

ヒドラジン一水加物のラットを用いた
経口投与によるがん原性試験(混水試験)報告書

試験番号：0284

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TABLE 1 EXPERIMENTAL DESIGN AND MATERIALS AND METHODS IN THE
2-YEAR DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE

2-year study	
<Method of Administration>	
Drinking Water	
<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	
110~111wk	
<Doses>	
<Male> 0, 20, 40, or 80 ppm	
<Female> 0, 20, 40, or 80 ppm	
<Duration of Dosing>	
7d/wk for 104wk	
<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 in duration of quarantine	
Glass bottle in duration of acclimation and administration	
Available <i>ad libitum</i>	
Animal per Cage	
Single (stainless steel wire)	
Animal Room Environment	
Barrier system	
Temperature : 24±2°C	
Humidity : 55±10%	
Fluorescent light 12h/d	
15~17 room air changes /h	
<Type and Frequency of Observation>	
Clinical Sign	
Observed 1 per d	
Body Weight	
Weighed 1 per wk for 14 wk	
Weighed 1 per 4wks thereafter	
Water Consumption	
Weighed 1 per wk for 14 wk	
Weighed 1 per 4wks thereafter	
Food Consumption	
Weighed 1 per wk for 14 wk	
Weighed 1 per 4wks thereafter	

**TABLE 1 EXPERIMENTAL DESIGN AND MATERIALS AND METHODS IN THE
(Continued) 2-YEAR DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE**

2-year study

<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, 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 (G-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, and brain.

<Histopathologic Examination>

Histopathologic examination performed on all animals per sex per groups.

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, Harderian gland, muscle, bone, other organs/tissues with gross lesions.

TABLE 2 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF MALE RATS
IN THE 2-YEAR DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE

Week on Study	Control		20ppm			40ppm			80ppm		
	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	126 (50)	50/50	126 (50)	100	50/50	126 (50)	100	50/50	126 (50)	100	50/50
1	156 (50)	50/50	154 (50)	99	50/50	150 (50)	96	50/50	145 (50)	93	50/50
2	184 (50)	50/50	180 (50)	98	50/50	176 (50)	96	50/50	166 (50)	90	50/50
3	204 (50)	50/50	200 (50)	98	50/50	194 (50)	95	50/50	182 (50)	89	50/50
4	219 (50)	50/50	215 (50)	98	50/50	209 (50)	95	50/50	193 (50)	88	50/50
5	232 (50)	50/50	230 (50)	99	50/50	223 (50)	96	50/50	204 (50)	88	50/50
6	244 (50)	50/50	242 (50)	99	50/50	234 (50)	96	50/50	212 (50)	87	50/50
7	260 (50)	50/50	258 (50)	99	50/50	249 (50)	96	50/50	224 (50)	86	50/50
8	270 (50)	50/50	269 (50)	100	50/50	261 (50)	97	50/50	234 (50)	87	50/50
9	280 (50)	50/50	279 (50)	100	50/50	270 (50)	96	50/50	243 (50)	87	50/50
10	289 (50)	50/50	288 (50)	100	50/50	278 (50)	96	50/50	249 (50)	86	50/50
11	299 (50)	50/50	297 (50)	99	50/50	287 (50)	96	50/50	257 (50)	86	50/50
12	305 (50)	50/50	303 (50)	99	50/50	292 (50)	96	50/50	261 (50)	86	50/50
13	313 (50)	50/50	310 (50)	99	50/50	300 (50)	96	50/50	269 (50)	86	50/50
14	321 (50)	50/50	318 (50)	99	50/50	307 (50)	96	50/50	275 (50)	86	50/50
18	348 (50)	50/50	341 (50)	98	50/50	328 (50)	94	50/50	293 (50)	84	50/50
22	367 (50)	50/50	355 (50)	97	50/50	339 (50)	92	50/50	300 (50)	82	50/50
26	382 (50)	50/50	371 (50)	97	50/50	353 (50)	92	50/50	311 (50)	81	50/50
30	399 (50)	50/50	383 (50)	96	50/50	364 (50)	91	50/50	318 (50)	80	50/50
34	413 (50)	50/50	397 (50)	96	50/50	377 (50)	91	50/50	327 (50)	79	50/50
38	426 (50)	50/50	406 (50)	95	50/50	386 (50)	91	50/50	330 (50)	77	50/50
42	438 (50)	50/50	420 (50)	96	50/50	397 (50)	91	50/50	336 (50)	77	50/50
46	448 (50)	50/50	426 (50)	95	50/50	403 (50)	90	50/50	335 (50)	75	50/50
50	448 (50)	50/50	428 (50)	96	50/50	401 (50)	90	50/50	330 (50)	74	50/50
54	463 (50)	50/50	440 (50)	95	50/50	413 (50)	89	50/50	339 (50)	73	50/50
58	468 (50)	50/50	446 (50)	95	50/50	420 (50)	90	50/50	342 (50)	73	50/50
62	479 (50)	50/50	454 (50)	95	50/50	423 (50)	88	50/50	344 (49)	72	49/50
66	485 (49)	49/50	461 (50)	95	50/50	430 (50)	89	50/50	349 (49)	72	49/50
70	493 (49)	49/50	465 (50)	94	50/50	433 (50)	88	50/50	350 (49)	71	49/50
74	498 (49)	49/50	466 (50)	94	50/50	435 (50)	87	50/50	350 (48)	70	48/50
78	502 (48)	48/50	466 (49)	93	49/50	432 (50)	86	50/50	351 (48)	70	48/50
82	501 (48)	48/50	464 (48)	93	48/50	429 (50)	86	50/50	349 (47)	70	47/50
86	500 (46)	46/50	462 (47)	92	47/50	421 (49)	84	49/50	341 (46)	68	46/50
90	501 (46)	46/50	461 (46)	92	46/50	418 (49)	83	49/50	338 (45)	67	45/50
94	496 (44)	44/50	460 (46)	93	46/50	416 (47)	84	47/50	344 (42)	69	42/50
98	482 (44)	44/50	454 (44)	94	44/50	407 (47)	84	47/50	335 (40)	70	40/50
102	473 (39)	39/50	454 (41)	96	41/50	407 (46)	86	46/50	331 (40)	70	40/50
104	468 (37)	37/50	452 (39)	97	39/50	397 (44)	85	44/50	330 (39)	71	39/50

< > : 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 DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE

Week on Study	Control		20ppm			40ppm			80ppm		
	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	101 (50)	50/50	101 (50)	100	50/50	101 (50)	100	50/50	101 (50)	100	50/50
1	118 (50)	50/50	116 (50)	98	50/50	112 (50)	95	50/50	105 (50)	89	50/50
2	131 (50)	50/50	129 (50)	98	50/50	124 (50)	95	50/50	115 (50)	88	50/50
3	141 (50)	50/50	139 (50)	99	50/50	134 (50)	95	50/50	124 (50)	88	50/50
4	150 (50)	50/50	148 (50)	99	50/50	143 (50)	95	50/50	132 (50)	88	50/50
5	158 (50)	50/50	155 (50)	98	50/50	150 (50)	95	50/50	136 (50)	86	50/50
6	163 (50)	50/50	160 (50)	98	50/50	155 (50)	95	50/50	140 (50)	86	50/50
7	169 (50)	50/50	165 (50)	98	50/50	159 (50)	94	50/50	144 (50)	85	50/50
8	172 (50)	50/50	168 (50)	98	50/50	162 (50)	94	50/50	146 (50)	85	50/50
9	176 (50)	50/50	172 (50)	98	50/50	165 (50)	94	50/50	149 (50)	85	50/50
10	181 (50)	50/50	176 (50)	97	50/50	168 (50)	93	50/50	150 (50)	83	50/50
11	185 (50)	50/50	179 (50)	97	50/50	171 (50)	92	50/50	153 (50)	83	50/50
12	189 (50)	50/50	181 (50)	96	50/50	172 (50)	91	50/50	153 (50)	81	50/50
13	191 (50)	50/50	183 (50)	96	50/50	174 (50)	91	50/50	158 (50)	83	50/50
14	193 (50)	50/50	185 (50)	96	50/50	176 (50)	91	50/50	158 (50)	82	50/50
18	201 (50)	50/50	192 (50)	96	50/50	180 (50)	90	50/50	161 (50)	80	50/50
22	207 (50)	50/50	197 (50)	95	50/50	182 (50)	88	50/50	162 (50)	78	50/50
26	214 (50)	50/50	203 (50)	95	50/50	189 (50)	88	50/50	166 (50)	78	50/50
30	219 (50)	50/50	206 (50)	94	50/50	186 (50)	85	50/50	167 (50)	76	50/50
34	228 (50)	50/50	214 (50)	94	50/50	191 (50)	84	50/50	170 (50)	75	50/50
38	234 (50)	50/50	216 (50)	92	50/50	190 (50)	81	50/50	169 (50)	72	50/50
42	242 (50)	50/50	225 (50)	93	50/50	195 (50)	81	50/50	172 (50)	71	50/50
46	248 (50)	50/50	227 (50)	92	50/50	193 (50)	78	50/50	172 (50)	69	50/50
50	254 (49)	49/50	230 (49)	91	49/50	195 (50)	77	50/50	171 (50)	67	50/50
54	261 (49)	49/50	235 (49)	90	49/50	193 (50)	74	50/50	168 (50)	64	50/50
58	269 (49)	49/50	242 (49)	90	49/50	198 (50)	74	50/50	173 (49)	64	49/50
62	278 (49)	49/50	246 (49)	88	49/50	196 (50)	71	50/50	170 (48)	61	48/50
66	287 (49)	49/50	255 (49)	89	49/50	203 (50)	71	50/50	171 (46)	60	46/50
70	296 (49)	49/50	263 (49)	89	49/50	205 (50)	69	50/50	177 (46)	60	46/50
74	301 (49)	49/50	268 (48)	89	48/50	206 (50)	68	50/50	172 (45)	57	45/50
78	308 (48)	48/50	275 (48)	89	48/50	211 (49)	69	49/50	177 (42)	57	42/50
82	308 (47)	47/50	279 (48)	91	48/50	213 (49)	69	49/50	176 (40)	57	40/50
86	307 (46)	46/50	280 (47)	91	47/50	213 (48)	69	48/50	174 (39)	57	39/50
90	315 (44)	44/50	285 (46)	90	46/50	216 (48)	69	48/50	176 (39)	56	39/50
94	316 (44)	44/50	283 (46)	90	46/50	220 (47)	70	47/50	177 (37)	56	37/50
98	322 (42)	42/50	287 (44)	89	44/50	219 (47)	68	47/50	177 (34)	55	34/50
102	327 (41)	41/50	292 (40)	89	40/50	223 (46)	68	46/50	179 (31)	55	31/50
104	322 (40)	40/50	286 (39)	89	39/50	219 (44)	68	44/50	181 (29)	56	29/50

< > : 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 DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE

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	1/50	2/49	6/48	14/46	15/50(3/13)
20ppm	0/50	0/50	1/50	1/50	2/50	2/50	8/49	12/46	12/50(3/11)
40ppm	0/50	0/50	0/50	0/50	1/50	2/50	3/50	7/47	9/50(2/ 6)
80ppm	0/50	0/50	0/50	0/50	0/50	4/49	6/48	8/43	11/50(2/11)
Internal mass									
Control	0/50	0/50	0/50	0/50	0/50	0/49	0/48	3/46	3/50(2/13)
20ppm	0/50	0/50	0/50	0/50	0/50	0/50	0/49	1/46	1/50(1/11)
40ppm	0/50	0/50	0/50	0/50	0/50	0/50	1/50	2/47	2/50(1/ 6)
80ppm	0/50	0/50	0/50	0/50	0/50	1/49	0/48	1/43	2/50(1/11)

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

TABLE 5 INCIDENCE OF EXTERNAL AND INTERNAL MASS IN CLINICAL OBSERVATION OF FEMALE RATS IN THE 2-YEAR DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE

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	0/50	0/49	2/49	9/48	12/44	14/50(5/10)
20ppm	0/50	0/50	0/50	0/50	1/49	1/49	2/48	8/46	8/50(1/11)
40ppm	0/50	0/50	0/50	0/50	0/50	0/50	3/49	2/47	4/50(2/ 6)
80ppm	0/50	0/50	0/50	0/50	0/50	2/46	1/42	3/38	4/50(2/21)
Internal mass									
Control	0/50	0/50	0/50	0/50	0/49	1/49	0/48	1/44	2/50(1/10)
20ppm	0/50	0/50	0/50	0/50	0/49	0/49	0/48	1/46	1/50(1/11)
40ppm	0/50	0/50	0/50	0/50	0/50	0/50	0/49	1/47	1/50(1/ 6)
80ppm	0/50	0/50	0/50	0/50	0/50	0/46	0/42	1/38	1/50(1/21)

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

TABLE 6 WATER CONSUMPTION CHANGES OF MALE RATS IN THE 2-YEAR DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE

Week on Study	Control		20ppm			40ppm			80ppm		
	Av.WC.	No. of Surviv. <50>	Av.WC.	% of cont. <50>	No. of Surviv.	Av.WC.	% of cont. <50>	No. of Surviv.	Av.WC.	% of cont. <50>	No. of Surviv.
1	17.8 (50)	50/50	15.2 (50)	85	50/50	13.5 (50)	76	50/50	13.1 (50)	74	50/50
2	19.1 (50)	50/50	15.1 (50)	79	50/50	14.0 (50)	73	50/50	13.3 (50)	70	50/50
3	20.0 (49)	50/50	15.4 (50)	77	50/50	14.2 (50)	71	50/50	13.0 (50)	65	50/50
4	20.1 (50)	50/50	15.1 (49)	75	50/50	14.0 (50)	70	50/50	12.6 (50)	63	50/50
5	19.5 (50)	50/50	15.0 (50)	77	50/50	13.8 (50)	71	50/50	12.0 (50)	62	50/50
6	18.5 (50)	50/50	14.3 (50)	77	50/50	12.9 (50)	70	50/50	11.1 (50)	60	50/50
7	18.4 (50)	50/50	14.9 (49)	81	50/50	13.3 (50)	72	50/50	11.7 (50)	64	50/50
8	17.8 (50)	50/50	14.7 (50)	83	50/50	13.4 (50)	75	50/50	11.5 (50)	65	50/50
9	18.2 (50)	50/50	14.8 (50)	81	50/50	13.4 (50)	74	50/50	11.6 (50)	64	50/50
10	17.7 (50)	50/50	14.5 (50)	82	50/50	13.1 (50)	74	50/50	11.6 (50)	66	50/50
11	18.2 (50)	50/50	14.9 (50)	82	50/50	13.2 (50)	73	50/50	11.5 (50)	63	50/50
12	18.5 (50)	50/50	14.7 (50)	79	50/50	13.3 (50)	72	50/50	11.4 (50)	62	50/50
13	18.2 (50)	50/50	14.4 (50)	79	50/50	13.0 (50)	71	50/50	11.4 (50)	63	50/50
14	17.3 (50)	50/50	14.2 (50)	82	50/50	12.7 (50)	73	50/50	11.5 (50)	66	50/50
18	18.5 (50)	50/50	15.3 (50)	83	50/50	13.8 (50)	75	50/50	11.7 (50)	63	50/50
22	18.1 (50)	50/50	15.5 (50)	86	50/50	13.4 (50)	74	50/50	12.1 (50)	67	50/50
26	18.3 (50)	50/50	15.2 (50)	83	50/50	13.9 (50)	76	50/50	12.4 (50)	68	50/50
30	18.0 (50)	50/50	15.0 (50)	83	50/50	13.4 (50)	74	50/50	12.4 (50)	69	50/50
34	18.1 (50)	50/50	15.9 (50)	88	50/50	14.3 (50)	79	50/50	13.1 (50)	72	50/50
38	18.7 (50)	50/50	15.9 (50)	85	50/50	14.5 (50)	78	50/50	13.5 (50)	72	50/50
42	19.2 (50)	50/50	17.6 (50)	92	50/50	15.5 (50)	81	50/50	14.4 (50)	75	50/50
46	19.1 (50)	50/50	16.1 (49)	84	50/50	14.9 (50)	78	50/50	14.0 (50)	73	50/50
50	18.4 (50)	50/50	17.0 (50)	92	50/50	15.3 (50)	83	50/50	14.8 (50)	80	50/50
54	19.3 (50)	50/50	16.8 (49)	87	50/50	15.7 (50)	81	50/50	15.5 (50)	80	50/50
58	19.2 (50)	50/50	17.1 (50)	89	50/50	16.5 (50)	86	50/50	16.1 (50)	84	50/50
62	20.3 (50)	50/50	16.8 (50)	83	50/50	15.2 (50)	75	50/50	14.7 (49)	72	49/50
66	20.1 (49)	49/50	18.8 (50)	94	50/50	16.6 (50)	83	50/50	15.6 (49)	78	49/50
70	20.4 (49)	49/50	18.0 (50)	88	50/50	16.4 (50)	80	50/50	15.6 (49)	76	49/50
74	20.7 (48)	49/50	18.2 (50)	88	50/50	16.6 (50)	80	50/50	15.2 (48)	73	48/50
78	20.6 (48)	48/50	17.8 (49)	86	49/50	16.2 (50)	79	50/50	15.2 (48)	74	48/50
82	21.8 (47)	48/50	18.9 (48)	87	48/50	16.4 (50)	75	50/50	15.4 (47)	71	47/50
86	21.8 (46)	46/50	17.5 (46)	80	47/50	15.9 (49)	73	49/50	14.8 (46)	68	46/50
90	22.4 (46)	46/50	18.3 (45)	82	46/50	16.7 (49)	75	49/50	15.3 (45)	68	45/50
94	23.4 (44)	44/50	19.3 (44)	82	46/50	17.0 (47)	73	47/50	15.4 (42)	66	42/50
98	23.6 (44)	44/50	19.5 (44)	83	44/50	17.2 (47)	73	47/50	15.7 (40)	67	40/50
102	25.6 (38)	39/50	20.8 (41)	81	41/50	17.3 (46)	68	46/50	15.4 (40)	60	40/50
104	26.8 (35)	37/50	22.1 (39)	82	39/50	18.6 (44)	69	44/50	16.0 (39)	60	39/50

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

TABLE 7 WATER CONSUMPTION CHANGES OF FEMALE RATS IN THE 2-YEAR DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE

Week on Study	Control		20ppm			40ppm			80ppm		
	Av.WC.	No. of Surviv. <50>	Av.WC.	% of cont. <50>	No. of Surviv.	Av.WC.	% of cont. <50>	No. of Surviv.	Av.WC.	% of cont. <50>	No. of Surviv.
1	16.7 (50)	50/50	14.1 (50)	84	50/50	11.7 (50)	70	50/50	10.8 (50)	65	50/50
2	16.7 (50)	50/50	12.4 (50)	74	50/50	10.8 (50)	65	50/50	9.8 (50)	59	50/50
3	16.9 (48)	50/50	12.0 (50)	71	50/50	10.5 (50)	62	50/50	9.5 (50)	56	50/50
4	17.7 (45)	50/50	13.0 (50)	73	50/50	10.7 (50)	60	50/50	9.6 (50)	54	50/50
5	19.2 (46)	50/50	12.7 (50)	66	50/50	10.4 (50)	54	50/50	8.9 (50)	46	50/50
6	18.5 (45)	50/50	12.2 (50)	66	50/50	10.1 (50)	55	50/50	8.7 (50)	47	50/50
7	18.8 (46)	50/50	12.5 (50)	66	50/50	9.7 (50)	52	50/50	8.4 (50)	45	50/50
8	18.2 (44)	50/50	11.6 (50)	64	50/50	9.3 (50)	51	50/50	8.1 (50)	45	50/50
9	16.6 (46)	50/50	11.0 (50)	66	50/50	8.8 (50)	53	50/50	8.1 (50)	49	50/50
10	17.1 (45)	50/50	11.5 (50)	67	50/50	8.9 (50)	52	50/50	8.1 (50)	47	50/50
11	18.2 (46)	50/50	11.7 (50)	64	50/50	9.1 (50)	50	50/50	8.0 (50)	44	50/50
12	19.2 (42)	50/50	12.1 (50)	63	50/50	9.2 (50)	48	50/50	8.1 (50)	42	50/50
13	19.3 (46)	50/50	11.0 (50)	57	50/50	9.0 (49)	47	50/50	8.9 (50)	46	50/50
14	19.1 (47)	50/50	11.7 (50)	61	50/50	10.0 (50)	52	50/50	8.2 (50)	43	50/50
18	19.4 (45)	50/50	11.3 (50)	58	50/50	9.1 (50)	47	50/50	8.4 (50)	43	50/50
22	20.0 (46)	50/50	12.0 (50)	60	50/50	9.8 (50)	49	50/50	9.0 (50)	45	50/50
26	19.0 (48)	50/50	11.8 (50)	62	50/50	10.1 (50)	53	50/50	8.5 (50)	45	50/50
30	19.9 (49)	50/50	11.2 (50)	56	50/50	9.6 (50)	48	50/50	9.2 (50)	46	50/50
34	17.9 (43)	50/50	12.2 (50)	68	50/50	10.1 (50)	56	50/50	9.0 (50)	50	50/50
38	18.8 (48)	50/50	11.5 (50)	61	50/50	9.9 (50)	53	50/50	8.8 (50)	47	50/50
42	20.6 (50)	50/50	13.3 (50)	65	50/50	11.4 (50)	55	50/50	10.1 (50)	49	50/50
46	18.3 (49)	50/50	12.0 (50)	66	50/50	10.3 (50)	56	50/50	9.9 (50)	54	50/50
50	17.5 (48)	49/50	14.0 (49)	80	49/50	12.3 (50)	70	50/50	10.4 (50)	59	50/50
54	17.7 (49)	49/50	12.5 (49)	71	49/50	10.5 (50)	59	50/50	10.0 (50)	56	50/50
58	16.6 (49)	49/50	13.6 (49)	82	49/50	11.7 (50)	70	50/50	11.0 (49)	66	49/50
62	17.0 (49)	49/50	12.6 (49)	74	49/50	11.0 (50)	65	50/50	10.7 (48)	63	48/50
66	15.8 (49)	49/50	14.4 (49)	91	49/50	12.7 (50)	80	50/50	10.9 (46)	69	46/50
70	16.4 (49)	49/50	13.4 (49)	82	49/50	11.7 (50)	71	50/50	12.7 (46)	77	46/50
74	16.2 (49)	49/50	14.0 (47)	86	48/50	11.9 (50)	73	50/50	11.3 (45)	70	45/50
78	17.2 (48)	48/50	14.3 (48)	83	48/50	12.8 (49)	74	49/50	13.4 (42)	78	42/50
82	17.3 (47)	47/50	15.0 (48)	87	48/50	13.4 (49)	77	49/50	14.5 (40)	84	40/50
86	18.4 (46)	46/50	14.9 (47)	81	47/50	13.8 (48)	75	48/50	13.8 (39)	75	39/50
90	17.8 (43)	44/50	15.6 (46)	88	46/50	14.7 (48)	83	48/50	15.4 (39)	87	39/50
94	16.9 (43)	44/50	15.4 (46)	91	46/50	14.2 (47)	84	47/50	15.0 (37)	89	37/50
98	18.9 (42)	42/50	15.9 (44)	84	44/50	15.7 (47)	83	47/50	16.1 (34)	85	34/50
102	19.1 (41)	41/50	16.2 (40)	85	40/50	17.1 (46)	90	46/50	16.4 (31)	86	31/50
104	19.0 (40)	40/50	17.0 (39)	89	39/50	17.1 (44)	90	44/50	18.2 (29)	96	29/50

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

TABLE 8 FOOD CONSUMPTION CHANGES OF MALE RATS IN THE 2-YEAR DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE

Week on Study	Control		20ppm			40ppm			80ppm		
	Av.FC.	No. of Surviv. <50>	Av.FC.	% of cont. <50>	No. of Surviv.	Av.FC.	% of cont. <50>	No. of Surviv.	Av.FC.	% of cont. <50>	No. of Surviv.
1	13.8 (50)	50/50	13.0 (50)	94	50/50	12.4 (50)	90	50/50	11.9 (50)	86	50/50
2	15.1 (50)	50/50	14.3 (50)	95	50/50	13.9 (50)	92	50/50	13.4 (50)	89	50/50
3	15.3 (50)	50/50	14.4 (50)	94	50/50	13.9 (50)	91	50/50	13.3 (50)	87	50/50
4	15.1 (50)	50/50	14.3 (50)	95	50/50	13.7 (50)	91	50/50	12.9 (50)	85	50/50
5	15.0 (50)	50/50	14.5 (50)	97	50/50	14.2 (50)	95	50/50	13.1 (50)	87	50/50
6	14.1 (50)	50/50	13.6 (50)	96	50/50	13.1 (50)	93	50/50	12.1 (50)	86	50/50
7	14.7 (50)	50/50	14.0 (50)	95	50/50	13.4 (50)	91	50/50	12.2 (50)	83	50/50
8	14.6 (50)	50/50	14.5 (50)	99	50/50	13.8 (50)	95	50/50	12.7 (50)	87	50/50
9	14.7 (50)	50/50	14.6 (50)	99	50/50	13.9 (50)	95	50/50	13.0 (50)	88	50/50
10	14.6 (50)	50/50	14.5 (50)	99	50/50	13.8 (50)	95	50/50	13.0 (50)	89	50/50
11	15.1 (50)	50/50	14.8 (50)	98	50/50	14.1 (50)	93	50/50	13.1 (50)	87	50/50
12	14.6 (50)	50/50	14.3 (50)	98	50/50	13.7 (50)	94	50/50	12.8 (50)	88	50/50
13	14.5 (50)	50/50	14.2 (50)	98	50/50	13.7 (50)	94	50/50	13.1 (50)	90	50/50
14	14.5 (50)	50/50	14.1 (50)	97	50/50	13.6 (50)	94	50/50	13.0 (50)	90	50/50
18	15.7 (50)	50/50	15.1 (50)	96	50/50	14.6 (50)	93	50/50	13.7 (50)	87	50/50
22	15.4 (50)	50/50	14.8 (50)	96	50/50	14.1 (50)	92	50/50	13.1 (50)	85	50/50
26	15.5 (50)	50/50	15.0 (50)	97	50/50	14.4 (50)	93	50/50	13.7 (50)	88	50/50
30	15.9 (50)	50/50	15.2 (50)	96	50/50	14.4 (50)	91	50/50	13.6 (50)	86	50/50
34	16.2 (50)	50/50	15.9 (50)	98	50/50	15.1 (50)	93	50/50	13.9 (50)	86	50/50
38	16.7 (50)	50/50	16.2 (50)	97	50/50	15.6 (50)	93	50/50	14.3 (50)	86	50/50
42	16.7 (50)	50/50	16.4 (50)	98	50/50	15.8 (50)	95	50/50	14.5 (50)	87	50/50
46	16.8 (50)	50/50	15.8 (50)	94	50/50	15.5 (50)	92	50/50	14.1 (50)	84	50/50
50	16.6 (50)	50/50	16.4 (50)	99	50/50	15.3 (50)	92	50/50	14.2 (50)	86	50/50
54	16.6 (50)	50/50	15.7 (50)	95	50/50	15.2 (50)	92	50/50	14.0 (50)	84	50/50
58	17.0 (50)	50/50	16.7 (50)	98	50/50	16.3 (50)	96	50/50	14.9 (50)	88	50/50
62	17.7 (49)	50/50	16.7 (50)	94	50/50	15.7 (50)	89	50/50	14.6 (49)	82	49/50
66	17.3 (49)	49/50	17.1 (50)	99	50/50	16.3 (50)	94	50/50	15.0 (49)	87	49/50
70	17.6 (49)	49/50	16.9 (50)	96	50/50	16.1 (50)	91	50/50	15.0 (49)	85	49/50
74	17.6 (49)	49/50	16.7 (50)	95	50/50	15.8 (50)	90	50/50	14.8 (48)	84	48/50
78	17.3 (48)	48/50	16.3 (49)	94	49/50	15.5 (50)	90	50/50	14.7 (48)	85	48/50
82	17.4 (48)	48/50	16.4 (48)	94	48/50	15.2 (50)	87	50/50	14.5 (47)	83	47/50
86	17.3 (46)	46/50	16.2 (47)	94	47/50	15.1 (49)	87	49/50	14.4 (46)	83	46/50
90	16.8 (45)	46/50	16.0 (46)	95	46/50	14.8 (49)	88	49/50	14.2 (45)	85	45/50
94	16.9 (44)	44/50	16.3 (46)	96	46/50	15.1 (47)	89	47/50	14.9 (42)	88	42/50
98	16.0 (43)	44/50	15.6 (44)	98	44/50	14.6 (47)	91	47/50	14.0 (40)	88	40/50
102	16.1 (38)	39/50	16.0 (40)	99	41/50	15.1 (46)	94	46/50	14.0 (39)	87	40/50
104	15.5 (36)	37/50	15.7 (39)	101	39/50	14.5 (44)	94	44/50	13.8 (39)	89	39/50

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

TABLE 9 FOOD CONSUMPTION CHANGES OF FEMALE RATS IN THE 2-YEAR DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE

Week on Study	Control		20ppm			40ppm			80ppm		
	Av.FC.	No. of <50>	Av.FC.	% of <49>	No. of Surviv.	Av.FC.	% of <50>	No. of Surviv.	Av.FC.	% of <50>	No. of Surviv.
	1	11.0 (50) 50/50	10.5 (50) 95	50/50	9.6 (50) 87	50/50	8.7 (50) 79	50/50	8.7 (50) 86	50/50	8.7 (50) 83
2	11.1 (50) 50/50	10.7 (50) 96	50/50	10.1 (50) 91	50/50	9.6 (50) 86	50/50	9.6 (50) 82	50/50	9.6 (50) 80	50/50
3	11.1 (50) 50/50	10.3 (50) 93	50/50	9.8 (50) 88	50/50	9.2 (50) 83	50/50	9.2 (50) 80	50/50	9.2 (50) 79	50/50
4	11.1 (50) 50/50	10.6 (50) 95	50/50	10.0 (50) 90	50/50	9.1 (50) 82	50/50	9.1 (50) 80	50/50	9.1 (50) 78	50/50
5	11.1 (50) 50/50	10.7 (50) 96	50/50	10.0 (50) 90	50/50	9.1 (50) 82	50/50	9.1 (50) 80	50/50	9.1 (50) 78	50/50
6	10.7 (50) 50/50	9.9 (50) 93	50/50	9.6 (50) 90	50/50	8.7 (50) 81	50/50	8.7 (50) 80	50/50	8.7 (50) 79	50/50
7	10.8 (50) 50/50	10.0 (50) 93	50/50	9.5 (50) 88	50/50	8.7 (50) 81	50/50	8.7 (50) 80	50/50	8.7 (50) 79	50/50
8	10.4 (50) 50/50	9.9 (50) 95	50/50	9.3 (50) 89	50/50	8.8 (50) 85	50/50	8.8 (50) 83	50/50	8.8 (50) 80	50/50
9	10.6 (50) 50/50	9.9 (50) 93	50/50	9.3 (50) 88	50/50	8.8 (50) 83	50/50	8.8 (50) 80	50/50	8.8 (50) 78	50/50
10	10.6 (50) 50/50	9.9 (50) 93	50/50	9.2 (50) 87	50/50	8.5 (50) 80	50/50	8.5 (50) 78	50/50	8.5 (50) 76	50/50
11	10.7 (50) 50/50	9.8 (50) 92	50/50	9.2 (50) 86	50/50	8.6 (50) 80	50/50	8.6 (50) 78	50/50	8.6 (50) 76	50/50
12	10.8 (50) 50/50	9.7 (50) 90	50/50	9.2 (50) 85	50/50	8.5 (50) 79	50/50	8.5 (50) 77	50/50	8.5 (50) 75	50/50
13	10.8 (50) 50/50	9.7 (50) 90	50/50	9.2 (50) 85	50/50	8.9 (50) 82	50/50	8.9 (50) 80	50/50	8.9 (50) 78	50/50
14	10.5 (50) 50/50	9.9 (50) 94	50/50	9.3 (50) 89	50/50	8.8 (50) 84	50/50	8.8 (50) 81	50/50	8.8 (50) 78	50/50
18	10.7 (50) 50/50	9.8 (50) 92	50/50	9.2 (50) 86	50/50	8.7 (50) 81	50/50	8.7 (50) 79	50/50	8.7 (50) 77	50/50
22	10.6 (50) 50/50	9.9 (50) 93	50/50	9.3 (50) 88	50/50	8.8 (50) 83	50/50	8.8 (50) 80	50/50	8.8 (50) 78	50/50
26	11.3 (50) 50/50	10.5 (50) 93	50/50	9.7 (50) 86	50/50	9.0 (50) 80	50/50	8.7 (50) 79	50/50	8.7 (50) 77	50/50
30	11.0 (50) 50/50	10.0 (50) 91	50/50	9.2 (50) 84	50/50	8.9 (50) 75	50/50	8.9 (50) 72	50/50	8.9 (50) 70	50/50
34	11.8 (50) 50/50	10.9 (50) 92	50/50	9.6 (50) 81	50/50	8.8 (50) 75	50/50	8.8 (50) 72	50/50	8.8 (50) 70	50/50
38	11.7 (50) 50/50	10.6 (50) 91	50/50	9.5 (50) 81	50/50	8.8 (50) 75	50/50	8.8 (50) 72	50/50	8.8 (50) 70	50/50
42	12.0 (50) 50/50	11.3 (50) 94	50/50	10.0 (50) 83	50/50	9.0 (50) 75	50/50	9.0 (50) 72	50/50	9.0 (50) 70	50/50
46	11.6 (50) 50/50	10.7 (50) 92	50/50	9.4 (50) 81	50/50	8.9 (50) 77	50/50	8.9 (50) 74	50/50	8.9 (50) 72	50/50
50	11.9 (49) 49/50	11.2 (49) 94	49/50	10.1 (50) 85	50/50	9.1 (50) 76	50/50	9.1 (50) 73	50/50	9.1 (50) 71	50/50
54	11.7 (49) 49/50	10.7 (49) 91	49/50	9.4 (50) 80	50/50	8.6 (50) 74	50/50	8.6 (50) 71	50/50	8.6 (50) 69	50/50
58	12.2 (49) 49/50	11.6 (49) 95	49/50	10.2 (50) 84	50/50	9.5 (49) 78	49/50	9.5 (49) 75	49/50	9.5 (49) 73	49/50
62	12.5 (49) 49/50	11.1 (49) 89	49/50	9.7 (50) 78	50/50	9.2 (48) 74	48/50	9.2 (48) 71	48/50	9.2 (48) 69	48/50
66	12.0 (49) 49/50	12.1 (49) 101	49/50	10.6 (50) 88	50/50	9.4 (46) 78	46/50	9.4 (46) 75	46/50	9.4 (46) 72	46/50
70	12.5 (49) 49/50	12.0 (49) 96	49/50	10.6 (50) 85	50/50	10.4 (46) 83	46/50	10.4 (46) 80	46/50	10.4 (46) 77	46/50
74	12.3 (49) 49/50	11.9 (48) 97	48/50	10.6 (50) 86	50/50	9.6 (45) 78	45/50	9.6 (45) 75	45/50	9.6 (45) 72	45/50
78	12.6 (48) 48/50	12.1 (48) 96	48/50	10.8 (49) 86	49/50	10.2 (42) 81	42/50	10.2 (42) 78	42/50	10.2 (42) 75	42/50
82	12.4 (47) 47/50	11.9 (48) 96	48/50	10.7 (49) 86	49/50	10.3 (40) 83	40/50	10.3 (40) 80	40/50	10.3 (40) 77	40/50
86	12.4 (46) 46/50	11.9 (47) 96	47/50	10.6 (48) 85	48/50	10.3 (39) 83	39/50	10.3 (39) 80	39/50	10.3 (39) 77	39/50
90	13.0 (44) 44/50	12.5 (46) 96	46/50	11.0 (48) 85	48/50	10.8 (39) 83	39/50	10.8 (39) 80	39/50	10.8 (39) 77	39/50
94	12.7 (44) 44/50	11.9 (46) 94	46/50	11.0 (47) 87	47/50	10.6 (37) 83	37/50	10.6 (37) 80	37/50	10.6 (37) 77	37/50
98	13.0 (42) 42/50	12.1 (44) 93	44/50	10.9 (47) 84	47/50	10.8 (34) 83	34/50	10.8 (34) 80	34/50	10.8 (34) 77	34/50
102	13.7 (40) 41/50	12.7 (39) 93	40/50	11.5 (46) 84	46/50	11.0 (31) 80	31/50	11.0 (31) 78	31/50	11.0 (31) 75	31/50
104	12.1 (39) 40/50	11.5 (39) 95	39/50	10.7 (44) 88	44/50	11.0 (29) 91	29/50	11.0 (29) 88	29/50	11.0 (29) 85	29/50

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

**TABLE 10 NEOPLASTIC LESIONS INCIDENCE AND STATISTICAL ANALYSIS OF MALE RAT
IN THE 2-YEAR DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE**

Group Name	Control	20ppm	40ppm	80ppm
SITE : liver				
TUMOR : hepatocellular adenoma				
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	7.69
Terminal rates(c)	0/37(0.0)	0/39(0.0)	0/44(0.0)	3/39(7.7)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0038**?			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0079**			
Fisher Exact test(e)		P=0.5000	P=0.5000	P=0.1212
SITE : liver				
TUMOR : hepatocellular adenoma, hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	0/50(0.0)	0/50(0.0)	4/50(8.0)
Adjusted rates(b)	0.0	0.0	0.0	10.26
Terminal rates(c)	0/37(0.0)	0/39(0.0)	0/44(0.0)	4/39(10.3)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0009**?			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0021**			
Fisher Exact test(e)		P=0.5000	P=0.5000	P=0.0587

(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 11 NEOPLASTIC LESIONS INCIDENCE AND STATISTICAL ANALYSIS OF FEMALE RAT IN THE 2-YEAR DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE

Group Name	Control	20ppm	40ppm	80ppm
SITE : liver				
TUMOR : hepatocellular adenoma				
Tumor rate				
Overall rates(a)	1/50(2.0)	0/50(0.0)	3/50(6.0)	4/50(8.0)
Adjusted rates(b)	2.50	0.0	6.82	10.81
Terminal rates(c)	1/40(2.5)	0/39(0.0)	3/44(6.8)	2/29(6.9)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0165*			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0510			
Fisher Exact test(e)		P=0.5000	P=0.3087	P=0.1811
SITE : liver				
TUMOR : hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	0/50(0.0)	0/50(0.0)	4/50(8.0)
Adjusted rates(b)	0.0	0.0	0.0	11.43
Terminal rates(c)	0/40(0.0)	0/39(0.0)	0/44(0.0)	2/29(6.9)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0004**?			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0021**			
Fisher Exact test(e)		P=0.5000	P=0.5000	P=0.0587
SITE : liver				
TUMOR : hepatocellular adenoma, hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	1/50(2.0)	0/50(0.0)	3/50(6.0)	6/50(12.0)
Adjusted rates(b)	2.50	0.0	6.82	16.22
Terminal rates(c)	1/40(2.5)	0/39(0.0)	3/44(6.8)	3/29(10.3)
Statistical analysis				
Peto test				
Standard method(d)	P=-----			
Prevalence method(d)	P=0.0015**			
Combined analysis (d)	P=-----			
Cochran-Armitage test(e)	P=0.0061**			
Fisher Exact test(e)		P=0.5000	P=0.3087	P=0.0559

(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 12 NUMBER OF RATS WITH SELECTED NON-NEOPLASTIC LESIONS IN THE 2-YEAR DRINKING WATER STUDY
OF HYDRAZINE MONOHYDRATE

Group name <all animal No.>(sacrificed animal No.)	Male				Female			
	Control <50> (37)	20ppm <50> (39)	40ppm <50> (44)	80ppm <50> (39)	Control <50> (40)	20ppm <50> (39)	40ppm <50> (44)	80ppm <50> (29)
Liver acidophilic cell focus	7 (7) 6 (6)	12 (12) 8 (8)	20** (20)** 7 (7)	36** (36)** 10 (10)	0 (0) 0 (0)	4 (4) 3 (3)	22** (22)** 11 (11)	26** (24)** 9 (7)
2+ 3+ 4+	1 (1) 0 (0) 0 (0)	4 (4) 0 (0) 0 (0)	13 (13) 0 (0) 0 (0)	26 (26) 0 (0) 0 (0)	0 (0) 0 (0) 0 (0)	1 (1) 0 (0) 0 (0)	11 (11) 0 (0) 0 (0)	17 (17) 0 (0) 0 (0)
Liver basophilic cell focus	17 (16) 13 (12)	15 (13) 10 (8)	16 (15) 13 (13)	20 (17) 18 (15)	4 (4) 4 (4)	8 (7) 7 (7)	19** (18)** 14 (13)	19** (17)** 11 (10)
2+ 3+ 4+	4 (4) 0 (0) 0 (0)	5 (5) 0 (0) 0 (0)	3 (2) 0 (0) 0 (0)	2 (2) 0 (0) 0 (0)	0 (0) 0 (0) 0 (0)	1 (0) 0 (0) 0 (0)	5 (5) 0 (0) 0 (0)	8 (7) 0 (0) 0 (0)
Kidney infarct	0 (0) 0 (0)	1 (1) 1 (1)	5 (5) 5 (5)	11** (9)** 11 (9)	0 (0) 0 (0)	3 (3) 2 (2)	35** (32)** 15 (13)	29** (20)** 21 (14)
2+ 3+ 4+	0 (0) 0 (0) 0 (0)	0 (0) 0 (0) 0 (0)	0 (0) 0 (0) 0 (0)	0 (0) 0 (0) 0 (0)	0 (0) 0 (0) 0 (0)	1 (1) 1 (1) 0 (0)	16 (15) 4 (4) 0 (0)	7 (5) 1 (1) 0 (0)
Kidney papillary necrosis	0 (0) 0 (0)	0 (0) 0 (0)	1 (1) 1 (1)	20** (16)** 10 (9)	0 (0) 0 (0)	1 (1) 1 (1)	35** (32)** 11 (11)	42** (25)** 4 (3)
2+ 3+ 4+	0 (0) 0 (0) 0 (0)	0 (0) 0 (0) 0 (0)	0 (0) 0 (0) 0 (0)	9 (6) 1 (1) 0 (0)	0 (0) 0 (0) 0 (0)	0 (0) 0 (0) 0 (0)	16 (14) 8 (7) 0 (0)	10 (7) 28 (15) 0 (0)

Grade +:Slight 2+:Moderate 3+:Marked 4+:Severe

< >:Number of animals examined at the site

():Sacrificed animals

Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

TABLE 12 NUMBER OF RATS WITH SELECTED NON-NEOPLASTIC LESIONS IN THE 2-YEAR DRINKING WATER STUDY
OF HYDRAZINE MONOHYDRATE (Continued)

Group name <all animal No.>(sacrificed animal No.)	Male			Female		
	Control <50> (37)	20ppm <50> (39)	40ppm <50> (44)	80ppm <50> (39)	Control <50> (40)	20ppm <50> (39)
Kidney mineralization : papilla	0 (0)	6* (6)*	8** (8)*	29** (24)**	0 (0)	13** (10)**
2+	0 (0)	6 (6)	8 (8)	28 (24)	0 (0)	13 (10)
3+	0 (0)	0 (0)	0 (0)	1 (0)	0 (0)	3 (3)
4+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
				0 (0)	0 (0)	0 (0)
Kidney urothelial hyperplasia : pelvis	6 (4)	16* (15)*	27** (24)**	28** (21)**	19 (15)	22 (21)
2+	6 (4)	15 (14)	27 (24)	28 (21)	19 (15)	22 (21)
3+	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	9 (8)
4+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
				0 (0)	0 (0)	0 (0)

Grade +:Slight 2+:Moderate 3+:Marked 4+:Severe

< >:Number of animals examined at the site

():Sacrificed animals

Significant difference ; *:P≤0.05 **:P≤0.01 Test of Chi Square

TABLE 13 CAUSE OF DEATH OF RATS IN THE 2-YEAR DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE

Group	Male				Female			
	Control	20ppm	40ppm	80ppm	Control	20ppm	40ppm	80ppm
Number of dead or moribund animals	13	11	6	11	10	11	6	21
No microscopical confirmation	0	0	0	1	0	0	0	2
Pneumonia	0	0	0	0	1	0	0	0
Urinary system lesion	0	0	0	1	0	0	0	0
Nervous system disorder	0	0	0	1	0	0	0	0
Urinary retention	0	1	0	0	0	0	1	0
Renal lesion	0	0	0	0	0	0	0	15
Chronic nephropathy	0	2	1	0	0	0	0	0
Tumor death	leukemia	3	2	0	1	3	2	0
skin/appendage	0	1	1	0	1	0	0	0
subcutis	1	2	1	1	1	1	0	1
lung	0	0	0	1	0	1	0	0
lymph node	0	1	0	0	0	0	0	0
spleen	0	0	1	1	0	0	0	0
pituitary	7	0	2	0	4	5	2	1
uterus	0	0	0	0	0	2	1	0
preputial/clitoral gland	1	0	0	0	0	0	1	0
bone	0	1	0	0	0	0	0	0
vertebra	0	0	0	1	0	0	0	0
mediastinum	0	0	0	1	0	0	0	0
peritoneum	1	1	0	1	0	0	0	0
retroperitoneum	0	0	0	1	0	0	1	0