

2-アミノ-4-クロロフェノール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： 0483

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TABLE 1 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF MALE MICE
IN THE 2-WEEK FEED STUDY OF 2-AMINO-4-CHLOROPHENOL

Week-Day on Study	Control		1280 ppm			3200 ppm			8000 ppm			20000 ppm			50000 ppm		
	Av. Wt.	No. of Surviv.	Av. Wt.	% of cont.	No. of Surviv.	Av. Wt.	% of cont.	No. of Surviv.	Av. Wt.	% of cont.	No. of Surviv.	Av. Wt.	% of cont.	No. of Surviv.	Av. Wt.	% of cont.	No. of Surviv.
	<5>		<5>			<5>			<5>			<5>			<5>		
0-0	24.2 (5)	5 / 5	24.3 (5)	100	5 / 5	24.2 (5)	100	5 / 5	24.2 (5)	100	5 / 5	24.2 (5)	100	5 / 5	24.2 (5)	100	5 / 5
1-4	23.5 (5)	5 / 5	24.3 (5)	103	5 / 5	24.2 (5)	103	5 / 5	23.3 (5)	99	5 / 5	22.5 (5)	96	5 / 5	16.7 (5)	71	5 / 5
1-7	24.4 (5)	5 / 5	25.0 (5)	102	5 / 5	25.1 (5)	103	5 / 5	24.1 (5)	99	5 / 5	23.6 (5)	97	5 / 5	16.0 (2)	66	2 / 5
2-4	25.9 (5)	5 / 5	26.1 (5)	101	5 / 5	26.1 (5)	101	5 / 5	25.4 (5)	98	5 / 5	23.9 (5)	92	5 / 5	— (—)	—	0 / 5
2-7	26.6 (5)	5 / 5	26.5 (5)	100	5 / 5	26.8 (5)	101	5 / 5	26.0 (5)	98	5 / 5	24.6 (5)	92	5 / 5	— (—)	—	0 / 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 2-AMINO-4-CHLOROPHENOL

Week-Day on Study	Control		1280 ppm			3200 ppm			8000 ppm			20000 ppm			50000 ppm		
	Av. Wt.	No. of Surviv.	Av. Wt.	% of cont.	No. of Surviv.	Av. Wt.	% of cont.	No. of Surviv.	Av. Wt.	% of cont.	No. of Surviv.	Av. Wt.	% of cont.	No. of Surviv.	Av. Wt.	% of cont.	No. of Surviv.
	<5>		<5>			<5>			<5>			<5>			<5>		
0-0	19.0 (5)	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	19.1 (5)	101	5 / 5
1-4	19.1 (5)	5 / 5	18.9 (5)	99	5 / 5	19.0 (5)	99	5 / 5	18.4 (5)	96	5 / 5	18.2 (5)	95	5 / 5	13.3 (5)	70	5 / 5
1-7	19.8 (5)	5 / 5	19.9 (5)	101	5 / 5	19.0 (5)	96	5 / 5	19.1 (5)	96	5 / 5	19.1 (5)	96	5 / 5	12.4 (5)	63	5 / 5
2-4	20.7 (5)	5 / 5	20.7 (5)	100	5 / 5	19.7 (5)	95	5 / 5	19.7 (5)	95	5 / 5	20.1 (5)	97	5 / 5	— (—)	—	0 / 5
2-7	19.9 (5)	5 / 5	20.8 (5)	105	5 / 5	20.1 (5)	101	5 / 5	19.4 (5)	97	5 / 5	20.1 (5)	101	5 / 5	— (—)	—	0 / 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 2-AMINO-4-CHLOROPHENOL

Week-Day on Study	Control		1280 ppm			3200 ppm			8000 ppm			20000 ppm			50000 ppm		
	Av. Fc.	No. of Surviv.	Av. Fc.	% of cont.	No. of Surviv.	Av. Fc.	% of cont.	No. of Surviv.	Av. Fc.	% of cont.	No. of Surviv.	Av. Fc.	% of cont.	No. of Surviv.	Av. Fc.	% of cont.	No. of Surviv.
	<5>		<5>			<5>			<5>			<5>			<5>		
1-4	3.4 (5)	5 / 5	4.0 (5)	118	5 / 5	3.9 (5)	115	5 / 5	3.3 (5)	97	5 / 5	2.8 (5)	82	5 / 5	1.2 (5)	35	5 / 5
1-7	4.3 (5)	5 / 5	4.3 (5)	100	5 / 5	4.2 (5)	98	5 / 5	4.1 (5)	95	5 / 5	4.3 (5)	100	5 / 5	1.8 (2)	42	2 / 5
2-4	3.9 (5)	5 / 5	4.0 (5)	103	5 / 5	3.8 (5)	97	5 / 5	4.1 (5)	105	5 / 5	3.7 (5)	95	5 / 5	— (—)	—	0 / 5
2-7	3.8 (5)	5 / 5	4.0 (5)	105	5 / 5	4.0 (5)	105	5 / 5	3.9 (5)	103	5 / 5	4.0 (4)	105	5 / 5	— (—)	—	0 / 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 2-AMINO-4-CHLOROPHENOL

Week-Day on Study	Control		1280 ppm			3200 ppm			8000 ppm			20000 ppm			50000 ppm		
	Av. Fc.	No. of Surviv.	Av. Fc.	% of cont.	No. of Surviv.	Av. Fc.	% of cont.	No. of Surviv.	Av. Fc.	% of cont.	No. of Surviv.	Av. Fc.	% of cont.	No. of Surviv.	Av. Fc.	% of cont.	No. of Surviv.
	<5>		<5>			<5>			<5>			<5>			<5>		
1-4	3.6 (5)	5 / 5	3.4 (5)	94	5 / 5	3.6 (5)	100	5 / 5	3.2 (5)	89	5 / 5	3.0 (5)	83	5 / 5	1.5 (5)	42	5 / 5
1-7	3.7 (5)	5 / 5	4.0 (5)	108	5 / 5	3.6 (5)	97	5 / 5	3.7 (5)	100	5 / 5	3.7 (5)	100	5 / 5	1.7 (5)	46	5 / 5
2-4	3.4 (5)	5 / 5	3.3 (5)	97	5 / 5	3.4 (5)	100	5 / 5	3.2 (5)	94	5 / 5	3.4 (4)	100	5 / 5	— (—)	—	0 / 5
2-7	3.3 (5)	5 / 5	3.5 (5)	106	5 / 5	3.8 (5)	115	5 / 5	3.2 (5)	97	5 / 5	3.3 (5)	100	5 / 5	— (—)	—	0 / 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 2-AMINO-4-CHLOROPHENOL

Group name	Control	1280 ppm	3200 ppm	8000 ppm	20000 ppm	50000 ppm
No. of examined animals	5	5	5	4	4	0
Red blood cell ($10^6/\mu\text{L}$)	10.70 \pm 0.31	10.70 \pm 0.17	10.84 \pm 0.38	9.86 \pm 0.62 *	8.35 \pm 0.39 **	—
Hemoglobin (g/dL)	15.7 \pm 0.5	15.6 \pm 0.4	15.7 \pm 0.6	14.8 \pm 0.6	14.4 \pm 0.8 *	—
Hematocrit (%)	47.8 \pm 1.8	47.4 \pm 0.8	47.8 \pm 1.5	43.2 \pm 2.5 **	40.0 \pm 1.9 **	—
MCV (fL)	44.7 \pm 0.7	44.3 \pm 0.4	44.1 \pm 0.5	43.8 \pm 0.9	47.8 \pm 0.9 **	—
MCHC (g/dL)	32.9 \pm 0.5	32.9 \pm 0.4	32.8 \pm 0.3	34.4 \pm 0.7 **	36.1 \pm 1.0 **	—
WBC ($10^3/\mu\text{L}$)	1.68 \pm 0.58	3.58 \pm 1.64	2.66 \pm 1.59	3.03 \pm 1.52	5.33 \pm 0.73 **	—

Mean \pm S.D.
^{*)} Significant difference, $p < 0.05$ (Test of Dunnett)
^{**)} Significant difference, $p < 0.01$ (Test of Dunnett)

TABLE 6 HEMATOLOGY OF FEMALE MICE IN THE 2-WEEK FEED STUDY OF 2-AMINO-4-CHLOROPHENOL

Group name	Control	1280 ppm	3200 ppm	8000 ppm	20000 ppm	50000 ppm
No. of examined animals	5	5	4	4	5	0
Red blood cell ($10^6/\mu\text{L}$)	10.61 \pm 0.44	10.58 \pm 0.35	10.39 \pm 0.13	9.63 \pm 0.39 **	8.77 \pm 0.14 **	—
Hemoglobin (g/dL)	15.5 \pm 0.5	15.3 \pm 0.5	15.3 \pm 0.2	14.7 \pm 0.7	14.7 \pm 0.4 *	—
Hematocrit (%)	46.9 \pm 1.7	46.2 \pm 1.3	45.7 \pm 0.4	43.0 \pm 1.9 **	42.6 \pm 0.7 **	—
MCV (fL)	44.2 \pm 0.4	43.6 \pm 0.6	44.0 \pm 0.3	44.6 \pm 0.5	48.5 \pm 0.5 **	—
MCH (pg)	14.6 \pm 0.1	14.5 \pm 0.2	14.7 \pm 0.1	15.2 \pm 0.1 **	16.7 \pm 0.2 **	—
MCHC (g/dL)	33.0 \pm 0.3	33.2 \pm 0.3	33.4 \pm 0.2	34.1 \pm 0.5 *	34.5 \pm 0.7 **	—
Platelet ($10^3/\mu\text{L}$)	1000 \pm 44	970 \pm 52	966 \pm 36	1041 \pm 28	1104 \pm 82 *	—

Mean \pm S.D.
^{*)} Significant difference, $p < 0.05$ (Test of Dunnett)
^{**)} Significant difference, $p < 0.01$ (Test of Dunnett)

TABLE 7 BIOCHEMISTRY OF MALE MICE IN THE 2-WEEK FEED STUDY OF 2-AMINO-4-CHLOROPHENOL

Group name	Control	1280 ppm	3200 ppm	8000 ppm	20000 ppm	50000 ppm
No. of examined animals	5	5	5	4	5	0
T-bilirubin (mg/dL)	0.15 ± 0.04	0.11 ± 0.01	0.13 ± 0.03	0.17 ± 0.04	0.24 ± 0.03 **	—
Mean ± S.D.						
*) Significant difference, p<0.05 (Test of Dunnett)						
**) Significant difference, p<0.01 (Test of Dunnett)						

TABLE 8 BIOCHEMISTRY OF FEMALE MICE IN THE 2-WEEK FEED STUDY OF 2-AMINO-4-CHLOROPHENOL

Group name	Control	1280 ppm	3200 ppm	8000 ppm	20000 ppm	50000 ppm
No. of examined animals	5	5	5	5	5	0
T-bilirubin (mg/dL)	0.14 ± 0.02	0.14 ± 0.01	0.14 ± 0.02	0.19 ± 0.02 **	0.20 ± 0.03 **	—
T-cholesterol (mg/dL)	72 ± 4	83 ± 9	78 ± 6	80 ± 2	95 ± 10 **	—
Phospholipid (mg/dL)	154 ± 7	168 ± 14	162 ± 13	166 ± 7	192 ± 19 **	—
Mean ± S.D.						
*) Significant difference, p<0.05 (Test of Dunnett)						
**) Significant difference, p<0.01 (Test of Dunnett)						

TABLE 9 ORGAN WEIGHTS OF MALE MICE IN THE 2-WEEK FEED STUDY OF 2-AMINO-4-CHLOROPHENOL

Group name	Control	1280 ppm	3200 ppm	8000 ppm	20000 ppm	50000 ppm
No. of examined animals	5	5	5	5	5	0
Body weight (g)	26.6 ± 1.0	26.5 ± 1.2	26.8 ± 1.0	26.0 ± 1.0	24.6 ± 1.0 *	—
Lungs (g)	0.147 ± 0.009	0.149 ± 0.009	0.150 ± 0.007	0.147 ± 0.008	0.147 ± 0.008	—
Lungs (%)	0.554 ± 0.023	0.560 ± 0.015	0.558 ± 0.020	0.567 ± 0.039	0.600 ± 0.017 *	—
Kidneys (g)	0.351 ± 0.024	0.373 ± 0.023	0.364 ± 0.023	0.356 ± 0.030	0.369 ± 0.014	—
Kidneys (%)	1.320 ± 0.079	1.404 ± 0.059	1.357 ± 0.078	1.367 ± 0.062	1.502 ± 0.017 **	—
Spleen (g)	0.044 ± 0.005	0.054 ± 0.003	0.054 ± 0.007	0.086 ± 0.014 **	0.197 ± 0.024 **	—
Spleen (%)	0.166 ± 0.018	0.202 ± 0.016	0.203 ± 0.022	0.333 ± 0.051 **	0.802 ± 0.094 **	—
Liver (g)	1.202 ± 0.076	1.335 ± 0.153	1.299 ± 0.091	1.277 ± 0.058	1.384 ± 0.093	—
Liver (%)	4.520 ± 0.194	5.016 ± 0.349 *	4.842 ± 0.261	4.915 ± 0.118	5.636 ± 0.289 **	—
Brain (g)	0.428 ± 0.011	0.436 ± 0.011	0.427 ± 0.013	0.426 ± 0.012	0.428 ± 0.010	—
Brain (%)	1.614 ± 0.077	1.646 ± 0.057	1.593 ± 0.039	1.641 ± 0.040	1.744 ± 0.089 *	—

Mean ± S.D.

*) Significant difference, p<0.05 (Test of Dunnett)

**) Significant difference, p<0.01 (Test of Dunnett)

TABLE 10 ORGAN WEIGHTS OF FEMALE MICE IN THE 2-WEEK FEED STUDY OF 2-AMINO-4-CHLOROPHENOL

Group name	Control	1280 ppm	3200 ppm	8000 ppm	20000 ppm	50000 ppm
No. of examined animals	5	5	5	5	5	0
Body weight (g)	19.9 ± 0.9	20.8 ± 0.6	20.1 ± 0.7	19.4 ± 0.9	20.1 ± 0.8	—
Spleen (g)	0.059 ± 0.008	0.067 ± 0.018	0.069 ± 0.006	0.096 ± 0.010 **	0.160 ± 0.019 **	—
Spleen (%)	0.294 ± 0.034	0.322 ± 0.090	0.341 ± 0.029	0.497 ± 0.058 **	0.794 ± 0.082 **	—
Liver (g)	0.873 ± 0.072	0.949 ± 0.017	0.929 ± 0.086	0.915 ± 0.077	1.167 ± 0.058 **	—
Liver (%)	4.376 ± 0.296	4.575 ± 0.147	4.609 ± 0.314	4.730 ± 0.409	5.811 ± 0.213 **	—
Brain (g)	0.440 ± 0.010	0.433 ± 0.011	0.426 ± 0.004	0.434 ± 0.020	0.421 ± 0.006	—
Brain (%)	2.210 ± 0.071	2.087 ± 0.061 *	2.118 ± 0.083	2.241 ± 0.058	2.096 ± 0.052 *	—

Mean ± S.D.

*) Significant difference, p<0.05 (Test of Dunnett)

**) Significant difference, p<0.01 (Test of Dunnett)

TABLE 11 INCIDENCES OF SELECTED LESIONS OF MALE MICE IN THE 2-WEEK FEED STUDY OF 2-AMINO-4-CHLOROPHENOL

Group		Control	1280 ppm	3200 ppm	8000 ppm	20000 ppm	50000 ppm	
Number of examined animals		5	5	5	5	5	0	(5)
Organ	Grade of lesion							
Findings								
Thymus								
Atrophy	3+	0	0	0	0	0	—	(5)
Spleen								
Extramedullary hematopoiesis	2+	0	0	0	5	5	—	(0)
Engorgement of erythrocyte	1+	0	0	0	0	5	—	(1)
	2+	0	0	0	0	0	—	(2)
Stomach								
Ulcer: forestomach	1+	0	0	0	0	4	—	(0)
Hyperplasia: forestomach	1+	0	1	1	2	0	—	(0)
	2+	0	0	1	2	3	—	(0)
	3+	0	0	0	1	2	—	(0)
Liver								
Swelling: central	1+	0	0	0	0	4	—	(0)
Urinary bladder								
Dilatation	1+	1	0	0	0	0	—	(1)
Degeneration	1+	0	0	0	3	4	—	(0)
Testis								
Germ cell necrosis	1+	0	0	0	0	0	—	(1)
Epididymis								
Debris of spermatic elements	1+	0	0	0	0	0	—	(1)
Grade : 1+ Slight 2+ Moderate 3+ Marked 4+ Severe								
() : Number of dead and moribund animals.								

TABLE 12 INCIDENCES OF SELECTED LESIONS OF FEMALE MICE IN THE 2-WEEK FEED STUDY OF 2-AMINO-4-CHLOROPHENOL

Group		Control	1280 ppm	3200 ppm	8000 ppm	20000 ppm	50000 ppm	
Number of examined animals		5	5	5	5	5	0	(5)
Organ	Grade of lesion							
Findings								
Thymus								
Atrophy	3+	0	0	0	0	0	—	(5)
Spleen								
Extramedullary hematopoiesis	1+	0	0	2	0	1	—	(0)
	2+	0	0	0	5	4	—	
Engorgement of erythrocyte	1+	0	0	0	0	5	—	(1)
	2+	0	0	0	0	0	—	(4)
Stomach								
Ulcer: forestomach	3+	0	0	0	0	2	—	(0)
Hyperplasia: forestomach	1+	0	0	0	2	2	—	(0)
	2+	0	0	2	2	1	—	(0)
	3+	0	0	0	0	2	—	(0)
Liver								
Swelling: central	1+	0	0	0	0	5	—	(0)
Urinary bladder								
Degeneration	1+	0	0	0	5	5	—	(0)
Grade : 1+ Slight 2+ Moderate 3+ Marked 4+ Severe								
() : Number of dead animals.								