

2-アミノエタノールのラットを用いた  
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：0594

# APPENDICES

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2-AMINOETHANOL

## APPENDIX A 1

### IDENTITY OF 2-AMINOETHANOL IN THE 2-WEEK DRINKING WATER STUDY

## IDENTITY OF 2-AMINOETHANOL IN THE 2-WEEK DRINKING WATER STUDY

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

Lot No. : SDQ5459

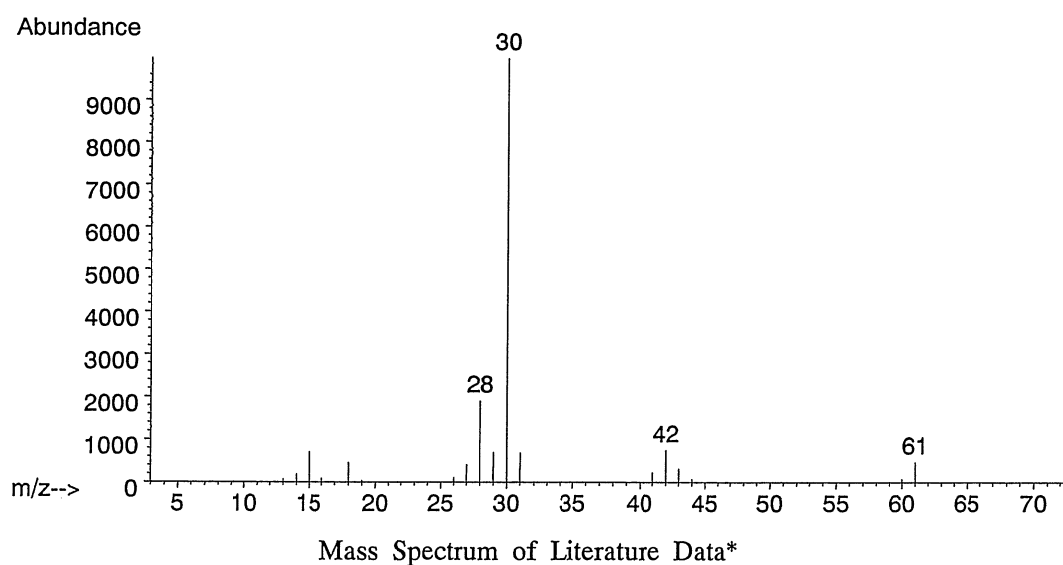
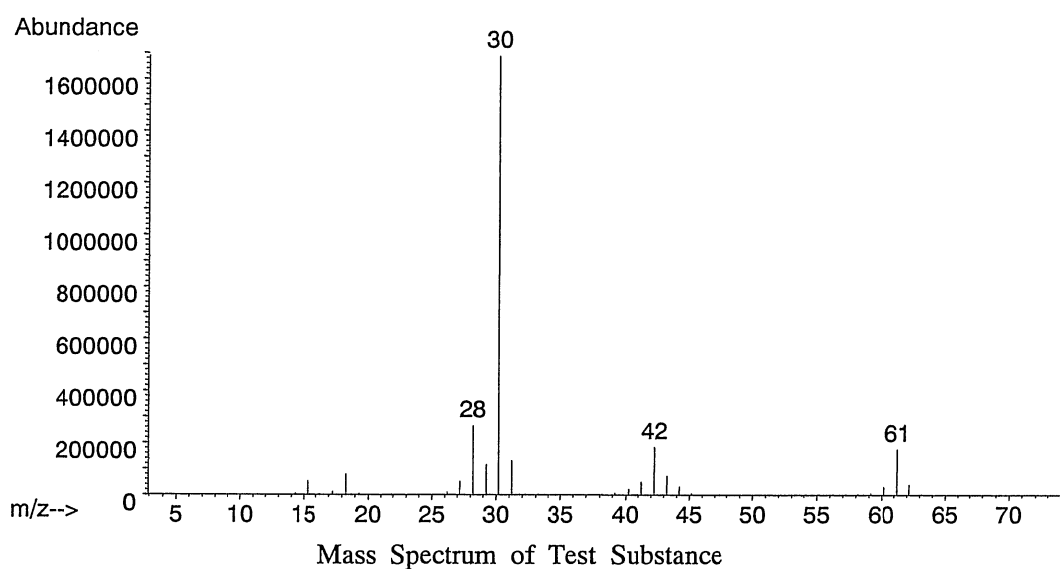
## 1. Spectral Data

Mass Spectrometry

Instrument : Hewlett Packard 5989B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Result: The mass spectrum was consistent with literature spectrum.

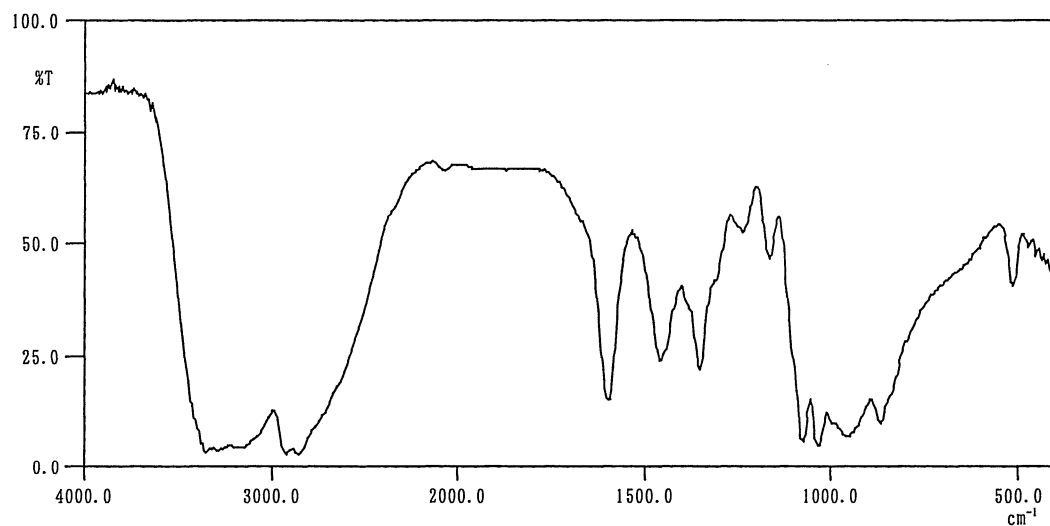
(\*McLafferty FW, ed. 1994. Wiley Registry of Mass Spectral Data. 6th ed.  
New York, NY : John Wiley and Sons.)

Infrared Spectrometry

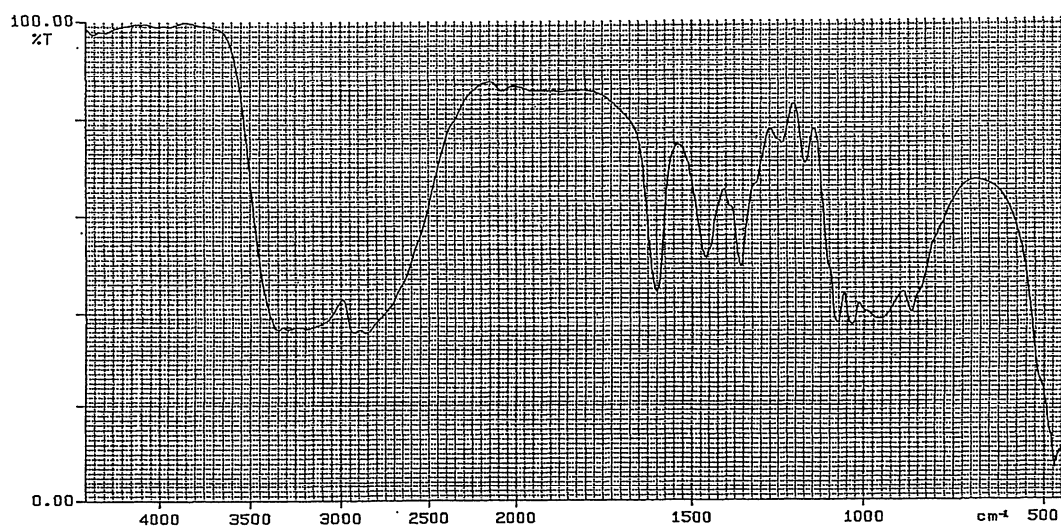
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 2  $\text{cm}^{-1}$



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 2-WEEK DRINKING WATER STUDY

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

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

Lot No. : SDQ5459

1. Sample : This lot was used from 2005.6.16 to 2005.6.30. Test substance was stored in a dark place at room temperature.

## 2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Carbowax-20M + KOH 0.8% (2 mm  $\phi$   $\times$  2 m)

Column Temperature : 190 °C

Flow Rate : 20 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1  $\mu$ L

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
2005.06.13	1	1.052	100
2005.07.11	1	1.062	100

Result: Gas chromatography indicated one major peak (peak No.1) analyzed on 2005.6.13 and one major peak (peak No.1) and analyzed on 2005.7.11. No new trace impurity peak in the test substance analyzed on 2005.7.11 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-AMINOETHANOL  
IN FORMULATED WATER IN THE 2-WEEK  
DRINKING WATER STUDY

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

Date Analyzed	Target Concentration				
	1250 <sup>a</sup>	2500	5000	10000	20000
2005.06.16	1230 ( 98.4) <sup>b</sup>	2480 ( 99.2)	5100 (102)	10000 (100)	20800 (104)

<sup>a</sup> ppm

<sup>b</sup> %

Analytical Method : The samples were analyzed by gas chromatography.

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Carbowax-20M + KOH 0.8% (2 mm  $\phi$   $\times$  2 m)

Column Temperature : 190 °C

Flow Rate : 20 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1  $\mu$ L

## APPENDIX A 4

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

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

Date Prepared	Date Analyzed	Target Concentration	
		1250 <sup>a</sup>	20000
2005.05.20	2005.05.20	1260 (100) <sup>b</sup>	20100 (100)
	2005.05.24 <sup>c</sup>	1240 ( 98.4)	20200 (100)

<sup>a</sup> ppm

<sup>b</sup> % (Percentage was based on the concentration on date of preparation.)

<sup>c</sup> Animal room samples

Analytical method : The samples were analyzed by gas chromatography.

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Carbowax-20M + KOH 0.8% (2 mm  $\phi$   $\times$  2 m)

Column Temperature : 190 °C

Flow Rate : 20 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1  $\mu$ L

## APPENDIX B 1

### CLINICAL OBSERVATION : MALE

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day			
		1-4	1-7	2-4	2-7
		1	1	1	1
DEATH	Control	0	0	0	0
	1250 ppm	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	0	0	0	0
	20000 ppm	0	0	0	1
SOILED	Control	0	0	0	0
	1250 ppm	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	1	0	0	0
	20000 ppm	0	4	4	4
PILOERECTION	Control	0	0	0	0
	1250 ppm	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	5	4	1	0
	20000 ppm	5	5	5	4
SOILED PERI-GENITALIA	Control	0	0	0	0
	1250 ppm	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	0	0	0	0
	20000 ppm	1	1	1	2
NOSE HEMORRHAGIC DISCHA	Control	0	0	0	0
	1250 ppm	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	0	0	0	0
	20000 ppm	0	0	0	3
SMALL STOOL	Control	0	0	0	0
	1250 ppm	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	0	0	0	0
	20000 ppm	1	5	5	4

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

PAGE : 2

Clinical sign	Group Name	Administration Week-day			
		1-4	1-7	2-4	2-7
		1	1	1	1
OLIGO-STOOL	Control	0	0	0	0
	1250 ppm	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	0	0	0	0
	20000 ppm	3	5	5	4
NON REMARKABLE	Control	5	5	5	5
	1250 ppm	5	5	5	5
	2500 ppm	5	5	5	5
	5000 ppm	5	5	5	5
	10000 ppm	0	1	4	5
	20000 ppm	0	0	0	0

(HAN190)

BAIS 4

## APPENDIX B 2

### CLINICAL OBSERVATION : FEMALE



STUDY NO. : 0594  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : FEMALE

PAGE : 3

Clinical sign	Group Name	Administration Week-day			
		1-4	1-7	2-4	2-7
		1	1	1	1
DEATH	Control	0	0	0	0
	1250 ppm	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	0	0	0	0
	20000 ppm	0	0	3	3
HUNCHBACK POSITION	Control	0	0	0	0
	1250 ppm	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	0	0	0	0
	20000 ppm	0	5	2	2
SOILED	Control	0	0	0	0
	1250 ppm	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	2	1	1	1
	20000 ppm	5	5	2	2
PILOERECTION	Control	0	0	0	0
	1250 ppm	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	5	5	5	5
	20000 ppm	5	5	2	2
SOILED PERI-GENITALIA	Control	0	0	0	0
	1250 ppm	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	2	3	3	2
	20000 ppm	2	5	2	2
NOSE HEMORRHAGIC DISCHA	Control	0	0	0	0
	1250 ppm	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	0	0	0	0
	20000 ppm	0	0	0	2

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 4

Clinical sign	Group Name	Administration Week-day			
		1-4	1-7	2-4	2-7
		1	1	1	1
SMALL STOOL	Control	0	0	0	0
	1250 ppm	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	1	1	1	0
	20000 ppm	5	5	2	1
OLIGO-STOOL	Control	0	0	0	0
	1250 ppm	0	0	0	0
	2500 ppm	0	0	0	0
	5000 ppm	0	0	0	0
	10000 ppm	0	0	0	0
	20000 ppm	1	5	2	1
NON REMARKABLE	Control	5	5	5	5
	1250 ppm	5	5	5	5
	2500 ppm	5	5	5	5
	5000 ppm	5	5	5	5
	10000 ppm	0	0	0	0
	20000 ppm	0	0	0	0

(HAN190)

BATS 4

## APPENDIX C 1

### BODY WEIGHT CHANGES : MALE

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 2  
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 1

Group Name	Administration		week-day							
	0-0		1-4		1-7		2-4		2-7	
Control	126±	4	144±	6	158±	7	176±	9	189±	10
1250 ppm	126±	3	141±	5	154±	7	170±	6	182±	8
2500 ppm	126±	3	142±	5	154±	7	168±	10	181±	11
5000 ppm	125±	5	139±	5	153±	6	169±	7	182±	6
10000 ppm	126±	3	122±	9**	135±	9**	151±	7**	161±	6**
20000 ppm	125±	4	106±	13**	90±	5**	86±	14**	97±	16**

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

Test of Dunnett

## APPENDIX C 2

### BODY WEIGHT CHANGES : FEMALE

STUDY NO. : 0594  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 2  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 2

Group Name	Administration		week-day							
	0-0		1-4		1-7		2-4		2-7	
Control	98±	3	106±	4	113±	5	119±	6	122±	7
1250 ppm	99±	3	107±	3	112±	3	118±	5	122±	5
2500 ppm	99±	3	106±	3	112±	5	119±	7	122±	7
5000 ppm	99±	3	105±	4	110±	4	118±	3	122±	3
10000 ppm	99±	3	90±	8**	99±	5**	107±	4**	111±	4*
20000 ppm	98±	3	74±	2**	63±	2**	66±	4 ?	74±	7 ?

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

Test of Dunnett

? : Significant test is not applied, because No. of data in this group is less than 3.

## APPENDIX D 1

### FOOD CONSUMPTION CHANGES : MALE

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 2  
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 1

Group Name	Administration week-day(effective)			
	1-4(4)	1-7(3)	2-4(4)	2-7(3)
Control	13.5± 0.9	14.2± 0.5	14.5± 0.9	15.3± 0.8
1250 ppm	12.8± 0.3	13.8± 0.3	13.9± 0.6	14.8± 1.2
2500 ppm	12.6± 1.0	13.5± 1.0	13.3± 2.1	14.7± 1.2
5000 ppm	12.1± 0.7*	13.2± 0.5	13.7± 0.6	14.6± 0.7
10000 ppm	9.1± 1.2**	11.7± 1.0**	12.7± 0.5	13.1± 0.4*
20000 ppm	5.6± 0.4**	4.0± 1.1**	5.7± 1.7**	8.1± 2.1**

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

Test of Dunnett



## APPENDIX D 2

### FOOD CONSUMPTION CHANGES : FEMALE

STUDY NO. : 0594  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 2  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day(effective)			
	1-4(4)	1-7(3)	2-4(4)	2-7(3)
Control	10.3± 1.0	10.9± 1.2	10.2± 1.1	10.1± 1.3
1250 ppm	10.4± 0.4	10.5± 0.8	10.3± 0.5	10.4± 0.7
2500 ppm	10.4± 0.4	10.5± 0.4	10.1± 1.0	10.1± 0.9
5000 ppm	9.6± 0.5	9.6± 0.4*	10.0± 0.4	9.7± 0.5
10000 ppm	6.4± 1.5	8.6± 0.5**	9.6± 0.9	9.5± 0.8
20000 ppm	3.8± 0.3**	2.7± 0.4**	5.1± 0.9 ?	7.3± 1.4 ?

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

Test of Dunnett

? : Significant test is not applied, because No. of data in this group is less than 3.

## APPENDIX E 1

### WATER CONSUMPTION CHANGES : MALE

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 2  
SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 1

Group Name	Administration		week-day(effective)			
	1-4(4)		1-7(3)		2-4(4)	2-7(3)
Control	16.9±	1.2	17.4±	1.1	17.8± 1.0	18.2± 1.2
1250 ppm	15.7±	0.9	16.1±	0.9	16.7± 1.5	16.7± 1.6
2500 ppm	15.2±	0.9	15.3±	1.1	14.9± 2.1	15.7± 0.9
5000 ppm	13.7±	0.7**	13.6±	0.5**	13.9± 0.7*	14.5± 0.5
10000 ppm	8.1±	1.9**	12.2±	1.4**	12.9± 2.1*	12.4± 1.1**
20000 ppm	2.5±	1.1**	3.5±	2.5**	6.7± 6.3**	11.7± 7.9*

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

Test of Dunnett

(HAN260)

BATS 4

## APPENDIX E 2

### WATER CONSUMPTION CHANGES : FEMALE

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 2  
SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 2

Group Name	Administration week-day(effective)			
	1-4(4)	1-7(3)	2-4(4)	2-7(3)
Control	13.5± 1.1	14.1± 1.0	13.5± 0.9	13.0± 1.6
1250 ppm	14.2± 0.8	15.8± 2.6	18.6± 7.2	23.8± 14.3
2500 ppm	13.3± 0.8	13.4± 1.1	14.6± 4.2	13.6± 3.3
5000 ppm	11.8± 0.8	11.4± 0.8	11.4± 0.7	11.1± 0.8
10000 ppm	6.7± 2.2*	10.8± 2.0	10.1± 1.6*	9.0± 1.0*
20000 ppm	1.7± 0.1**	1.3± 0.5**	6.5± 0.6 ?	8.4± 0.9 ?

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

Test of Dunnett

? : Significant test is not applied, because No. of data in this group is less than 3.

## APPENDIX F 1

### CHEMICAL INTAKE CHANGES : MALE

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : mg/kg/day  
REPORT TYPE : A1 2  
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 1

Group Name	Administration (Week-Day)							
	1-4		1-7		2-4		2-7	
Control	0±	0	0±	0	0±	0	0±	0
1250 ppm	139±	7	131±	6	122±	8	115±	8
2500 ppm	268±	9	248±	13	220±	23	218±	10
5000 ppm	494±	39	447±	10	410±	14	399±	13
10000 ppm	657±	122	908±	74	860±	172	770±	54
20000 ppm	487±	241	777±	526	1434±	1292	2345±	1442

(HAN300)

BAIS 4



## APPENDIX F 2

### CHEMICAL INTAKE CHANGES : FEMALE

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : mg/kg/d a y  
REPORT TYPE : A1 2  
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 2

Group Name	Administration (Week-Day)							
	1-4		1-7		2-4		2-7	
Control	0±	0	0±	0	0±	0	0±	0
1250 ppm	166±	5	177±	32	198±	80	245±	151
2500 ppm	312±	17	298±	21	307±	95	280±	75
5000 ppm	561±	30	516±	22	482±	26	456±	31
10000 ppm	726±	180	1095±	236	946±	152	809±	80
20000 ppm	470±	34	417±	149	1953±	67	2255±	33

(HAN300)

BAIS 4

## APPENDIX G 1

### HEMATOLOGY : MALE

STUDY NO. : 0594  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 MEASURE. TIME : 1  
 SEX : MALE

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS ( 2W)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 <sup>6</sup> /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 <sup>3</sup> /μl	
Control	5	7.73±	0.09	14.6±	0.2	41.5±	0.6	53.7±	0.1	18.8±	0.1	35.1±	0.1	859±	53
1250 ppm	5	7.72±	0.21	14.4±	0.3	41.1±	0.9	53.3±	0.5	18.7±	0.2	35.1±	0.5	840±	52
2500 ppm	5	7.78±	0.18	14.4±	0.4	41.3±	0.8	53.1±	0.2	18.5±	0.2	34.9±	0.3	832±	62
5000 ppm	5	7.70±	0.12	14.4±	0.2	40.7±	0.6	52.9±	0.3	18.7±	0.3	35.3±	0.3	848±	34
10000 ppm	5	7.86±	0.12	14.6±	0.2	41.2±	0.6	52.4±	0.3**	18.6±	0.1	35.4±	0.1	799±	50
20000 ppm	4	9.28±	1.01*	17.1±	2.0	48.8±	6.2	52.5±	1.0*	18.5±	0.2*	35.1±	0.4	456±	164**

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

Test of Dunnett

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
MEASURE. TIME : 1  
SEX : MALE

HEMATOLOGY (SUMMARY)  
ALL ANIMALS ( 2W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	RETICULOCYTE %	
Control	5	3.7±	0.2
1250 ppm	5	3.5±	0.5
2500 ppm	5	3.5±	0.3
5000 ppm	5	3.6±	0.2
10000 ppm	5	2.6±	0.2**
20000 ppm	4	0.3±	0.3**

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

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
MEASURE. TIME : 1  
SEX : MALE

HEMATOLOGY (SUMMARY)  
ALL ANIMALS ( 2W)

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl	
Control	5	5.40 ± 0.72	
1250 ppm	5	5.09 ± 0.76	
2500 ppm	5	4.78 ± 0.90	
5000 ppm	5	5.23 ± 1.20	
10000 ppm	5	4.76 ± 0.76	
20000 ppm	4	4.08 ± 0.26	

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

Test of Dunnett

(ICL070)

BAIS 4

## APPENDIX G 2

### HEMATOLOGY : FEMALE

STUDY NO. : 0594

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

## HEMATOLOGY (SUMMARY)

ALL ANIMALS ( 2W)

PAGE : 4

Group Name	NO. of Animals	RED BLOOD CELL 10 <sup>6</sup> /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 <sup>3</sup> /μl	
Control	5	8.28±	0.20	15.7±	0.4	43.3±	1.0	52.3±	0.5	18.9±	0.1	36.1±	0.3	786±	38
1250 ppm	5	8.41±	0.13	15.7±	0.3	43.8±	0.6	52.2±	0.3	18.7±	0.2	35.9±	0.3	781±	62
2500 ppm	5	8.10±	0.07	15.3±	0.2	42.4±	0.6	52.4±	0.3	18.9±	0.2	36.2±	0.1	793±	70
5000 ppm	5	8.19±	0.12	15.4±	0.1	42.9±	0.7	52.3±	0.3	18.8±	0.2	35.9±	0.3	731±	64
10000 ppm	5	8.18±	0.20	15.3±	0.3	42.4±	0.8	51.9±	0.4	18.7±	0.1	36.0±	0.2	708±	71
20000 ppm	2	9.06±	0.94 ?	17.1±	1.7 ?	47.8±	5.2 ?	52.8±	0.3 ?	18.9±	0.1 ?	35.7±	0.4 ?	485±	47 ?
Significant difference ; * : P ≤ 0.05      ** : P ≤ 0.01      Test of Dunnett															

? : Significant test is not applied, because No. of data in this group is less than 3.

(HCL070)

BATS 4



STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
MEASURE. TIME : 1  
SEX : FEMALE

HEMATOLOGY (SUMMARY)  
ALL ANIMALS ( 2W)

REPORT TYPE : A1

PAGE : 5

Group Name	NO. of Animals	RETICULOCYTE %	
Control	5	1.7±	0.3
1250 ppm	5	1.7±	0.2
2500 ppm	5	1.9±	0.3
5000 ppm	5	1.9±	0.2
10000 ppm	5	1.6±	0.3
20000 ppm	2	0.2±	0.1 ?

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

Test of Dunnett

? : Significant test is not applied, because No. of data in this group is less than 3.

(HCL070)

BATS 4

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
MEASURE. TIME : 1  
SEX : FEMALE

HEMATOLOGY (SUMMARY)  
ALL ANIMALS ( 2W)

REPORT TYPE : A1

PAGE : 6

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl	
Control	5	4.34±	0.76
1250 ppm	5	4.97±	0.97
2500 ppm	5	4.22±	0.72
5000 ppm	5	4.35±	1.17
10000 ppm	5	3.72±	0.93
20000 ppm	2	5.15±	0.04 ?

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

Test of Dunnett

? : Significant test is not applied, because No. of data in this group is less than 3.

(HCL070)

BATS 4

## APPENDIX H 1

GROSS FINDINGS : MALE :  
DEAD AND MORIBUND ANIMALS

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0- 2W)

PAGE : 1

Organ_____	Findings_____	Group Name NO. of Animals	Control	1250 ppm	2500 ppm	5000 ppm
			0 (%)	0 (%)	0 (%)	0 (%)
thymus	atrophic		- ( -)	- ( -)	- ( -)	- ( -)
	red zone		- ( -)	- ( -)	- ( -)	- ( -)

(HPT080)

BAIS 4

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0- 2W)

PAGE : 2

Organ	Findings	Group Name	10000 ppm	20000 ppm
		NO. of Animals	0 (%)	1 (%)
thymus	atrophic		- ( -)	1 (100)
	red zone		- ( -)	1 (100)

(IPT080)

BAIS 4

## APPENDIX H 2

GROSS FINDINGS : MALE :  
SACRIFICED ANIMALS

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr-j]  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 2W)

PAGE : 1

Organ	Findings	Group Name	Control	1250 ppm	2500 ppm	5000 ppm
		NO. of Animals	5 (%)	5 (%)	5 (%)	5 (%)
thymus	atrophic		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
liver	herniation		1 ( 20)	1 ( 20)	2 ( 40)	0 ( 0)

(HPT080)

BAIS 4

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 2W)

PAGE : 2

Organ	Findings	Group Name	10000 ppm	20000 ppm
		NO. of Animals	5 (%)	4 (%)
thymus	atrophic		0 ( 0)	3 ( 75)
liver	herniation		1 ( 20)	1 ( 25)

(HPT080)

BAIS 4



## APPENDIX H 3

GROSS FINDINGS : FEMALE :  
DEAD AND MORIBUND ANIMALS

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0- 2W)

PAGE : 3

Organ_____	Findings_____	Group Name	Control	1250 ppm	2500 ppm	5000 ppm
		NO. of Animals	0 (%)	0 (%)	0 (%)	0 (%)
thymus	atrophic		- ( -)	- ( -)	- ( -)	- ( -)
	red zone		- ( -)	- ( -)	- ( -)	- ( -)

(HPT080)

BAIS 4

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0- 2W)

PAGE : 4

Organ	Findings	Group Name	10000 ppm	20000 ppm
		NO. of Animals	0 (%)	3 (%)
thymus	atrophic		- ( -)	2 ( 67)
	red zone		- ( -)	3 (100)

(IPT080)

BAIS 4

## APPENDIX H 4

### GROSS FINDINGS : FEMALE : SACRIFICED ANIMALS

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 2W)

PAGE : 3

Organ_____	Findings_____	Group Name NO. of Animals	Control	1250 ppm	2500 ppm	5000 ppm
			5 (%)	5 (%)	5 (%)	5 (%)
thymus	atrophic		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
liver	herniation		0 ( 0)	1 ( 20)	1 ( 20)	1 ( 20)

(HPT080)

BAIS 4

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 2W)

PAGE : 4

Organ	Findings	Group Name	10000 ppm	20000 ppm
		NO. of Animals	5 (%)	2 (%)
thymus	atrophic		0 ( 0)	2 (100)
liver	herniation		1 ( 20)	0 ( 0)

(HPT080)

BAIS 4

## APPENDIX I 1

ORGAN WEIGHT, ABSOLUTE : MALE

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE  
UNIT: g

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

PAGE : 1

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	5	189± 10	0.368± 0.023	0.037± 0.002	2.412± 0.143	0.678± 0.019	0.809± 0.045
1250 ppm	5	182± 8	0.373± 0.018	0.038± 0.002	2.378± 0.120	0.686± 0.025	0.784± 0.040
2500 ppm	5	181± 11	0.346± 0.010	0.039± 0.002	2.370± 0.179	0.649± 0.034	0.798± 0.051
5000 ppm	5	182± 6	0.382± 0.011	0.038± 0.002	2.397± 0.171	0.649± 0.025	0.814± 0.034
10000 ppm	5	161± 6**	0.336± 0.021	0.037± 0.002	2.309± 0.127	0.590± 0.038**	0.721± 0.024**
20000 ppm	4	97± 16**	0.110± 0.063*	0.032± 0.003**	0.995± 0.376**	0.414± 0.066**	0.586± 0.026**
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Dunnett							

(HCL040)

BAIS 4



STUDY NO. : 0594  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr1j]  
 REPORT TYPE : A1  
 SEX : MALE  
 UNIT: g

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	5	1.400±	0.054	0.484±	0.034	7.614±	0.448	1.777±	0.035
1250 ppm	5	1.403±	0.034	0.466±	0.015	7.298±	0.483	1.758±	0.035
2500 ppm	5	1.401±	0.073	0.464±	0.029	7.237±	0.586	1.766±	0.041
5000 ppm	5	1.451±	0.102	0.475±	0.024	7.368±	0.529	1.755±	0.023
10000 ppm	5	1.426±	0.084	0.386±	0.008**	6.194±	0.343**	1.728±	0.029
20000 ppm	4	1.091±	0.097**	0.215±	0.032**	3.439±	0.777**	1.636±	0.040**

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

Test of Dunnett

(HCL040)

BAIS 4

## APPENDIX I 2

ORGAN WEIGHT, ABSOLUTE : FEMALE

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE  
UNIT: g

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

PAGE : 3

Group Name	NO. of Animals	Body Weight		THYMUS		ADRENALS		OVARIES		HEART		LUNGS	
Control	5	122±	7	0.298±	0.033	0.041±	0.005	0.081±	0.019	0.504±	0.028	0.643±	0.040
1250 ppm	5	122±	5	0.300±	0.025	0.043±	0.005	0.078±	0.015	0.489±	0.021	0.626±	0.025
2500 ppm	5	122±	7	0.295±	0.022	0.043±	0.006	0.084±	0.012	0.492±	0.037	0.649±	0.038
5000 ppm	5	122±	3	0.305±	0.020	0.041±	0.002	0.075±	0.009	0.480±	0.025	0.636±	0.041
10000 ppm	5	111±	4*	0.305±	0.026	0.039±	0.005	0.066±	0.011	0.459±	0.025	0.582±	0.047
20000 ppm	2	74±	7 ?	0.064±	0.021 ?	0.033±	0.005 ?	0.044±	0.001 ?	0.342±	0.001 ?	0.471±	0.012 ?

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

Test of Dunnett

? : Significant test is not applied, because No. of data in this group is less than 3.

(HCL040)

BAIS 4

STUDY NO. : 0594  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE  
 UNIT: g

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	5	1.004±	0.040	0.339±	0.020	4.380±	0.447	1.647±	0.055
1250 ppm	5	0.967±	0.036	0.327±	0.011	4.278±	0.498	1.647±	0.024
2500 ppm	5	1.016±	0.035	0.322±	0.020	4.485±	0.253	1.647±	0.018
5000 ppm	5	1.039±	0.043	0.331±	0.023	4.458±	0.191	1.633±	0.036
10000 ppm	5	1.083±	0.067*	0.298±	0.006**	3.991±	0.267	1.625±	0.031
20000 ppm	2	0.945±	0.003 ?	0.162±	0.005 ?	2.869±	0.380 ?	1.524±	0.026 ?

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

Test of Dunnett

? : Significant test is not applied,because No. of data in this group is less than 3.

(HCL040)

BAIS 4

## APPENDIX J 1

ORGAN WEIGHT, RELATIVE : MALE

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE  
UNIT: %

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

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	5	189± 10	0.195± 0.004	0.019± 0.002	1.278± 0.046	0.360± 0.015	0.429± 0.013
1250 ppm	5	182± 8	0.205± 0.012	0.021± 0.001	1.308± 0.027	0.378± 0.015	0.432± 0.020
2500 ppm	5	181± 11	0.192± 0.014	0.022± 0.002	1.311± 0.071	0.359± 0.009	0.442± 0.024
5000 ppm	5	182± 6	0.210± 0.010	0.021± 0.001	1.316± 0.052	0.357± 0.006	0.447± 0.011
10000 ppm	5	161± 6**	0.209± 0.020	0.023± 0.002*	1.433± 0.073*	0.366± 0.016	0.447± 0.024
20000 ppm	4	97± 16**	0.108± 0.046	0.033± 0.005**	1.008± 0.248	0.428± 0.014**	0.619± 0.109**

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

Test of Dunnett

(HCL042)

BAIS 4

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE  
UNIT: %

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	0.742± 0.018	0.256± 0.008	4.032± 0.052	0.943± 0.033
1250 ppm	5	0.773± 0.037	0.257± 0.010	4.012± 0.152	0.969± 0.057
2500 ppm	5	0.775± 0.023	0.257± 0.009	4.002± 0.210	0.979± 0.054
5000 ppm	5	0.797± 0.039	0.261± 0.004	4.046± 0.203	0.965± 0.024
10000 ppm	5	0.884± 0.045**	0.240± 0.008*	3.841± 0.130	1.073± 0.036*
20000 ppm	4	1.138± 0.083**	0.223± 0.014**	3.529± 0.215**	1.729± 0.304**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett					

(HCL042)

BAIS 4

## APPENDIX J 2

ORGAN WEIGHT, RELATIVE : FEMALE



STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE  
UNIT: %

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

PAGE : 3

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	5	122± 7	0.244± 0.022	0.033± 0.003	0.067± 0.013	0.413± 0.016	0.527± 0.017
1250 ppm	5	122± 5	0.247± 0.019	0.035± 0.004	0.064± 0.011	0.401± 0.009	0.515± 0.029
2500 ppm	5	122± 7	0.243± 0.027	0.035± 0.005	0.069± 0.009	0.405± 0.015	0.534± 0.015
5000 ppm	5	122± 3	0.251± 0.018	0.034± 0.001	0.061± 0.007	0.394± 0.013	0.522± 0.022
10000 ppm	5	111± 4*	0.275± 0.017	0.035± 0.004	0.059± 0.009	0.414± 0.022	0.524± 0.030
20000 ppm	2	74± 7 ?	0.086± 0.021 ?	0.045± 0.011 ?	0.060± 0.004 ?	0.464± 0.042 ?	0.640± 0.077 ?

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

Test of Dunnett

? : Significant test is not applied, because No. of data in this group is less than 3.

STUDY NO. : 0594  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE  
UNIT: %

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	0.824± 0.029	0.278± 0.011	3.589± 0.274	1.353± 0.072
1250 ppm	5	0.794± 0.014	0.269± 0.005	3.506± 0.298	1.354± 0.055
2500 ppm	5	0.837± 0.024	0.265± 0.002	3.690± 0.145	1.358± 0.076
5000 ppm	5	0.853± 0.032	0.272± 0.013	3.659± 0.076	1.341± 0.047
10000 ppm	5	0.976± 0.043**	0.268± 0.007	3.595± 0.193	1.465± 0.036*
20000 ppm	2	1.283± 0.126 ?	0.219± 0.014 ?	3.870± 0.144 ?	2.070± 0.233 ?
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett					

? : Significant test is not applied,because No. of data in this group is less than 3.

## APPENDIX K

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

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

Item	Method	Unit	Decimal place
<b>Hematology</b>			
Red blood cell (RBC)	Light scattering method <sup>1)</sup>	$\times 10^6/\mu\text{L}$	2
Hemoglobin(Hgb)	Cyanmethemoglobin method <sup>1)</sup>	g/dL	1
Hematocrit(Hct)	Calculated as $\text{RBC} \times \text{MCV} / 10$ <sup>1)</sup>	%	1
Mean corpuscular volume(MCV)	Light scattering method <sup>1)</sup>	fL	1
Mean corpuscular hemoglobin(MCH)	Calculated as $\text{Hgb} / \text{RBC} \times 10$ <sup>1)</sup>	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as $\text{Hgb} / \text{Hct} \times 100$ <sup>1)</sup>	g/dL	1
Platelet	Light scattering method <sup>1)</sup>	$\times 10^3/\mu\text{L}$	0
Reticulocyte	Light scattering method <sup>1)</sup>	%	1
White blood cell(WBC)	Light scattering method <sup>1)</sup>	$\times 10^3/\mu\text{L}$	2

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