

酢酸イソプロピルのマウスを用いた
吸入による13週間毒性試験報告書

試験番号：0559

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TABLE 1 CONCENTRATION OF ISOPROPYL ACETATE IN THE INHALATION CHAMBER OF THE 13-WEEK INHALATION STUDY

Group Name	Concentration(ppm) Mean \pm S.D.
Control	0.0 \pm 0.0
250 ppm	250.4 \pm 2.2
500 ppm	499.9 \pm 5.3
1000 ppm	998.5 \pm 11.7
2000 ppm	1997.3 \pm 19.3
4000 ppm	3990.6 \pm 45.2

TABLE 2 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF MALE MICE
IN THE 13-WEEK INHALATION STUDY OF ISOPROPYL ACETATE

Week on Study	Control		250 ppm			500 ppm			1000 ppm			2000 ppm			4000 ppm		
	Av. Wt. <10>	No. of Surviv.	Av. Wt. <10>	% of cont.	No. of Surviv.	Av. Wt. <10>	% of cont.	No. of Surviv.	Av. Wt. <10>	% of cont.	No. of Surviv.	Av. Wt. <10>	% of cont.	No. of Surviv.	Av. Wt. <10>	% of cont.	No. of Surviv.
0	23.5 (10)	10 / 10	23.5 (10)	100	10 / 10	23.5 (10)	100	10 / 10	23.5 (10)	100	10 / 10	23.5 (10)	100	10 / 10	23.5 (10)	100	10 / 10
1	24.2 (10)	10 / 10	23.8 (10)	98	10 / 10	24.7 (10)	102	10 / 10	24.4 (10)	101	10 / 10	25.0 (10)	103	10 / 10	24.9 (10)	103	10 / 10
2	25.1 (10)	10 / 10	24.3 (10)	97	10 / 10	26.1 (10)	104	10 / 10	25.1 (10)	100	10 / 10	25.7 (10)	102	10 / 10	25.0 (10)	100	10 / 10
3	25.7 (10)	10 / 10	24.6 (10)	96	10 / 10	26.7 (10)	104	10 / 10	25.6 (10)	100	10 / 10	26.2 (10)	102	10 / 10	25.9 (10)	101	10 / 10
4	26.6 (10)	10 / 10	26.2 (9)	98	9 / 10	27.6 (10)	104	10 / 10	26.6 (10)	100	10 / 10	26.9 (10)	101	10 / 10	27.0 (10)	102	10 / 10
5	27.7 (10)	10 / 10	26.9 (9)	97	9 / 10	28.2 (10)	102	10 / 10	27.1 (10)	98	10 / 10	27.1 (10)	98	10 / 10	27.4 (10)	99	10 / 10
6	28.3 (10)	10 / 10	27.4 (9)	97	9 / 10	28.6 (10)	101	10 / 10	27.9 (10)	99	10 / 10	27.9 (10)	99	10 / 10	28.1 (10)	99	10 / 10
7	28.9 (10)	10 / 10	27.9 (9)	97	9 / 10	29.4 (10)	102	10 / 10	28.2 (10)	98	10 / 10	28.0 (10)	97	10 / 10	28.6 (10)	99	10 / 10
8	29.6 (10)	10 / 10	28.6 (9)	97	9 / 10	29.7 (10)	100	10 / 10	28.9 (10)	98	10 / 10	29.0 (10)	98	10 / 10	28.7 (10)	97	10 / 10
9	30.6 (10)	10 / 10	28.9 (9)	94	9 / 10	30.3 (10)	99	10 / 10	29.6 (10)	97	10 / 10	29.9 (10)	98	10 / 10	29.7 (10)	97	10 / 10
10	31.5 (10)	10 / 10	29.7 (9)	94	9 / 10	30.9 (10)	98	10 / 10	30.3 (10)	96	10 / 10	30.4 (10)	97	10 / 10	29.9 (10)	95	10 / 10
11	31.8 (10)	10 / 10	30.2 (9)	95	9 / 10	31.0 (10)	97	10 / 10	30.7 (10)	97	10 / 10	30.9 (10)	97	10 / 10	30.5 (10)	96	10 / 10
12	32.4 (10)	10 / 10	30.5 (9)	94	9 / 10	31.5 (10)	97	10 / 10	31.2 (10)	96	10 / 10	31.3 (10)	97	10 / 10	30.7 (10)	95	10 / 10
13	32.9 (10)	10 / 10	31.0 (9)	94	9 / 10	32.6 (10)	99	10 / 10	31.8 (10)	97	10 / 10	31.6 (10)	96	10 / 10	31.1 (10)	95	10 / 10

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

TABLE 3 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF FEMALE MICE IN THE 13-WEEK INHALATION STUDY OF ISOPROPYL ACETATE

Week on Study	Control		250 ppm			500 ppm			1000 ppm			2000 ppm			4000 ppm		
	Av. Wt. <10>	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.
0	19.1 (10)	10 / 10	19.1 (10)	100	10 / 10	19.1 (10)	100	10 / 10	19.1 (10)	100	10 / 10	19.1 (10)	100	10 / 10	19.1 (10)	100	10 / 10
1	20.6 (10)	10 / 10	20.2 (10)	98	10 / 10	20.4 (10)	99	10 / 10	20.6 (10)	100	10 / 10	20.0 (10)	97	10 / 10	20.3 (10)	99	10 / 10
2	21.3 (10)	10 / 10	20.6 (10)	97	10 / 10	21.2 (10)	100	10 / 10	21.5 (10)	101	10 / 10	20.7 (10)	97	10 / 10	20.8 (10)	98	10 / 10
3	21.8 (10)	10 / 10	21.0 (10)	96	10 / 10	21.7 (10)	100	10 / 10	22.1 (10)	101	10 / 10	21.3 (10)	98	10 / 10	21.6 (10)	99	10 / 10
4	22.6 (10)	10 / 10	22.0 (10)	97	10 / 10	22.6 (10)	100	10 / 10	23.0 (10)	102	10 / 10	22.2 (10)	98	10 / 10	22.9 (10)	101	10 / 10
5	23.3 (10)	10 / 10	22.6 (10)	97	10 / 10	22.9 (10)	98	10 / 10	23.4 (10)	100	10 / 10	22.4 (10)	96	10 / 10	22.6 (10)	97	10 / 10
6	23.8 (10)	10 / 10	23.0 (10)	97	10 / 10	23.8 (10)	100	10 / 10	24.1 (10)	101	10 / 10	22.8 (10)	96	10 / 10	23.7 (10)	100	10 / 10
7	24.1 (10)	10 / 10	23.5 (10)	98	10 / 10	24.1 (10)	100	10 / 10	24.4 (10)	101	10 / 10	23.5 (10)	98	10 / 10	23.8 (10)	99	10 / 10
8	24.5 (10)	10 / 10	24.1 (10)	98	10 / 10	24.9 (10)	102	10 / 10	25.2 (10)	103	10 / 10	23.9 (10)	98	10 / 10	24.7 (10)	101	10 / 10
9	24.9 (10)	10 / 10	24.1 (10)	97	10 / 10	24.7 (10)	99	10 / 10	25.3 (10)	102	10 / 10	24.1 (10)	97	10 / 10	24.9 (10)	100	10 / 10
10	25.1 (10)	10 / 10	24.7 (10)	98	10 / 10	26.0 (10)	104	10 / 10	25.6 (10)	102	10 / 10	24.7 (10)	98	10 / 10	24.8 (10)	99	10 / 10
11	25.5 (10)	10 / 10	24.7 (10)	97	10 / 10	25.8 (10)	101	10 / 10	25.5 (10)	100	10 / 10	25.3 (10)	99	10 / 10	25.4 (10)	100	10 / 10
12	25.5 (10)	10 / 10	24.5 (10)	96	10 / 10	26.3 (10)	103	10 / 10	25.9 (10)	102	10 / 10	25.6 (10)	100	10 / 10	25.5 (10)	100	10 / 10
13	25.4 (10)	10 / 10	24.8 (10)	98	10 / 10	26.4 (10)	104	10 / 10	26.0 (10)	102	10 / 10	24.9 (10)	98	10 / 10	25.8 (10)	102	10 / 10

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

TABLE 4 FOOD CONSUMPTION CHANGES OF MALE MICE IN THE 13-WEEK INHALATION STUDY OF ISOPROPYL ACETATE

Week on Study	Control		250 ppm			500 ppm			1000 ppm			2000 ppm			4000 ppm		
	Av. FC. <10>	No. of Surviv.	Av. FC. <10>	% of cont.	No. of Surviv.	Av. FC. <10>	% of cont.	No. of Surviv.	Av. FC. <10>	% of cont.	No. of Surviv.	Av. FC. <10>	% of cont.	No. of Surviv.	Av. FC. <10>	% of cont.	No. of Surviv.
1	3.8 (10)	10 / 10	3.8 (10)	100	10 / 10	4.2 (10)	111	10 / 10	4.0 (10)	105	10 / 10	4.1 (10)	108	10 / 10	4.0 (10)	105	10 / 10
2	3.8 (10)	10 / 10	4.0 (10)	105	10 / 10	4.3 (10)	113	10 / 10	4.0 (10)	105	10 / 10	3.8 (10)	100	10 / 10	3.6 (10)	95	10 / 10
3	4.2 (10)	10 / 10	4.1 (10)	98	10 / 10	4.3 (10)	102	10 / 10	4.1 (10)	98	10 / 10	4.0 (10)	95	10 / 10	3.9 (10)	93	10 / 10
4	4.3 (10)	10 / 10	4.4 (9)	102	9 / 10	4.7 (10)	109	10 / 10	4.4 (10)	102	10 / 10	4.2 (10)	98	10 / 10	4.1 (10)	95	10 / 10
5	4.3 (10)	10 / 10	4.4 (9)	102	9 / 10	4.7 (10)	109	10 / 10	4.3 (10)	100	10 / 10	4.1 (10)	95	10 / 10	4.0 (10)	93	10 / 10
6	4.4 (10)	10 / 10	4.3 (9)	98	9 / 10	4.7 (10)	107	10 / 10	4.4 (10)	100	10 / 10	4.2 (10)	95	10 / 10	4.1 (10)	93	10 / 10
7	4.4 (10)	10 / 10	4.3 (9)	98	9 / 10	4.6 (10)	105	10 / 10	4.3 (10)	98	10 / 10	4.1 (10)	93	10 / 10	4.0 (10)	91	10 / 10
8	4.5 (10)	10 / 10	4.5 (9)	100	9 / 10	4.8 (10)	107	10 / 10	4.4 (10)	98	10 / 10	4.3 (10)	96	10 / 10	4.1 (10)	91	10 / 10
9	4.5 (10)	10 / 10	4.4 (9)	98	9 / 10	4.6 (10)	102	10 / 10	4.4 (10)	98	10 / 10	4.2 (10)	93	10 / 10	4.1 (10)	91	10 / 10
10	4.6 (10)	10 / 10	4.5 (9)	98	9 / 10	4.7 (10)	102	10 / 10	4.5 (10)	98	10 / 10	4.3 (10)	93	10 / 10	4.1 (10)	89	10 / 10
11	4.5 (10)	10 / 10	4.5 (9)	100	9 / 10	4.6 (10)	102	10 / 10	4.4 (10)	98	10 / 10	4.3 (10)	96	10 / 10	4.2 (10)	93	10 / 10
12	4.5 (10)	10 / 10	4.5 (9)	100	9 / 10	4.7 (10)	104	10 / 10	4.5 (10)	100	10 / 10	4.3 (10)	96	10 / 10	4.2 (10)	93	10 / 10
13	4.4 (10)	10 / 10	4.4 (9)	100	9 / 10	4.6 (10)	105	10 / 10	4.5 (10)	102	10 / 10	4.2 (10)	95	10 / 10	4.1 (10)	93	10 / 10

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

TABLE 5 FOOD CONSUMPTION CHANGES OF FEMALE MICE IN THE 13-WEEK INHALATION STUDY OF ISOPROPYL ACETATE

Week on Study	Control		250 ppm			500 ppm			1000 ppm			2000 ppm			4000 ppm		
	Av. FC. <10>	No. of Surviv.	Av. FC. <10>	% of cont.	No. of Surviv.	Av. FC. <10>	% of cont.	No. of Surviv.	Av. FC. <10>	% of cont.	No. of Surviv.	Av. FC. <10>	% of cont.	No. of Surviv.	Av. FC. <10>	% of cont.	No. of Surviv.
1	3.6 (10)	10 / 10	3.5 (10)	97	10 / 10	3.6 (10)	100	10 / 10	3.6 (10)	100	10 / 10	3.4 (10)	94	10 / 10	3.2 (10)	89	10 / 10
2	3.7 (10)	10 / 10	3.5 (10)	95	10 / 10	3.7 (10)	100	10 / 10	3.7 (10)	100	10 / 10	3.5 (10)	95	10 / 10	3.4 (10)	92	10 / 10
3	4.0 (10)	10 / 10	3.7 (10)	93	10 / 10	3.8 (10)	95	10 / 10	3.9 (10)	98	10 / 10	3.6 (10)	90	10 / 10	3.5 (10)	88	10 / 10
4	4.3 (10)	10 / 10	4.0 (10)	93	10 / 10	4.2 (10)	98	10 / 10	4.1 (10)	95	10 / 10	3.8 (10)	88	10 / 10	3.8 (10)	88	10 / 10
5	4.5 (10)	10 / 10	4.1 (10)	91	10 / 10	4.1 (10)	91	10 / 10	4.1 (10)	91	10 / 10	3.7 (10)	82	10 / 10	3.6 (10)	80	10 / 10
6	4.5 (10)	10 / 10	4.2 (10)	93	10 / 10	4.4 (10)	98	10 / 10	4.3 (10)	96	10 / 10	3.9 (10)	87	10 / 10	3.9 (10)	87	10 / 10
7	4.6 (10)	10 / 10	4.2 (10)	91	10 / 10	4.4 (10)	96	10 / 10	4.3 (10)	93	10 / 10	3.8 (10)	83	10 / 10	3.8 (10)	83	10 / 10
8	4.6 (10)	10 / 10	4.5 (10)	98	10 / 10	4.6 (10)	100	10 / 10	4.4 (10)	96	10 / 10	4.0 (10)	87	10 / 10	3.9 (10)	85	10 / 10
9	4.7 (10)	10 / 10	4.2 (10)	89	10 / 10	4.4 (10)	94	10 / 10	4.3 (10)	91	10 / 10	3.9 (10)	83	10 / 10	3.9 (10)	83	10 / 10
10	4.6 (10)	10 / 10	4.3 (10)	93	10 / 10	4.6 (10)	100	10 / 10	4.4 (10)	96	10 / 10	4.1 (10)	89	10 / 10	4.0 (10)	87	10 / 10
11	4.7 (10)	10 / 10	4.3 (10)	91	10 / 10	4.4 (10)	94	10 / 10	4.2 (10)	89	10 / 10	3.9 (10)	83	10 / 10	4.0 (10)	85	10 / 10
12	4.5 (10)	10 / 10	4.3 (10)	96	10 / 10	4.7 (10)	104	10 / 10	4.4 (10)	98	10 / 10	4.0 (10)	89	10 / 10	4.0 (10)	89	10 / 10
13	4.5 (10)	10 / 10	4.4 (10)	98	10 / 10	4.5 (10)	100	10 / 10	4.4 (10)	98	10 / 10	3.8 (10)	84	10 / 10	4.0 (10)	89	10 / 10

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

TABLE 6 HEMATOLOGY OF MALE MICE IN THE 13-WEEK INHALATION STUDY OF ISOPROPYL ACETATE

Group Name	Control	250 ppm	500 ppm	1000 ppm	2000 ppm	4000 ppm
No. of examined animals	9	8	9	9	10	9
HEMOGLOBIN (g/dL)	16.1 ± 0.7	15.9 ± 0.5	16.0 ± 0.2	16.1 ± 0.3	16.6 ± 0.4	16.9 ± 0.5 *
HEMATOCRIT (%)	51.6 ± 1.2	51.0 ± 1.3	51.1 ± 1.2	51.9 ± 0.9	52.8 ± 1.3	54.3 ± 2.0 **
MCV (fL)	47.3 ± 1.0	46.8 ± 1.2	47.7 ± 0.8	47.6 ± 0.6	47.6 ± 0.5	48.7 ± 1.0 **
MCH (pg)	14.7 ± 0.3	14.6 ± 0.5	14.9 ± 0.2	14.8 ± 0.2	15.0 ± 0.1	15.2 ± 0.1 **
Mean ± S.D.						
Significant difference: * : $p \leq 0.05$ ** : $p \leq 0.01$ Test of Dunnett						

TABLE 7 HEMATOLOGY OF FEMALE MICE IN THE 13-WEEK INHALATION STUDY OF ISOPROPYL ACETATE

Group Name	Control	250 ppm	500 ppm	1000 ppm	2000 ppm	4000 ppm
No. of examined animals	10	10	9	10	10	9
HEMATOCRIT (%)	50.8 ± 1.8	50.1 ± 1.5	51.5 ± 1.5	52.2 ± 1.0	52.5 ± 0.9	53.2 ± 2.0 **
MCV (fL)	47.5 ± 1.0	47.5 ± 0.5	47.5 ± 0.7	47.6 ± 0.7	48.2 ± 0.5	49.3 ± 0.5 **
MCH (pg)	15.1 ± 0.2	14.9 ± 0.1	15.2 ± 0.2	15.1 ± 0.1	15.3 ± 0.2 *	15.6 ± 0.2 **
Mean ± S.D.						
Significant difference: * : $p \leq 0.05$ ** : $p \leq 0.01$ Test of Dunnett						

TABLE 8 BIOCHEMISTRY OF FEMALE MICE IN THE 13-WEEK INHALATION STUDY OF ISOPROPYL ACETATE

Group Name	Control	250 ppm	500 ppm	1000 ppm	2000 ppm	4000 ppm
No. of examined animals	10	10	9	10	10	9
T-CHOLESTEROL (mg/dL)	72 ± 11	74 ± 10	81 ± 12	86 ± 13 *	76 ± 9	88 ± 9 **
PHOSPHOLIPID (mg/dL)	145 ± 13	140 ± 24	154 ± 15	167 ± 25 *	149 ± 15	163 ± 12
ALP (IU/L)	260 ± 31	252 ± 40	228 ± 31	243 ± 37	223 ± 18 *	193 ± 20 **

Mean ± S.D.

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

TABLE 9 ORGAN WEIGHTS OF MALE MICE IN THE 13-WEEK INHALATION STUDY OF ISOPROPYL ACETATE

Group Name	Control	250 ppm	500 ppm	1000 ppm	2000 ppm	4000 ppm
No. of examined animal	10	9	10	10	10	10
Body weight (g)	29.1 ± 2.1	27.3 ± 1.9	28.7 ± 2.0	28.0 ± 2.8	28.1 ± 2.5	27.5 ± 2.2
Liver (g)	1.131 ± 0.070	1.121 ± 0.070	1.148 ± 0.080	1.093 ± 0.091	1.116 ± 0.075	1.137 ± 0.105
Liver (%)	3.885 ± 0.123	4.116 ± 0.174 *	4.008 ± 0.211	3.916 ± 0.180	3.990 ± 0.224	4.139 ± 0.179 *

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

TABLE 10 ORGAN WEIGHTS OF FEMALE MICE IN THE 13-WEEK INHALATION STUDY OF ISOPROPYL ACETATE

Group Name	Control	250 ppm	500 ppm	1000 ppm	2000 ppm	4000 ppm
No. of examined animal	10	10	10	10	10	10
Body weight (g)	21.1 ± 1.2	20.9 ± 1.1	22.0 ± 1.0	21.9 ± 1.6	21.6 ± 1.0	22.3 ± 1.0
Heart (g)	0.127 ± 0.006	0.124 ± 0.007	0.130 ± 0.009	0.128 ± 0.008	0.121 ± 0.003	0.123 ± 0.010
Heart (%)	0.604 ± 0.029	0.593 ± 0.042	0.593 ± 0.048	0.587 ± 0.036	0.560 ± 0.027 *	0.553 ± 0.039 *
Liver (g)	0.907 ± 0.041	0.882 ± 0.093	0.975 ± 0.051	0.945 ± 0.102	0.918 ± 0.049	0.998 ± 0.063 *
Liver (%)	4.303 ± 0.175	4.217 ± 0.353	4.438 ± 0.162	4.303 ± 0.223	4.249 ± 0.186	4.477 ± 0.287
Brain (g)	0.457 ± 0.016	0.451 ± 0.008	0.453 ± 0.008	0.453 ± 0.014	0.449 ± 0.011	0.435 ± 0.011 **
Brain (%)	2.168 ± 0.089	2.167 ± 0.125	2.066 ± 0.117	2.076 ± 0.149	2.078 ± 0.065	1.955 ± 0.100 **

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

TABLE 11 INCIDENCES OF SELECTED LESIONS OF MALE MICE IN THE 13-WEEK INHALATION STUDY OF ISOPROPYL ACETATE

Group Name	Control				250 ppm				500 ppm				1000 ppm				2000 ppm				4000 ppm							
Number of examined animals	10				10				10				10				10				10							
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				
nasal cavity	<10>				<10>				<10>				<10>				<10>				<10>							
atrophy:olfactory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	10	0	0	0	0	0	0	0	10	0	0	0
respiratory metaplasia:olfactory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	10	0	0	0

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < > : Number of animals examined at the site
 Significant difference : * : $p \leq 0.05$ ** : $p \leq 0.01$ Test of Chi Square

TABLE 12 INCIDENCES OF SELECTED LESIONS OF FEMALE MICE IN THE 13-WEEK INHALATION STUDY OF ISOPROPYL ACETATE

Group Name	Control				250 ppm				500 ppm				1000 ppm				2000 ppm				4000 ppm							
Number of examined animals	10				10				10				10				10				10							
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				
nasal cavity	<10>				<10>				<10>				<10>				<10>				<10>							
atrophy:olfactory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	9	0	0	0	0	0	0	0	10	0	0	0
respiratory metaplasia:olfactory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	10	0	0	0
eosinophilic change:olfactory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
eosinophilic change:respiratory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	0	0	0	0	5	2	0	0

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < > : Number of animals examined at the site
 Significant difference : * : $p \leq 0.05$ ** : $p \leq 0.01$ Test of Chi Square