

グリシドールのラットを用いた
吸入によるがん原性試験報告書

試験番号：0342

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

Weeks on Study	Control		3ppm		10ppm		30ppm								
	Av.Wt.	No.of Surviv. <50>	Av.Wt.	% of cont. <50>	No.of Surviv.	Av.Wt.	% of cont. <50>	No.of Surviv.	Av.Wt.	% of cont. <50>	No.of Surviv.				
0	122	50)	50/50	122	50)	100	50/50	122	50)	100	50/50	122	50)	100	50/50
1	152	50)	50/50	152	50)	100	50/50	152	50)	100	50/50	152	50)	100	50/50
2	180	50)	50/50	180	50)	100	50/50	180	50)	100	50/50	179	50)	99	50/50
3	204	50)	50/50	202	50)	99	50/50	203	50)	100	50/50	201	50)	99	50/50
4	221	50)	50/50	219	50)	99	50/50	219	50)	99	50/50	217	50)	98	50/50
5	242	50)	50/50	238	50)	98	50/50	238	50)	98	50/50	235	50)	97	50/50
6	256	50)	50/50	252	50)	98	50/50	251	50)	98	50/50	249	50)	97	50/50
7	270	50)	50/50	265	50)	98	50/50	264	50)	98	50/50	261	50)	97	50/50
8	280	50)	50/50	276	50)	99	50/50	274	50)	98	50/50	271	50)	97	50/50
9	289	50)	50/50	284	50)	98	50/50	283	50)	98	50/50	279	50)	97	50/50
10	297	50)	50/50	292	50)	98	50/50	291	50)	98	50/50	288	50)	97	50/50
11	304	50)	50/50	299	50)	98	50/50	298	50)	98	50/50	295	50)	97	50/50
12	311	50)	50/50	305	50)	98	50/50	305	50)	98	50/50	300	50)	96	50/50
13	317	50)	50/50	314	50)	99	50/50	312	50)	98	50/50	307	50)	97	50/50
14	324	50)	50/50	319	50)	98	50/50	317	50)	98	50/50	313	50)	97	50/50
18	340	50)	50/50	337	50)	99	50/50	333	50)	98	50/50	328	50)	96	50/50
22	354	50)	50/50	350	50)	99	50/50	347	50)	98	50/50	341	50)	96	50/50
26	368	50)	50/50	365	50)	99	50/50	359	50)	98	50/50	351	50)	95	50/50
30	378	50)	50/50	376	50)	99	50/50	368	50)	97	50/50	360	50)	95	50/50
34	387	50)	50/50	385	50)	99	50/50	378	50)	98	50/50	370	50)	96	50/50
38	393	50)	50/50	393	50)	100	50/50	384	50)	98	50/50	377	50)	96	50/50
42	401	50)	50/50	400	50)	100	50/50	391	50)	98	50/50	385	50)	96	50/50
46	406	50)	50/50	405	50)	100	50/50	395	50)	97	50/50	390	50)	96	50/50
50	412	50)	50/50	411	50)	100	50/50	402	50)	98	50/50	397	50)	96	50/50
54	416	50)	50/50	415	50)	100	50/50	407	50)	98	50/50	401	50)	96	50/50
58	420	50)	50/50	417	49)	99	49/50	409	50)	97	50/50	404	50)	96	50/50
62	422	50)	50/50	420	49)	100	49/50	411	50)	97	50/50	402	50)	95	50/50
66	423	50)	50/50	419	49)	99	49/50	411	50)	97	50/50	401	50)	95	50/50
70	427	49)	49/50	421	48)	99	48/50	414	50)	97	50/50	400	48)	94	48/50
74	427	49)	49/50	419	48)	98	48/50	415	50)	97	50/50	395	47)	93	47/50
78	426	49)	49/50	423	46)	99	46/50	413	50)	97	50/50	389	46)	91	46/50
82	422	47)	47/50	421	46)	100	46/50	408	48)	97	48/50	393	44)	93	43/50
86	421	46)	46/50	423	46)	100	46/50	408	47)	97	46/50	386	42)	92	42/50
90	419	46)	46/50	419	44)	100	44/50	406	46)	97	46/50	376	39)	90	39/50
94	413	44)	44/50	415	43)	100	43/50	403	44)	98	44/50	370	37)	90	36/50
98	412	42)	42/50	415	42)	101	42/50	395	42)	96	42/50	349	33)	85	31/50
102	406	40)	40/50	413	42)	102	42/50	395	39)	97	39/50	347	26)	85	25/50
104	401	40)	40/50	411	42)	102	42/50	392	38)	98	38/50	336	23)	84	23/50

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

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

Weeks on Study	Control			3ppm			10ppm			30ppm		
	Av.Wt.	No.of Surviv. <50>		Av.Wt.	% of cont. <50>	No.of Surviv.	Av.Wt.	% of cont. <49>	No.of Surviv.	Av.Wt.	% of cont. <50>	No.of Surviv.
0	96 50)	50/50		96 50)	100	50/50	96 49)	100	50/50	96 50)	100	50/50
1	110 50)	50/50		109 50)	99	50/50	110 49)	100	50/50	110 50)	100	50/50
2	122 50)	50/50		122 50)	100	50/50	122 49)	100	50/50	121 50)	99	50/50
3	133 50)	50/50		132 50)	99	50/50	132 49)	99	50/50	132 50)	99	50/50
4	139 50)	50/50		138 50)	99	50/50	138 49)	99	50/50	137 50)	99	50/50
5	150 50)	50/50		148 50)	99	50/50	148 49)	99	50/50	147 50)	98	50/50
6	156 50)	50/50		154 50)	99	50/50	153 49)	98	50/50	152 50)	97	50/50
7	162 50)	50/50		159 50)	98	50/50	158 49)	98	50/50	157 50)	97	50/50
8	165 50)	50/50		161 50)	98	50/50	161 49)	98	50/50	159 50)	96	50/50
9	170 50)	50/50		166 50)	98	50/50	166 49)	98	50/50	164 50)	96	50/50
10	176 50)	50/50		172 50)	98	50/50	171 49)	97	49/49	168 50)	95	50/50
11	180 50)	50/50		175 50)	97	50/50	174 49)	97	49/49	171 50)	95	50/50
12	182 50)	50/50		178 50)	98	50/50	176 49)	97	49/49	173 50)	95	50/50
13	185 50)	50/50		182 50)	98	50/50	180 49)	97	49/49	177 50)	96	50/50
14	188 50)	50/50		182 50)	97	50/50	182 49)	97	49/49	179 50)	95	50/50
18	192 50)	50/50		188 50)	98	50/50	185 49)	96	49/49	183 50)	95	50/50
22	197 50)	50/50		195 50)	99	50/50	190 49)	96	49/49	188 50)	95	50/50
26	205 50)	50/50		204 50)	100	50/50	198 49)	97	49/49	195 50)	95	50/50
30	211 50)	50/50		209 50)	99	50/50	203 49)	96	49/49	200 50)	95	50/50
34	216 50)	50/50		215 50)	100	50/50	208 49)	96	49/49	206 50)	95	50/50
38	217 50)	50/50		216 50)	100	50/50	211 49)	97	49/49	206 50)	95	50/50
42	221 50)	50/50		220 50)	100	50/50	214 49)	97	49/49	211 50)	95	50/50
46	224 50)	50/50		225 50)	100	50/50	219 49)	98	49/49	215 50)	96	50/50
50	227 50)	50/50		230 50)	101	50/50	222 49)	98	49/49	220 50)	97	50/50
54	232 50)	50/50		234 50)	101	50/50	228 49)	98	49/49	225 50)	97	50/50
58	234 50)	50/50		235 50)	100	50/50	230 49)	98	49/49	226 50)	97	50/50
62	240 49)	49/50		239 50)	100	50/50	233 47)	97	47/49	229 50)	95	50/50
66	243 49)	49/50		244 50)	100	50/50	238 47)	98	47/49	235 50)	97	50/50
70	246 48)	48/50		250 50)	102	50/50	244 47)	99	47/49	239 50)	97	50/50
74	250 47)	47/50		254 49)	102	49/50	247 47)	99	47/49	240 49)	96	49/50
78	254 47)	47/50		259 49)	102	49/50	252 47)	99	47/49	243 47)	96	47/50
82	258 46)	46/50		262 48)	102	48/50	256 47)	99	47/49	249 45)	97	45/50
86	262 46)	46/50		266 48)	102	48/50	262 47)	100	47/49	252 45)	96	45/50
90	266 45)	45/50		267 44)	100	43/50	267 45)	100	45/49	256 43)	96	43/50
94	266 45)	45/50		270 42)	102	41/50	267 45)	100	45/49	256 40)	96	40/50
98	269 42)	42/50		274 38)	102	38/50	266 43)	99	43/49	254 35)	94	34/50
102	270 41)	41/50		272 38)	101	38/50	267 40)	99	39/49	255 33)	94	33/50
104	267 41)	41/50		271 38)	101	38/50	271 39)	101	39/49	251 32)	94	32/50

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

TABLE 3 INCIDENCE OF EXTERNAL AND INTERNAL MASS IN CLINICAL OBSERVATION OF MALE RATS 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	1/50	3/50	5/50	6/50	6/48	12/45	16/50 (4/10)
3ppm	0/50	0/50	0/50	0/50	2/50	8/49	8/46	11/43	15/50 (3/8)
10ppm	0/50	0/50	0/50	2/50	4/50	6/50	11/50	11/44	16/50 (6/12)
30ppm	0/50	0/50	0/50	0/50	3/50	11/50	12/46	22/38	29/50 (15/27)
Internal mass									
0ppm	0/50	0/50	0/50	0/50	0/50	1/50	2/48	3/45	6/50 (5/10)
3ppm	0/50	0/50	0/50	0/50	0/50	0/49	0/46	0/43	0/50 (0/8)
10ppm	0/50	0/50	0/50	0/50	0/50	0/50	0/50	1/44	1/50 (0/12)
30ppm	0/50	0/50	0/50	0/50	0/50	0/50	0/46	2/38	2/50 (1/27)

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 RATS 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	3/49	5/47	7/45	10/50 (1/9)
3ppm	0/50	0/50	0/50	0/50	0/50	0/50	4/48	7/43	7/50 (2/12)
10ppm	0/50	0/49	0/49	0/49	1/49	1/47	6/47	17/45	20/49 (5/10)
30ppm	0/50	0/50	0/50	1/50	2/50	4/50	10/46	22/42	23/50 (8/18)
Internal mass									
0ppm	0/50	0/50	0/50	0/50	0/50	1/49	2/47	1/45	2/50 (2/9)
3ppm	0/50	0/50	0/50	0/50	0/50	0/50	1/48	2/43	3/50 (1/12)
10ppm	0/50	0/49	0/49	0/49	0/49	0/47	1/47	6/45	7/49 (5/10)
30ppm	0/50	0/50	0/50	0/50	0/50	1/50	2/46	5/42	8/50 (5/18)

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 RATS
IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

Weeks on Study	Control		3ppm			10ppm			30ppm		
	Av.FC.		Av.FC.	% of							
	<50>		<50>	cont.	<50>	cont.	<50>	cont.	<50>	cont.	
1	15.2	(50)	15.4	(50)	101	15.3	(50)	101	15.1	(50)	99
2	15.8	(50)	16.1	(50)	102	16.0	(50)	101	16.1	(50)	102
3	16.9	(50)	17.0	(50)	101	16.9	(50)	100	17.5	(50)	104
4	17.5	(50)	17.1	(50)	98	17.1	(50)	98	17.2	(50)	98
5	17.3	(50)	16.8	(50)	97	16.8	(50)	97	17.1	(50)	99
6	17.1	(50)	16.5	(50)	96	16.3	(50)	95	16.9	(50)	99
7	17.6	(50)	16.9	(50)	96	17.0	(50)	97	17.1	(50)	97
8	17.4	(50)	16.8	(50)	97	16.8	(50)	97	17.1	(50)	98
9	17.1	(50)	16.6	(50)	97	16.6	(50)	97	16.6	(50)	97
10	16.8	(50)	16.4	(50)	98	16.1	(50)	96	16.1	(50)	96
11	16.8	(50)	16.2	(50)	96	16.0	(50)	95	16.5	(50)	98
12	16.4	(50)	15.7	(50)	96	16.1	(50)	98	16.2	(50)	99
13	16.6	(50)	16.2	(50)	98	16.2	(50)	98	16.2	(50)	98
14	16.7	(50)	16.0	(50)	96	16.0	(50)	96	15.9	(50)	95
18	16.4	(50)	16.4	(50)	100	16.2	(50)	99	15.9	(50)	97
22	16.4	(50)	16.2	(50)	99	16.2	(50)	99	16.1	(50)	98
26	16.8	(50)	16.6	(50)	99	16.7	(50)	99	16.4	(50)	98
30	16.4	(50)	16.3	(50)	99	16.2	(50)	99	16.3	(50)	99
34	16.9	(50)	16.7	(50)	99	16.7	(50)	99	16.5	(50)	98
38	17.2	(50)	17.2	(50)	100	16.9	(50)	98	16.7	(50)	97
42	17.4	(50)	17.3	(50)	99	17.0	(50)	98	17.1	(50)	98
46	17.1	(50)	17.0	(50)	99	16.7	(50)	98	16.9	(50)	99
50	17.4	(50)	17.2	(50)	99	16.9	(50)	97	16.9	(50)	97
54	17.4	(50)	17.4	(50)	100	17.0	(50)	98	17.1	(50)	98
58	17.5	(50)	17.3	(49)	99	16.8	(50)	96	16.7	(50)	95
62	17.8	(50)	17.6	(49)	99	17.1	(50)	96	16.9	(50)	95
66	17.8	(50)	17.7	(49)	99	17.3	(50)	97	17.0	(50)	96
70	17.9	(49)	17.8	(48)	99	17.4	(50)	97	16.8	(48)	94
74	17.8	(49)	17.4	(48)	98	17.2	(50)	97	16.6	(47)	93
78	17.9	(49)	17.6	(46)	98	17.2	(50)	96	16.7	(46)	93
82	17.9	(47)	17.9	(46)	100	16.7	(48)	93	16.7	(44)	93
86	17.3	(46)	17.4	(46)	101	16.9	(46)	98	15.8	(42)	91
90	17.1	(46)	17.0	(44)	99	16.4	(46)	96	16.2	(39)	95
94	16.1	(44)	16.9	(43)	105	16.3	(43)	101	16.1	(37)	100
98	17.2	(42)	17.7	(42)	103	16.5	(42)	96	14.7	(33)	85
102	17.4	(39)	18.3	(42)	105	17.0	(39)	98	16.2	(25)	93
104	17.2	(39)	18.1	(42)	105	16.9	(37)	98	16.2	(23)	94

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

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

Weeks on Study	Control		3ppm			10ppm			30ppm		
	Av.FC.		Av.FC.	% of cont.							
	<50>	(50)	<50>	(50)	<49>	(49)	<50>	(50)	<50>	(50)	
1	11.0	(50)	11.3	(50)	103	11.1	(49)	101	11.0	(50)	100
2	10.8	(50)	10.5	(50)	97	10.7	(49)	99	10.7	(50)	99
3	11.3	(50)	11.4	(50)	101	11.4	(49)	101	11.6	(50)	103
4	11.7	(50)	11.4	(50)	97	11.5	(49)	98	11.3	(50)	97
5	11.8	(50)	11.6	(50)	98	11.6	(49)	98	11.6	(50)	98
6	11.5	(50)	11.2	(50)	97	11.0	(49)	96	11.2	(50)	97
7	11.9	(50)	11.4	(50)	96	11.3	(49)	95	11.2	(50)	94
8	10.9	(50)	10.8	(50)	99	10.9	(49)	100	10.5	(50)	96
9	11.8	(50)	11.4	(50)	97	11.1	(49)	94	11.0	(50)	93
10	12.1	(50)	11.8	(50)	98	11.1	(49)	92	10.9	(50)	90
11	12.2	(50)	11.5	(50)	94	11.2	(49)	92	11.1	(50)	91
12	11.5	(50)	11.1	(50)	97	11.3	(49)	98	11.1	(50)	97
13	11.6	(50)	11.6	(50)	100	11.4	(49)	98	11.2	(50)	97
14	11.7	(50)	11.1	(50)	95	11.3	(49)	97	10.9	(50)	93
18	11.2	(50)	11.2	(50)	100	10.6	(49)	95	10.9	(50)	97
22	11.2	(50)	11.2	(50)	100	10.8	(49)	96	10.7	(50)	96
26	11.6	(50)	11.9	(50)	103	11.5	(49)	99	11.3	(50)	97
30	11.6	(50)	11.6	(50)	100	11.0	(49)	95	11.2	(50)	97
34	11.7	(50)	12.1	(50)	103	11.8	(49)	101	11.8	(50)	101
38	11.8	(50)	11.9	(50)	101	11.6	(49)	98	11.2	(50)	95
42	11.8	(50)	11.8	(50)	100	11.4	(49)	97	11.5	(50)	97
46	11.8	(50)	12.2	(50)	103	11.8	(49)	100	11.6	(50)	98
50	12.1	(50)	12.3	(50)	102	11.8	(49)	98	12.0	(50)	99
54	11.9	(50)	12.1	(50)	102	11.9	(49)	100	11.7	(50)	98
58	12.0	(50)	11.9	(50)	99	11.6	(49)	97	11.6	(50)	97
62	12.6	(49)	12.4	(50)	98	11.7	(47)	93	11.5	(50)	91
66	12.7	(49)	12.8	(50)	101	12.4	(47)	98	12.4	(50)	98
70	13.0	(48)	13.1	(50)	101	12.8	(47)	98	12.3	(50)	95
74	12.8	(47)	12.5	(49)	98	12.2	(47)	95	11.8	(49)	92
78	12.8	(47)	12.8	(49)	100	12.5	(47)	98	12.0	(47)	94
82	12.9	(46)	12.9	(48)	100	12.5	(47)	97	12.4	(45)	96
86	12.9	(46)	12.4	(48)	96	12.7	(47)	98	12.2	(45)	95
90	12.7	(45)	12.1	(44)	95	12.5	(45)	98	12.1	(43)	95
94	12.2	(45)	12.1	(42)	99	12.0	(45)	98	11.7	(40)	96
98	13.0	(42)	13.0	(38)	100	12.6	(43)	97	12.6	(35)	97
102	13.4	(41)	13.2	(38)	99	12.8	(40)	96	12.3	(33)	92
104	12.9	(41)	12.7	(38)	98	13.1	(39)	102	11.9	(32)	92

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

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

Group Name	Control	3 ppm	10 ppm	30 ppm	
No. of examined animals	40	42	38	23	
Body weight (g)	376 ± 50	384 ± 52	365 ± 48	313 ± 36	**
Adrenals (g)	0.081 ± 0.024	0.078 ± 0.013	0.079 ± 0.015	0.076 ± 0.011	
Adrenals (%)	0.022 ± 0.007	0.021 ± 0.004	0.022 ± 0.005	0.025 ± 0.006	*
Testes (g)	3.360 ± 1.462	3.577 ± 1.744	4.051 ± 1.426	4.043 ± 1.752	
Testes (%)	0.917 ± 0.421	0.943 ± 0.480	1.140 ± 0.464	1.282 ± 0.514	**
Heart (g)	1.167 ± 0.098	1.190 ± 0.107	1.179 ± 0.121	1.177 ± 0.110	
Heart (%)	0.313 ± 0.031	0.314 ± 0.045	0.325 ± 0.027	0.382 ± 0.063	**
Lung (g)	1.421 ± 0.171	1.391 ± 0.104	1.400 ± 0.135	1.493 ± 0.306	
Lung (%)	0.381 ± 0.050	0.367 ± 0.046	0.387 ± 0.035	0.482 ± 0.107	**
Kidneys (g)	2.680 ± 0.224	2.701 ± 0.240	2.681 ± 0.275	2.779 ± 0.365	
Kidneys (%)	0.720 ± 0.080	0.711 ± 0.079	0.741 ± 0.080	0.898 ± 0.150	**
Liver (g)	11.254 ± 2.244	11.201 ± 1.654	10.938 ± 1.569	10.865 ± 1.906	
Liver (%)	3.013 ± 0.601	2.937 ± 0.403	3.009 ± 0.370	3.488 ± 0.621	**
Brain (g)	1.955 ± 0.050	1.957 ± 0.061	1.940 ± 0.057	1.932 ± 0.070	
Brain (%)	0.527 ± 0.055	0.516 ± 0.052	0.539 ± 0.063	0.626 ± 0.084	**

Mean ± S.D.

Significant difference: * : p<0.05 ** : p<0.01 Test of Dunnett

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

Group Name	Control	3 ppm	10 ppm	30 ppm	
No. of examined animals	41	38	39	32	
Body weight (g)	249 ± 25	251 ± 22	252 ± 25	235 ± 22	*
Kidneys (g)	1.721 ± 0.112	1.797 ± 0.270	1.788 ± 0.147	1.874 ± 0.167	**
Kidneys (%)	0.698 ± 0.067	0.723 ± 0.141	0.713 ± 0.060	0.803 ± 0.096	**
Spleen (g)	0.628 ± 0.840	0.611 ± 0.500	0.648 ± 0.972	0.836 ± 0.935	*
Spleen (%)	0.252 ± 0.326	0.248 ± 0.222	0.255 ± 0.368	0.362 ± 0.410	*
Heart (g)	0.834 ± 0.067	0.836 ± 0.054	0.838 ± 0.061	0.854 ± 0.075	
Heart (%)	0.338 ± 0.033	0.335 ± 0.029	0.335 ± 0.024	0.366 ± 0.050	**
Lung (g)	1.014 ± 0.176	0.990 ± 0.071	0.978 ± 0.071	1.055 ± 0.187	
Lung (%)	0.411 ± 0.074	0.397 ± 0.038	0.391 ± 0.038	0.453 ± 0.100	*
Liver (g)	6.434 ± 1.080	6.695 ± 0.890	6.507 ± 0.880	6.593 ± 0.933	
Liver (%)	2.596 ± 0.392	2.683 ± 0.367	2.583 ± 0.225	2.817 ± 0.423	**
Brain (g)	1.792 ± 0.057	1.785 ± 0.057	1.790 ± 0.050	1.797 ± 0.048	
Brain (%)	0.728 ± 0.079	0.717 ± 0.061	0.717 ± 0.068	0.771 ± 0.075	*

Mean ± S.D.

Significant difference: * : p<0.05 ** : p<0.01 Test of Dunnett

TABLE 9 INCIDENCES OF SELECTED LESIONS OF MALE RATS
IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

Group		Control	3ppm	10ppm	30ppm	Peto	Cochran-
Number of examined animals		50	50	50	50		Armitage
Organ	Grade of Nonneoplastic lesion						
Findings							
Skin/Appendage							
Squamous cell papilloma		0	0	1	3	**	
Subcutis							
Fibroma		10	2 *	10	9		
Nasal cavity							
Inflammation: transitional epithelium	+	9	15	3	0 **		
Hyperplasia: transitional epithelium	+	0	0	11 **	5 *		
	2+	0	0	0	1		
Hyperplasia with atypia: transitional epithelium	+	0	0	3	4		
Inflammation: respiratory epithelium	+	7	6	5	9 **		
	2+	0	0	1	23		
Necrosis: respiratory epithelium	+	0	0	1	4		
	2+	0	0	0	2		
	3+	0	0	0	1		
Hyperplasia: respiratory epithelium	+	0	0	0	6 *		
	2+	0	0	0	1		
Hyperplasia with atypia: respiratory epithelium	+	0	0	0	5		
Squamous cell metaplasia: respiratory epithelium	+	1	2	3	1		
	2+	0	0	0	0		
	3+	0	0	0	1		
Squamous cell metaplasia with atypia: respiratory epithelium	+	0	1	5	9 **		
	2+	0	0	0	38		
Squamous cell hyperplasia	+	0	0	0	2		
	2+	0	0	0	2		
Squamous cell hyperplasia with atypia	+	0	0	0	15 **		
	2+	0	0	0	15		
Hyperplasia with atypia: nasal gland	2+	0	0	0	3		
Necrosis: olfactory epithelium	+	0	1	0	3		
Atrophy: olfactory epithelium	+	0	0	0	11 *		
Eosinophilic change: olfactory epithelium	+	24	28	19	33 **		
	2+	17	15	16	2		
	3+	3	2	5	0		
Thickening of bone: turbinate	+	0	3	24 **	15 **		
	2+	0	0	14	6		
Adenoma 1)		0	0	3	5 *	**	**
Adenocarcinoma 2)		0	0	0	1		
1) +2)		0	0	3	6 *	**	**
Squamous cell carcinoma		0	0	0	14 **	**	**
Basal cell carcinoma		0	0	0	1		
Bone marrow							
Erythropoiesis: increased	+	0	3	3	5 **		
	2+	3	1	4	8		

TABLE 9 INCIDENCES OF SELECTED LESIONS OF MALE RATS
 IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL (CONTINUED)

Group		Control	3ppm	10ppm	30ppm	Peto	Cochran-
Number of examined animals		50	50	50	50		Armitage
Organ	Grade of Nonneoplastic lesion						
Findings							
Spleen							
Deposit of hemosiderin	+	17	4 **	2 **	9		
	2+	1	0	0	1		
Extramedullary hematopoiesis	+	18	29	23	19 *		
	2+	3	2	7	9		
	3+	1	3	3	6		
Fibrosis	+	0	5	3	10 **		
	2+	0	0	0	0		
	3+	0	0	0	1		
Heart							
Myocardial fibrosis	+	18	34 **	29	35 **		
	2+	28	15	16	9		
Liver							
Acidophilic cell focus	+	6	16	4	5		
	2+	1	1	1	0		
Basophilic cell focus	+	3	21 **	16 **	3		
	2+	1	0	2	1		
Hepatocellular adenoma		0	2	1	0		
Hepatocellular carcinoma		1	0	0	0		
Pancreas							
Islet cell adenoma 1)		4	0	1	2		
Islet cell adenocarcinoma 2)		2	0	0	0		
1)+2)		6	0 *	1	2		
Pituitary							
Hyperplasia	+	11	7	6	1 **		
	2+	2	2	5	1		
Thyroid							
Follicular adenoma 1)		0	1	2	0		
Follicular adenocarcinoma 2)		0	1	0	4	**	**
1)+2)		0	2	2	4	*	
Testis							
Interstitial cell tumor		41	37	44	47	**	*
Mammary gland							
Adenoma 1)		0	0	0	1		
Fibroadenoma 2)		0	0	0	6 *	**	**
1)+2)		0	0	0	7 **	**	**
Eye							
Retinal atrophy	+	45	46	40	34 **		
	2+	0	0	0	0		
	3+	2	0	1	2		
Peritoneum							
Mesothelioma		2	3	12 **	22 **	**	**
Grade		+: Slight	2+: Moderate	3+: Marked	4+: Severe		
Significant difference		* : p<0.05		** : p<0.01		Chi square test	

TABLE 10 INCIDENCES OF SELECTED LESIONS OF FEMALE RATS
IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

Group		Control	3ppm	10ppm	30ppm	Peto	Cochran-
Number of examined animals		50	50	49	50		Armitage
Organ	Grade of Nonneoplastic lesion						
Findings							
Nasal cavity							
Inflammation:	+	6	16 *	13	7		
transitional epithelium	2+	1	0	0	0		
Hyperplasia: transitional	+	0	2	8 **	13 **		
epithelium	2+	0	0	0	2		
Hyperplasia with atypia:	+	0	0	0	4		
transitional epithelium							
Inflammation:	+	1	1	3	21 **		
respiratory epithelium	2+	0	0	0	5		
Necrosis: respiratory epithelium	+	0	0	2	3		
	2+	0	0	0	1		
Squamous cell metaplasia:	+	0	0	2	6 *		
respiratory epithelium							
Squamous cell metaplasia with	+	0	0	2	10 **		
atypia: respiratory epithelium	2+	0	0	0	26		
Squamous cell hyperplasia	+	0	0	0	3		
Squamous cell hyperplasia with	+	0	0	0	8 **		
atypia	2+	0	0	0	2		
Eosinophilic change:	+	36	36	37	27 *		
respiratory epithelium	2+	6	2	1	2		
Hyperplasia: nasal gland	+	0	0	0	1		
Hyperplasia with atypia:	+	0	0	0	1		
nasal gland							
Necrosis: olfactory epithelium	+	0	0	0	2		
Atrophy: olfactory epithelium	+	0	0	0	12 **		
	2+	0	0	0	1		
Eosinophilic change:	+	10	1 **	2 *	9		
olfactory epithelium	2+	29	18	27	37		
	3+	10	30	20	3		
Thickening of bone: turbinate	+	0	0	17 **	20 **		
	2+	0	0	0	22		
Mineralization	+	43	13 **	21 **	38		
Adenoma 1)		0	0	4	8 **	**	**
Adenocarcinoma 2)		0	0	0	2		
1) +2)		0	0	4	10 **	**	**
Squamous cell carcinoma		0	0	0	2		
Nasolacrimal duct							
Inflammation	+	22	13	8 **	4 **		
	2+	6	6	0	0		
Spleen							
Deposit of hemosiderin	+	40	41	41	28 *		
	2+	0	0	1	0		

TABLE 10 INCIDENCES OF SELECTED LESIONS OF FEMALE RATS
 IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL (CONTINUED)

Group		Control	3ppm	10ppm	30ppm	Peto	Cochran-
Number of examined animals		50	50	49	50		Armitage
Organ	Grade of Nonneoplastic lesion						
Findings							
Mononuclear cell leukemia		3	3	1	8	**	*
Liver							
Granulation	+	28	22	23	12 **		
	2+	2	6	4	4		
	3+	0	1	0	0		
Herniation	+	15	4 *	14	4 *		
Kidney							
Mineralization: pelvis	+	9	2	1 *	2		
Adrenal							
Peliosis-like lesion	+	23	28	29 *	27 **		
	2+	19	11	7	6		
	3+	1	0	0	0		
Focal fatty change: cortex	+	8	12	11	10 *		
	2+	2	1	6	10		
	3+	0	0	0	1		
Pheochromocytoma 1)		3	3	1	0		
Pheochromocytoma: malignant 2)		0	2	0	0		
1)+2)		3	5	1	0		*
Uterus							
Endometrial stromal polyp		6	11	11	13	*	
Endometrial stromal sarcoma		1	4	4	7 *	*	*
Mammary gland							
Adenoma 1)		2	1	3	2		
Fibroadenoma 2)		8	6	18 *	17 *	**	*
Adenocarcinoma 3)		2	1	1	2		
1)+2)		10	7	20 *	17	*	*
1)+2)+3)		10	8	21 *	19 *	**	*
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 RATS
IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

Group Name	Control	3ppm	10ppm	30ppm
SITE : skin/appendage				
TUMOR : squamous cell papilloma				
Tumor rate				
Overall rates(a)	0/50(0.0)	0/50(0.0)	1/50(2.0)	3/50(6.0)
Adjusted rates(b)	0.0	0.0	2.63	8.70
Terminal rates(c)	0/40(0.0)	0/42(0.0)	1/38(2.6)	2/23(8.7)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0069**			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0138*			
Fisher Exact test(e)		P=N.C.	P=0.5000	P=0.1212
SITE : nasal cavity				
TUMOR : adenoma				
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	7.89	17.39
Terminal rates(c)	0/40(0.0)	0/42(0.0)	3/38(7.9)	4/23(17.4)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0006**			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0037**			
Fisher Exact test(e)		P=N.C.	P=0.1212	P=0.0281*
SITE : nasal cavity				
TUMOR : squamous cell carcinoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	0/50(0.0)	0/50(0.0)	14/50(28.0)
Adjusted rates(b)	0.0	0.0	0.0	34.78
Terminal rates(c)	0/40(0.0)	0/42(0.0)	0/38(0.0)	8/23(34.8)
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=N.C.	P=N.C.	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)	6/50(12.0)
Adjusted rates(b)	0.0	0.0	7.89	21.74
Terminal rates(c)	0/40(0.0)	0/42(0.0)	3/38(7.9)	5/23(21.7)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P<0.0001**			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P<0.0010**			
Fisher Exact test(e)		P=N.C.	P=0.1212	P=0.0133*

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

Group Name	Control	3ppm	10ppm	30ppm
SITE : lung				
TUMOR : bronchiolar-alveolar adenoma				
Tumor rate				
Overall rates(a)	2/50(4.0)	4/50(8.0)	5/50(10.0)	3/50(6.0)
Adjusted rates(b)	4.76	8.33	13.16	10.34
Terminal rates(c)	1/40(2.5)	3/42(7.1)	5/38(13.2)	2/23(8.7)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.3220			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.9716			
Fisher Exact test(e)		P=0.3389	P=0.2180	P=0.5000
SITE : lung				
TUMOR : bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	4/50(8.0)	3/50(6.0)	2/50(4.0)	0/50(0.0)
Adjusted rates(b)	10.00	4.76	2.63	0.0
Terminal rates(c)	4/40(10.0)	2/42(4.8)	1/38(2.6)	0/23(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.5903			
Prevalence method(d)	P=0.9683			
Combined analysis (d)	P=0.9624			
Cochran-Armitage test(e)	P=0.0481*			
Fisher Exact test(e)		P=0.5000	P=0.3389	P=0.0587
SITE : lung				
TUMOR : bronchiolar-alveolar adenoma, bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	6/50(12.0)	7/50(14.0)	7/50(14.0)	3/50(6.0)
Adjusted rates(b)	14.29	12.77	15.79	10.34
Terminal rates(c)	5/40(12.5)	5/42(11.9)	6/38(15.8)	2/23(8.7)
Statistical analysis				
Peto test				
Standard method(d)	P=0.5903			
Prevalence method(d)	P=0.7406			
Combined analysis (d)	P=0.7756			
Cochran-Armitage test(e)	P=0.2091			
Fisher Exact test(e)		P=0.5000	P=0.5000	P=0.2435
SITE : thyroid				
TUMOR : follicular adenocarcinoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	1/50(2.0)	0/50(0.0)	4/50(8.0)
Adjusted rates(b)	0.0	2.38	0.0	14.29
Terminal rates(c)	0/40(0.0)	1/42(2.4)	0/38(0.0)	3/23(13.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0014**			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0073**			
Fisher Exact test(e)		P=0.5000	P=N.C.	P=0.0587

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

Group Name	Control	3ppm	10ppm	30ppm
SITE : thyroid				
TUMOR : follicular adenoma, follicular adenocarcinoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	2/50(4.0)	2/50(4.0)	4/50(8.0)
Adjusted rates(b)	0.0	4.76	5.26	14.29
Terminal rates(c)	0/40(0.0)	2/42(4.8)	2/38(5.3)	3/23(13.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0114*			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0640			
Fisher Exact test(e)		P=0.2475	P=0.2475	P=0.0587
SITE : testis				
TUMOR : interstitial cell tumor				
Tumor rate				
Overall rates(a)	41/50(82.0)	37/50(74.0)	44/50(88.0)	47/50(94.0)
Adjusted rates(b)	90.91	80.95	97.44	97.30
Terminal rates(c)	36/40(90.0)	34/42(81.0)	37/38(97.4)	22/23(95.7)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0001**			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0159*			
Fisher Exact test(e)		P=0.2348	P=0.2883	P=0.0606
SITE : mammary gland				
TUMOR : fibroadenoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	0/50(0.0)	0/50(0.0)	6/50(12.0)
Adjusted rates(b)	0.0	0.0	0.0	16.67
Terminal rates(c)	0/40(0.0)	0/42(0.0)	0/38(0.0)	3/23(13.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0805			
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=N.C.	P=N.C.	P=0.0133*
SITE : mammary gland				
TUMOR : fibroadenoma, adenoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	0/50(0.0)	0/50(0.0)	7/50(14.0)
Adjusted rates(b)	0.0	0.0	0.0	20.00
Terminal rates(c)	0/40(0.0)	0/42(0.0)	0/38(0.0)	4/23(17.4)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0805			
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=N.C.	P=N.C.	P=0.0062**

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

Group Name	Control	3ppm	10ppm	30ppm
SITE : peritoneum				
TUMOR : mesothelioma				
Tumor rate				
Overall rates(a)	2/50(4.0)	3/50(6.0)	12/50(24.0)	22/50(44.0)
Adjusted rates(b)	5.00	4.76	25.00	32.00
Terminal rates(c)	2/40(5.0)	2/42(4.8)	9/38(23.7)	7/23(30.4)
Statistical analysis				
Peto test				
Standard method(d)	P<0.0001**			
Prevalence method(d)	P=0.0003**			
Combined analysis (d)	P<0.0001**			
Cochran-Armitage test(e)	P<0.0001**			
Fisher Exact test(e)		P=0.5000	P=0.0038**	P<0.0001**

(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 RATS IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

Group Name	Control	3ppm	10ppm	30ppm
SITE : nasal cavity				
TUMOR : adenoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	0/50(0.0)	4/49(8.2)	8/50(16.0)
Adjusted rates(b)	0.0	0.0	9.52	21.21
Terminal rates(c)	0/41(0.0)	0/38(0.0)	3/39(7.7)	6/32(18.8)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0001**			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0001**			
Fisher Exact test(e)		P=N.C.	P=0.0563	P=0.0029**
SITE : nasal cavity				
TUMOR : adenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	0/50(0.0)	4/49(8.2)	10/50(20.0)
Adjusted rates(b)	0.0	0.0	9.52	21.43
Terminal rates(c)	0/41(0.0)	0/38(0.0)	3/39(7.7)	6/32(18.8)
Statistical analysis				
Peto test				
Standard method(d)	P=0.1407			
Prevalence method(d)	P<0.0001**			
Combined analysis (d)	P<0.0001**			
Cochran-Armitage test(e)	P<0.0001**			
Fisher Exact test(e)		P=N.C.	P=0.0563	P=0.0006**
SITE : spleen				
TUMOR : mononuclear cell leukemia				
Tumor rate				
Overall rates(a)	3/50(6.0)	3/50(6.0)	1/49(2.0)	8/50(16.0)
Adjusted rates(b)	4.88	2.63	0.0	12.50
Terminal rates(c)	2/41(4.9)	1/38(2.6)	0/39(0.0)	4/32(12.5)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0599			
Prevalence method(d)	P=0.0398*			
Combined analysis (d)	P=0.0097**			
Cochran-Armitage test(e)	P=0.0252*			
Fisher Exact test(e)		P=0.6611	P=0.3163	P=0.0999
SITE : adrenal gland				
TUMOR : pheochromocytoma				
Tumor rate				
Overall rates(a)	3/50(6.0)	3/50(6.0)	1/49(2.0)	0/50(0.0)
Adjusted rates(b)	7.32	7.89	2.56	0.0
Terminal rates(c)	3/41(7.3)	3/38(7.9)	1/39(2.6)	0/32(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.9717			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0647			
Fisher Exact test(e)		P=0.6611	P=0.3163	P=0.1212

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

Group Name	Control	3ppm	10ppm	30ppm
SITE : adrenal gland				
TUMOR : pheochromocytoma, pheochromocytoma: malignant				
Tumor rate				
Overall rates(a)	3/50(6.0)	5/50(10.0)	1/49(2.0)	0/50(0.0)
Adjusted rates(b)	7.32	10.53	2.56	0.0
Terminal rates(c)	3/41(7.3)	4/38(10.5)	1/39(2.6)	0/32(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.5280			
Prevalence method(d)	P=0.9796			
Combined analysis (d)	P=0.9855			
Cochran-Armitage test(e)	P=0.0367*			
Fisher Exact test(e)		P=0.3575	P=0.3163	P=0.1212
SITE : uterus				
TUMOR : endometrial stromal polyp				
Tumor rate				
Overall rates(a)	6/50(12.0)	11/50(22.0)	11/49(22.4)	13/50(26.0)
Adjusted rates(b)	14.63	26.19	26.83	34.29
Terminal rates(c)	6/41(14.6)	9/38(23.7)	9/38(23.1)	10/23(31.3)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0471*			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.1685			
Fisher Exact test(e)		P=0.1434	P=0.1330	P=0.0624
SITE : uterus				
TUMOR : endometrial stromal sarcoma				
Tumor rate				
Overall rates(a)	1/50(2.0)	4/50(8.0)	4/49(8.2)	7/50(14.0)
Adjusted rates(b)	0.0	5.26	2.56	3.13
Terminal rates(c)	0/41(0.0)	2/38(5.3)	1/39(2.6)	1/32(3.1)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0152*			
Prevalence method(d)	P=0.3505			
Combined analysis (d)	P=0.0201*			
Cochran-Armitage test(e)	P=0.0454*			
Fisher Exact test(e)		P=0.1811	P=0.1748	P=0.0297*
SITE : mammary gland				
TUMOR : adenoma				
Tumor rate				
Overall rates(a)	2/50(4.0)	1/50(2.0)	3/49(6.1)	2/50(4.0)
Adjusted rates(b)	4.26	2.56	7.14	6.25
Terminal rates(c)	1/41(2.4)	0/38(0.0)	2/39(5.1)	2/32(6.3)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.3835			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.8301			
Fisher Exact test(e)		P=0.5000	P=0.4903	P=0.6913

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

Group Name	Control	3ppm	10ppm	30ppm
SITE : mammary gland				
TUMOR : fibroadenoma				
Tumor rate				
Overall rates(a)	8/50(16.0)	6/50(12.0)	18/49(36.7)	17/50(34.0)
Adjusted rates(b)	19.51	15.79	38.46	43.75
Terminal rates(c)	8/41(19.5)	6/38(15.8)	15/39(38.5)	14/32(43.8)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0014**			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0110*			
Fisher Exact test(e)		P=0.3871	P=0.0167*	P=0.0317*
SITE : mammary gland				
TUMOR : adenoma, fibroadenoma				
Tumor rate				
Overall rates(a)	10/50(20.0)	7/50(14.0)	20/49(40.8)	17/50(34.0)
Adjusted rates(b)	21.95	17.95	42.55	43.75
Terminal rates(c)	9/41(22.0)	6/38(15.8)	16/39(41.0)	14/32(43.8)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0112*			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0409*			
Fisher Exact test(e)		P=0.2977	P=0.0205*	P=0.0880
SITE : mammary gland				
TUMOR : adenoma, fibroadenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	10/50(20.0)	8/50(16.0)	21/49(42.9)	19/50(38.0)
Adjusted rates(b)	21.95	20.51	44.68	46.88
Terminal rates(c)	9/41(22.0)	7/38(18.4)	17/39(43.6)	15/32(46.9)
Statistical analysis				
Peto test				
Standard method(d)	P=0.1346			
Prevalence method(d)	P=0.0073**			
Combined analysis (d)	P=0.0038**			
Cochran-Armitage test(e)	P=0.0164*			
Fisher Exact test(e)		P=0.3976	P=0.0123*	P=0.0385*

(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.

† :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 13 CAUSE OF DEATH OF MALE AND FEMALE RATS
IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

Group	Male				Female			
	0ppm	3ppm	10ppm	30ppm	0ppm	3ppm	10ppm	30ppm
Number of dead or moribund animals	10	8	12	27	9	12	10	18
No microscopical confirmation	0	1	0	2	2	2	0	0
Central nervous system lesion	0	0	1	0	0	0	0	1
Renal lesion	0	0	0	1	0	0	0	0
Thrombosis	0	0	0	0	0	0	0	1
Tumor death : peritoneum	0	1	2	12	0	0	0	0
nasal cavity	0	0	0	5	0	0	0	1
leukemia	5	1	3	2	1	2	2	4
skin/appendage	0	1	0	0	0	0	0	0
subcutis	2	0	1	0	0	0	0	1
lung	0	1	1	0	0	0	0	0
spleen	1	0	0	0	0	0	0	0
oral cavity	0	0	1	0	0	0	0	0
tongue	0	0	0	0	0	0	0	1
salivary gland	0	1	0	0	0	0	0	0
pancreas	0	0	0	0	1	0	0	1
urinary bladder	0	0	0	0	1	0	0	0
pituitary gland	1	0	0	1	3	4	1	1
adrenal gland	0	1	1	0	0	1	1	0
uterus					1	2	4	6
ovary					0	1	0	0
mammary gland	0	0	0	1	0	0	0	1
preputial/clitoral gland	0	0	1	0	0	0	0	0
brain	0	0	0	1	0	0	1	0
Zymbal gland	0	1	1	1	0	0	1	0
retroperitoneum	1	0	0	1	0	0	0	0

TABLE 14 HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC LESIONS
IN JAPAN BIOASSAY RESEARCH CENTER : F344/DuCrj MALE RATS

Organs Tumors	No. of animals examined	No. of tumor- bearing animals	Incidence (%)	Min. - Max. (%)
Skin/Appendage	<1248>			
Squamous cel papilloma		14	1.1	0 - 4
Nasal cavity	<1249>			
Adenoma		2	0.2	0 - 2
Adenocarcinoma		0	0.0	0 - 0
Squamous cell carcinoma		0	0.0	0 - 0
Basal cell carcinoma		0	0.0	0 - 0
Lung	<1249>			
Bronchiolar-alveolar carcinoma		12	1.0	0 - 4
Pancreas	<1249>			
Islet cell adenoma 1)		75	6.0	0 - 14
Islet cell adenocarcinoma 2)		5	0.4	0 - 2
1)+2)		80	6.4	0 - 14
Thyroid	<1243>			
Follicular adenoma 1)		12	1.0	0 - 4
Follicular adenocarcinoma 2)		27	2.2	0 - 8
1)+2)		39	3.1	0 - 8
Testis	<1249>			
Interstitial cell tumor		1099	88.0	74 - 98
Mammary gland	<1249>			
Adenoma 1)		8	0.6	0 - 4
Fibroadenoma 2)		27	2.2	0 - 6
1)+2)		35	2.8	0 - 8
Subcutis	<1249>			
fibroma		90	7.2	2 - 14
Peritoneum	<1249>			
Mesothelioma		31	2.5	0 - 8

25 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, 0284, 0288, 0294, 0296, 0318

TABLE 15 HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC LESIONS
IN JAPAN BIOASSAY RESEARCH CENTER : F344/DuCrj FEMALE RATS

Organs Tumors	No. of animals examined	No. of tumor- bearing animals	Incidence (%)	Min. - Max. (%)
Nasal cavity	<1197>			
Adenoma		0	0.0	0 - 0
Adenocarcinoma		0	0.0	0 - 0
Squamous cell carcinoma		0	0.0	0 - 0
Spleen	<1197>			
Mononuclear cell leukemia		160	13.4	2 - 26
Adrenal	<1197>			
Pheochromocytoma		48	4.0	0 - 16
Pheochromocytoma : malignant 1)+2)		13	1.1	0 - 6
		61	5.1	0 - 18
Uterus	<1197>			
Endometrial stromal polyp		172	14.4	2 - 28
Endometrial stromal sarcoma		7	0.6	0 - 2
Mammary gland	<1197>			
Adenoma		45	3.8	0 - 18
Fibroadenoma		130	10.9	0 - 20
Adenocarcinoma		19	1.6	0 - 6

24 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, 0284, 0296, 0303, 0318