ヒドラジン一水加物のマウスを用いた
経口投与によるがん原性試験(混水試験)報告書

試験番号：０２８５

TABLES

TABLES

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	
	Crj:BDF_1 mouse
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, 40, 80, or 160 ppm
<Duration of Dosing>	
7d/wk for 104wk	
<Animal Maintenance>	
Feed	
	CRF-1 (Oriental Yeast Co., Ltd.)
	Sterilized by γ-ray
	Available *ad libitum*
Water	
	Filtrated and sterilized by ultraviolet ray
	Automatic watering system in duration of quarantine
	Glass bottle in duration of acclimation and administration
	Available *ad libitum*
Animal per Cage	
	Single (stainless steel wire)
Animal Room Environment	
	Barrier system
	Temperature : 24±2℃
	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 (Continued) EXPERIMENTAL DESIGN AND MATERIALS AND METHODS IN THE 2-YEAR DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE

2-year study
<Hematology> Hematological examination performed on scheduled sacrficed 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> Biochemistrical examination performed on scheduled sacrficed animals. The following measurement parameters were examined; Total protein, Albumin, A/G ratio, Total bilirubin, Glucose, Total cholesterol Triglyceride, Glutamic oxaloacetic transaminase (GOT), Glutamic pyruvic transaminase (GPT), Lactate dehydrogenase (LDH), Alkaline Phosphatase (ALP), Creatine phosphokinase (CPK), Urea nitrogen, 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, 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. 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, gall bladder, 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 MICE 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	24.4 (50)	50/50	24.4 (50)	100	50/50	24.4 (50)	100	50/50	24.4 (50)	100	50/50
1	25.6 (50)	50/50	25.1 (50)	98	50/50	24.6 (50)	96	50/50	23.5 (50)	92	50/50
2	26.8 (50)	50/50	26.3 (50)	98	50/50	25.8 (50)	96	50/50	24.5 (50)	91	50/50
3	27.8 (50)	50/50	26.9 (50)	97	50/50	26.3 (50)	95	50/50	25.2 (50)	91	50/50
4	28.9 (50)	50/50	27.7 (50)	96	50/50	26.8 (50)	93	50/50	25.8 (50)	89	50/50
5	29.9 (50)	50/50	28.2 (50)	94	50/50	27.3 (50)	91	50/50	26.3 (50)	88	50/50
6	31.5 (50)	50/50	29.4 (50)	93	50/50	27.9 (50)	89	50/50	27.2 (50)	86	50/50
7	31.7 (50)	50/50	28.9 (50)	91	50/50	27.9 (50)	88	50/50	26.7 (50)	84	50/50
8	32.7 (50)	50/50	29.7 (50)	91	50/50	28.5 (50)	87	50/50	27.4 (50)	84	50/50
9	33.1 (50)	50/50	30.2 (50)	91	50/50	29.0 (50)	88	50/50	27.5 (50)	83	50/50
10	34.7 (50)	50/50	31.2 (50)	90	50/50	29.6 (50)	85	50/50	27.9 (50)	80	50/50
11	35.4 (50)	50/50	31.9 (50)	90	50/50	30.2 (50)	85	50/50	28.3 (50)	80	50/50
12	36.0 (50)	50/50	32.3 (50)	90	50/50	30.4 (50)	84	50/50	28.4 (50)	79	50/50
13	37.2 (50)	50/50	33.4 (50)	90	50/50	31.0 (50)	83	50/50	28.7 (50)	77	50/50
14	37.6 (50)	50/50	33.4 (50)	89	50/50	31.0 (50)	82	50/50	28.9 (50)	77	50/50
18	41.3 (50)	50/50	36.1 (50)	87	50/50	33.6 (50)	81	50/50	30.8 (50)	75	50/50
22	43.9 (50)	50/50	37.5 (50)	85	50/50	34.4 (50)	78	50/50	31.4 (50)	72	50/50
26	46.0 (50)	50/50	38.7 (50)	84	50/50	35.8 (49)	78	49/50	31.9 (50)	69	50/50
30	47.6 (50)	50/50	40.4 (49)	85	49/50	37.3 (49)	78	49/50	33.0 (50)	69	50/50
34	49.0 (50)	50/50	41.4 (49)	84	49/50	38.2 (49)	78	49/50	33.7 (50)	69	50/50
38	50.7 (50)	50/50	43.2 (49)	85	49/50	39.6 (49)	78	49/50	34.7 (50)	68	50/50
42	52.5 (50)	50/50	44.7 (49)	85	49/50	41.0 (49)	78	49/50	35.5 (50)	68	50/50
46	53.5 (50)	50/50	46.4 (49)	87	49/50	42.7 (49)	80	49/50	37.1 (50)	69	50/50
50	53.6 (50)	50/50	46.7 (49)	87	49/50	43.2 (49)	81	49/50	37.7 (50)	70	50/50
54	54.9 (50)	50/50	47.8 (49)	87	49/50	44.0 (48)	80	48/50	38.6 (50)	70	50/50
58	55.0 (48)	48/50	47.8 (49)	87	49/50	44.0 (48)	80	48/50	38.4 (50)	70	50/50
62	55.3 (48)	48/50	49.0 (49)	89	49/50	44.7 (48)	81	48/50	39.2 (50)	71	50/50
66	55.8 (48)	48/50	48.7 (49)	87	49/50	44.3 (48)	79	48/50	39.1 (50)	70	50/50
70	55.6 (46)	46/50	48.3 (48)	87	48/50	44.4 (47)	80	47/50	38.9 (50)	70	50/50
74	56.2 (46)	46/50	48.8 (47)	87	47/50	45.8 (45)	81	45/50	39.4 (50)	70	50/50
78	56.3 (46)	46/50	49.2 (46)	87	46/50	45.1 (44)	80	44/50	39.7 (48)	71	48/50
82	55.8 (46)	46/50	48.3 (45)	87	45/50	44.5 (43)	80	43/50	39.4 (48)	71	48/50
86	55.1 (45)	45/50	48.2 (44)	87	44/50	44.0 (42)	80	42/50	39.0 (46)	71	46/50
90	54.6 (44)	44/50	47.7 (44)	87	44/50	44.6 (40)	82	40/50	39.0 (46)	71	46/50
94	55.0 (42)	42/50	48.8 (39)	89	39/50	44.3 (38)	81	38/50	39.2 (44)	71	44/50
98	52.5 (40)	40/50	48.0 (39)	91	39/50	44.0 (38)	84	38/50	38.1 (43)	73	43/50
102	51.1 (33)	33/50	45.8 (37)	90	37/50	42.5 (36)	83	36/50	37.0 (41)	72	41/50
104	50.0 (31)	31/50	47.5 (30)	95	30/50	41.4 (36)	83	36/50	35.8 (40)	72	40/50

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

TABLE 3 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF FEMALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE

Week on Study	Control		40ppm			80ppm			160ppm		
	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	19.6 (50)	50/50	19.6 (50)	100	50/50	19.6 (50)	100	50/50	19.6 (50)	100	50/50
1	20.7 (50)	50/50	20.1 (50)	97	50/50	19.5 (50)	94	50/50	16.6 (50)	80	50/50
2	21.5 (50)	50/50	21.0 (50)	98	50/50	20.6 (50)	96	50/50	17.8 (50)	83	50/50
3	21.6 (50)	50/50	21.4 (50)	99	50/50	21.0 (50)	97	50/50	19.2 (50)	89	50/50
4	22.4 (50)	50/50	22.0 (50)	98	50/50	21.8 (50)	97	50/50	19.9 (50)	89	50/50
5	23.0 (50)	50/50	22.8 (50)	99	50/50	22.3 (50)	97	50/50	20.5 (50)	89	50/50
6	23.9 (50)	50/50	23.1 (50)	97	50/50	22.9 (50)	96	50/50	21.0 (50)	88	50/50
7	24.1 (50)	50/50	23.2 (50)	96	50/50	23.0 (50)	95	50/50	21.3 (50)	88	50/50
8	24.9 (50)	50/50	23.7 (50)	95	50/50	23.3 (50)	94	50/50	21.7 (50)	87	50/50
9	24.8 (50)	50/50	24.1 (50)	97	50/50	23.5 (50)	95	50/50	21.9 (50)	88	50/50
10	25.1 (50)	50/50	24.3 (50)	97	50/50	23.8 (50)	95	50/50	21.9 (50)	87	50/50
11	25.3 (50)	50/50	24.2 (50)	96	50/50	24.0 (50)	95	50/50	22.4 (50)	89	50/50
12	25.9 (50)	50/50	24.6 (50)	95	50/50	24.2 (50)	93	50/50	22.4 (50)	86	50/50
13	26.3 (50)	50/50	24.7 (50)	94	50/50	24.2 (50)	92	50/50	22.3 (50)	85	50/50
14	26.3 (50)	50/50	24.7 (50)	94	50/50	24.0 (50)	91	50/50	22.2 (50)	84	50/50
18	28.5 (50)	50/50	25.6 (50)	90	50/50	24.9 (50)	87	50/50	23.1 (50)	81	50/50
22	30.1 (50)	50/50	26.2 (50)	87	50/50	25.7 (50)	85	50/50	23.4 (50)	78	50/50
26	30.9 (50)	50/50	26.7 (50)	86	50/50	26.0 (50)	84	50/50	23.7 (50)	77	50/50
30	32.1 (50)	50/50	27.2 (50)	85	50/50	26.3 (50)	82	50/50	24.1 (50)	75	50/50
34	33.6 (50)	50/50	28.0 (50)	83	50/50	27.2 (50)	81	50/50	24.3 (50)	72	50/50
38	34.6 (50)	50/50	28.3 (50)	82	50/50	26.9 (50)	78	50/50	24.4 (50)	71	50/50
42	36.0 (50)	50/50	28.9 (50)	80	50/50	27.4 (50)	76	50/50	24.6 (50)	68	50/50
46	37.5 (50)	50/50	29.8 (50)	79	50/50	28.3 (50)	75	50/50	25.1 (50)	67	50/50
50	38.5 (50)	50/50	30.3 (50)	79	50/50	28.3 (50)	74	50/50	24.7 (49)	64	49/50
54	39.2 (49)	49/50	30.7 (50)	78	50/50	28.8 (50)	73	50/50	25.2 (49)	64	49/50
58	39.7 (49)	49/50	30.9 (50)	78	50/50	28.6 (49)	72	49/50	25.1 (49)	63	49/50
62	40.2 (49)	49/50	31.6 (50)	79	50/50	28.8 (49)	72	49/50	25.1 (49)	62	49/50
66	41.0 (49)	49/50	31.7 (50)	77	50/50	29.0 (49)	71	49/50	25.2 (49)	61	49/50
70	40.8 (48)	48/50	31.6 (50)	77	50/50	28.9 (49)	71	49/50	25.0 (49)	61	49/50
74	40.9 (46)	46/50	31.5 (50)	77	50/50	28.8 (48)	70	48/50	24.9 (48)	61	48/50
78	41.8 (44)	44/50	31.8 (50)	76	50/50	29.3 (44)	70	44/50	25.2 (46)	60	46/50
82	40.9 (41)	41/50	31.6 (49)	77	49/50	29.1 (44)	71	44/50	24.8 (45)	61	45/50
86	42.0 (40)	40/50	31.8 (47)	76	47/50	29.4 (42)	70	42/50	25.3 (41)	60	41/50
90	41.7 (36)	36/50	31.4 (45)	75	45/50	29.6 (42)	71	42/50	25.2 (39)	60	38/50
94	41.5 (33)	33/50	31.7 (44)	76	44/50	29.4 (41)	71	41/50	24.5 (35)	59	35/50
98	40.6 (28)	28/50	32.1 (41)	79	41/50	29.4 (34)	72	34/50	24.1 (34)	59	34/50
102	40.0 (27)	27/50	32.0 (41)	80	41/50	28.5 (31)	71	31/50	23.4 (29)	58	29/50
104	39.8 (26)	26/50	31.2 (37)	78	37/50	29.0 (29)	73	29/50	23.6 (23)	59	23/50

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

TABLE 4 INCIDENCE OF EXTERNAL AND INTERNAL MASS IN CLINICAL OBSERVATION OF MALE MICE 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	1/50	1/48	1/46	7/44	8/50(5/19)
	20ppm	0/50	0/50	0/50	0/49	0/49	1/49	3/45	4/42	4/50(1/20)
	40ppm	0/50	0/50	0/49	0/49	0/48	0/48	0/43	0/40	0/50(0/14)
	80ppm	0/50	0/50	0/50	0/50	0/50	0/50	2/48	2/44	2/50(1/10)
Internal mass										
	Control	0/50	1/50	0/50	0/50	0/50	1/48	6/46	8/44	10/50(6/19)
	20ppm	0/50	1/50	1/50	0/49	1/49	2/49	3/45	2/42	6/50(6/20)
	40ppm	0/50	0/50	0/49	1/49	1/48	4/48	2/43	3/40	8/50(6/14)
	80ppm	0/50	1/50	0/50	1/50	1/50	2/50	2/48	2/44	4/50(4/10)

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 MICE 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	0/50	0/49	1/44	1/35	1/50(1/24)
	40ppm	0/50	0/50	0/50	0/50	0/50	0/50	3/50	5/44	6/50(2/13)
	80ppm	0/50	0/50	1/50	1/50	2/50	2/49	1/44	4/41	5/50(2/21)
	160ppm	0/50	0/50	0/50	0/50	0/49	2/49	2/46	2/36	3/50(2/27)
Internal mass										
	Control	0/50	0/50	0/50	0/50	1/50	5/49	7/44	4/35	9/50(9/24)
	40ppm	0/50	1/50	1/50	1/50	1/50	1/50	5/50	9/44	11/50(5/13)
	80ppm	0/50	0/50	1/50	1/50	2/50	3/49	5/44	7/41	13/50(12/21)
	160ppm	0/50	0/50	0/50	0/50	0/49	3/49	3/46	1/36	4/50(4/27)

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 MICE 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	4.4 (50)	50/50	3.2 (50)	73	50/50	2.4 (50)	55	50/50	1.9 (50)	43	50/50
2	4.0 (50)	50/50	3.0 (50)	75	50/50	2.3 (50)	58	50/50	1.8 (50)	45	50/50
3	4.3 (50)	50/50	2.7 (50)	63	50/50	2.2 (50)	51	50/50	1.9 (50)	44	50/50
4	4.4 (50)	50/50	2.8 (50)	64	50/50	2.2 (50)	50	50/50	1.8 (50)	41	50/50
5	4.4 (49)	50/50	3.2 (50)	73	50/50	2.5 (50)	57	50/50	2.2 (50)	50	50/50
6	4.1 (50)	50/50	2.9 (50)	71	50/50	2.2 (50)	54	50/50	1.8 (50)	44	50/50
7	3.8 (47)	50/50	2.6 (50)	68	50/50	2.0 (50)	53	50/50	1.7 (50)	45	50/50
8	3.8 (49)	50/50	2.4 (50)	63	50/50	2.0 (50)	53	50/50	1.8 (50)	47	50/50
9	3.6 (49)	50/50	2.4 (50)	67	50/50	2.1 (50)	58	50/50	1.7 (50)	47	50/50
10	3.8 (49)	50/50	2.4 (50)	63	50/50	2.1 (50)	55	50/50	1.7 (50)	45	50/50
11	3.5 (50)	50/50	2.4 (50)	69	50/50	2.0 (50)	57	50/50	1.8 (50)	51	50/50
12	3.5 (50)	50/50	2.3 (50)	66	50/50	2.0 (50)	57	50/50	1.7 (50)	49	50/50
13	3.5 (50)	50/50	2.2 (50)	63	50/50	1.9 (50)	54	50/50	1.6 (50)	46	50/50
14	3.5 (50)	50/50	2.1 (50)	60	50/50	1.8 (50)	51	50/50	1.6 (50)	46	50/50
18	3.5 (50)	50/50	2.3 (50)	66	50/50	2.1 (50)	60	50/50	1.7 (50)	49	50/50
22	3.4 (50)	50/50	2.1 (50)	62	50/50	1.8 (50)	53	50/50	1.7 (50)	50	50/50
26	3.4 (50)	50/50	2.4 (50)	71	50/50	2.1 (49)	62	49/50	1.8 (50)	53	50/50
30	3.5 (50)	50/50	2.4 (49)	69	49/50	2.2 (49)	63	49/50	1.9 (50)	54	50/50
34	3.5 (50)	50/50	2.4 (49)	69	49/50	2.2 (49)	63	49/50	1.9 (50)	54	50/50
38	3.7 (50)	50/50	2.6 (49)	70	49/50	2.3 (49)	62	49/50	1.9 (50)	51	50/50
42	3.6 (50)	50/50	2.3 (49)	64	49/50	2.1 (49)	58	49/50	1.8 (50)	50	50/50
46	3.7 (50)	50/50	2.7 (49)	73	49/50	2.4 (49)	65	49/50	2.1 (50)	57	50/50
50	3.9 (50)	50/50	2.7 (49)	69	49/50	2.4 (49)	62	49/50	2.1 (50)	54	50/50
54	3.8 (50)	50/50	2.7 (49)	71	49/50	2.4 (48)	63	48/50	2.1 (50)	55	50/50
58	4.0 (48)	48/50	2.7 (49)	67	49/50	2.5 (48)	63	48/50	2.2 (50)	55	50/50
62	4.1 (48)	48/50	3.1 (49)	76	49/50	2.6 (48)	63	48/50	2.3 (50)	56	50/50
66	4.1 (48)	48/50	2.8 (49)	68	49/50	2.6 (48)	63	48/50	2.1 (50)	51	50/50
70	4.1 (46)	46/50	2.8 (48)	68	48/50	2.6 (47)	63	47/50	2.2 (50)	54	50/50
74	4.1 (45)	46/50	2.8 (47)	68	47/50	2.6 (45)	63	45/50	2.2 (50)	54	50/50
78	4.3 (44)	46/50	3.0 (46)	70	46/50	2.6 (44)	60	44/50	2.2 (48)	51	48/50
82	4.5 (46)	46/50	3.0 (45)	67	45/50	2.8 (43)	62	43/50	2.3 (48)	51	48/50
86	4.5 (44)	45/50	3.2 (44)	71	44/50	2.9 (42)	64	42/50	2.4 (46)	53	46/50
90	4.6 (41)	44/50	3.3 (44)	72	44/50	3.1 (40)	67	40/50	2.6 (46)	57	46/50
94	4.7 (41)	42/50	3.1 (39)	66	39/50	2.9 (38)	62	38/50	2.5 (44)	53	44/50
98	4.9 (39)	40/50	3.2 (39)	65	39/50	2.8 (38)	57	38/50	2.4 (43)	49	43/50
102	5.0 (31)	33/50	2.7 (37)	54	37/50	2.7 (36)	54	36/50	2.3 (41)	46	41/50
104	5.4 (29)	31/50	3.1 (30)	57	30/50	2.8 (36)	52	36/50	2.4 (40)	44	40/50

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

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

Week on Study	Control		40ppm			80ppm			160ppm		
	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	3.9 (50)	50/50	2.3 (50)	59	50/50	1.9 (50)	49	50/50	1.1 (50)	28	50/50
2	3.8 (50)	50/50	2.2 (50)	58	50/50	1.9 (50)	50	50/50	1.4 (49)	37	50/50
3	4.0 (49)	50/50	2.2 (50)	55	50/50	1.9 (50)	47	50/50	1.4 (50)	35	50/50
4	4.2 (50)	50/50	2.3 (50)	55	50/50	2.2 (50)	52	50/50	1.5 (50)	36	50/50
5	4.1 (49)	50/50	2.4 (50)	59	50/50	2.3 (50)	56	50/50	1.6 (49)	39	50/50
6	4.2 (49)	50/50	2.3 (50)	55	50/50	2.2 (50)	52	50/50	1.6 (50)	38	50/50
7	4.0 (48)	50/50	2.2 (50)	55	50/50	2.1 (50)	53	50/50	1.5 (50)	38	50/50
8	4.2 (48)	50/50	2.3 (50)	55	50/50	2.3 (50)	55	50/50	1.4 (50)	33	50/50
9	4.1 (50)	50/50	2.2 (50)	54	50/50	2.1 (50)	51	50/50	1.5 (50)	37	50/50
10	4.1 (49)	50/50	2.2 (50)	54	50/50	2.0 (49)	49	50/50	1.4 (50)	34	50/50
11	4.1 (48)	50/50	2.3 (50)	56	50/50	2.2 (50)	54	50/50	1.6 (50)	39	50/50
12	4.1 (49)	50/50	2.3 (50)	56	50/50	2.2 (50)	54	50/50	1.5 (50)	37	50/50
13	4.0 (49)	50/50	2.4 (50)	60	50/50	2.0 (50)	50	50/50	1.5 (50)	38	50/50
14	4.0 (49)	50/50	2.3 (50)	58	50/50	2.1 (50)	53	50/50	1.5 (50)	38	50/50
18	4.1 (49)	50/50	2.3 (50)	56	50/50	2.1 (50)	51	50/50	1.5 (50)	37	50/50
22	4.0 (49)	50/50	2.3 (50)	58	50/50	2.1 (50)	53	50/50	1.4 (50)	35	50/50
26	4.2 (49)	50/50	2.3 (50)	55	50/50	2.2 (50)	52	50/50	1.6 (50)	38	50/50
30	4.1 (50)	50/50	2.5 (50)	61	50/50	2.2 (50)	54	50/50	1.7 (50)	41	50/50
34	4.0 (50)	50/50	2.4 (50)	60	50/50	2.2 (50)	55	50/50	1.7 (50)	42	50/50
38	4.1 (50)	50/50	2.5 (50)	61	50/50	2.2 (50)	54	50/50	1.7 (50)	41	50/50
42	4.1 (50)	50/50	2.2 (50)	54	50/50	2.0 (50)	49	50/50	1.7 (50)	41	50/50
46	3.7 (49)	50/50	2.5 (50)	68	50/50	2.2 (50)	59	50/50	1.8 (50)	49	50/50
50	4.0 (50)	50/50	2.3 (50)	58	50/50	2.1 (50)	53	50/50	1.7 (49)	42	49/50
54	3.8 (49)	49/50	2.5 (50)	66	50/50	2.3 (50)	61	50/50	1.9 (49)	50	49/50
58	4.0 (49)	49/50	2.3 (50)	58	50/50	2.1 (48)	53	49/50	1.7 (49)	42	49/50
62	3.9 (49)	49/50	2.3 (50)	59	50/50	2.1 (49)	54	49/50	1.6 (49)	41	49/50
66	3.9 (49)	49/50	2.4 (50)	62	50/50	2.1 (49)	54	49/50	1.7 (49)	44	49/50
70	3.9 (48)	48/50	2.5 (50)	64	50/50	2.2 (49)	56	49/50	1.7 (49)	44	49/50
74	4.0 (45)	46/50	2.3 (49)	58	50/50	2.1 (47)	53	48/50	1.7 (48)	42	48/50
78	4.0 (42)	44/50	2.4 (49)	60	50/50	2.3 (44)	58	44/50	1.9 (46)	47	46/50
82	4.1 (40)	41/50	2.5 (49)	61	49/50	2.4 (44)	59	44/50	1.9 (45)	46	45/50
86	4.1 (40)	40/50	2.5 (47)	61	47/50	2.4 (42)	59	42/50	1.9 (41)	46	41/50
90	4.2 (36)	36/50	2.5 (44)	60	45/50	2.5 (42)	60	42/50	2.0 (39)	48	38/50
94	4.4 (33)	33/50	2.7 (44)	61	44/50	2.3 (41)	52	41/50	1.9 (35)	43	35/50
98	4.5 (28)	28/50	2.6 (41)	58	41/50	2.6 (34)	58	34/50	2.0 (34)	44	34/50
102	4.2 (24)	27/50	2.6 (41)	62	41/50	2.4 (31)	57	31/50	1.9 (29)	45	29/50
104	4.3 (26)	26/50	2.8 (37)	65	37/50	2.6 (29)	60	29/50	1.9 (23)	44	23/50

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

TABLE 8 FOOD CONSUMPTION CHANGES OF MALE MICE 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	3.7 (50)	50/50	3.6 (50)	97	50/50	3.6 (50)	97	50/50	3.2 (50)	86	50/50
2	3.8 (50)	50/50	3.7 (50)	97	50/50	3.6 (50)	95	50/50	3.4 (50)	89	50/50
3	3.8 (50)	50/50	3.5 (50)	92	50/50	3.5 (50)	92	50/50	3.4 (50)	89	50/50
4	4.9 (50)	50/50	4.8 (50)	98	50/50	3.4 (50)	69	50/50	3.3 (50)	67	50/50
5	3.9 (50)	50/50	3.6 (50)	92	50/50	3.6 (50)	92	50/50	3.4 (50)	87	50/50
6	4.1 (50)	50/50	3.6 (50)	88	50/50	3.7 (49)	90	50/50	3.6 (50)	88	50/50
7	4.0 (50)	50/50	3.7 (50)	92	50/50	3.6 (50)	90	50/50	3.5 (50)	88	50/50
8	4.1 (50)	50/50	3.8 (50)	93	50/50	3.6 (50)	88	50/50	3.5 (50)	85	50/50
9	4.0 (50)	50/50	3.8 (50)	95	50/50	3.6 (50)	90	50/50	3.5 (50)	88	50/50
10	4.0 (50)	50/50	3.8 (50)	95	50/50	3.6 (50)	90	50/50	3.4 (50)	85	50/50
11	4.0 (50)	50/50	3.8 (50)	95	50/50	3.6 (50)	90	50/50	3.5 (50)	88	50/50
12	4.0 (50)	50/50	3.7 (50)	92	50/50	3.5 (50)	88	50/50	3.4 (50)	85	50/50
13	4.0 (50)	50/50	3.6 (50)	90	50/50	3.5 (50)	88	50/50	3.3 (50)	83	50/50
14	4.0 (50)	50/50	3.7 (50)	92	50/50	3.5 (50)	88	50/50	3.4 (50)	85	50/50
18	4.3 (50)	50/50	3.9 (50)	91	50/50	3.8 (50)	88	50/50	3.7 (50)	86	50/50
22	4.2 (50)	50/50	3.7 (50)	88	50/50	3.5 (50)	83	50/50	3.5 (50)	83	50/50
26	4.3 (50)	50/50	4.0 (50)	93	50/50	3.8 (49)	88	49/50	3.6 (50)	84	50/50
30	4.4 (50)	50/50	4.0 (49)	91	49/50	3.8 (49)	86	49/50	3.7 (50)	84	50/50
34	4.5 (50)	50/50	4.1 (49)	91	49/50	3.9 (49)	87	49/50	3.8 (50)	84	50/50
38	4.4 (50)	50/50	3.9 (49)	89	49/50	3.8 (49)	86	49/50	3.6 (50)	82	50/50
42	4.5 (50)	50/50	4.0 (49)	89	49/50	3.8 (49)	84	49/50	3.7 (50)	82	50/50
46	4.5 (50)	50/50	4.1 (49)	91	49/50	4.0 (49)	89	49/50	3.9 (50)	87	50/50
50	4.8 (50)	50/50	4.4 (49)	92	49/50	4.2 (49)	87	49/50	3.9 (50)	81	50/50
54	4.7 (50)	50/50	4.4 (49)	94	49/50	4.3 (48)	91	48/50	4.0 (50)	85	50/50
58	4.6 (48)	48/50	4.3 (49)	93	49/50	4.2 (48)	91	48/50	3.9 (50)	85	50/50
62	4.7 (48)	48/50	4.5 (49)	96	49/50	4.3 (48)	91	48/50	4.0 (50)	85	50/50
66	4.7 (48)	48/50	4.4 (49)	94	49/50	4.2 (48)	89	48/50	4.0 (50)	85	50/50
70	4.6 (46)	46/50	4.3 (48)	93	48/50	4.2 (47)	91	47/50	3.9 (50)	85	50/50
74	4.5 (46)	46/50	4.2 (47)	93	47/50	4.0 (45)	89	45/50	3.8 (50)	84	50/50
78	4.7 (46)	46/50	4.4 (46)	94	46/50	4.2 (44)	89	44/50	4.0 (48)	85	48/50
82	4.5 (46)	46/50	4.3 (45)	96	45/50	4.2 (43)	93	43/50	3.8 (48)	84	48/50
86	4.5 (45)	45/50	4.2 (44)	93	44/50	4.1 (42)	91	42/50	3.8 (46)	84	46/50
90	4.7 (44)	44/50	4.5 (44)	96	44/50	4.5 (40)	96	40/50	4.0 (46)	85	46/50
94	4.7 (42)	42/50	4.4 (39)	94	39/50	4.2 (38)	89	38/50	4.1 (44)	87	44/50
98	4.5 (40)	40/50	4.4 (39)	98	39/50	4.4 (38)	98	38/50	3.9 (43)	87	43/50
102	4.5 (33)	33/50	4.1 (36)	91	37/50	4.3 (36)	96	36/50	3.8 (41)	84	41/50
104	4.6 (31)	31/50	4.2 (30)	91	30/50	4.1 (36)	89	36/50	3.8 (40)	83	40/50

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

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

Week on Study	Control		40ppm			80ppm			160ppm		
	Av.FC.	No. of Surviv. <50>	Av.FC.	% of cont. <49>	No. of Surviv.	Av.FC.	% of cont. <50>	No. of Surviv.	Av.FC.	% of cont. <50>	No. of Surviv.
1	3.2 (50)	50/50	3.0 (50)	94	50/50	3.0 (50)	94	50/50	2.3 (50)	72	50/50
2	3.2 (50)	50/50	3.2 (50)	100	50/50	3.2 (50)	100	50/50	2.9 (50)	91	50/50
3	3.1 (50)	50/50	3.1 (50)	100	50/50	3.1 (50)	100	50/50	3.1 (50)	100	50/50
4	3.4 (50)	50/50	3.3 (50)	97	50/50	3.3 (50)	97	50/50	3.1 (50)	91	50/50
5	3.4 (50)	50/50	3.3 (50)	97	50/50	3.3 (50)	97	50/50	3.1 (50)	91	50/50
6	3.6 (50)	50/50	3.5 (50)	97	50/50	3.6 (50)	100	50/50	3.3 (50)	92	50/50
7	3.4 (50)	50/50	3.4 (50)	100	50/50	3.4 (50)	100	50/50	3.2 (50)	94	50/50
8	3.7 (50)	50/50	3.6 (50)	97	50/50	3.6 (50)	97	50/50	3.3 (50)	89	50/50
9	3.6 (50)	50/50	3.6 (50)	100	50/50	3.5 (50)	97	50/50	3.2 (50)	89	50/50
10	3.6 (50)	50/50	3.4 (50)	94	50/50	3.5 (50)	97	50/50	3.2 (50)	89	50/50
11	3.5 (50)	50/50	3.4 (50)	97	50/50	3.4 (50)	97	50/50	3.2 (50)	91	50/50
12	3.7 (50)	50/50	3.5 (50)	95	50/50	3.6 (50)	97	50/50	3.2 (50)	86	50/50
13	3.8 (50)	50/50	3.6 (50)	95	50/50	3.5 (50)	92	50/50	3.2 (50)	84	50/50
14	3.6 (50)	50/50	3.5 (50)	97	50/50	3.4 (50)	94	50/50	3.2 (50)	89	50/50
18	3.9 (50)	50/50	3.6 (50)	92	50/50	3.6 (50)	92	50/50	3.4 (50)	87	50/50
22	3.9 (50)	50/50	3.5 (50)	90	50/50	3.5 (50)	90	50/50	3.3 (50)	85	50/50
26	4.0 (50)	50/50	3.6 (50)	90	50/50	3.6 (50)	90	50/50	3.4 (50)	85	50/50
30	4.0 (50)	50/50	3.7 (50)	92	50/50	3.5 (50)	88	50/50	3.4 (50)	85	50/50
34	4.0 (50)	50/50	3.8 (50)	95	50/50	3.7 (50)	92	50/50	3.4 (50)	85	50/50
38	4.1 (50)	50/50	3.5 (50)	85	50/50	3.4 (50)	83	50/50	3.3 (50)	80	50/50
42	4.1 (50)	50/50	3.6 (50)	88	50/50	3.5 (50)	85	50/50	3.5 (50)	85	50/50
46	4.2 (50)	50/50	3.8 (50)	90	50/50	3.7 (50)	88	50/50	3.6 (50)	86	50/50
50	4.2 (50)	50/50	3.8 (50)	90	50/50	3.8 (50)	90	50/50	3.6 (49)	86	49/50
54	4.3 (49)	49/50	4.0 (50)	93	50/50	3.8 (50)	88	50/50	3.8 (49)	88	49/50
58	4.3 (49)	49/50	4.0 (50)	93	50/50	3.8 (49)	88	49/50	3.5 (49)	81	49/50
62	4.2 (49)	49/50	3.9 (50)	93	50/50	3.7 (49)	88	49/50	3.5 (49)	83	49/50
66	4.1 (49)	49/50	3.9 (50)	95	50/50	3.7 (49)	90	49/50	3.5 (49)	85	49/50
70	4.1 (48)	48/50	3.9 (50)	95	50/50	3.6 (49)	88	49/50	3.4 (49)	83	49/50
74	4.3 (46)	46/50	3.8 (50)	88	50/50	3.5 (48)	81	48/50	3.3 (48)	77	48/50
78	4.4 (44)	44/50	3.9 (50)	89	50/50	3.8 (44)	86	44/50	3.5 (46)	80	46/50
82	4.4 (41)	41/50	3.9 (49)	89	49/50	3.8 (44)	86	44/50	3.5 (45)	80	45/50
86	4.2 (40)	40/50	3.7 (47)	88	47/50	3.7 (42)	88	42/50	3.4 (41)	81	41/50
90	4.6 (36)	36/50	3.9 (45)	85	45/50	4.1 (42)	89	42/50	3.6 (39)	78	38/50
94	4.5 (33)	33/50	3.8 (44)	84	44/50	3.8 (41)	84	41/50	3.5 (35)	78	35/50
98	4.7 (28)	28/50	4.1 (41)	87	41/50	3.8 (34)	81	34/50	3.3 (34)	70	34/50
102	4.5 (27)	27/50	3.8 (41)	84	41/50	3.8 (31)	84	31/50	3.1 (29)	69	29/50
104	4.5 (26)	26/50	3.9 (37)	87	37/50	3.8 (29)	84	29/50	3.2 (23)	71	23/50

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

TABLE 10 NEOPLASTIC LESIONS INCIDENCE AND STATISTICAL ANALYSIS OF MALE MOUSE 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)	17/50(34.0)	12/50(24.0)	8/50(16.0)	6/50(12.0)
Adjusted rates(b)	50.00	30.00	22.22	15.00
Terminal rates(c)	15/31(48.4)	9/30(30.0)	8/36(22.2)	6/40(15.0)
Statistical analysis				
Peto test				
Standard method(d)	P=0.7369			
Prevalence method(d)	P=0.9995			
Combined analysis (d)	P=0.9996			
Cochran-Armitage test(e)	P=0.0068**			
Fisher Exact test(e)		P=0.1891	P=0.0317*	P=0.0082**
SITE : liver				
TUMOR : hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	21/50(42.0)	14/50(28.0)	9/50(18.0)	4/50(8.0)
Adjusted rates(b)	48.39	27.03	16.67	8.00
Terminal rates(c)	15/31(48.4)	8/30(26.7)	6/36(16.7)	3/40(7.5)
Statistical analysis				
Peto test				
Standard method(d)	P=0.9539			
Prevalence method(d)	P=1.0000			
Combined analysis (d)	P=1.0000			
Cochran-Armitage test(e)	P=0.0001**			
Fisher Exact test(e)		P=0.1041	P=0.0078**	P=0.0001**
SITE : liver				
TUMOR : hepatocellular adenoma, hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	34/50(68.0)	24/50(48.0)	15/50(30.0)	10/50(20.0)
Adjusted rates(b)	84.38	50.00	33.33	22.50
Terminal rates(c)	26/31(83.9)	15/30(50.0)	12/36(33.3)	9/40(22.5)
Statistical analysis				
Peto test				
Standard method(d)	P=0.9683			
Prevalence method(d)	P=1.0000			
Combined analysis (d)	P=1.0000			
Cochran-Armitage test(e)	P<0.0001**			
Fisher Exact test(e)		P=0.0338*	P=0.0001**	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):Beneth 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≦0.05 **:P≦0.01

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

Group Name	Control	40ppm	80ppm	160ppm
SITE : liver				
TUMOR : hepatocellular adenoma				
Tumor rate				
Overall rates(a)	5/50(10.0)	6/50(12.0)	2/50(4.0)	14/50(28.0)
Adjusted rates(b)	14.81	13.51	5.71	35.71
Terminal rates(c)	3/26(11.5)	5/37(13.5)	1/29(3.4)	8/23(34.8)
Statistical analysis				
Peto test				
Standard method(d)	P=0.5777			
Prevalence method(d)	P=0.0036**			
Combined analysis (d)	P=0.0056**			
Cochran-Armitage test(e)	P=0.0087**			
Fisher Exact test(e)		P=0.5000	P=0.2180	P=0.0198*
SITE : liver				
TUMOR : hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	2/50(4.0)	2/50(4.0)	1/50(2.0)	4/50(8.0)
Adjusted rates(b)	7.69	5.41	2.33.	4.35
Terminal rates(c)	2/26(7.7)	2/37(5.4)	0/29(0.0)	1/23(4.3)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0031**?			
Prevalence method(d)	P=0.7087			
Combined analysis (d)	P=0.1271			
Cochran-Armitage test(e)	P=0.3270			
Fisher Exact test(e)		P=0.3087	P=0.5000	P=0.3389
SITE : liver				
TUMOR : hepatocellular adenoma, hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	7/50(14.0)	8/50(16.0)	3/50(6.0)	17/50(34.0)
Adjusted rates(b)	22.22	18.92	6.98	38.71
Terminal rates(c)	5/26(19.2)	7/37(18.9)	1/29(3.4)	8/23(34.8)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0192*			
Prevalence method(d)	P=0.0199*			
Combined analysis (d)	P=0.0036**			
Cochran-Armitage test(e)	P=0.0090**			
Fisher Exact test(e)		P=0.5000	P=0.1589	P=0.0169*
SITE : liver				
TUMOR : hemangioma				
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	3.45	8.70
Terminal rates(c)	0/26(0.0)	0/37(0.0)	1/29(3.4)	2/23(8.7)
Statistical analysis				
Peto test				
Standard method(d)	P=0.0879 ?			
Prevalence method(d)	P=0.0217*			
Combined analysis (d)	P=0.0051**			
Cochran-Armitage test(e)	P=0.0168*			
Fisher Exact test(e)		P=0.5000	P=0.5000	P=0.1212

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

(Continued)

Group Name	Control	40ppm	80ppm	160ppm
SITE : liver				
TUMOR : hemangioma, hemangiosarcoma				
Tumor rate				
Overall rates(a)	1/50(2.0)	2/50(4.0)	1/50(2.0)	4/50(8.0)
Adjusted rates(b)	0.0	2.70	3.45	11.54
Terminal rates(c)	0/26(0.0)	1/37(2.7)	1/29(3.4)	2/23(8.7)
Statistical analysis				
Peto test				
Standard method(d)	P=0.5039			
Prevalence method(d)	P=0.0206*			
Combined analysis (d)	P=0.0578			
Cochran-Armitage test(e)	P=0.1432			
Fisher Exact test(e)		P=0.5000	P=0.2475	P=0.1811

(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):Beneth 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≦0.05 **:P≦0.01

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

Group name		Male				Female			
		Control	20ppm	40ppm	80ppm	Control	40ppm	80ppm	160ppm
<all animal No.>(sacrificed animal No.)		<50> (31)	<50> (30)	<50> (36)	<50> (40)	<50> (26)	<50> (37)	<50> (29)	<50> (23)
Kidney		0 (0)	0 (0)	4 (3)	12** (11)**	3 (1)	22** (17)**	11* (10)*	6 (4)
desquamation: pelvis	+	0 (0)	0 (0)	1 (1)	6 (5)	3 (1)	11 (8)	7 (6)	4 (2)
	2+	0 (0)	0 (0)	3 (2)	6 (6)	0 (0)	11 (9)	4 (4)	2 (2)
	3+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	4+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nasal cavity		27 (19)	8** (3)**	9** (5)**	11** (9)**	25 (13)	35 (28)	39* (23)	36* (17)
eosinophilic change:	+	19 (12)	7 (3)	6 (4)	8 (6)	13 (8)	15 (10)	21 (9)	16 (6)
respiratory epithelium	2+	8 (7)	0 (0)	3 (1)	3 (3)	9 (4)	18 (16)	16 (13)	19 (10)
	3+	0 (0)	1 (0)	0 (0)	0 (0)	3 (1)	2 (2)	2 (1)	1 (1)
	4+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nasal cavity		31 (21)	11** (7)**	9** (8)**	5** (5)**	5 (1)	18** (16)**	21** (14)**	15* (10)**
respiratory metaplasia:	+	12 (8)	8 (5)	8 (7)	3 (3)	5 (1)	14 (12)	12 (7)	15 (10)
gland	2+	16 (11)	3 (2)	1 (1)	2 (2)	0 (0)	4 (4)	9 (7)	0 (0)
	3+	3 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	4+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	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 MICE IN THE 2-YEAR DRINKING WATER STUDY OF HYDRAZINE MONOHYDRATE

		Male				Female			
Group		Control	20ppm	40ppm	80ppm	Control	40ppm	80ppm	160ppm
Number of dead or moribund animals		19	20	14	10	24	13	21	27
No microscopical confirmation		0	2	0	0	0	0	0	8
Hepatic lesion		0	0	0	0	0	1	1	1
Body cavity lesion		0	0	0	0	0	0	1	0
Renal lesion		0	1	1	0	0	0	0	0
Urinary retention		3	0	1	0	0	0	0	0
Arteritis		0	0	1	0	0	0	0	1
Hydronephrosis		0	1	3	0	2	0	1	2
Tumor death	leukemia	1	0	2	3	13	5	10	7
	subcutis	2	0	0	0	0	0	0	0
	lung	4	5	1	1	0	0	0	0
	lymph node	0	0	0	0	0	1	0	0
	spleen	0	0	0	0	0	0	0	1
	tooth	0	0	0	1	0	0	0	0
	liver	8	9	4	3	1	2	2	4
	kidney	0	1	0	1	0	0	0	0
	epididymis	1	0	1	1	0	0	0	0
	uterus	0	0	0	0	7	3	6	2
	spinal cord	0	0	0	0	1	0	0	0
	bone	0	0	0	0	0	1	0	1
	peripheral nerve	0	1	0	0	0	0	0	0