

N,N-ジメチルホルムアミドのラットを用いた
吸入によるがん原性試験報告書

試験番号：0296

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TABLE 1 EXPERIMENTAL DESIGN AND MATERIALS AND METHODS
IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

<Method of Administration>	Inhalation
<Number of Groups>	Male 4, Female 4
<Size of Groups>	50 males and 50 females of each group
<Animals>	
Strain and Species	F344/DuCrj(Fischer)rat
Animal Source	Charles River Japan, Inc.
Duration Held Before Study	2 wk
Age When Placed on Study	6 wk
Age When Killed	110~111 wk
<Doses>	
Male and Female	0, 200, 400, 800ppm
<Duration of Dosing>	6 h/d, 5 d/wk for 104 wk
<Animal Maintenance>	
Feed	CRF-1 (Oriental Yeast Co., Ltd.) Sterilized by γ -ray Available <i>ad libitum</i>
Water	Filtrated and sterilized by ultraviolet ray Automatic watering system Available <i>ad libitum</i>
Animal per Cage	Single (stainless steel wire)
Animal Room Environment	Barrier system
	Temperature : 22±2°C
	Fluorescent light : 12 h/d
Chamber Environment	Barrier system
	Temperature : 22±2°C
	Humidity : 55±15%
	Air changes : 12±1 time/h (6±0.5 time/h) ():during exposure
	Pressure : 0~-15mmAq
<Type and Frequency of Observation>	
Clinical Sign	Observed 1 per day for mortality, Detailed clinical observation performed on once weekly before exposure.
Body Weight	Weighed 1 per wk for 14wk Weighed 1 per 4wks thereafter
Food Consumption	Weighed 1 per wk for 14wk Weighed 1 per 4wks thereafter

TABLE 1 EXPERIMENTAL DESIGN AND MATERIALS AND METHODS
(Continued) IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

<Hematology>

Hematological examination performed on scheduled sacrificed animals.

The following measurement parameters were examined;

Red blood cell (RBC), Hemoglobin, Hematocrit,
Mean Corpuscular Volume (MCV),
Mean Corpuscular hemoglobin (MCH),
Mean Corpuscular hemoglobin concentrate (MCHC),
Platelet, Reticulocyte,
White blood cell (WBC), Differential WBC.

<Biochemistry>

Biochemical examination performed on scheduled sacrificed animals.

The following measurement parameters were examined;

Total protein, Albumin, A/G ratio,
Total bilirubin, Glucose, Total cholesterol,
Triglyceride, Phospholipid,
Glutamic oxaloacetic transaminase (GOT),
Glutamic pyruvic transaminase (GPT),
Lactate dehydrogenase (LDH),
Alkaline phosphatase (ALP),
 γ -Glutamyl transpeptidase (γ -GTP),
Creatine phosphokinase (CPK),
Urea nitrogen, Creatinine,
Sodium, Potassium, Chloride,
Calcium, Inorganic phosphorus.

<Urinalysis>

Urinalysis performed on all animals that survived to end of dosing period using fresh urine collection.

The following measurement parameters were examined;

pH, Protein, Glucose, Ketone body, Bilirubin,
Occult blood, Urobilinogen.

<Necropsy>

Necropsy performed on all animals.

<Organ Weight>

Organ weight measurement performed on scheduled sacrificed animals.

The following organs were weighed;

adrenal, testis, ovary, heart, lung, kidney, spleen, liver, brain.

<Histopathologic Examination>

Histopathologic examination performed on all animals.

The following organs were examined;

skin, nasal cavity, nasopharynx, larynx, trachea, lung,
bone marrow, lymph node, thymus, spleen, heart, tongue,
salivary gland, esophagus, stomach, small intestine,
large intestine, liver, pancreas, kidney, urinary bladder,
pituitary, thyroid, parathyroid, adrenal, testis, epididymis, seminal vesicle,
prostate, ovary, uterus, vagina, mammary gland,
brain, spinal cord, peripheral nerve, eye, hardierian gland, muscle, bone.

TABLE 2 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF MALE RATS
IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

Week on Study	Control		200ppm			400ppm			800ppm		
	Av.Wt.	No.of Surviv. <50>	Av.Wt.	% of cont. <50>	No.of Surviv. <50>	Av.Wt.	% of cont. <50>	No.of Surviv. <50>	Av.Wt.	% of cont. <50>	No.of Surviv. <50>
0	128 (50)	50/50	128 (50)	100	50/50	128 (50)	100	50/50	128 (50)	100	50/50
1	157 (50)	50/50	152 (50)	97	50/50	143 (50)	91	50/50	140 (49)	89	49/50
2	186 (50)	50/50	185 (50)	99	50/50	168 (50)	90	50/50	152 (49)	82	49/50
3	210 (50)	50/50	211 (50)	100	50/50	192 (50)	91	50/50	175 (49)	83	49/50
4	230 (50)	50/50	231 (50)	100	50/50	210 (50)	91	50/50	187 (49)	81	49/50
5	245 (50)	50/50	247 (50)	101	50/50	229 (50)	93	50/50	201 (49)	82	49/50
6	259 (50)	50/50	260 (50)	100	50/50	236 (50)	91	50/50	208 (49)	80	49/50
7	272 (50)	50/50	273 (50)	100	50/50	245 (50)	90	50/50	214 (49)	79	49/50
8	285 (50)	50/50	286 (50)	100	50/50	253 (50)	89	50/50	219 (48)	77	48/50
9	295 (50)	50/50	297 (50)	101	50/50	262 (50)	89	50/50	225 (48)	76	48/50
10	304 (50)	50/50	307 (50)	101	50/50	269 (50)	88	50/50	231 (48)	76	48/50
11	311 (50)	50/50	314 (50)	101	50/50	278 (50)	89	50/50	245 (48)	79	48/50
12	318 (50)	50/50	320 (50)	101	50/50	279 (50)	88	50/50	245 (48)	77	48/50
13	323 (50)	50/50	325 (50)	101	50/50	284 (50)	88	50/50	252 (47)	78	47/50
14	329 (50)	50/50	330 (50)	100	50/50	285 (50)	87	50/50	249 (47)	76	47/50
18	348 (50)	50/50	347 (50)	100	50/50	297 (50)	85	50/50	262 (47)	75	47/50
22	362 (50)	50/50	361 (50)	100	50/50	310 (50)	86	50/50	276 (47)	76	47/50
26	376 (50)	50/50	374 (50)	99	50/50	319 (50)	85	50/50	280 (47)	74	47/50
30	385 (50)	50/50	384 (49)	100	49/50	330 (50)	86	50/50	292 (47)	76	47/50
34	398 (50)	50/50	394 (49)	99	49/50	340 (50)	85	50/50	303 (47)	76	47/50
38	402 (50)	50/50	398 (49)	99	49/50	343 (50)	85	50/50	309 (46)	77	46/50
42	410 (50)	50/50	405 (49)	99	49/50	353 (49)	86	49/50	314 (46)	77	46/50
46	415 (49)	49/50	410 (49)	99	49/50	357 (49)	86	49/50	315 (46)	76	46/50
50	420 (49)	49/50	413 (49)	98	49/50	360 (49)	86	49/50	320 (46)	76	46/50
54	423 (49)	49/50	414 (48)	98	48/50	362 (49)	86	49/50	318 (46)	75	46/50
58	430 (49)	49/50	418 (48)	97	48/50	364 (49)	85	49/50	318 (46)	74	46/50
62	434 (49)	49/50	422 (48)	97	48/50	367 (49)	85	49/50	317 (46)	73	46/50
66	435 (49)	49/50	422 (48)	97	48/50	371 (48)	85	48/50	322 (46)	74	46/50
70	436 (49)	49/50	421 (48)	97	48/50	374 (48)	86	48/50	322 (46)	74	46/50
74	435 (49)	49/50	419 (48)	96	48/50	376 (48)	86	48/50	328 (45)	75	45/50
78	435 (48)	48/50	417 (48)	96	48/50	372 (48)	86	48/50	321 (44)	74	44/50
82	433 (47)	47/50	415 (47)	96	47/50	373 (48)	86	48/50	324 (44)	75	44/50
86	430 (46)	46/50	410 (46)	95	45/50	368 (47)	86	47/50	317 (44)	74	44/50
90	426 (46)	46/50	408 (44)	96	44/50	365 (47)	86	47/50	317 (43)	74	43/50
94	419 (46)	46/50	393 (43)	94	43/50	357 (44)	85	44/50	313 (43)	75	43/50
98	409 (43)	43/50	381 (41)	93	41/50	351 (43)	86	43/50	306 (41)	75	41/50
102	400 (42)	42/50	374 (38)	94	38/50	346 (41)	87	41/50	303 (38)	76	38/50
104	393 (42)	42/50	366 (38)	93	38/50	340 (41)	87	40/50	299 (37)	76	37/50

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

TABLE 3 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF FEMALE RATS IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

Week on Study	Control		200ppm		400ppm		800ppm				
	Av.Wt.	No.of Surviv. <49>	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	99 (49)	50/50	99 (50)	100	50/50	99 (50)	100	50/50	99 (50)	100	50/50
1	112 (49)	50/50	105 (50)	94	50/50	99 (50)	88	50/50	100 (49)	89	49/50
2	124 (49)	50/50	122 (50)	98	50/50	111 (50)	90	50/50	102 (46)	82	46/50
3	135 (49)	50/50	133 (50)	99	50/50	121 (50)	90	50/50	114 (46)	84	46/50
4	144 (49)	50/50	140 (50)	97	50/50	127 (50)	88	50/50	117 (46)	81	46/50
5	151 (49)	50/50	148 (50)	98	50/50	140 (50)	93	50/50	123 (46)	81	46/50
6	157 (49)	50/50	151 (50)	96	50/50	138 (50)	88	50/50	124 (46)	79	46/50
7	162 (49)	50/50	156 (50)	96	50/50	141 (50)	87	50/50	125 (46)	77	46/50
8	166 (49)	50/50	160 (50)	96	50/50	144 (50)	87	50/50	124 (46)	75	46/50
9	171 (49)	50/50	165 (50)	96	50/50	146 (50)	85	50/50	124 (45)	73	45/50
10	176 (49)	50/50	168 (50)	95	50/50	150 (50)	85	50/50	124 (45)	70	45/50
11	180 (49)	50/50	173 (50)	96	50/50	155 (50)	86	50/50	138 (45)	77	45/50
12	183 (49)	50/50	174 (50)	95	50/50	157 (50)	86	50/50	131 (44)	72	44/50
13	186 (49)	50/50	175 (50)	94	50/50	159 (50)	85	50/50	138 (44)	74	44/50
14	187 (49)	50/50	177 (50)	95	50/50	158 (50)	84	50/50	135 (44)	72	44/50
18	196 (49)	50/50	181 (50)	92	50/50	162 (50)	83	50/50	140 (43)	71	43/50
22	202 (49)	50/50	188 (50)	93	50/50	170 (50)	84	50/50	147 (40)	73	40/50
26	207 (49)	50/50	192 (50)	93	50/50	174 (50)	84	50/50	148 (40)	71	40/50
30	214 (49)	49/49	197 (50)	92	50/50	179 (50)	84	50/50	155 (39)	72	39/50
34	220 (49)	49/49	202 (50)	92	50/50	184 (50)	84	50/50	153 (39)	70	39/50
38	220 (49)	49/49	204 (50)	93	50/50	187 (50)	85	50/50	152 (39)	69	39/50
42	226 (49)	49/49	209 (50)	92	50/50	190 (50)	84	50/50	155 (39)	69	39/50
46	232 (49)	49/49	214 (50)	92	50/50	191 (50)	82	50/50	157 (39)	68	39/50
50	236 (49)	49/49	216 (50)	92	50/50	192 (50)	81	50/50	161 (39)	68	39/50
54	240 (49)	49/49	219 (50)	91	50/50	197 (49)	82	49/50	165 (38)	69	38/50
58	248 (49)	49/49	224 (50)	90	50/50	200 (48)	81	48/50	165 (37)	67	37/50
62	253 (49)	49/49	231 (50)	91	50/50	203 (48)	80	48/50	173 (37)	68	37/50
66	258 (48)	48/49	234 (50)	91	50/50	204 (48)	79	48/50	178 (37)	69	37/50
70	264 (47)	47/49	241 (50)	91	50/50	206 (48)	78	48/50	184 (36)	70	36/50
74	269 (47)	47/49	242 (50)	90	50/50	212 (48)	79	48/50	191 (36)	71	36/50
78	272 (47)	47/49	245 (49)	90	49/50	209 (47)	77	47/50	187 (36)	69	36/50
82	277 (47)	47/49	250 (48)	90	48/50	213 (47)	77	46/50	193 (36)	70	36/50
86	281 (46)	46/49	253 (45)	90	45/50	217 (45)	77	45/50	193 (35)	69	35/50
90	286 (46)	46/49	256 (43)	90	43/50	219 (43)	77	43/50	194 (34)	68	34/50
94	289 (46)	46/49	258 (43)	89	43/50	218 (42)	75	41/50	198 (34)	69	34/50
98	287 (44)	44/49	258 (42)	90	42/50	217 (41)	76	40/50	196 (34)	68	34/50
102	284 (43)	43/49	259 (41)	91	41/50	218 (40)	77	40/50	198 (32)	70	32/50
104	277 (43)	42/49	254 (38)	92	38/50	213 (38)	77	38/50	196 (30)	71	30/50

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

TABLE 4 INCIDENCE OF EXTERNAL AND INTERNAL MASS IN CLINICAL OBSERVATION OF MALE RATS IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

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										
Control	0/50	0/50	0/50	1/50	1/49	3/49	4/48	10/46	10/50(1/8)	
200ppm	0/50	0/50	0/50	0/49	1/48	5/48	9/48	12/43	16/50(7/12)	
400ppm	0/50	0/50	0/50	0/50	2/49	3/48	5/48	7/45	9/50(3/10)	
800ppm	0/50	0/47	0/47	0/46	1/46	2/46	2/44	3/43	4/50(2/13)	
Internal mass										
Control	0/50	0/50	0/50	0/50	0/49	0/49	1/48	0/46	1/50(1/8)	
200ppm	0/50	0/50	0/50	0/49	0/48	0/48	0/48	1/43	1/50(0/12)	
400ppm	0/50	0/50	0/50	0/50	0/49	0/48	0/48	3/45	3/50(2/10)	
800ppm	0/50	0/47	0/47	0/46	0/46	0/46	0/44	2/43	2/50(1/13)	

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 a:

TABLE 5 INCIDENCE OF EXTERNAL AND INTERNAL MASS IN CLINICAL OBSERVATION OF FEMALE RATS IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

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										
Control	0/49	0/49	0/49	0/49	1/49	3/48	7/47	10/46	11/49(3/8)	
200ppm	0/50	0/50	0/50	0/50	2/50	2/50	3/49	7/43	9/50(4/12)	
400ppm	0/50	0/50	0/50	0/50	0/49	1/48	1/47	2/42	3/50(1/12)	
800ppm	0/50	0/44	0/40	0/39	1/39	2/37	3/36	4/34	4/50(1/20)	
Internal mass										
Control	0/49	0/49	0/49	0/49	1/49	1/48	0/47	1/46	3/49(3/8)	
200ppm	0/50	0/50	0/50	0/50	0/50	0/50	0/49	4/43	4/50(4/12)	
400ppm	0/50	0/50	0/50	0/50	0/49	0/48	2/47	7/42	8/50(6/12)	
800ppm	0/50	1/44	1/40	0/39	0/39	0/37	1/36	5/34	6/50(2/20)	

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 a:

TABLE 6 FOOD CONSUMPTION CHANGES OF MALE RATS
IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

Week on Study	Control		200ppm			400ppm			800ppm		
	Av.FC.	No.of Surviv. <50>	Av.FC.	% of cont. <50>	No.of Surviv. <50>	Av.FC.	% of cont. <50>	No.of Surviv. <50>	Av.FC.	% of cont. <50>	No.of Surviv. <50>
1	16.5 (50)	50/50	15.3 (50)	93	50/50	13.9 (50)	84	50/50	13.4 (49)	81	49/50
2	16.7 (50)	50/50	16.6 (50)	99	50/50	15.5 (50)	93	50/50	12.0 (49)	72	49/50
3	17.2 (50)	50/50	17.6 (50)	102	50/50	17.0 (50)	99	50/50	14.9 (49)	87	49/50
4	17.4 (50)	50/50	17.4 (50)	100	50/50	17.0 (50)	98	50/50	14.3 (49)	82	49/50
5	17.3 (50)	50/50	17.8 (50)	103	50/50	18.1 (50)	105	50/50	15.2 (49)	88	49/50
6	16.9 (50)	50/50	17.2 (50)	102	50/50	16.1 (50)	95	50/50	15.2 (49)	90	49/50
7	17.5 (50)	50/50	17.8 (50)	102	50/50	17.1 (50)	98	50/50	15.6 (49)	89	49/50
8	17.6 (50)	50/50	17.9 (50)	102	50/50	17.7 (50)	101	50/50	15.4 (48)	88	48/50
9	17.8 (50)	50/50	18.1 (50)	102	50/50	18.2 (50)	102	50/50	14.8 (48)	83	48/50
10	17.7 (50)	50/50	17.7 (50)	100	50/50	17.7 (50)	100	50/50	14.7 (48)	83	48/50
11	17.3 (50)	50/50	17.6 (50)	102	50/50	17.5 (50)	101	50/50	16.2 (48)	94	48/50
12	17.1 (50)	50/50	17.0 (50)	99	50/50	16.2 (50)	95	50/50	14.6 (48)	85	48/50
13	17.6 (50)	50/50	17.6 (50)	100	50/50	18.6 (50)	106	50/50	15.2 (47)	86	47/50
14	17.0 (50)	50/50	16.8 (50)	99	50/50	16.7 (50)	98	50/50	13.9 (47)	82	47/50
18	17.3 (50)	50/50	17.0 (50)	98	50/50	16.5 (49)	95	50/50	15.6 (47)	90	47/50
22	17.6 (50)	50/50	17.8 (50)	101	50/50	17.6 (50)	100	50/50	16.4 (47)	93	47/50
26	17.6 (50)	50/50	17.9 (50)	102	50/50	17.0 (50)	97	50/50	15.9 (47)	90	47/50
30	17.6 (50)	50/50	17.9 (49)	102	49/50	17.8 (50)	101	50/50	15.9 (47)	90	47/50
34	17.7 (50)	50/50	17.9 (49)	101	49/50	17.5 (50)	99	50/50	15.9 (47)	90	47/50
38	17.4 (50)	50/50	17.8 (49)	102	49/50	17.3 (50)	99	50/50	16.0 (46)	92	46/50
42	17.5 (50)	50/50	17.7 (49)	101	49/50	16.3 (49)	93	49/50	15.1 (46)	86	46/50
46	17.6 (49)	49/50	17.8 (49)	101	49/50	17.4 (49)	99	49/50	15.9 (46)	90	46/50
50	17.6 (49)	49/50	17.6 (49)	100	49/50	17.9 (49)	102	49/50	16.5 (46)	94	46/50
54	17.9 (49)	49/50	17.8 (48)	99	48/50	17.7 (49)	99	49/50	16.0 (46)	89	46/50
58	18.2 (49)	49/50	18.0 (48)	99	48/50	17.7 (49)	97	49/50	16.1 (46)	88	46/50
62	17.9 (49)	49/50	17.9 (48)	100	48/50	17.3 (49)	97	49/50	16.3 (46)	91	46/50
66	18.2 (49)	49/50	17.5 (48)	96	48/50	17.9 (48)	98	48/50	15.7 (46)	86	46/50
70	18.0 (49)	49/50	17.2 (48)	96	48/50	17.9 (48)	99	48/50	16.6 (46)	92	46/50
74	17.5 (49)	49/50	17.7 (48)	101	48/50	18.3 (48)	105	48/50	17.4 (45)	99	45/50
78	17.4 (48)	48/50	17.2 (48)	99	48/50	17.7 (48)	102	48/50	16.1 (44)	93	44/50
82	17.8 (47)	47/50	17.6 (47)	99	47/50	17.8 (48)	100	48/50	16.3 (44)	92	44/50
86	17.0 (46)	46/50	17.3 (46)	102	45/50	17.7 (47)	104	47/50	16.1 (44)	95	44/50
90	17.5 (46)	46/50	17.1 (43)	98	44/50	17.4 (47)	99	47/50	16.1 (43)	92	43/50
94	17.6 (46)	46/50	18.1 (43)	103	43/50	18.3 (44)	104	44/50	17.1 (43)	97	43/50
98	18.0 (42)	43/50	18.0 (41)	100	41/50	19.2 (43)	107	43/50	16.7 (41)	93	41/50
102	18.0 (41)	42/50	18.4 (38)	102	38/50	17.9 (39)	99	41/50	17.2 (38)	96	38/50
104	17.8 (42)	42/50	18.5 (38)	104	38/50	17.7 (40)	99	40/50	17.0 (35)	96	37/50

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

TABLE 7 FOOD CONSUMPTION CHANGES OF FEMALE RATS
IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

Week on Study	Control		200ppm		400ppm		800ppm				
	Av.FC.	No.of Surviv. <49>	Av.FC.	% of cont. <50>	No.of Surviv. <50>	Av.FC.	% of cont. <50>	No.of Surviv. <50>	Av.FC.	% of cont. <50>	No.of Surviv. <50>
1	11.8 (49)	50/50	10.3 (50)	87	50/50	9.1 (50)	77	50/50	9.3 (49)	79	49/50
2	11.4 (49)	50/50	11.6 (50)	102	50/50	9.7 (50)	85	50/50	7.7 (46)	68	46/50
3	11.8 (49)	50/50	11.5 (50)	97	50/50	10.6 (50)	90	50/50	10.5 (46)	89	46/50
4	11.7 (49)	50/50	11.4 (50)	97	50/50	10.2 (50)	87	50/50	8.8 (46)	75	46/50
5	11.8 (49)	50/50	11.5 (50)	97	50/50	11.5 (50)	97	50/50	8.8 (46)	75	46/50
6	11.7 (49)	50/50	11.0 (50)	94	50/50	9.8 (50)	84	50/50	8.8 (46)	75	46/50
7	12.0 (49)	50/50	11.6 (50)	97	50/50	10.5 (50)	88	50/50	8.8 (46)	73	46/50
8	11.8 (49)	50/50	11.4 (50)	97	50/50	10.4 (50)	88	50/50	8.4 (46)	71	46/50
9	11.9 (49)	50/50	11.5 (50)	97	50/50	10.6 (50)	89	50/50	7.9 (45)	66	45/50
10	12.0 (49)	50/50	11.9 (50)	99	50/50	10.3 (50)	86	50/50	8.0 (45)	67	45/50
11	12.0 (49)	50/50	12.2 (49)	102	50/50	10.9 (50)	91	50/50	10.3 (45)	86	45/50
12	11.9 (49)	50/50	11.2 (50)	94	50/50	9.5 (50)	80	50/50	8.0 (44)	67	44/50
13	12.2 (49)	50/50	11.7 (50)	96	50/50	10.8 (50)	89	50/50	9.4 (44)	77	44/50
14	11.8 (49)	50/50	11.4 (50)	97	50/50	9.8 (50)	83	50/50	8.3 (44)	70	44/50
18	11.9 (49)	50/50	10.8 (50)	91	50/50	9.7 (50)	82	50/50	8.6 (43)	72	43/50
22	11.9 (49)	50/50	11.9 (50)	100	50/50	10.5 (50)	88	50/50	9.6 (40)	81	40/50
26	12.1 (49)	50/50	11.5 (50)	95	50/50	10.6 (50)	88	50/50	9.2 (40)	76	40/50
30	12.3 (49)	49/49	11.5 (50)	93	50/50	10.6 (50)	86	50/50	9.1 (39)	74	39/50
34	12.5 (49)	49/49	11.6 (50)	93	50/50	10.6 (50)	85	50/50	8.6 (39)	69	39/50
38	12.1 (49)	49/49	11.3 (50)	93	50/50	10.5 (50)	87	50/50	9.0 (39)	74	39/50
42	12.1 (49)	49/49	11.3 (50)	93	50/50	9.9 (50)	82	50/50	9.0 (39)	74	39/50
46	12.2 (49)	49/49	11.2 (50)	92	50/50	10.3 (50)	84	50/50	9.4 (39)	77	39/50
50	12.2 (49)	49/49	11.2 (50)	92	50/50	10.4 (50)	85	50/50	9.0 (39)	74	39/50
54	12.7 (49)	49/49	11.7 (50)	92	50/50	10.8 (49)	85	49/50	9.3 (38)	73	38/50
58	13.3 (49)	49/49	12.0 (50)	90	50/50	10.8 (48)	81	48/50	9.3 (37)	70	37/50
62	12.5 (49)	49/49	12.4 (50)	99	50/50	11.1 (48)	89	48/50	9.9 (37)	79	37/50
66	12.9 (48)	48/49	11.9 (50)	92	50/50	10.9 (48)	84	48/50	9.9 (37)	77	37/50
70	13.4 (47)	47/49	12.5 (50)	93	50/50	11.1 (48)	83	48/50	10.6 (36)	79	36/50
74	12.7 (47)	47/49	12.4 (50)	98	50/50	11.7 (48)	92	48/50	10.7 (36)	84	36/50
78	12.7 (47)	47/49	12.0 (49)	94	49/50	10.8 (47)	85	47/50	10.2 (36)	80	36/50
82	13.2 (47)	47/49	12.6 (48)	95	48/50	10.9 (47)	83	46/50	10.6 (36)	80	36/50
86	12.9 (46)	46/49	12.3 (45)	95	45/50	11.2 (45)	87	45/50	10.8 (35)	84	35/50
90	13.1 (46)	46/49	12.5 (43)	95	43/50	11.1 (43)	85	43/50	10.6 (34)	81	34/50
94	13.9 (46)	46/49	12.8 (43)	92	43/50	11.6 (42)	83	41/50	11.8 (34)	85	34/50
98	13.5 (44)	44/49	12.8 (42)	95	42/50	11.6 (41)	86	40/50	11.0 (34)	81	34/50
102	13.6 (43)	43/49	13.1 (41)	96	41/50	12.0 (40)	88	40/50	11.3 (32)	83	32/50
104	13.1 (42)	42/49	12.9 (38)	98	38/50	11.5 (38)	88	38/50	11.4 (30)	87	30/50

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

TABLE 8 NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS IN MALE RATS
IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

Group Name	Control	200ppm	400ppm	800ppm
SITE : liver				
TUMOR : hepatocellular adenoma				
Tumor rate				
Overall rates(a)	1/50(2.0)	3/50(6.0)	13/50(26.0)	20/50(40.0)
Adjusted rates(b)	2.38	7.89	28.26	47.37
Terminal rates(c)	1/42(2.4)	3/38(7.9)	10/40(25.0)	17/37(45.9)
Statistical analysis				
Peto test				
Standard method(d)	P=0.1082			
Prevalence method(d)	P<0.0001**			
Combined analysis (d)	P<0.0001**			
Cochran-Armitage test(e)	P<0.0001**			
Fisher Exact test(e)		P=0.3087	P=0.0004**	P<0.0001**
SITE : liver				
TUMOR : hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	1/50(2.0)	0/50(0.0)	24/50(48.0)
Adjusted rates(b)	0.0	2.63	0.0	56.76
Terminal rates(c)	0/42(0.0)	1/38(2.6)	0/40(0.0)	21/37(56.8)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0175* ?			
Prevalence method(d)	P<0.0001**?			
Combined analysis (d)	P<0.0001**?			
Cochran-Armitage test(e)	P<0.0001**			
Fisher Exact test(e)		P=0.5000	P=0.5000	P<0.0001**
SITE : liver				
TUMOR : hepatocellular adenoma, hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	1/50(2.0)	4/50(8.0)	13/50(26.0)	33/50(66.0)
Adjusted rates(b)	2.38	10.53	28.26	75.68
Terminal rates(c)	1/42(2.4)	4/38(10.5)	10/40(25.0)	28/37(75.7)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0041**?			
Prevalence method(d)	P<0.0001**?			
Combined analysis (d)	P<0.0001**?			
Cochran-Armitage test(e)	P<0.0001**			
Fisher Exact test(e)		P=0.1811	P=0.0004**	P<0.0001**

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

(b):Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.

(c):Observed tumor incidence at terminal kill.

(d):Beneath the control incidence are the P-values associated with the trend test.

Standard method :Death analysis

Prevalence method :Incidental tumor test

Combined analysis :Death analysis + Incidental tumor test

(e):The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.

? :The conditional probabilities of the largest and smallest possible outcomes can not be estimated or this P-value is beyond the estimated P-value.

-----:There is no data which should be statistical analysis.

Significant difference; *: $P \leq 0.05$ **: $P \leq 0.01$

TABLE 8 NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS IN MALE RATS
IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE(continued)

Group Name	Control	200ppm	400ppm	800ppm
SITE : pituitary gland				
TUMOR : adenoma				
Tumor rate				
Overall rates(a)	9/50(18.0)	17/50(34.0)	4/50(8.0)	3/50(6.0)
Adjusted rates(b)	17.39	33.33	10.00	8.11
Terminal rates(c)	7/42(16.7)	12/38(31.6)	4/40(10.0)	3/37(8.1)
Statistical analysis				
Peto test				
Standard method(d)	P=0.8911			
Prevalence method(d)	P=0.9906			
Combined analysis (d)	P=0.9960			
Cochran-Armitage test(e)	P=0.0075**			
Fisher Exact test(e)		P=0.0548	P=0.1168	P=0.0606

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

(b):Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.

(c):Observed tumor incidence at terminal kill.

(d):Beneath the control incidence are the P-values associated with the trend test.

Standard method :Death analysis

Prevalence method :Incidental tumor test

Combined analysis :Death analysis + Incidental tumor test

(e):The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.

? :The conditional probabilities of the largest and smallest possible out comes can not be estimated
or this P-value is beyond the estimated P-value.

-----:There is no data which should be statistical analysis.

Significant difference; *: $P \leq 0.05$ **: $P \leq 0.01$

TABLE 9 NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS IN FEMALE RATS
IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

Group Name	Control	200ppm	400ppm	800ppm
SITE : liver				
TUMOR : hepatocellular adenoma				
Tumor rate				
Overall rates(a)	1/49(2.0)	1/50(2.0)	5/50(10.0)	16/50(32.0)
Adjusted rates(b)	2.38	2.50	13.16	53.33
Terminal rates(c)	1/42(2.4)	0/38(0.0)	5/38(13.2)	16/30(53.3)
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=0.2424	P=0.1068	P<0.0001**
SITE : liver				
TUMOR : hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	0/49(0.0)	0/50(0.0)	0/50(0.0)	5/50(10.0)
Adjusted rates(b)	0.0	0.0	0.0	15.15
Terminal rates(c)	0/42(0.0)	0/38(0.0)	0/38(0.0)	4/30(13.3)
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=0.5000	P=0.5000	P=0.0296*
SITE : liver				
TUMOR : hepatocellular adenoma, hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	1/49(2.0)	1/50(2.0)	5/50(10.0)	19/50(38.0)
Adjusted rates(b)	2.38	2.50	13.16	60.00
Terminal rates(c)	1/42(2.4)	0/38(0.0)	5/38(13.2)	18/30(60.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P<0.0001**?			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P<0.0001**			
Fisher Exact test(e)		P=0.2424	P=0.1068	P<0.0001**
SITE : pituitary gland				
TUMOR : adenoma				
Tumor rate				
Overall rates(a)	23/49(46.9)	20/50(40.0)	13/50(26.0)	4/50(8.0)
Adjusted rates(b)	45.45	37.21	26.32	10.00
Terminal rates(c)	18/42(42.9)	12/38(31.6)	10/38(26.3)	3/30(10.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.6171			
Prevalence method(d)	P=1.0000			
Combined analysis (d)	P=0.9999			
Cochran-Armitage test(e)	P<0.0001**			
Fisher Exact test(e)		P=0.3106	P=0.0249*	P<0.0001**

TABLE 9 NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS IN FEMALE RATS
IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE(continued)

Group Name	Control	200ppm	400ppm	800ppm
SITE : thyroid				
TUMOR : C-cell adenoma				
Tumor rate				
Overall rates(a)	7/49(14.3)	4/50(8.0)	2/50(4.0)	0/50(0.0)
Adjusted rates(b)	15.22	9.52	5.26	0.0
Terminal rates(c)	6/42(14.3)	3/38(7.9)	2/38(5.3)	0/30(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.9973			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0039**			
Fisher Exact test(e)		P=0.2505	P=0.0750	P=0.0058**
SITE : thyroid				
TUMOR : C-cell adenoma, C-cell carcinoma				
Tumor rate				
Overall rates(a)	8/49(16.3)	4/50(8.0)	2/50(4.0)	1/50(2.0)
Adjusted rates(b)	17.39	9.52	5.26	3.33
Terminal rates(c)	7/42(16.7)	3/38(7.9)	2/38(5.3)	1/30(3.3)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.9911			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0090**			
Fisher Exact test(e)		P=0.1685	P=0.0426*	P=0.0142*
SITE : thyroid				
TUMOR : follicular adenoma, follicular adenocarcinoma				
Tumor rate				
Overall rates(a)	3/49(6.1)	1/50(2.0)	0/50(0.0)	0/50(0.0)
Adjusted rates(b)	7.14	2.63	0.0	0.0
Terminal rates(c)	3/42(7.1)	1/38(2.6)	0/38(0.0)	0/30(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.9841			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0391*			
Fisher Exact test(e)		P=0.3010	P=0.1175	P=0.1175
SITE : mammary gland				
TUMOR : fibroadenoma				
Tumor rate				
Overall rates(a)	7/49(14.3)	5/50(10.0)	0/50(0.0)	0/50(0.0)
Adjusted rates(b)	13.33	11.11	0.0	0.0
Terminal rates(c)	5/42(11.9)	4/38(10.5)	0/38(0.0)	0/30(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.8966 ?			
Prevalence method(d)	P=0.9991			
Combined analysis (d)	P=0.9996			
Cochran-Armitage test(e)	P=0.0012**			
Fisher Exact test(e)		P=0.3654	P=0.0058**	P=0.0058**

TABLE 9 NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS IN FEMALE RATS
IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE(continued)

Group Name	Control	200ppm	400ppm	800ppm
SITE : mammary gland				
TUMOR : adenoma, fibroadenoma				
Tumor rate				
Overall rates(a)	7/49(14.3)	7/50(14.0)	0/50(0.0)	0/50(0.0)
Adjusted rates(b)	13.33	15.79	0.0	0.0
Terminal rates(c)	5/42(11.9)	6/38(15.8)	0/38(0.0)	0/30(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.8966 ?			
Prevalence method(d)	P=0.9991			
Combined analysis (d)	P=0.9996			
Cochran-Armitage test(e)	P=0.0009**			
Fisher Exact test(e)		P=0.3713	P=0.0058**	P=0.0058**
SITE : ovary				
TUMOR : granulosa-theca cell tumor				
Tumor rate				
Overall rates(a)	3/49(6.1)	0/50(18.0)	0/50(0.0)	0/50(0.0)
Adjusted rates(b)	7.14	0.0	0.0	0.0
Terminal rates(c)	3/42(7.1)	0/38(0.0)	0/38(0.0)	0/30(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.9910			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0378*			
Fisher Exact test(e)		P=0.1175	P=0.1175	P=0.1175

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

(b):Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.

(c):Observed tumor incidence at terminal kill.

(d):Beneath the control incidence are the P-values associated with the trend test.

Standard method :Death analysis

Prevalence method :Incidental tumor test

Combined analysis :Death analysis + Incidental tumor test

(e):The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.

? :The conditional probabilities of the largest and smallest possible out comes can not be estimated or this P-value is beyond the estimated P-value.

-----:There is no data which should be statistical analysis.

Significant difference; *: $P \leq 0.05$ **: $P \leq 0.01$

TABLE 10 SELECTED NON NEOPLASTIC LESIONS OF MALE RATS
IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

Organ	Findings	Group Name No. of Animals Grade a)	Control				200 ppm				400 ppm				800 ppm			
			50				50				50				50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
nasal cavit			<50>				<50>				<50>				<50>			
	mineralization	43	2	0	0	0	34	16	0	0**	19	29	0	0**	23	17	0	0**
	eosinophilic change: olfactory epithelium	39	3	0	0	0	38	1	0	0	29	4	0	0	28	12	0	0*
	inflammation: foreign body	22	2	0	0	0	17	3	0	0	15	0	0	0	4	0	0	0**
liver			<50>				<50>				<50>				<50>			
	necrosis:central	0	0	1	0	0	0	5	0	0*	0	0	0	0	0	2	3	0
	necrosis:focal	0	0	0	0	0	3	0	0	0	6	1	0	0*	2	0	0	0
	clear cell focus	10	1	0	0	0	19	2	0	0	21	14	0	0**	7	26	7	0**
	acidophilic cell focus	12	1	0	0	0	13	1	0	0	24	10	0	0**	13	26	1	0**
	basophilic cell focus	23	1	0	0	0	21	5	0	0	22	7	0	0	18	24	0	0**
	vacuolated cell focus	6	0	0	0	0	0	0	0	0*	6	1	0	0	10	5	1	0*
	mixed cell focus	0	0	0	0	0	0	0	0	0	0	1	0	0	3	3	0	0*
	spongiosis hepatis	4	0	0	0	0	17	4	0	0**	20	6	0	0**	21	3	0	0**
kidney			<50>				<50>				<50>				<50>			
	eosinophylic body	15	0	0	0	0	24	0	0	0	33	1	0	0**	28	0	0	0*
	chronic nephropathy	2	27	14	5	0	0	15	26	7	1	25	20	3	1	9	28	7**

a) 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

TABLE 11 SELECTED NON NEOPLASTIC LESIONS OF FEMALE RATS
IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

Organ	Findings	Group Name No. of Animals Grade a)	Control 49				200 ppm 50				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
nasal cavit			<50>				<50>				<50>				<50>			
	eosinophilic change: olfactory epithelium		15	28	4	0	22	19	1	0*	37	10	0	0**	6	28	3	0**
bone marrow			<49>				<50>				<50>				<50>			
	congestion		0	0	0	0	0	0	0	0	0	0	0	0	2	9	0	0**
	granulation		3	0	0	0	7	1	0	0	9	4	0	0*	9	4	0	0*
thymus			<49>				<50>				<50>				<50>			
	hemorrhage		0	0	0	0	0	0	0	0	1	0	0	0	9	1	0	0**
spleen			<50>				<50>				<50>				<50>			
	deposit of hemosiderin		25	11	1	0	31	5	0	0	34	3	0	0	30	0	0	0**
	extramedullary hematopoiesis		25	13	2	0	32	4	4	0	36	4	1	0	26	4	1	0*
liver			<49>				<50>				<50>				<50>			
	necrosis:central		0	0	0	0	3	0	0	0	1	1	0	0	0	0	13	0**
	necrosis:focal		0	0	0	0	2	0	0	0	0	1	0	0	3	0	0	0
	necrosis:single cell		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	clear cell focus		2	1	0	0	14	9	0	0**	15	18	0	0**	0	21	12	0**
	acidophilic cell focus		0	0	0	0	3	1	0	0	8	2	0	0**	4	14	2	0**
	basophilic cell focus		20	3	0	0	15	12	0	0*	11	2	2	0	5	17	7	0**
kidney			<49>				<50>				<50>				<50>			
	chronic nephropathy		12	18	3	1	25	5	1	0**	16	6	0	0**	9	20	6	0
pituitary			<49>				<50>				<50>				<50>			
	cyst		20	3	0	0	17	5	1	0	16	2	0	0	6	2	0	0**
bone			<49>				<50>				<50>				<50>			
	osteosclerosis		4	2	0	0	2	2	0	0	3	1	0	0	0	0	0	0*

a) 1: Slight 2: Moderate 3: Marked 4: Severe

Significant difference; *: $P \leq 0.05$ **: $P \leq 0.01$ Test of Chi Square

TABLE 12 CAUSE OF DEATH OF RATS IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

Group	Male				Female			
	Control	200ppm	400ppm	800ppm	Control	200ppm	400ppm	800ppm
Number of dead or moribund animals	8	12	10	13	7	12	12	20
No microscopical confirmation	0	0	2	0	0	0	0	1
Respiratory system lesion	0	0	0	0	0	0	0	1
Cardiovascular lesion	0	0	0	0	0	0	0	1
Digestive system lesion	0	1	0	0	0	0	0	0
Hepatic lesion	1	0	0	3	0	0	0	13
Renal lesion	0	1	0	0	0	0	0	0
Tumor death :leukemia	2	1	2	2	2	4	7	1
skin/apendage	0	1	0	0	0	0	0	0
subcutis	1	2	1	2	0	1	0	0
lung	0	0	0	1	0	0	0	0
spleen	0	0	0	1	0	0	0	0
large intestine	0	0	0	0	0	0	1	0
liver	0	0	2	3	0	0	1	0
kidney	0	0	0	0	0	0	0	1
pituitary gland	1	2	0	0	2	3	3	1
adrenal gland	1	0	1	0	0	0	0	0
uterus	-	-	-	-	1	2	0	0
mammary gland	0	1	0	0	1	1	0	0
preputial/clitoral gland	0	0	0	0	0	1	0	0
brain	1	1	1	1	0	0	0	1
peripheral nerves	1	0	0	0	0	0	0	0
Zymbal gland	0	1	0	0	1	0	0	0
bone	0	1	1	0	0	0	0	0