | 59.2 $\pm$ 2.3 **   |
| MCH (pg)                              | 15.4 $\pm$ 0.1   | 19.5 $\pm$ 0.3 **  | 19.8 $\pm$ 0.4 **  | 18.0 $\pm$ 0.3 **  | 17.4 $\pm$ 0.3 **  | 15.3 $\pm$ 0.9      |
| MCHC (g/dL)                           | 33.5 $\pm$ 0.4   | 39.4 $\pm$ 0.8 **  | 35.2 $\pm$ 0.4     | 27.1 $\pm$ 0.6 **  | 25.1 $\pm$ 0.9 **  | 25.8 $\pm$ 2.2 **   |
| PLATELET ( $10^3/\mu\text{L}$ )       | 1042 $\pm$ 84    | 1087 $\pm$ 65      | 942 $\pm$ 80       | 835 $\pm$ 47 **    | 741 $\pm$ 41 **    | 1018 $\pm$ 146      |
| METHEMOGLOBIN (%)                     | 0.5 $\pm$ 0.1    | 3.1 $\pm$ 0.8      | 9.9 $\pm$ 0.5 **   | 15.7 $\pm$ 3.6 **  | 17.6 $\pm$ 1.8 **  | 15.9 $\pm$ 1.9 **   |
| WBC ( $10^3/\mu\text{L}$ )            | 3.71 $\pm$ 1.34  | 5.04 $\pm$ 2.64    | 5.89 $\pm$ 1.42    | 4.90 $\pm$ 1.04    | 5.08 $\pm$ 1.70    | 12.23 $\pm$ 5.51 ** |

Mean  $\pm$  S.D.Significant difference: \* :  $p \leq 0.05$  \*\* :  $p \leq 0.01$  Test of Dunnett

TABLE 6 HEMATOLOGY OF FEMALE MICE IN THE 2-WEEK FEED STUDY OF DIPHENYLAMINE

| Group Name                            | Control         | 1600 ppm           | 4000 ppm           | 7000 ppm           | 10000 ppm          | 25000 ppm           |
|---------------------------------------|-----------------|--------------------|--------------------|--------------------|--------------------|---------------------|
| No. of examined animals               | 5               | 4                  | 5                  | 5                  | 5                  | 3                   |
| RED BLOOD CELL ( $10^6/\mu\text{L}$ ) | 9.74 $\pm$ 0.48 | 8.18 $\pm$ 0.33 ** | 7.54 $\pm$ 0.44 ** | 6.46 $\pm$ 0.29 ** | 5.74 $\pm$ 0.34 ** | 1.69 $\pm$ 0.25 **  |
| HEMOGLOBIN (g/dL)                     | 15.0 $\pm$ 0.6  | 15.3 $\pm$ 0.6     | 16.0 $\pm$ 0.9     | 11.9 $\pm$ 0.5 **  | 10.2 $\pm$ 0.6 **  | 2.7 $\pm$ 0.5 **    |
| HEMATOCRIT (%)                        | 44.7 $\pm$ 1.6  | 40.9 $\pm$ 2.4     | 39.2 $\pm$ 2.2 **  | 39.8 $\pm$ 2.3 *   | 39.0 $\pm$ 2.8 **  | 9.1 $\pm$ 1.5 **    |
| MCV (fL)                              | 45.8 $\pm$ 1.0  | 49.9 $\pm$ 0.9 *   | 52.0 $\pm$ 1.4 **  | 61.5 $\pm$ 2.9 **  | 67.9 $\pm$ 1.4 **  | 54.0 $\pm$ 2.6 **   |
| MCH (pg)                              | 15.4 $\pm$ 0.2  | 18.7 $\pm$ 0.1 **  | 21.2 $\pm$ 0.2 **  | 18.5 $\pm$ 0.5 **  | 17.8 $\pm$ 0.3 **  | 15.9 $\pm$ 0.8      |
| MCHC (g/dL)                           | 33.6 $\pm$ 0.3  | 37.5 $\pm$ 0.6 **  | 40.8 $\pm$ 1.5 **  | 30.1 $\pm$ 1.4 **  | 26.2 $\pm$ 0.8 **  | 29.6 $\pm$ 2.6 **   |
| PLATELET ( $10^3/\mu\text{L}$ )       | 945 $\pm$ 46    | 930 $\pm$ 58       | 898 $\pm$ 37       | 843 $\pm$ 91       | 710 $\pm$ 72 **    | 817 $\pm$ 201       |
| METHEMOGLOBIN (%)                     | 0.5 $\pm$ 0.1   | 4.0 $\pm$ 2.1      | 8.6 $\pm$ 2.4 **   | 9.6 $\pm$ 3.0 **   | 11.5 $\pm$ 2.0 **  | 13.2 $\pm$ 1.8 **   |
| WBC ( $10^3/\mu\text{L}$ )            | 3.30 $\pm$ 0.69 | 5.78 $\pm$ 2.77    | 5.67 $\pm$ 1.47    | 4.66 $\pm$ 1.97    | 2.63 $\pm$ 0.74    | 11.07 $\pm$ 2.47 ** |

Mean  $\pm$  S.D.Significant difference: \* :  $p \leq 0.05$  \*\* :  $p \leq 0.01$  Test of Dunnett

TABLE 7 BIOCHEMISTRY OF MALE MICE IN THE 2-WEEK FEED STUDY OF DIPHENYLAMINE

| Group Name              | Control     | 1600 ppm      | 4000 ppm       | 7000 ppm       | 10000 ppm      | 25000 ppm      |
|-------------------------|-------------|---------------|----------------|----------------|----------------|----------------|
| No. of examined animals | 5           | 5             | 5              | 5              | 5              | 4              |
| TOTAL PROTEIN (g/dL)    | 4.7 ± 0.1   | 5.1 ± 0.2 **  | 5.1 ± 0.1 **   | 5.3 ± 0.1 **   | 5.6 ± 0.1 **   | 4.7 ± 0.1 **   |
| ALBUMIN (g/dL)          | 2.6 ± 0.1   | 2.9 ± 0.1 **  | 3.0 ± 0.1 **   | 3.2 ± 0.0 **   | 3.5 ± 0.1 **   | 2.9 ± 0.1 **   |
| A/G RATIO               | 1.2 ± 0.1   | 1.4 ± 0.1 *   | 1.4 ± 0.1 **   | 1.6 ± 0.1 **   | 1.7 ± 0.1 **   | 1.7 ± 0.1 **   |
| T-BILIRUBIN (mg/dL)     | 0.12 ± 0.01 | 0.24 ± 0.02 * | 0.34 ± 0.03 ** | 0.48 ± 0.08 ** | 0.58 ± 0.08 ** | 0.69 ± 0.12 ** |
| GLUCOSE (mg/dL)         | 315 ± 10    | 296 ± 16      | 269 ± 19 *     | 280 ± 32       | 248 ± 24 **    | 60 ± 45 **     |
| PHOSPHOLIPID (mg/dL)    | 198 ± 29    | 225 ± 5       | 214 ± 16       | 202 ± 12       | 181 ± 20       | 143 ± 29 **    |
| AST (IU/L)              | 31 ± 2      | 32 ± 2        | 35 ± 2 **      | 44 ± 4 **      | 52 ± 7 **      | 501 ± 53 **    |
| ALT (IU/L)              | 18 ± 1      | 18 ± 1        | 19 ± 0         | 22 ± 3 **      | 27 ± 6 **      | 398 ± 23 **    |
| LDH (IU/L)              | 150 ± 27    | 282 ± 50 **   | 319 ± 67 **    | 464 ± 100 **   | 550 ± 96 **    | 6840 ± 1222 ** |
| CK (IU/L)               | 53 ± 13     | 39 ± 5        | 44 ± 8         | 66 ± 22        | 44 ± 12        | 474 ± 368 *    |
| UREA NITROGEN (mg/dL)   | 21.7 ± 4.5  | 22.5 ± 5.3    | 26.0 ± 7.9     | 23.9 ± 7.1     | 22.1 ± 4.4     | 37.5 ± 19.9    |
| SODIUM (mEq/L)          | 151 ± 1     | 151 ± 1       | 151 ± 2        | 150 ± 1        | 152 ± 2        | 160 ± 4 **     |

Mean ± S.D.

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

TABLE 8 BIOCHEMISTRY OF FEMALE MICE IN THE 2-WEEK FEED STUDY OF DIPHENYLAMINE

| Group Name              | Control     | 1600 ppm    | 4000 ppm       | 7000 ppm       | 10000 ppm      | 25000 ppm      |
|-------------------------|-------------|-------------|----------------|----------------|----------------|----------------|
| No. of examined animals | 5           | 4           | 5              | 5              | 5              | 3              |
| TOTAL PROTEIN (g/dL)    | 4.7 ± 0.2   | 4.8 ± 0.2   | 5.1 ± 0.2      | 5.5 ± 0.2 **   | 5.9 ± 0.2 **   | 5.0 ± 0.6 **   |
| ALBUMIN (g/dL)          | 2.9 ± 0.1   | 3.0 ± 0.1   | 3.2 ± 0.1 **   | 3.4 ± 0.2 **   | 3.7 ± 0.1 **   | 3.2 ± 0.5 **   |
| T-BILIRUBIN (mg/dL)     | 0.15 ± 0.05 | 0.19 ± 0.02 | 0.26 ± 0.04 ** | 0.43 ± 0.03 ** | 0.54 ± 0.07 ** | 0.78 ± 0.18 ** |
| GLUCOSE (mg/dL)         | 287 ± 17    | 271 ± 24    | 253 ± 31       | 241 ± 22       | 252 ± 22       | 48 ± 64 **     |
| T-CHOLESTEROL (mg/dL)   | 73 ± 10     | 88 ± 6      | 130 ± 59 **    | 125 ± 6 **     | 125 ± 26 **    | 65 ± 9 **      |
| PHOSPHOLIPID (mg/dL)    | 155 ± 17    | 183 ± 9     | 227 ± 49 **    | 237 ± 9 **     | 235 ± 38 **    | 107 ± 29 **    |
| AST (IU/L)              | 40 ± 4      | 35 ± 2      | 45 ± 7         | 46 ± 5         | 49 ± 3 **      | 578 ± 72 **    |
| ALT (IU/L)              | 19 ± 3      | 19 ± 3      | 20 ± 5         | 19 ± 2         | 26 ± 3 *       | 321 ± 27 **    |
| LDH (IU/L)              | 238 ± 105   | 228 ± 65    | 282 ± 66       | 351 ± 53       | 464 ± 67 **    | 7697 ± 465 **  |
| CK (IU/L)               | 92 ± 61     | 58 ± 15     | 56 ± 15        | 50 ± 15        | 51 ± 12        | 745 ± 513      |
| UREA NITROGEN (mg/dL)   | 20.7 ± 2.7  | 22.9 ± 4.7  | 20.8 ± 4.1     | 21.4 ± 3.1     | 25.1 ± 3.1     | 77.3 ± 47.0    |
| SODIUM (mEq/L)          | 149 ± 2     | 150 ± 1     | 150 ± 1        | 149 ± 1        | 152 ± 1 *      | 166 ± 4 **     |
| CHLORIDE (mEq/L)        | 120 ± 1     | 118 ± 2     | 118 ± 2 *      | 118 ± 1 *      | 118 ± 1        | 131 ± 6        |
| CALCIUM (mg/dL)         | 9.2 ± 0.5   | 9.2 ± 0.2   | 9.3 ± 0.2      | 9.3 ± 0.3      | 10.1 ± 0.4 **  | 10.2 ± 0.3 **  |

Mean ± S.D.

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

TABLE 9 URINALYSIS OF MALE MICE IN THE 2-WEEK FEED STUDY OF DIPHENYLAMINE

| Group Name              |       | Control | 1600 ppm | 4000 ppm | 7000 ppm | 10000 ppm | 25000 ppm |
|-------------------------|-------|---------|----------|----------|----------|-----------|-----------|
| No. of examined animals |       | 5       | 5        | 5        | 5        | 5         | 4         |
| pH                      | Grade |         |          |          |          |           |           |
|                         | 5.0   | 0       | 0        | 0        | 0        | 0         | 0         |
|                         | 6.0   | 0       | 0        | 0        | 0        | 0         | 2         |
|                         | 6.5   | 0       | 0        | 0        | 0        | 0         | 2         |
|                         | 7.0   | 0       | 0        | 0        | 0        | 0         | 0         |
|                         | 7.5   | 0       | 0        | 0        | 1        | 0         | 0         |
|                         | 8.0   | 4       | 4        | 5        | 3        | 5         | 0         |
|                         | 8.5   | 1       | 1        | 0        | 1        | 0         | 0         |
| Protein                 | —     | 0       | 0        | 0        | 0        | 0         | 1         |
|                         | ±     | 0       | 0        | 0        | 0        | 2         | 2         |
|                         | +     | 1       | 1        | 4        | 5        | 3         | 1         |
|                         | 2+    | 4       | 4        | 1        | 0        | 0         | 0         |
|                         | 3+    | 0       | 0        | 0        | 0        | 0         | 0         |
|                         | 4+    | 0       | 0        | 0        | 0        | 0         | 0         |

TABLE 10 URINALYSIS OF FEMALE MICE IN THE 2-WEEK FEED STUDY OF DIPHENYLAMINE

| Group Name              |       | Control | 1600 ppm | 4000 ppm | 7000 ppm | 10000 ppm | 25000 ppm |
|-------------------------|-------|---------|----------|----------|----------|-----------|-----------|
| No. of examined animals |       | 5       | 5        | 5        | 5        | 5         | 5         |
| pH                      | Grade |         |          |          |          |           |           |
|                         | 5.0   | 0       | 0        | 0        | 0        | 0         | 0         |
|                         | 6.0   | 0       | 0        | 0        | 0        | 0         | 2         |
|                         | 6.5   | 0       | 0        | 0        | 0        | 0         | 3         |
|                         | 7.0   | 0       | 0        | 1        | 0        | 0         | 0         |
|                         | 7.5   | 0       | 0        | 0        | 0        | 0         | 0         |
|                         | 8.0   | 5       | 5        | 4        | 5        | 5         | 0         |
|                         | 8.5   | 0       | 0        | 0        | 0        | 0         | 0         |
| Protein                 | —     | 0       | 0        | 0        | 0        | 0         | 1         |
|                         | ±     | 0       | 0        | 0        | 3        | 4         | 3         |
|                         | +     | 3       | 4        | 5        | 2        | 1         | 1         |
|                         | 2+    | 2       | 1        | 0        | 0        | 0         | 0         |
|                         | 3+    | 0       | 0        | 0        | 0        | 0         | 0         |
|                         | 4+    | 0       | 0        | 0        | 0        | 0         | 0         |

TABLE 11 ORGAN WEIGHTS OF MALE MICE IN THE 2-WEEK FEED STUDY OF DIPHENYLAMINE

| Group Name             | Control       | 1600 ppm      | 4000 ppm         | 7000 ppm         | 10000 ppm        | 25000 ppm        |
|------------------------|---------------|---------------|------------------|------------------|------------------|------------------|
| No. of examined animal | 5             | 5             | 5                | 5                | 5                | 4                |
| Body weight (g)        | 25.5 ± 0.9    | 25.5 ± 0.8    | 25.1 ± 0.6       | 24.8 ± 0.8       | 22.8 ± 1.3       | ** 14.3 ± 1.1 ** |
| Thymus (g)             | 0.051 ± 0.006 | 0.056 ± 0.006 | 0.045 ± 0.007    | 0.039 ± 0.006 *  | 0.025 ± 0.005 ** | 0.007 ± 0.003 ** |
| Thymus (%)             | 0.199 ± 0.030 | 0.220 ± 0.018 | 0.179 ± 0.025    | 0.159 ± 0.025 *  | 0.109 ± 0.018 ** | 0.048 ± 0.020 ** |
| Adrenals (g)           | 0.007 ± 0.001 | 0.006 ± 0.001 | 0.007 ± 0.002    | 0.007 ± 0.001    | 0.008 ± 0.002    | 0.008 ± 0.002    |
| Adrenals (%)           | 0.028 ± 0.005 | 0.025 ± 0.005 | 0.029 ± 0.006    | 0.027 ± 0.006    | 0.036 ± 0.007    | 0.058 ± 0.011 ** |
| Testes (g)             | 0.174 ± 0.023 | 0.169 ± 0.022 | 0.159 ± 0.020    | 0.176 ± 0.022    | 0.174 ± 0.038    | 0.126 ± 0.018    |
| Testes (%)             | 0.684 ± 0.090 | 0.661 ± 0.074 | 0.634 ± 0.075    | 0.707 ± 0.079    | 0.765 ± 0.169    | 0.885 ± 0.106 *  |
| Heart (g)              | 0.134 ± 0.005 | 0.131 ± 0.015 | 0.131 ± 0.004    | 0.134 ± 0.005    | 0.127 ± 0.006    | 0.105 ± 0.010 ** |
| Heart (%)              | 0.527 ± 0.029 | 0.515 ± 0.067 | 0.523 ± 0.009    | 0.540 ± 0.027    | 0.556 ± 0.031    | 0.736 ± 0.029 *  |
| Lungs (g)              | 0.135 ± 0.005 | 0.130 ± 0.006 | 0.132 ± 0.004    | 0.142 ± 0.011    | 0.132 ± 0.009    | 0.123 ± 0.012    |
| Lungs (%)              | 0.528 ± 0.010 | 0.511 ± 0.034 | 0.528 ± 0.017    | 0.573 ± 0.047    | 0.578 ± 0.021    | 0.861 ± 0.038 ** |
| Kidneys (g)            | 0.367 ± 0.006 | 0.372 ± 0.012 | 0.420 ± 0.073 ** | 0.382 ± 0.013    | 0.332 ± 0.013 *  | 0.248 ± 0.025 ** |
| Kidneys (%)            | 1.439 ± 0.051 | 1.462 ± 0.060 | 1.676 ± 0.326 ** | 1.540 ± 0.022 ** | 1.454 ± 0.040    | 1.737 ± 0.079 ** |
| Spleen (g)             | 0.053 ± 0.003 | 0.161 ± 0.009 | 0.245 ± 0.021 ** | 0.298 ± 0.028 ** | 0.327 ± 0.027 ** | 0.238 ± 0.086 ** |
| Spleen (%)             | 0.207 ± 0.020 | 0.632 ± 0.035 | 0.976 ± 0.074 ** | 1.201 ± 0.076 ** | 1.430 ± 0.083 ** | 1.643 ± 0.507 ** |
| Liver (g)              | 1.270 ± 0.095 | 1.386 ± 0.104 | 1.491 ± 0.074 *  | 1.573 ± 0.150 ** | 1.623 ± 0.121 ** | 0.828 ± 0.160 ** |
| Liver (%)              | 4.978 ± 0.259 | 5.445 ± 0.467 | 5.938 ± 0.241 ** | 6.333 ± 0.489 ** | 7.104 ± 0.322 ** | 5.776 ± 0.742 *  |
| Brain (g)              | 0.428 ± 0.008 | 0.435 ± 0.016 | 0.433 ± 0.004    | 0.430 ± 0.012    | 0.419 ± 0.011    | 0.406 ± 0.008 *  |
| Brain (%)              | 1.682 ± 0.069 | 1.710 ± 0.089 | 1.725 ± 0.048    | 1.734 ± 0.069    | 1.837 ± 0.086    | 2.860 ± 0.215 ** |

Mean ± S.D.

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

TABLE 12 ORGAN WEIGHTS OF FEMALE MICE IN THE 2-WEEK FEED STUDY OF DIPHENYLAMINE

| Group Name             | Control       | 1600 ppm      | 4000 ppm      | 7000 ppm      | 10000 ppm     | 25000 ppm     |    |
|------------------------|---------------|---------------|---------------|---------------|---------------|---------------|----|
| No. of examined animal | 5             | 5             | 5             | 5             | 5             | 5             |    |
| Body weight (g)        | 20.6 ± 0.4    | 20.9 ± 0.9    | 20.5 ± 0.3    | 20.4 ± 0.8    | 19.5 ± 1.3    | 11.4 ± 1.0    | ** |
| Thymus (g)             | 0.076 ± 0.008 | 0.075 ± 0.004 | 0.067 ± 0.002 | 0.059 ± 0.004 | 0.037 ± 0.009 | 0.006 ± 0.002 | ** |
| Thymus (%)             | 0.368 ± 0.038 | 0.358 ± 0.011 | 0.327 ± 0.006 | 0.291 ± 0.018 | 0.187 ± 0.037 | 0.049 ± 0.013 | ** |
| Adrenals (g)           | 0.011 ± 0.002 | 0.010 ± 0.001 | 0.010 ± 0.001 | 0.009 ± 0.001 | 0.009 ± 0.001 | 0.008 ± 0.002 |    |
| Adrenals (%)           | 0.052 ± 0.010 | 0.048 ± 0.004 | 0.050 ± 0.005 | 0.046 ± 0.005 | 0.047 ± 0.005 | 0.074 ± 0.008 | ** |
| Ovaries (g)            | 0.016 ± 0.005 | 0.015 ± 0.004 | 0.013 ± 0.003 | 0.014 ± 0.002 | 0.012 ± 0.003 | 0.008 ± 0.001 | ** |
| Ovaries (%)            | 0.076 ± 0.024 | 0.072 ± 0.020 | 0.065 ± 0.016 | 0.068 ± 0.011 | 0.061 ± 0.012 | 0.071 ± 0.016 |    |
| Heart (g)              | 0.119 ± 0.008 | 0.115 ± 0.012 | 0.110 ± 0.013 | 0.113 ± 0.007 | 0.107 ± 0.011 | 0.097 ± 0.008 | ** |
| Heart (%)              | 0.581 ± 0.043 | 0.553 ± 0.053 | 0.538 ± 0.060 | 0.556 ± 0.036 | 0.550 ± 0.054 | 0.854 ± 0.114 | ** |
| Lungs (g)              | 0.124 ± 0.011 | 0.126 ± 0.005 | 0.123 ± 0.007 | 0.121 ± 0.009 | 0.121 ± 0.014 | 0.108 ± 0.004 |    |
| Lungs (%)              | 0.603 ± 0.051 | 0.606 ± 0.038 | 0.599 ± 0.032 | 0.592 ± 0.050 | 0.621 ± 0.065 | 0.955 ± 0.092 | ** |
| Kidneys (g)            | 0.267 ± 0.011 | 0.266 ± 0.011 | 0.266 ± 0.019 | 0.263 ± 0.010 | 0.245 ± 0.017 | 0.211 ± 0.014 | ** |
| Kidneys (%)            | 1.298 ± 0.038 | 1.278 ± 0.025 | 1.299 ± 0.091 | 1.289 ± 0.077 | 1.256 ± 0.045 | 1.864 ± 0.142 | *  |
| Spleen (g)             | 0.064 ± 0.008 | 0.153 ± 0.011 | 0.211 ± 0.042 | 0.262 ± 0.040 | 0.250 ± 0.023 | 0.157 ± 0.068 | *  |
| Spleen (%)             | 0.313 ± 0.041 | 0.734 ± 0.027 | 1.030 ± 0.196 | 1.284 ± 0.202 | 1.285 ± 0.123 | 1.347 ± 0.467 | ** |
| Liver (g)              | 1.009 ± 0.081 | 1.084 ± 0.111 | 1.144 ± 0.056 | 1.234 ± 0.066 | 1.322 ± 0.061 | 0.649 ± 0.187 | ** |
| Liver (%)              | 4.905 ± 0.336 | 5.184 ± 0.307 | 5.576 ± 0.192 | 6.049 ± 0.218 | 6.796 ± 0.233 | 5.632 ± 1.159 |    |
| Brain (g)              | 0.441 ± 0.015 | 0.440 ± 0.009 | 0.435 ± 0.019 | 0.438 ± 0.008 | 0.416 ± 0.010 | 0.404 ± 0.004 | ** |
| Brain (%)              | 2.146 ± 0.051 | 2.110 ± 0.056 | 2.121 ± 0.083 | 2.148 ± 0.106 | 2.142 ± 0.097 | 3.570 ± 0.285 | *  |

Mean ± S.D.

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

TABLE 13 INCIDENCES OF SELECTED LESIONS OF MALE MICE IN THE 2-WEEK FEED STUDY OF DIPHENYLAMINE (DEAD AND MORIBUND ANIMALS)

| Group Name                         | Control |   |   |   | 1600 ppm |   |   |   | 4000 ppm |   |   |   | 7000 ppm |   |   |   | 10000 ppm |   |   |   | 25000 ppm |   |   |   |
|------------------------------------|---------|---|---|---|----------|---|---|---|----------|---|---|---|----------|---|---|---|-----------|---|---|---|-----------|---|---|---|
| Number of examined animals         | 0       |   |   |   | 0        |   |   |   | 0        |   |   |   | 0        |   |   |   | 0         |   |   |   | 1         |   |   |   |
| Grade                              | 1       | 2 | 3 | 4 | 1        | 2 | 3 | 4 | 1        | 2 | 3 | 4 | 1        | 2 | 3 | 4 | 1         | 2 | 3 | 4 | 1         | 2 | 3 | 4 |
| spleen                             | <1>     |   |   |   |          |   |   |   |          |   |   |   |          |   |   |   |           |   |   |   |           |   |   |   |
| deposit of hemosiderin             | —       | — | — | — | —        | — | — | — | —        | — | — | — | —        | — | — | — | —         | — | — | — | 0         | 1 | 0 | 0 |
| extramedullary hematopoiesis       | —       | — | — | — | —        | — | — | — | —        | — | — | — | —        | — | — | — | —         | — | — | — | 0         | 1 | 0 | 0 |
| engorgement of erythrocyte         | —       | — | — | — | —        | — | — | — | —        | — | — | — | —        | — | — | — | —         | — | — | — | 0         | 1 | 0 | 0 |
| liver                              | <1>     |   |   |   |          |   |   |   |          |   |   |   |          |   |   |   |           |   |   |   |           |   |   |   |
| necrosis:central                   | —       | — | — | — | —        | — | — | — | —        | — | — | — | —        | — | — | — | —         | — | — | — | 0         | 0 | 1 | 0 |
| deposit of pigment                 | —       | — | — | — | —        | — | — | — | —        | — | — | — | —        | — | — | — | —         | — | — | — | 0         | 1 | 0 | 0 |
| hepatocellular hypertrophy:central | —       | — | — | — | —        | — | — | — | —        | — | — | — | —        | — | — | — | —         | — | — | — | 0         | 1 | 0 | 0 |
| kidney                             | <1>     |   |   |   |          |   |   |   |          |   |   |   |          |   |   |   |           |   |   |   |           |   |   |   |
| hyaline cast                       | —       | — | — | — | —        | — | — | — | —        | — | — | — | —        | — | — | — | —         | — | — | — | 0         | 1 | 0 | 0 |
| tubular necrosis                   | —       | — | — | — | —        | — | — | — | —        | — | — | — | —        | — | — | — | —         | — | — | — | 0         | 1 | 0 | 0 |

Grade 1: Slight    2: Moderate    3: Marked    4: Severe  
 < > : Number of animals examined at the site  
 — : All animals survived at the terminal necropsy

TABLE 14 INCIDENCES OF SELECTED LESIONS OF MALE MICE IN THE 2-WEEK FEED STUDY OF DIPHENYLAMINE (SACRIFICED ANIMALS)

| Group Name                          | Control |   |   |   | 1600 ppm |   |   |   | 4000 ppm |   |   |   | 7000 ppm |   |   |   | 10000 ppm |   |   |   | 25000 ppm |   |   |   |
|-------------------------------------|---------|---|---|---|----------|---|---|---|----------|---|---|---|----------|---|---|---|-----------|---|---|---|-----------|---|---|---|
| Number of examined animals          | 5       |   |   |   | 5        |   |   |   | 5        |   |   |   | 5        |   |   |   | 5         |   |   |   | 4         |   |   |   |
| Grade                               | 1       | 2 | 3 | 4 | 1        | 2 | 3 | 4 | 1        | 2 | 3 | 4 | 1        | 2 | 3 | 4 | 1         | 2 | 3 | 4 | 1         | 2 | 3 | 4 |
| spleen                              | <5>     |   |   |   | <5>      |   |   |   | <5>      |   |   |   | <5>      |   |   |   | <5>       |   |   |   | <4>       |   |   |   |
| deposit of hemosiderin              | 0       | 0 | 0 | 0 | 5        | 0 | 0 | 0 | 1        | 4 | 0 | 0 | 0        | 5 | 0 | 0 | 0         | 5 | 0 | 0 | 0         | 4 | 0 | 0 |
| extramedullary hematopoiesis        | 0       | 0 | 0 | 0 | 0        | 5 | 0 | 0 | 0        | 5 | 0 | 0 | 0        | 4 | 1 | 0 | 0         | 5 | 0 | 0 | 0         | 0 | 4 | 0 |
| engorgement of erythrocyte          | 0       | 0 | 0 | 0 | 5        | 0 | 0 | 0 | 5        | 0 | 0 | 0 | 5        | 0 | 0 | 0 | 0         | 0 | 0 | 0 | 1         | 0 | 0 | 0 |
| liver                               | <5>     |   |   |   | <5>      |   |   |   | <5>      |   |   |   | <5>      |   |   |   | <5>       |   |   |   | <4>       |   |   |   |
| necrosis:centeral                   | 0       | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0         | 0 | 0 | 0 | 2         | 2 | 0 | 0 |
| deposit of pigment                  | 0       | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 4        | 0 | 0 | 0 | 5        | 0 | 0 | 0 | 5         | 0 | 0 | 0 | 0         | 4 | 0 | 0 |
| extramedullary hematopoiesis        | 0       | 0 | 0 | 0 | 1        | 0 | 0 | 0 | 3        | 0 | 0 | 0 | 4        | 0 | 0 | 0 | 5         | 0 | 0 | 0 | 0         | 0 | 0 | 0 |
| hepatocellular hypertrophy:centeral | 0       | 0 | 0 | 0 | 4        | 0 | 0 | 0 | 0        | 5 | 0 | 0 | 0        | 5 | 0 | 0 | 0         | 1 | 4 | 0 | 1         | 3 | 0 | 0 |
| kidney                              | <5>     |   |   |   | <5>      |   |   |   | <5>      |   |   |   | <5>      |   |   |   | <5>       |   |   |   | <4>       |   |   |   |
| dilatation:tubular lumen            | 0       | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0         | 0 | 0 | 0 | 4         | 0 | 0 | 0 |

Grade 1: Slight    2: Moderate    3: Marked    4: Severe  
 < > : Number of animals examined at the site

TABLE 15 INCIDENCES OF SELECTED LESIONS OF FEMALE MICE IN THE 2-WEEK FEED STUDY OF DIPHENYLAMINE (ALL ANIMALS)

| Group Name                          | Control |   |   |   | 1600 ppm |   |   |   | 4000 ppm |   |   |   | 7000 ppm |   |   |   | 10000 ppm |   |   |   | 25000 ppm |   |   |   |
|-------------------------------------|---------|---|---|---|----------|---|---|---|----------|---|---|---|----------|---|---|---|-----------|---|---|---|-----------|---|---|---|
| Number of examined animals          | 5       |   |   |   | 5        |   |   |   | 5        |   |   |   | 5        |   |   |   | 5         |   |   |   | 5         |   |   |   |
| Grade                               | 1       | 2 | 3 | 4 | 1        | 2 | 3 | 4 | 1        | 2 | 3 | 4 | 1        | 2 | 3 | 4 | 1         | 2 | 3 | 4 | 1         | 2 | 3 | 4 |
| spleen                              | <5>     |   |   |   | <5>      |   |   |   | <5>      |   |   |   | <5>      |   |   |   | <5>       |   |   |   | <5>       |   |   |   |
| deposit of hemosiderin              | 0       | 0 | 0 | 0 | 5        | 0 | 0 | 0 | 5        | 0 | 0 | 0 | 4        | 1 | 0 | 0 | 0         | 5 | 0 | 0 | 1         | 4 | 0 | 0 |
| extramedullary hematopoiesis        | 0       | 0 | 0 | 0 | 5        | 0 | 0 | 0 | 5        | 0 | 0 | 0 | 4        | 1 | 0 | 0 | 0         | 5 | 0 | 0 | 0         | 2 | 3 | 0 |
| engorgement of erythrocyte          | 0       | 0 | 0 | 0 | 5        | 0 | 0 | 0 | 5        | 0 | 0 | 0 | 5        | 0 | 0 | 0 | 4         | 0 | 0 | 0 | 3         | 1 | 0 | 0 |
| liver                               | <5>     |   |   |   | <5>      |   |   |   | <5>      |   |   |   | <5>      |   |   |   | <5>       |   |   |   |           |   |   |   |
| necrosis:centeral                   | 0       | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0         | 0 | 0 | 0 | 2         | 2 | 1 | 0 |
| deposit of pigment                  | 0       | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 5        | 0 | 0 | 0 | 5         | 0 | 0 | 0 | 0         | 3 | 2 | 0 |
| extramedullary hematopoiesis        | 0       | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 1        | 0 | 0 | 0 | 4        | 0 | 0 | 0 | 3         | 0 | 0 | 0 | 0         | 0 | 0 | 0 |
| hepatocellular hypertrophy:centeral | 0       | 0 | 0 | 0 | 2        | 0 | 0 | 0 | 5        | 0 | 0 | 0 | 2        | 3 | 0 | 0 | 0         | 5 | 0 | 0 | 0         | 0 | 0 | 0 |
| kidney                              | <5>     |   |   |   | <5>      |   |   |   | <5>      |   |   |   | <5>      |   |   |   | <5>       |   |   |   |           |   |   |   |
| tubular necrosis                    | 0       | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0         | 0 | 0 | 0 | 0         | 1 | 0 | 0 |
| dilatation:tubular lumen            | 0       | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 1         | 0 | 0 | 0 | 4         | 0 | 0 | 0 |

Grade 1: Slight 2: Moderate 3: Marked 4: Severe  
 < > : Number of animals examined at the site