1,2-ジクロロプロパンのラットを用いた
吸入によるがん原性試験報告書

試験番号：0457

TABLES

TABLES

TABLES (CONTINUED)

TABLE 1 CONCENTRATIONS OF 1,2-DICHLOROPROPANE IN THE INHALATION CHAMBER OF THE 2-YEAR INHALATION STUDY

Group Name	Concentration(ppm) Mean ± S.D.
Control	0.0 ± 0.0
80 ppm	80.2 ± 0.5
200 ppm	200.5 ± 1.3
500 ppm	500.2 ± 2.4

TABLE 2 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF MALE RATS IN THE 2-YEAR INHALATION STUDY OF 1,2-DICHLOROPROPANE

Week on Study	Control		80 ppm			200 ppm			500 ppm		
	Av. Wt.	No. of Surviv. <50>	Av. Wt.	% of cont.	No. of Surviv. <50>	Av. Wt.	% of cont.	No. of Surviv. <50>	Av. Wt.	% of cont.	No. of Surviv. <50>
0	122 (50)	50 / 50	122 (50)	100	50 / 50	122 (50)	100	50 / 50	122 (50)	100	50 / 50
1	153 (50)	50 / 50	144 (50)	94	50 / 50	142 (50)	93	50 / 50	138 (50)	90	50 / 50
2	185 (50)	50 / 50	177 (50)	96	50 / 50	173 (50)	94	50 / 50	168 (50)	91	50 / 50
3	212 (50)	50 / 50	200 (50)	94	50 / 50	194 (50)	92	50 / 50	187 (50)	88	50 / 50
4	232 (50)	50 / 50	221 (50)	95	50 / 50	214 (50)	92	50 / 50	204 (50)	88	50 / 50
5	250 (50)	50 / 50	241 (50)	96	50 / 50	233 (50)	93	50 / 50	223 (50)	89	50 / 50
6	264 (50)	50 / 50	253 (50)	96	50 / 50	244 (50)	92	50 / 50	234 (50)	89	50 / 50
7	278 (50)	50 / 50	266 (50)	96	50 / 50	256 (50)	92	50 / 50	246 (50)	88	50 / 50
8	292 (50)	50 / 50	277 (50)	95	50 / 50	269 (50)	92	50 / 50	258 (50)	88	50 / 50
9	301 (50)	50 / 50	287 (50)	95	50 / 50	277 (50)	92	50 / 50	267 (50)	89	50 / 50
10	307 (50)	50 / 50	294 (50)	96	50 / 50	285 (50)	93	50 / 50	274 (50)	89	50 / 50
11	314 (50)	50 / 50	302 (50)	96	50 / 50	290 (50)	92	50 / 50	280 (50)	89	50 / 50
12	321 (50)	50 / 50	309 (50)	96	50 / 50	299 (50)	93	50 / 50	288 (50)	90	50 / 50
13	327 (50)	50 / 50	315 (50)	96	50 / 50	304 (50)	93	50 / 50	292 (50)	89	50 / 50
14	332 (50)	50 / 50	315 (50)	95	50 / 50	304 (50)	92	50 / 50	293 (50)	88	50 / 50
18	347 (50)	50 / 50	330 (50)	95	50 / 50	318 (50)	92	50 / 50	309 (50)	89	50 / 50
22	363 (50)	50 / 50	345 (50)	95	50 / 50	334 (50)	92	50 / 50	324 (50)	89	50 / 50
26	375 (50)	50 / 50	356 (50)	95	50 / 50	346 (50)	92	50 / 50	336 (50)	90	50 / 50
30	383 (50)	50 / 50	364 (50)	95	50 / 50	355 (50)	93	50 / 50	346 (50)	90	50 / 50
34	391 (50)	50 / 50	371 (50)	95	50 / 50	364 (50)	93	50 / 50	356 (49)	91	49 / 50
38	399 (50)	50 / 50	378 (50)	95	50 / 50	373 (50)	93	50 / 50	365 (49)	91	49 / 50
42	405 (50)	50 / 50	385 (49)	95	49 / 50	379 (50)	94	50 / 50	373 (49)	92	49 / 50
46	411 (50)	50 / 50	390 (49)	95	49 / 50	383 (50)	93	50 / 50	377 (49)	92	49 / 50
50	420 (50)	50 / 50	399 (49)	95	49 / 50	392 (50)	93	50 / 50	386 (49)	92	49 / 50
54	421 (50)	50 / 50	401 (49)	95	49 / 50	396 (50)	94	50 / 50	387 (49)	92	49 / 50
58	424 (50)	50 / 50	402 (49)	95	49 / 50	397 (50)	94	50 / 50	389 (48)	92	48 / 50
62	426 (50)	50 / 50	405 (49)	95	49 / 50	400 (50)	94	50 / 50	392 (48)	92	48 / 50
66	430 (49)	49 / 50	406 (49)	94	49 / 50	402 (50)	93	50 / 50	394 (47)	92	47 / 50
70	430 (49)	49 / 50	407 (48)	95	48 / 50	402 (50)	93	50 / 50	395 (47)	92	47 / 50
74	431 (49)	49 / 50	409 (47)	95	47 / 50	403 (50)	94	50 / 50	394 (46)	91	46 / 50
78	432 (48)	48 / 50	410 (47)	95	47 / 50	405 (50)	94	50 / 50	393 (44)	91	44 / 50
82	428 (47)	47 / 50	409 (45)	96	45 / 50	404 (50)	94	50 / 50	391 (43)	91	43 / 50
86	424 (47)	47 / 50	407 (43)	96	43 / 50	402 (49)	95	49 / 50	388 (43)	92	43 / 50
90	423 (46)	46 / 50	408 (42)	96	42 / 50	401 (49)	95	49 / 50	386 (41)	91	41 / 50
94	421 (45)	45 / 50	409 (42)	97	42 / 50	394 (48)	94	48 / 50	385 (41)	91	41 / 50
98	416 (45)	45 / 50	403 (41)	97	41 / 50	387 (46)	93	46 / 50	380 (39)	91	39 / 50
102	407 (42)	42 / 50	400 (40)	98	40 / 50	382 (43)	94	43 / 50	381 (37)	94	37 / 50
104	409 (40)	40 / 50	396 (39)	97	39 / 50	382 (41)	93	41 / 50	362 (36)	89	36 / 50

< > : 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 RATS IN THE 2-YEAR INHALATION STUDY OF 1,2-DICHLOROPROPANE

Week on Study	Control		80 ppm			200 ppm			500 ppm		
	Av. Wt.	No. of Surviv. <50>	Av. Wt.	% of cont.	No. of Surviv. <50>	Av. Wt.	% of cont.	No. of Surviv. <50>	Av. Wt.	% of cont.	No. of Surviv. <50>
0	96 (50)	50 / 50	96 (50)	100	50 / 50	96 (50)	100	50 / 50	96 (50)	100	50 / 50
1	111 (50)	50 / 50	106 (50)	95	50 / 50	105 (50)	95	50 / 50	103 (50)	93	50 / 50
2	124 (50)	50 / 50	119 (50)	96	50 / 50	118 (50)	95	50 / 50	117 (50)	94	50 / 50
3	134 (50)	50 / 50	129 (50)	96	50 / 50	127 (50)	95	50 / 50	124 (50)	93	50 / 50
4	142 (50)	50 / 50	136 (50)	96	50 / 50	135 (50)	95	50 / 50	133 (50)	94	50 / 50
5	150 (50)	50 / 50	145 (50)	97	50 / 50	144 (50)	96	50 / 50	141 (50)	94	50 / 50
6	155 (50)	50 / 50	151 (50)	97	50 / 50	148 (50)	95	50 / 50	146 (50)	94	50 / 50
7	160 (50)	50 / 50	156 (50)	98	50 / 50	152 (50)	95	50 / 50	151 (50)	94	50 / 50
8	165 (50)	50 / 50	160 (50)	97	50 / 50	157 (50)	95	50 / 50	156 (50)	95	50 / 50
9	170 (50)	50 / 50	164 (50)	96	50 / 50	160 (50)	94	50 / 50	160 (50)	94	50 / 50
10	173 (50)	50 / 50	167 (50)	97	50 / 50	165 (50)	95	50 / 50	164 (50)	95	50 / 50
11	176 (50)	50 / 50	172 (50)	98	50 / 50	167 (50)	95	50 / 50	166 (50)	94	50 / 50
12	179 (50)	50 / 50	174 (50)	97	50 / 50	171 (50)	96	50 / 50	170 (50)	95	50 / 50
13	182 (50)	50 / 50	177 (50)	97	50 / 50	171 (50)	94	50 / 50	170 (50)	93	50 / 50
14	183 (50)	50 / 50	176 (50)	96	50 / 50	171 (50)	93	50 / 50	169 (50)	92	50 / 50
18	189 (50)	50 / 50	182 (50)	96	50 / 50	179 (50)	95	50 / 50	177 (50)	94	50 / 50
22	196 (50)	50 / 50	188 (50)	96	50 / 50	187 (50)	95	50 / 50	186 (50)	95	50 / 50
26	201 (50)	50 / 50	194 (50)	97	50 / 50	194 (50)	97	50 / 50	194 (50)	97	50 / 50
30	205 (50)	50 / 50	200 (50)	98	50 / 50	199 (50)	97	50 / 50	200 (50)	98	50 / 50
34	208 (50)	50 / 50	202 (50)	97	50 / 50	203 (50)	98	50 / 50	204 (50)	98	50 / 50
38	212 (50)	50 / 50	207 (50)	98	50 / 50	210 (50)	99	50 / 50	208 (50)	98	50 / 50
42	214 (50)	50 / 50	210 (50)	98	50 / 50	212 (50)	99	50 / 50	212 (50)	99	50 / 50
46	220 (50)	50 / 50	216 (50)	98	50 / 50	217 (50)	99	50 / 50	217 (50)	99	50 / 50
50	225 (50)	50 / 50	219 (49)	97	49 / 50	225 (50)	100	50 / 50	224 (48)	100	48 / 50
54	227 (50)	50 / 50	221 (49)	97	49 / 50	226 (49)	100	49 / 50	226 (48)	100	48 / 50
58	229 (50)	50 / 50	224 (49)	98	49 / 50	227 (48)	99	48 / 50	228 (47)	100	47 / 50
62	234 (50)	50 / 50	228 (49)	97	49 / 50	232 (47)	99	47 / 50	232 (46)	99	46 / 50
66	237 (49)	49 / 50	232 (49)	98	49 / 50	236 (47)	100	47 / 50	236 (46)	100	46 / 50
70	243 (47)	47 / 50	237 (49)	98	49 / 50	240 (47)	99	47 / 50	238 (46)	98	46 / 50
74	247 (46)	46 / 50	240 (48)	97	48 / 50	247 (46)	100	46 / 50	240 (46)	97	46 / 50
78	255 (46)	46 / 50	244 (47)	96	47 / 50	250 (46)	98	46 / 50	241 (44)	95	44 / 50
82	257 (45)	45 / 50	248 (47)	96	47 / 50	253 (46)	98	46 / 50	240 (43)	93	43 / 50
86	258 (44)	44 / 50	249 (47)	97	47 / 50	258 (46)	100	46 / 50	241 (41)	93	41 / 50
90	262 (43)	43 / 50	252 (47)	96	47 / 50	260 (46)	99	46 / 50	243 (40)	93	40 / 50
94	262 (43)	43 / 50	255 (47)	97	47 / 50	262 (44)	100	44 / 50	246 (38)	94	38 / 50
98	268 (40)	40 / 50	253 (45)	94	45 / 50	264 (42)	99	42 / 50	243 (36)	91	36 / 50
102	267 (38)	38 / 50	254 (42)	95	42 / 50	264 (40)	99	40 / 50	245 (34)	92	34 / 50
104	267 (37)	37 / 50	252 (41)	94	41 / 50	266 (38)	100	38 / 50	246 (32)	92	32 / 50

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

TABLE 4 FOOD CONSUMPTION CHANGES OF MALE RATS IN THE 2-YEAR INHALATION STUDY OF 1,2-DICHLOROPROPANE

Week on Study	Control		80 ppm			200 ppm			500 ppm		
	Av. FC.	No. of Surviv. <50>	Av. FC.	% of cont.	No. of Surviv. <50>	Av. FC.	% of cont.	No. of Surviv. <50>	Av. FC.	% of cont.	No. of Surviv. <50>
1	15.7 (50)	50 / 50	13.5 (50)	86	50 / 50	13.1 (50)	83	50 / 50	12.3 (50)	78	50 / 50
2	16.1 (50)	50 / 50	15.2 (50)	94	50 / 50	14.5 (50)	90	50 / 50	14.6 (50)	91	50 / 50
3	16.6 (50)	50 / 50	15.8 (50)	95	50 / 50	14.9 (50)	90	50 / 50	14.8 (50)	89	50 / 50
4	17.5 (50)	50 / 50	17.0 (50)	97	50 / 50	16.9 (50)	97	50 / 50	16.8 (50)	96	50 / 50
5	17.0 (50)	50 / 50	17.2 (50)	101	50 / 50	16.6 (50)	98	50 / 50	16.4 (50)	96	50 / 50
6	17.0 (50)	50 / 50	16.7 (50)	98	50 / 50	15.9 (50)	94	50 / 50	16.2 (50)	95	50 / 50
7	16.7 (50)	50 / 50	16.7 (50)	100	50 / 50	16.0 (50)	96	50 / 50	16.2 (50)	97	50 / 50
8	17.0 (50)	50 / 50	16.7 (50)	98	50 / 50	15.9 (50)	94	50 / 50	15.8 (50)	93	50 / 50
9	16.8 (50)	50 / 50	16.6 (50)	99	50 / 50	16.0 (50)	95	50 / 50	16.0 (50)	95	50 / 50
10	16.9 (50)	50 / 50	16.9 (50)	100	50 / 50	16.1 (50)	95	50 / 50	15.7 (50)	93	50 / 50
11	16.4 (50)	50 / 50	16.2 (50)	99	50 / 50	15.6 (50)	95	50 / 50	15.5 (50)	95	50 / 50
12	16.4 (50)	50 / 50	16.4 (50)	100	50 / 50	15.5 (50)	95	50 / 50	15.1 (50)	92	50 / 50
13	16.0 (50)	50 / 50	15.9 (50)	99	50 / 50	15.4 (50)	96	50 / 50	14.8 (50)	93	50 / 50
14	16.5 (50)	50 / 50	15.4 (50)	93	50 / 50	14.4 (50)	87	50 / 50	14.0 (50)	85	50 / 50
18	16.3 (50)	50 / 50	15.7 (50)	96	50 / 50	14.9 (50)	91	50 / 50	14.9 (50)	91	50 / 50
22	16.5 (50)	50 / 50	16.2 (50)	98	50 / 50	15.5 (50)	94	50 / 50	15.3 (50)	93	50 / 50
26	16.5 (50)	50 / 50	15.9 (50)	96	50 / 50	15.5 (50)	94	50 / 50	15.2 (50)	92	50 / 50
30	16.7 (50)	50 / 50	16.2 (50)	97	50 / 50	16.0 (50)	96	50 / 50	16.0 (50)	96	50 / 50
34	16.7 (50)	50 / 50	16.3 (50)	98	50 / 50	16.3 (50)	98	50 / 50	16.0 (49)	96	49 / 50
38	16.9 (50)	50 / 50	16.5 (50)	98	50 / 50	16.4 (50)	97	50 / 50	16.4 (49)	97	49 / 50
42	17.2 (50)	50 / 50	16.9 (49)	98	49 / 50	16.7 (50)	97	50 / 50	16.7 (49)	97	49 / 50
46	17.1 (50)	50 / 50	16.7 (49)	98	49 / 50	16.4 (50)	96	50 / 50	16.5 (49)	96	49 / 50
50	17.3 (50)	50 / 50	17.3 (49)	100	49 / 50	17.0 (50)	98	50 / 50	16.8 (49)	97	49 / 50
54	16.7 (50)	50 / 50	16.7 (49)	100	49 / 50	16.4 (50)	98	50 / 50	16.4 (49)	98	49 / 50
58	16.9 (50)	50 / 50	16.7 (49)	99	49 / 50	16.4 (50)	97	50 / 50	16.3 (48)	96	48 / 50
62	16.7 (50)	50 / 50	16.5 (49)	99	49 / 50	16.4 (50)	98	50 / 50	16.3 (48)	98	48 / 50
66	17.0 (49)	49 / 50	16.3 (49)	96	49 / 50	16.3 (50)	96	50 / 50	16.2 (47)	95	47 / 50
70	16.9 (49)	49 / 50	16.4 (48)	97	48 / 50	16.4 (50)	97	50 / 50	16.4 (47)	97	47 / 50
74	16.6 (49)	49 / 50	16.5 (47)	99	47 / 50	16.4 (50)	99	50 / 50	16.1 (46)	97	46 / 50
78	16.9 (48)	48 / 50	16.3 (47)	96	47 / 50	16.7 (50)	99	50 / 50	16.2 (44)	96	44 / 50
82	16.5 (47)	47 / 50	16.5 (45)	100	45 / 50	16.5 (50)	100	50 / 50	16.1 (43)	98	43 / 50
86	16.8 (47)	47 / 50	16.8 (43)	100	43 / 50	16.7 (49)	99	49 / 50	16.2 (43)	96	43 / 50
90	16.8 (46)	46 / 50	16.8 (42)	100	42 / 50	16.9 (49)	101	49 / 50	16.6 (41)	99	41 / 50
94	16.9 (45)	45 / 50	17.3 (42)	102	42 / 50	16.1 (48)	95	48 / 50	16.6 (41)	98	41 / 50
98	16.6 (45)	45 / 50	16.6 (41)	100	41 / 50	15.6 (46)	94	46 / 50	15.7 (39)	95	39 / 50
102	16.6 (42)	42 / 50	17.0 (40)	102	40 / 50	16.1 (43)	97	43 / 50	16.0 (36)	96	37 / 50
104	16.5 (40)	40 / 50	16.2 (39)	98	39 / 50	16.2 (41)	98	41 / 50	15.2 (36)	92	36 / 50

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

TABLE 5 FOOD CONSUMPTION CHANGES OF FEMALE RATS IN THE 2-YEAR INHALATION STUDY OF 1,2-DICHLOROPROPANE

Week on Study	Control		80 ppm			200 ppm			500 ppm		
	Av. FC.	No. of Surviv. <50>	Av. FC.	% of cont.	No. of Surviv. <50>	Av. FC.	% of cont.	No. of Surviv. <50>	Av. FC.	% of cont.	No. of Surviv. <50>
1	11.8 (50)	50 / 50	10.6 (50)	90	50 / 50	9.9 (50)	84	50 / 50	9.4 (50)	80	50 / 50
2	10.9 (50)	50 / 50	10.5 (50)	96	50 / 50	10.8 (50)	99	50 / 50	11.1 (50)	102	50 / 50
3	11.1 (50)	50 / 50	11.1 (50)	100	50 / 50	10.4 (50)	94	50 / 50	10.5 (50)	95	50 / 50
4	11.4 (50)	50 / 50	11.3 (50)	99	50 / 50	11.5 (50)	101	50 / 50	11.7 (50)	103	50 / 50
5	11.2 (50)	50 / 50	11.8 (50)	105	50 / 50	11.1 (50)	99	50 / 50	11.4 (50)	102	50 / 50
6	11.0 (50)	50 / 50	11.2 (50)	102	50 / 50	11.0 (50)	100	50 / 50	11.3 (50)	103	50 / 50
7	10.7 (50)	50 / 50	11.3 (50)	106	50 / 50	10.5 (50)	98	50 / 50	10.9 (50)	102	50 / 50
8	10.7 (50)	50 / 50	10.6 (50)	99	50 / 50	10.8 (50)	101	50 / 50	11.2 (50)	105	50 / 50
9	11.1 (50)	50 / 50	11.1 (50)	100	50 / 50	10.4 (50)	94	50 / 50	10.9 (50)	98	50 / 50
10	11.0 (50)	50 / 50	11.1 (50)	101	50 / 50	10.9 (50)	99	50 / 50	11.3 (50)	103	50 / 50
11	11.0 (50)	50 / 50	10.9 (50)	99	50 / 50	10.2 (50)	93	50 / 50	10.6 (50)	96	50 / 50
12	10.6 (50)	50 / 50	10.9 (50)	103	50 / 50	10.6 (50)	100	50 / 50	10.8 (50)	102	50 / 50
13	10.9 (50)	50 / 50	11.0 (50)	101	50 / 50	10.0 (50)	92	50 / 50	10.3 (50)	94	50 / 50
14	10.7 (50)	50 / 50	10.5 (50)	98	50 / 50	9.9 (50)	93	50 / 50	9.9 (50)	93	50 / 50
18	10.6 (50)	50 / 50	10.5 (50)	99	50 / 50	10.7 (50)	101	50 / 50	10.8 (50)	102	50 / 50
22	10.5 (50)	50 / 50	10.7 (50)	102	50 / 50	11.2 (50)	107	50 / 50	11.2 (50)	107	50 / 50
26	10.9 (50)	50 / 50	10.8 (50)	99	50 / 50	10.9 (50)	100	50 / 50	11.2 (50)	103	50 / 50
30	11.2 (50)	50 / 50	11.3 (50)	101	50 / 50	11.5 (50)	103	50 / 50	11.8 (50)	105	50 / 50
34	10.5 (50)	50 / 50	10.7 (50)	102	50 / 50	11.3 (50)	108	50 / 50	11.6 (50)	110	50 / 50
38	11.2 (50)	50 / 50	11.2 (50)	100	50 / 50	11.9 (50)	106	50 / 50	11.8 (50)	105	50 / 50
42	11.1 (50)	50 / 50	11.6 (50)	105	50 / 50	11.9 (50)	107	50 / 50	12.0 (50)	108	50 / 50
46	11.4 (50)	50 / 50	11.6 (50)	102	50 / 50	12.0 (50)	105	50 / 50	12.1 (50)	106	50 / 50
50	11.4 (50)	50 / 50	11.2 (49)	98	49 / 50	12.3 (50)	108	50 / 50	12.4 (48)	109	48 / 50
54	10.8 (50)	50 / 50	11.2 (49)	104	49 / 50	11.4 (49)	106	49 / 50	11.9 (48)	110	48 / 50
58	11.1 (50)	50 / 50	11.5 (49)	104	49 / 50	11.5 (48)	104	48 / 50	11.7 (47)	105	47 / 50
62	11.3 (50)	50 / 50	11.5 (49)	102	49 / 50	12.0 (47)	106	47 / 50	12.1 (46)	107	46 / 50
66	11.3 (49)	49 / 50	11.3 (49)	100	49 / 50	11.8 (47)	104	47 / 50	12.1 (46)	107	46 / 50
70	11.7 (47)	47 / 50	11.8 (49)	101	49 / 50	12.0 (47)	103	47 / 50	12.0 (46)	103	46 / 50
74	11.7 (46)	46 / 50	11.8 (48)	101	48 / 50	12.4 (46)	106	46 / 50	11.7 (46)	100	46 / 50
78	12.0 (46)	46 / 50	12.1 (47)	101	47 / 50	12.3 (46)	103	46 / 50	12.1 (44)	101	44 / 50
82	11.8 (45)	45 / 50	11.9 (47)	101	47 / 50	12.2 (46)	103	46 / 50	11.8 (43)	100	43 / 50
86	12.5 (44)	44 / 50	12.4 (47)	99	47 / 50	12.8 (46)	102	46 / 50	12.3 (41)	98	41 / 50
90	12.5 (43)	43 / 50	12.3 (47)	98	47 / 50	12.6 (46)	101	46 / 50	12.4 (40)	99	40 / 50
94	12.4 (43)	43 / 50	12.7 (47)	102	47 / 50	12.7 (44)	102	44 / 50	12.6 (38)	102	38 / 50
98	12.7 (40)	40 / 50	11.9 (45)	94	45 / 50	12.3 (42)	97	42 / 50	11.8 (36)	93	36 / 50
102	12.9 (38)	38 / 50	12.6 (42)	98	42 / 50	12.4 (40)	96	40 / 50	12.5 (34)	97	34 / 50
104	12.7 (37)	37 / 50	11.9 (41)	94	41 / 50	12.4 (38)	98	38 / 50	12.6 (32)	99	32 / 50

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

TABLE 6 HEMATOLOGY OF MALE RATS IN THE 2-YEAR INHALATION STUDY OF 1,2-DICHLOROPROPANE

Group Name	Control	80 ppm	200 ppm	500 ppm
No. of examined animals	40	39	41	36
WBC ($10^3/\mu$ L)	5.85 ± 1.47	11.11 ± 25.55	5.59 ± 1.40	5.04 ± 1.49 *

Mean ± S.D.
Significant difference: * : p≦0.05 ** : p≦0.01 Test of Dunnett

TABLE 7 HEMATOLOGY OF FEMALE RATS IN THE 2-YEAR INHALATION STUDY OF 1,2-DICHLOROPROPANE

Group Name	Control	80 ppm	200 ppm	500 ppm
No. of examined animals	37	41	38	32
RED BLOOD CELL ($10^6/\mu$ L)	7.96 ± 1.13	7.90 ± 1.06	8.03 ± 0.52	7.67 ± 0.78 *
MCV (fL)	52.7 ± 4.8	52.7 ± 4.2	52.5 ± 1.6	54.1 ± 1.9 **
MCHC (g/dL)	35.6 ± 1.2	35.3 ± 1.7	35.5 ± 0.6	34.9 ± 1.2 **
Differential WBC (%)				
EOSINO	2 ± 1	2 ± 1	1 ± 1 *	1 ± 1 **

Mean ± S.D.
Significant difference: * : p≦0.05 ** : p≦0.01 Test of Dunnett

TABLE 8 BIOCHEMISTRY OF MALE RATS IN THE 2-YEAR INHALATION STUDY OF 1,2-DICHLOROPROPANE

Group Name	Control	80 ppm	200 ppm	500 ppm	
No. of examined animals	40	39	41	36	
POTASSIUM (mEq/L)	3.5 ± 0.2	3.7 ± 0.3	3.6 ± 0.3	3.8 ± 0.4	**

Mean ± S.D.
Significant difference: * : p≦0.05 ** : p≦0.01 Test of Dunnett

TABLE 9 BIOCHEMISTRY OF FEMALE RATS IN THE 2-YEAR INHALATION STUDY OF 1,2-DICHLOROPROPANE

Group Name	Control	80 ppm		200 ppm	500 ppm	
No. of examined animals	37	41		38	32	
G-GTP (IU/L)	3 ± 2	3 ± 2		3 ± 2	5 ± 4	**
UREA NITOROGEN (mg/dL)	17.3 ± 1.9	18.4 ± 2.3	*	17.5 ± 1.8	17.8 ± 2.8	

Mean ± S.D.
Significant difference: * : p≦0.05 ** : p≦0.01 Test of Dunnett

TABLE 10 ORGAN WEIGHTS OF MALE RATS IN THE 2-YEAR INHALATION STUDY OF 1,2-DICHLOROPROPANE

Group Name	Control	80 ppm		200 ppm		500 ppm	
No. of examined animals	40	39		41		36	
Body weight (g)	381 ± 28	372 ± 44		357 ± 31	**	339 ± 39	**
Testes (g)	3.193 ± 1.411	3.730 ± 1.553		3.589 ± 1.278		4.639 ± 1.865	**
Testes (%)	0.838 ± 0.365	0.999 ± 0.406		1.001 ± 0.341		1.358 ± 0.492	**
Heart (g)	1.229 ± 0.084	1.232 ± 0.089		1.211 ± 0.096		1.197 ± 0.102	
Heart (%)	0.324 ± 0.029	0.335 ± 0.037		0.341 ± 0.036		0.357 ± 0.049	**
Lungs (g)	1.438 ± 0.141	1.476 ± 0.225		1.379 ± 0.099		1.365 ± 0.085	*
Lungs (%)	0.379 ± 0.046	0.404 ± 0.094		0.388 ± 0.040		0.408 ± 0.054	**
Kidneys (g)	2.709 ± 0.171	2.753 ± 0.253		2.761 ± 0.310		2.706 ± 0.265	
Kidneys (%)	0.714 ± 0.069	0.746 ± 0.070	*	0.777 ± 0.099	**	0.808 ± 0.125	**
Spleen (g)	1.029 ± 0.506	1.625 ± 3.568		0.853 ± 0.219	*	0.835 ± 0.373	**
Spleen (%)	0.270 ± 0.136	0.476 ± 1.211		0.238 ± 0.055		0.248 ± 0.125	
Liver (g)	11.016 ± 1.269	11.094 ± 2.037		10.346 ± 1.156	*	10.105 ± 1.530	*
Liver (%)	2.896 ± 0.331	2.994 ± 0.532		2.903 ± 0.301		2.982 ± 0.291	
Brain (g)	2.041 ± 0.050	2.017 ± 0.050		2.000 ± 0.063	**	1.967 ± 0.041	**
Brain (%)	0.538 ± 0.040	0.549 ± 0.063		0.563 ± 0.046	*	0.589 ± 0.080	**

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

TABLE 11 ORGAN WEIGHTS OF FEMALE RATS IN THE 2-YEAR INHALATION STUDY OF 1,2-DICHLOROPROPANE

Group Name	Control	80 ppm		200 ppm		500 ppm	
No. of examined animals	37	41		38		32	
Body weight (g)	249 ± 35	234 ± 19		249 ± 21		230 ± 35	**
Adrenals (g)	0.107 ± 0.228	0.069 ± 0.006		0.077 ± 0.023		0.094 ± 0.115	
Adrenals (%)	0.043 ± 0.089	0.030 ± 0.003		0.031 ± 0.010		0.043 ± 0.058	**
Ovaries (g)	0.137 ± 0.064	0.320 ± 1.231		0.131 ± 0.028		0.181 ± 0.216	
Ovaries (%)	0.055 ± 0.024	0.150 ± 0.608		0.053 ± 0.012		0.083 ± 0.109	*
Heart (g)	0.884 ± 0.082	0.868 ± 0.073		0.885 ± 0.067		0.894 ± 0.085	
Heart (%)	0.359 ± 0.037	0.373 ± 0.043		0.357 ± 0.031		0.394 ± 0.043	**
Lungs (g)	1.041 ± 0.138	1.025 ± 0.143		1.025 ± 0.047		1.046 ± 0.107	
Lungs (%)	0.423 ± 0.065	0.441 ± 0.089		0.414 ± 0.039		0.463 ± 0.075	**
Kidneys (g)	1.789 ± 0.159	1.729 ± 0.100		1.767 ± 0.097		1.810 ± 0.159	
Kidneys (%)	0.729 ± 0.092	0.741 ± 0.061		0.714 ± 0.066		0.799 ± 0.107	**
Liver (g)	6.717 ± 1.111	6.412 ± 0.893		6.724 ± 0.603		6.764 ± 1.190	
Liver (%)	2.715 ± 0.401	2.743 ± 0.380		2.710 ± 0.249		2.958 ± 0.415	**
Brain (g)	1.855 ± 0.055	1.824 ± 0.042	*	1.828 ± 0.055	*	1.789 ± 0.046	**
Brain (%)	0.759 ± 0.099	0.783 ± 0.064		0.740 ± 0.076		0.793 ± 0.099	

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

TABLE 12 INCIDENCES OF SELECTED NEOPLASTIC LESIONS OF MALE RATS IN THE 2-YEAR INHALATION STUDY OF 1,2-DICHLOROPROPANE

Group Name	Control	80 ppm	200 ppm	500 ppm	Peto	Cochran-
Number of examined animals	50	50	50	50	test	Armitage test
subcutis	<50>	<50>	<50>	<50>		
fibroma	2 (4 %)	4 (8 %)	8 (16 %) *	6 (12 %)	↑	
fibrosarcoma	0 (0 %)	1 (2 %)	0 (0 %)	0 (0 %)		
nasal cavity	<50>	<50>	<50>	<50>		
squamous cell papilloma	0 (0 %)	0 (0 %)	2 (4 %)	14 (28 %) **	↑ ↑	↑ ↑
adenoma	0 (0 %)	0 (0 %)	1 (2 %)	1 (2 %)		
adenoacanthoma	0 (0 %)	0 (0 %)	0 (0 %)	1 (2 %)		
ethesioneuroepithelioma	0 (0 %)	2 (4 %)	1 (2 %)	0 (0 %)		
pancreas	<50>	<50>	<50>	<50>		
islet cell adenoma	6 (12 %)	2 (4 %)	0 (0 %) *	2 (4 %)		
thyroid	<50>	<50>	<50>	<50>		
follicular adenoma	1 (2 %)	0 (0 %)	0 (0 %)	3 (6 %)	↑	
follicular adenocarcinoma	0 (0 %)	0 (0 %)	1 (2 %)	1 (2 %)		

Significant difference : * : p≦0.05 ** : p≦0.01 Fisher's exact test for neoplastic lesion
↑(↓) : p≦0.05 ↑ ↑(↓ ↓) : p≦0.01 Peto or Cochran-Armitage test for neoplastic lesion
< > : Number of animals examined at the site

TABLE 13 INCIDENCES OF SELECTED NEOPLASTIC LESIONS OF FEMALE RATS IN THE 2-YEAR INHALATION STUDY OF 1,2-DICHLOROPROPANE

Group Name	Control	80 ppm	200 ppm	500 ppm	Peto	Cochran-
Number of examined animals	50	50	50	50	test	Armitage test
nasal cavity	<50>	<50>	<50>	<50>		
squamous cell papilloma	0 (0 %)	0 (0 %)	0 (0 %)	9 (18 %) **	↑ ↑	↑ ↑
spleen	<50>	<50>	<50>	<50>		
mononuclear cell leukemia	8 (16 %)	6 (12 %)	3 (6 %)	2 (4 %) *		↓
uterus	<50>	<50>	<50>	<50>		
endometrial stromal polyp	10 (20 %)	15 (30 %)	2 (4 %) *	3 (6 %) *		↓ ↓
mammary gland	<50>	<50>	<50>	<50>		
adenoma	0 (0 %)	2 (4 %)	0 (0 %)	4 (8 %)	↑	↑
fibroadenoma	2 (4 %)	4 (8 %)	3 (6 %)	5 (10 %)		

Significant difference : * : p≦0.05 ** : p≦0.01 Fisher's exact test for neoplastic lesion
↑(↓) : p≦0.05 ↑ ↑(↓ ↓) : p≦0.01 Peto or Cochran-Armitage test for neoplastic lesion
< > : Number of animals examined at the site

TABLE 14 INCIDENCES OF SELECTED NON-NEOPLASTIC LESIONS OF MALE RATS IN THE 2-YEAR INHALATION STUDY OF 1,2-DICHLOROPROPANE

Group Name	Control				80 ppm				200 ppm				500 ppm			
Number of examined animals	50				50				50				50			
Grade of non-neoplastic lesion	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
nasal cavity	<50>				<50>				<50>				<50>			
inflammation:respiratory epithelium	20	0	0	0	35	0	0	0 **	46	1	0	0 **	37	10	0	0 **
squamous cell metaplasia:respiratory epithelium	5	0	0	0	30	1	0	0 **	40	1	0	0 **	37	12	0	0 **
hyperplasia:transitional epithelium	0	0	0	0	27	4	0	0 **	36	3	0	0 **	20	17	11	0 **
goblet cell hyperplasia	0	0	0	0	15	0	0	0 **	39	2	0	0 **	37	7	1	0 **
squamous cell hyperplasia	0	0	0	0	2	0	0	0	6	0	0	0 *	23	4	0	0 **
atrophy:olfactory epithelium	0	0	0	0	41	7	0	0 **	4	46	0	0 **	0	49	0	0 **
respiratory metaplasia:olfactory epithelium	21	0	0	0	49	1	0	0 **	50	0	0	0 **	2	42	5	0 **
sclerosis:lamina propria	0	0	0	0	2	0	0	0	9	0	0	0 **	15	0	0	0 **
hyperplasia:gland	0	0	0	0	44	2	0	0 **	8	37	5	0 **	3	19	27	0 **
adhesion	0	0	0	0	0	0	0	0	2	0	0	0	5	0	0	0
eosinophilic change:olfactory epithelium	40	6	0	0	0	0	0	0 **	0	0	0	0 **	0	0	0	0 **
eosinophilic change:respiratory epithelium	36	0	0	0	0	0	0	0 **	1	0	0	0 **	1	0	0	0 **
liver	<50>				<50>				<50>				<50>			
bile duct hyperplasia	49	0	0	0	48	0	0	0	45	0	0	0	42	0	0	0 *

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

TABLE 15 INCIDENCES OF SELECTED NON-NEOPLASTIC LESIONS OF FEMALE RATS IN THE 2-YEAR INHALATION STUDY OF 1,2-DICHLOROPROPANE

Group Name	Control				80 ppm					200 ppm					500 ppm				
Number of examined animals	50				50					50					50				
Grade of non-neoplastic lesion	1	2	3	4	1	2	3	4		1	2	3	4		1	2	3	4	
nasal cavity	<50>				<50>					<50>					<50>				
inflammation:respiratory epithelium	10	0	0	0	29	1	0	0	**	38	1	0	0	**	35	5	0	0	**
squamous cell metaplasia:respiratory epithelium	3	0	0	0	15	0	0	0	**	31	6	0	0	**	25	21	0	0	**
hyperplasia:transitional epithelium	2	0	0	0	17	3	1	0	**	35	4	0	0	**	31	10	7	0	**
goblet cell hyperplasia	0	0	0	0	0	0	0	0		15	0	0	0	**	41	0	0	0	**
squamous cell hyperplasia	0	0	0	0	0	0	0	0		3	0	0	0		15	5	0	0	**
atrophy:olfactory epithelium	0	0	0	0	50	0	0	0	**	3	47	0	0	**	2	48	0	0	**
respiratory metaplasia:olfactory epithelium	0	0	0	0	49	0	0	0	**	18	32	0	0	**	1	48	1	0	**
sclerosis:lamina propria	0	0	0	0	8	0	0	0	**	12	0	0	0	**	24	0	0	0	**
hyperplasia:gland	0	0	0	0	41	1	0	0	**	7	41	2	0	**	4	31	15	0	**
adhesion	0	0	0	0	0	0	0	0		3	0	0	0		1	0	0	0	
eosinophilic change:olfactory epithelium	7	42	0	0	1	0	0	0	**	1	0	0	0	**	0	0	0	0	**
eosinophilic change:respiratory epithelium	41	0	0	0	12	0	0	0	**	5	0	0	0	**	2	0	0	0	**
liver	<50>				<50>					<50>					<50>				
granulation	10	0	1	0	19	3	0	0	*	23	3	1	0	**	16	0	0	0	
pancreas	<50>				<50>					<50>					<50>				
atrophy	11	0	0	0	8	0	0	0		2	0	0	0	*	4	0	1	0	

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

TABLE 16 HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC LESIONS IN JAPAN BIOASSAY RESEARCH CENTER : F344/DuCrlCrlj MALE RATS

Organs Tumors	No. of animals examined	No. of animals bearing tumor	Incidence (%)	Min. - Max. (%)
Nasal cavity	1949			
Adenoma		2	0.1	0 - 2
Adenoacanthoma		0	0.0	0 - 0
Squamous cell papilloma		0	0.0	0 - 0
Ethesioneuroepithelioma		0	0.0	0 - 0
Thyroid	1942			
Follicular adenoma 1)		16	0.8	0 - 4
Follicular adenocarcinoma 2)		34	1.8	0 - 8
1)+2)		50	2.6	0 - 8
Subcutis	1949			
Fibroma		151	7.7	2 - 20

Thirty nine carcinogenicity studies examined in Japan Bioassay Research Center were used.
Study No. : 0043, 0059, 0061, 0063, 0065, 0067, 0095, 0104, 0115, 0130, 0141, 0158, 0162, 0189, 0205, 0210, 0224, 0242, 0267, 0269, 0278, 0284, 0288, 0294, 0296, 0318, 0328, 0342, 0347, 0365, 0371, 0396, 0399, 0401, 0407, 0417, 0421, 0437, 0448

TABLE 17 HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC LESIONS IN JAPAN BIOASSAY RESEARCH CENTER : F344/DuCrlCrlj FEMALE RATS

Organs Tumors	No. of animals examined	No. of animals bearing tumor	Incidence (%)	Min. - Max. (%)
Nasal cavity	1797			
Squamous cell papilloma		0	0.0	0 - 0
Mammary gland	1797			
Adenoma 1)		202	11.2	0 - 20
Fibroadenoma 2)		55	3.1	0 - 18
1)+2)		254	14.1	4 - 24

Thirty six carcinogenicity studies examined in Japan Bioassay Research Center were used.
Study No. : 0043, 0059, 0061, 0063, 0065, 0067, 0095, 0104, 0115, 0130, 0141, 0158, 0162, 0189, 0205, 0210, 0224, 0242, 0267, 0269, 0278, 0284, 0296, 0303, 0318, 0328, 0342, 0347, 0365, 0371, 0399, 0401, 0417, 0421, 0437, 0448

TABLE 18 CAUSE OF DEATH OF RATS IN THE 2-YEAR INHALATION STUDY OF 1,2-DICHLOROPROPANE

	Male				Female			
Group name	Control	80 ppm	200 ppm	500 ppm	Control	80 ppm	200 ppm	500 ppm
Number of dead or moribund animals	10	11	9	14	13	9	12	18
Urinary retention	1	2	0	0	0	0	0	0
Hepatic lesion	0	0	0	0	1	0	0	0
Renal lesion	0	0	0	0	0	0	0	2
Nasal lesion	0	0	0	2	0	0	0	0
Endcrine system lesion	0	0	0	0	1	1	0	1
Central nervous system lesion	0	0	0	0	0	0	0	1
Deglutition disorder	0	0	0	0	0	0	0	2
Arteritis	0	0	0	1	0	0	0	0
Tumor death : leukemia	5	0	4	4	5	3	3	1
skin / appendage	0	0	0	0	0	0	0	1
subcutis	0	1	2	2	0	0	0	1
bone marrow	0	0	0	1	0	0	0	0
liver	0	0	0	1	0	0	0	0
pituitary gland	2	0	2	0	3	3	4	3
thyroid	1	0	1	0	0	0	0	0
adrenal gland	0	1	0	0	0	0	0	0
ovary	—	—	—	—	1	0	0	0
uterus	—	—	—	—	0	0	2	1
brain	0	0	0	1	0	0	0	0
spinal cord	0	0	0	0	0	1	0	0
Zymbal gland	0	1	0	0	0	0	1	1
muscle	0	1	0	0	0	0	0	0
bone	0	1	0	0	0	0	1	0
peritoneum	0	1	0	0	0	0	0	0
retroperitoneum	1	1	0	0	0	0	0	0
No microscopical confirmation	0	2	0	2	2	1	1	4