2-メチル-1-プロパノールのマウスを用いた
経口投与による2週間毒性試験（混水試験）報告書

試験番号：0556

APPENDICES

APPENDICES

APPENDICES (CONTINUED)

APPENDIX A 1

IDENTITY AND IMPURITY OF 2-METHYL-1-PROPANOLIN THE 2-WEEK DRINKING WATER STUDY

IDENTITY AND IMPURITY OF 2-METHYL-1-PROPANOL IN THE 2-WEEK DRINKING WATER STUDY

Test Substance : 2-Methyl-1-propanol (Wako Pure Chemical Industries, Ltd.)

Lot No. : KLN7146

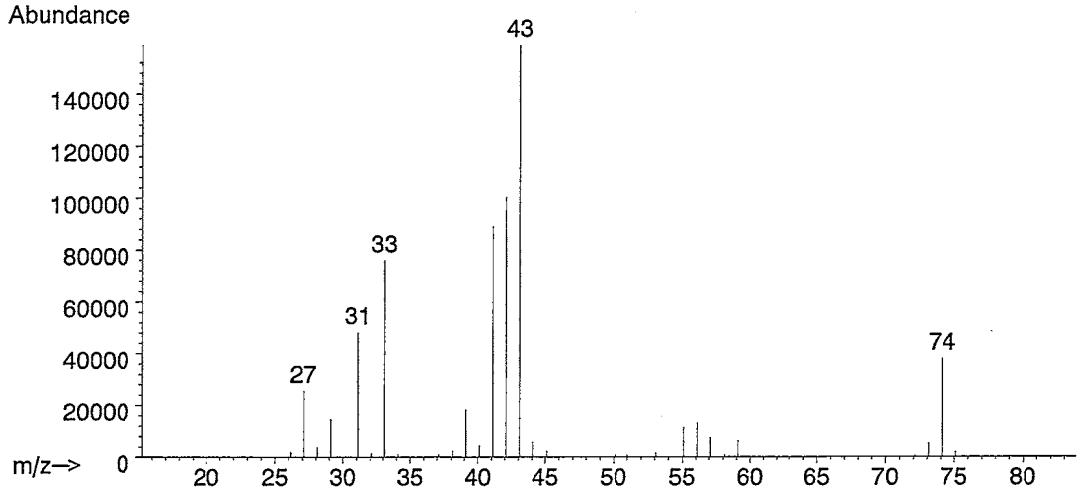
1. Spectral Data

Mass Spectrometry

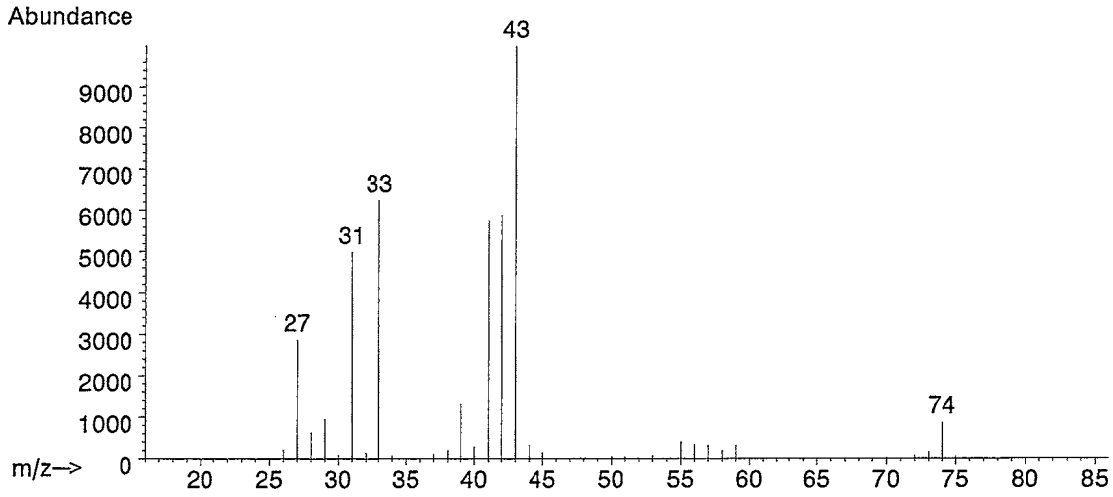
Instrument : Hewlett Packard 5989B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance



Mass Spectrum of Literature Data*

Result: The mass spectrum was consistent with literature spectrum.

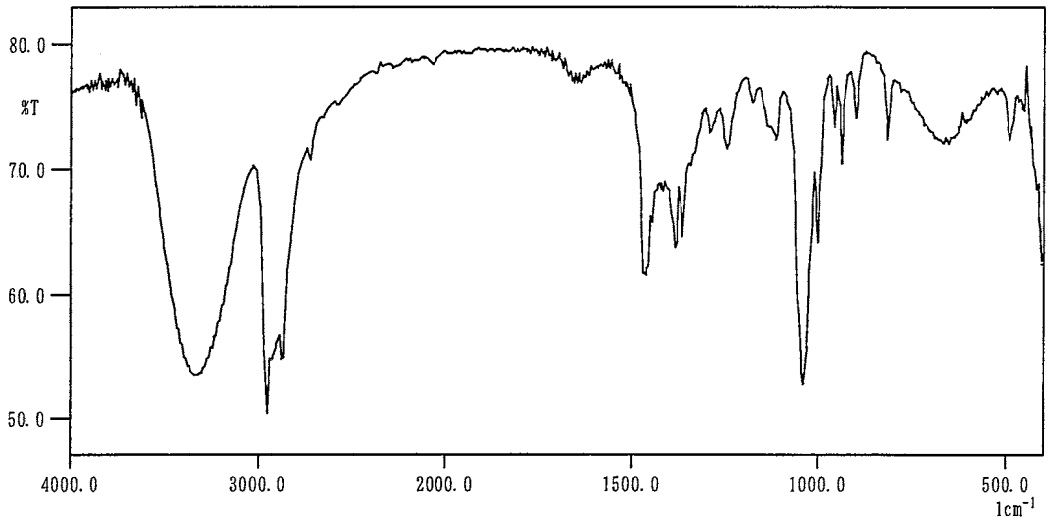
(*McLafferty FW, ed. 1994. Wiley Registry of Mass Spectral Data. 6th ed. New York, NY : John Wiley and Sons.)

Infrared Spectrometry

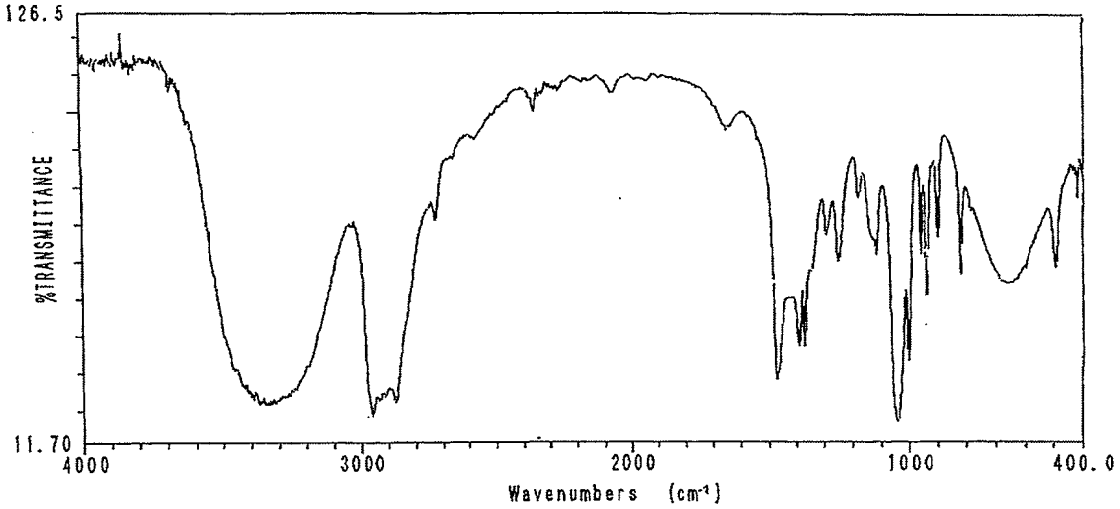
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 2 cm^{-1}



Infrared Spectrum of Test Substance



Infrared Spectrum of Literature Data*

Result: The infrared spectrum was consistent with literature spectrum.
(*Performed by Wako Pure Chemical Industries, Ltd.)

2. Impurity

Instrument	: Hewlett Packard 5890A Gas Chromatograph
Column	: INNOWAX (0.2 mmϕ × 50 m)
Column Temperature	: 80 °C (1 min) → (10 °C/min) → 200 °C
Flow Rate	: 1 mL/min
Detector	: FID (Flame Ionization Detector)
Injection Volume	: 1 μL

Sample Name	Peak No.	Area (%)	Peak Name
	1	0.071	Diisobutyl ether
Test Substance	2	99.886	2-Methyl-1-propanol
	3	0.043	1-Butanol

Result: Gas chromatography indicated one major peak (peak No.2) and two impurities. Those impurities (peak No.1 and peak No.3) were identified as diisobutyl ether and 1-butanol by comparing GC-MS with the standard samples. The amount in the test substance was 0.071% (The quantity value by the standard sample was 0.069%.) for diisobutyl ether and 0.043% (The quantity value by the standard sample was 0.043%.) for 1-butanol with a gas chromatograph.

3. Conclusion: The test substance was identified as 2-methyl-1-propanol by mass spectrum and infrared spectrum. Gas chromatography indicated one major peak (2-methyl-1-propanol) and two impurities. Those impurities were diisobutyl ether and 1-butanol in the test substance.

APPENDIX A 2

STABILITY OF 2-METHYL-1-PROPANOL IN THE 2-WEEK DRINKING WATER STUDY

STABILITY OF 2-METHYL-1-PROPANOL IN THE 2-WEEK DRINKING WATER STUDY

Test Substance : 2-Methyl-1-propanol (Wako Pure Chemical Industries, Ltd.)

Lot No. : KLN7146

1. Sample : This lot was used from 2004.9.23 to 2004.10.7. Test substance was stored in a dark place at room temperature.

2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : INNOWAX (0.2 mmϕ × 50 m)

Column Temperature : 80 °C (1 min) → (10 °C/min) → 200 °C

Flow Rate : 1 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μL

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
2004.09.21	1	3.751	0.071
	2	5.266	99.886
	3	5.580	0.043
2004.10.19	1	3.744	0.070
	2	5.252	99.884
	3	5.569	0.046

Result: Gas chromatography indicated one major peak (peak No.2) and two impurities (peak No.1 and No.3 < 0.2% of total area) analyzed on 2004.9.21 and one major peak (peak No.2) and two impurities (peak No.1 and No.3 < 0.2% of total area) analyzed on 2004.10.19. No new trace impurity peak in the test substance analyzed on 2004.10.19 was detected.

3. Conclusion: The test substance was stable for about 4 weeks in a dark place at room temperature.

APPENDIX A 3

CONCENTRATION OF 2-METHYL-1-PROPANOL IN FORMULATED WATER IN THE 2-WEEK DRINKING WATER STUDY

CONCENTRATION OF 2-METHYL-1-PROPANOL IN FORMULATED WATER IN THE 2-WEEK DRINKING WATER STUDY

	Target Concentration				
Date Analyzed	2500[a]	5000	10000	20000	40000
2004.09.23	2460 (98.4)[b]	4920 (98.4)	9710 (97.1)	19700 (98.5)	38500 (96.3)

[a] ppm
[b] %

Analytical method : The samples were analyzed by gas chromatography.

Instrument : Hewlett Packard 5890A Gas Chromatograph
Column : INNOWAX (0.2 mmϕ × 50 m)
Column Temperature : 80 °C (1 min) → (10 °C/min) → 200 °C
Flow Rate : 1 mL/min
Detector : FID (Flame Ionization Detector)
Injection Volume : 1 μL

APPENDIX A 4

STABILITY OF 2-METHYL-1-PROPANOL IN FORMULATED WATER IN THE 2-WEEK DRINKING WATER STUDY

STABILITY OF 2-METHYL-1-PROPANOL IN FORMULATED WATER IN THE 2-WEEK DRINKING WATER STUDY

		Target Concentration	
Date Prepared	Date Analyzed	2500[a]	40000
2004.08.12	2004.08.12	2450 (100)[b]	40800 (100)
	2004.08.16[c]	2280 (93.1)	38800 (95.1)

[a] ppm
[b] % (Percentage was based on the concentration on date of preparation.)
[c] Animal room samples

Analytical method : The samples were analyzed by gas chromatography.

Instrument : Hewlett Packard 5890A Gas Chromatograph
Column : INNOWAX (0.2 mmϕ × 50 m)
Column Temperature : 80 °C (1 min) → (10 °C/min) → 200 °C
Flow Rate : 1 mL/min
Detector : FID (Flame Ionization Detector)
Injection Volume : 1 μL

APPENDIX B 1

CLINICAL OBSERVATION : MALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Administration Week-day 1-4	1-7	2-4	2-7
NON REMARKABLE	Control	5	5	5	5
	2500 ppm	5	5	5	5
	5000 ppm	5	5	5	5
	10000 ppm	5	5	5	5
	20000 ppm	5	5	5	5
	40000 ppm	5	5	5	5

APPENDIX B 2

CLINICAL OBSERVATION : FEMALE

Clinical sign	Group Name	Administration Week-day 1-4	1-7	2-4	2-7
PILOERECTION	Control	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	0	1	0	0
	20000 ppm	0	0	0	0
	40000 ppm	0	0	0	0
OLIGO-STOOL	Control	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	1	1	0	1
	20000 ppm	0	0	0	0
	40000 ppm	0	0	0	0
NON REMARKABLE	Control	5	5	5	5
	2500 ppm	5	5	5	5
	5000 ppm	5	5	5	5
	10000 ppm	4	4	5	4
	20000 ppm	5	5	5	5
	40000 ppm	5	5	5	5

APPENDIX C 1

BODY WEIGHT CHANGES : MALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
UNIT : g
REPORT TYPE : A1 2
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day 0-0	1-4	1-7	2-4	2-7
Control	24.3± 0.9	24.7± 1.0	24.5± 1.3	25.2± 1.9	25.9± 1.4
2500 ppm	24.4± 0.8	24.5± 0.6	24.7± 1.0	25.5± 1.0	26.4± 0.9
5000 ppm	24.4± 0.8	24.3± 0.6	24.3± 0.5	25.1± 0.9	26.3± 0.8
10000 ppm	24.3± 0.8	24.6± 0.6	24.5± 0.1	26.0± 0.6	27.2± 0.7
20000 ppm	24.3± 0.8	24.9± 1.0	24.5± 1.1	25.6± 1.0	26.9± 1.3
40000 ppm	24.4± 0.7	24.4± 0.9	24.0± 0.9	25.3± 1.1	26.6± 1.0

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

APPENDIX C 2

BODY WEIGHT CHANGES : FEMALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
UNIT : g
REPORT TYPE : A1 2
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day 0-0	1-4	1-7	2-4	2-7
Control	19.4± 0.6	19.6± 0.7	19.7± 1.2	20.2± 1.2	21.4± 1.4
2500 ppm	19.3± 0.9	20.0± 0.5	20.0± 1.1	20.6± 1.2	21.9± 0.9
5000 ppm	19.4± 0.7	19.4± 0.7	18.9± 0.4	20.6± 0.7	21.7± 0.7
10000 ppm	19.4± 0.6	18.0± 2.6	18.0± 2.8	19.7± 1.6	19.3± 1.9*
20000 ppm	19.4± 0.7	19.7± 1.0	19.8± 0.8	20.4± 1.2	20.9± 0.3
40000 ppm	19.4± 0.6	19.3± 0.8	19.0± 0.8	19.8± 1.0	21.0± 1.2

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

APPENDIX D 1

FOOD CONSUMPTION CHANGES : MALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
UNIT : g
REPORT TYPE : A1 2
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective) 1-4(4)	1-7(3)	2-4(4)	2-7(3)
Control	3.9± 0.4	4.3± 0.3	4.0± 0.4	4.1± 0.4
2500 ppm	3.7± 0.1	4.3± 0.3	3.9± 0.3	3.8± 0.3
5000 ppm	3.6± 0.4	4.1± 0.2	3.8± 0.5	4.0± 0.2
10000 ppm	3.6± 0.2	4.1± 0.2	4.1± 0.2	4.1± 0.4
20000 ppm	3.6± 0.2	4.0± 0.2	3.9± 0.3	4.2± 0.3
40000 ppm	3.3± 0.2**	3.8± 0.3*	3.7± 0.2	3.9± 0.2

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

APPENDIX D 2

FOOD CONSUMPTION CHANGES : FEMALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
UNIT : g
REPORT TYPE : A1 2
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective) 1-4(4)	1-7(3)	2-4(4)	2-7(3)
Control	3.3± 0.2	3.7± 0.3	3.4± 0.2	3.7± 0.4
2500 ppm	3.5± 0.2	3.7± 0.4	3.4± 0.2	3.6± 0.3
5000 ppm	3.1± 0.2	3.4± 0.3	3.5± 0.1	3.4± 0.2
10000 ppm	2.7± 0.7	3.2± 0.7	3.3± 0.2	2.9± 0.6
20000 ppm	3.2± 0.3	3.4± 0.2	3.3± 0.1	3.3± 0.5
40000 ppm	2.6± 0.3*	3.2± 0.2	3.2± 0.2	3.3± 0.2

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

APPENDIX E 1

WATER CONSUMPTION CHANGES : MALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
UNIT : g
REPORT TYPE : A1 2
SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective) 1-4(4)	1-7(3)	2-4(4)	2-7(3)
Control	5.5± 1.6	5.9± 1.6	4.7± 1.2	5.0± 1.8
2500 ppm	4.2± 0.4	4.7± 0.4	4.1± 0.3	3.7± 0.3
5000 ppm	4.5± 0.7	4.8± 0.7	4.5± 0.9	4.2± 0.7
10000 ppm	4.0± 0.4	4.7± 0.8	4.2± 0.6	3.7± 0.4
20000 ppm	3.7± 0.5	4.0± 0.5*	3.8± 0.5	3.6± 0.5
40000 ppm	3.1± 0.4**	3.6± 0.3**	3.4± 0.2	3.3± 0.3

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

APPENDIX E 2

WATER CONSUMPTION CHANGES : FEMALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
UNIT : g
REPORT TYPE : A1 2
SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective) 1-4(4)	1-7(3)	2-4(4)	2-7(3)
Control	4.4± 0.7	4.9± 0.8	4.7± 1.0	4.7± 0.6
2500 ppm	4.3± 0.1	4.2± 0.4	4.1± 0.1	4.0± 0.4
5000 ppm	3.6± 0.6	3.8± 0.5	4.2± 0.5	3.9± 0.4
10000 ppm	3.2± 1.5	3.9± 1.4	4.0± 1.0	3.5± 1.3
20000 ppm	3.4± 0.3	3.8± 0.5	3.8± 0.5	3.7± 0.7
40000 ppm	2.9± 0.3**	3.4± 0.3**	3.3± 0.5	3.3± 0.5

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

APPENDIX F 1

CHEMICAL INTAKE CHANGES : MALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
UNIT : g／kg／d a y
REPORT TYPE : A1 2
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration (Week-Day) 1-4	1-7	2-4	2-7
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
2500 ppm	0.432± 0.049	0.480± 0.055	0.408± 0.046	0.351± 0.037
5000 ppm	0.931± 0.131	0.992± 0.134	0.883± 0.150	0.795± 0.114
10000 ppm	1.618± 0.173	1.933± 0.316	1.627± 0.258	1.368± 0.150
20000 ppm	2.956± 0.338	3.258± 0.311	2.996± 0.348	2.639± 0.266
40000 ppm	5.061± 0.671	6.042± 0.592	5.345± 0.334	4.950± 0.575

APPENDIX F 2

CHEMICAL INTAKE CHANGES : FEMALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
UNIT : g／kg／d a y
REPORT TYPE : A1 2
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration (Week-Day) 1-4	1-7	2-4	2-7
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
2500 ppm	0.539± 0.018	0.530± 0.027	0.501± 0.025	0.457± 0.052
5000 ppm	0.925± 0.140	1.004± 0.126	1.018± 0.137	0.888± 0.092
10000 ppm	1.711± 0.688	2.102± 0.533	2.032± 0.383	1.787± 0.601
20000 ppm	3.439± 0.415	3.892± 0.562	3.716± 0.649	3.525± 0.680
40000 ppm	5.963± 0.511	7.113± 0.747	6.747± 1.087	6.347± 0.851

APPENDIX G 1

HEMATOLOGY : MALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (2W)

Group Name	NO. of Animals	RED BLOOD CELL $10^5/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV f ℓ	MCH p g	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	5	10.28± 0.47	15.7± 0.8	50.1± 1.9	48.9± 3.6	15.3± 0.1	31.5± 2.2	1099± 72
2500 ppm	5	10.04± 0.35	15.4± 0.7	48.1± 1.4	47.9± 1.1	15.4± 0.4	32.1± 0.7	1160± 101
5000 ppm	5	10.24± 0.63	15.6± 0.9	49.4± 3.1	48.2± 1.9	15.3± 0.2	31.7± 1.1	1078± 61
10000 ppm	4	10.18± 0.18	15.8± 0.2	48.8± 0.3	47.9± 0.7	15.6± 0.1	32.4± 0.4	1130± 45
20000 ppm	5	10.20± 0.31	15.6± 0.6	48.7± 1.2	47.8± 0.5	15.3± 0.1	32.1± 0.5	1080± 99
40000 ppm	5	10.32± 0.57	15.7± 0.8	48.8± 1.7	47.4± 1.4	15.2± 0.2	32.1± 0.7	1099± 51

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

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (2W)

Group Name	NO. of Animals	RETICULOCYTE %
Control	5	2.1± 0.2
2500 ppm	5	1.9± 0.1
5000 ppm	5	2.0± 0.3
10000 ppm	4	2.2± 0.1
20000 ppm	5	2.1± 0.3
40000 ppm	5	2.2± 0.3

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

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (2W)

Group Name	NO. of Animals	WBC $10^3/\mu\ell$	Differential WBC (%)
Control	5	1.71± 0.37	
2500 ppm	5	2.77± 1.06	
5000 ppm	5	1.84± 0.66	
10000 ppm	4	1.96± 0.64	
20000 ppm	5	2.56± 1.32	
40000 ppm	5	2.01± 1.28	

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

APPENDIX G 2

HEMATOLOGY : FEMALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (2W)

Group Name	NO. of Animals	RED BLOOD CELL $10^5/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV f ℓ	MCH p g	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	5	10.12± 0.44	15.2± 0.9	48.4± 1.1	47.9± 2.1	15.1± 0.2	31.6± 1.6	904± 151
2500 ppm	4	10.01± 0.23	15.3± 0.4	47.7± 1.2	47.6± 0.3	15.3± 0.1	32.1± 0.4	966± 26
5000 ppm	4	10.21± 0.75	15.5± 0.9	47.5± 2.8	46.6± 0.9	15.2± 0.3	32.6± 0.1	1028± 282
10000 ppm	5	10.30± 0.47	15.6± 0.7	49.6± 1.3	48.1± 2.2	15.2± 0.2	31.7± 1.2	1076± 306
20000 ppm	5	9.96± 0.35	15.2± 0.6	47.4± 1.7	47.6± 0.4	15.2± 0.2	32.0± 0.3	887± 70
40000 ppm	5	10.08± 0.44	15.3± 0.8	48.0± 1.4	47.6± 1.4	15.3± 0.2	32.0± 1.0	885± 101

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

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (2W)

Group Name	NO. of Animals	RETICULOCYTE %
Control	5	2.4± 0.3
2500 ppm	4	2.3± 0.2
5000 ppm	4	2.6± 0.9
10000 ppm	5	2.5± 0.7
20000 ppm	5	2.5± 0.3
40000 ppm	5	2.1± 0.4

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

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (2W)

Group Name	NO. of Animals	WBC $10^3/\mu\ell$	Differential WBC (%)
Control	5	1.66± 1.04	
2500 ppm	4	1.91± 0.96	
5000 ppm	4	2.38± 1.71	
10000 ppm	5	1.48± 0.88	
20000 ppm	5	2.16± 0.71	
40000 ppm	5	2.07± 0.91	

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

APPENDIX H 1

BIOCHEMISTRY : MALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (2W)

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	PHOSPHOLIPID mg/dl
Control	5	4.9± 0.1	2.7± 0.1	1.2± 0.1	0.15± 0.01	258± 75	104± 12	195± 18
2500 ppm	5	4.8± 0.3	2.6± 0.1	1.2± 0.1	0.15± 0.01	304± 46	107± 14	204± 22
5000 ppm	5	4.7± 0.2	2.6± 0.2	1.2± 0.1	0.15± 0.02	294± 26	100± 12	195± 12
10000 ppm	4	4.9± 0.2	2.8± 0.1	1.3± 0.1	0.15± 0.01	304± 32	109± 8	202± 14
20000 ppm	5	4.6± 0.1	2.6± 0.1	1.3± 0.1	0.14± 0.01	316± 18	95± 11	194± 13
40000 ppm	5	4.7± 0.2	2.6± 0.1	1.3± 0.2	0.15± 0.02	300± 34	95± 7	186± 19

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

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (2W)

Group Name	NO. of Animals	AST IU/ℓ	ALT IU/ℓ	LDH IU/ℓ	G-GTP IU/ℓ	CK IU/ℓ	UREA NITOROGEN mg/dℓ	SODIUM mEq/ℓ
Control	5	33± 7	18± 2	203± 63	1± 0	141± 86	26.1± 5.6	149± 2
2500 ppm	5	29± 2	17± 1	200± 86	1± 0	90± 46	22.2± 6.2	147± 1
5000 ppm	5	38± 14	24± 12	267± 169	1± 0	166± 178	24.2± 4.1	148± 1
10000 ppm	4	31± 3	18± 2	194± 68	1± 0	159± 95	23.2± 8.9	149± 2
20000 ppm	5	27± 2	17± 1	166± 36	1± 0	78± 35	24.8± 6.1	148± 1
40000 ppm	5	28± 3	15± 2	199± 127	1± 1	86± 64	23.7± 4.5	148± 2

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

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (2W)

Group Name	NO. of Animals	POTASSIUM mEq/ℓ	CHLORIDE mEq/ℓ	CALCIUM mg/dℓ	INORGANIC PHOSPHORUS mg/dℓ
Control	5	5.2± 0.6	116± 3	9.2± 0.6	8.5± 1.4
2500 ppm	5	4.5± 0.6	114± 2	9.0± 0.5	7.2± 1.9
5000 ppm	5	4.7± 0.8	114± 2	8.8± 0.4	7.4± 1.4
10000 ppm	4	4.6± 0.3	115± 2	9.1± 0.4	6.8± 1.3
20000 ppm	5	4.3± 0.4	115± 1	9.0± 0.1	6.4± 1.4
40000 ppm	5	4.3± 0.2	115± 1	8.9± 0.2	6.6± 1.5

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

APPENDIX H 2

BIOCHEMISTRY : FEMALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (2W)

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	PHOSPHOLIPID mg/dℓ
Control	5	4.9± 0.3	3.0± 0.2	1.6± 0.0	0.17± 0.03	247± 17	86± 6	160± 11
2500 ppm	5	4.7± 0.3	2.9± 0.2	1.6± 0.1	0.16± 0.02	279± 17	89± 11	166± 14
5000 ppm	5	4.8± 0.3	2.9± 0.2	1.6± 0.3	0.19± 0.07	275± 16	89± 22	172± 26
10000 ppm	5	5.2± 0.4	3.1± 0.1	1.5± 0.2	0.17± 0.01	237± 37	91± 27	165± 34
20000 ppm	5	4.6± 0.2	2.9± 0.1	1.6± 0.1	0.15± 0.02	279± 15	84± 8	156± 14
40000 ppm	5	4.5± 0.1	2.8± 0.1	1.7± 0.1	0.15± 0.01	283± 18	79± 18	151± 25

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

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (2W)

Group Name	NO. of Animals	AST IU/ℓ		ALT IU/ℓ		LDH IU/ℓ		G-GTP IU/ℓ		CK IU/ℓ		UREA NITOROGEN mg/dℓ		SODIUM mEq/ℓ	
Control	5	36±	4	17±	2	216±	75	1±	1	94±	27	20.4±	2.6	150±	2
2500 ppm	5	37±	6	18±	5	184±	44	1±	0	95±	61	22.7±	6.9	149±	1
5000 ppm	5	37±	5	19±	3	282±	140	1±	0	90±	29	23.9±	2.4	148±	3
10000 ppm	5	50±	19	24±	14	314±	135	1±	1	121±	103	25.8±	6.3	149±	2
20000 ppm	5	35±	3	15±	2	190±	36	1±	1	99±	46	22.0±	3.5	147±	1
40000 ppm	5	38±	10	17±	4	181±	43	1±	0	94±	22	19.6±	1.9	147±	2

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

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (2W)

Group Name	NO. of Animals	POTASSIUM mEq／ℓ	CHLORIDE mEq／ℓ	CALCIUM mg／dℓ	INORGANIC PHOSPHORUS mg／dℓ
Control	5	4.4± 0.1	119± 2	9.0± 0.3	6.9± 1.2
2500 ppm	5	4.4± 0.4	119± 2	8.9± 0.1	6.1± 0.8
5000 ppm	5	4.5± 0.6	117± 6	8.9± 0.5	6.6± 1.1
10000 ppm	5	4.5± 0.5	119± 6	9.1± 0.9	6.9± 1.3
20000 ppm	5	4.2± 0.3	118± 2	8.5± 0.2	6.8± 1.0
40000 ppm	5	4.3± 0.3	118± 2	8.5± 0.1	5.9± 1.2

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

APPENDIX I 1

GROSS FINDINGS : MALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 2W)

Organ	Findings	Group Name / NO. of Animals	Control 5 (%)	2500 ppm 5 (%)	5000 ppm 5 (%)	10000 ppm 5 (%)
spleen	black zone		0 (0)	0 (0)	0 (0)	0 (0)
kidney	enlarged		0 (0)	1 (20)	0 (0)	0 (0)

Organ	Findings	Group Name NO. of Animals	20000 ppm 5 (%)	40000 ppm 5 (%)
spleen	black zone		0 (0)	1 (20)
kidney	enlarged		0 (0)	0 (0)

APPENDIX I 2

GROSS FINDINGS : FEMALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 2W)

Organ	Findings	Group Name / NO. of Animals	Control 5 (%)	2500 ppm 5 (%)	5000 ppm 5 (%)	10000 ppm 5 (%)
spleen	black zone		0 (0)	1 (20)	0 (0)	0 (0)
kidney	hydronephrosis		0 (0)	0 (0)	1 (20)	1 (20)

Organ	Findings	Group Name / NO. of Animals	20000 ppm 5 (%)	40000 ppm 5 (%)
spleen	black zone		1 (20)	0 (0)
kidney	hydronephrosis		0 (0)	0 (0)

APPENDIX J 1

ORGAN WEIGHT, ABSOLUTE : MALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (2W)

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	5	25.9± 1.4	0.057± 0.007	0.010± 0.003	0.199± 0.012	0.138± 0.008	0.163± 0.018
2500 ppm	5	26.4± 0.9	0.054± 0.005	0.010± 0.003	0.185± 0.011	0.132± 0.013	0.157± 0.018
5000 ppm	5	26.3± 0.8	0.050± 0.005	0.010± 0.001	0.197± 0.011	0.137± 0.013	0.156± 0.006
10000 ppm	5	27.2± 0.7	0.058± 0.007	0.010± 0.003	0.195± 0.024	0.142± 0.011	0.158± 0.010
20000 ppm	5	26.9± 1.3	0.057± 0.004	0.008± 0.002	0.191± 0.020	0.137± 0.014	0.163± 0.007
40000 ppm	5	26.6± 1.0	0.055± 0.010	0.009± 0.003	0.188± 0.008	0.135± 0.009	0.149± 0.009

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

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (2W)

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	0.410± 0.030	0.053± 0.005	1.228± 0.125	0.430± 0.015
2500 ppm	5	0.461± 0.116	0.060± 0.014	1.345± 0.023	0.441± 0.012
5000 ppm	5	0.412± 0.033	0.054± 0.004	1.366± 0.078	0.426± 0.011
10000 ppm	5	0.431± 0.033	0.053± 0.004	1.420± 0.114	0.431± 0.007
20000 ppm	5	0.436± 0.026	0.057± 0.004	1.487± 0.158**	0.440± 0.014
40000 ppm	5	0.441± 0.013	0.054± 0.005	1.354± 0.153	0.430± 0.011

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

APPENDIX J 2

ORGAN WEIGHT, ABSOLUTE : FEMALE

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (2W)

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	5	21.4± 1.4	0.065± 0.008	0.012± 0.004	0.035± 0.010	0.114± 0.011	0.145± 0.003
2500 ppm	5	21.9± 0.9	0.072± 0.009	0.012± 0.004	0.032± 0.006	0.115± 0.002	0.145± 0.010
5000 ppm	5	21.7± 0.7	0.073± 0.008	0.012± 0.001	0.029± 0.004	0.112± 0.003	0.146± 0.008
10000 ppm	5	19.3± 1.9*	0.055± 0.015	0.012± 0.002	0.021± 0.006	0.108± 0.010	0.138± 0.014
20000 ppm	5	20.9± 0.3	0.074± 0.005	0.012± 0.002	0.031± 0.008	0.115± 0.005	0.145± 0.003
40000 ppm	5	21.0± 1.2	0.065± 0.011	0.013± 0.002	0.026± 0.004	0.108± 0.004	0.152± 0.006

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

STUDY NO. : 0556
ANIMAL : MOUSE B6D2F1/Crlj[Crj:BDF1]
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (2W)

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	0.283± 0.008	0.063± 0.004	0.989± 0.061	0.441± 0.010
2500 ppm	5	0.285± 0.011	0.061± 0.003	1.064± 0.035	0.436± 0.015
5000 ppm	5	0.385± 0.233	0.078± 0.037	1.079± 0.099	0.428± 0.008
10000 ppm	5	0.345± 0.151	0.056± 0.003	0.900± 0.160	0.427± 0.027
20000 ppm	5	0.289± 0.009	0.066± 0.007	0.993± 0.043	0.437± 0.006
40000 ppm	5	0.294± 0.017	0.061± 0.007	1.022± 0.072	0.436± 0.013

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

APPENDIX K 1

ORGAN WEIGHT, RELATIVE : MALE

STUDY NO. : 0556
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (2W)

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	5	25.9± 1.4	0.220± 0.025	0.040± 0.012	0.770± 0.053	0.534± 0.033	0.629± 0.076
2500 ppm	5	26.4± 0.9	0.203± 0.016	0.040± 0.014	0.700± 0.045	0.500± 0.060	0.594± 0.069
5000 ppm	5	26.3± 0.8	0.191± 0.018	0.037± 0.005	0.747± 0.024	0.520± 0.035	0.592± 0.018
10000 ppm	5	27.2± 0.7	0.215± 0.025	0.037± 0.011	0.717± 0.084	0.521± 0.047	0.581± 0.044
20000 ppm	5	26.9± 1.3	0.212± 0.024	0.031± 0.005	0.710± 0.053	0.509± 0.035	0.606± 0.046
40000 ppm	5	26.6± 1.0	0.205± 0.033	0.033± 0.011	0.708± 0.041	0.508± 0.015	0.560± 0.025

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

STUDY NO. : 0556
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (2W)

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	1.583± 0.138	0.203± 0.013	4.736± 0.417	1.661± 0.104
2500 ppm	5	1.757± 0.484	0.228± 0.058	5.105± 0.257	1.673± 0.073
5000 ppm	5	1.562± 0.080	0.204± 0.015	5.190± 0.374	1.618± 0.042
10000 ppm	5	1.585± 0.142	0.196± 0.020	5.229± 0.527	1.586± 0.058
20000 ppm	5	1.622± 0.050	0.212± 0.016	5.524± 0.465	1.640± 0.102
40000 ppm	5	1.662± 0.071	0.202± 0.012	5.090± 0.409	1.620± 0.059

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

APPENDIX K 2

ORGAN WEIGHT, RELATIVE : FEMALE

STUDY NO. : 0556
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (2W)

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	5	21.4± 1.4	0.304± 0.025	0.055± 0.015	0.163± 0.042	0.532± 0.056	0.678± 0.036
2500 ppm	5	21.9± 0.9	0.329± 0.049	0.053± 0.016	0.144± 0.030	0.524± 0.017	0.662± 0.026
5000 ppm	5	21.7± 0.7	0.335± 0.044	0.057± 0.006	0.132± 0.018	0.514± 0.015	0.673± 0.020
10000 ppm	5	19.3± 1.9*	0.282± 0.059	0.062± 0.005	0.107± 0.028	0.562± 0.021	0.717± 0.044
20000 ppm	5	20.9± 0.3	0.353± 0.026	0.059± 0.010	0.147± 0.040	0.550± 0.030	0.693± 0.023
40000 ppm	5	21.0± 1.2	0.312± 0.061	0.062± 0.009	0.125± 0.021	0.514± 0.018	0.724± 0.033

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

STUDY NO. : 0556
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (2W)

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	1.325± 0.054	0.295± 0.016	4.631± 0.197	2.071± 0.131
2500 ppm	5	1.298± 0.061	0.280± 0.019	4.850± 0.094	1.992± 0.103
5000 ppm	5	1.755± 1.020	0.359± 0.160	4.958± 0.342	1.972± 0.065
10000 ppm	5	1.868± 1.076	0.294± 0.021	4.649± 0.467	2.225± 0.115
20000 ppm	5	1.383± 0.060	0.315± 0.036	4.758± 0.275	2.093± 0.053
40000 ppm	5	1.397± 0.045	0.289± 0.019	4.857± 0.066	2.077± 0.110

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

APPENDIX L

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK DRINKING WATER STUDY OF 2-METHYL-1-PROPANOL

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2- WEEK DRINKING WATER STUDY OF 2-METHYL-1-PROPANOL

Item	Method	Unit	Decimal place
Hematology			
Red blood cell (RBC)	Light scattering method[1)]	$\times 10^6/\mu L$	2
Hemoglobin(Hgb)	Cyanmethemoglobin method [1)]	g/dL	1
Hematocrit(Hct)	Calculated as RBC×MCV/10 [1)]	%	1
Mean corpuscular volume(MCV)	Light scattering method [1)]	fL	1
Mean corpuscular hemoglobin(MCH)	Calculated as Hgb/RBC×10 [1)]	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as Hgb/Hct×100 [1)]	g/dL	1
Platelet	Light scattering method [1)]	$\times 10^3/\mu L$	0
Reticulocyte	Light scattering method [1)]	%	1
White blood cell(WBC)	Light scattering method [1)]	$\times 10^3/\mu L$	2
Biochemistry			
Total protein(TP)	Biuret method [2)]	g/dL	1
Albumin (Alb)	BCG method [2)]	g/dL	1
A/G ratio	Calculated as Alb/(TP−Alb) [2)]	−	1
T-bilirubin	Alkaline azobilirubin method [2)]	mg/dL	2
Glucose	GlcK·G-6-PDH method [2)]	mg/dL	0
T-cholesterol	CE·COD·POD method [2)]	mg/dL	0
Phospholipid	PLD·ChOD·POD method [2)]	mg/dL	0
Aspartate aminotransferase (AST)	JSCC method [2)]	IU/L	0
Alanine aminotransferase (ALT)	JSCC method [2)]	IU/L	0
Lactate dehydrogenase (LDH)	SFBC method [2)]	IU/L	0
γ-Glutamyl transpeptidase (γ-GTP)	JSCC method [2)]	IU/L	0
Creatine kinase (CK)	JSCC method [2)]	IU/L	0
Urea nitrogen	Urease·GLDH method [2)]	mg/dL	1
Sodium	Ion selective electrode method [2)]	mEq/L	0
Potassium	Ion selective electrode method [2)]	mEq/L	1
Chloride	Ion selective electrode method [2)]	mEq/L	0
Calcium	OCPC method [2)]	mg/dL	1
Inorganic phosphorus	PNP·XOD·POD method [2)]	mg/dL	1

1) Automatic blood cell analyzer (ADVIA120 : Bayer Corporation)

2) Automatic analyzer (Hitachi 7080 : Hitachi,Ltd.)