

Summary of Drinking Water Carcinogenicity Study
of 2-Aminoethanol
in B6D2F1 Mice

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Japan Bioassay Research Center

Japan Industrial Safety and Health Association

PREFACE

The tests were contracted and supported by the Ministry of Health, Labour and Welfare of Japan. The tests were conducted by Japan Bioassay Research Center (JBRC) and the report was prepared by JBRC and peer reviewed by outside expert pathologist. Complete report was submitted to Ministry of Health, Labour and Welfare of Japan on June 29, 2010.

This English Summary was translated by JBRC from Japanese complete report.

Summary of Drinking Water Carcinogenicity Study of 2-Aminoethanol in B6D2F1 Mice

Purpose, materials and methods

2-Aminoethanol (CAS No. 141-43-5) is a colorless clear viscosity liquid with a melting point of 10.3°C. It is soluble in water, methanol, and acetone.

The carcinogenicity and chronic toxicity of 2-aminoethanol were examined in B6D2F1/Crlj mice. Groups of test animals were administered 2-aminoethanol in their drinking water for 2 years (104 weeks). Each group consisted of either 50 male or 50 female mice. The drinking water concentrations of 2-aminoethanol were 0, 800, 2000 or 5000 ppm (w/w). Both sexes were administered each concentration of 2-aminoethanol. The highest dose level was chosen so as not to exceed the maximum tolerated dose (MTD), based on both growth rate and toxicity in a previous 13-week toxicity study. The identity of the 2-aminoethanol used in these experiments was confirmed by both infrared spectrometry and mass spectrometry, and it was analyzed by high performance liquid chromatography before and after its use to affirm its stability. The concentrations of 2-aminoethanol in the drinking water were determined by high performance liquid chromatography at the time of preparation and on the 4th day after preparation while stored at room temperature. The animals were observed daily for clinical signs and mortality. Body weight, water consumption and food consumption were measured once a week for the first 14 weeks and every 4 weeks thereafter. Animals found dead, in a moribund state, or surviving to the end of the 2-year administration period underwent complete necropsy. Urinalysis was performed near the end of the administration period. Hematology and blood biochemistry analysis were performed at the terminal necropsy: surviving animals were fasted overnight and bled under deep ether anesthesia. Organs and tissues were removed, weighed and examined for macroscopic lesions at necropsy. The organs and tissues were then fixed and embedded in paraffin. Five µm thick tissue sections were prepared and stained with hematoxylin and eosin and examined microscopically. Incidences of neoplastic lesions were statistically analyzed by Fisher's exact test. Any positive dose-response trends of 2-aminoethanol induction of neoplastic lesions were analyzed by Peto's test. Incidences of non-neoplastic lesions and urinalysis were analyzed by the Chi-square test. Changes in body weight, water consumption, food consumption, hematological and blood biochemical parameters, and organ weights were analyzed by Dunnett's test. The present studies were conducted in accordance with the

Organisation for Economic Co-operation and Development (OECD) Good Laboratory Practice and with reference to the OECD Guideline for Testing of Chemicals 451 “Carcinogenicity Studies”.

Results

Survival rates of the males administered 800 ppm and 5000 ppm 2-aminoethanol, and females administered 2000 and 5000 ppm 2-aminoethanol were decreased compared with the respective controls, however, the decreased survival rates were not causally related to the administration of the test substance. Survival rate of the males administered 2000 ppm 2-aminoethanol was similar to the male control. There were no differences in growth rates or food consumption between any 2-aminoethanol administered group of either sex and their respective controls. No administration related clinical signs were observed in any of the 2-aminoethanol administered groups of either sex. Water consumption was decreased in males administered 5000 ppm 2-aminoethanol toward the end of the 2-year administration period and in the females administered 5000 ppm 2-aminoethanol throughout most of the 2-year administration period. Plasma levels of creatine kinase was significantly decreased in males administered 5000 ppm 2-aminoethanol. White zones in the liver and enlargement of the ovary and lymph node were observed all groups of 2-aminoethanol administered females. There were no 2-aminoethanol related changes in the hematology parameters, urinalysis parameters or organ weights in any of the 2-aminoethanol administered groups.

No significant increases in the incidence of neoplastic or non-neoplastic lesions was found in any of the 2-aminoethanol-administered groups of either sex: the no-observed-adverse-effect-level (NOAEL) for both males and females of 2-aminoethanol in the drinking water was 5000 ppm (male: 528 mg/kg body weight per day, female: 656 mg/kg body weight per day).

Conclusions

There was no evidence for carcinogenicity of 2-aminoethanol in male or female mice.

Incidences of selected neoplastic lesions of male mice in the 2-year drinking water carcinogenicity study of 2-aminoethanol

Dose (ppm)		0	800	2000	5000	Peto test	Cochran-Armitage test
Number of examined animals		50	50	50	50		
benign tumor							
lung	bronchiolar-alveolar adenoma	2	1	4	6	↑ ^{a)}	↑
spleen	hemangioma	1	3	1	0		
liver	hemangioma	2	1	4	2		
	hepatocellular adenoma	15	10	10	5 *		↓
malignant tumor							
lung	bronchiolar-alveolar carcinoma	9	7	9	6		
lymph node	malignant lymphoma	5	5	5	5		
liver	histiocytic sarcoma	1	4	1	2		
	hepatocellular carcinoma	8	11	7	5		
lung	bronchiolar-alveolar adenoma + bronchiolar-alveolar carcinoma	11	8	12	11		
liver	hepatocellular adenoma+ hepatocellular carcinoma	21	20	16	10 *		↓

^{a)} :Significant in prevalence method only.

Significant difference

* : $p \leq 0.05$

** : $p \leq 0.01$

(Fisher test)

↑ : $p \leq 0.05$ increase

↑ ↑ : $p \leq 0.01$ increase

(Peto, Cochran-Armitage test)

↓ : $p \leq 0.05$ decrease

↓ ↓ : $p \leq 0.01$ decrease

(Cochran-Armitage test)

Incidences of selected neoplastic lesions of female mice in the 2-year drinking water carcinogenicity study of 2-aminoethanol

Dose (ppm)		0	800	2000	5000	Peto test	Cochran-Armitage test
Number of examined animals		50	50	50	50		
benign tumor							
lung	bronchiolar-alveolar adenoma	3	0	1	1		
liver	hemangioma	3	0	2	1		
	hepatocellular adenoma	2	1	5	3		
pituitary	adenoma	11	4 *	6	9		
uterus	endometrial stromal polyp	1	1	1	3		
Harderian gland	adenoma	0	5 *	0	2		
malignant tumor							
lung	bronchiolar-alveolar carcinoma	2	4	2	0		
lymph node	malignant lymphoma	14	19	17	15		
uterus	histiocytic sarcoma	7	6	8	8	↑ ^{a)}	

^{a)} :Significant in standard method only.

Significant difference

* : $p \leq 0.05$

** : $p \leq 0.01$

(Fisher test)

↑ : $p \leq 0.05$ increase

↑ ↑ : $p \leq 0.01$ increase

(Peto, Cochran-Armitage test)

↓ : $p \leq 0.05$ decrease

↓ ↓ : $p \leq 0.01$ decrease

(Cochran-Armitage test)

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TABLE C 1

BODY WEIGHT CHANGES AND
SURVIVAL ANIMAL NUMBERS: MALE

STUDY NO. : 0642
ANIMAL : MOUSE B6D2F1/Cr1j[Crj:BDFl]
UNIT : g
REPORT TYPE : AI 104
SEX : MALE

MEAN BODY WEIGHTS AND SURVIVAL

PAGE : 1

Week-Day on Study	Control			800 ppm			2000 ppm			5000 ppm		
	Av.Wt.	No. of Surviv.	Av.Wt.	% of cont.	No. of Surviv.	Av.Wt.	% of cont.	No. of Surviv.	Av.Wt.	% of cont.	No. of Surviv.	% of cont.
	<50>	<50>	<50>	<50>	<50>	<50>	<50>	<50>	<50>	<50>	<50>	<50>
0-0	23.5 (50)	50/50	23.5 (50)	100	50/50	23.5 (50)	100	50/50	23.5 (50)	100	50/50	100
1-7	24.4 (50)	50/50	24.4 (50)	100	50/50	24.1 (50)	99	50/50	24.3 (50)	100	50/50	100
2-7	25.2 (50)	50/50	25.3 (50)	100	50/50	25.0 (50)	99	50/50	25.1 (50)	100	50/50	100
3-7	26.1 (50)	50/50	26.0 (50)	100	50/50	26.7 (50)	98	50/50	25.8 (50)	99	50/50	100
4-7	26.6 (50)	50/50	26.7 (50)	100	50/50	26.5 (50)	100	50/50	26.4 (50)	99	50/50	100
5-7	27.3 (50)	50/50	27.3 (50)	100	50/50	27.2 (50)	100	50/50	27.0 (50)	99	50/50	100
6-7	27.9 (50)	50/50	27.9 (50)	100	50/50	27.7 (50)	99	50/50	27.6 (50)	99	50/50	100
7-7	28.5 (50)	50/50	28.6 (50)	100	50/50	28.3 (50)	99	50/50	28.4 (49)	100	49/50	100
8-7	29.4 (50)	50/50	29.3 (50)	100	50/50	29.0 (50)	99	50/50	29.2 (49)	99	49/50	100
9-7	29.4 (50)	50/50	29.4 (50)	100	50/50	29.2 (50)	99	50/50	29.3 (49)	100	49/50	100
10-7	30.3 (50)	50/50	30.3 (50)	100	50/50	30.3 (50)	100	50/50	30.3 (49)	100	49/50	100
11-7	31.0 (50)	50/50	31.0 (50)	100	50/50	30.7 (50)	99	50/50	30.8 (49)	99	49/50	100
12-7	31.8 (50)	50/50	31.7 (50)	100	50/50	31.5 (50)	99	50/50	31.4 (49)	99	49/50	100
13-7	32.3 (50)	50/50	32.4 (50)	100	50/50	32.1 (50)	99	50/50	32.0 (49)	99	49/50	100
14-7	32.9 (50)	50/50	33.0 (50)	100	50/50	32.6 (50)	99	50/50	32.6 (49)	99	49/50	100
18-7	35.0 (50)	50/50	35.1 (50)	100	50/50	34.7 (50)	99	50/50	35.0 (49)	100	49/50	100
22-7	36.7 (50)	50/50	36.8 (50)	100	50/50	36.4 (50)	99	50/50	36.6 (49)	100	49/50	100
26-7	38.8 (50)	50/50	39.1 (50)	101	50/50	38.6 (50)	99	50/50	38.7 (49)	100	49/50	100
30-7	40.8 (50)	50/50	41.3 (50)	101	50/50	40.6 (50)	100	50/50	40.8 (49)	100	49/50	100
34-7	42.3 (50)	50/50	42.7 (50)	101	50/50	41.9 (50)	99	50/50	42.2 (49)	100	49/50	100
38-7	43.5 (50)	50/50	44.0 (50)	101	50/50	44.0 (50)	101	50/50	43.5 (49)	100	49/50	100
42-7	44.7 (50)	50/50	44.9 (50)	100	50/50	44.2 (50)	99	50/50	44.4 (49)	99	49/50	100
46-7	45.5 (50)	50/50	45.4 (49)	100	49/50	44.9 (50)	99	50/50	44.9 (48)	99	48/50	100
50-7	46.6 (50)	50/50	46.6 (49)	100	49/50	46.1 (50)	99	50/50	46.2 (47)	99	47/50	100
54-7	46.4 (50)	50/50	46.6 (49)	100	49/50	46.1 (50)	99	50/50	46.3 (47)	100	47/50	100
58-7	47.3 (50)	50/50	47.8 (48)	101	48/50	46.7 (50)	99	50/50	47.4 (45)	100	45/50	100
62-7	48.0 (50)	50/50	48.7 (48)	101	48/50	47.6 (50)	99	50/50	47.8 (44)	100	44/50	100
66-7	48.5 (50)	50/50	49.0 (48)	101	48/50	48.3 (50)	100	50/50	48.6 (43)	100	43/50	100
70-7	49.0 (50)	50/50	49.2 (48)	100	48/50	48.5 (50)	99	50/50	48.7 (42)	99	42/50	100
74-7	48.9 (50)	50/50	49.4 (47)	101	47/50	48.1 (49)	98	49/50	48.6 (42)	99	42/50	100
78-7	49.1 (49)	49/50	50.1 (47)	102	47/50	49.6 (47)	101	47/50	48.6 (42)	99	42/50	100
82-7	49.8 (49)	49/50	50.2 (45)	101	45/50	50.6 (45)	102	45/50	50.2 (39)	101	39/50	100
86-7	50.3 (48)	48/50	49.9 (44)	99	44/50	51.3 (43)	102	43/50	50.9 (39)	101	39/50	100
90-7	50.0 (47)	47/50	50.3 (42)	101	42/50	51.2 (42)	102	42/50	51.3 (36)	103	36/50	100
94-7	49.6 (46)	46/50	48.6 (39)	98	39/50	49.8 (42)	100	42/50	51.5 (35)	104	35/50	100
98-7	50.2 (45)	45/50	49.3 (35)	98	35/50	49.0 (41)	98	41/50	51.7 (34)	103	34/50	100
102-7	51.3 (42)	42/50	48.9 (34)	95	34/50	48.9 (38)	96	38/50	51.1 (33)	100	33/50	100
104-7	51.2 (41)	41/50	48.5 (31)	95	31/50	49.0 (37)	95	37/50	50.3 (33)	98	33/50	100

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

Av. Wt. : g

(B10040)

BAIS 4

TABLE C 2

BODY WEIGHT CHANGES AND
SURVIVAL ANIMAL NUMBERS: FEMALE

STUDY NO. : 0642
ANIMAL : MOUSE B6D2F1/Cr-lj[Cr-J:BDFl]
UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

MEAN BODY WEIGHTS AND SURVIVAL

PAGE : 2

Week-Day on Study	Control			800 ppm			2000 ppm			5000 ppm		
	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.	
0-0	19.2 (50)	50/50	19.2 (50)	100	50/50	19.2 (50)	100	50/50	19.2 (50)	100	50/50	
1-7	19.6 (50)	50/50	19.8 (50)	101	50/50	19.7 (50)	101	50/50	19.5 (50)	99	50/50	
2-7	20.4 (50)	50/50	20.3 (50)	100	50/50	20.4 (50)	100	50/50	20.2 (50)	99	50/50	
3-7	21.1 (50)	50/50	21.1 (50)	100	50/50	21.1 (50)	100	50/50	21.0 (50)	100	50/50	
4-7	21.8 (50)	50/50	21.6 (50)	99	50/50	21.6 (50)	99	50/50	21.4 (50)	98	50/50	
5-7	22.2 (50)	50/50	22.1 (50)	100	50/50	22.0 (50)	99	50/50	21.9 (50)	99	50/50	
6-7	22.6 (50)	50/50	22.7 (50)	100	50/50	22.4 (50)	99	50/50	22.4 (50)	99	50/50	
7-7	23.2 (50)	50/50	23.3 (50)	100	50/50	23.2 (50)	100	50/50	23.0 (50)	99	50/50	
8-7	23.9 (50)	50/50	23.8 (50)	100	50/50	23.7 (50)	99	50/50	23.7 (50)	99	50/50	
9-7	23.7 (50)	50/50	23.7 (50)	100	50/50	23.4 (50)	99	50/50	23.5 (50)	99	50/50	
10-7	24.2 (50)	50/50	24.3 (50)	100	50/50	24.1 (50)	100	50/50	24.0 (50)	99	50/50	
11-7	24.6 (50)	50/50	24.7 (50)	100	50/50	24.4 (50)	99	50/50	24.4 (50)	99	50/50	
12-7	25.0 (50)	50/50	25.1 (50)	100	50/50	24.8 (50)	99	50/50	24.7 (50)	99	50/50	
13-7	25.2 (50)	50/50	25.4 (50)	101	50/50	24.7 (50)	98	50/50	25.0 (50)	99	50/50	
14-7	25.4 (50)	50/50	25.6 (50)	101	50/50	25.2 (50)	99	50/50	25.2 (50)	99	50/50	
18-7	26.5 (50)	50/50	26.7 (50)	101	50/50	26.2 (50)	99	50/50	26.1 (50)	98	50/50	
22-7	27.4 (50)	50/50	27.9 (50)	102	50/50	27.1 (50)	99	50/50	27.4 (50)	100	50/50	
26-7	28.8 (50)	50/50	29.1 (50)	101	50/50	28.6 (50)	99	50/50	28.5 (50)	99	50/50	
30-7	30.1 (49)	49/50	30.7 (50)	102	50/50	29.7 (50)	99	50/50	29.7 (50)	99	50/50	
34-7	30.8 (49)	49/50	31.5 (50)	102	50/50	30.4 (50)	99	50/50	30.3 (50)	98	50/50	
38-7	31.4 (49)	49/50	32.3 (50)	103	50/50	31.2 (49)	99	49/50	31.2 (50)	99	50/50	
42-7	32.4 (49)	49/50	32.7 (50)	101	50/50	31.9 (49)	98	49/50	31.9 (50)	98	50/50	
46-7	32.7 (49)	49/50	33.3 (50)	102	50/50	32.3 (49)	99	49/50	32.4 (49)	99	49/50	
50-7	33.1 (49)	49/50	33.9 (50)	102	50/50	33.2 (49)	100	49/50	32.7 (49)	99	49/50	
54-7	33.2 (49)	49/50	33.9 (49)	102	49/50	33.5 (49)	101	49/50	32.8 (49)	99	49/50	
58-7	33.5 (49)	49/50	34.4 (49)	103	49/50	33.5 (49)	100	49/50	33.5 (49)	100	49/50	
62-7	33.8 (49)	49/50	35.1 (49)	104	49/50	33.7 (49)	100	49/50	34.2 (48)	101	48/50	
66-7	34.5 (48)	48/50	35.1 (49)	102	49/50	34.7 (49)	101	49/50	34.5 (48)	100	48/50	
70-7	34.5 (48)	48/50	35.4 (47)	103	47/50	34.4 (47)	100	47/50	35.0 (46)	101	46/50	
74-7	34.6 (48)	48/50	36.1 (46)	104	46/50	34.3 (47)	99	47/50	35.3 (45)	102	45/50	
78-7	35.6 (45)	45/50	36.8 (46)	103	46/50	35.1 (44)	99	44/50	35.1 (45)	99	45/50	
82-7	35.5 (44)	44/50	36.9 (46)	104	46/50	35.5 (43)	100	43/50	35.2 (45)	99	45/50	
86-7	36.0 (44)	44/50	37.4 (43)	104	43/50	36.3 (40)	101	40/50	35.8 (40)	99	40/50	
90-7	36.3 (43)	43/50	36.9 (39)	102	39/50	36.0 (40)	99	40/50	35.7 (37)	98	37/50	
94-7	35.8 (42)	42/50	37.0 (34)	103	34/50	35.4 (36)	99	36/50	36.3 (33)	101	33/50	
98-7	36.0 (38)	38/50	37.1 (33)	103	33/50	34.6 (34)	96	34/50	35.9 (30)	100	30/50	
102-7	36.2 (37)	37/50	38.0 (32)	105	32/50	36.2 (26)	100	26/50	35.8 (26)	99	26/50	
104-7	35.7 (36)	36/50	36.1 (29)	101	29/50	36.0 (23)	101	23/50	35.9 (24)	101	24/50	

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

Av. Wt. : g

(B10040)

BAIS 4

TABLE C 3

BODY WEIGHT CHANGES: MALE

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[CrJ:BDP]
 UNIT : g
 REPORT TYPE : AI 104
 SEX : MALE

PAGE : 1

Group Name	Administration week-day						
	0-0	1-7	2-7	3-7	4-7	5-7	6-7
Control	23.5 ± 0.8	24.4 ± 1.0	25.2 ± 1.0	26.1 ± 1.1	26.6 ± 1.2	27.3 ± 1.3	27.9 ± 1.4
800 ppm	23.5 ± 0.8	24.4 ± 0.9	25.3 ± 1.0	26.0 ± 1.1	26.7 ± 1.2	27.3 ± 1.3	27.9 ± 1.4
2000 ppm	23.5 ± 0.8	24.1 ± 1.0	25.0 ± 1.1	25.7 ± 1.2	26.5 ± 1.1	27.2 ± 1.4	27.7 ± 1.5
5000 ppm	23.5 ± 0.8	24.3 ± 1.0	25.1 ± 1.1	25.8 ± 1.1	26.4 ± 1.4	27.0 ± 1.7	27.6 ± 2.3

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$		Test of Dunnett
(HAN260)		BATS 4

STUDY NO. : 0642
ANIMAL : MOUSE D6D2F1/CrJ[Crj:BDNF]
UNIT : g
REPORT TYPE : AI 104
SEX : MALE

PAGE : 2

STUDY NO. : 0642		ANIMAL : MOUSE B6D2F1/CrJ[Crj:EDF1]		UNIT : g		REPORT TYPE : AI 104		SEX : MALE		PAGE : 2							
BODY WEIGHT CHANGES ALL ANIMALS		(SUMMARY)															
Group Name		Administration week-day		7-7		8-7		9-7		10-7		11-7		12-7		13-7	
Control		28.5± 1.6		29.4± 1.6		29.4± 1.8		30.3± 2.0		31.0± 1.9		31.8± 2.1		32.3± 2.2			
800 ppm		28.6± 1.6		29.3± 1.7		29.4± 1.8		30.3± 2.0		31.0± 2.0		31.7± 2.0		32.4± 2.2			
2000 ppm		28.3± 1.6		29.0± 1.6		29.2± 1.7		30.2± 1.9		30.7± 2.0		31.5± 2.1		32.1± 2.0			
5000 ppm		28.4± 1.4		29.2± 1.6		29.3± 1.9		30.3± 1.9		30.8± 2.0		31.4± 2.2		32.0± 2.3			
Significant difference ;		* : P ≤ 0.05		** : P ≤ 0.01		Test of Dunnett											
(HAN260)																BAIS 4	

STUDY NO. : 0642
ANIMAL : MOUSE B6D2F1/CrJ[Crj:BDNF]
UNIT : g
REPORT TYPE : A1 104
SEX : MALE

PAGE : 3

Group Name	Administration week day							Test of Dunnett	BAIS 4
	14-7	18-7	22-7	26-7	30-7	34-7	38-7		
Control	32.9 ± 2.2	35.0 ± 2.7	36.7 ± 3.0	38.8 ± 3.6	40.8 ± 4.1	42.3 ± 4.2	43.5 ± 4.2		
800 ppm	33.0 ± 2.2	35.1 ± 2.6	36.8 ± 2.9	39.1 ± 3.5	41.3 ± 3.9	42.7 ± 3.9	44.0 ± 4.0		
2000 ppm	32.6 ± 2.1	34.7 ± 2.4	36.4 ± 2.6	38.6 ± 2.9	40.6 ± 3.1	41.9 ± 3.4	44.0 ± 4.4		
5000 ppm	32.6 ± 2.4	35.0 ± 2.6	36.6 ± 3.0	38.7 ± 3.4	40.8 ± 3.7	42.2 ± 3.8	43.5 ± 4.0		
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01									
Test of Dunnett									
(HAN260)									

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[Crj:BDP1]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

PAGE : 4

Group Name	Administration week-day					(SUMMARY)				
	42-7	46-7	50-7	54-7	58-7	62-7	66-7			
Control	44.7± 4.3	45.5± 4.6	46.6± 4.6	46.4± 4.6	47.3± 4.8	48.0± 5.2	48.5± 5.3			
800 ppm	44.9± 4.0	45.4± 4.5	46.6± 4.7	46.6± 4.6	47.8± 3.8	48.7± 3.8	49.0± 4.0			
2000 ppm	44.2± 3.6	44.9± 3.8	46.1± 3.5	46.1± 3.6	46.7± 4.2	47.6± 4.8	48.3± 4.2			
5000 ppm	44.4± 4.2	44.9± 4.4	46.2± 4.1	46.3± 4.7	47.4± 4.0	47.8± 4.3	48.6± 3.8			

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

(HAN260)

BALS 4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/Cr1j[Crj:BDFl]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

PAGE : 5

Group Name	Administration week-day						
	70-7	74-7	78-7	82-7	86-7	90-7	94-7
Control	49.0 ± 5.5	48.9 ± 5.8	49.1 ± 6.5	49.8 ± 7.3	50.3 ± 7.5	50.0 ± 7.9	49.6 ± 8.4
800 ppm	49.2 ± 4.0	49.4 ± 4.5	50.1 ± 4.6	50.2 ± 5.5	49.9 ± 5.7	50.3 ± 6.2	48.6 ± 8.2
2000 ppm	48.5 ± 4.8	48.1 ± 5.4	49.6 ± 5.6	50.6 ± 5.1	51.3 ± 4.2	51.2 ± 5.1	49.8 ± 6.5
5000 ppm	48.7 ± 3.8	48.6 ± 4.3	48.6 ± 6.4	50.2 ± 4.7	50.9 ± 4.7	51.3 ± 5.1	51.5 ± 5.0
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01							Test of Dunnett
HAN260)							
							BATS 4

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

(HAN260)

BATS 4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/Cr1J[Crj:BDFl]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

PAGE : 6

Group Name	Administration week day		BODY WEIGHT CHANGES (SUMMARY)	
	98-7	102-7	ALL ANIMALS	
Control	50.2± 8.4	51.3± 6.2	51.2± 5.6	
800 ppm	49.3± 8.5	48.9± 9.0	48.5± 8.9	
2000 ppm	49.0± 8.1	48.9± 8.3	49.0± 7.7	
5000 ppm	51.7± 5.1	51.1± 6.2	50.3± 7.3	
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett				
(HAN260)				BALS 4

TABLE C 4

BODY WEIGHT CHANGES: FEMALE

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[CrJ:BDFl]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

PAGE : 7

Group Name	Administration week-day						
	0-0	1-7	2-7	3-7	4-7	5-7	6-7
Control	19.2± 0.8	19.6± 0.7	20.4± 0.8	21.1± 0.8	21.8± 0.7	22.2± 0.9	22.6± 0.8
800 ppm	19.2± 0.8	19.8± 1.0	20.3± 0.9	21.1± 1.0	21.6± 1.0	22.1± 0.9	22.7± 1.0
2000 ppm	19.2± 0.8	19.7± 0.8	20.4± 0.8	21.1± 0.9	21.6± 1.0	22.0± 0.9	22.4± 0.9
5000 ppm	19.2± 0.8	19.5± 0.8	20.2± 0.9	21.0± 0.8	21.4± 0.9	21.9± 1.0	22.4± 0.9
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01							Test of Dunnett
(HAN260)							BATS 4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[CrJ:DDF1]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

PAGE : 8

Group Name	Administration week day						
	7-7	8-7	9-7	10-7	11-7	12-7	13-7
Control	23.2± 1.1	23.9± 1.1	23.7± 1.2	24.2± 1.2	24.6± 1.2	25.0± 1.4	25.2± 1.5
800 ppm	23.3± 1.2	23.8± 1.3	23.7± 1.2	24.3± 1.5	24.7± 1.4	25.1± 1.5	25.4± 1.7
2000 ppm	23.2± 1.1	23.7± 1.0	23.4± 1.2	24.1± 1.2	24.4± 1.4	24.8± 1.4	24.7± 1.4
5000 ppm	23.0± 1.2	23.7± 1.3	23.5± 1.1	24.0± 1.1	24.4± 1.4	24.7± 1.4	25.0± 1.4

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

(HAN260)

BAIS 4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[CrJ:DDF1]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

PAGE : 9

Group Name	Administration week-day							BODY WEIGHT CHANGES ALL ANIMALS		(SUMMARY)	
	14-7	18-7	22-7	26-7	30-7	34-7	38-7				
Control	25.4± 1.6	26.5± 1.7	27.4± 2.2	28.8± 2.5	30.1± 3.2	30.8± 3.0	31.4± 3.4				
800 ppm	25.6± 1.6	26.7± 2.1	27.9± 2.4	29.1± 2.9	30.7± 3.4	31.5± 3.6	32.3± 3.5				
2000 ppm	25.2± 1.6	26.2± 2.0	27.1± 2.1	28.6± 3.1	29.7± 3.2	30.4± 3.2	31.2± 3.1				
5000 ppm	25.2± 1.4	26.1± 1.7	27.4± 1.7	28.5± 2.3	29.7± 2.6	30.3± 2.8	31.2± 3.0				
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$											
Test of Dunnett											
(HAN260)											
BALS 4											

PAGE : 10

BAIS 4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/Cr1j[Cr-j:BDFl]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

PAGE : 11

Group Name	Administration week-day						
	70-7	74-7	78-7	82-7	86-7	90-7	94-7
Control	34.5± 4.7	34.6± 4.9	35.6± 4.6	35.5± 4.4	36.0± 5.1	36.3± 5.0	35.8± 5.2
800 ppm	35.4± 4.8	36.1± 4.9	36.8± 4.8	36.9± 4.7	37.4± 4.6	36.9± 4.5	37.0± 4.4
2000 ppm	34.4± 3.9	34.3± 4.5	35.1± 4.6	35.5± 3.9	36.3± 4.2	36.0± 3.8	35.4± 3.9
5000 ppm	35.0± 3.8	35.3± 4.1	35.1± 4.0	35.2± 4.0	35.8± 4.1	35.7± 5.0	36.3± 4.1
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Dunnett							
BATS 4							

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[Crj:BDP1]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

PAGE : 12

Group Name	Administration week day		BODY WEIGHT CHANGES		(SUMMARY)
	99-7	102-7	ALL ANIMALS		
Control	36.0 ± 4.7	36.2 ± 5.2	35.7 ± 5.2		
800 ppm	37.1 ± 3.8	38.0 ± 6.4	36.1 ± 4.2		
2000 ppm	34.6 ± 5.2	36.2 ± 3.8	36.0 ± 3.7		
5000 ppm	35.9 ± 4.1	35.8 ± 5.1	35.9 ± 6.7		
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett					
(HAN260)					
BALS 4					

TABLE D 1

FOOD CONSUMPTION CHANGES AND
SURVIVAL ANIMAL NUMBERS: MALE

STUDY NO. : 0642
ANIMAL : MOUSE B6D2F1/Cr-lj[Crl:BDPL]
UNIT : g
REPORT TYPE : A1 104
SEX : MALE

MEAN FOOD CONSUMPTION(PC) AND SURVIVAL

PAGE : 1

Week-Day on Study	Control			800 ppm			2000 ppm			5000 ppm		
	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.
1-7	4.2 (50)	50/50		4.1 (50)	98	50/50	4.1 (50)	98	50/50	4.2 (50)	100	50/50
2-7	4.0 (50)	50/50		3.9 (50)	98	50/50	3.9 (50)	98	50/50	4.0 (50)	100	50/50
3-7	4.0 (50)	50/50		4.0 (50)	100	50/50	4.0 (50)	100	50/50	4.0 (50)	100	50/50
4-7	4.1 (50)	50/50		4.1 (50)	100	50/50	4.0 (50)	98	50/50	4.0 (50)	98	50/50
5-7	4.1 (50)	50/50		4.1 (50)	100	50/50	4.1 (50)	100	50/50	4.1 (50)	100	50/50
6-7	4.2 (50)	50/50		4.1 (50)	98	50/50	4.1 (50)	98	50/50	4.1 (50)	98	50/50
7-7	4.2 (50)	50/50		4.1 (50)	98	50/50	4.1 (50)	98	50/50	4.1 (48)	98	49/50
8-7	4.2 (50)	50/50		4.1 (50)	98	50/50	4.2 (50)	100	50/50	4.2 (49)	100	49/50
9-7	4.1 (50)	50/50		4.1 (50)	100	50/50	4.0 (50)	98	50/50	4.1 (49)	100	49/50
10-7	4.0 (50)	50/50		4.0 (50)	100	50/50	4.0 (50)	100	50/50	4.1 (49)	103	49/50
11-7	4.1 (50)	50/50		4.1 (50)	100	50/50	4.1 (50)	100	50/50	4.1 (49)	100	49/50
12-7	4.2 (50)	50/50		4.2 (50)	100	50/50	4.1 (50)	98	50/50	4.1 (49)	98	49/50
13-7	4.2 (50)	50/50		4.2 (50)	100	50/50	4.1 (50)	98	50/50	4.1 (49)	98	49/50
14-7	4.1 (50)	50/50		4.1 (50)	100	50/50	4.1 (50)	100	50/50	4.1 (49)	100	49/50
18-7	4.3 (50)	50/50		4.2 (50)	98	50/50	4.2 (50)	98	50/50	4.3 (49)	100	49/50
22-7	4.2 (50)	50/50		4.1 (50)	98	50/50	4.1 (50)	98	50/50	4.2 (49)	100	49/50
26-7	4.1 (50)	50/50		4.1 (50)	100	50/50	4.1 (50)	100	50/50	4.1 (49)	100	49/50
30-7	4.2 (50)	50/50		4.1 (50)	98	50/50	4.1 (50)	98	50/50	4.1 (49)	98	49/50
34-7	4.2 (50)	50/50		4.2 (50)	100	50/50	4.2 (50)	100	50/50	4.2 (49)	100	49/50
38-7	4.2 (50)	50/50		4.2 (50)	100	50/50	4.2 (50)	100	50/50	4.2 (49)	100	49/50
42-7	4.4 (50)	50/50		4.4 (50)	100	50/50	4.5 (50)	102	50/50	4.5 (49)	102	49/50
46-7	4.5 (50)	50/50		4.5 (49)	100	49/50	4.5 (50)	100	50/50	4.4 (48)	98	48/50
50-7	4.5 (50)	50/50		4.4 (49)	98	49/50	4.5 (50)	100	50/50	4.4 (47)	98	47/50
54-7	4.4 (50)	50/50		4.4 (49)	100	49/50	4.3 (50)	98	50/50	4.3 (47)	98	47/50
58-7	4.5 (50)	50/50		4.5 (48)	100	48/50	4.5 (50)	100	50/50	4.5 (45)	100	45/50
62-7	4.6 (50)	50/50		4.6 (48)	100	48/50	4.5 (50)	98	50/50	4.5 (44)	98	44/50
66-7	4.6 (50)	50/50		4.6 (48)	100	48/50	4.6 (50)	100	50/50	4.7 (43)	102	43/50
70-7	4.8 (50)	50/50		4.7 (48)	98	48/50	4.6 (50)	96	50/50	4.7 (42)	98	42/50
74-7	4.8 (50)	50/50		4.8 (47)	100	47/50	4.7 (49)	98	49/50	4.7 (42)	98	42/50
78-7	4.7 (49)	49/50		4.7 (47)	100	47/50	4.6 (47)	98	47/50	4.6 (42)	98	42/50
82-7	4.7 (49)	49/50		4.6 (45)	98	45/50	4.6 (45)	98	45/50	4.5 (39)	96	39/50
86-7	4.7 (48)	48/50		4.5 (44)	96	44/50	4.6 (43)	98	43/50	4.7 (39)	100	39/50
90-7	4.7 (47)	47/50		4.7 (42)	100	42/50	4.6 (42)	98	42/50	4.8 (36)	102	36/50
94-7	4.7 (46)	46/50		4.7 (39)	100	39/50	4.6 (42)	98	42/50	4.8 (35)	102	35/50
98-7	4.9 (45)	45/50		4.8 (35)	98	35/50	4.6 (41)	94	41/50	4.7 (34)	96	34/50
102-7	4.8 (42)	42/50		4.7 (34)	98	34/50	4.7 (38)	98	38/50	4.7 (33)	98	33/50
104-7	4.8 (41)	41/50		4.6 (31)	96	31/50	4.7 (37)	98	37/50	4.8 (33)	100	33/50

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

Av. FC. : g

(B10040)

B1S 4

TABLE D 2

FOOD CONSUMPTION CHANGES AND
SURVIVAL ANIMAL NUMBERS: FEMALE

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[CrJ:BDFl]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

MEAN FOOD CONSUMPTION(FC) AND SURVIVAL

PAGE : 2

Week-Day on Study	Control			800 ppm			2000 ppm			5000 ppm		
	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.	
1-7	3.6 (50)	50/50	3.6 (50)	100	50/50	3.7 (50)	103	50/50	3.5 (50)	97	50/50	
2-7	3.5 (50)	50/50	3.5 (50)	100	50/50	3.5 (50)	100	50/50	3.5 (50)	100	50/50	
3-7	3.6 (50)	50/50	3.5 (50)	97	50/50	3.6 (50)	100	50/50	3.6 (50)	100	50/50	
4-7	3.6 (50)	50/50	3.6 (50)	100	50/50	3.7 (50)	103	50/50	3.6 (50)	100	50/50	
5-7	3.7 (50)	50/50	3.6 (50)	97	50/50	3.7 (50)	100	50/50	3.7 (50)	100	50/50	
6-7	3.8 (50)	50/50	3.7 (50)	97	50/50	3.8 (50)	100	50/50	3.8 (50)	100	50/50	
7-7	3.8 (50)	50/50	3.8 (50)	100	50/50	3.9 (50)	103	50/50	3.8 (50)	100	50/50	
8-7	3.9 (49)	50/50	3.9 (50)	100	50/50	4.0 (50)	103	50/50	3.9 (50)	100	50/50	
9-7	3.9 (50)	50/50	3.8 (50)	97	50/50	3.8 (50)	97	50/50	3.9 (50)	100	50/50	
10-7	3.7 (50)	50/50	3.7 (50)	100	50/50	3.8 (50)	103	50/50	3.7 (50)	100	50/50	
11-7	3.7 (50)	50/50	3.7 (50)	100	50/50	3.8 (50)	103	50/50	3.8 (50)	103	50/50	
12-7	3.8 (49)	50/50	3.7 (50)	97	50/50	3.8 (50)	100	50/50	3.9 (50)	103	50/50	
13-7	3.8 (49)	50/50	3.7 (50)	97	50/50	3.8 (50)	100	50/50	3.8 (50)	100	50/50	
14-7	3.7 (50)	50/50	3.7 (50)	100	50/50	3.8 (50)	103	50/50	3.8 (50)	103	50/50	
18-7	3.8 (50)	50/50	3.8 (50)	100	50/50	3.8 (50)	100	50/50	3.9 (50)	103	50/50	
22-7	3.8 (50)	50/50	3.8 (50)	100	50/50	3.8 (50)	100	50/50	3.9 (50)	103	50/50	
26-7	3.8 (50)	50/50	3.8 (50)	100	50/50	3.8 (50)	100	50/50	3.9 (50)	103	50/50	
30-7	3.8 (49)	49/50	3.9 (50)	103	50/50	3.8 (50)	100	50/50	3.8 (50)	100	50/50	
34-7	3.9 (49)	49/50	3.9 (50)	100	50/50	3.9 (50)	100	50/50	3.9 (50)	100	50/50	
38-7	3.9 (49)	49/50	3.9 (50)	100	50/50	4.0 (49)	103	49/50	3.9 (50)	100	50/50	
42-7	4.1 (49)	49/50	3.9 (50)	95	50/50	4.0 (49)	98	49/50	4.1 (50)	100	50/50	
46-7	4.0 (49)	49/50	3.9 (50)	98	50/50	4.0 (49)	100	49/50	4.0 (49)	100	49/50	
50-7	3.8 (49)	49/50	3.8 (50)	100	50/50	3.9 (49)	103	49/50	3.9 (49)	103	49/50	
54-7	3.9 (49)	49/50	3.9 (49)	100	49/50	4.0 (49)	103	49/50	3.9 (49)	100	49/50	
58-7	4.0 (49)	49/50	4.1 (49)	103	49/50	4.1 (49)	103	49/50	4.1 (49)	103	49/50	
62-7	4.1 (49)	49/50	4.3 (49)	105	49/50	4.2 (49)	102	49/50	4.3 (48)	105	48/50	
66-7	4.2 (48)	48/50	4.2 (49)	100	49/50	4.3 (49)	102	49/50	4.2 (48)	100	48/50	
70-7	4.1 (47)	48/50	4.0 (47)	98	47/50	4.1 (47)	100	47/50	4.1 (46)	100	46/50	
74-7	4.1 (48)	48/50	4.1 (46)	100	46/50	4.1 (47)	100	47/50	4.3 (45)	105	45/50	
78-7	4.3 (45)	45/50	4.3 (45)	100	46/50	4.2 (44)	98	44/50	4.2 (45)	98	45/50	
82-7	4.1 (44)	44/50	3.9 (46)	95	46/50	4.0 (43)	98	43/50	4.1 (45)	100	45/50	
86-7	4.0 (44)	44/50	4.0 (43)	100	43/50	4.1 (40)	103	40/50	4.1 (40)	103	40/50	
90-7	4.2 (43)	43/50	4.0 (39)	95	39/50	4.1 (40)	98	40/50	4.2 (37)	100	37/50	
94-7	4.2 (42)	42/50	4.3 (34)	102	34/50	4.3 (36)	102	36/50	4.5 (33)	107	33/50	
98-7	4.2 (38)	38/50	4.4 (33)	105	33/50	4.1 (34)	98	34/50	4.4 (30)	105	30/50	
102-7	4.5 (37)	37/50	4.6 (32)	102	32/50	4.6 (26)	102	26/50	4.4 (26)	98	26/50	
104-7	4.4 (36)	36/50	4.1 (29)	93	29/50	4.4 (23)	100	23/50	4.6 (24)	105	24/50	

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

(B10040)

BAIS 4

TABLE D 3

FOOD CONSUMPTION CHANGES: MALE

STUDY NO. : 0642
 ANIMAL : MOUSE D6D2F1/CrJ[Crj:BDP1]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

PAGE : 1

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	1-7(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	4.2± 0.4	4.0± 0.3	4.0± 0.3	4.1± 0.3	4.1± 0.3	4.2± 0.3	4.2± 0.3
800 ppm	4.1± 0.3	3.9± 0.3	4.0± 0.3	4.1± 0.3	4.1± 0.4	4.1± 0.3	4.1± 0.3
2000 ppm	4.1± 0.3	3.9± 0.4	4.0± 0.3	4.0± 0.3	4.1± 0.3	4.1± 0.3	4.1± 0.3
5000 ppm	4.2± 0.3	4.0± 0.3	4.0± 0.3	4.0± 0.3	4.1± 0.4	4.1± 0.5	4.1± 0.3

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(HAN260)

BATS 4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[CxJ:BDP1]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

PAGE : 2

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	4.2± 0.3	4.1± 0.3	4.0± 0.3	4.1± 0.3	4.2± 0.3	4.2± 0.3	4.1± 0.3
800 ppm	4.1± 0.3	4.1± 0.2	4.0± 0.3	4.1± 0.3	4.2± 0.3	4.2± 0.3	4.1± 0.3
2000 ppm	4.2± 0.3	4.0± 0.3	4.0± 0.3	4.1± 0.3	4.1± 0.3	4.1± 0.3	4.1± 0.3
5000 ppm	4.2± 0.3	4.1± 0.3	4.1± 0.3	4.1± 0.3	4.1± 0.3	4.1± 0.3	4.1± 0.3
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01							Test of Dunnett

(HAN260)

BATS 4

PAGE : 3

(HAN260)

STUDY NO. : 0642
 ANIMAL : MOUSE D602F1/CrJ[Crj:BDFl]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

PAGE : 4

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

Group Name	Administration week-day(effective)							70-7(7)
	46-7(7)	50-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)		
Control	4.5± 0.3	4.5± 0.3	4.4± 0.4	4.5± 0.3	4.6± 0.3	4.6± 0.3	4.8± 0.3	
800 ppm	4.5± 0.5	4.4± 0.3	4.4± 0.3	4.5± 0.3	4.6± 0.3	4.6± 0.3	4.7± 0.3	
2000 ppm	4.5± 0.3	4.5± 0.3	4.3± 0.4	4.5± 0.3	4.5± 0.3	4.6± 0.3	4.6± 0.5	
5000 μm	4.4± 0.5	4.4± 0.3	4.3± 0.5	4.5± 0.3	4.5± 0.4	4.7± 0.3	4.7± 0.4	
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01							Test of Dunnett	
(HAN260)							BALS 4	

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/Cr-Lj[Cr-j:BDNF]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

PAGE : 5

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

Group Name	Administration week day(effective)						
	74-7(7)	78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)	98-7(7)
Control	4.8± 0.4	4.7± 0.5	4.7± 0.5	4.7± 0.4	4.7± 0.7	4.7± 0.4	4.9± 0.6
800 ppm	4.8± 0.3	4.7± 0.7	4.6± 0.7	4.5± 0.7	4.7± 0.4	4.7± 0.7	4.8± 0.4
2000 ppm	4.7± 0.4	4.6± 0.6	4.6± 0.4	4.6± 0.3	4.6± 0.4	4.6± 0.6	4.6± 0.8
5000 ppm	4.7± 0.6	4.6± 0.5	4.5± 0.5	4.7± 0.5	4.8± 0.4	4.8± 0.4	4.7± 0.4
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01							Test of Dunnett
(HAN260)							BATS 4

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/Cr-l₁[Cr-j:BDF1]

UNIT : g

REPORT TYPE : A1 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE : 6

Group Name	Administration week-day(effective) 102-7(7)	104-7(7)	
Control	4.8± 0.5	4.8± 0.4	
800 ppm	4.7± 0.4	4.6± 0.5	
2000 ppm	4.7± 0.5	4.7± 0.5	
5000 ppm	4.7± 0.5	4.8± 0.4	
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Dunnett			
(HAN260)			BAIS 4

TABLE D 4

FOOD CONSUMPTION CHANGES: FEMALE

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[CrJ:BDP1]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

PAGE : 7

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	1-7(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	3.6± 0.4	3.5± 0.3	3.6± 0.2	3.6± 0.2	3.7± 0.3	3.8± 0.2	3.8± 0.3
800 ppm	3.6± 0.3	3.5± 0.2	3.5± 0.2	3.6± 0.2	3.6± 0.2	3.7± 0.2	3.8± 0.2
2000 ppm	3.7± 0.3	3.5± 0.2	3.6± 0.2	3.7± 0.2	3.7± 0.2	3.8± 0.2	3.9± 0.2
5000 ppm	3.5± 0.4	3.5± 0.3	3.6± 0.2	3.6± 0.2	3.7± 0.2	3.8± 0.2	3.8± 0.3

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

(HAN260)

BALS 4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[CrJ:BDNF]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

PAGE : 8

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

Group Name	Administration week day(effective)						
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	3.9± 0.3	3.9± 0.3	3.7± 0.2	3.7± 0.2	3.8± 0.2	3.8± 0.3	3.7± 0.3
800 ppm	3.9± 0.3	3.8± 0.2	3.7± 0.3	3.7± 0.3	3.7± 0.3	3.7± 0.3	3.7± 0.3
2000 ppm	4.0± 0.4	3.8± 0.2	3.8± 0.2	3.8± 0.3	3.8± 0.3	3.8± 0.3	3.8± 0.3
5000 ppm	3.9± 0.4	3.9± 0.3	3.7± 0.3	3.8± 0.3	3.9± 0.3	3.8± 0.3	3.8± 0.3
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01							
Test of Dunnett							
(HAN260)							
BAIS 4							

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/Cr1j[Crj:BDFl]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

PAGE : 9

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

Group Name	Administration week day(effective)				
	18-7(7)	22-7(7)	26-7(7)	30-7(7)	34-7(7)
Control	3.8± 0.3	3.8± 0.3	3.8± 0.3	3.8± 0.4	3.9± 0.3
800 ppm	3.8± 0.3	3.8± 0.4	3.8± 0.3	3.9± 0.4	3.9± 0.4
2000 ppm	3.8± 0.4	3.8± 0.4	3.8± 0.4	3.8± 0.4	4.0± 0.4
5000 ppm	3.9± 0.3	3.9± 0.4	3.9± 0.3	3.9± 0.4	4.1± 0.4

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

(HAN260) BALS 4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ1j[Crj:BDFl]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

PAGE : 10

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

Group Name	Administration week day(effective)						
	46-7(7)	50-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)	70-7(7)
Control	4.0± 0.3	3.8± 0.4	3.9± 0.4	4.0± 0.4	4.1± 0.5	4.2± 0.5	4.1± 0.4
800 ppm	3.9± 0.4	3.8± 0.4	3.9± 0.5	4.1± 0.5	4.3± 0.5	4.2± 0.5	4.0± 0.5
2000 ppm	4.0± 0.4	3.9± 0.3	4.0± 0.4	4.1± 0.3	4.2± 0.4	4.3± 0.5	4.1± 0.4
5000 ppm	4.0± 0.4	3.9± 0.5	3.9± 0.4	4.1± 0.4	4.3± 0.4	4.2± 0.4	4.1± 0.5
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Dunnett							
LIAN260)							
BALS 4							

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/Cr-L1[Cr-j:BDNF1]
 UNIT : g
 REPORT TYPE : AI 104
 SEX : FEMALE

PAGE : 11

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

Group Name	Administration week-day(effective)				
	74-7(7)	78-7(7)	82-7(7)	86-7(7)	90-7(7)
Control	4.1± 0.5	4.3± 0.5	4.1± 0.4	4.0± 0.6	4.2± 0.4
800 ppm	4.1± 0.4	4.3± 0.5	3.9± 0.6	4.0± 0.6	4.3± 0.6
2000 ppm	4.1± 0.5	4.2± 0.5	4.0± 0.6	4.1± 0.4	4.1± 0.6
5000 ppm	4.3± 0.5	4.2± 0.6	4.1± 0.8	4.1± 0.7	4.4± 0.5

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(HAN260)

BALS 4

STUDY NO. : 0642
ANIMAL : MOUSE B6D2F1/Cr1j[Crj:BDF1]
UNIT : g
REPORT TYPE : AI 104
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 12

Group Name	Administration week day(effective) 102-7(7)	104-7(7)	
Control	4.5± 0.7	4.4± 0.8	
800 ppm	4.6± 0.9	4.1± 0.8	
2000 ppm	4.6± 0.8	4.4± 0.5	
5000 ppm	4.4± 0.8	4.6± 1.0	
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Dunnett			
(HAN260)			BATS 4

TABLE E 1

WATER CONSUMPTION CHANGES AND
SURVIVAL ANIMAL NUMBERS: MALE

STUDY NO. : 0642
ANIMAL : MOUSE B6D2F1/CrJ[Crj-BDF1]
UNIT : #
REPORT TYPE : AI 104
SEX : MALE

MEAN WATER CONSUMPTION(WC) AND SURVIVAL

PAGE : 1

Week-Day on Study	Control			800 ppm			2000 ppm			5000 ppm		
	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.	
1-7	4.4 (49)	50/50	4.2 (49)	95	50/50	4.1 (50)	93	50/50	4.3 (49)	98	50/50	
2-7	4.3 (48)	50/50	4.2 (50)	98	50/50	4.0 (50)	93	50/50	4.3 (49)	100	50/50	
3-7	4.3 (48)	50/50	4.3 (50)	100	50/50	3.9 (49)	91	50/50	4.1 (47)	95	50/50	
4-7	4.3 (50)	50/50	4.2 (50)	98	50/50	3.9 (49)	91	50/50	4.1 (49)	95	50/50	
5-7	4.2 (50)	50/50	4.2 (50)	100	50/50	3.9 (49)	93	50/50	4.0 (49)	95	50/50	
6-7	4.1 (50)	50/50	4.0 (50)	98	50/50	3.8 (50)	93	50/50	3.7 (49)	90	50/50	
7-7	4.1 (50)	50/50	3.9 (50)	95	50/50	3.9 (50)	95	50/50	3.8 (49)	93	49/50	
8-7	4.0 (50)	50/50	4.0 (50)	100	50/50	3.9 (50)	98	50/50	3.9 (48)	98	49/50	
9-7	3.9 (50)	50/50	3.9 (50)	100	50/50	3.9 (50)	100	50/50	3.8 (49)	97	49/50	
10-7	3.9 (50)	50/50	3.8 (50)	97	50/50	3.7 (50)	95	50/50	3.6 (49)	92	49/50	
11-7	3.8 (50)	50/50	3.8 (50)	100	50/50	3.6 (50)	95	50/50	3.6 (49)	95	49/50	
12-7	3.8 (50)	50/50	3.8 (50)	100	50/50	3.7 (50)	97	50/50	3.7 (49)	97	49/50	
13-7	3.8 (50)	50/50	3.9 (50)	103	50/50	3.7 (50)	97	50/50	3.7 (49)	97	49/50	
14-7	3.7 (50)	50/50	3.7 (50)	100	50/50	3.6 (50)	97	50/50	3.6 (49)	97	49/50	
18-7	3.6 (50)	50/50	3.7 (50)	103	50/50	3.6 (50)	100	50/50	3.5 (49)	97	49/50	
22-7	3.5 (50)	50/50	3.5 (50)	100	50/50	3.4 (50)	97	50/50	3.4 (49)	100	49/50	
26-7	3.4 (50)	50/50	3.4 (50)	100	50/50	3.4 (50)	100	50/50	3.4 (49)	100	49/50	
30-7	3.3 (50)	50/50	3.4 (50)	103	50/50	3.3 (50)	100	50/50	3.3 (49)	100	49/50	
34-7	3.5 (50)	50/50	3.7 (50)	106	50/50	3.6 (50)	103	50/50	3.6 (49)	103	49/50	
38-7	3.5 (50)	50/50	3.6 (50)	103	50/50	3.5 (50)	100	50/50	3.4 (49)	97	49/50	
42-7	3.6 (46)	50/50	3.8 (50)	106	50/50	3.7 (50)	103	50/50	3.6 (49)	100	49/50	
46-7	3.6 (50)	50/50	3.7 (49)	103	49/50	3.6 (50)	100	50/50	3.5 (48)	97	48/50	
50-7	3.8 (50)	50/50	3.7 (49)	97	49/50	3.7 (50)	97	50/50	3.6 (47)	95	47/50	
54-7	3.8 (50)	50/50	4.0 (49)	105	49/50	3.8 (50)	100	50/50	3.7 (47)	97	47/50	
58-7	3.9 (50)	50/50	3.9 (48)	100	48/50	3.9 (50)	100	50/50	3.7 (44)	95	45/50	
62-7	4.0 (50)	50/50	4.0 (48)	100	48/50	3.9 (49)	98	50/50	3.8 (44)	95	44/50	
66-7	4.1 (50)	50/50	4.1 (48)	100	48/50	4.1 (50)	100	50/50	3.9 (43)	95	43/50	
70-7	4.2 (49)	50/50	4.3 (48)	102	48/50	3.9 (48)	93	50/50	4.0 (42)	95	42/50	
74-7	4.4 (50)	50/50	4.5 (47)	102	47/50	4.2 (48)	95	49/50	4.1 (42)	93	42/50	
78-7	4.3 (49)	49/50	4.3 (47)	100	47/50	4.0 (46)	93	47/50	3.9 (41)	91	42/50	
82-7	4.3 (48)	49/50	4.4 (45)	102	45/50	3.9 (44)	91	45/50	3.9 (39)	91	39/50	
86-7	4.4 (48)	48/50	4.5 (42)	102	44/50	4.2 (42)	95	43/50	4.1 (38)	93	39/50	
90-7	4.3 (46)	47/50	4.6 (40)	107	42/50	4.2 (41)	98	42/50	4.2 (35)	98	36/50	
94-7	4.6 (42)	46/50	4.5 (35)	98	39/50	4.4 (41)	96	42/50	4.2 (35)	91	35/50	
98-7	4.7 (42)	45/50	4.8 (32)	102	35/50	4.4 (38)	94	41/50	4.2 (34)	89	34/50	
102-7	5.2 (10)	42/50	4.9 (32)	94	34/50	4.8 (35)	92	38/50	4.4 (33)	85	33/50	
104-7	4.7 (38)	41/50	4.9 (29)	104	31/50	4.7 (33)	100	37/50	4.5 (32)	96	33/50	

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

(B10040)

BAIS 4

TABLE E 2

WATER CONSUMPTION CHANGES AND
SURVIVAL ANIMAL NUMBERS: FEMALE

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/Cr-lj[Cr-j:BDF1]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

MEAN WATER CONSUMPTION(WC) AND SURVIVAL

PAGE : 2

Week-Day on Study	Control			800 ppm			2000 ppm			5000 ppm		
	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.	
1-7	4.3 (50)	50/50	4.2 (50)	98	50/50	4.2 (50)	98	50/50	3.9 (50)	91	50/50	
2-7	4.2 (50)	50/50	3.9 (50)	93	50/50	4.1 (50)	98	50/50	3.9 (50)	93	50/50	
3-7	4.2 (50)	50/50	4.0 (50)	95	50/50	4.2 (50)	100	50/50	4.0 (50)	95	50/50	
4-7	4.1 (50)	50/50	3.9 (50)	95	50/50	4.1 (50)	100	50/50	3.9 (50)	95	50/50	
5-7	4.1 (50)	50/50	4.0 (50)	98	50/50	4.1 (50)	100	50/50	3.9 (50)	95	50/50	
6-7	4.0 (50)	50/50	4.0 (50)	100	50/50	4.0 (50)	100	50/50	3.9 (50)	98	50/50	
7-7	4.1 (50)	50/50	4.0 (50)	98	50/50	4.0 (50)	98	50/50	3.8 (50)	93	50/50	
8-7	4.2 (50)	50/50	4.0 (50)	95	50/50	4.0 (50)	95	50/50	3.9 (50)	93	50/50	
9-7	4.1 (50)	50/50	4.0 (50)	98	50/50	4.1 (50)	100	50/50	3.9 (50)	95	50/50	
10-7	4.0 (50)	50/50	3.8 (50)	95	50/50	3.9 (50)	98	50/50	3.6 (50)	90	50/50	
11-7	4.0 (50)	50/50	3.9 (50)	98	50/50	3.8 (50)	95	50/50	3.6 (50)	90	50/50	
12-7	4.1 (50)	50/50	3.9 (50)	95	50/50	4.0 (50)	98	50/50	3.7 (50)	90	50/50	
13-7	3.9 (50)	50/50	3.8 (50)	97	50/50	3.7 (50)	95	50/50	3.6 (50)	92	50/50	
14-7	3.8 (50)	50/50	3.6 (50)	95	50/50	3.7 (50)	97	50/50	3.5 (50)	92	50/50	
18-7	4.0 (50)	50/50	3.8 (50)	95	50/50	3.9 (50)	98	50/50	3.5 (50)	88	50/50	
22-7	3.8 (50)	50/50	3.7 (50)	97	50/50	3.6 (50)	95	50/50	3.4 (50)	89	50/50	
26-7	3.8 (50)	50/50	3.7 (50)	97	50/50	3.6 (50)	95	50/50	3.2 (50)	84	50/50	
30-7	3.8 (49)	49/50	3.7 (50)	97	50/50	3.5 (50)	92	50/50	3.2 (50)	84	50/50	
34-7	3.8 (49)	49/50	3.7 (50)	97	50/50	3.6 (48)	95	50/50	3.3 (50)	87	50/50	
38-7	3.9 (49)	49/50	3.6 (50)	92	50/50	3.6 (49)	92	49/50	3.3 (50)	85	50/50	
42-7	4.0 (49)	49/50	3.8 (50)	95	50/50	3.8 (49)	95	49/50	3.3 (49)	83	50/50	
46-7	3.9 (49)	49/50	3.7 (50)	95	50/50	- (-)	-	49/50	3.0 (49)	77	49/50	
50-7	4.0 (49)	49/50	3.7 (50)	93	50/50	3.7 (49)	93	49/50	3.4 (49)	85	49/50	
54-7	4.0 (49)	49/50	3.7 (49)	93	49/50	3.7 (49)	93	49/50	3.4 (49)	85	49/50	
58-7	4.1 (49)	49/50	4.0 (49)	98	49/50	3.9 (49)	95	49/50	3.4 (49)	83	49/50	
62-7	4.0 (49)	49/50	3.7 (48)	93	49/50	3.7 (48)	93	49/50	3.4 (48)	85	48/50	
66-7	4.3 (48)	48/50	3.8 (48)	88	49/50	3.8 (49)	88	49/50	3.3 (48)	77	48/50	
70-7	4.0 (47)	48/50	3.7 (46)	93	47/50	3.7 (47)	93	47/50	3.4 (46)	85	46/50	
74-7	4.2 (47)	48/50	3.8 (46)	90	46/50	3.8 (46)	90	47/50	3.6 (45)	86	45/50	
78-7	4.4 (45)	45/50	3.9 (46)	89	46/50	4.0 (43)	91	44/50	3.4 (45)	77	45/50	
82-7	4.1 (44)	44/50	3.6 (46)	88	46/50	3.7 (43)	90	43/50	3.4 (45)	83	45/50	
86-7	4.1 (44)	44/50	3.8 (43)	93	43/50	3.6 (40)	88	40/50	3.4 (39)	83	40/50	
90-7	4.3 (43)	43/50	3.8 (39)	88	39/50	3.7 (40)	86	40/50	3.6 (37)	84	37/50	
94-7	4.5 (42)	42/50	4.0 (33)	89	34/50	3.8 (36)	84	36/50	3.6 (33)	80	33/50	
98-7	4.2 (38)	38/50	4.3 (33)	102	33/50	4.0 (34)	95	34/50	3.7 (30)	88	30/50	
102-7	4.4 (37)	37/50	4.2 (32)	95	32/50	4.0 (26)	91	26/50	3.8 (26)	86	26/50	
104-7	4.4 (35)	36/50	4.1 (29)	93	29/50	4.0 (22)	91	23/50	3.9 (24)	89	24/50	

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

(B10040)

BALS 4

TABLE E 3

WATER CONSUMPTION CHANGES: MALE

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/Crj[Crj:DDF1]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

PAGE : 1

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	1-7(3)	2-7(3)	3-7(3)	4-7(3)	5-7(3)	6-7(3)	7-7(3)
Control	4.4± 1.1	4.3± 0.9	4.3± 0.8	4.3± 0.9	4.2± 0.9	4.1± 0.9	4.1± 0.7
800 ppm	4.2± 0.7	4.2± 0.8	4.3± 0.7	4.2± 0.7	4.2± 0.7	4.0± 0.7	3.9± 0.6
2000 ppm	4.1± 0.8	4.0± 0.9	3.9± 0.6*	3.9± 0.6	3.9± 0.6	3.8± 0.8	3.9± 0.8
5000 ppm	4.3± 0.8	4.3± 1.1	4.1± 0.7	4.1± 0.9	4.0± 0.7	3.7± 0.7*	3.8± 0.8

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(HAN260)

BAIS 4

Group Name	Administration week-day(effective)						
	8-7(3)	9-7(3)	10-7(3)	11-7(3)	12-7(3)	13-7(3)	14-7(3)
Control	4.0± 0.7	3.9± 0.6	3.9± 0.6	3.8± 0.7	3.8± 0.5	3.8± 0.5	3.7± 0.6
800 ppm	4.0± 0.6	3.9± 0.6	3.8± 0.6	3.8± 0.6	3.8± 0.6	3.9± 0.6	3.7± 0.5
2000 ppm	3.9± 0.8	3.9± 0.7	3.7± 0.7	3.6± 0.6	3.7± 0.5	3.7± 0.5	3.6± 0.6
5000 ppm	3.9± 0.6	3.8± 0.9	3.6± 0.7	3.6± 0.7	3.7± 0.7	3.7± 0.6	3.6± 0.7
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01							
Test of Dunnett							
(HAN260)							
BATS 4							

PAGE : 3

BAIS 4

STUDY NO. : 0642
ANIMAL : MOUSE B6D2F1/Crj[Crj:EDF1]
UNIT : g
REPORT TYPE : A1 104
SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 4

Group Name	Administration week-day(effective)						
	46-7(3)	50-7(3)	54-7(3)	58-7(3)	62-7(3)	66-7(3)	70-7(3)
Control	3.6± 0.3	3.8± 0.4	3.8± 0.4	3.9± 0.5	4.0± 0.5	4.1± 0.6	4.2± 0.5
800 ppm	3.7± 0.5	3.7± 0.4	4.0± 0.7	3.9± 0.4	4.0± 0.4	4.1± 0.5	4.3± 0.4
2000 ppm	3.6± 0.4	3.7± 0.5	3.8± 0.5	3.9± 0.6	3.9± 0.5	4.1± 0.8	3.9± 0.5*
5000 ppm	3.5± 0.6	3.6± 0.4	3.7± 0.5	3.7± 0.6*	3.8± 0.6	3.9± 0.6	4.0± 0.6
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Dunnett							
(HAN260)							
BALS 4							

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/Cr1j[Cr1:BDFl]
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

PAGE : 5

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

Group Name	Administration week-day(effective)				
	74-7(3)	78-7(3)	82-7(3)	86-7(3)	90-7(3)
Control	4.4± 0.7	4.3± 0.7	4.3± 0.9	4.4± 0.8	4.3± 0.8
800 ppm	4.5± 0.5	4.3± 0.9	4.4± 1.0	4.5± 0.9	4.6± 0.8
2000 ppm	4.2± 0.7	4.0± 0.6	3.9± 0.4	4.2± 0.6	4.2± 0.7
5000 ppm	4.1± 0.8*	3.9± 0.7*	3.9± 0.9*	4.1± 0.6*	4.2± 0.6

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(HAN260) BAIS 4

STUDY NO. : 0642
ANIMAL : MOUSE B6D2F1/Cr1j[BDF1]
UNIT : g
REPORT TYPE : AI 104
SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 6

Group Name	Administration 102-7(3)	week-day(effective) 104-7(3)		Test of Dunnett
Control	5.2± 1.1	4.7± 0.8		
800 ppm	4.9± 0.9	4.9± 1.0		
2000 ppm	4.8± 0.9	4.7± 0.8		
5000 ppm	4.4± 0.7**	4.5± 0.7		
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01				
(HAN260)				BAIS 4

TABLE E 4

WATER CONSUMPTION CHANGES: FEMALE

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/CrJ1[Crj:BDFl]

UNIT : g

REPORT TYPE : AI 104

SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 7

Group Name	Administration week-day(effective)						
	1-7 (3)	2-7 (3)	3-7 (3)	4-7 (3)	5-7 (3)	6-7 (3)	7-7 (3)
Control	4.3 ± 0.4	4.2 ± 0.4	4.2 ± 0.4	4.1 ± 0.4	4.1 ± 0.4	4.0 ± 0.4	4.1 ± 0.4
800 ppm	4.2 ± 0.5	3.9 ± 0.5**	4.0 ± 0.5*	3.9 ± 0.4	4.0 ± 0.4	4.0 ± 0.5	4.0 ± 0.5
2000 ppm	4.2 ± 0.4	4.1 ± 0.4	4.2 ± 0.4	4.1 ± 0.4	4.1 ± 0.4	4.0 ± 0.4	4.0 ± 0.4
5000 ppm	3.9 ± 0.4**	3.9 ± 0.4**	4.0 ± 0.4*	3.9 ± 0.4	3.9 ± 0.4	3.9 ± 0.4	3.8 ± 0.4**

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(HAN260)

BATS 4

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/Cr1J[Crj:BDFl]

UNIT : g

REPORT TYPE : AI 104

SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 8

Group Name	Administration week-day(effective)						
	8-7(3)	9-7(3)	10-7(3)	11-7(3)	12-7(3)	13-7(3)	14-7(3)
Control	4.2± 0.4	4.1± 0.4	4.0± 0.4	4.0± 0.4	4.1± 0.4	3.9± 0.5	3.8± 0.4
800 ppm	4.0± 0.5	4.0± 0.4	3.8± 0.4	3.9± 0.4	3.9± 0.4*	3.8± 0.4	3.6± 0.4
2000 ppm	4.0± 0.4	4.1± 0.5	3.9± 0.4	3.8± 0.4	4.0± 0.6	3.7± 0.4*	3.7± 0.5
5000 ppm	3.9± 0.4**	3.9± 0.3*	3.6± 0.4**	3.6± 0.4**	3.7± 0.4**	3.6± 0.4**	3.5± 0.5**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							
(HAN260)							
BAIS 4							

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/Cr1j[Crj:BDFl]

UNIT : g

REPORT TYPE : AI 104

SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 9

Group Name	Administration week-day(effective)				
	18-7(3)	22-7(3)	26-7(3)	30-7(3)	34-7(3)
Control	4.0± 0.5	3.8± 0.5	3.8± 0.5	3.8± 0.8	3.8± 0.7
800 ppm	3.8± 0.5	3.7± 0.6	3.7± 0.5	3.7± 0.6	3.7± 0.5
2000 ppm	3.9± 0.5	3.6± 0.5	3.6± 0.5	3.5± 0.5*	3.6± 0.5
5000 ppm	3.5± 0.6**	3.4± 0.5**	3.2± 0.4**	3.2± 0.5**	3.3± 0.4**

4.0± 0.7

3.8± 0.5

3.8± 0.5

3.3± 0.4**

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

(HAN260)

BAIS 4

SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE : 10

Group Name	Administration week-day(effective)						
	46-7(3)	50-7(3)	54-7(3)	58-7(3)	62-7(3)	66-7(3)	70-7(3)
Control	3.9 ± 0.6	4.0 ± 0.5	4.0 ± 0.7	4.1 ± 0.7	4.0 ± 0.8	4.3 ± 0.9	4.0 ± 0.7
800 ppm	3.7 ± 0.5*	3.7 ± 0.5*	3.7 ± 0.6*	4.0 ± 0.8	3.7 ± 0.7	3.8 ± 0.6**	3.7 ± 0.7*
2000 ppm	-	3.7 ± 0.6**	3.7 ± 0.5*	3.9 ± 0.7	3.7 ± 0.6	3.8 ± 0.5**	3.7 ± 0.6
5000 ppm	3.0 ± 0.5**	3.4 ± 0.4**	3.4 ± 0.5**	3.4 ± 1.0**	3.4 ± 0.4**	3.3 ± 0.5**	3.4 ± 0.5**

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

(HAN260)

BAIS 4

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/Cr-Li[Crj:BDFl]

UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 11

Group Name	Administration week day(effective)				
	74-7(3)	78-7(3)	82-7(3)	86-7(3)	90-7(3)
Control	4.2± 0.8	4.4± 0.9	4.1± 0.9	4.1± 1.0	4.3± 0.9
800 ppm	3.8± 0.7	3.9± 0.6*	3.6± 0.8*	3.8± 0.8	3.8± 1.0
2000 ppm	3.8± 0.7	4.0± 0.6	3.7± 0.7	3.6± 0.7*	3.7± 0.6**
5000 ppm	3.6± 0.5**	3.4± 0.6**	3.4± 0.8**	3.4± 0.7**	3.6± 0.7**

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

(HAN260)

BAIS 4

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/Cr1j[Crj-BDF1]

UNIT : g

REPORT TYPE : AI 104

SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE : 12

Group Name	Administration	week-day(effective)	
	102-7(3)	104-7(3)	
Control	4.4± 1.0	4.4± 0.9	
800 ppm	4.2± 0.9	4.1± 0.9	
2000 ppm	4.0± 1.0	4.0± 0.8	
5000 ppm	3.8± 1.1	3.9± 1.0	
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01			
Test of Dunnett			
(HAN260)			
BATS 4			

TABLE F 1

CHEMICAL INTAKE CHANGES: MALE

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/CrJ[Crj:BDP1]

UNIT : mg/kg/d a y

REPORT TYPE : AI 104

SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration (Week-Day)						
	1-7	2-7	3-7	4-7	5-7	6-7	7-7
Control	0± 0	0± 0	0± 0	0± 0	0± 0	0± 0	0± 0
800 ppm	139± 21	134± 26	133± 23	125± 20	123± 21	114± 19	110± 17
2000 ppm	338± 61	319± 68	306± 43	298± 44	290± 51	277± 61	276± 58
5000 ppm	879± 170	848± 204	786± 117	778± 173	746± 134	676± 114	673± 150

(HAN300)

BATS 4

Group Name	Administration (Week-Day)									
	8-7	9-7	10-7	11-7	12-7	13-7	14-7			
Control	0± 0	0± 0	0± 0	0± 0	0± 0	0± 0	0± 0			
800 ppm	110± 18	107± 18	100± 15	99± 16	97± 16	97± 17	90± 15			
2000 ppm	272± 59	266± 52	249± 50	237± 43	236± 38	231± 39	220± 39			
5000 ppm	664± 116	653± 166	604± 127	589± 120	587± 127	579± 121	552± 127			

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[Crj:BDFl]
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 104
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration (Week-Day)					
	18-7	22-7	28-7	30-7	34-7	42-7
Control	0± 0	0± 0	0± 0	0± 0	0± 0	0± 0
800 ppm	84± 12	77± 10	71± 11	67± 10	66± 9	68± 10
2000 ppm	207± 32	189± 29	178± 27	165± 27	160± 31	170± 31
5000 ppm	509± 100	471± 91	448± 81	403± 71	400± 66	405± 65

(HN300)

BATS 4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/Cr1j[Crj:BDFl]
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 104
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration (Week Day)													
	46-7	50-7	54-7	58-7	62-7	66-7	70-7							
Control	0 ±	0	0 ±	0	0 ±	0	0 ±	0						
800 ppm	65 ±	10	65 ±	10	71 ±	24	66 ±	11	66 ±	10	69 ±	13	70 ±	10
2000 ppm	163 ±	26	162 ±	28	167 ±	30	168 ±	46	163 ±	28	172 ±	52	162 ±	26
5000 ppm	387 ±	72	390 ±	65	410 ±	98	389 ±	63	402 ±	68	409 ±	80	416 ±	68

(HAN300)

BATS 4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[Crl:BDP1]
 UNIT : mg/kg/d a y
 REPORT TYPE : AI 104
 SEX : MALE

CHEMICAL INTAKE CHANGES
 ALL ANIMALS

(SUMMARY)

PAGE : 5

Group Name	Administration (Week-Day)						
	74-7	78-7	82-7	86-7	90-7	94-7	98-7
Control	0±	0	0±	0	0±	0	0±
800 ppm	73±	13	72±	20	74±	21	73±
2000 ppm	174±	32	161±	29	166±	31	177±
5000 ppm	422±	93	395±	108	408±	69	415±

(HAN300)

BATS 4

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

STUDY NO. : 0642
ANIMAL : MOUSE B6D2F1/Cr1j[Crj:BDF1]
UNIT : $\mu\text{g}/\text{kg}/\text{d a y}$
REPORT TYPE : A1 I04
SEX : MALE

PAGE : 6

Group Name	Administration (Week-Day)	
	102-7	104-7
Control	0 ± 0	0 ± 0
800 ppm	82 ± 27	81 ± 30
2000 ppm	207 ± 82	190 ± 50
5000 ppm	440 ± 122	445 ± 108

(HAN300)

BATS 4

TABLE F 2

CHEMICAL INTAKE CHANGES: FEMALE

Group Name	Administration (Week-Day)						
	1-7	2-7	3-7	4-7	5-7	6-7	7-7
Control	0±	0±	0±	0±	0±	0±	0±
800 ppm	172±	154±	152±	146±	143±	141±	137±
2000 ppm	426±	403±	401±	381±	369±	358±	346±
5000 ppm	1014±	969±	951±	920±	889±	861±	832±

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/CrJ[Crj:BDFl]

UNIT : mg/kg/d a y

REPORT TYPE : AI 104

SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 8

Group Name	Administration (Week-Day)						
	8-7	9-7	10-7	11-7	12-7	13-7	14-7
Control	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0
800 ppm	135 ± 14	134 ± 15	127 ± 16	125 ± 14	123 ± 12	120 ± 13	113 ± 13
2000 ppm	335 ± 38	349 ± 48	323 ± 35	313 ± 38	320 ± 57	302 ± 38	298 ± 37
5000 ppm	825 ± 83	831 ± 78	758 ± 80	746 ± 74	757 ± 81	728 ± 91	693 ± 112

(HAN300)

BATS 4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[Crj:BDP1]
 UNIT : mg/kg/d a y
 REPORT TYPE : AI 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 9

Group Name	Administration (Week-Day)						
	18-7	22-7	26-7	30-7	34-7	38-7	42-7
Control	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0
800 ppm	113 ± 18	106 ± 21	103 ± 19	97 ± 21	94 ± 19	91 ± 16	93 ± 17
2000 ppm	298 ± 44	269 ± 41	252 ± 44	235 ± 40	240 ± 43	235 ± 41	242 ± 41
5000 ppm	676 ± 121	623 ± 91	569 ± 89	544 ± 102	555 ± 95	528 ± 86	526 ± 83

(HAN300)

BATS 4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/Cr1j[Crj:BDNF1]
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 10

Group Name	Administration (Week-Day)						
	46-7	50-7	54-7	58-7	62-7	66-7	70-7
Control	0± 0	0± 0	0± 0	0± 0	0± 0	0± 0	0± 0
800 ppm	89± 18	90± 16	89± 18	95± 29	86± 22	88± 17	85± 22
2000 ppm	-	224± 46	224± 44	236± 44	219± 41	222± 37	219± 42
5000 ppm	468± 94	522± 76	520± 104	517± 164	501± 83	489± 94	487± 91

(HAN300)

BAIS 4

PAGE : 11

BAIS 4

STUDY NO. : 0642
ANIMAL : MOUSE B6D2F1/CrJ[Crj:BDP1]
UNIT : mg/kg/d a y
REPORT TYPE : AI 104
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration (Week-Day)	
	102-7	104-7
Control	0 ± 0	0 ± 0
800 ppm	90 ± 23	91 ± 25
2000 ppm	223 ± 59	224 ± 54
5000 ppm	538 ± 151	546 ± 121

TABLE G 1

HEMATOLOGY: MALE

STUDY NO. : 0642
 ANIMAL : MOUSE B602F1/Crj[Crj:BDFl]
 MEASURE TIME : 1
 SEX : MALE
 REPORT TYPE : A1
 HEMATOLOGY (SUMMARY)
 ALL ANIMALS (105W)
 PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl	HEMOGLOBIN g/dl	HEMATOCRIT %	MCV fl	MCH pg	MCHC g/dl	PLATELET 10 ³ /μl
Control	41	9.45± 0.70	13.8± 0.9	43.4± 2.9	46.0± 1.6	14.6± 0.5	31.9± 0.7	1654± 336
800 ppm	30	9.44± 0.60	13.8± 0.9	43.4± 2.3	46.0± 1.5	14.7± 0.5	31.9± 0.6	1676± 387
2000 ppm	37	9.22± 1.23	13.4± 1.8	42.5± 4.9	46.3± 1.9	14.6± 0.6	31.5± 0.9	1834± 301
5000 ppm	33	9.50± 1.51	13.7± 2.0	43.4± 5.8	45.8± 2.0	14.4± 0.5	31.5± 0.9	1703± 242

Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Dunnett

(HCL070)

BATS 4

STUDY NO. : 0642

ANIMAL : MOUSE B6D2f1/Cr-lj[Crj:BDF1]

MEASURE TIME : 1

SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (105W)

PAGE : 2

Group Name	NO. of Animals	RETICULOCYTE %
Control	41	2.6 ± 1.0
800 ppm	30	2.8 ± 1.9
2000 ppm	37	3.5 ± 2.7
5000 ppm	33	3.0 ± 2.5

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(HCL070)

BALS 4

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/CrJ[Crj:BDPL]

MEASURE TIME : 1

SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (105W)

PAGE : 3

Group Name	No. of Animals	WBC 10 ³ /μl	Differential		WBC (%)	LYMPHO	MONO	EOSINO	BASO	OTHER
			NEUTRO							
Control	41	3.49 ± 2.50	27 ± 13	66 ± 13	4 ± 2	3 ± 1	0 ± 0	0 ± 0	0 ± 0	0
800 ppm	30	3.29 ± 2.21	27 ± 12	66 ± 12	3 ± 2	3 ± 2	0 ± 0	0 ± 0	0 ± 0	1
2000 ppm	37	3.22 ± 1.91	30 ± 14	62 ± 14	4 ± 2	3 ± 1	0 ± 0	0 ± 0	0 ± 0	0
5000 ppm	33	2.87 ± 1.49	26 ± 11	65 ± 13	3 ± 2	4 ± 3	0 ± 0	0 ± 0	1 ± 1	3

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

Test of Dunnett

(HCL070)

BAIS-4

TABLE G 2

HEMATOLOGY: FEMALE

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/Cr1j[Crj:BDFl]

MEASURE TIME : 1

SEX : FEMALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (105W)

PAGE : 4

Group Name	No. of Animals	RED BLOOD CELL 10 ⁶ /μl	HEMOGLOBIN g/dl	HEMATOCRIT %	MCV fl	MCH pg	MCHC g/dl	PLATELET 10 ³ /μl
Control	35	9.24 ± 1.63	13.7 ± 2.2	42.9 ± 6.2	46.9 ± 3.5	14.9 ± 0.8	31.7 ± 1.2	982 ± 402
800 ppm	28	9.45 ± 1.06	13.8 ± 1.8	43.3 ± 4.1	46.0 ± 1.7	14.5 ± 0.8	31.7 ± 2.0	1143 ± 242
2000 ppm	23	9.62 ± 0.83	13.9 ± 1.3	43.9 ± 3.5	45.7 ± 1.9	14.5 ± 0.6	31.7 ± 0.8	1106 ± 277
5000 ppm	24	8.95 ± 1.59	13.0 ± 2.7	41.1 ± 6.9	46.2 ± 2.8	14.5 ± 0.7	31.4 ± 2.1	1123 ± 314

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

Test of Dunnett

(HCL070)

BAIS-4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[Crj:EDF1]
 MEASURE, TIME : 1
 SEX : FEMALE
 REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (105W)

PAGE : 5

Group Name	NO. of Animals	RETICULOCYTE %
Control	35	3.8± 3.5
800 ppm	28	2.7± 2.5
2000 ppm	23	2.7± 1.7
5000 ppm	24	3.9± 4.7

Significant difference ;	* : P ≤ 0.05	** : P ≤ 0.01	Test of Dunnett
(HCL070)			BAIS-4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/Crj[Crj:BDP1]
 MEASURE, TIME : 1
 SEX : FEMALE
 REPORT TYPE : A1

PAGE : 6

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (105W)

Group Name	No. of Animals	WBC 1 O ³ /μl	Differential NEUTRO	WBC (%) LYMPHO	MONO	EOSINO	BASO	OTHER
Control	35	7.32± 15.44	25± 15	67± 16	3± 2	3± 2	0± 0	1± 1
800 ppm	28	29.15± 142.95	23± 10	69± 11	3± 1	4± 2	0± 0	2± 5
2000 ppm	23	2.74± 1.66	25± 10	67± 13	3± 2	4± 2	0± 0	1± 1
5000 ppm	24	40.54± 185.52	26± 15	62± 20	3± 2	4± 2	0± 0	5± 19

Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Dunnett

(HCL070)

BATS 4

TABLE H 1

BIOCHEMISTRY: MALE

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/Crj[Crj:DDF1]

MEASURE TIME : 1

SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (105W)

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g/dl	ALBUMIN g/dl	A/G RATIO	T-BILIRUBIN mg/dl	GLUCOSE mg/dl	T-CHOLESTEROL mg/dl	TRIGLYCERIDE mg/dl
Control	41	5.1±	2.5±	0.9±	0.13±	195±	116±	52±
800 ppm	30	5.2±	2.5±	0.9±	0.13±	179±	103±	44±
2000 ppm	37	5.3±	2.5±	0.9±	0.13±	181±	108±	46±
5000 ppm	33	5.0±	2.4±	1.0±	0.14±	173±	102±	44±

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

Test of Dunnett

(HCL074)

BATS 4

Group Name	NO. of Animals	PHOSPHOLIPID mg/dL	AST IU/L	ALT IU/L	LDH IU/L	ALP IU/L	G-GTP IU/L	CK IU/L
Control	41	205 ± 75	74 ± 74	47 ± 77	407 ± 196	165 ± 122	1 ± 0	52 ± 49
800 ppm	30	183 ± 52	81 ± 69	45 ± 48	433 ± 193	139 ± 37	1 ± 1	63 ± 72
2000 ppm	37	185 ± 48	77 ± 71	49 ± 60	432 ± 177	126 ± 34*	1 ± 0	58 ± 34
5000 ppm	33	178 ± 45	151 ± 325	76 ± 162	583 ± 646	142 ± 46	1 ± 1	102 ± 150**

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

Test of Dunnett

(HCL074)

BATS 4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/Cr1j(BDF1)
 MEASURE TIME : 1
 SEX : MALE
 REPORT TYPE : A1

PAGE : 3

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (105W)

Group Name	No. of Animals	UREA NITROGEN mg/dl	SODIUM mEq/l	POTASSIUM mEq/l	CHLORIDE mEq/l	CALCIUM mg/dl	INORGANIC PHOSPHORUS mg/dl
Control	41	23.6 ± 4.8	153 ± 2	4.2 ± 0.3	122 ± 2	8.8 ± 0.4	6.1 ± 0.6
800 ppm	30	24.3 ± 8.0	153 ± 3	4.3 ± 0.4	122 ± 4	8.8 ± 0.4	6.1 ± 0.9
2000 ppm	37	24.4 ± 11.5	152 ± 2	4.2 ± 0.3	121 ± 2	8.9 ± 0.4	6.1 ± 0.8
5000 ppm	33	26.1 ± 19.4	153 ± 5	4.5 ± 1.1	123 ± 6	8.8 ± 0.5	6.4 ± 1.2

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

Test of Dunnett

(HCL074)

BATS 4

TABLE H 2

BIOCHEMISTRY: FEMALE

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/Crj:BDP1

MEASURE TIME : 1

SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (105W)

PAGE : 4

Group Name	No. of Animals	TOTAL PROTEIN g/dl	ALBUMIN g/dl	A/G RATIO	T-BILIRUBIN mg/dl	GLUCOSE mg/dl	T-CHOLESTEROL mg/dl	TRIGLYCERIDE mg/dl
Control	35	5.0 ± 0.6	2.5 ± 0.3	1.0 ± 0.2	0.24 ± 0.56	144 ± 32	78 ± 24	43 ± 32
800 ppm	28	5.1 ± 0.4	2.5 ± 0.2	1.0 ± 0.2	0.14 ± 0.04	147 ± 31	70 ± 14	37 ± 17
2000 ppm	23	5.1 ± 0.7	2.5 ± 0.3	1.0 ± 0.2	0.14 ± 0.02	148 ± 25	76 ± 28	47 ± 52
5000 ppm	24	5.0 ± 0.6	2.5 ± 0.4	1.0 ± 0.1	0.15 ± 0.05	137 ± 37	78 ± 30	33 ± 16

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

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/CrJ[Crj:BDP1]

MEASURE TIME : 1

SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (105W)

PAGE : 5

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl	AST IU/l	ALT IU/l	LDH IU/l	ALP IU/l	G-GTP IU/l	CK IU/l							
Control	35	142±	41	363±	1335	523	137±	1174±	3682	245±	130	1±	1	90±	84
800 ppm	28	125±	24	107±	111	35	40±	556±	894	243±	65	13±	66	60±	49
2000 ppm	23	131±	41	113±	95	23	40±	510±	576	223±	84	1±	1	61±	21
5000 ppm	24	135±	55	127±	171	70	48±	674±	1060	348±	576	1±	1	101±	151

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

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/CrJ[Crj:BDPf1]

MEASURE TIME : 1

SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (105W)

PAGE : 6

Group Name	No. of Animals	UREA NITROGEN mg/dl	SODIUM mEq/l	POTASSIUM mEq/l	CHLORIDE mEq/l	CALCIUM mg/dl	INORGANIC PHOSPHORUS mg/dl
Control	35	17.4 ± 7.4	152 ± 2	4.1 ± 0.5	122 ± 2	9.2 ± 0.6	6.2 ± 1.1
800 ppm	28	17.3 ± 5.5	152 ± 1	4.3 ± 0.7	122 ± 2	8.8 ± 0.3**	6.0 ± 1.2
2000 ppm	23	17.5 ± 4.8	152 ± 2	4.0 ± 0.4	122 ± 2	8.9 ± 0.7*	5.7 ± 1.2
5000 ppm	24	22.7 ± 17.7	151 ± 3	4.2 ± 0.7	121 ± 3	9.0 ± 0.6	6.2 ± 1.3

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

Test of Dunnett

(HCL074)

BAIS 4

TABLE I 1

URINALYSIS: MALE

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/Cr1J[Crj:BDFl]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

PAGE : 1

URINALYSIS

Group Name	NO. of Animals	pH								Protein		Glucose		Ketone body		Occult blood							
		5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	-	+	2+	3+	4+	CHI	-	+	2+	3+	4+	CHI		
Control	41	0	2	9	11	13	6	0		0	5	27	6	3	0		16	13	9	3	0	0	3
800 ppm	32	0	2	5	9	8	2	6		0	6	18	8	0	0		15	7	10	0	0	0	3
2000 ppm	36	0	1	10	12	7	5	1		0	5	25	3	3	0		10	16	10	0	0	0	4
5000 ppm	33	0	3	6	9	9	5	1		0	5	17	10	1	0		8	14	11	0	0	0	2

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

(HCl101)

Test of CHI SQUARE

BATS 4

URINMLYSIS

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/Cr1j(Crj:BDF1)

MEASURE TIME : 1

SEX : MALE

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+	CHI
Control	41	41 0 0 0 0	
800 ppm	32	32 0 0 0 0	
2000 ppm	36	36 0 0 0 0	
5000 ppm	33	33 0 0 0 0	
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$			
(HCl/101)			
Test of CHI SQUARE			RATS 4

TABLE I 2

URINALYSIS: FEMALE

STUDY NO. : 0642

ANIMAL : MOUSE B6D2F1/Cr1j[BDF1]

MEASURE TIME : 1

SEX : FEMALE

REPORT TYPE : A1

URINALYSIS

PAGE : 3

Group Name	NO. of Animals	pH								Protein			Glucose			Ketone body			Occult blood									
		5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	--	±	+	2+	3+	4+	CHI	--	±	+	2+	3+	4+	CHI					
Control	36	0	1	5	2	4	19	5		0	2	13	19	2	0	36	0	0	0	0	0	0	0	28	0	0	2	6
800 ppm	29	0	0	3	2	7	16	1		0	3	9	15	2	0	29	0	0	0	0	0	0	0	22	1	1	2	3
2000 ppm	23	0	0	2	5	7	7	2		0	0	10	10	3	0	23	0	0	0	0	0	0	0	18	0	1	1	3
5000 ppm	23	0	2	2	3	5	10	1		0	0	6	13	3	1	23	0	0	0	0	0	0	0	14	1	4	1	3

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of CHI SQUARE

(HCL101)

RAIS 4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[Crj:BDFl]
 MEASURE TIME : 1
 SEX : FEMALE
 REPORT TYPE : A1
 URINALYSIS
 PAGE : 4

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+	CHI
Control	36	36 0 0 0 0	
800 ppm	29	29 0 0 0 0	
2000 ppm	23	23 0 0 0 0	
5000 ppm	23	23 0 0 0 0	

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$
 (HCL101)
 Test of CHI SQUARE
 BATS 4

TABLE K 1

ORGAN WEIGHT, ABSOLUTE: MALE

STUDY NO. : 0642
 ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 ANIMAL : MOUSE B6D2F1/CrJ[CrJ:DOF1]
 SURVIVAL ANIMALS (105W)
 REPORT TYPE : AI
 SEX : MALE
 UNIT : g

PAGE : 1

Group Name	No. of Animals	Body Weight	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	41	47.7 ± 5.7	0.010 ± 0.002	0.218 ± 0.038	0.224 ± 0.023	0.213 ± 0.088	0.646 ± 0.064
800 ppm	30	45.9 ± 7.8	0.011 ± 0.002	0.220 ± 0.040	0.219 ± 0.027	0.222 ± 0.081	0.637 ± 0.075
2000 ppm	37	45.5 ± 7.9	0.010 ± 0.002	0.234 ± 0.040	0.221 ± 0.017	0.206 ± 0.062	0.970 ± 1.600
5000 ppm	33	46.7 ± 7.2	0.010 ± 0.002	0.210 ± 0.048	0.225 ± 0.020	0.194 ± 0.016	0.633 ± 0.051

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(ICL040)

BAIS 4

STUDY NO. : 0642
 ANIMAL : MOUSE D602F1/CrJ[Crj:BDP1]
 REPORT TYPE : AI
 SEX : MALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (105W)

PAGE : 2

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	41	0.103± 0.105	1.717± 0.650	0.451± 0.020
800 ppm	30	0.099± 0.130	1.714± 0.556	0.451± 0.016
2000 ppm	37	0.105± 0.051	1.733± 0.389	0.460± 0.015
5000 ppm	33	0.082± 0.038	1.665± 0.308	0.458± 0.013

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(ICL040)

BAS 4

TABLE K 2

ORGAN WEIGHT, ABSOLUTE: FEMALE

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105W)

STUDY NO. : 0642
ANIMAL : MOUSE D6D2F1/CrJ[Crj:DDF1]
REPORT TYPE : AI
SEX : FEMALE
UNIT: g

PAGE : 3

Group Name	No. of Animals	Body Weight	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	35	32.8± 5.1	0.014± 0.002	0.299± 1.263	0.177± 0.025	0.231± 0.199	0.482± 0.185
800 ppm	28	33.0± 4.0	0.015± 0.004	0.103± 0.167	0.166± 0.017	0.189± 0.024	0.548± 0.634
2000 ppm	23	32.7± 3.6	0.015± 0.002	0.076± 0.094	0.173± 0.027	0.189± 0.020	0.525± 0.423
5000 ppm	24	33.2± 7.2	0.014± 0.004	0.053± 0.026	0.180± 0.024	0.209± 0.104	0.458± 0.046

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(ICL040)

BALS 4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[Crj:DDF1]
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT : g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (105W)

PAGE : 4

Group Name	No. of Animals	SPLGDN	LIVER	BRAIN
Control	35	0.202±	1.727±	0.476±
800 ppm	28	0.272±	1.441±	0.479±
2000 ppm	23	0.245±	1.478±	0.477±
5000 ppm	24	0.171±	1.463±	0.478±

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

(HCL040)

BAIS 4

TABLE L 1

ORGAN WEIGHT, RELATIVE: MALE

STUDY NO. : 0642
 ORGAN WEIGHT:RELATIVE (SUMMARY)
 ANIMAL : MOUSE B6D2F1/CrJj[CxJ:BDF1]
 SURVIVAL ANIMALS (105W)
 REPORT TYPE : A1
 SEX : MALE
 UNIT: %

PAGE : 1

Group Name	No. of Animals	Body Weight (g)	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	41	47.7± 5.7	0.021± 0.006	0.464± 0.099	0.476± 0.080	0.455± 0.209	1.375± 0.233
800 ppm	30	45.9± 7.8	0.024± 0.007	0.487± 0.083	0.485± 0.067	0.522± 0.367	1.417± 0.221
2000 ppm	37	45.5± 7.9	0.023± 0.008	0.530± 0.123*	0.503± 0.109	0.470± 0.174	2.212± 3.493
5000 ppm	33	46.7± 7.2	0.023± 0.007	0.454± 0.106	0.495± 0.103	0.427± 0.084	1.384± 0.223

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(ICL042)

BAIS 4

STUDY NO. : 0542
 ANIMAL : MOUSE B6D2F1/CrJ[Crj:BDP1]
 REPORT TYPE : AI
 SEX : MALE
 UNIT : %

ORGAN WEIGHT:RELATIVE (SUMMARY)
 SURVIVAL ANIMALS (105W)

PAGE : 2

Group Name	No. of Animals	SPLEEN	LIVER	BRAIN
Control	41	0.222 ± 0.254	3.706 ± 1.969	0.961 ± 0.134
800 ppm	30	0.227 ± 0.310	3.815 ± 1.340	1.019 ± 0.238
2000 ppm	37	0.250 ± 0.156	3.969 ± 1.341	1.051 ± 0.236
5000 ppm	33	0.186 ± 0.111	3.674 ± 1.061	1.008 ± 0.197

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(ICL042)

BAIS 4

TABLE L 2

ORGAN WEIGHT, RELATIVE: FEMALE

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105W)

STUDY NO. : 0642
ANIMAL : MOUSE B6D2F1/CrJ[CrJ:BDNF]
REPORT TYPE : AI
SEX : FEMALE
UNIT: %

PAGE : 3

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	35	32.8 ± 5.1	0.044 ± 0.007	0.863 ± 3.615	0.555 ± 0.127	0.768 ± 0.928	1.554 ± 0.908
800 ppm	28	33.0 ± 4.0	0.048 ± 0.013	0.302 ± 0.448	0.507 ± 0.063	0.581 ± 0.099	1.707 ± 2.136
2000 ppm	23	32.7 ± 3.6	0.045 ± 0.008	0.229 ± 0.262	0.538 ± 0.113	0.584 ± 0.082	1.626 ± 1.333
5000 ppm	24	33.2 ± 7.2	0.045 ± 0.014	0.170 ± 0.089	0.561 ± 0.121	0.682 ± 0.510	1.428 ± 0.266

Test of Dunnett

** : P ≤ 0.01

* : P ≤ 0.05

Significant difference ;

(ICL042)

BAIS 4

STUDY NO. : 0642
 ANIMAL : MOUSE D602F1/CrJ1J[Crl:BDFl]
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT : %

ORGAN WEIGHT:RELATIVE (SUMMARY)
 SURVIVAL ANIMALS (105W)

PAGE : 4

Group Name	No. of Animals	SPLEEN	LIVER	BRAIN
Control	35	0.627 ± 0.588	5.269 ± 3.148	1.489 ± 0.260
800 ppm	28	0.802 ± 1.568	4.389 ± 1.166	1.469 ± 0.173
2000 ppm	23	0.751 ± 1.186	4.540 ± 1.199	1.473 ± 0.175
5000 ppm	24	0.548 ± 0.669	4.582 ± 1.147	1.503 ± 0.315

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(ICL042)

BALS 4

TABLE M 1

HISTOPATHOLOGICAL FINDINGS:

NON-NEOPLASTIC LESIONS:

MALE: ALL ANIMALS

Organ	Findings	Group Name				Control				800 µm				2000 µm				5000 µm			
		No. of Animals on Study				50				50				50				50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appendage}																					
skin/app																					
	ulcer	0	0	0	0	<50>				<50>				0	3	0	0	0	0	0	0
		(0)	(0)	(0)	(0)					(0)	(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)
	erosion	0	0	0	0					0	1	0	0	0	1	0	0	0	1	0	0
		(0)	(0)	(0)	(0)					(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)
	squamous cell hyperplasia	0	1	0	0					0	0	0	0	0	0	0	0	0	1	0	0
		(0)	(2)	(0)	(0)					(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
	scab	1	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0
		(2)	(0)	(0)	(0)					(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Respiratory system}																					
nasal cavity																					
	eosinophilic change:olfactory epithelium	11	1	0	0	<50>				<50>				5	0	0	0	8	0	0	0
		(22)	(2)	(0)	(0)					(14)	(2)	(0)	(0)	(10)	(0)	(0)	(0)	(16)	(0)	(0)	(0)
	eosinophilic change:respiratory epithelium	10	0	0	0					8	0	1	0	11	0	0	0	8	0	1	0
		(20)	(0)	(0)	(0)					(16)	(0)	(2)	(0)	(22)	(0)	(0)	(0)	(16)	(0)	(2)	(0)
	respiratory metaplasia:olfactory epithelium	5	0	0	0					4	1	0	0	6	0	0	0	6	0	0	0
		(10)	(0)	(0)	(0)					(8)	(2)	(0)	(0)	(12)	(0)	(0)	(0)	(12)	(0)	(0)	(0)
Grade																					
< a >																					
b																					
(c)																					
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																					

Organ	Findings	Group Name											
		No. of Animals on Study				Control				800 µm			
		1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}													
nasal cavit	respiratory metaplasia:gland	4	0	0	0	<50>	<50>	<50>	<50>	5	3	0	0
		(8)	(0)	(0)	(0)	(8)	(2)	(0)	(0)	(10)	(6)	(0)	(0)
trachea	eosinophilic change	0	0	0	0	<50>	<50>	<50>	<50>	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)
lung	congestion	0	0	0	0	<50>	<50>	<50>	<50>	1	0	0	0
		(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(2)	(0)	(0)	(0)
	inflammation	0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)
	inflammatory infiltration	0	1	0	0	0	0	0	0	0	0	0	0
		(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	bronchiolar-alveolar cell hyperplasia	0	0	0	0	0	0	0	0	1	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	accumulation:macrophage	0	0	0	0	0	0	0	0	0	1	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)

Grade	1 : Slight	2 : Moderate	3 : Marked	4 : Severe
< a >	a : Number of animals examined at the site			
b	b : Number of animals with lesion			
(c)	c : b / a * 100			
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square				
(UPT150)				
BATS4				

STUDY NO. : 0642
ANIMAL : MOUSE B6D2F1/Cr-lj[Crj:BDFl]
REPORT TYPE : A1
SEX : MALE

HISTOPATHOLOGICAL FINDINGS -NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study															
		Control				800 ppm				2000 ppm				5000 ppm			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																	
bone marrow	increased hematopoiesis	2	0	0	0	<50>	<50>	<50>	<50>	<50>	<50>	<50>	<50>	<50>	<50>	<50>	<50>
		(4)	(0)	(0)	(0)	(8)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(6)	(0)	(0)	(0)
	granulopoiesis: increased	3	0	0	0	1	0	0	0	3	0	0	0	0	0	0	0
		(6)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
lymph node	lymphadenitis	0	0	0	0	<50>	<50>	<50>	<50>	0	1	0	0	0	4	0	0
		(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(8)	(0)	(0)	(0)	(0)	(0)	(0)
spleen	deposit of melanin	2	0	0	0	<50>	<50>	<50>	<50>	0	0	0	0	1	0	0	0
		(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	extramedullary hematopoiesis	5	2	0	0	6	2	1	0	5	5	0	0	9	1	0	0
		(10)	(4)	(0)	(0)	(12)	(4)	(2)	(0)	(10)	(10)	(0)	(0)	(18)	(2)	(0)	(0)
	follicular hyperplasia	3	0	0	0	2	1	0	0	4	0	0	0	0	0	0	0
		(6)	(0)	(0)	(0)	(4)	(2)	(0)	(0)	(8)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Circulatory system}																	
heart	thrombus	0	0	0	0	<50>	<50>	<50>	<50>	0	1	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

(HPT150)

BA154

Group Name	No. of Animals on Study	Control				800 ppm				2000 ppm				5000 ppm			
		Grade				Grade				Grade				Grade			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ	Findings	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Circulatory system)																	
heart	mineralization	0 (0)	0 (0)	0 (0)	0 (0)	<50>	3 (6)	0 (0)	0 (0)	<50>	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	1 (2)	0 (0)
	arteritis	0 (0)	0 (0)	0 (0)	0 (0)	<50>	0 (0)	1 (2)	0 (0)	<50>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
(Digestive system)																	
tongue	arteritis	0 (0)	0 (0)	0 (0)	0 (0)	<50>	1 (2)	0 (0)	0 (0)	<50>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
stomach	erosion:forestomach	0 (0)	0 (0)	0 (0)	0 (0)	<50>	0 (0)	0 (0)	0 (0)	<50>	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)
	hyperplasia:forestomach	0 (0)	0 (0)	0 (0)	0 (0)	<50>	0 (0)	1 (2)	0 (0)	<50>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	erosion:glandular stomach	1 (2)	0 (0)	0 (0)	0 (0)	<50>	2 (4)	0 (0)	0 (0)	<50>	3 (6)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																	
Grade	1 : Slight	2 : Moderate				3 : Marked				4 : Severe							
a :	Number of animals examined at the site																
b :	Number of animals with lesion																
(c)	c : b / a * 100																
(HPT150)																	
EATS4																	

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

STUDY NO. : 0642
ANIMAL : MOUSE B6D2F1/Cr-lj[Crj:BDF1]
REPORT TYPE : A1
SEX : MALE

PAGE : 5

Organ	Findings	Group Name No. of Animals on Study											
		Control				800 µm				2000 µm			
		1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}													
stomach	hyperplasia:glandular stomach	33 (66)	0 (0)	0 (0)	0 (0)	27 (54)	0 (0)	0 (0)	0 (0)	32 (64)	0 (0)	0 (0)	0 (0)
small intes	invagination	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
liver	angiectasis	2 (4)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)
	hemorrhage	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)
	necrosis:focal	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	fatty change	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)
	inflammatory cell nest	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

(IPT150)

BA154

STUDY NO. : 0642
ANIMAL : MOUSE B6DZF1/Cr-LJ[Crj-BDF1]
REPORT TYPE : AI
SEX : MALE

HISTOPATHOLOGICAL FINDINGS -NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 6

Organ	Findings	Group Name No. of Animals on Study											
		Control				800 ppm				2000 ppm			
		1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}													
liver	clear cell focus	<50>				<50>				<50>			
		0	0	0	0	0	0	0	0	2	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)
	basophilic cell focus	<50>				<50>				<50>			
		1	2	0	0	1	2	0	0	0	2	0	0
		(2)	(4)	(0)	(0)	(2)	(4)	(0)	(0)	(0)	(4)	(0)	(0)
	biliary cyst	<50>				<50>				<50>			
		1	0	0	0	0	0	0	0	0	0	0	0
		(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	intestinal metaplasia:bile duct	<50>				<50>				<50>			
		0	0	0	0	1	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
pancreas	fibrosis:focal	<50>				<50>				<50>			
		0	1	0	0	0	0	0	0	0	0	0	0
		(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	islet cell hyperplasia	<50>				<50>				<50>			
		0	0	0	0	1	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Urinary system}													
kidney	cyst	<50>				<50>				<50>			
		1	0	0	0	0	0	0	0	0	0	0	0
		(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P \leq 0.05 ** : P \leq 0.01 Test of Chi Square

(IPT150)

BA154

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[Crj-BDF1]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 7

Organ	Findings	Group Name No. of Animals on Study										Control										800 ppm										2000 ppm										5000 ppm																													
		Grade					50					50					50					50					50					50					50					50					50																								
		1	2	3	4	(%)	1	2	3	4	(%)	1	2	3	4	(%)	1	2	3	4	(%)	1	2	3	4	(%)	1	2	3	4	(%)	1	2	3	4	(%)	1	2	3	4	(%)																														
(Urinary system)																																																																							
kidney	hyaline droplet	<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>														
		2	0	0	0	(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)	2	0	0	0	(4)	0	0	0	0	(0)																									
		1	0	0	0	(2)	0	0	0	0	(0)	0	1	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	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	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	0	0	0	(2)	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)	0	0	0	0	(0)	0	0	0	0	(0)																									
	inflammatory infiltration	<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>														
		0	0	0	0	(0)	0	0	0	0	(0)	0	0	0	0	(0)	0	0	0	0	(0)	0	1	0	0	0	(0)	0	0	0	0	(0)	0	0	0	0	(0)	0	0	0	0	(0)	0	0	0	0	(0)																								
	osseous metaplasia	<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>									
		1	0	0	0	(2)	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)	0	0	0	0	(0)	0	0	0	0	(0)																									
	inflammatory polyp	<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>									
		0	0	0	0	(0)	0	0	0	0	(0)	0	1	0	0	(0)	0	0	0	0	(0)	0	1	0	0	0	(0)	0	0	0	0	(0)	0	0	0	0	(0)	1	1	0	0	(2)	0	0	0	0	(0)																								
	hydronephrosis	<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>									
		0	1	0	0	(0)	0	2	0	0	(0)	0	2	0	0	(0)	0	0	0	0	(0)	0	5	2	0	0	(0)	0	0	0	0	(0)	0	0	0	0	(0)	0	1	2	0	(0)	0	0	0	0	(0)																								
	mineralization:pelvis	<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>									
		0	0	0	0	(0)	0	0	0	0	(0)	0	0	0	0	(0)	0	0	0	0	(0)	1	0	0	0	0	(0)	0	0	0	0	(0)	0	0	0	0	(0)	1	0	0	0	(2)	0	0	0	0	(0)																								
	regeneration:proximal tubule	<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>					<50>				
		4	1	0	0	(8)	0	2	0	0	(0)	0	2	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	0	0	(2)	0	0	0	0	(0)																									

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

(HPT150)

BA154

STUDY NO. : 0642
ANIMAL : MOUSE B6D2F1/CrJ[Crj-BDF1]
REPORT TYPE : A1
SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) ALL ANIMALS (0-105W)

PAGE : 8

Organ	Findings	Group Name No. of Animals on Study										Control										800 µm										2000 µm										5000 µm									
		50					50					50					50					50					50					50					50					50					50				
		1	2	3	4	(%)	1	2	3	4	(%)	1	2	3	4	(%)	1	2	3	4	(%)	1	2	3	4	(%)	1	2	3	4	(%)	1	2	3	4	(%)	1	2	3	4	(%)										
{Urinary system}																																																			
urin bladd	dilatation	0	2	0	0	(0) (4) (0) (0)	<49>	0	5	0	0	(0) (10) (0) (0)	<50>	0	1	0	0	(0) (2) (0) (0)	<50>	0	4	0	0	(0) (8) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	1	0	0	0	(0) (0) (0) (0)	0	0	0	0	(0) (0) (0) (0)											
		0	0	0	0	(0) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	0	1	0	0	(0) (2) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	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) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	0	1	0	0	(0) (2) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	0	0	0	0	(0) (0) (0) (0)	0	0	0	0	(0) (0) (0) (0)											
	inflammation	0	0	0	0	(0) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	0	1	0	0	(0) (2) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	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	0	0	0	(2) (0) (0) (0)	<50>	2	0	0	0	(4) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	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	0	0	(0) (2) (0) (0)	<50>	0	1	0	0	(0) (2) (0) (0)	<50>	1	0	0	0	(2) (0) (0) (0)	<50>	1	0	0	0	(2) (0) (0) (0)	<50>	1	0	0	0	(2) (0) (0) (0)	1	0	0	0	(2) (0) (0) (0)	1	0	0	0	(2) (0) (0) (0)											
{Endocrine system}																																																			
pituitary	hyperplasia	1	0	0	0	(2) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	1	0	0	0	(2) (0) (0) (0)	1	0	0	0	(2) (0) (0) (0)	1	0	0	0	(2) (0) (0) (0)											
		1	0	0	0	(2) (0) (0) (0)	<50>	1	0	0	0	(2) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	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	0	0	0	(2) (0) (0) (0)	<50>	1	0	0	0	(2) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	0	0	0	0	(0) (0) (0) (0)	0	0	0	0	(0) (0) (0) (0)											
{Reproductive system}																																																			
testis	mineralization	1	0	0	0	(2) (0) (0) (0)	<50>	3	0	0	0	(6) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	1	0	0	0	(2) (0) (0) (0)	1	0	0	0	(2) (0) (0) (0)	1	0	0	0	(2) (0) (0) (0)											
		1	0	0	0	(2) (0) (0) (0)	<50>	3	0	0	0	(6) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	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	0	0	0	(2) (0) (0) (0)	<50>	3	0	0	0	(6) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	<50>	0	0	0	0	(0) (0) (0) (0)	0	0	0	0	(0) (0) (0) (0)	0	0	0	0	(0) (0) (0) (0)											

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

(HPT150)

BATS4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[Crl-BDF1]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) ALL ANIMALS (0-105W)

PAGE : 9

Organ	Findings	Group Name No. of Animals on Study										Control										800 µm										2000 µm										5000 µm																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																												
		Grade					50					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1					2					1				

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 a : Number of animals examined at the site
 b : Number of animals with lesion
 c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

(HPT150)

BA154

Organ	Findings	Control				800 ppm				2000 ppm				5000 ppm			
		1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
(Special sense organs/appendage)																	
Harder gl	hyperplasia	0 (0)	<50> 1 (2)	0 (0)	0 (0)	<50> 0 (0)	0 (0)	0 (0)	0 (0)	<50> 0 (0)	0 (0)	0 (0)	0 (0)	<50> 0 (0)	0 (0)	0 (0)	0 (0)
(Musculoskeletal system)																	
muscle	mineralization	0 (0)	<50> 0 (0)	0 (0)	0 (0)	<50> 0 (0)	0 (0)	0 (0)	0 (0)	<50> 0 (0)	0 (0)	0 (0)	0 (0)	<50> 1 (2)	0 (0)	0 (0)	0 (0)
bone	osteosclerosis	0 (0)	<50> 0 (0)	0 (0)	0 (0)	<50> 1 (2)	0 (0)	0 (0)	0 (0)	<50> 0 (0)	0 (0)	0 (0)	0 (0)	<50> 0 (0)	0 (0)	0 (0)	0 (0)
(Body cavities)																	
peritoneum	inflammation	0 (0)	<50> 0 (0)	0 (0)	0 (0)	<50> 0 (0)	0 (0)	0 (0)	0 (0)	<50> 0 (0)	2 (4)	0 (0)	0 (0)	<50> 0 (0)	0 (0)	0 (0)	0 (0)
Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe a : Number of animals examined at the site b : Number of animals with lesion c : b / a * 100 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																	

(IPT150)

BAISA

TABLE M 4

HISTOPATHOLOGICAL FINDINGS:

NON-NEOPLASTIC LESIONS:

FEMALE: ALL ANIMALS

STUDY NO. : 0642
ANIMAL : MOUSE B6D2F1/CrJ[CrJ:BDFl]
REPORT TYPE : A1
SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 11

Organ	Findings	Group Name				Control				800 µm				2000 µm				5000 µm			
		No. of Animals on Study				50				50				50				50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appendage}																					
skin/app	squamous cell hyperplasia	0	0	0	0	<50>				0	1	0	0	0	0	0	0	<50>			
		(0)	(0)	(0)	(0)					(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
	scab	0	0	0	0					0	0	0	0	0	0	0	0	0	1	0	0
		(0)	(0)	(0)	(0)					(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
{Respiratory system}																					
nasal cavit	eosinophilic change:olfactory epithelium	4	0	0	0	<50>				3	0	0	0	2	2	0	0	<50>			
		(8)	(0)	(0)	(0)					(6)	(0)	(0)	(0)	(4)	(4)	(0)	(0)	(8)	(4)	(0)	(0)
	eosinophilic change:respiratory epithelium	20	2	0	0					18	2	0	0	14	5	1	0	21	1	0	0
		(40)	(4)	(0)	(0)					(36)	(4)	(0)	(0)	(28)	(10)	(2)	(0)	(42)	(2)	(0)	(0)
	inflammation:foreign body	0	0	0	0					0	0	0	0	0	1	0	0	0	0	0	0
		(0)	(0)	(0)	(0)					(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	respiratory metaplasia:olfactory epithelium	6	0	0	0					8	0	0	0	6	0	0	0	6	0	0	0
		(12)	(0)	(0)	(0)					(16)	(0)	(0)	(0)	(12)	(0)	(0)	(0)	(12)	(0)	(0)	(0)
	respiratory metaplasia:gland	4	0	0	0					1	0	0	0	3	0	0	0	4	0	0	0
		(8)	(0)	(0)	(0)					(2)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(8)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

(UPT150)

BATS4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/Cr-L1[Cr-J:BDFl]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS -NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105#)

PAGE : 12

Organ	Findings	Group Name No. of Animals on Study															
		Control				800 μm				2000 μm				5000 μm			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																	
lung	congestion	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)
	inflammatory infiltration	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
{Hematopoietic system}																	
bone marrow	increased hematopoiesis	1	0	0	0	3	0	0	0	5	0	0	0	4	0	0	0
		(2)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(8)	(0)	(0)
	granulopoiesis:increased	1	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
		(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
lymph node	lymphadenitis	0	0	0	0	0	2	0	0	0	1	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)
	deposit of melanin	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
spleen		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)	(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)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

(IPT150)

BAIS4

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 13

Group Name		Control								800 ppm				2000 ppm				5000 ppm			
Organ	Findings	No. of Animals on Study				Grade															
		1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)				
(Hematopoietic system)																					
spleen		<50>				<50>				<50>				<50>							
	extramedullary hematopoiesis	4 (8)	3 (6)	0 (0)	0 (0)	2 (4)	2 (4)	0 (0)	0 (0)	4 (8)	4 (8)	0 (0)	0 (0)	7 (14)	2 (4)	0 (0)	0 (0)				
	follicular hyperplasia	3 (6)	0 (0)	0 (0)	0 (0)	3 (6)	1 (2)	0 (0)	0 (0)	1 (2)	1 (2)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)				
(Circulatory system)																					
heart		<50>				<50>				<50>				<50>							
	necrosis:focal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
	mineralization	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)				
		<50>				<50>				<50>				<50>							
	arteritis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
		<50>				<50>				<50>				<50>							
(Digestive system)																					
tongue		<50>				<50>				<50>				<50>							
	arteritis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
		<50>				<50>				<50>				<50>							

Grade
< a > 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
a : Number of animals examined at the site
b : Number of animals with lesion
c : b / a * 100
(c)
(Significant difference; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

(IIPT150)

BAIS4

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

PAGE : 14

Group Name No. of Animals on Study Grade	Findings	Control				800 μm				2000 μm				5000 μm			
		50				50				50				50			
		1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
(Digestive system)																	
stomach	hyperplasia:forestomach	0 (0)	0 (0)	0 (0)	0 (0)	<50>	1 (2)	0 (0)	0 (0)	<50>	1 (2)	0 (0)	0 (0)	<50>	0 (0)	0 (0)	0 (0)
	erosion:glandular stomach	1 (2)	0 (0)	0 (0)	0 (0)	<50>	1 (2)	0 (0)	0 (0)	<50>	0 (0)	0 (0)	0 (0)	<50>	1 (2)	0 (0)	0 (0)
	hyperplasia:glandular stomach	11 (22)	0 (0)	0 (0)	0 (0)	<50>	7 (14)	0 (0)	0 (0)	<50>	7 (14)	0 (0)	0 (0)	<50>	9 (18)	0 (0)	0 (0)
	angiectasis	2 (4)	1 (2)	0 (0)	0 (0)	<50>	1 (2)	1 (2)	0 (0)	<50>	1 (2)	0 (0)	0 (0)	<50>	1 (2)	1 (2)	0 (0)
liver	necrosis:focal	0 (0)	0 (0)	0 (0)	0 (0)	<50>	0 (0)	0 (0)	0 (0)	<50>	0 (0)	1 (2)	0 (0)	<50>	0 (0)	0 (0)	0 (0)
	inflammatory infiltration	0 (0)	0 (0)	0 (0)	0 (0)	<50>	1 (2)	0 (0)	0 (0)	<50>	0 (0)	0 (0)	0 (0)	<50>	1 (2)	0 (0)	0 (0)
	lymphocytic infiltration	1 (2)	0 (0)	0 (0)	0 (0)	<50>	0 (0)	0 (0)	0 (0)	<50>	0 (0)	0 (0)	0 (0)	<50>	1 (2)	0 (0)	0 (0)
	inflammatory cell nest	2 (4)	0 (0)	0 (0)	0 (0)	<50>	1 (2)	0 (0)	0 (0)	<50>	2 (4)	0 (0)	0 (0)	<50>	3 (6)	0 (0)	0 (0)
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																	

(IIPT150)

BATS4

STUDY NO. : 0642
ANIMAL : MOUSE B6DZF1/CrJ1j[CrJ:BDFl]
REPORT TYPE : A1
SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) ALL ANIMALS (0-105W)

PAGE : 15

Organ	Findings	Group Name No. of Animals on Study				Control				800 µm				2000 µm				5000 µm			
		Grade				50				50				50				50			
		1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
{Digestive system}																					
liver	clear cell focus	0 (0)	0 (0)	0 (0)	0 (0)	<50>				0 (0)	4 (8)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)
	basophilic cell focus	0 (0)	0 (0)	0 (0)	0 (0)					0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)
	biliary cyst	0 (0)	0 (0)	0 (0)	0 (0)					1 (2)	2 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)
{Urinary system}																					
kidney	hyaline droplet	3 (6)	0 (0)	0 (0)	0 (0)	<50>				3 (6)	0 (0)	0 (0)	0 (0)	5 (10)	0 (0)	0 (0)	0 (0)	6 (12)	0 (0)	0 (0)	0 (0)
	lymphocytic infiltration	4 (8)	0 (0)	0 (0)	0 (0)					3 (6)	0 (0)	0 (0)	0 (0)	4 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	osseous metaplasia	0 (0)	0 (0)	0 (0)	0 (0)					1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	inflammatory polyp	1 (2)	0 (0)	0 (0)	0 (0)					0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
Grade	1 : Slight	2 : Moderate				3 : Marked				4 : Severe											
< a >	a : Number of animals examined at the site																				
b	b : Number of animals with lesion																				
(c)	c : b / a * 100																				
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																					

(HPT150)

BAIS4

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[CrJ-BDF1]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 16

Organ	Findings	Group Name No. of Animals on Study															
		Control				800 μm				2000 μm				5000 μm			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																	
kidney	hydronephrosis	0	1	3	0	<50>	1	1	1	0	0	0	2	0	1	2	3
		(0)	(2)	(6)	(0)	(2)	(2)	(2)	(0)	(0)	(0)	(4)	(0)	(2)	(4)	(6)	(0)
	regeneration:proximal tubule	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	desquamation:pelvis	0	0	0	0	2	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)
urin bladd	simple hyperplasia:transitional epithelium	0	0	0	0	<50>	0	0	0	0	0	0	0	0	1	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	xanthogranuloma	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Endocrine system}																	
pituitary	angiectasis	0	0	0	0	<50>	2	0	0	0	3	1	0	0	1	0	0
		(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(6)	(2)	(0)	(0)	(2)	(0)	(0)	(0)
{Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																	

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

(HPT150)

BA154

Organ	Findings	Group Name															
		No. of Animals on Study				Control				800 μm							
		Grade				50				50							
		1	2	3	4	1	2	3	4	1	2	3	4				
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
		50				50				50				50			
		1				1				1				1			
		2				2				2				2			
		3				3				3				3			
		4				4				4				4			
		50				50				50				50			
		1				1				1				1			
		2				2				2				2			
		3				3				3				3			
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		1				1				1				1			
		2				2				2</							

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[Crj-BDF1]
 REPORT TYPE : AI
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY) ALL ANIMALS (0-105W)

PAGE : 18

Organ	Findings	Group Name											
		No. of Animals on Study				Control				800 ppm			
		Grade				50				500 ppm			
		1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
5000 ppm													
50													
1													
(%)													
2													
(%)													
3													
(%)													
4													
(%)													
(Reproductive system)													
ovary	thrombus	<50>				<50>				<50>			
		0	0	0	0	0	0	0	0	0	1	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)
	cyst	1	2	0	0	2	4	0	0	1	1	0	0
		(2)	(4)	(0)	(0)	(4)	(8)	(0)	(0)	(2)	(2)	(0)	(0)
		(2)	(4)	(0)	(0)	(4)	(8)	(0)	(0)	(2)	(2)	(0)	(0)
		(2)	(4)	(0)	(0)	(4)	(8)	(0)	(0)	(2)	(2)	(0)	(0)
	xanthogranuloma	0	0	0	0	0	0	0	0	0	1	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)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
uterus	<50>				<50>				<50>				
	2	0	0	0	0	0	0	0	0	0	0	0	
	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
cystic endometrial hyperplasia	16	1	0	0	20	1	0	0	16	2	0	0	
	(32)	(2)	(0)	(0)	(40)	(2)	(0)	(0)	(32)	(4)	(0)	(0)	
	(32)	(2)	(0)	(0)	(40)	(2)	(0)	(0)	(32)	(4)	(0)	(0)	
	(32)	(2)	(0)	(0)	(40)	(2)	(0)	(0)	(32)	(4)	(0)	(0)	
(Nervous system)													
brain	hemorrhage	<50>				<50>				<50>			
		0	0	0	0	0	0	0	0	1	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square													
(HPT150)													
BA154													

Organ	Findings	Group Name No. of Animals on Study															
		Control				800 μm				2000 μm				5000 μm			
		1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
(Nervous system)																	
brain	mineralization	24 (48)	0 (0)	0 (0)	0 (0)	16 (32)	0 (0)	0 (0)	0 (0)	18 (36)	0 (0)	0 (0)	0 (0)	19 (38)	0 (0)	0 (0)	0 (0)
		<50>															
(Special sense organs/appendage)																	
eye	keratitis	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
		<50>															
Harder gl	hyperplasia	1 (2)	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)
		<50>															
(Musculoskeletal system)																	
muscle	mineralization	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)
		<50>															
bone	osteosclerosis	1 (2)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
		<50>															

Grade	1 : Slight	2 : Moderate	3 : Marked	4 : Severe
< a >	a : Number of animals examined at the site			
b	b : Number of animals with lesion			
(c)	c : b / a * 100			
Significant difference :	* : P ≤ 0.05		** : P ≤ 0.01	
Test of Chi Square				
(IPT150)				
BAISA				

Organ	Findings	Group Name																			
		No. of Animals on Study				Control				800 μm				2000 μm				5000 μm			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4				
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)				
(Body cavities)																					
peritoneum	inflammation	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
		(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)				
		<50>				<50>				<50>				<50>							
Grade		1 : Slight				2 : Moderate				3 : Marked				4 : Severe							
< a >		a : Number of animals examined at the site				b : Number of animals with lesion				c : b / a * 100											
(c)		Significant difference ;				* : P ≤ 0.05				** : P ≤ 0.01				Test of Chi Square							
(HPT150)																					
		BATS4																			

TABLE P 1

NEOPLASTIC LESIONS-INCIDENCE AND
STATISTICAL ANALYSIS: MALE

Group Name	Control	800 ppm	2000 ppm	5000 ppm
SITE : lung				
TUMOR : bronchiolar-alveolar adenoma				
Tumor rate				
Overall rates(a)	2/50(4.0)	1/50(2.0)	4/50(8.0)	6/50(12.0)
Adjusted rates(b)	4.88	3.23	9.76	15.38
Terminal rates(c)	2/41(4.9)	1/31(3.2)	3/37(8.1)	3/33(9.1)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0132*			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0422*			
Fisher Exact test(e)		P = 0.5000	P = 0.3389	P = 0.1343
SITE : lung				
TUMOR : bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	9/50(18.0)	7/50(14.0)	9/50(18.0)	6/50(12.0)
Adjusted rates(b)	19.51	22.58	18.92	15.15
Terminal rates(c)	8/41(19.5)	7/31(22.6)	7/37(18.9)	5/33(15.2)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.3073			
Prevalence method(d)	P = 0.7307			
Combined analysis(d)	P = 0.6492			
Cochran-Armitage test(e)	P = 0.4810			
Fisher Exact test(e)		P = 0.3929	P = 0.6024	P = 0.2883
SITE : lung				
TUMOR : bronchiolar-alveolar adenoma, bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	11/50(22.0)	8/50(16.0)	12/50(24.0)	11/50(22.0)
Adjusted rates(b)	24.39	25.81	25.00	25.64
Terminal rates(c)	10/41(24.4)	8/31(25.8)	9/37(24.3)	7/33(21.2)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.3073			
Prevalence method(d)	P = 0.2560			
Combined analysis(d)	P = 0.2196			
Cochran-Armitage test(e)	P = 0.7490			
Fisher Exact test(e)		P = 0.3055	P = 0.5000	P = 0.5952

Group Name	Control	800 ppm	2000 ppm	5000 ppm
SITE : lymph node				
TUMOR : malignant lymphoma				
Tumor rate				
Overall rates(a)	5/50(10.0)	5/50(10.0)	5/50(10.0)	5/50(10.0)
Adjusted rates(b)	9.76	6.45	5.41	6.06
Terminal rates(c)	4/41(9.8)	2/31(6.5)	2/37(5.4)	2/33(6.1)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1929			
Prevalence method(d)	P = 0.6837			
Combined analysis(d)	P = 0.3886			
Cochran-Armitage test(e)	P = 1.0000			
Fisher Exact test(e)		P = 0.6297	P = 0.6297	P = 0.6297
SITE : spleen				
TUMOR : hemangioma				
Tumor rate				
Overall rates(a)	1/50(2.0)	3/50(6.0)	1/50(2.0)	0/50(0.0)
Adjusted rates(b)	2.44	6.52	2.70	0.0
Terminal rates(c)	1/41(2.4)	0/31(0.0)	1/37(2.7)	0/33(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.8782			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.2020			
Fisher Exact test(e)		P = 0.3087	P = 0.7525	P = 0.5000
SITE : spleen				
TUMOR : hemangioma, hemangiosarcoma				
Tumor rate				
Overall rates(a)	1/50(2.0)	3/50(6.0)	2/50(4.0)	0/50(0.0)
Adjusted rates(b)	2.44	6.52	5.41	0.0
Terminal rates(c)	1/41(2.4)	0/31(0.0)	2/37(5.4)	0/33(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.8429			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.2474			
Fisher Exact test(e)		P = 0.3087	P = 0.5000	P = 0.5000

(HPT360A)

BALS4

Group Name	Control	800 ppm	2000 ppm	5000 ppm
SITE : liver TUMOR : hemangioma				
Tumor rate				
Overall rates(a)	2/50(4.0)	1/50(2.0)	4/50(8.0)	2/50(4.0)
Adjusted rates(b)	4.88	2.94	5.13	3.03
Terminal rates(c)	2/41(4.9)	0/31(0.0)	1/37(2.7)	1/33(3.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1480			
Prevalence method(d)	P = 0.5600			
Combined analysis(d)	P = 0.3086			
Cochran-Armitage test(e)	P = 0.8224			
Fisher Exact test(e)		P = 0.5000	P = 0.3389	P = 0.6913
SITE : liver TUMOR : hepatocellular adenoma				
Tumor rate				
Overall rates(a)	15/50(30.0)	10/50(20.0)	10/50(20.0)	5/50(10.0)
Adjusted rates(b)	34.15	32.26	27.03	15.15
Terminal rates(c)	14/41(34.1)	10/31(32.3)	10/37(27.0)	5/33(15.2)
Statistical analysis				
Peto test				
Standard method(d)	P = 1.0000 ?			
Prevalence method(d)	P = 0.9757			
Combined analysis(d)	P = 0.9833			
Cochran-Armitage test(e)	P = 0.0200*			
Fisher Exact test(e)		P = 0.1779	P = 0.1779	P = 0.0114*
SITE : liver TUMOR : histiocytic sarcoma				
Tumor rate				
Overall rates(a)	1/50(2.0)	4/50(8.0)	1/50(2.0)	2/50(4.0)
Adjusted rates(b)	0.0	0.0	0.0	0.0
Terminal rates(c)	0/41(0.0)	0/31(0.0)	0/37(0.0)	0/33(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.4427			
Prevalence method(d)	P = 0.4427			
Combined analysis(d)	P = 0.4427			
Cochran-Armitage test(e)	P = 0.9394			
Fisher Exact test(e)		P = 0.1811	P = 0.7525	P = 0.5000

(HPT360A)

BALB4

Group Name	Control	800 ppm	2000 ppm	5000 ppm
SITE : liver				
TUMOR : hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	8/50(16.0)	11/50(22.0)	7/50(14.0)	5/50(10.0)
Adjusted rates(b)	11.90	16.13	16.67	9.09
Terminal rates(c)	4/41(9.8)	5/31(16.1)	5/37(13.5)	3/33(9.1)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.7488			
Prevalence method(d)	P = 0.7171			
Combined analysis(d)	P = 0.8133			
Cochran-Armitage test(e)	P = 0.1932			
Fisher Exact test(e)		P = 0.3055	P = 0.5000	P = 0.2768
SITE : liver				
TUMOR : hemangioma, hemangiosarcoma				
Tumor rate				
Overall rates(a)	2/50(4.0)	2/50(4.0)	5/50(10.0)	2/50(4.0)
Adjusted rates(b)	4.88	2.94	2.70	3.03
Terminal rates(c)	2/41(4.9)	0/31(0.0)	1/37(2.7)	1/33(3.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.2492			
Prevalence method(d)	P = 0.5967			
Combined analysis(d)	P = 0.3787			
Cochran-Armitage test(e)	P = 0.9805			
Fisher Exact test(e)		P = 0.6913	P = 0.2180	P = 0.6913
(HPT360A)				
BA1S4				

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

STUDY No. : 0642
ANIMAL : MOUSE B6D2F1/Cr1j[G-j:BDP1]
SEX : MALE

PAGE : 5

Group Name		Control	800 ppm	2000 ppm	5000 ppm
SITE : liver					
TUMOR : hepatocellular adenoma, hepatocellular carcinoma					
Tumor rate					
Overall rates(a)	21/50(42.0)	20/50(40.0)	16/50(32.0)	10/50(20.0)	
Adjusted rates(b)	40.48	45.16	38.46	24.24	
Terminal rates(c)	16/41(39.0)	14/31(45.2)	14/37(37.8)	8/33(24.2)	
Statistical analysis					
Peto test					
Standard method(d)	P = 0.8299				
Prevalence method(d)	P = 0.9531				
Combined analysis(d)	P = 0.9746				
Cochran-Armitage test(e)	P = 0.0100*				
Fisher Exact test(e)		P = 0.5000	P = 0.2038	P = 0.0149*	

(HPT360A)

BAISI

- (a): Number of tumor-bearing animals/number of animals examined at the site.
 (b): Kaplan-Meier 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 : * : $P \leq 0.05$ ** : $P \leq 0.01$
 N.C.:Statistical value cannot be calculated and was not significant.

TABLE P 2

NEOPLASTIC LESIONS-INCIDENCE AND
STATISTICAL ANALYSIS: FEMALE

Group Name	Control	800 ppm	2000 ppm	5000 ppm
SITE : lung				
TUMOR : bronchiolar-alveolar adenoma				
Tumor rate				
Overall rates(a)	3/50(6.0)	0/50(0.0)	1/50(2.0)	1/50(2.0)
Adjusted rates(b)	8.33	0.0	3.23	4.17
Terminal rates(c)	3/36(8.3)	0/29(0.0)	0/23(0.0)	1/24(4.2)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.6618			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.5120			
Fisher Exact test(e)		P = 0.1212	P = 0.3087	P = 0.3087
SITE : lung				
TUMOR : bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	2/50(4.0)	4/50(8.0)	2/50(4.0)	0/50(0.0)
Adjusted rates(b)	5.26	6.67	6.67	0.0
Terminal rates(c)	1/36(2.8)	1/29(3.4)	0/23(0.0)	0/24(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.5520			
Prevalence method(d)	P = 0.9218			
Combined analysis(d)	P = 0.9410			
Cochran-Armitage test(e)	P = 0.1105			
Fisher Exact test(e)		P = 0.3389	P = 0.6913	P = 0.2475
SITE : lung				
TUMOR : bronchiolar-alveolar adenoma, bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	5/50(10.0)	4/50(8.0)	3/50(6.0)	1/50(2.0)
Adjusted rates(b)	13.16	6.67	9.68	4.17
Terminal rates(c)	4/36(11.1)	1/29(3.4)	0/23(0.0)	1/24(4.2)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.5520			
Prevalence method(d)	P = 0.9253			
Combined analysis(d)	P = 0.9417			
Cochran-Armitage test(e)	P = 0.0922			
Fisher Exact test(e)		P = 0.5000	P = 0.3575	P = 0.1022

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

STUDY No. : 0642
ANIMAL : MOUSE B6D2F1/CrJ[Crj:DDF1]
SEX : FEMALE

PAGE : 7

Group Name	Control	800 ppm	2000 ppm	5000 ppm
<p>SITE : lymph node TUMOR : malignant lymphoma</p>				
Tumor rate				
Overall rates(a)	14/50(28.0)	19/50(38.0)	17/50(34.0)	15/50(30.0)
Adjusted rates(b)	16.67	13.79	17.39	16.67
Terminal rates(c)	6/36(16.7)	4/29(13.8)	4/23(17.4)	4/24(16.7)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.3014			
Prevalence method(d)	P = 0.4462			
Combined analysis(d)	P = 0.3063			
Cochran-Armitage test(e)	P = 0.8394			
Fisher Exact test(e)		P = 0.1976	P = 0.3329	P = 0.5000
<p>SITE : liver TUMOR : hemangioma</p>				
Tumor rate				
Overall rates(a)	3/50(6.0)	0/50(0.0)	2/50(4.0)	1/50(2.0)
Adjusted rates(b)	8.33	0.0	4.35	0.0
Terminal rates(c)	3/36(8.3)	0/29(0.0)	1/23(4.3)	0/24(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1342			
Prevalence method(d)	P = 0.9133			
Combined analysis(d)	P = 0.5974			
Cochran-Armitage test(e)	P = 0.5557			
Fisher Exact test(e)		P = 0.1212	P = 0.5000	P = 0.3087
<p>SITE : liver TUMOR : hepatocellular adenoma</p>				
Tumor rate				
Overall rates(a)	2/50(4.0)	1/50(2.0)	5/50(10.0)	3/50(6.0)
Adjusted rates(b)	5.56	2.38	13.79	12.50
Terminal rates(c)	2/36(5.6)	0/29(0.0)	3/23(13.0)	3/24(12.5)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1924			
Prevalence method(d)	P = 0.1924			
Combined analysis(d)	P = 0.4775			
Cochran-Armitage test(e)	P = 0.4775			
Fisher Exact test(e)		P = 0.5000	P = 0.2180	P = 0.5000

(HPT360A)

BAIS4

Group Name	Control	800 ppm	2000 ppm	5000 ppm
SITE : liver				
TUMOR : hepatocellular adenoma, hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	2/50(4.0)	2/50(4.0)	6/50(12.0)	4/50(8.0)
Adjusted rates(b)	5.56	4.76	17.39	12.50
Terminal rates(c)	2/36(5.6)	0/29(0.0)	4/23(17.4)	3/24(12.5)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1088			
Prevalence method(d)	P = 0.2550			
Combined analysis(d)	P = 0.1415			
Cochran-Armitage test(e)	P = 0.3580			
Fisher Exact test(e)		P = 0.6913	P = 0.1343	P = 0.3389
SITE : pituitary gland				
TUMOR : adenoma				
Tumor rate				
Overall rates(a)	11/50(22.0)	4/50(8.0)	6/50(12.0)	9/50(18.0)
Adjusted rates(b)	23.26	10.34	14.81	29.63
Terminal rates(c)	8/36(22.2)	3/29(10.3)	2/23(8.7)	6/24(25.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.3049			
Prevalence method(d)	P = 0.3244			
Combined analysis(d)	P = 0.2735			
Cochran-Armitage test(e)	P = 0.8593			
Fisher Exact test(e)		P = 0.0453*	P = 0.1431	P = 0.4016
SITE : uterus				
TUMOR : endometrial stromal polyp				
Tumor rate				
Overall rates(a)	1/50(2.0)	1/50(2.0)	1/50(2.0)	3/50(6.0)
Adjusted rates(b)	2.78	2.27	4.35	8.82
Terminal rates(c)	1/36(2.8)	0/29(0.0)	1/23(4.3)	2/24(8.3)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0860			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.1831			
Fisher Exact test(e)		P = 0.7525	P = 0.7525	P = 0.3087

(HPT360A)

BAIS4

NEOPLASTIC LESIONS—INCIDENCE AND STATISTICAL ANALYSIS

STUDY No. : 0642
ANIMAL : MOUSE B6D2F1/CrJ[CrI:DDF1]
SEX : FEMALE

PAGE : 9

Group Name	Control	800 ppm	2000 ppm	5000 ppm
<p>SITE : uterus TUMOR : histiocytic sarcoma</p>				
Tumor rate				
Overall rates(a)	7/50(14.0)	6/50(12.0)	8/50(16.0)	8/50(16.0)
Adjusted rates(b)	13.89	11.76	13.04	6.06
Terminal rates(c)	5/36(13.9)	3/29(10.3)	3/23(13.0)	1/24(4.2)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0419*			
Prevalence method(d)	P = 0.7963			
Combined analysis(d)	P = 0.2240			
Cochran-Armitage test(e)	P = 0.6532			
Fisher Exact test(e)		P = 0.5000	P = 0.5000	P = 0.5000
<p>SITE : Harderian gland TUMOR : adenoma</p>				
Tumor rate				
Overall rates(a)	0/50(0.0)	5/50(10.0)	0/50(0.0)	2/50(4.0)
Adjusted rates(b)	0.0	11.63	0.0	8.33
Terminal rates(c)	0/36(0.0)	3/29(10.3)	0/23(0.0)	2/24(8.3)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.4014			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.9435			
Fisher Exact test(e)		P = 0.0281*	P = N.C.	P = 0.2475

(HPT360A)

BATS4

(a): Number of tumor-bearing animals/number of animals examined at the site.
(b): Kaplan-Meier 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 : * : $P \leq 0.05$ ** : $P \leq 0.01$
N.C.:Statistical value cannot be calculated and was not significant.

TABLE R 1

HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC
LESIONS IN JAPAN BIOASSAY RESEARCH CENTER:
B6D2F1/Crlj MALE MICE

HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC LESIONS IN JAPAN
BIOASSAY RESEARCH CENTER : B6D2F1/Crlj MALE MICE

Organs Tumors	No. of animals examined	No. of animals bearing tumor	Incidence (%)	Min. - Max. (%)
Lung	2144			
Bronchiolar-alveolar adenoma		187	8.7	2 - 18
Bronchiolar-alveolar carcinoma		215	10.0	0 - 24
Bronchiolar-alveolar adenoma + Bronchiolar-alveolar carcinoma		401	18.7	2 - 34

43 carcinogenicity studies examined in Japan Bioassay Research Center were used.

Study No. : 0044, 0060, 0062, 0064, 0066, 0068, 0096, 0105, 0116, 0140, 0159, 0163, 0190,
0206, 0211, 0225, 0243, 0268, 0270, 0279, 0285, 0297, 0319, 0329, 0343, 0348,
0366, 0372, 0402, 0406, 0418, 0422, 0438, 0449, 0458, 0462, 0498, 0515, 0561,
0580, 0611, 0613, 0676

TABLE R 2

HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC
LESIONS IN JAPAN BIOASSAY RESEARCH CENTER:
B6D2F1/Crlj FEMALE MICE

HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC LESIONS IN JAPAN
BIOASSAY RESEARCH CENTER : B6D2F1/Crlj FEMALE MICE

Organs Tumors	No. of animals examined	No. of animals bearing tumor	Incidence (%)	Min. - Max. (%)
Uterus Histiocytic sarcoma	2145	440	20.5	10 - 32

43 carcinogenicity studies examined in Japan Bioassay Research Center were used.

Study No. : 0044, 0060, 0062, 0064, 0066, 0068, 0096, 0105, 0116, 0140, 0159, 0163, 0190,
0206, 0211, 0225, 0243, 0268, 0270, 0279, 0285, 0297, 0319, 0329, 0343, 0348,
0366, 0372, 0402, 0406, 0418, 0422, 0438, 0449, 0458, 0462, 0498, 0515, 0561,
0580, 0611, 0613, 0676

TABLE S 1

CAUSE OF DEATH: MALE

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[Crlj-BDF1]
 SEX : MALE

COUSE OF DEATH (SUMMARY)
 (0-105W)

PAGE : 1

Group Name	Control	800 ppm	2000 ppm	5000 ppm
Number of Dead and Moribund Animal	9	19	13	17
no microscop confirm	1	0	0	0
respiratory sy les	0	0	0	1
hepatic lesion	0	0	0	1
urinary retention	1	2	0	3
hydronephrosis	0	1	1	3
peritonitis	0	0	1	0
tumor d:leukemia	1	3	3	3
tumor d:subcutis	0	1	0	0
tumor d:lung	1	0	2	1
tumor d:liver	5	10	5	5
tumor d:pituitary	0	1	0	0
tumor d:periph nerv	0	0	1	0
tumor d:muscle	0	1	0	0

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TABLE S 2

CAUSE OF DEATH: FEMALE

STUDY NO. : 0642
 ANIMAL : MOUSE B6D2F1/CrJ[Crl-BDF1]
 SEX : FEMALE

CAUSE OF DEATH (SUMMARY)
 (0-105W)
 PAGE : 2

Group Name	Control	800 ppm	2000 ppm	5000 ppm
Number of Dead and Moribund Animal	14	21	27	26
no microscop confirm	0	0	1	0
arteritis	0	0	1	0
hydromepirosis	1	1	2	3
tumor d:leukemia	8	15	13	11
tumor d:lung	0	1	0	0
tumor d:liver	1	0	2	3
tumor d:pituitary	1	0	2	1
tumor d:ovary	0	0	0	1
tumor d:uterus	2	3	5	6
tumor d:bone	1	1	0	0
tumor d:peritoneum	0	0	0	1
tumor d:retroperit	0	0	1	0

(310120)

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FIGURES

- FIGURE 1 SURVIVAL ANIMAL RATE OF MALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF 2-AMINOETHANOL
- FIGURE 2 SURVIVAL ANIMAL RATE OF FEMALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF 2-AMINOETHANOL
- FIGURE 3 BODY WEIGHT CHANGES OF MALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF 2-AMINOETHANOL
- FIGURE 4 BODY WEIGHT CHANGES OF FEMALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF 2-AMINOETHANOL
- FIGURE 5 FOOD CONSUMPTION CHANGES OF MALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF 2-AMINOETHANOL
- FIGURE 6 FOOD CONSUMPTION CHANGES OF FEMALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF 2-AMINOETHANOL
- FIGURE 7 WATER CONSUMPTION CHANGES OF MALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF 2-AMINOETHANOL
- FIGURE 8 WATER CONSUMPTION CHANGES OF FEMALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF 2-AMINOETHANOL

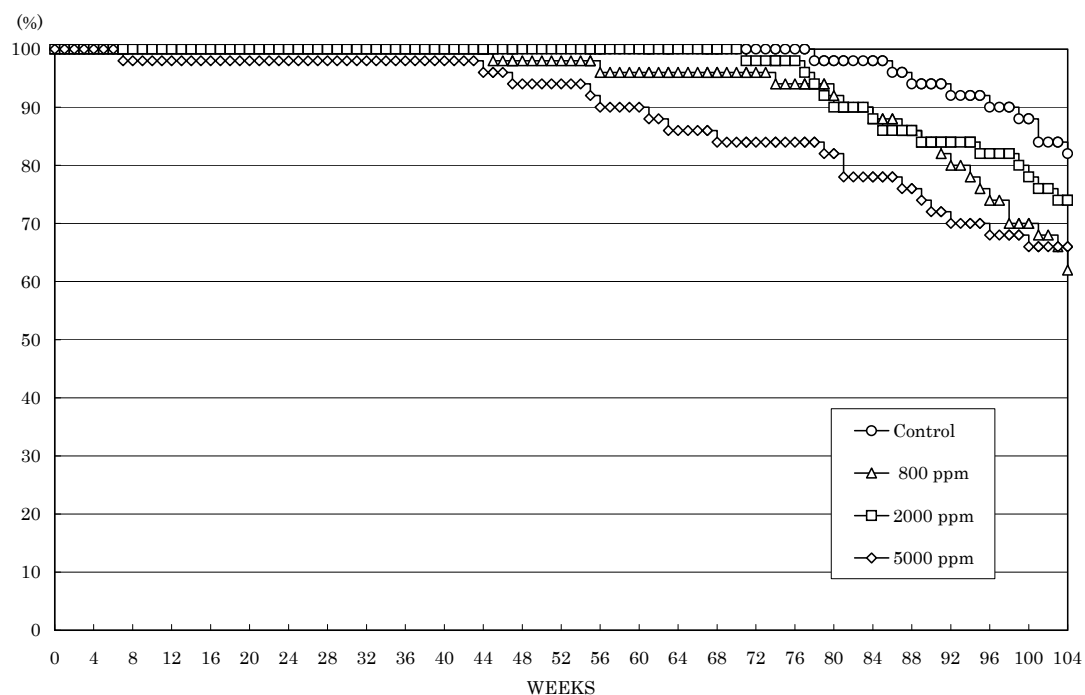


FIGURE 1 SURVIVAL ANIMAL RATE OF MALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF 2-AMINOETHANOL

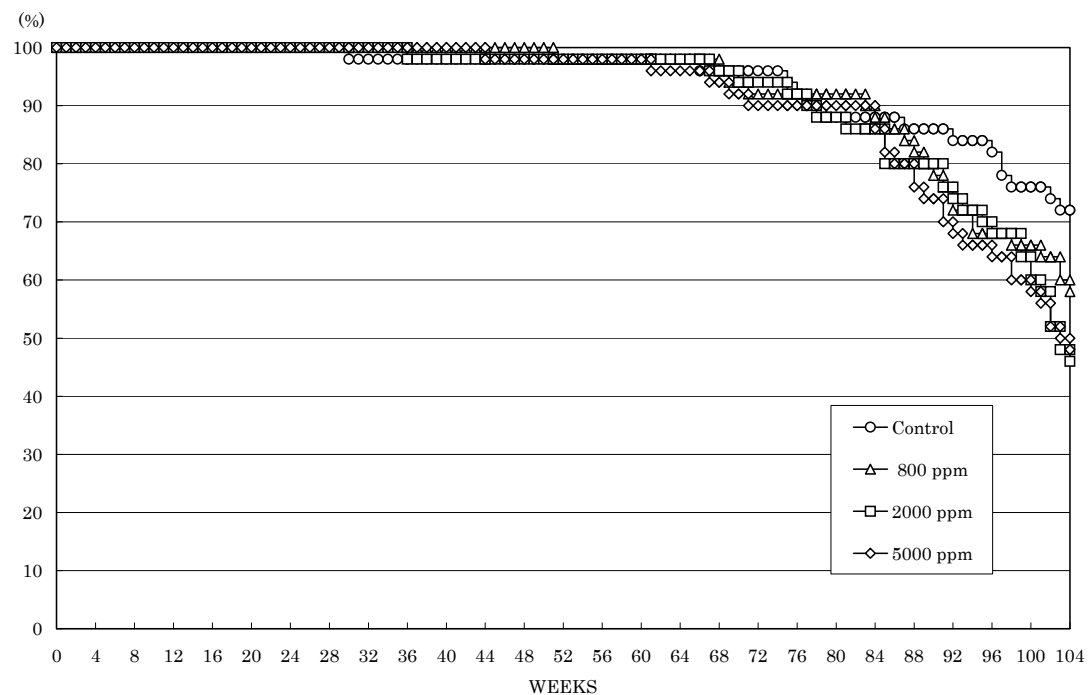


FIGURE 2 SURVIVAL ANIMAL RATE OF FEMALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF 2-AMINOETHANOL

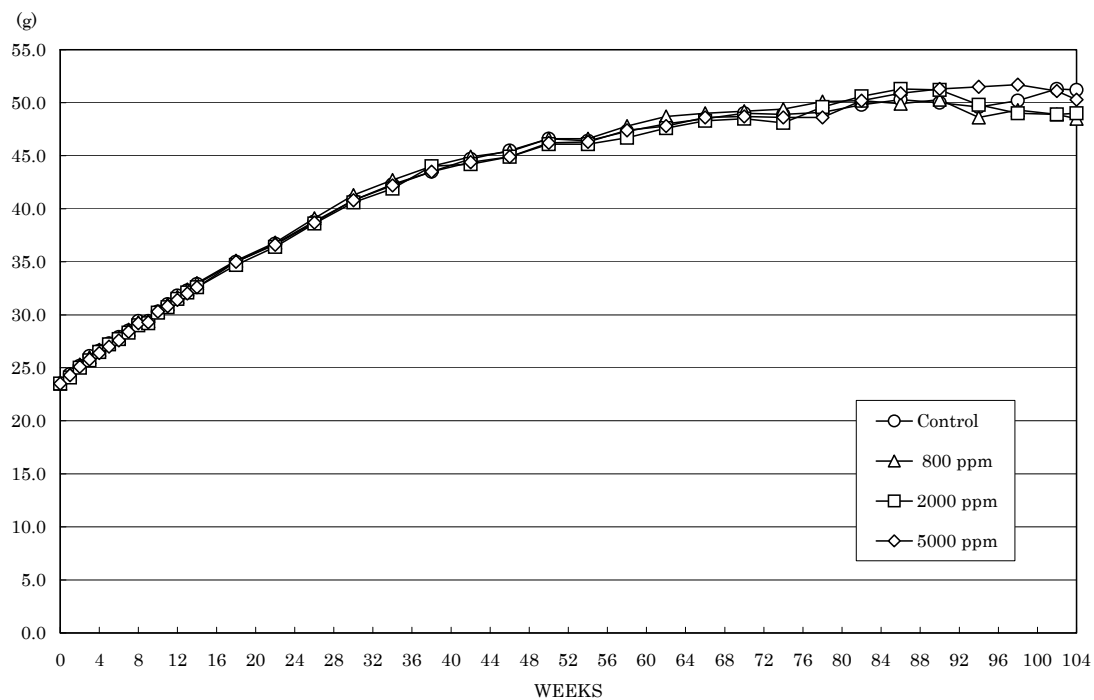


FIGURE 3 BODY WEIGHT CHANGES OF MALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF 2-AMINOETHANOL

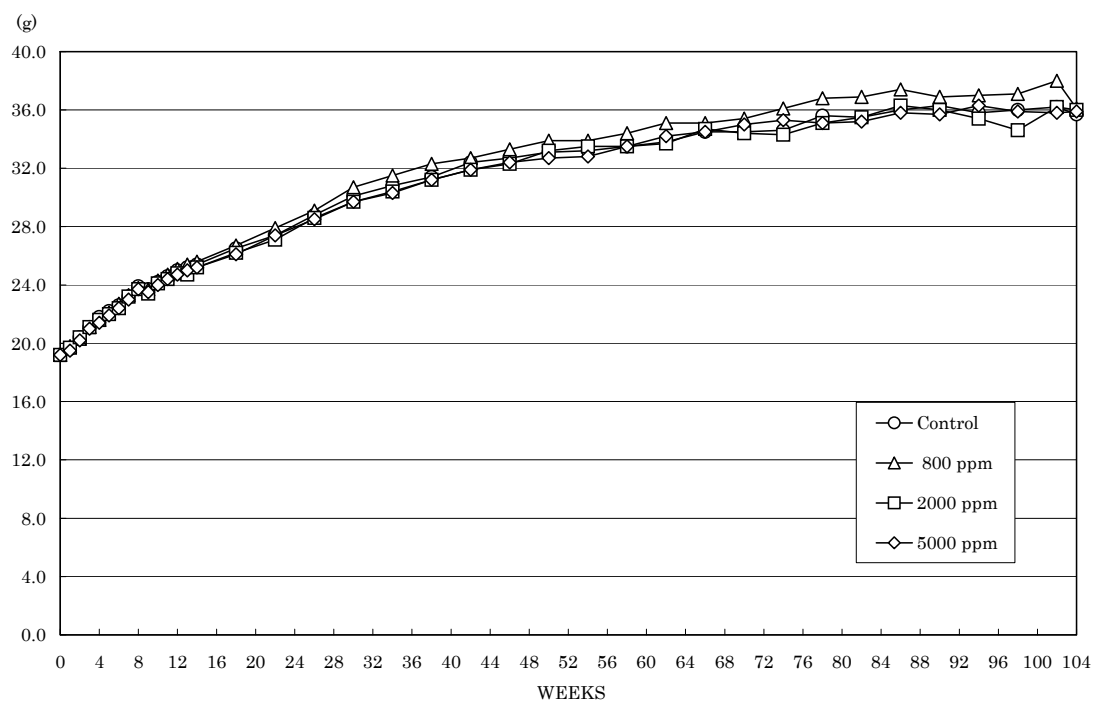


FIGURE 4 BODY WEIGHT CHANGES OF FEMALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF 2-AMINOETHANOL

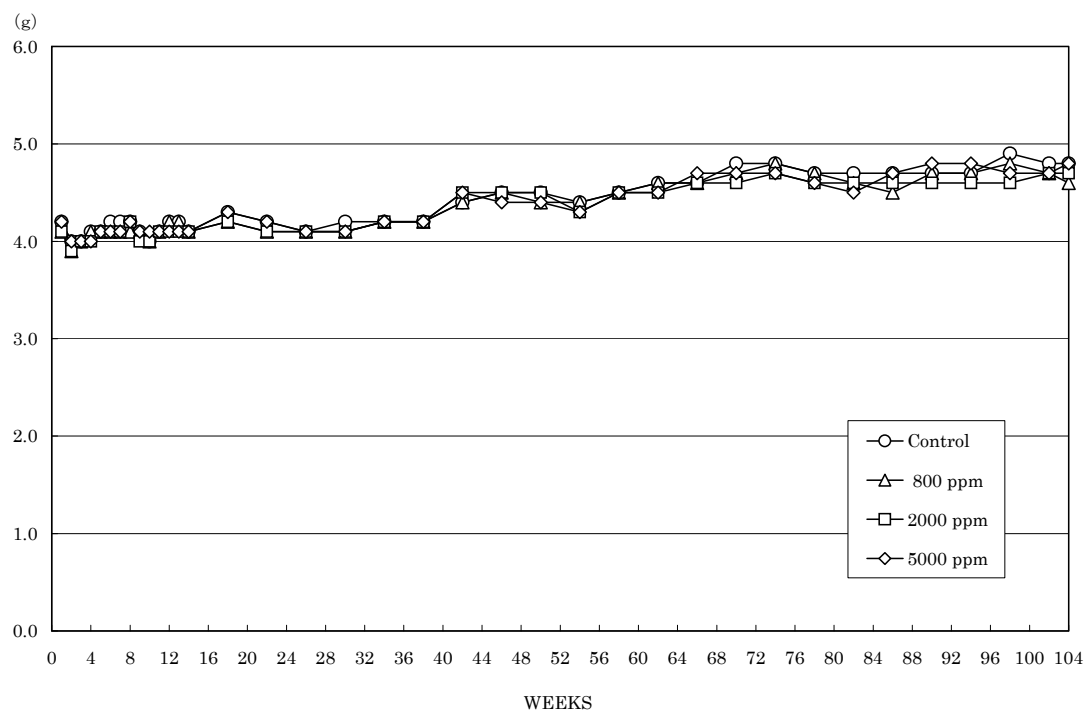


FIGURE 5 FOOD CONSUMPTION CHANGES OF MALE MICE IN THE 2-YEAR DRINKING WATER STUDY 2-AMINOETHANOL

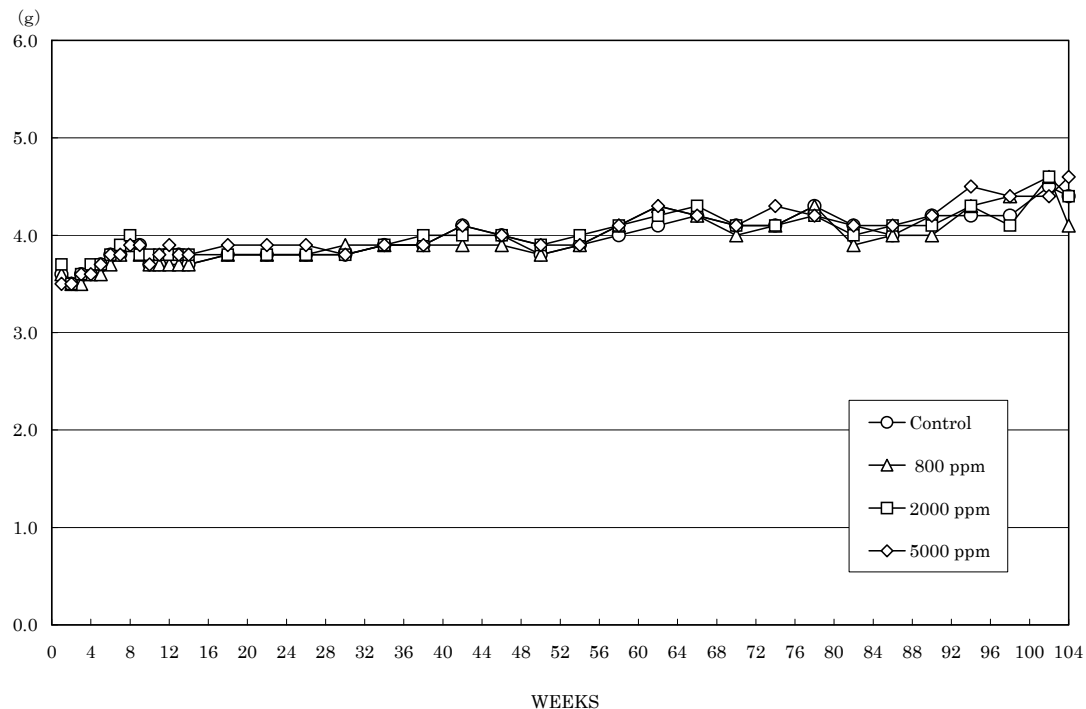


FIGURE 6 FOOD CONSUMPTION CHANGES OF FEMALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF 2-AMINOETHANOL

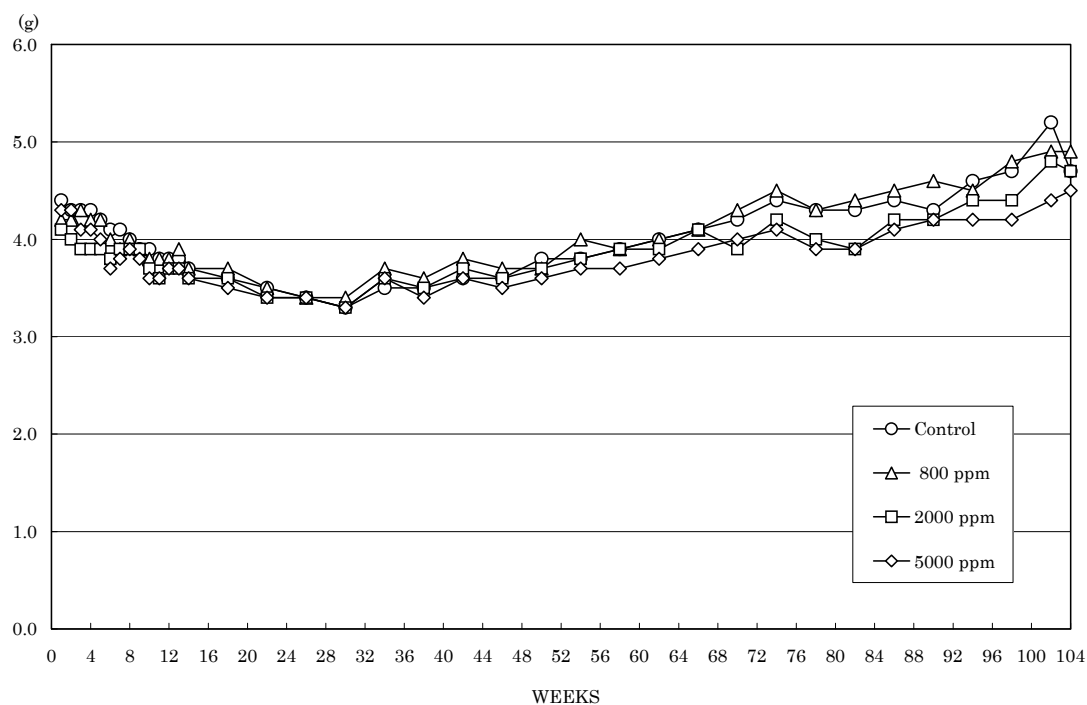


FIGURE 7 WATER CONSUMPTION CHANGES OF MALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF 2-AMINOETHANOL

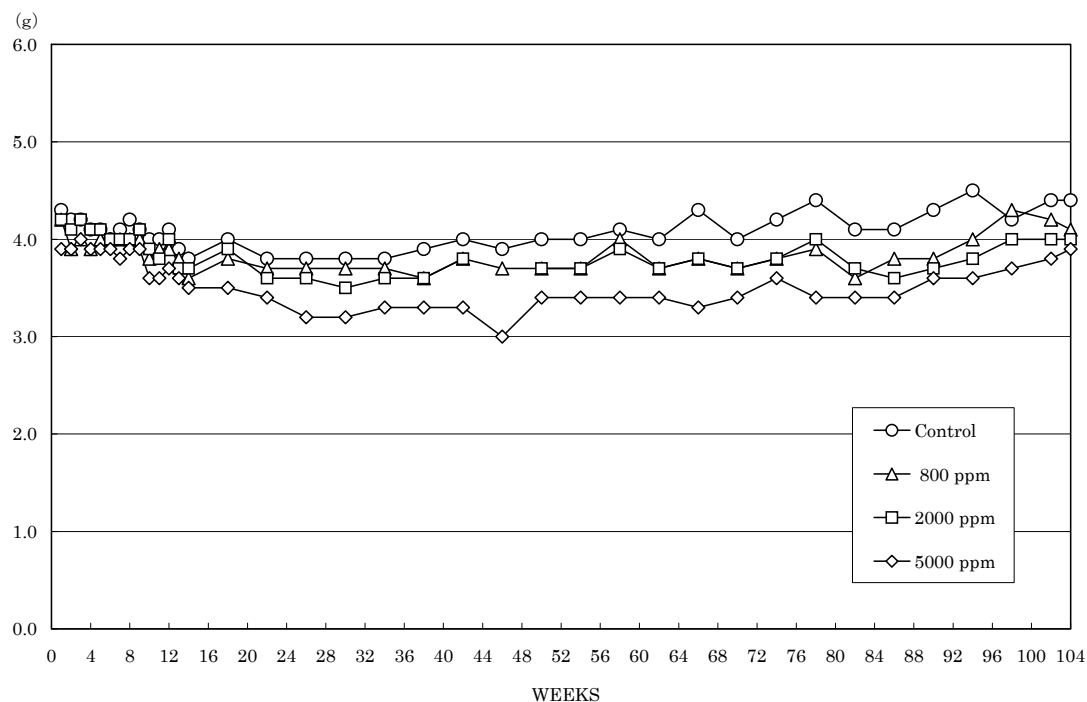


FIGURE 8 WATER CONSUMPTION CHANGES OF FEMALE MICE IN THE 2-YEAR DRINKING WATER STUDY OF 2-AMINOETHANOL