2-アミノエタノールのラットを用いた
経口投与による13週間毒性試験（混水試験）報告書

試験番号：0602

APPENDICES

APPENDICES

APPENDICES (CONTINUED)

APPENDIX A 1

IDENTITY OF 2-AMINOETHANOL

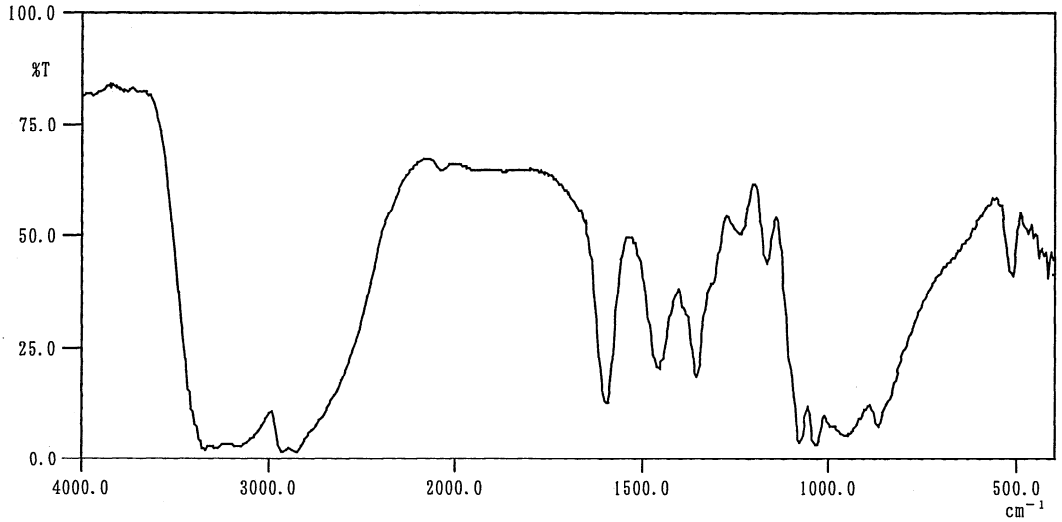
IN THE 13-WEEK DRINKING WATER STUDY

Infrared Spectrometry

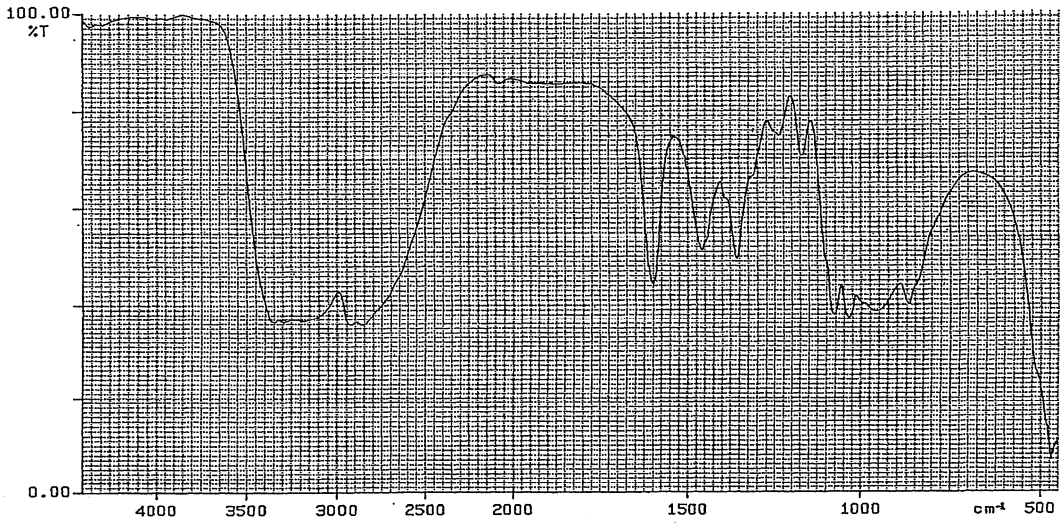
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

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. Conclusion: The test substance was identified as 2-aminoethanol by mass spectrum and infrared spectrum.

APPENDIX A 2

STABILITY OF 2-AMINOETHANOL IN THE 13-WEEK DRINKING WATER STUDY

STABILITY OF 2-AMINOETHANOL IN THE 13-WEEK DRINKING WATER STUDY

Test Substance : 2-Aminoethanol (Wako Pure Chemical Industries, Ltd.)

Lot No. : SDP0398

1. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Carbowax-20M + KOH 0.8% (2 mmϕ × 2 m)

Column Temperature: 190 °C

Flow Rate : 20 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μL

Date Analyzed	Peak No.	Retention Time (min)	Area (%)
2005.08.23	1	1.128	100
2005.12.22	1	1.126	100

Result: Gas chromatography indicated one major peak (peak No.1) analyzed on 2005.8.23 and one major peak (peak No.1) analyzed on 2005.12.22. No new trace impurity peak in the test substance analyzed on 2005.12.22 was detected.

2. Conclusion: The test substance was stable for the period that the test substance had been used for the study.

APPENDIX A 3

CONCENTRATION OF 2-AMINOETHANOL IN FORMULATED WATER IN THE 13-WEEK DRINKING WATER STUDY

CONCENTRATION OF 2-AMINOETHANOL IN FORMULATED WATER IN THE 13-WEEK DRINKING WATER STUDY

Analytical Method : The samples were analyzed by gas chromatography.

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Carbowax-20M + KOH 0.8% (2 mmϕ × 2 m)

Column Temperature: 190 °C

Flow Rate : 20 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μL

	Target Concentration				
Date Analyzed	625[a]	1250	2500	5000	10000
2005.09.08	608[b] (97.3)[c]	1230 (98.4)	2530 (101)	5010 (100)	9920 (99.2)

[a] ppm
[b] ppm (Mean measured concentration.)
[c] % (Mean measured concentration/target concentration × 100.)

APPENDIX A 4

STABILITY OF 2-AMINOETHANOL IN FORMULATED WATER IN THE 13-WEEK DRINKING WATER STUDY

STABILITY OF 2-AMINOETHANOL IN FORMULATED WATER IN THE 13-WEEK DRINKING WATER STUDY

Analytical Method : The samples were analyzed by gas chromatography.

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Carbowax-20M + KOH 0.8% (2 mmϕ × 2 m)

Column Temperature: 190 °C

Flow Rate : 20 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μL

	Target Concentration	
Date Analyzed	625[a]	10000
2005.08.12	610 (100)[b]	10200 (100)
2005.08.16[c]	617 (101)	10200 (100)

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

APPENDIX B 1

CLINICAL OBSERVATION : MALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Administration Week-day 1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	625 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	1250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	2500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	6	5	2	2	1	0	0	0	0	0	0	0	0
NON REMARKABLE	Control	10	10	10	10	10	10	10	10	10	10	10	10	10
	625 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	1250 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	2500 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	5000 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	10000 ppm	4	5	8	8	9	10	10	10	10	10	10	10	10

APPENDIX B 2

CLINICAL OBSERVATION : FEMALE

Clinical sign	Group Name	Administration Week-day 1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	625 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	1250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	2500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	1	0	0	0	0	0	0	0	0	0	0	0	0
SOILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	625 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	1250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	2500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	3	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	1	0	1	1	1	1	0	0	0	0
	625 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	1250 ppm	0	0	0	0	0	1	1	1	1	1	0	0	0
	2500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	10	10	6	4	2	1	1	1	1	1	0	0	0
SOILED PERI-GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	625 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	1250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	2500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	3	2	1	2	2	2	4	4	5	4	6	6	6
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	1	1
	625 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	1250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	2500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	625 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	1250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	2500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	2	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Administration Week-day 1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
NON REMARKABLE	Control	10	10	10	9	10	9	9	9	9	10	10	9	9
	625 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	1250 ppm	10	10	10	10	10	9	9	9	9	9	10	10	10
	2500 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	5000 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	10000 ppm	0	0	4	6	8	8	6	6	5	6	4	4	4

APPENDIX C 1

BODY WEIGHT CHANGES : MALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day 0-0	1-7	2-7	3-7	4-7	5-7	6-7
Control	126± 5	156± 7	185± 9	210± 11	229± 11	245± 12	259± 14
625 ppm	126± 6	153± 8	183± 12	206± 17	226± 17	241± 15	254± 16
1250 ppm	126± 6	154± 8	184± 9	208± 10	228± 9	244± 11	258± 13
2500 ppm	126± 5	153± 8	180± 9	204± 12	223± 13	239± 14	252± 16
5000 ppm	126± 6	152± 8	180± 13	204± 15	221± 17	238± 18	252± 18
10000 ppm	126± 6	138± 7**	164± 11**	184± 13**	202± 15**	216± 16**	227± 16**

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day 7-7	8-7	9-7	10-7	11-7	12-7	13-7
Control	271± 15	283± 17	293± 20	302± 20	310± 20	316± 19	322± 20
625 ppm	267± 16	279± 16	287± 16	297± 15	305± 15	310± 14	314± 15
1250 ppm	271± 12	283± 14	292± 15	301± 16	309± 18	315± 18	319± 18
2500 ppm	267± 16	277± 17	287± 17	298± 18	304± 17	311± 18	315± 18
5000 ppm	264± 20	275± 21	284± 20	293± 20	299± 20	305± 22	311± 22
10000 ppm	239± 17**	247± 16**	253± 18**	259± 19**	261± 21**	265± 23**	269± 24**

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

APPENDIX C 2

BODY WEIGHT CHANGES : FEMALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day 0-0	1-7	2-7	3-7	4-7	5-7	6-7
Control	99± 3	114± 4	125± 6	133± 8	137± 10	144± 12	146± 14
625 ppm	99± 3	113± 5	123± 6	132± 8	138± 8	144± 9	146± 9
1250 ppm	99± 3	115± 5	125± 6	135± 7	141± 8	147± 9	150± 10
2500 ppm	99± 3	113± 4	124± 4	132± 4	139± 5	146± 6	150± 6
5000 ppm	99± 3	111± 5	122± 5	130± 6	136± 6	142± 6	147± 6
10000 ppm	99± 3	98± 7**	111± 6**	122± 7**	128± 8*	131± 9*	136± 10

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day 7-7	8-7	9-7	10-7	11-7	12-7	13-7
Control	151± 15	153± 15	155± 15	159± 16	161± 17	164± 17	164± 18
625 ppm	149± 10	152± 11	154± 10	158± 11	161± 11	163± 11	163± 12
1250 ppm	155± 10	159± 11	162± 12	165± 12	168± 12	170± 14	171± 14
2500 ppm	154± 7	156± 7	159± 7	163± 7	167± 7	168± 8	168± 8
5000 ppm	151± 8	153± 8	156± 9	160± 10	163± 11	165± 11	167± 11
10000 ppm	139± 10	142± 10	145± 10	147± 9	150± 10	151± 10	153± 10

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

APPENDIX D 1

FOOD CONSUMPTION CHANGES : MALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

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	13.5± 0.6	14.9± 0.8	15.6± 1.1	15.7± 0.9	15.6± 1.3	15.0± 1.0	15.1± 0.9
625 ppm	13.5± 0.8	14.9± 1.1	15.6± 1.3	16.0± 1.4	15.5± 0.7	14.6± 1.0	15.0± 0.9
1250 ppm	13.1± 0.9	14.9± 0.8	15.3± 0.8	15.7± 0.5	14.9± 0.7	14.3± 0.7	14.8± 0.8
2500 ppm	12.7± 0.7	14.3± 0.6	14.9± 0.6	15.1± 0.6	14.7± 1.1	14.2± 1.0	14.8± 0.9
5000 ppm	12.4± 0.8**	13.9± 1.0	14.6± 1.0	15.1± 1.4	14.0± 1.1**	13.9± 1.1	14.3± 1.2
10000 ppm	10.3± 0.7**	13.1± 0.9**	13.7± 1.0**	14.2± 1.4*	13.0± 0.9**	12.6± 0.9**	12.9± 0.6**

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

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)
Control	15.0± 1.1	15.5± 1.2	15.3± 1.1	15.2± 1.6	15.3± 1.1	15.0± 1.2
625 ppm	15.0± 0.9	15.0± 0.7	15.2± 0.7	14.7± 0.7	14.8± 0.7	14.8± 0.6
1250 ppm	15.0± 1.0	15.0± 0.8	15.3± 0.8	14.9± 0.9	14.9± 0.8	14.8± 1.1
2500 ppm	14.6± 1.0	14.9± 1.3	14.8± 0.8	14.3± 0.9	14.5± 0.8	14.6± 0.8
5000 ppm	14.0± 0.8	14.0± 1.0*	13.9± 1.1*	14.0± 1.1	14.1± 1.1*	14.0± 1.1
10000 ppm	13.0± 0.9**	12.8± 0.9**	12.8± 0.9**	12.6± 1.0**	12.5± 0.9**	12.4± 1.1**

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

APPENDIX D 2

FOOD CONSUMPTION CHANGES : FEMALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

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	10.3± 0.6	10.4± 0.8	10.4± 0.9	10.0± 0.9	10.1± 1.1	9.9± 1.2	9.8± 1.1
625 ppm	9.9± 0.6	10.1± 0.8	10.3± 0.8	10.2± 0.7	9.9± 0.6	9.4± 0.6	9.4± 0.9
1250 ppm	10.5± 0.5	10.4± 0.5	10.7± 0.6	10.3± 0.8	10.3± 0.6	9.9± 0.7	10.0± 0.8
2500 ppm	9.9± 0.4	10.1± 0.4	10.0± 0.4	9.9± 0.4	10.0± 0.7	9.7± 0.8	9.8± 0.7
5000 ppm	9.3± 0.6**	9.8± 0.7	9.5± 0.6*	9.5± 0.5	9.6± 0.6	9.2± 0.4	9.0± 0.5
10000 ppm	6.9± 0.9**	9.2± 0.7**	9.3± 0.9**	9.0± 0.8**	8.6± 0.8**	8.1± 0.7**	8.3± 0.8**

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

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)
Control	9.6± 0.9	9.5± 1.1	9.9± 0.7	9.5± 1.0	9.3± 0.9	9.4± 0.9
625 ppm	9.1± 0.8	9.2± 0.8	9.4± 0.7	9.5± 0.6	9.3± 0.7	9.2± 0.9
1250 ppm	9.9± 0.9	9.4± 1.0	9.8± 0.8	9.5± 0.9	9.7± 1.0	9.5± 0.9
2500 ppm	9.5± 0.5	9.1± 0.7	9.7± 0.8	9.6± 0.7	9.3± 0.8	9.3± 0.8
5000 ppm	8.9± 0.6	8.9± 0.7	9.3± 0.6	9.2± 0.5	9.0± 0.6	9.1± 0.6
10000 ppm	8.1± 0.8**	8.0± 0.6**	8.3± 0.8**	8.2± 0.9**	8.0± 0.9**	8.2± 0.6**

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

APPENDIX E 1

WATER CONSUMPTION CHANGES : MALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

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	17.1± 0.6	18.3± 1.1	18.9± 0.9	19.7± 0.7	20.0± 4.5	19.1± 1.4	18.3± 1.1
625 ppm	17.2± 3.1	18.2± 2.2	20.1± 6.9	18.7± 2.2*	18.2± 2.3	17.4± 1.3**	17.8± 1.5
1250 ppm	16.1± 1.3	17.2± 1.2	17.5± 1.3**	17.9± 1.3**	16.8± 0.9**	16.6± 0.8**	16.8± 0.8*
2500 ppm	16.6± 4.3*	16.3± 0.7**	16.7± 1.0**	16.9± 0.7**	16.5± 1.2**	16.2± 1.1**	16.4± 1.1**
5000 ppm	13.8± 1.0**	14.2± 1.3**	15.0± 0.9**	15.2± 1.1**	14.7± 1.1**	14.3± 0.8**	14.2± 1.2**
10000 ppm	12.8± 1.2**	13.1± 1.8**	12.2± 1.5**	12.7± 1.3**	11.6± 0.9**	11.4± 0.8**	11.7± 1.2**

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective) 8-7(3)	9-7(3)	10-7(3)	11-7(3)	12-7(3)	13-7(3)
Control	18.2± 1.1	18.0± 1.7	18.5± 1.5	18.1± 1.6	18.0± 1.5	17.7± 1.1
625 ppm	17.1± 1.4	17.3± 1.0	18.4± 1.7	17.4± 0.7	17.2± 0.7	17.4± 1.2
1250 ppm	17.0± 1.0	17.2± 1.0	17.4± 1.3	16.8± 1.1*	16.8± 1.1	16.1± 1.1**
2500 ppm	16.1± 0.8**	16.3± 1.1**	16.7± 0.7*	16.0± 0.7**	16.4± 1.0*	15.9± 0.8**
5000 ppm	14.2± 1.3**	14.5± 1.1**	14.6± 1.0**	14.0± 0.9**	14.3± 1.0**	14.5± 0.8**
10000 ppm	11.3± 0.9**	11.1± 0.7**	11.8± 1.2**	11.3± 0.8**	11.5± 1.3**	11.2± 1.1**

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

APPENDIX E 2

WATER CONSUMPTION CHANGES : FEMALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

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	15.6± 1.1	18.3± 6.7	21.2± 11.7	18.4± 5.6	25.2± 13.6	20.9± 9.0	21.9± 12.4
625 ppm	14.9± 1.2	17.3± 4.4	20.7± 8.8	17.3± 6.4	17.4± 4.4	17.6± 3.8	17.7± 9.9
1250 ppm	17.3± 5.6	23.2± 13.7	23.8± 16.4	19.1± 7.8	19.7± 10.0	16.7± 5.3	19.7± 9.9
2500 ppm	14.7± 6.1**	16.8± 11.3	13.5± 1.8**	13.4± 2.6*	16.5± 8.8	15.6± 6.8	17.3± 8.9
5000 ppm	11.9± 3.2**	11.1± 0.9**	11.3± 1.0**	10.3± 0.5**	11.3± 2.8**	10.5± 0.7**	10.6± 1.0**
10000 ppm	10.0± 2.3**	9.8± 0.8**	9.6± 1.5**	9.0± 1.6**	8.9± 1.7**	8.8± 1.6**	8.2± 0.8**

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective) 8-7(3)	9-7(3)	10-7(3)	11-7(3)	12-7(3)	13-7(3)
Control	17.5± 8.4	16.9± 4.8	20.7± 5.8	16.6± 5.1	17.4± 3.6	15.8± 3.2
625 ppm	18.0± 7.7	17.6± 9.5	16.7± 4.3	15.9± 2.7	19.5± 7.8	18.3± 6.5
1250 ppm	19.8± 9.4	16.4± 4.6	20.5± 10.3	15.5± 2.3	16.6± 3.8	14.2± 1.1
2500 ppm	15.3± 9.0	12.7± 1.1*	17.6± 9.7*	14.7± 2.7	16.2± 5.1	13.9± 4.1
5000 ppm	10.1± 1.1**	10.4± 1.5**	10.8± 1.0**	11.0± 2.0**	10.7± 1.1**	9.9± 1.0**
10000 ppm	8.2± 1.1**	7.9± 1.4**	9.2± 2.3**	9.2± 2.5**	9.6± 5.1**	8.8± 2.0**

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

APPENDIX F 1

CHEMICAL INTAKE CHANGES : MALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : mg／kg／d a y
REPORT TYPE : A1 13
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration (weeks) 1		2		3		4		5		6		7	
Control	0±	0	0±	0	0±	0	0±	0	0±	0	0±	0	0±	0
625 ppm	70±	10	62±	5	60±	16	52±	4	47±	7	43±	3	42±	3
1250 ppm	131±	5	117±	5	105±	6	98±	7	87±	4	81±	3	78±	5
2500 ppm	272±	70	226±	10	205±	15	190±	9	173±	7	160±	9	153±	9
5000 ppm	455±	25	395±	17	370±	17	344±	8	310±	10	286±	14	267±	10
10000 ppm	927±	90	800±	98	665±	67	631±	47	537±	38	505±	33	492±	40

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : mg／kg／d a y
REPORT TYPE : A1 13
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration (weeks) 8		9		10		11		12		13	
Control	0±	0	0±	0	0±	0	0±	0	0±	0	0±	0
625 ppm	38±	4	38±	2	39±	4	36±	2	35±	2	35±	3
1250 ppm	75±	4	74±	3	72±	3	68±	3	67±	4	63±	4
2500 ppm	145±	5	142±	8	141±	6	132±	6	132±	9	126±	7
5000 ppm	257±	12	256±	13	249±	8	235±	14	235±	8	234±	12
10000 ppm	457±	31	438±	26	454±	29	434±	14	432±	26	416±	26

APPENDIX F 2

CHEMICAL INTAKE CHANGES : FEMALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : mg/kg/day
REPORT TYPE : A1 13
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration (weeks) 1		2		3		4		5		6		7	
Control	0±	0	0±	0	0±	0	0±	0	0±	0	0±	0	0±	0
625 ppm	83±	5	88±	23	98±	39	78±	25	75±	16	75±	14	74±	39
1250 ppm	189±	61	233±	143	222±	158	169±	66	168±	86	139±	48	160±	85
2500 ppm	325±	138	339±	232	256±	30	239±	39	282±	149	259±	104	279±	139
5000 ppm	535±	134	457±	35	433±	39	378±	20	399±	107	357±	23	352±	36
10000 ppm	1006±	182	885±	77	788±	93	701±	99	681±	108	647±	93	588±	47

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : mg／kg／d a y
REPORT TYPE : A1 13
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration (weeks) 8	9	10	11	12	13
Control	0± 0	0± 0	0± 0	0± 0	0± 0	0± 0
625 ppm	73± 28	71± 36	66± 15	62± 9	75± 28	70± 26
1250 ppm	157± 78	127± 39	156± 82	115± 20	123± 32	102± 7
2500 ppm	244± 139	199± 12	269± 143	221± 34	240± 70	206± 58
5000 ppm	329± 35	333± 54	336± 35	336± 59	324± 34	298± 23
10000 ppm	578± 53	544± 83	621± 135	606± 142	626± 312	571± 123

APPENDIX G 1

HEMATOLOGY : MALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV f ℓ	MCH p g	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	10	9.53± 0.31	16.2± 0.4	46.0± 1.1	48.2± 0.6	17.0± 0.2	35.4± 0.3	715± 39
625 ppm	10	9.51± 0.18	16.2± 0.2	45.8± 0.8	48.2± 0.5	17.0± 0.2	35.4± 0.2	718± 28
1250 ppm	10	9.45± 0.11	16.2± 0.3	45.5± 0.7	48.1± 0.4	17.1± 0.1	35.5± 0.2	725± 30
2500 ppm	10	9.52± 0.25	16.3± 0.4	45.8± 1.1	48.2± 0.7	17.1± 0.4	35.5± 0.4	732± 31
5000 ppm	10	9.31± 0.20	15.8± 0.3**	44.6± 0.8**	48.0± 0.5	16.9± 0.2	35.3± 0.3	705± 30
10000 ppm	10	8.94± 0.15**	15.4± 0.3**	43.4± 0.7**	48.5± 0.4	17.3± 0.2	35.5± 0.4	670± 50*

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

(HCL070)

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	RETICULOCYTE %	PROTHROMBIN TIME sec	APTT sec
Control	10	1.8± 0.2	13.4± 1.1	23.7± 0.9
625 ppm	10	1.8± 0.2	14.6± 2.0	25.0± 1.7
1250 ppm	10	1.7± 0.1	14.3± 1.5	24.6± 1.3
2500 ppm	10	1.7± 0.1	13.2± 1.1	23.3± 1.6
5000 ppm	10	1.7± 0.1	13.5± 1.0	23.6± 1.8
10000 ppm	10	1.8± 0.2	13.0± 0.8	22.9± 1.5

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	WBC $10^3/\mu\ell$	Differential WBC (%) N-BAND	N-SEG	EOSINO	BASO	MONO	LYMPHO	OTHER
Control	10	7.47± 1.28	0± 1	20± 4	1± 1	0± 0	3± 1	76± 4	0± 0
625 ppm	10	6.92± 1.33	0± 1	21± 3	1± 1	0± 0	3± 2	74± 3	0± 0
1250 ppm	10	7.10± 1.09	1± 1	19± 4	1± 1	0± 0	3± 2	76± 5	0± 0
2500 ppm	10	7.68± 1.38	0± 1	21± 6	1± 1	0± 0	3± 1	74± 7	0± 0
5000 ppm	10	7.04± 0.84	1± 1	20± 3	1± 1	0± 0	3± 2	75± 3	0± 0
10000 ppm	10	7.04± 1.23	0± 1	19± 2	1± 1	0± 0	3± 1	78± 3	0± 0

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

APPENDIX G 2

HEMATOLOGY : FEMALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV f ℓ	MCH p g	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	10	8.82± 0.19	16.1± 0.4	44.4± 1.0	50.3± 0.3	18.3± 0.2	36.3± 0.5	777± 56
625 ppm	10	8.81± 0.13	16.2± 0.3	44.6± 0.5	50.6± 0.4	18.4± 0.2	36.4± 0.4	778± 68
1250 ppm	10	8.67± 0.36	15.9± 0.7	43.9± 1.6	50.7± 0.4	18.3± 0.2	36.1± 0.4	752± 126
2500 ppm	10	8.66± 0.14	16.0± 0.3	43.8± 0.7	50.5± 0.6	18.4± 0.1	36.4± 0.4	772± 62
5000 ppm	10	8.56± 0.22*	15.8± 0.4	43.4± 1.2	50.8± 0.5	18.4± 0.1	36.3± 0.4	781± 48
10000 ppm	10	8.45± 0.20**	15.5± 0.4**	42.8± 0.8**	50.7± 0.4	18.3± 0.1	36.2± 0.3	713± 41

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

Group Name	NO. of Animals	RETICULOCYTE %	PROTHROMBIN TIME sec	APTT sec
Control	10	1.6± 0.2	11.9± 0.3	19.0± 1.4
625 ppm	10	1.6± 0.2	11.8± 0.4	18.8± 1.0
1250 ppm	10	1.6± 0.2	12.0± 0.4	18.6± 0.9
2500 ppm	10	1.6± 0.3	11.9± 0.3	18.6± 0.8
5000 ppm	10	1.7± 0.3	12.2± 0.3	19.1± 0.8
10000 ppm	10	2.0± 0.4*	12.2± 0.4	19.1± 0.8

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	WBC $10^3/\mu\ell$		Differential WBC (%) N-BAND		N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	10	4.39±	0.95	0±	0	17±	3	1±	1	0±	0	3±	1	79±	4	0±	0
625 ppm	10	3.94±	0.74	1±	1	19±	4	1±	1	0±	0	3±	1	77±	4	0±	0
1250 ppm	10	4.53±	0.98	0±	0	17±	3	1±	1	0±	0	3±	1	78±	3	0±	0
2500 ppm	10	4.52±	0.96	1±	1	15±	3	1±	1	0±	0	3±	1	80±	4	0±	0
5000 ppm	10	4.46±	1.01	1±	1	18±	4	1±	1	0±	0	3±	2	78±	5	0±	0
10000 ppm	10	5.12±	1.61	0±	0	16±	4	1±	1	0±	0	2±	1	80±	4	0±	1

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

APPENDIX H 1

BIOCHEMISTRY : MALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (14W)

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	10	6.5±	0.1	3.6±	0.1	1.3±	0.1	0.11±	0.01	181±	10	61±	5	63±	24
625 ppm	10	6.4±	0.1	3.6±	0.1	1.2±	0.1	0.11±	0.01	186±	17	50±	3**	45±	16
1250 ppm	10	6.4±	0.1	3.6±	0.1	1.3±	0.1	0.11±	0.01	188±	12	52±	5**	43±	11
2500 ppm	10	6.4±	0.2	3.6±	0.1	1.3±	0.1	0.10±	0.01	186±	12	53±	4**	40±	10
5000 ppm	10	6.3±	0.1**	3.5±	0.1**	1.3±	0.1	0.11±	0.01	183±	10	50±	4**	43±	13
10000 ppm	10	6.2±	0.1**	3.5±	0.1**	1.3±	0.1	0.11±	0.01	182±	9	52±	3**	39±	8

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (14W)

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	10	115±	7	77±	14	43±	7	161±	37	249±	12	1±	0	101±	13
625 ppm	10	99±	5**	79±	15	44±	9	158±	49	254±	24	1±	0	106±	18
1250 ppm	10	100±	6**	90±	16	48±	8	184±	66	248±	20	1±	1	104±	21
2500 ppm	10	101±	6**	96±	30	50±	11	211±	61	252±	22	1±	0	108±	15
5000 ppm	10	98±	5**	82±	17	44±	6	174±	55	248±	24	1±	0	102±	20
10000 ppm	10	97±	5**	99±	27	48±	10	188±	39	250±	20	1±	0	100±	13

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	UREA NITOROGEN mg/dl	CREATININE mg/dl	SODIUM mEq/ℓ	POTASSIUM mEq/ℓ	CHLORIDE mEq/ℓ	CALCIUM mg/dl	INORGANIC PHOSPHORUS mg/dl
Control	10	17.8± 1.0	0.5± 0.0	141± 1	3.4± 0.1	104± 1	10.3± 0.2	5.5± 0.9
625 ppm	10	17.4± 0.9	0.5± 0.0	141± 1	3.4± 0.2	104± 1	10.2± 0.1	5.7± 0.8
1250 ppm	10	17.9± 1.5	0.5± 0.0	141± 1	3.3± 0.2	104± 1	10.3± 0.2	5.8± 0.7
2500 ppm	10	18.9± 1.8	0.5± 0.0	140± 1	3.4± 0.2	104± 1	10.2± 0.2	5.5± 0.8
5000 ppm	10	19.2± 1.0	0.5± 0.0	140± 1	3.5± 0.2	103± 1	10.2± 0.1	5.7± 0.7
10000 ppm	10	22.1± 1.1**	0.5± 0.0	141± 1	3.6± 0.3	104± 1	10.1± 0.2	5.9± 0.4

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

APPENDIX H 2

BIOCHEMISTRY : FEMALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (14W)

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	10	6.2±	0.1	3.6±	0.1	1.4±	0.1	0.12±	0.01	146±	14	68±	6	12±	4
625 ppm	10	6.2±	0.2	3.6±	0.1	1.4±	0.1	0.11±	0.01	149±	10	62±	9	12±	3
1250 ppm	10	6.1±	0.2	3.5±	0.1	1.4±	0.1	0.12±	0.01	164±	20**	68±	4	18±	9
2500 ppm	10	6.0±	0.2	3.5±	0.0	1.4±	0.1	0.12±	0.01	149±	8	59±	5*	12±	2
5000 ppm	10	6.1±	0.2	3.5±	0.1	1.4±	0.1	0.12±	0.01	150±	9	60±	7*	13±	3
10000 ppm	10	5.8±	0.1**	3.4±	0.1**	1.4±	0.1	0.12±	0.01	155±	12	54±	6**	12±	4

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (14W)

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	10	128± 11	69± 6	30± 4	206± 56	181± 14	2± 1	111± 23
625 ppm	10	120± 16	73± 9	33± 5	200± 37	191± 26	2± 1	112± 19
1250 ppm	10	131± 10	84± 19	41± 13	217± 58	281± 117	1± 1	100± 24
2500 ppm	10	114± 9*	70± 5	30± 5	180± 38	191± 16	2± 1	102± 18
5000 ppm	10	118± 11	71± 9	30± 4	184± 42	189± 27	2± 1	98± 15
10000 ppm	10	107± 10**	75± 7	30± 4	205± 63	199± 14	2± 1	102± 18

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	UREA NITOROGEN mg/dl	CREATININE mg/dl	SODIUM mEq/ℓ	POTASSIUM mEq/ℓ	CHLORIDE mEq/ℓ	CALCIUM mg/dl	INORGANIC PHOSPHORUS mg/dl
Control	10	19.1± 2.4	0.5± 0.1	141± 2	3.5± 0.2	106± 2	9.9± 0.2	4.9± 1.4
625 ppm	10	18.8± 2.5	0.5± 0.1	141± 1	3.5± 0.2	107± 1	10.0± 0.2	4.9± 1.2
1250 ppm	10	17.3± 2.4	0.5± 0.0	141± 1	3.4± 0.3	106± 1	10.1± 0.2	4.3± 1.3
2500 ppm	10	18.4± 1.7	0.5± 0.0	141± 1	3.5± 0.3	107± 1	9.9± 0.2	5.0± 0.9
5000 ppm	10	20.8± 2.9	0.5± 0.1	140± 2	3.5± 0.2	105± 2**	9.9± 0.2	5.1± 1.1
10000 ppm	10	23.2± 2.8**	0.5± 0.0	140± 1	3.7± 0.2	105± 1	9.7± 0.2	5.2± 0.6

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

APPENDIX I 1

URINALYSIS : MALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	pH 5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	Protein −	±	+	2+	3+	4+	CHI	Glucose −	±	+	2+	3+	4+	CHI	Ketone body −	±	+	2+	3+	4+	CHI	Bilirubin −	+	2+	3+	CHI
Control	10	0	0	0	0	0	6	4		0	0	4	6	0	0		10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	
625 ppm	10	0	0	0	0	0	6	4		0	0	3	7	0	0		10	0	0	0	0	0		1	9	0	0	0	0		10	0	0	0	
1250 ppm	10	0	0	0	0	0	7	3		0	0	2	8	0	0		10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	
2500 ppm	10	0	0	0	0	0	6	4		0	0	0	10	0	0	*	10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	
5000 ppm	10	0	0	0	0	0	7	3		0	0	1	9	0	0		10	0	0	0	0	0		0	8	2	0	0	0		10	0	0	0	
10000 ppm	10	0	0	0	0	1	1	8		0	0	0	10	0	0	*	10	0	0	0	0	0		0	7	3	0	0	0		10	0	0	0	

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	Occult blood −	±	+	2+	3+	CHI	Urobilinogen ±	+	2+	3+	4+	CHI
Control	10	10	0	0	0	0		10	0	0	0	0	
625 ppm	10	10	0	0	0	0		10	0	0	0	0	
1250 ppm	10	10	0	0	0	0		10	0	0	0	0	
2500 ppm	10	10	0	0	0	0		10	0	0	0	0	
5000 ppm	10	10	0	0	0	0		10	0	0	0	0	
10000 ppm	10	10	0	0	0	0		10	0	0	0	0	

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

APPENDIX I 2

URINALYSIS : FEMALE

STUDY NO. : 0602 URINALYSIS
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

Group Name	NO. of Animals	pH 5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	Protein −	±	+	2+	3+	4+	CHI	Glucose −	±	+	2+	3+	4+	CHI	Ketone body −	±	+	2+	3+	4+	CHI	Bilirubin −	+	2+	3+	CHI
Control	10	0	0	1	0	0	5	4		0	1	8	1	0	0		10	0	0	0	0	0		3	7	0	0	0	0		10	0	0	0	
625 ppm	10	0	0	0	0	0	5	5		0	1	9	0	0	0		10	0	0	0	0	0		3	7	0	0	0	0		10	0	0	0	
1250 ppm	10	0	0	0	0	1	6	3		0	4	5	1	0	0		10	0	0	0	0	0		6	4	0	0	0	0		10	0	0	0	
2500 ppm	10	0	0	0	0	3	5	2		0	1	7	2	0	0		10	0	0	0	0	0		3	7	0	0	0	0		10	0	0	0	
5000 ppm	10	0	0	0	0	0	4	6		0	0	4	6	0	0		10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	
10000 ppm	10	0	0	0	0	1	1	8		0	0	3	7	0	0	*	10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	Occult blood −	±	+	2+	3+	CHI	Urobilinogen ±	+	2+	3+	4+	CHI
Control	10	10	0	0	0	0		10	0	0	0	0	
625 ppm	10	10	0	0	0	0		10	0	0	0	0	
1250 ppm	10	10	0	0	0	0		10	0	0	0	0	
2500 ppm	10	10	0	0	0	0		10	0	0	0	0	
5000 ppm	10	10	0	0	0	0		10	0	0	0	0	
10000 ppm	10	10	0	0	0	0		10	0	0	0	0	

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

APPENDIX J 1

GROSS FINDINGS : MALE : ALL ANIMALS

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

Organ	Findings	Group Name NO. of Animals	Control 10 (%)	625 ppm 10 (%)	1250 ppm 10 (%)	2500 ppm 10 (%)
liver	herniation		0 (0)	2 (20)	0 (0)	0 (0)

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

Organ	Findings	Group Name NO. of Animals	5000 ppm 10 (%)	10000 ppm 10 (%)
liver	herniation		0 (0)	1 (10)

APPENDIX J 2

GROSS FINDINGS : FEMALE : ALL ANIMALS

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

Organ	Findings	Group Name / NO. of Animals	Control 10 (%)	625 ppm 10 (%)	1250 ppm 10 (%)	2500 ppm 10 (%)
liver	herniation		2 (20)	0 (0)	1 (10)	2 (20)
eye	white		1 (10)	0 (0)	0 (0)	0 (0)

Organ	Findings	Group Name NO. of Animals	5000 ppm 10 (%)	10000 ppm 10 (%)
liver	herniation		0 (0)	2 (20)
eye	white		0 (0)	0 (0)

APPENDIX K 1

ORGAN WEIGHT, ABSOLUTE : MALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (14W)

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	300± 20	0.215± 0.031	0.050± 0.003	3.190± 0.082	0.898± 0.054	0.949± 0.064
625 ppm	10	297± 15	0.222± 0.017	0.049± 0.004	3.176± 0.096	0.882± 0.056	0.924± 0.039
1250 ppm	10	299± 17	0.237± 0.022	0.050± 0.004	3.171± 0.105	0.873± 0.045	0.938± 0.030
2500 ppm	10	295± 16	0.211± 0.023	0.047± 0.004	3.141± 0.146	0.866± 0.073	0.914± 0.037
5000 ppm	10	294± 20	0.211± 0.026	0.048± 0.003	3.060± 0.284	0.854± 0.106	0.926± 0.062
10000 ppm	10	257± 23**	0.189± 0.033	0.045± 0.003**	3.053± 0.121	0.781± 0.064**	0.860± 0.055**

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (14W)

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.872± 0.114	0.558± 0.046	7.339± 0.576	1.914± 0.058
625 ppm	10	1.854± 0.102	0.528± 0.035	7.184± 0.350	1.895± 0.051
1250 ppm	10	1.872± 0.105	0.535± 0.033	7.283± 0.563	1.905± 0.026
2500 ppm	10	1.863± 0.061	0.525± 0.026	7.141± 0.543	1.868± 0.059
5000 ppm	10	1.930± 0.146	0.525± 0.047	6.972± 0.416	1.884± 0.042
10000 ppm	10	1.807± 0.122	0.461± 0.046**	6.087± 0.551**	1.854± 0.049

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

APPENDIX K 2

ORGAN WEIGHT, ABSOLUTE : FEMALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (14W)

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	151± 17	0.169± 0.023	0.051± 0.004	0.102± 0.018	0.557± 0.069	0.672± 0.039
625 ppm	10	150± 12	0.161± 0.014	0.054± 0.005	0.100± 0.013	0.537± 0.056	0.661± 0.023
1250 ppm	10	165± 13	0.182± 0.020	0.052± 0.005	0.100± 0.019	0.567± 0.049	0.679± 0.034
2500 ppm	10	157± 8	0.177± 0.027	0.052± 0.004	0.100± 0.012	0.563± 0.020	0.682± 0.037
5000 ppm	10	157± 10	0.170± 0.018	0.053± 0.004	0.102± 0.010	0.581± 0.044	0.672± 0.038
10000 ppm	10	146± 10	0.155± 0.022	0.049± 0.005	0.094± 0.016	0.520± 0.046	0.622± 0.039*

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (14W)

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.074± 0.063	0.337± 0.020	3.563± 0.331	1.743± 0.047
625 ppm	10	1.081± 0.063	0.336± 0.023	3.613± 0.281	1.726± 0.065
1250 ppm	10	1.119± 0.080	0.357± 0.021	4.193± 0.649*	1.740± 0.053
2500 ppm	10	1.154± 0.061*	0.345± 0.015	3.728± 0.193	1.741± 0.038
5000 ppm	10	1.200± 0.064**	0.350± 0.014	3.641± 0.215	1.731± 0.048
10000 ppm	10	1.225± 0.060**	0.325± 0.039	3.384± 0.269	1.695± 0.046

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

APPENDIX L 1

ORGAN WEIGHT, RELATIVE : MALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (14W)

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	300± 20	0.072± 0.009	0.017± 0.001	1.068± 0.076	0.300± 0.013	0.317± 0.015
625 ppm	10	297± 15	0.075± 0.004	0.017± 0.002	1.073± 0.050	0.297± 0.015	0.312± 0.009
1250 ppm	10	299± 17	0.080± 0.008	0.017± 0.002	1.063± 0.043	0.293± 0.012	0.314± 0.012
2500 ppm	10	295± 16	0.072± 0.006	0.016± 0.001	1.068± 0.059	0.294± 0.021	0.311± 0.008
5000 ppm	10	294± 20	0.072± 0.007	0.016± 0.001	1.047± 0.115	0.291± 0.034	0.316± 0.013
10000 ppm	10	257± 23**	0.073± 0.008	0.018± 0.002	1.195± 0.107*	0.304± 0.015	0.336± 0.024

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (14W)

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.625± 0.021	0.186± 0.007	2.446± 0.056	0.640± 0.037
625 ppm	10	0.625± 0.018	0.178± 0.009	2.423± 0.053	0.640± 0.035
1250 ppm	10	0.627± 0.016	0.179± 0.006	2.435± 0.072	0.639± 0.033
2500 ppm	10	0.634± 0.021	0.179± 0.008	2.423± 0.084	0.635± 0.028
5000 ppm	10	0.658± 0.032*	0.179± 0.007	2.377± 0.071	0.644± 0.034
10000 ppm	10	0.705± 0.037**	0.179± 0.009	2.368± 0.084	0.726± 0.065**

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

APPENDIX L 2

ORGAN WEIGHT, RELATIVE : FEMALE

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (14W)

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	151± 17	0.112± 0.011	0.034± 0.004	0.068± 0.012	0.367± 0.015	0.447± 0.035
625 ppm	10	150± 12	0.108± 0.008	0.036± 0.004	0.067± 0.010	0.358± 0.025	0.442± 0.029
1250 ppm	10	165± 13	0.110± 0.006	0.032± 0.004	0.061± 0.012	0.345± 0.024	0.414± 0.023
2500 ppm	10	157± 8	0.113± 0.013	0.033± 0.003	0.064± 0.009	0.361± 0.020	0.436± 0.028
5000 ppm	10	157± 10	0.108± 0.007	0.034± 0.002	0.065± 0.006	0.370± 0.026	0.428± 0.018
10000 ppm	10	146± 10	0.106± 0.010	0.034± 0.003	0.065± 0.009	0.357± 0.033	0.427± 0.013

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

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (14W)

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.714± 0.044	0.224± 0.017	2.358± 0.067	1.163± 0.116
625 ppm	10	0.721± 0.030	0.225± 0.017	2.408± 0.063	1.155± 0.072
1250 ppm	10	0.681± 0.031	0.217± 0.009	2.539± 0.251	1.061± 0.070*
2500 ppm	10	0.738± 0.038	0.221± 0.008	2.382± 0.080	1.114± 0.061
5000 ppm	10	0.764± 0.051*	0.223± 0.010	2.316± 0.055	1.103± 0.051
10000 ppm	10	0.842± 0.039**	0.223± 0.019	2.320± 0.055	1.167± 0.066

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

APPENDIX M 1

HISTOPATHOLOGICAL FINDINGS :

NON-NEOPLASTIC LESIONS : MALE : ALL ANIMALS

STUDY NO. : 0602
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 14W)

Organ	Findings	Group Name	Control				625 ppm				1250 ppm				2500 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Circulatory system}																		
heart			<10>				<10>				<10>				<10>			
	inflammatory cell nest		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Digestive system}																		
liver			<10>				<10>				<10>				<10>			
	herniation		0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	necrosis:focal		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Urinary system}																		
kidney			<10>				<10>				<10>				<10>			
	eosinophilic body		8	2	0	0	8	2	0	0	8	2	0	0	7	3	0	0
			(80)	(20)	(0)	(0)	(80)	(20)	(0)	(0)	(80)	(20)	(0)	(0)	(70)	(30)	(0)	(0)
	hyaline cast		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

Organ	Findings	Group Name	5000 ppm				10000 ppm			
		No. of Animals on Study	10				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Circulatory system}										
heart			<10>				<10>			
	inflammatory cell nest		1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Digestive system}										
liver			<10>				<10>			
	herniation		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	necrosis:focal		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Urinary system}										
kidney			<10>				<10>			
	eosinophilic body		9	1	0	0	7	0	0	0
			(90)	(10)	(0)	(0)	(70)	(0)	(0)	(0)
	hyaline cast		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(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

Organ	Findings	Group Name / No. of Animals on Study / Grade	Control 10				625 ppm 10				1250 ppm 10				2500 ppm 10			
			1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
{Urinary system}																		
kidney			<10>				<10>				<10>				<10>			
	degeneration:papilla		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)
{Endocrine system}																		
pituitary			<10>				<10>				<10>				<10>			
	cyst		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Rathke pouch		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)
{Special sense organs/appendage}																		
Harder gl			<10>				<10>				<10>				<10>			
	lymphocytic infiltration		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	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

Organ	Findings	Group Name	5000 ppm				10000 ppm			
		No. of Animals on Study	10				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}										
kidney			<10>				<10>			
	degeneration:papilla		9	0	0	0 **	8	0	0	0 **
			(90)	(0)	(0)	(0)	(80)	(0)	(0)	(0)
{Endocrine system}										
pituitary			<10>				<10>			
	cyst		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	Rathke pouch		1	0	0	0	1	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Special sense organs/appendage}										
Harder gl			<10>				<10>			
	lymphocytic infiltration		1	0	0	0	0	0	0	0
			(10)	(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

APPENDIX M 2

HISTOPATHOLOGICAL FINDINGS :

NON-NEOPLASTIC LESIONS : FEMALE : ALL ANIMALS

Organ	Findings	Group Name	Control				625 ppm				1250 ppm				2500 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																		
bone marrow			<10>				<10>				<10>				<10>			
	granulation		0	0	0	0	1	0	0	0	1	0	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(10)	(0)	(0)
{Digestive system}																		
liver			<10>				<10>				<10>				<10>			
	herniation		2	0	0	0	0	0	0	0	1	0	0	0	2	0	0	0
			(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
pancreas			<10>				<10>				<10>				<10>			
	atrophy		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)
{Urinary system}																		
kidney			<10>				<10>				<10>				<10>			
	mineralization:cortico-medullary junction		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	mineralization:papilla		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(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

Organ	Findings	Group Name	5000 ppm				10000 ppm			
		No. of Animals on Study	10				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}										
bone marrow			<10>				<10>			
	granulation		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Digestive system}										
liver			<10>				<10>			
	herniation		0	0	0	0	2	0	0	0
			(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
pancreas			<10>				<10>			
	atrophy		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Urinary system}										
kidney			<10>				<10>			
	mineralization:cortico-medullary junction		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	mineralization:papilla		1	0	0	0	2	0	0	0
			(10)	(0)	(0)	(0)	(20)	(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

Organ	Findings	Group Name	Control				625 ppm				1250 ppm				2500 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney			<10>				<10>				<10>				<10>			
	degeneration:papilla		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)
{Special sense organs/appendage}																		
eye			<10>				<10>				<10>				<10>			
	cataract		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	iritis		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Harder gl			<10>				<10>				<10>				<10>			
	lymphocytic infiltration		1	0	0	0	1	0	0	0	2	1	0	0	2	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(20)	(10)	(0)	(0)	(20)	(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

Organ	Findings	Group Name	5000 ppm				10000 ppm			
		No. of Animals on Study	10				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}										
kidney			<10>				<10>			
	degeneration:papilla		5	0	0	0 *	10	0	0	0 **
			(50)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
{Special sense organs/appendage}										
eye			<10>				<10>			
	cataract		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	iritis		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Harder gl			<10>				<10>			
	lymphocytic infiltration		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

APPENDIX N

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 13-WEEK DRINKING WATER STUDY OF 2-AMINOETHANOL

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 13- WEEK DRINKING WATER STUDY OF 2-AMINOETHANOL

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
Prothrombin time	Quick one stage method[2)]	sec	1
Activated partial thromboplastin time(APTT)	Ellagic acid activated method[2)]	sec	1
White blood cell(WBC)	Light scattering method[1)]	$\times 10^3/\mu L$	2
Differential WBC	Pattern recognition method[3)] (Wright staining)	%	0
Biochemistry			
Total protein(TP)	Biuret method[4)]	g/dL	1
Albumin (Alb)	BCG method[4)]	g/dL	1
A/G ratio	Calculated as Alb/(TP−Alb)[4)]	−	1
T-bilirubin	Alkaline azobilirubin method[4)]	mg/dL	2
Glucose	GlcK·G-6-PDH method[4)]	mg/dL	0
T-cholesterol	CE·COD·POD method[4)]	mg/dL	0
Triglyceride	LPL·GK·GPO·POD method[4)]	mg/dL	0
Phospholipid	PLD·ChOD·POD method[4)]	mg/dL	0
Aspartate aminotransferase (AST)	JSCC method[4)]	IU/L	0
Alanine aminotransferase (ALT)	JSCC method[4)]	IU/L	0
Lactate dehydrogenase (LDH)	SFBC method[4)]	IU/L	0
Alkaline phosphatase (ALP)	GSCC method[4)]	IU/L	0
γ-Glutamyl transpeptidase (γ-GTP)	JSCC method[4)]	IU/L	0
Creatine kinase (CK)	JSCC method[4)]	IU/L	0
Urea nitrogen	Urease·GLDH method[4)]	mg/dL	1
Creatinine	Jaffe method[4)]	mg/dL	1
Sodium	Ion selective electrode method[4)]	mEq/L	0
Potassium	Ion selective electrode method[4)]	mEq/L	1
Chloride	Ion selective electrode method[4)]	mEq/L	0
Calcium	OCPC method[4)]	mg/dL	1
Inorganic phosphorus	PNP·XOD·POD method[4)]	mg/dL	1

1) Automatic blood cell analyzer (ADVIA120 : Bayer Corporation)
2) Automatic coagulometer (Sysmex CA-5000 : Sysmex Corporation)
3) Automatic blood cell differential analyzer (MICROX HEG-120NA : OMRON Corporation)
4) Automatic analyzer (Hitachi 7080 : Hitachi,Ltd.)