

グリシドールのマウスを用いた  
吸入によるがん原性試験報告書

試験番号：0343

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

Weeks on Study	Control		4ppm		13ppm		40ppm				
	Av.Wt.	No.of Surviv. <50>	Av.Wt.	% of cont. Surviv. <50>	Av.Wt.	% of cont. Surviv. <50>	Av.Wt.	% of cont. Surviv. <50>			
0	22.3 (50)	50/50	22.3 (50)	100	50/50	22.3 (50)	100	50/50	22.3 (50)	100	50/50
1	23.8 (50)	50/50	23.5 (50)	99	50/50	23.7 (50)	100	50/50	23.1 (50)	97	50/50
2	24.6 (50)	50/50	24.0 (50)	98	50/50	24.6 (50)	100	50/50	23.7 (50)	96	50/50
3	25.4 (50)	50/50	24.6 (50)	97	50/50	25.3 (50)	100	50/50	24.2 (50)	95	50/50
4	25.9 (50)	50/50	25.2 (50)	97	50/50	26.0 (50)	100	50/50	24.9 (50)	96	50/50
5	26.4 (50)	50/50	25.8 (50)	98	50/50	26.5 (50)	100	50/50	25.3 (50)	96	50/50
6	27.4 (50)	50/50	26.4 (50)	96	50/50	27.1 (50)	99	50/50	25.9 (50)	95	50/50
7	27.7 (50)	50/50	26.7 (50)	96	50/50	27.9 (50)	101	50/50	26.1 (50)	94	50/50
8	28.3 (50)	50/50	27.3 (50)	96	50/50	28.2 (50)	100	50/50	26.4 (50)	93	50/50
9	28.9 (50)	50/50	27.7 (50)	96	50/50	28.7 (50)	99	50/50	27.0 (50)	93	50/50
10	29.3 (50)	50/50	28.2 (50)	96	50/50	29.1 (50)	99	50/50	27.4 (50)	94	50/50
11	30.4 (50)	50/50	29.1 (50)	96	50/50	29.9 (50)	98	50/50	27.9 (50)	92	50/50
12	30.8 (50)	50/50	29.5 (50)	96	50/50	30.8 (50)	100	50/50	28.5 (50)	93	50/50
13	31.2 (50)	50/50	30.0 (50)	96	50/50	30.9 (50)	99	50/50	29.0 (50)	93	50/50
14	32.1 (50)	50/50	30.7 (50)	96	50/50	31.5 (50)	98	50/50	29.5 (50)	92	50/50
18	34.9 (50)	50/50	33.1 (50)	95	50/50	33.9 (50)	97	50/50	31.7 (50)	91	50/50
22	36.6 (50)	50/50	35.2 (50)	96	50/50	35.9 (50)	98	50/50	33.7 (50)	92	50/50
26	39.0 (50)	50/50	37.7 (50)	97	50/50	38.3 (50)	98	50/50	35.7 (50)	92	50/50
30	40.5 (50)	50/50	39.0 (50)	96	50/50	39.9 (50)	99	50/50	36.7 (50)	91	50/50
34	41.4 (50)	50/50	40.3 (50)	97	50/50	41.3 (50)	100	50/50	37.5 (50)	91	50/50
38	43.0 (50)	50/50	41.8 (50)	97	50/50	42.5 (50)	99	50/50	38.4 (50)	89	50/50
42	44.4 (50)	50/50	43.4 (50)	98	50/50	43.3 (50)	98	50/50	39.2 (50)	88	50/50
46	45.4 (50)	50/50	43.9 (50)	97	50/50	43.8 (50)	96	50/50	39.7 (50)	87	50/50
50	46.8 (50)	50/50	44.5 (50)	95	50/50	44.9 (50)	96	50/50	40.3 (50)	86	50/50
54	47.7 (49)	49/50	45.9 (48)	96	48/50	45.7 (50)	96	50/50	40.5 (49)	85	49/50
58	47.6 (49)	49/50	46.1 (48)	97	48/50	46.1 (48)	97	48/50	39.8 (48)	84	48/50
62	49.1 (49)	49/50	47.3 (48)	96	48/50	47.1 (47)	96	47/50	40.4 (47)	82	47/50
66	49.1 (49)	49/50	47.7 (48)	97	48/50	47.5 (47)	97	47/50	39.7 (44)	81	44/50
70	49.3 (49)	49/50	48.4 (48)	98	48/50	47.3 (47)	96	47/50	38.2 (44)	77	44/50
74	49.6 (49)	49/50	49.1 (47)	99	47/50	46.8 (47)	94	47/50	37.3 (42)	75	41/50
78	49.8 (49)	49/50	49.7 (45)	100	45/50	46.8 (43)	94	43/50	35.2 (36)	71	36/50
82	50.3 (48)	48/50	50.3 (45)	100	45/50	47.0 (39)	93	39/50	33.9 (29)	67	28/50
86	49.3 (48)	48/50	50.1 (45)	102	45/50	45.5 (38)	92	38/50	35.3 (19)	72	18/50
90	50.2 (43)	43/50	50.2 (43)	100	43/50	43.4 (35)	86	34/50	35.2 (16)	70	16/50
94	49.2 (42)	42/50	50.1 (43)	102	43/50	41.9 (29)	85	29/50	32.4 (12)	66	12/50
98	48.6 (41)	41/50	49.7 (41)	102	41/50	39.0 (26)	80	26/50	30.0 (8)	62	8/50
102	48.3 (39)	39/50	49.3 (37)	102	37/50	37.7 (22)	78	20/50	27.2 (5)	56	5/50
104	47.7 (38)	38/50	49.1 (35)	103	35/50	38.2 (18)	80	18/50	29.0 (3)	61	3/50

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

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

Weeks on Study	Control		4ppm		13ppm		40ppm				
	Av.Wt.	No.of Surviv. <50>	Av.Wt.	% of cont. Surviv. <50>	Av.Wt.	% of cont. Surviv. <50>	Av.Wt.	% of cont. Surviv. <49>			
0	18.1 (50)	50/50	18.1 (50)	100	50/50	18.1 (50)	100	50/50	18.1 (49)	100	50/50
1	18.9 (50)	50/50	18.7 (50)	99	50/50	18.9 (50)	100	50/50	18.7 (49)	99	49/49
2	19.8 (50)	50/50	19.8 (50)	100	50/50	19.9 (50)	101	50/50	19.5 (49)	98	49/49
3	20.5 (50)	50/50	20.4 (50)	100	50/50	20.5 (50)	100	50/50	20.1 (49)	98	49/49
4	21.4 (50)	50/50	21.2 (50)	99	50/50	21.2 (50)	99	50/50	20.9 (49)	98	49/49
5	21.9 (50)	50/50	21.6 (50)	99	50/50	21.6 (50)	99	50/50	21.2 (49)	97	49/49
6	22.4 (50)	50/50	22.2 (50)	99	50/50	22.0 (50)	98	50/50	21.8 (49)	97	49/49
7	22.6 (50)	50/50	22.4 (50)	99	50/50	22.4 (50)	99	50/50	22.1 (49)	98	49/49
8	22.7 (50)	50/50	22.4 (50)	99	50/50	22.7 (50)	100	50/50	22.2 (49)	98	49/49
9	23.2 (50)	50/50	22.7 (50)	98	50/50	22.7 (50)	98	50/50	22.7 (49)	98	49/49
10	23.1 (50)	50/50	22.9 (50)	99	50/50	22.9 (50)	99	50/50	22.7 (49)	98	49/49
11	24.1 (50)	50/50	24.0 (50)	100	50/50	23.6 (50)	98	50/50	23.5 (49)	98	49/49
12	24.1 (50)	50/50	23.9 (50)	99	50/50	24.1 (50)	100	50/50	23.8 (49)	99	49/49
13	24.3 (50)	50/50	24.1 (50)	99	50/50	24.1 (50)	99	50/50	23.6 (49)	97	49/49
14	24.6 (50)	50/50	24.5 (50)	100	50/50	24.2 (50)	98	50/50	23.9 (49)	97	49/49
18	25.5 (50)	50/50	25.4 (50)	100	50/50	25.0 (50)	98	50/50	24.8 (49)	97	49/49
22	26.0 (50)	50/50	26.0 (50)	100	50/50	25.6 (50)	98	50/50	25.6 (49)	98	49/49
26	27.1 (50)	50/50	27.0 (49)	100	49/50	26.9 (50)	99	50/50	26.2 (49)	97	49/49
30	27.8 (50)	50/50	27.9 (49)	100	49/50	27.2 (50)	98	50/50	26.8 (49)	96	49/49
34	27.5 (50)	50/50	27.8 (49)	101	49/50	27.7 (50)	101	50/50	27.3 (49)	99	49/49
38	28.3 (50)	50/50	28.3 (49)	100	49/50	28.3 (49)	100	49/50	27.3 (49)	96	49/49
42	29.1 (50)	50/50	29.0 (49)	100	49/50	29.2 (49)	100	49/50	28.1 (49)	97	49/49
46	29.1 (50)	50/50	29.1 (49)	100	49/50	29.2 (49)	100	49/50	28.1 (49)	97	49/49
50	29.8 (50)	50/50	30.0 (49)	101	49/50	30.3 (49)	102	49/50	28.9 (48)	97	48/49
54	29.8 (50)	50/50	30.1 (48)	101	48/50	30.4 (49)	102	49/50	28.9 (47)	97	47/49
58	29.5 (50)	50/50	30.3 (48)	103	48/50	30.8 (48)	104	48/50	29.1 (46)	99	46/49
62	29.8 (49)	49/50	31.1 (48)	104	48/50	31.7 (48)	106	48/50	29.6 (44)	99	44/49
66	29.9 (47)	47/50	31.5 (48)	105	48/50	32.3 (47)	108	47/50	28.8 (43)	96	43/49
70	30.1 (47)	47/50	32.1 (47)	107	47/50	32.2 (44)	107	44/50	28.5 (39)	95	38/49
74	30.8 (46)	46/50	31.8 (46)	103	46/50	32.7 (43)	106	43/50	28.7 (35)	93	35/49
78	31.3 (46)	46/50	32.0 (45)	102	45/50	31.7 (37)	101	34/50	28.0 (30)	89	27/49
82	30.8 (43)	43/50	32.9 (43)	107	42/50	33.0 (31)	107	31/50	30.2 (19)	98	19/49
86	31.2 (43)	43/50	32.9 (40)	105	40/50	34.0 (30)	109	30/50	27.9 (16)	89	16/49
90	31.0 (40)	40/50	33.5 (35)	108	35/50	33.8 (26)	109	26/50	28.4 (12)	92	12/49
94	31.7 (37)	37/50	33.7 (30)	106	30/50	32.8 (24)	103	23/50	27.2 (4)	86	4/49
98	31.2 (33)	33/50	32.1 (28)	103	28/50	33.8 (18)	108	18/50	21.4 (3)	69	2/49
102	30.3 (29)	29/50	31.2 (25)	103	25/50	32.4 (14)	107	14/50	21.1 (2)	70	1/49
104	30.8 (28)	28/50	31.8 (22)	103	22/50	33.1 (10)	107	10/50	21.2 (1)	69	1/49

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

TABLE 3 INCIDENCE OF EXTERNAL AND INTERNAL MASS IN CLINICAL OBSERVATION OF MALE MICE IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

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	0/49	1/49	4/42	4/50 (0/12)
4ppm	0/50	0/50	0/50	0/50	1/49	1/48	2/45	5/43	5/50 (1/15)
13ppm	0/50	0/50	0/50	0/50	2/50	1/47	5/42	7/31	9/50 (4/32)
40ppm	0/50	0/50	0/50	0/50	2/49	6/44	11/35	7/15	14/50 (14/47)
Internal mass									
0ppm	0/50	1/50	1/50	2/50	4/49	5/49	7/49	6/42	10/50 (6/12)
4ppm	1/50	2/50	2/50	2/50	2/49	3/48	7/45	9/43	13/50 (9/15)
13ppm	1/50	1/50	1/50	1/50	3/50	3/47	7/42	6/31	10/50 (8/32)
40ppm	0/50	0/50	0/50	0/50	1/49	2/44	1/35	1/15	3/50 (3/47)

No. of animals with mass / No. of surviving animals at the first week in each period.  
(No. of dead and moribund animals with mass / No. of dead and moribund animals)

TABLE 4 INCIDENCE OF EXTERNAL AND INTERNAL MASS IN CLINICAL OBSERVATION OF FEMALE MICE IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

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	0/50	0/47	0/46	3/39	3/50 (1/22)
4ppm	0/50	0/50	0/49	0/49	0/48	0/48	0/45	1/33	1/50 (1/28)
13ppm	0/50	0/50	0/50	0/49	1/49	3/47	1/34	4/24	7/50 (5/40)
40ppm	0/50	0/49	0/49	0/49	0/47	5/43	5/25	3/7	8/49 (8/48)
Internal mass									
0ppm	1/50	1/50	1/50	1/50	4/50	8/47	11/46	11/39	20/50 (14/22)
4ppm	1/50	3/50	2/49	2/49	3/48	9/48	13/45	9/33	21/50 (21/28)
13ppm	1/50	0/50	0/50	0/49	4/49	10/47	9/34	12/24	22/50 (16/40)
40ppm	0/50	0/49	1/49	1/49	2/47	8/43	7/25	2/7	12/49 (12/48)

No. of animals with mass / No. of surviving animals at the first week in each period.  
(No. of dead and moribund animals with mass / No. of dead and moribund animals)

TABLE 5 FOOD CONSUMPTION CHANGES OF MALE MICE  
IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

Weeks on Study	Control		4ppm		13ppm		40ppm	
	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	4.1	(50) 100	3.9	(50) 95
2	4.0	(50)	3.9	(50) 98	4.0	(50) 100	3.9	(50) 98
3	4.1	(50)	4.1	(50) 100	4.1	(50) 100	4.0	(50) 98
4	4.1	(50)	4.1	(50) 100	4.2	(50) 102	4.1	(50) 100
5	4.2	(50)	4.2	(50) 100	4.2	(50) 100	4.0	(50) 95
6	4.4	(50)	4.3	(50) 98	4.3	(50) 98	4.1	(50) 93
7	4.3	(50)	4.3	(50) 100	4.2	(50) 98	4.0	(50) 93
8	4.5	(50)	4.3	(50) 96	4.3	(50) 96	4.2	(50) 93
9	4.5	(50)	4.4	(50) 98	4.3	(50) 96	4.1	(50) 91
10	4.6	(50)	4.5	(50) 98	4.4	(50) 96	4.2	(50) 91
11	4.6	(50)	4.5	(50) 98	4.4	(50) 96	4.3	(50) 93
12	4.7	(50)	4.5	(50) 96	4.5	(50) 96	4.3	(50) 91
13	4.6	(50)	4.5	(50) 98	4.5	(50) 98	4.5	(50) 98
14	4.7	(50)	4.5	(50) 96	4.6	(50) 98	4.4	(50) 94
18	4.8	(50)	4.7	(50) 98	4.7	(50) 98	4.5	(50) 94
22	4.8	(50)	4.7	(50) 98	4.7	(50) 98	4.5	(50) 94
26	4.9	(50)	4.8	(50) 98	4.9	(50) 100	4.7	(50) 96
30	4.9	(50)	4.8	(50) 98	4.8	(50) 98	4.5	(50) 92
34	5.0	(50)	5.0	(50) 100	5.1	(50) 102	4.7	(50) 94
38	5.2	(50)	5.1	(50) 98	5.2	(50) 100	4.9	(50) 94
42	5.0	(50)	4.8	(50) 96	4.9	(50) 98	4.6	(50) 92
46	5.1	(50)	5.0	(50) 98	5.0	(50) 98	4.7	(50) 92
50	5.2	(50)	5.0	(50) 96	5.1	(50) 98	4.8	(50) 92
54	5.2	(49)	5.1	(48) 98	5.2	(50) 100	4.8	(49) 92
58	5.2	(49)	5.1	(48) 98	5.1	(48) 98	4.6	(48) 88
62	5.4	(49)	5.1	(48) 94	5.3	(47) 98	4.7	(47) 87
66	5.4	(49)	5.3	(48) 98	5.3	(47) 98	4.6	(44) 85
70	5.4	(49)	5.2	(48) 96	5.2	(47) 96	4.4	(44) 81
74	5.4	(49)	5.2	(47) 96	5.3	(47) 98	4.5	(42) 83
78	5.4	(49)	5.4	(45) 100	5.2	(43) 96	4.2	(36) 78
82	5.2	(48)	5.3	(45) 102	5.2	(39) 100	4.2	(29) 81
86	5.0	(48)	5.2	(45) 104	5.0	(38) 100	4.2	(19) 84
90	5.2	(43)	5.3	(43) 102	4.8	(35) 92	4.1	(16) 79
94	5.4	(42)	5.5	(43) 102	4.8	(29) 89	4.1	(12) 76
98	5.5	(41)	5.5	(41) 100	4.8	(26) 87	4.0	(8) 73
102	5.4	(39)	5.4	(36) 100	4.8	(22) 89	3.9	(5) 72
104	5.4	(38)	5.4	(36) 100	4.9	(18) 91	4.7	(3) 87

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

TABLE 6 FOOD CONSUMPTION CHANGES OF FEMALE MICE  
IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

Weeks on Study	Control		4ppm		13ppm		40ppm	
	Av.FC.		Av.FC.	% of cont.	Av.FC.	% of cont.	Av.FC.	% of cont.
	<50>		<50>		<50>		<49>	
1	3.4	(50)	3.5	(50) 103	3.5	(50) 103	3.4	(49) 100
2	3.5	(50)	3.5	(50) 100	3.5	(50) 100	3.5	(49) 100
3	3.7	(50)	3.7	(50) 100	3.6	(50) 97	3.6	(49) 97
4	3.9	(50)	3.9	(50) 100	3.9	(50) 100	3.7	(49) 95
5	4.1	(50)	4.0	(50) 98	3.9	(50) 95	3.8	(49) 93
6	4.2	(50)	4.2	(50) 100	4.0	(50) 95	3.9	(49) 93
7	4.2	(50)	4.2	(50) 100	4.0	(50) 95	3.9	(49) 93
8	4.3	(50)	4.3	(50) 100	4.1	(50) 95	4.0	(49) 93
9	4.3	(50)	4.2	(50) 98	4.0	(50) 93	4.0	(49) 93
10	4.4	(50)	4.3	(50) 98	4.2	(50) 95	4.1	(49) 93
11	4.4	(50)	4.4	(50) 100	4.2	(50) 95	4.1	(49) 93
12	4.4	(50)	4.3	(50) 98	4.2	(50) 95	4.1	(49) 93
13	4.4	(50)	4.4	(50) 100	4.2	(50) 95	4.1	(49) 93
14	4.4	(50)	4.4	(50) 100	4.2	(50) 95	4.1	(49) 93
18	4.6	(50)	4.5	(50) 98	4.3	(50) 93	4.2	(49) 91
22	4.5	(50)	4.5	(50) 100	4.3	(50) 96	4.2	(49) 93
26	4.5	(50)	4.4	(49) 98	4.4	(50) 98	4.3	(49) 96
30	4.7	(50)	4.6	(49) 98	4.4	(50) 94	4.3	(49) 91
34	4.7	(50)	4.7	(49) 100	4.7	(50) 100	4.6	(49) 98
38	4.8	(50)	4.8	(49) 100	4.7	(49) 98	4.5	(49) 94
42	4.5	(50)	4.5	(49) 100	4.7	(49) 104	4.5	(49) 100
46	4.5	(50)	4.6	(49) 102	4.6	(49) 102	4.4	(49) 98
50	4.7	(50)	4.8	(49) 102	4.8	(49) 102	4.6	(48) 98
54	4.6	(50)	4.6	(48) 100	4.8	(49) 104	4.6	(47) 100
58	4.5	(50)	4.6	(48) 102	4.7	(48) 104	4.4	(46) 98
62	4.4	(49)	4.6	(48) 105	4.8	(48) 109	4.4	(44) 100
66	4.6	(47)	4.8	(48) 104	4.9	(47) 107	4.4	(43) 96
70	4.5	(47)	4.7	(47) 104	4.7	(44) 104	4.3	(39) 96
74	4.7	(46)	4.5	(46) 96	4.7	(43) 100	4.4	(35) 94
78	4.8	(46)	4.8	(45) 100	4.7	(37) 98	4.4	(30) 92
82	4.5	(43)	4.7	(43) 104	4.9	(31) 109	4.4	(19) 98
86	4.5	(43)	4.5	(40) 100	5.0	(30) 111	4.0	(16) 89
90	4.5	(40)	4.8	(35) 107	5.1	(26) 113	4.4	(12) 98
94	4.8	(37)	5.0	(30) 104	4.9	(24) 102	5.0	(4) 104
98	4.9	(33)	5.0	(28) 102	5.1	(18) 104	4.1	(3) 84
102	4.7	(29)	4.9	(25) 104	5.0	(14) 106	4.2	(2) 89
104	4.8	(28)	4.9	(22) 102	5.1	(11) 106	3.8	(1) 79

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

TABLE 7 ORGAN WEIGHT OF MALE MICE IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

Group Name	Control	4 ppm	13 ppm	40 ppm
No. of examined animals	38	35	18	3
Body weight (g)	43.2 ± 7.5	44.9 ± 7.9	34.3 ± 7.4 **	25.4 ± 2.4 **
Testes (g)	0.214 ± 0.034	0.204 ± 0.048	0.197 ± 0.033	0.196 ± 0.016
Testes (%)	0.508 ± 0.105	0.467 ± 0.130	0.598 ± 0.164 *	0.776 ± 0.087 **
Heart (g)	0.235 ± 0.040	0.235 ± 0.027	0.211 ± 0.026 *	0.176 ± 0.023 **
Heart (%)	0.561 ± 0.148	0.540 ± 0.115	0.633 ± 0.109	0.690 ± 0.052
Lung (g)	0.230 ± 0.059	0.254 ± 0.102	0.216 ± 0.027	0.224 ± 0.055
Lung (%)	0.550 ± 0.177	0.583 ± 0.249	0.652 ± 0.136 *	0.880 ± 0.181 *
Kidneys (g)	1.514 ± 3.370	1.012 ± 2.035	0.631 ± 0.065	0.560 ± 0.054
Kidneys (%)	3.457 ± 7.180	2.346 ± 4.791	1.889 ± 0.276 **	2.200 ± 0.009 *
Spleen(g)	0.128 ± 0.141	0.149 ± 0.203	0.063 ± 0.029 **	0.048 ± 0.006 *
Spleen(%)	0.317 ± 0.371	0.354 ± 0.493	0.189 ± 0.097	0.193 ± 0.043
Liver (g)	1.661 ± 0.445	1.870 ± 0.743	1.457 ± 0.221	1.046 ± 0.091 *
Liver (%)	3.970 ± 1.166	4.401 ± 2.513	4.436 ± 1.304	4.114 ± 0.084
Brain (g)	0.457 ± 0.017	0.456 ± 0.017	0.453 ± 0.018	0.439 ± 0.007
Brain (%)	1.093 ± 0.214	1.052 ± 0.219	1.378 ± 0.294 **	1.740 ± 0.196 **

Mean ± S.D.

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

TABLE 8 ORGAN WEIGHT OF FEMALE MICE IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

Group Name	Control	4 ppm	13 ppm	40 ppm
No. of examined animals	28	22	10	1
Body weight (g)	26.4 ± 3.4	27.8 ± 4.7	28.6 ± 3.3	18.7
Ovaries(g)	0.080 ± 0.080	0.034 ± 0.019 **	0.043 ± 0.021	0.011
Ovaries(%)	0.294 ± 0.281	0.126 ± 0.076 **	0.150 ± 0.062	0.059

Mean ± S.D.

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

TABLE9 INCIDENCES OF SELECTED LESIONS OF MALE MICE  
IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

Group		Control	4ppm	13ppm	40ppm	Peto	Cochran-
Number of examined animals		50	50	50	50		Armitage
Organ	Grade of Nonneoplastic lesion						
Findings							
Subcutis							
Histiocytic sarcoma		1	1	3	3	**	
Nasal cavity							
Hemorrhage	+	0	0	2 **	2 **		
	2+	0	0	3	11		
	3+	0	0	8	8		
Exudate	+	0	1	4 **	7 **		
	2+	0	0	7	12		
	3+	0	0	3	5		
Squamous cell metaplasia: respiratory epithelium	+	0	1	7 **	8 **		
	2+	0	1	24	18		
	3+	0	0	1	4		
Squamous cell metaplasia with atypia: respiratory epithelium	+	0	0	2 *	4 **		
	2+	0	0	6	11		
	3+	0	0	0	1		
Squamous cell hyperplasia	+	0	0	2	3		
	2+	0	1	0	0		
Squamous cell hyperplasia with atypia	+	0	0	5 *	12 **		
	2+	0	0	1	5		
Respiratory metaplasia: gland	+	26	9 **	41 **	9 **		
	2+	0	1	6	41		
Respiratory metaplasia: olfactory epithelium	+	11	2 *	37 **	8 **		
	2+	0	0	12	40		
	3+	0	0	0	1		
Hemangioma 1)		0	3	13 **	7 **	**	
Hemangiosarcoma 2)		0	0	17 **	33 **	**	**
1) +2)		0	3	30 **	40 **	**	**
Adenoma 3)		0	0	3	2	*	
Adenocarcinoma 4)		0	0	0	3	**	**
3) +4)		0	0	3	5 *	**	**
Squamous cell papilloma		0	0	1	0		
Squamous cell carcinoma		0	0	0	1		
Lung							
Bronchiolar-alveolar carcinoma		4	7	3	4	*	
Lymph node							
Malignant lymphoma		5	8	9	4	*	
Salivary gland							
Lymphocytic infiltration	+	35	33	26	23 *		
Stomach							
Hyperplasia: forestomach	+	0	0	1	4 *		
	2+	0	0	2	3		
	3+	0	0	1	0		
Liver							
Granulation	+	18	22	9	5 **		
	2+	1	0	0	0		
Hepatocellular adenoma 1)		11	11	5	3 *		*
Hepatocellular carcinoma 2)		4	8	5	0		*
1) +2)		15	18	10	3 **		**

TABLE9 INCIDENCES OF SELECTED LESIONS OF MALE MICE  
IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL (CONTINUED)

Group		Control	4ppm	13ppm	40ppm	Peto	Cochran
Number of examined animals		50	50	50	50		Armitage
Organ	Grade of Nonneoplastic lesion						
Findings							
Liver							
Hemangioma 3)		3	2	3	2	*	
Hemangiosarcoma 4)		1	0	0	0		
3) +4)		4	2	3	2		
Kidney							
Lymphocytic infiltration	+	8	7	2	0 **		
Mineralization: cortex	+	16	12	29 *	32 **		
	2+	0	0	0	1		
Brain							
Mineralization	+	34	36	29	21 *		
Peripheral nerves							
Histiocytic sarcoma		1	0	3	3	*	
Harderian gland							
Adenoma		2	6	7	10 *	*	*
All SITE							
Histiocytic sarcoma		7	9	12	13	**	
Malignant lymphoma		6	10	10	4		
Grade		+: Slight	2+: Moderate	3+: Marked	4+: Severe		
Significant difference		* : p<0.05		** : p<0.01		Chi square test	

TABLE10 INCIDENCES OF SELECTED LESIONS OF FEMALE MICE  
IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

Group		Control	4ppm	13ppm	40ppm	Peto	Cochran-
Number of examined animals		50	50	50	49		Armitage
Organ	Grade of Nonneoplastic lesion						
Findings							
<b>Nasal cavity</b>							
Hemorrhage	+	0	0	4 *	7 **		
	2+	0	0	4	11		
	3+	0	0	2	10		
	4+	0	0	0	1		
Exudate	+	1	0	2	2 **		
	2+	1	0	3	7		
	3+	0	0	0	7		
Squamous cell metaplasia: respiratory epithelium	+	0	0	11 **	4 **		
	2+	0	0	9	11		
	3+	0	0	0	1		
Squamous cell metaplasia with atypia: respiratory epithelium	+	0	0	1 *	3 **		
	2+	0	0	5	23		
	3+	0	0	0	1		
Squamous cell hyperplasia:	+	0	0	3	6 *		
	2+	0	0	0	1		
Squamous cell hyperplasia with atypia	+	0	0	1	3 *		
	2+	0	0	0	4		
Hyperplasia: transitional epithelium	+	0	1	6 *	1		
Respiratory metaplasia: gland	+	7	27 **	21 **	0 **		
	2+	0	1	29	44		
	3+	0	0	0	5		
Respiratory metaplasia: olfactory epithelium	+	1	33 **	19 **	0 **		
	2+	1	0	29	42		
	3+	0	0	2	7		
Eosinophilic change: olfactory epithelium	+	11	9	3 *	4		
	2+	0	1	0	0		
Eosinophilic change: respiratory epithelium	+	19	15	10 *	22 *		
	2+	18	17	33	9		
	3+	6	6	1	2		
	4+	1	1	0	0		
Hemangioma 1)		0	0	5 *	10 **	**	**
Hemangiosarcoma 2)		0	1	16 **	21 **	**	**
1) +2)		0	1	21 **	31 **	**	**
Adenoma 3)		0	0	0	3	**	**
Adenocarcinoma 4)		0	0	0	2		
3) +4)		0	0	0	5 *	**	**
Squamous cell papilloma 5)		0	0	1	1		
Squamous cell carcinoma 6)		0	0	0	4	**	**
5) +6)		0	0	1	5 *	**	**
Sarcoma:NOS		0	0	0	1		
<b>Lung</b>							
Inflammatory infiltration	+	5	3	4	0 *		
	2+	0	0	1	1		
Bronchiolar-alveolar adenoma 1)		2	1	1	3	*	
Bronchiolar-alveolar carcinoma 2)		2	0	2	1		
1) +2)		4	1	3	4	**	

TABLE10 INCIDENCES OF SELECTED LESIONS OF FEMALE MICE  
IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL (CONTINUED)

Group		Control	4ppm	13ppm	40ppm	Peto	Cochran-
Number of examined animals		50	50	50	49		Armitage
Organ	Grade of Nonneoplastic lesion						
Findings							
Lymph node							
Malignant lymphoma		17	14	14	6 **		*
Liver							
Granulation	+	21	18	8 **	2 **		
	2+	0	0	0	1		
Kidney							
Hyaline droplet	+	8	11	21 *	10		
	2+	3	1	1	1		
Uterus							
Cystic endometrial hyperplasia	+	18	8	10	8 *		
	2+	5	6	8	2		
Histiocytic sarcoma		12	15	22 *	18	**	
Mammary gland							
Adenocarcinoma		2	0	5	4	*	
Brain							
Mineralization	+	20	22	20	9 *		
Harderian gland							
Adenoma		1	1	6	7 *	**	**
All SITE							
Histiocytic sarcoma		12	17	27 **	21 *	**	
Malignant lymphoma		21	17	16	7 **		**
Grade		+: Slight	2+: Moderate	3+: Marked	4+: Severe		
Significant difference		* : p<0.05		** : p<0.01		Chi square test	

TABLE 11 NEOPLASTIC LESIONS INCIDENCES AND STATISTICAL ANALYSIS IN MALE MICE IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

Group Name	Control	4ppm	13ppm	40ppm
SITE : subcutis				
TUMOR : histiocytic sarcoma				
Tumor rate				
Overall rates(a)	1/50( 2.0)	1/50( 2.0)	3/50( 6.0)	3/50( 6.0)
Adjusted rates(b)	2.63	2.86	16.67	7.69
Terminal rates(c)	1/38( 2.6)	1/35( 2.9)	3/18(16.7)	0/ 3( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0254* f)			
Prevalence method(d)	P=0.0341*			
Combined analysis (d)	P=0.0039**			
Cochran-Armitage test(e)	P=0.2569			
Fisher Exact test(e)		P=0.7525	P=0.3087	P=0.3087
SITE : nasal cavity				
TUMOR : adenoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	3/50( 6.0)	2/50( 4.0)
Adjusted rates(b)	0.0	0.0	13.64	12.50
Terminal rates(c)	0/38( 0.0)	0/35( 0.0)	2/18(11.1)	0/ 3( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0103*			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.1655			
Fisher Exact test(e)		P=N.C.	P=0.1212	P=0.2475
SITE : nasal cavity				
TUMOR : hemangioma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	3/50( 6.0)	13/50(26.0)	7/50(14.0)
Adjusted rates(b)	0.0	7.14	38.89	20.00
Terminal rates(c)	0/38( 0.0)	2/35( 5.7)	7/18(38.9)	0/ 3( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0006**			
Prevalence method(d)	P=0.0122*			
Combined analysis (d)	P=0.0001**			
Cochran-Armitage test(e)	P=0.0582			
Fisher Exact test(e)		P=0.1212	P<0.0001**	P=0.0062**
SITE : nasal cavity				
TUMOR : adenocarcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	0/50( 0.0)	3/50( 6.0)
Adjusted rates(b)	0.0	0.0	0.0	8.00
Terminal rates(c)	0/38( 0.0)	0/35( 0.0)	0/18( 0.0)	0/ 3( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.1204			
Prevalence method(d)	P=0.0038**f)			
Combined analysis (d)	P=0.0005**f)			
Cochran-Armitage test(e)	P=0.0040**			
Fisher Exact test(e)		P=N.C.	P=N.C.	P=0.1212

TABLE 11 NEOPLASTIC LESIONS INCIDENCES AND STATISTICAL ANALYSIS IN MALE MICE IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL (CONTINUED)

Group Name	Control	4ppm	13ppm	40ppm
SITE : nasal cavity				
TUMOR : hemangiosarcoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	17/50(34.0)	33/50(66.0)
Adjusted rates(b)	0.0	0.0	31.82	66.67
Terminal rates(c)	0/38( 0.0)	0/35( 0.0)	4/18(22.2)	2/ 3(66.7)
Statistical analysis				
Peto test				
Standard method(d)	P<0.0001**f)			
Prevalence method(d)	P<0.0001**			
Combined analysis (d)	P<0.0001**f)			
Cochran-Armitage test(e)	P<0.0001**			
Fisher Exact test(e)		P=N.C.	P<0.0001**	P<0.0001**
SITE : nasal cavity				
TUMOR : adenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	3/50( 6.0)	5/50(10.0)
Adjusted rates(b)	0.0	0.0	13.64	14.29
Terminal rates(c)	0/38( 0.0)	0/35( 0.0)	2/18(11.1)	0/ 3( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.1204			
Prevalence method(d)	P=0.0016**			
Combined analysis (d)	P=0.0004**			
Cochran-Armitage test(e)	P=0.0038**			
Fisher Exact test(e)		P=N.C.	P=0.1212	P=0.0281*
SITE : nasal cavity				
TUMOR : hemangioma, hemangiosarcoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	3/50( 6.0)	30/50(60.0)	40/50(80.0)
Adjusted rates(b)	0.0	7.14	65.22	75.00
Terminal rates(c)	0/38( 0.0)	2/35( 5.7)	11/18(61.1)	2/ 3(66.7)
Statistical analysis				
Peto test				
Standard method(d)	P<0.0001**f)			
Prevalence method(d)	P<0.0001**f)			
Combined analysis (d)	P<0.0001**f)			
Cochran-Armitage test(e)	P<0.0001**			
Fisher Exact test(e)		P=0.1212	P<0.0001**	P<0.0001**
SITE : lung				
TUMOR : bronchiolar-alveolar adenoma				
Tumor rate				
Overall rates(a)	3/50( 6.0)	5/50(10.0)	5/50(10.0)	5/50(10.0)
Adjusted rates(b)	7.89	13.89	13.79	25.00
Terminal rates(c)	3/38( 7.9)	4/35(11.4)	2/18(11.1)	0/ 3( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0533			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.6516			
Fisher Exact test(e)		P=0.3575	P=0.3575	P=0.3575

TABLE 11 NEOPLASTIC LESIONS INCIDENCES AND STATISTICAL ANALYSIS IN MALE MICE IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL (CONTINUED)

Group Name	Control	4ppm	13ppm	40ppm
SITE : lung				
TUMOR : bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	4/50( 8.0)	7/50(14.0)	3/50( 6.0)	4/50( 8.0)
Adjusted rates(b)	6.52	17.14	5.56	33.33
Terminal rates(c)	2/38( 5.3)	6/35(17.1)	1/18( 5.6)	1/ 3(33.3)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0253*			
Prevalence method(d)	P=0.4185			
Combined analysis (d)	P=0.0725			
Cochran-Armitage test(e)	P=0.6402			
Fisher Exact test(e)		P=0.2623	P=0.5000	P=0.6425
SITE : lung				
TUMOR : bronchiolar-alveolar adenoma, bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	7/50(14.0)	11/50(22.0)	8/50(16.0)	9/50(18.0)
Adjusted rates(b)	13.16	27.78	19.05	40.00
Terminal rates(c)	5/38(13.2)	9/35(25.7)	3/18(16.7)	1/ 3(33.3)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0253*			
Prevalence method(d)	P=0.1039			
Combined analysis (d)	P=0.0200*			
Cochran-Armitage test(e)	P=0.9121			
Fisher Exact test(e)		P=0.2178	P=0.5000	P=0.3929
SITE : lymph node				
TUMOR : malignant lymphoma				
Tumor rate				
Overall rates(a)	5/50(10.0)	8/50(16.0)	9/50(18.0)	4/50( 8.0)
Adjusted rates(b)	7.89	17.14	22.22	20.00
Terminal rates(c)	3/38( 7.9)	6/35(17.1)	4/18(22.2)	0/ 3( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.2001			
Prevalence method(d)	P=0.0487*			
Combined analysis (d)	P=0.0405*			
Cochran-Armitage test(e)	P=0.4070			
Fisher Exact test(e)		P=0.2768	P=0.1940	P=0.5000
SITE : liver				
TUMOR : hemangioma				
Tumor rate				
Overall rates(a)	3/50( 6.0)	2/50( 4.0)	3/50( 6.0)	2/50( 4.0)
Adjusted rates(b)	5.26	4.44	5.88	0.0
Terminal rates(c)	2/38( 5.3)	1/35( 2.9)	0/18( 0.0)	0/ 3( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0279*			
Prevalence method(d)	P=0.7360			
Combined analysis (d)	P=0.1787			
Cochran-Armitage test(e)	P=0.7471			
Fisher Exact test(e)		P=0.5000	P=0.6611	P=0.5000

TABLE 11 NEOPLASTIC LESIONS INCIDENCES AND STATISTICAL ANALYSIS IN MALE MICE IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL (CONTINUED)

Group Name	Control	4ppm	13ppm	40ppm
SITE : liver				
TUMOR : hepatocellular adenoma				
Tumor rate				
Overall rates(a)	11/50(22.0)	11/50(22.0)	5/50(10.0)	3/50( 6.0)
Adjusted rates(b)	23.40	28.57	22.22	9.38
Terminal rates(c)	8/38(21.1)	10/35(28.6)	4/18(22.2)	0/ 3( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.3343			
Prevalence method(d)	P=0.7838			
Combined analysis (d)	P=0.7745			
Cochran-Armitage test(e)	P=0.0117*			
Fisher Exact test(e)		P=0.5952	P=0.0857	P=0.0204*
SITE : liver				
TUMOR : hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	4/50( 8.0)	8/50(16.0)	5/50(10.0)	0/50( 0.0)
Adjusted rates(b)	4.88	13.95	20.00	0.0
Terminal rates(c)	1/38( 2.6)	3/35( 8.6)	3/18(16.7)	0/ 3( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.9176			
Prevalence method(d)	P=0.6486			
Combined analysis (d)	P=0.8513			
Cochran-Armitage test(e)	P=0.0182*			
Fisher Exact test(e)		P=0.1783	P=0.5000	P=0.0587
SITE : liver				
TUMOR : hepatocellular adenoma, hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	15/50(30.0)	18/50(36.0)	10/50(20.0)	3/50( 6.0)
Adjusted rates(b)	28.89	37.21	38.89	9.38
Terminal rates(c)	9/38(23.7)	12/35(34.3)	7/18(38.9)	0/ 3( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.8523			
Prevalence method(d)	P=0.9211			
Combined analysis (d)	P=0.9603			
Cochran-Armitage test(e)	P=0.0003**			
Fisher Exact test(e)		P=0.3355	P=0.1779	P=0.0017**
SITE : peripheral nerves				
TUMOR : histiocytic sarcoma				
Tumor rate				
Overall rates(a)	1/50( 2.0)	0/50( 0.0)	3/50( 6.0)	3/50( 6.0)
Adjusted rates(b)	0.0	0.0	0.0	0.0
Terminal rates(c)	0/38( 0.0)	0/35( 0.0)	0/18( 0.0)	0/ 3( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0232*			
Prevalence method(d)	P=-----			
Combined analysis (d)	P=0.0232*			
Cochran-Armitage test(e)	P=0.1438			
Fisher Exact test(e)		P=0.5000	P=0.3087	P=0.3087

TABLE 11 NEOPLASTIC LESIONS INCIDENCES AND STATISTICAL ANALYSIS IN MALE MICE  
IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL (CONTINUED)

Group Name	Control	4ppm	13ppm	40ppm
SITE : Harderian gland				
TUMOR : adenoma				
Tumor rate				
Overall rates(a)	2/50( 4.0)	6/50(12.0)	7/50(14.0)	10/49(20.4)
Adjusted rates(b)	4.26	12.50	24.00	22.22
Terminal rates(c)	0/38( 0.0)	3/35( 8.6)	2/18(11.1)	0/ 3( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0146*			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0256*			
Fisher Exact test(e)		P=0.1343	P=0.0798	P=0.0126*
SITE : ALL SITE				
TUMOR : histiocytic sarcoma				
Tumor rate				
Overall rates(a)	7/50(14.0)	9/50(18.0)	12/50(24.0)	13/50(26.0)
Adjusted rates(b)	13.16	14.29	27.78	33.33
Terminal rates(c)	5/38(13.2)	5/35(14.3)	5/18(27.8)	1/ 3(33.3)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0003**			
Prevalence method(d)	P=0.0075**			
Combined analysis (d)	P<0.0001**			
Cochran-Armitage test(e)	P=0.1513			
Fisher Exact test(e)		P=0.3929	P=0.1540	P=0.1054
SITE : ALL SITE				
TUMOR : malignant lymphoma				
Tumor rate				
Overall rates(a)	6/50(12.0)	10/50(20.0)	10/50(20.0)	4/50( 8.0)
Adjusted rates(b)	10.53	22.86	22.22	20.00
Terminal rates(c)	4/38(10.5)	8/35(22.9)	4/18(22.2)	0/ 3( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.1886			
Prevalence method(d)	P=0.0872			
Combined analysis (d)	P=0.0595			
Cochran-Armitage test(e)	P=0.2157			
Fisher Exact test(e)		P=0.2070	P=0.2070	P=0.3703

(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 colum 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.

f) :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 calculate.

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

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

TABLE 12 NEOPLASTIC LESIONS INCIDENCES AND STATISTICAL ANALYSIS IN FEMALE MICE IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

Group Name	Control	4ppm	13ppm	40ppm
SITE : nasal cavity				
TUMOR : adenoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	0/50( 0.0)	3/49( 6.1)
Adjusted rates(b)	0.0	0.0	0.0	100.00
Terminal rates(c)	0/28( 0.0)	0/22( 0.0)	0/10( 0.0)	1/ 1(100.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0007**f)			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0036**			
Fisher Exact test(e)		P=N.C.	P=N.C.	P=0.1175
SITE : nasal cavity				
TUMOR : hemangioma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	5/50(10.0)	10/49(20.4)
Adjusted rates(b)	0.0	0.0	20.00	13.04
Terminal rates(c)	0/28( 0.0)	0/22( 0.0)	2/10(20.0)	0/ 1( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0001**			
Prevalence method(d)	P=0.0023**			
Combined analysis (d)	P<0.0001**			
Cochran-Armitage test(e)	P<0.0001**			
Fisher Exact test(e)		P=N.C.	P=0.0281*	P=0.0005**
SITE : nasal cavity				
TUMOR : squamous cell carcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	0/50( 0.0)	4/49( 8.2)
Adjusted rates(b)	0.0	0.0	0.0	100.00
Terminal rates(c)	0/28( 0.0)	0/22( 0.0)	0/10( 0.0)	1/ 1(100.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0078**f)			
Prevalence method(d)	P<0.0001**f)			
Combined analysis (d)	P<0.0001**f)			
Cochran-Armitage test(e)	P=0.0008**			
Fisher Exact test(e)		P=N.C.	P=N.C.	P=0.0563
SITE : nasal cavity				
TUMOR : hemangiosarcoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	1/50( 2.0)	16/50(32.0)	21/49(42.9)
Adjusted rates(b)	0.0	2.50	33.33	50.00
Terminal rates(c)	0/28( 0.0)	0/22( 0.0)	1/10(10.0)	0/ 1( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P<0.0001**f)			
Prevalence method(d)	P<0.0001**			
Combined analysis (d)	P<0.0001**f)			
Cochran-Armitage test(e)	P<0.0001**			
Fisher Exact test(e)		P=0.5000	P<0.0001**	P<0.0001**

TABLE 12 NEOPLASTIC LESIONS INCIDENCES AND STATISTICAL ANALYSIS IN FEMALE MICE  
IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL (CONTINUED)

Group Name	Control	4ppm	13ppm	40ppm
SITE : nasal cavity				
TUMOR : squamous cell papilloma, squamous cell carcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	1/50( 2.0)	5/49(10.2)
Adjusted rates(b)	0.0	0.0	2.94	100.00
Terminal rates(c)	0/28( 0.0)	0/22( 0.0)	0/10( 0.0)	1/ 1(100.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0078**f)			
Prevalence method(d)	P=0.0005**			
Combined analysis (d)	P<0.0001**			
Cochran-Armitage test(e)	P=0.0006**			
Fisher Exact test(e)		P=N.C.	P=0.5000	P=0.0267*
SITE : nasal cavity				
TUMOR : adenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	0/50( 0.0)	5/49(10.2)
Adjusted rates(b)	0.0	0.0	0.0	100.00
Terminal rates(c)	0/28( 0.0)	0/22( 0.0)	0/10( 0.0)	1/ 1(100.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0851			
Prevalence method(d)	P=0.0003**f)			
Combined analysis (d)	P<0.0001**f)			
Cochran-Armitage test(e)	P=0.0002**			
Fisher Exact test(e)		P=N.C.	P=N.C.	P=0.0267*
SITE : nasal cavity				
TUMOR : hemangioma, hemangiosarcoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	1/50( 2.0)	21/50(42.0)	31/49(63.3)
Adjusted rates(b)	0.0	2.50	46.67	50.00
Terminal rates(c)	0/28( 0.0)	0/22( 0.0)	3/10(30.0)	0/ 1( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P<0.0001**f)			
Prevalence method(d)	P<0.0001**			
Combined analysis (d)	P<0.0001**f)			
Cochran-Armitage test(e)	P<0.0001**			
Fisher Exact test(e)		P=0.5000	P<0.0001**	P<0.0001**
SITE : lung				
TUMOR : bronchiolar-alveolar adenoma				
Tumor rate				
Overall rates(a)	2/50( 4.0)	1/50( 2.0)	1/50( 2.0)	3/49( 6.1)
Adjusted rates(b)	7.14	4.55	7.69	14.29
Terminal rates(c)	2/28( 7.1)	1/22( 4.5)	0/10( 0.0)	0/ 1( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0198*			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.3443			
Fisher Exact test(e)		P=0.5000	P=0.5000	P=0.4903

TABLE 12 NEOPLASTIC LESIONS INCIDENCES AND STATISTICAL ANALYSIS IN FEMALE MICE IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL (CONTINUED)

Group Name	Control	4ppm	13ppm	40ppm
SITE : lung				
TUMOR : bronchiolar-alveolar adenoma, bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	4/50( 8.0)	1/50( 2.0)	3/50( 6.0)	4/49( 8.2)
Adjusted rates(b)	14.29	4.55	15.38	22.22
Terminal rates(c)	4/28(14.3)	1/22( 4.5)	1/10(10.0)	0/ 1( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.3010			
Prevalence method(d)	P=0.0080**			
Combined analysis (d)	P=0.0122*			
Cochran-Armitage test(e)	P=0.5199			
Fisher Exact test(e)		P=0.1811	P=0.5000	P=0.6311
SITE : lymph node				
TUMOR : malignant lymphoma				
Tumor rate				
Overall rates(a)	17/50(34.0)	14/50(28.0)	14/50(28.0)	6/49(12.2)
Adjusted rates(b)	21.43	27.27	31.25	14.29
Terminal rates(c)	6/28(21.4)	6/22(27.3)	3/10(30.0)	0/ 1( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.2409			
Prevalence method(d)	P=0.1526			
Combined analysis (d)	P=0.1378			
Cochran-Armitage test(e)	P=0.0113*			
Fisher Exact test(e)		P=0.3329	P=0.3329	P=0.0094**
SITE : spleen				
TUMOR : malignant lymphoma				
Tumor rate				
Overall rates(a)	4/50( 8.0)	2/50( 4.0)	2/50( 4.0)	1/49( 2.0)
Adjusted rates(b)	10.71	9.09	0.0	0.0
Terminal rates(c)	3/28(10.7)	2/22( 9.1)	0/10( 0.0)	0/ 1( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.2841			
Prevalence method(d)	P=0.8503			
Combined analysis (d)	P=0.4353			
Cochran-Armitage test(e)	P=0.2435			
Fisher Exact test(e)		P=0.3389	P=0.3389	P=0.1874
SITE : uterus				
TUMOR : histiocytic sarcoma				
Tumor rate				
Overall rates(a)	12/50(24.0)	15/50(30.0)	22/50(44.0)	18/49(36.7)
Adjusted rates(b)	17.86	13.64	33.33	13.64
Terminal rates(c)	5/28(17.9)	3/22(13.6)	3/10(30.0)	0/ 1( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P<0.0001**			
Prevalence method(d)	P=0.0371*			
Combined analysis (d)	P<0.0001**			
Cochran-Armitage test(e)	P=0.2466			
Fisher Exact test(e)		P=0.3264	P=0.0283*	P=0.1230

TABLE 12 NEOPLASTIC LESIONS INCIDENCES AND STATISTICAL ANALYSIS IN FEMALE MICE  
IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL (CONTINUED)

Group Name	Control	4ppm	13ppm	40ppm
SITE : mammary gland				
TUMOR : adenocarcinoma				
Tumor rate				
Overall rates(a)	2/50( 4.0)	0/50( 0.0)	5/50(10.0)	4/49( 8.2)
Adjusted rates(b)	7.14	0.0	15.79	22.22
Terminal rates(c)	2/28( 7.1)	0/22( 0.0)	1/10(10.0)	0/ 1( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0264*			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.1639			
Fisher Exact test(e)		P=0.2475	P=0.2180	P=0.3292
SITE : Harderian gland				
TUMOR : adenoma				
Tumor rate				
Overall rates(a)	1/50( 2.0)	1/50( 2.0)	6/50(12.0)	7/49(14.3)
Adjusted rates(b)	3.57	4.55	17.86	25.00
Terminal rates(c)	1/28( 3.6)	1/22( 4.5)	0/10( 0.0)	0/ 1( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0025**			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0094**			
Fisher Exact test(e)		P=0.7525	P=0.0559	P=0.0277*
SITE : ALL SITE				
TUMOR : histiocytic sarcoma				
Tumor rate				
Overall rates(a)	12/50(24.0)	17/50(34.0)	27/50(54.0)	21/49(42.9)
Adjusted rates(b)	17.86	13.64	41.67	18.18
Terminal rates(c)	5/28(17.9)	3/22(13.6)	4/10(40.0)	0/ 1( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P<0.0001**			
Prevalence method(d)	P=0.0123*			
Combined analysis (d)	P<0.0001**			
Cochran-Armitage test(e)	P=0.1075			
Fisher Exact test(e)		P=0.1891	P=0.0019**	P=0.0375*
SITE : ALL SITE				
TUMOR : malignant lymphoma				
Tumor rate				
Overall rates(a)	21/50(42.0)	17/50(34.0)	16/50(32.0)	7/49(14.3)
Adjusted rates(b)	32.14	36.36	31.25	14.29
Terminal rates(c)	9/28(32.1)	8/22(36.4)	3/10(30.0)	0/ 1( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.2430			
Prevalence method(d)	P=0.2629			
Combined analysis (d)	P=0.1855			
Cochran-Armitage test(e)	P=0.0025**			
Fisher Exact test(e)		P=0.2684	P=0.2038	P=0.0020**

- (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.
- f) 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; \*: $P \leq 0.05$  \*\*: $P \leq 0.01$
- N.C. :Statistical value cannot be calculate.
- Significant difference; \*: $P \leq 0.05$  \*\*: $P \leq 0.01$
- N.C. :Statistical value cannot be calculated and was not significant.



TABLE 14 HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC LESIONS  
IN JAPAN BIOASSAY RESEARCH CENTER : Crj:BDF<sub>1</sub> MALE MICE

Organs Tumors	No. of animals examined	No. of tumor- bearing animals	Incidence (%)	Min. - Max. (%)
Subcutis	<1047>			
Histiocytic sarcoma		4	0.4	0 - 4
Nasal cavity	<1047>			
Adenoma		1	0.1	0 - 2
Adenocarcinoma		0	0.0	0 - 0
Squamous cell papilloma		0	0.0	0 - 0
Squamous cell carcinoma		0	0.0	0 - 0
Hemangioma		0	0.0	0 - 0
Hemangiosarcoma		0	0.0	0 - 0
Lung	<1046>			
Bronchiolar-alveolar adenoma		74	7.1	2 - 18
Bronchiolar-alveolar carcinoma		120	11.5	0 - 24
Liver	<1047>			
Hepatocellular adenoma		179	17.1	4 - 34
Hepatocellular carcinoma		224	21.4	2 - 42
Hemangioma		14	1.3	0 - 10
Hemangiosarcoma		50	4.8	0 - 12
Lymph node	<1047>			
Malignant lymphoma		111	10.6	2 - 22
Peripheral nerves	<1047>			
Histiocytic sarcoma		3	0.3	0 - 2
Harderian gland	<1047>			
Adenoma		45	4.3	0 - 10

21 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

TABLE 15 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				
Nasal cavity	<1048>			
Adenoma		0	0.0	0 - 0
Adenocarcinoma		0	0.0	0 - 0
Squamous cell papilloma		0	0.0	0 - 0
Squamous cell carcinoma		0	0.0	0 - 0
Hemangioma		0	0.0	0 - 0
Hemangiosarcoma		0	0.0	0 - 0
Sarcoma NOS+C25		0	0.0	0 - 0
Lung	<1048>			
Bronchiolar-alveolar adenoma		42	4.0	0 - 10
Bronchiolar-alveolar carcinoma		32	3.1	0 - 8
Lymph node	<1048>			
Malignant lymphoma		277	26.4	12 - 44
Uterus	<1046>			
Histiocytic sarcoma		207	19.8	10 - 30
Mammary gland	<1048>			
Adenocarcinoma		16	1.5	0 - 8
Harderian gland	<1048>			
Adenoma		32	3.1	0 - 12

21 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