

アリルクロリドのマウスを用いた  
吸入によるがん原性試験報告書

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TABLE 1 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF MALE MICE IN THE 2-YEAR INHALATION STUDY OF ALLYL CHLORIDE

Weeks on Study	Control		50ppm		100ppm		200ppm				
	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.
	<50>	<50>	<50>	<50>	<50>	<50>	<50>	<50>	<50>	<50>	<50>
0	22.6 (50)	50/50	22.6 (50)	100	50/50	22.6 (50)	100	50/50	22.6 (50)	100	50/50
1	23.9 (50)	50/50	23.7 (50)	99	50/50	23.9 (50)	100	50/50	23.8 (50)	100	50/50
2	24.9 (50)	50/50	24.8 (50)	100	50/50	24.8 (50)	100	50/50	24.9 (50)	100	50/50
3	25.6 (50)	50/50	25.1 (50)	98	50/50	25.4 (50)	99	50/50	26.0 (50)	102	50/50
4	26.2 (50)	50/50	25.5 (50)	97	50/50	26.2 (50)	100	50/50	26.6 (50)	102	50/50
5	26.6 (50)	50/50	25.8 (50)	97	50/50	26.4 (50)	99	50/50	27.0 (50)	102	50/50
6	27.3 (50)	50/50	26.5 (50)	97	50/50	27.0 (50)	99	50/50	27.6 (50)	101	50/50
7	27.9 (50)	50/50	26.9 (50)	96	50/50	27.3 (50)	98	50/50	27.2 (50)	97	50/50
8	28.5 (50)	50/50	27.4 (50)	96	50/50	27.9 (50)	98	50/50	28.0 (50)	98	50/50
9	29.1 (50)	50/50	28.0 (50)	96	50/50	28.4 (50)	98	50/50	28.7 (50)	99	50/50
10	29.8 (50)	50/50	28.5 (50)	96	50/50	29.0 (50)	97	50/50	29.5 (50)	99	50/50
11	30.4 (50)	50/50	29.1 (50)	96	50/50	29.8 (50)	98	50/50	30.2 (50)	99	50/50
12	31.1 (50)	50/50	29.6 (50)	95	50/50	30.0 (50)	96	50/50	30.6 (50)	98	50/50
13	31.4 (50)	50/50	30.1 (50)	96	50/50	30.3 (50)	96	50/50	30.9 (50)	98	50/50
14	31.7 (50)	50/50	30.6 (50)	97	50/50	30.9 (50)	97	50/50	31.4 (50)	99	50/50
18	33.4 (50)	50/50	33.0 (50)	99	50/50	32.5 (50)	97	50/50	33.0 (50)	99	50/50
22	35.2 (50)	50/50	34.7 (50)	99	50/50	34.1 (50)	97	50/50	34.8 (50)	99	50/50
26	36.6 (50)	50/50	36.3 (50)	99	50/50	35.1 (50)	96	50/50	35.8 (50)	98	50/50
30	38.1 (50)	50/50	37.9 (50)	99	50/50	36.8 (50)	97	50/50	38.2 (50)	100	50/50
34	39.3 (50)	50/50	39.4 (50)	100	50/50	38.3 (50)	97	50/50	38.7 (47)	98	47/50
38	40.3 (50)	50/50	40.6 (50)	101	50/50	39.1 (50)	97	50/50	39.6 (44)	98	44/50
42	41.3 (50)	50/50	41.4 (50)	100	50/50	39.6 (50)	96	50/50	40.3 (42)	98	42/50
46	42.3 (50)	50/50	42.6 (50)	101	50/50	40.8 (50)	96	50/50	40.5 (38)	96	38/50
50	42.6 (50)	50/50	43.4 (50)	102	50/50	41.9 (49)	98	49/50	41.1 (35)	96	35/50
54	43.6 (49)	49/50	43.9 (50)	101	50/50	42.8 (48)	98	48/50	40.9 (33)	94	33/50
58	44.1 (49)	49/50	44.4 (50)	101	50/50	43.6 (48)	99	48/50	39.8 (30)	90	30/50
62	43.9 (48)	48/50	44.0 (50)	100	50/50	43.1 (48)	98	48/50	40.5 (23)	92	23/50
66	44.2 (48)	48/50	44.4 (50)	100	50/50	43.3 (48)	98	48/50	39.5 (21)	89	21/50
70	45.2 (48)	48/50	45.2 (49)	100	49/50	45.1 (48)	100	48/50	38.5 (16)	85	16/50
74	45.6 (48)	47/50	45.9 (49)	101	49/50	45.2 (48)	99	48/50	37.2 (11)	82	11/50
78	46.5 (47)	47/50	45.8 (49)	98	49/50	44.9 (48)	97	48/50	35.5 ( 8)	76	8/50
82	46.2 (46)	46/50	46.5 (46)	101	46/50	45.2 (46)	98	46/50	34.8 ( 6)	75	5/50
86	46.2 (46)	46/50	46.6 (44)	101	44/50	46.1 (44)	100	44/50	32.4 ( 3)	70	3/50
90	46.0 (44)	44/50	45.7 (42)	99	42/50	45.0 (42)	98	42/50	31.3 ( 2)	68	2/50
94	45.5 (41)	41/50	44.1 (42)	97	42/50	43.4 (39)	95	39/50	35.8 ( 1)	79	1/50
98	44.3 (41)	41/50	43.6 (38)	98	38/50	42.7 (35)	96	35/50	— (—)	—	0/50
102	43.9 (37)	37/50	43.7 (37)	100	37/50	41.5 (35)	95	35/50	— (—)	—	0/50
104	44.3 (35)	35/50	42.9 (35)	97	35/50	40.7 (33)	92	33/50	— (—)	—	0/50

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

Av.Wt. : Average body weight (Unit : g).

TABLE 2 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF FEMALE MICE IN THE 2-YEAR INHALATION STUDY OF ALLYL CHLORIDE

Weeks on Study	Control		50ppm		100ppm		200ppm				
	Av.Wt. <50>	No.of Surviv. <50>	Av.Wt. <50>	% of cont. Surviv. <50>	Av.Wt. <49>	% of cont. Surviv. <49>	Av.Wt. <50>	% of cont. Surviv. <50>			
0	19.1 (50)	50/50	19.1 (50)	100	50/50	19.1 (49)	100	50/50	19.1 (50)	100	50/50
1	19.8 (50)	50/50	19.5 (50)	98	50/50	19.7 (49)	99	50/50	19.7 (50)	99	50/50
2	20.8 (50)	50/50	20.7 (50)	100	50/50	20.8 (49)	100	50/50	20.8 (50)	100	50/50
3	21.2 (50)	50/50	21.0 (50)	99	50/50	21.1 (49)	100	50/50	21.8 (50)	103	50/50
4	22.0 (50)	50/50	21.7 (50)	99	50/50	21.9 (49)	100	50/50	22.2 (50)	101	50/50
5	22.3 (50)	50/50	21.9 (50)	98	50/50	22.2 (49)	100	50/50	22.5 (50)	101	50/50
6	23.0 (50)	50/50	22.9 (50)	100	50/50	23.0 (49)	100	50/50	22.9 (50)	100	50/50
7	23.4 (50)	50/50	23.3 (50)	100	50/50	23.3 (49)	100	50/50	23.0 (50)	98	50/50
8	23.9 (50)	50/50	23.7 (50)	99	50/50	23.4 (49)	98	50/50	24.0 (50)	100	50/50
9	24.0 (50)	50/50	23.6 (50)	98	50/50	23.6 (49)	98	50/50	23.9 (50)	100	50/50
10	24.1 (50)	50/50	23.9 (50)	99	50/50	23.9 (49)	99	50/50	24.1 (50)	100	50/50
11	24.7 (50)	50/50	24.3 (50)	98	50/50	24.3 (49)	98	50/50	24.2 (50)	98	50/50
12	24.6 (50)	50/50	24.8 (50)	101	50/50	24.3 (49)	99	50/50	24.6 (50)	100	50/50
13	24.9 (50)	50/50	24.8 (50)	100	50/50	24.3 (49)	98	50/50	24.5 (50)	98	50/50
14	25.2 (50)	50/50	25.0 (50)	99	50/50	25.0 (49)	99	50/50	25.3 (50)	100	50/50
18	26.2 (50)	50/50	25.9 (50)	99	50/50	25.4 (49)	97	50/50	25.1 (50)	96	50/50
22	26.9 (50)	50/50	26.6 (50)	99	50/50	26.3 (49)	98	50/50	26.6 (50)	99	50/50
26	27.7 (50)	50/50	26.7 (50)	96	50/50	26.3 (49)	95	49/49	27.0 (50)	97	50/50
30	28.4 (50)	50/50	27.3 (50)	96	50/50	26.7 (49)	94	49/49	27.4 (50)	96	50/50
34	28.6 (50)	50/50	27.8 (50)	97	50/50	27.4 (49)	96	49/49	27.5 (49)	96	49/50
38	29.2 (50)	50/50	28.0 (50)	96	50/50	27.4 (49)	94	49/49	27.9 (48)	96	48/50
42	29.6 (50)	50/50	28.3 (50)	96	50/50	27.5 (49)	93	49/49	27.8 (48)	94	48/50
46	29.8 (50)	50/50	28.3 (50)	95	50/50	28.3 (48)	95	48/49	28.4 (47)	95	47/50
50	30.7 (50)	50/50	28.8 (50)	94	50/50	28.4 (48)	93	48/49	28.4 (47)	93	47/50
54	30.3 (49)	49/50	29.4 (50)	97	50/50	28.7 (48)	95	48/49	28.5 (46)	94	46/50
58	31.2 (49)	49/50	30.0 (49)	96	49/50	28.9 (47)	93	47/49	28.0 (46)	90	46/50
62	31.5 (49)	49/50	30.1 (47)	96	47/50	28.6 (47)	91	47/49	27.9 (46)	89	46/50
66	31.3 (49)	49/50	30.2 (43)	96	43/50	29.0 (46)	93	46/49	28.8 (44)	92	44/50
70	31.6 (47)	47/50	30.5 (42)	97	42/50	29.3 (45)	93	45/49	28.2 (42)	89	42/50
74	32.4 (46)	46/50	30.6 (42)	94	42/50	29.5 (44)	91	44/49	28.8 (41)	89	41/50
78	32.6 (44)	44/50	30.9 (41)	95	41/50	29.6 (41)	91	41/49	28.8 (41)	88	40/50
82	32.2 (43)	43/50	30.6 (40)	95	40/50	29.8 (40)	93	40/49	28.4 (38)	88	37/50
86	33.9 (41)	40/50	31.1 (38)	92	38/50	30.5 (37)	90	37/49	28.1 (36)	83	35/50
90	33.3 (37)	37/50	32.0 (38)	96	38/50	30.1 (34)	90	34/49	29.4 (34)	88	34/50
94	32.9 (34)	34/50	31.1 (36)	95	36/50	29.9 (32)	91	32/49	28.9 (28)	88	27/50
98	32.9 (33)	33/50	31.4 (29)	95	29/50	30.4 (31)	92	30/49	30.3 (14)	92	13/50
102	32.8 (30)	30/50	32.0 (28)	98	28/50	30.3 (28)	92	28/49	28.2 ( 7)	86	7/50
104	33.2 (27)	27/50	31.6 (26)	95	26/50	31.1 (25)	94	25/49	28.8 ( 6)	87	6/50

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

TABLE 3 INCIDENCES OF EXTERNAL AND INTERNAL MASSES IN CLINICAL OBSERVATION OF MALE MICE IN THE 2-YEAR INHALATION STUDY OF ALLYL CHLORIDE

Time of mass occurrence (week)	0~13	14~26	27~39	40~52	53~65	66~78	79~91	92~104	0~104
External mass									
0ppm	0/50	0/50	0/50	0/50	1/49	1/48	3/47	4/43	4/50 (2/15)
50ppm	0/50	0/50	0/50	0/50	0/50	1/50	4/49	3/42	5/50 (3/15)
100ppm	1/50	1/50	1/50	1/50	2/48	2/48	5/47	8/40	9/50 (3/17)
200ppm	0/50	0/50	1/50	1/44	0/33	0/21	0/6	0/2	2/50 (2/50)
Internal mass									
0ppm	0/50	0/50	0/50	0/50	1/49	2/48	5/47	11/43	12/50 (7/15)
50ppm	1/50	1/50	1/50	1/50	1/50	3/50	6/49	5/42	9/50 (7/15)
100ppm	0/50	0/50	0/50	0/50	0/48	0/48	4/47	5/40	7/50 (4/17)
200ppm	0/50	0/50	1/50	3/44	2/33	4/21	3/6	1/2	7/50 (7/50)

No. of animals with mass / No. of survival animals at first week on each period.  
(No. of dead and moribund animals with mass / No. of dead and moribund animals)

TABLE 4 INCIDENCES OF EXTERNAL AND INTERNAL MASSES IN CLINICAL OBSERVATION OF FEMALE MICE IN THE 2-YEAR INHALATION STUDY OF ALLYL CHLORIDE

Time of mass occurrence (week)	0~13	14~26	27~39	40~52	53~65	66~78	79~91	92~104	0~104
External mass									
0ppm	0/50	0/50	0/50	0/50	0/49	1/49	4/44	2/35	5/50 (4/23)
50ppm	0/50	0/50	0/50	1/50	4/50	3/43	3/41	7/36	12/50 (8/24)
100ppm	0/49	0/49	0/49	0/49	0/48	0/46	1/41	5/32	6/49 (4/24)
200ppm	0/50	0/50	0/50	0/48	0/46	2/44	1/39	7/29	8/50 (7/44)
Internal mass									
0ppm	0/50	0/50	0/50	1/50	3/49	4/49	5/44	9/35	17/50 (15/23)
50ppm	0/50	0/50	0/50	1/50	4/50	3/43	8/41	5/36	13/50 (11/24)
100ppm	0/49	0/49	0/49	1/49	2/48	8/46	5/41	7/32	15/49 (13/24)
200ppm	0/50	0/50	0/50	0/48	0/46	1/44	5/39	6/29	9/50 (8/44)

No. of animals with mass / No. of survival animals at first week on each period.  
(No. of dead and moribund animals with mass / No. of dead and moribund animals)

TABLE 5 INCIDENCES OF ATAXIC AND PARALYTIC GAITS IN CLINICAL OBSERVATION OF MALE MICE  
IN THE 2-YEAR INHALATION STUDY OF ALLYL CHLORIDE

		(week)												
Time of abnormal gait occurrence		0~49	50~54	55~59	60~64	65~69	70~74	75~79	80~84	85~89	90~94	95~99	100~104	0~104
Ataxic Gait	0ppm	—	—	—	—	—	—	—	—	—	—	—	—	—
	50ppm	—	—	—	—	—	—	—	—	—	—	—	—	—
	100ppm	1	—	—	—	—	—	—	—	—	—	—	1	2
	200ppm	2	—	4	2	13	13	9	6	3	2	1	—	27
Paralytic Gait	0ppm	—	—	—	—	—	—	—	—	—	—	—	—	—
	50ppm	—	—	—	—	—	—	1	—	—	—	—	—	1
	100ppm	—	—	—	—	—	—	—	—	—	—	—	—	—
	200ppm	—	1	1	—	—	—	—	—	—	—	—	—	1
No. of animals with ataxic gait or paralytic gait														

TABLE 6 INCIDENCES OF ATAXIC AND PARALYTIC GAITS IN CLINICAL OBSERVATION OF FEMALE MICE  
IN THE 2-YEAR INHALATION STUDY OF ALLYL CHLORIDE

		(week)												
Time of abnormal gait occurrence		0~49	50~54	55~59	60~64	65~69	70~74	75~79	80~84	85~89	90~94	95~99	100~104	0~104
Ataxic Gait	0ppm	—	—	—	—	—	—	—	—	—	—	—	—	—
	50ppm	—	—	—	—	—	—	—	—	—	—	—	—	—
	100ppm	—	—	—	—	—	1	1	—	1	1	1	2	4
	200ppm	3	1	2	4	28	35	38	37	36	34	23	11	42
Paralytic Gait	0ppm	—	—	—	—	—	—	—	—	—	—	—	—	—
	50ppm	—	—	—	—	—	—	—	—	—	—	—	—	—
	100ppm	—	—	—	—	—	—	1	—	—	—	—	—	1
	200ppm	1	—	1	1	1	—	—	—	1	1	—	—	5
No. of animals with ataxic gait or paralytic gait														

TABLE 7 FOOD CONSUMPTION CHANGES OF MALE MICE  
IN THE 2-YEAR INHALATION STUDY OF ALLYL CHLORIDE

Weeks on Study	Control		50ppm			100ppm			200ppm		
	Av.Fc.		Av.Fc.	% of cont.		Av.Fc.	% of cont.		Av.Fc.	% of cont.	
	<50>		<50>			<50>			<50>		
1	4.1	(50)	4.1	(50)	100	4.0	(50)	98	4.0	(50)	98
2	4.1	(50)	4.1	(50)	100	4.0	(50)	98	4.2	(50)	102
3	4.2	(50)	4.1	(50)	98	4.1	(50)	98	4.3	(50)	102
4	4.4	(50)	4.3	(50)	98	4.3	(50)	98	4.4	(50)	100
5	4.4	(50)	4.3	(50)	98	4.4	(50)	100	4.5	(50)	102
6	4.4	(50)	4.4	(50)	100	4.4	(50)	100	4.5	(50)	102
7	4.5	(50)	4.4	(50)	98	4.3	(50)	96	4.2	(50)	93
8	4.5	(50)	4.5	(50)	100	4.5	(50)	100	4.7	(50)	104
9	4.6	(50)	4.6	(50)	100	4.4	(50)	96	4.6	(50)	100
10	4.6	(50)	4.5	(50)	98	4.5	(50)	98	4.8	(50)	104
11	4.7	(50)	4.6	(50)	98	4.5	(50)	96	4.8	(50)	102
12	4.8	(50)	4.7	(50)	98	4.5	(50)	94	4.8	(50)	100
13	4.6	(50)	4.5	(50)	98	4.5	(50)	98	4.7	(50)	102
14	4.7	(50)	4.7	(50)	100	4.6	(50)	98	4.8	(50)	102
18	4.7	(50)	4.8	(50)	102	4.7	(50)	100	4.9	(50)	104
22	4.9	(50)	4.8	(50)	98	4.7	(50)	96	5.0	(50)	102
26	4.7	(50)	4.8	(50)	102	4.6	(50)	98	4.8	(50)	102
30	4.8	(50)	4.8	(50)	100	4.8	(50)	100	5.0	(50)	104
34	4.8	(50)	4.8	(50)	100	4.8	(50)	100	4.9	(47)	102
38	5.0	(50)	5.1	(50)	102	4.9	(50)	98	5.0	(44)	100
42	5.1	(50)	5.1	(50)	100	4.9	(50)	96	5.1	(42)	100
46	5.1	(50)	5.1	(50)	100	5.0	(50)	98	5.0	(38)	98
50	5.0	(50)	5.2	(50)	104	5.0	(49)	100	5.0	(35)	100
54	5.1	(49)	5.1	(50)	100	5.0	(48)	98	4.9	(33)	96
58	5.1	(49)	5.2	(50)	102	5.1	(48)	100	4.8	(30)	94
62	4.9	(48)	5.0	(50)	102	4.9	(48)	100	4.9	(23)	100
66	5.2	(48)	5.3	(50)	102	5.1	(48)	98	4.9	(21)	94
70	5.1	(48)	5.1	(49)	100	5.1	(48)	100	4.5	(16)	88
74	5.1	(48)	5.2	(49)	102	5.0	(48)	98	4.6	(11)	90
78	5.2	(47)	5.0	(49)	96	4.9	(48)	94	4.1	( 8)	79
82	4.9	(46)	5.0	(46)	102	4.9	(46)	100	4.4	( 6)	90
86	5.0	(46)	5.0	(44)	100	4.9	(44)	98	4.5	( 3)	90
90	5.0	(44)	4.9	(42)	98	4.8	(42)	96	4.2	( 2)	84
94	4.8	(41)	4.7	(42)	98	4.5	(39)	94	4.8	( 1)	100
98	4.9	(41)	4.9	(38)	100	4.8	(35)	98	—	(—)	—
102	4.8	(37)	4.7	(37)	98	4.6	(35)	96	—	(—)	—
104	4.9	(35)	4.8	(35)	98	4.6	(33)	94	—	(—)	—

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

Av.Fc. : Average food consumption (Unit : g).

TABLE 8 FOOD CONSUMPTION CHANGES OF FEMALE MICE  
IN THE 2-YEAR INHALATION STUDY OF ALLYL CHLORIDE

Weeks on Study	Control		50ppm			100ppm			200ppm		
	Av.Fc.		Av.Fc.	% of cont.		Av.Fc.	% of cont.		Av.Fc.	% of cont.	
	<50>		<50>			<49>			<50>		
1	3.5	(50)	3.5	(50)	100	3.5	(49)	100	3.5	(50)	100
2	3.6	(50)	3.6	(50)	100	3.7	(49)	103	3.7	(50)	103
3	3.7	(50)	3.8	(50)	103	3.8	(49)	103	3.9	(50)	105
4	4.0	(50)	4.0	(50)	100	4.1	(49)	103	4.0	(50)	100
5	4.1	(50)	4.2	(50)	102	4.3	(49)	105	4.2	(50)	102
6	4.2	(50)	4.4	(50)	105	4.4	(49)	105	4.1	(50)	98
7	4.3	(50)	4.5	(49)	105	4.4	(49)	102	4.0	(50)	93
8	4.4	(50)	4.5	(50)	102	4.5	(49)	102	4.5	(50)	102
9	4.4	(50)	4.5	(50)	102	4.4	(49)	100	4.3	(50)	98
10	4.3	(50)	4.5	(50)	105	4.4	(49)	102	4.4	(50)	102
11	4.4	(50)	4.6	(50)	105	4.4	(49)	100	4.3	(50)	98
12	4.5	(50)	4.6	(50)	102	4.4	(49)	98	4.3	(50)	96
13	4.4	(50)	4.5	(50)	102	4.4	(49)	100	4.3	(50)	98
14	4.5	(50)	4.7	(50)	104	4.6	(49)	102	4.5	(50)	100
18	4.6	(50)	4.6	(50)	100	4.5	(49)	98	4.4	(50)	96
22	4.6	(50)	4.7	(50)	102	4.6	(49)	100	4.5	(50)	98
26	4.4	(50)	4.4	(50)	100	4.5	(49)	102	4.6	(50)	105
30	4.5	(50)	4.4	(50)	98	4.5	(49)	100	4.3	(50)	96
34	4.7	(50)	4.7	(50)	100	4.7	(49)	100	4.5	(49)	96
38	4.7	(49)	4.7	(50)	100	4.6	(49)	98	4.5	(48)	96
42	4.8	(50)	4.7	(50)	98	4.5	(49)	94	4.6	(48)	96
46	4.7	(50)	4.6	(50)	98	4.7	(48)	100	4.7	(47)	100
50	4.6	(50)	4.5	(50)	98	4.4	(48)	96	4.4	(47)	96
54	4.5	(49)	4.6	(50)	102	4.5	(48)	100	4.4	(46)	98
58	4.7	(49)	4.7	(49)	100	4.6	(47)	98	4.4	(46)	94
62	4.6	(49)	4.4	(47)	96	4.2	(47)	91	4.2	(46)	91
66	4.8	(49)	4.7	(43)	98	4.6	(46)	96	4.5	(44)	94
70	4.6	(47)	4.6	(42)	100	4.5	(45)	98	4.3	(42)	93
74	4.7	(46)	4.5	(42)	96	4.5	(44)	96	4.4	(40)	94
78	4.6	(44)	4.5	(41)	98	4.4	(41)	96	4.5	(41)	98
82	4.3	(43)	4.4	(40)	102	4.3	(40)	100	4.2	(38)	98
86	4.5	(41)	4.4	(38)	98	4.3	(37)	96	4.2	(36)	93
90	4.5	(37)	4.6	(38)	102	4.3	(34)	96	4.2	(34)	93
94	4.5	(34)	4.4	(36)	98	4.4	(32)	98	4.3	(28)	96
98	4.7	(33)	4.6	(29)	98	4.5	(31)	96	4.4	(14)	94
102	4.5	(30)	4.4	(28)	98	4.3	(28)	96	4.3	( 7)	96
104	4.7	(26)	4.4	(26)	94	4.4	(25)	94	4.4	( 6)	94

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

Av.Fc. : Average food consumption (Unit : g).

TABLE 9 ORGAN WEIGHT OF MALE MICE IN THE 2-YEAR INHALATION STUDY OF ALLYL CHLORIDE

Group Name	Control	50 ppm	100 ppm	200 ppm
No. of examined animals	35	35	33	0
Body weight (g)	40.5 ± 7.8	39.0 ± 7.0	36.7 ± 6.2	-
Lung (g)	0.234 ± 0.151	0.271 ± 0.183	0.234 ± 0.110	-
Lung (%)	0.610 ± 0.491	0.732 ± 0.583	0.651 ± 0.319 **	-
Kidneys (g)	0.647 ± 0.186	0.700 ± 0.353	0.654 ± 0.061	-
Kidneys (%)	1.649 ± 0.569	1.870 ± 1.211	1.815 ± 0.238 **	-

Mean ± S.D.

Significant difference: \* : p&lt;0.05 \*\* : p&lt;0.01 Test of Dunnett

TABLE 10 ORGAN WEIGHT OF FEMALE MICE IN THE 2-YEAR INHALATION STUDY OF ALLYL CHLORIDE

Group Name	Control	50 ppm	100 ppm	200 ppm
No. of examined animals	27	26	25	6
Body weight (g)	28.8 ± 2.2	27.5 ± 2.5	26.9 ± 2.6 *	24.5 ± 1.5 **
Heart (g)	0.174 ± 0.021	0.169 ± 0.026	0.160 ± 0.019 *	0.149 ± 0.009 **
Heart (%)	0.606 ± 0.063	0.613 ± 0.071	0.595 ± 0.049	0.611 ± 0.058
Lung (g)	0.202 ± 0.026	0.220 ± 0.042	0.209 ± 0.023	0.215 ± 0.036
Lung (%)	0.702 ± 0.091	0.807 ± 0.173 *	0.784 ± 0.107 *	0.874 ± 0.122 **
Kidneys (g)	0.445 ± 0.049	0.446 ± 0.048	0.428 ± 0.038	0.449 ± 0.034
Kidneys (%)	1.547 ± 0.146	1.627 ± 0.141	1.595 ± 0.118	1.830 ± 0.091 **
Brain (g)	0.470 ± 0.020	0.469 ± 0.016	0.465 ± 0.013	0.426 ± 0.009 **
Brain (%)	1.640 ± 0.133	1.721 ± 0.151	1.744 ± 0.158	1.742 ± 0.077

Mean ± S.D.

Significant difference: \* : p&lt;0.05 \*\* : p&lt;0.01 Test of Dunnett

TABLE 11 INCIDENCES OF SELECTED LESIONS OF MALE MICE  
IN THE 2-YEAR INHALATION STUDY OF ALLYL CHLORIDE

Group		Control	50ppm	100ppm	200ppm	Peto	Cochran-
Number of examined animals		50	50	50	50	test	Armitage
Organ	Grade of nonneoplastic lesion						test
Findings							
Harderian gland							
Hyperplasia	+	0	3	3	1		
Adenoma		3	4	14**	8	↑ ↑	
Lung							
Bronchiolar-alveolar cell hyperplasia	+ 2+	0 0	2 1	4* 2	0 0		
Bronchiolar-alveolar adenoma		4	13*	11*	3	↑ ↑	
Bronchiolar-alveolar carcinoma		3	4	2	0		
Nasal cavity							
Eosinophilic change: olfactory epithelium	+ 2+	6 0	17** 4	20** 2	6 0		
Skin/appendage							
Inflammation	+ 2+	0 0	1 0	4** 8	4** 28		
Bone marrow							
Granulopoiesis: increased	+	2	3	8	17**		
Spleen							
Extramedullary hematopoiesis	+ 2+	5 0	5 2	8 1	23** 3		
Grade: + : Slight, 2+ : Moderate, 3+ : Marked, 4+ : Severe							
Significant difference: * : p<0.05, ** : p<0.01 Chi square test							
↑ : p<0.05, ↑ ↑ : p<0.01 Peto test, Cochran-Armitage test							

TABLE 12 INCIDENCES OF SELECTED LESIONS OF FEMALE MICE  
IN THE 2-YEAR INHALATION STUDY OF ALLYL CHLORIDE

Group		Control	50ppm	100ppm	200ppm	Peto	Cochran-
Number of examined animals		50	50	49	50	test	Armitage
Organ	Grade of nonneoplastic lesion						test
Findings							
Harderian gland							
Hyperplasia	2+	0	0	1	0		
Adenoma		0	4	8**	9**	↑↑	↑↑
Lung							
Bronchiolar-alveolar cell hyperplasia	+ 2+	0 0	0 1	1 0	0 1		
Bronchiolar-alveolar adenoma		0	3	6*	5*	↑↑	↑
Bronchiolar-alveolar carcinoma		1	1	1	0		

Grade: + : Slight, 2+ : Moderate, 3+ : Marked, 4+ : Severe  
Significant difference: \* : p<0.05, \*\* : p<0.01 Chi square test  
↑ : p<0.05, ↑↑ : p<0.01 Peto test, Cochran-Armitage test

TABLE 13 INCIDENCES OF NEOPLASTIC LESIONS AND STATISTICAL ANALYSIS IN MALE MICE IN THE 2-YEAR INHALATION STUDY OF ALLYL CHLORIDE

Group Name	Control	50ppm	100ppm	200ppm
SITE : Harderian gland				
TUMOR : adenoma				
Tumor rate				
Overall rates(a)	3/50( 6.0)	4/50( 8.0)	14/50(28.0)	8/50(16.0)
Adjusted rates(b)	8.57	9.09	40.00	50.00
Terminal rates(c)	3/35( 8.6)	3/35( 8.6)	12/33(36.4)	0/ 0( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P<0.0001**			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0720			
Fisher Exact test(e)		P=0.5000	P=0.0032**	P=0.0999
SITE : lung				
TUMOR : bronchiolar-alveolar adenoma				
Tumor rate				
Overall rates(a)	4/50( 8.0)	13/50(26.0)	11/50( 22.0)	3/50( 6.0)
Adjusted rates(b)	8.57	29.73	27.27	37.50
Terminal rates(c)	3/35( 8.6)	10/35(28.6)	9/33(27.3)	0/ 0( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0100**			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.3382			
Fisher Exact test(e)		P=0.0155*	P=0.0453*	P=0.5000
SITE : lung				
TUMOR : bronchiolar-alveolar adenoma, bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	7/50(14.0)	17/50(34.0)	13/50(26.0)	3/50( 6.0)
Adjusted rates(b)	14.29	40.54	33.33	37.50
Terminal rates(c)	5/35(14.3)	14/35(40.0)	11/33(33.3)	0/ 0( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.8277			
Prevalence method(d)	P=0.0141*			
Combined analysis (d)	P=0.0235*			
Cochran-Armitage test(e)	P=0.0730			
Fisher Exact test(e)		P=0.0169*	P=0.1054	P=0.1589

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

(b):Kaplan-Meire-estimated tumor incidence at the time of terminal necropsy after adjusting for intercurrent mortality.

(c):Observed tumor incidence at the time of terminal necropsy.

(d):P-value of the trend tests was given in the column of control incidence.

Standard method :Death analysis

Prevalence method :Incidental tumor test

Combined analysis :Death analysis + Incidental tumor test

(e):Cochran-Armitage test and Fisher exact test were applied to directly with the overall incidence rates.

# indicates either the case that the upper or lower limit of the probability is not given or the case that the P-value exceeds the expected one.

-----:The P-value can not be calculated because the number of tumor-bearing animals was zero.

Significant difference; \*:P≤0.05 \*\*:P≤0.01

N.C. :Statistical value cannot be calculated and was not significant.

TABLE 14 INCIDENCES OF NEOPLASTIC LESIONS AND STATISTICAL ANALYSIS IN FEMALE MICE IN THE 2-YEAR INHALATION STUDY OF ALLYL CHLORIDE

Group Name	Control	50ppm	100ppm	200ppm
SITE : Harderian gland				
TUMOR : adenoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	4/50( 8.0)	8/49(16.3)	9/50( 18.0)
Adjusted rates(b)	0.0	9.09	24.00	33.33
Terminal rates(c)	0/27( 0.0)	1/26( 3.8)	6/25(24.0)	2/ 6(33.3)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0009**			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0027**			
Fisher Exact test(e)		P=0.0587	P=0.0026**	P=0.0013**
SITE : lung				
TUMOR : bronchiolar-alveolar adenoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	3/50( 6.0)	6/49(12.2)	5/50(10.0)
Adjusted rates(b)	0.0	7.69	20.00	44.44
Terminal rates(c)	0/27( 0.0)	2/26( 7.7)	5/25(20.0)	2/ 6(33.3)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0012**			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0493*			
Fisher Exact test(e)		P=0.1212	P=0.0125*	P=0.0281*
SITE : lung				
TUMOR : bronchiolar-alveolar adenoma, bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	1/50( 2.0)	4/50( 8.0)	7/49(14.3)	5/50(10.0)
Adjusted rates(b)	3.70	7.69	20.00	44.44
Terminal rates(c)	1/27( 3.7)	2/26( 7.7)	5/25(20.0)	2/ 6(33.3)
Statistical analysis				
Peto test				
Standard method(d)	P=0.4466			
Prevalence method(d)	P=0.0033**			
Combined analysis (d)	P=0.0057**			
Cochran-Armitage test(e)	P=0.1571			
Fisher Exact test(e)		P=0.1811	P=0.0277*	P=0.1022

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

(b):Kaplan-Meire-estimated tumor incidence at the time of terminal necropsy after adjusting for intercurrent mortality.

(c):Observed tumor incidence at the time of terminal necropsy.

(d):P-value of the trend tests was given in the column of control incidence.

Standard method :Death analysis

Prevalence method :Incidental tumor test

Combined analysis :Death analysis + Incidental tumor test

(e):Cochran-Armitage test and Fisher exact test were applied to directly with the overall incidence rates.

# :indicates either the case that the upper or lower limit of the probability is not given or the case that the P-value exceeds the expected one.

-----:The P-value can not be calculated because the number of tumor-bearing animals was zero.

Significant difference; \*:P≤0.05 \*\*:P≤0.01

N.C. :Statistical value cannot be calculated and was not significant.

TABLE 15 CAUSE OF DEATH OF MALE AND FEMALE MICE IN THE  
2-YEAR INHALATION STUDY OF ALLYL CHLORIDE

Group	Male				Female			
	0ppm	50ppm	100ppm	200ppm	0ppm	50ppm	100ppm	200ppm
Number of dead or moribund animals	15	15	17	50	23	24	24	44
No microscopical confirmation	2	1	2	7	0	1	0	3
Cardiovascular lesion	0	0	0	1	0	0	0	0
Urinary retention	2	2	8	42	0	0	1	17
Urinary system lesion	1	1	1	0	0	0	0	0
Hydronephrosis	0	0	0	0	0	1	1	0
Reproductive system lesion	1	0	0	0	0	0	0	0
Hepatic lesion	0	0	0	0	0	0	1	0
Tumor death : leukemia	3	4	2	0	14	8	12	14
subcutis	0	1	0	0	1	0	0	0
lung	1	0	0	0	0	1	1	0
lymph node	1	0	0	0	0	0	0	0
liver	3	5	3	0	1	1	0	2
kidney	1	0	0	0	0	0	0	0
pituitary gland	0	1	0	0	0	1	1	1
peripheral nerves	0	0	1	0	0	0	1	0
spleen	0	0	0	0	0	1	0	0
salivary gland	0	0	0	0	0	0	0	1
uterus					5	7	6	6
mammary gland	0	0	0	0	1	0	0	0
bone	0	0	0	0	0	1	0	0
vertebra	0	0	0	0	0	2	0	0
retroperitoneum	0	0	0	0	1	0	0	0

TABLE 16 HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC LESIONS  
IN JAPAN BIOASSAY RESEARCH CENTER : Crj:BDF<sub>1</sub> MALE MICE

Organs	No. of animals examined	No. of tumor-bearing animals	Incidence (%)	Min. - Max. (%)
Tumors				
Lung	<1195>			
Bronchiolar-alveolar adenoma 1)		88	7.4	2 - 18
Bronchiolar-alveolar carcinoma 2)		134	11.2	0 - 24
1)+ 2)		221	18.5	2 - 34
Harderian gland	<1196>			
Adenoma 1)		51	4.3	0 - 10
Adenocarcinoma 2)		1	0.1	0 - 2
1)+ 2)		52	4.3	0 - 10

24 carcinogenicity studies examined in Japan Bioassay Research Center were used.  
Study No. 0044, 0060, 0062, 0064, 0066, 0068, 0096, 0105, 0116, 0140, 0159, 0163, 0190, 0206, 0211, 0225, 0243, 0270, 0285, 0297, 0319, 0329, 0343, 0348

TABLE 17 HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC LESIONS  
IN JAPAN BIOASSAY RESEARCH CENTER : Crj:BDF<sub>1</sub> FEMALE MICE

Organs	No. of animals examined	No. of tumor-bearing animals	Incidence (%)	Min. - Max. (%)
Tumors				
Lung	<1198>			
Bronchiolar-alveolar adenoma 1)		47	3.9	0 - 10
Bronchiolar-alveolar carcinoma 2)		34	2.8	0 - 8
1)+ 2)		81	6.8	0 - 14
Harderian gland	<1198>			
Adenoma 1)		37	3.1	0 - 12
Adenocarcinoma 2)		1	0.1	0 - 2
1)+ 2)		38	3.2	0 - 12

24 carcinogenicity studies examined in Japan Bioassay Research Center were used.  
Study No. 0044, 0060, 0062, 0064, 0066, 0068, 0096, 0105, 0116, 0140, 0159, 0163, 0190, 0206, 0211, 0225, 0243, 0270, 0285, 0297, 0319, 0329, 0343, 0348