

2-メチル-1-プロパ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：0571

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APPENDIX A 1

IDENTITY AND IMPURITY OF 2-METHYL-1-PROPANOL IN THE 13-WEEK DRINKING WATER STUDY

IDENTITY AND IMPURITY OF 2-METHYL-1-PROPANOL IN THE 13-WEEK DRINKING WATER STUDY

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

Lot No. : KLH5528

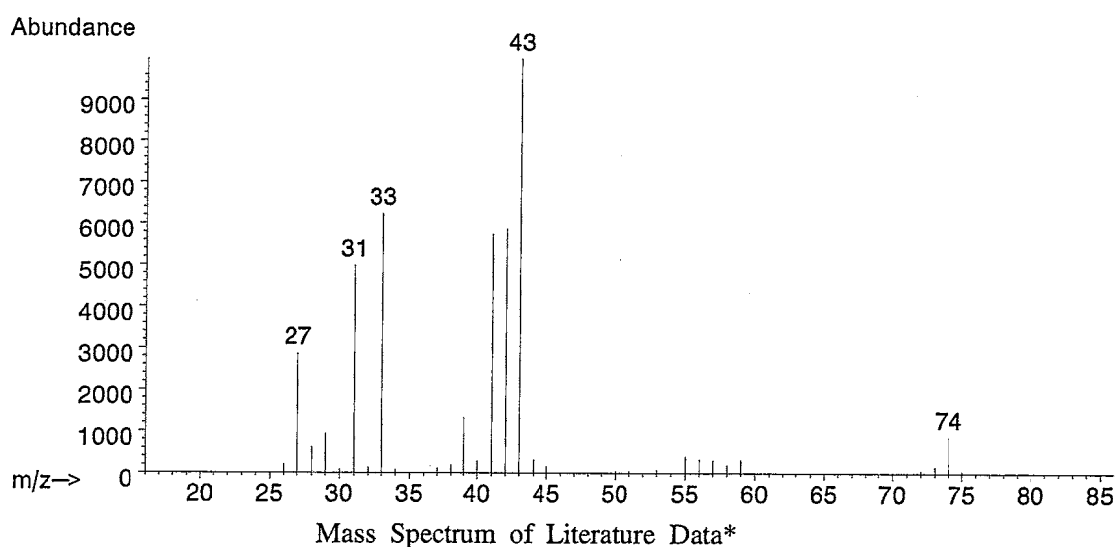
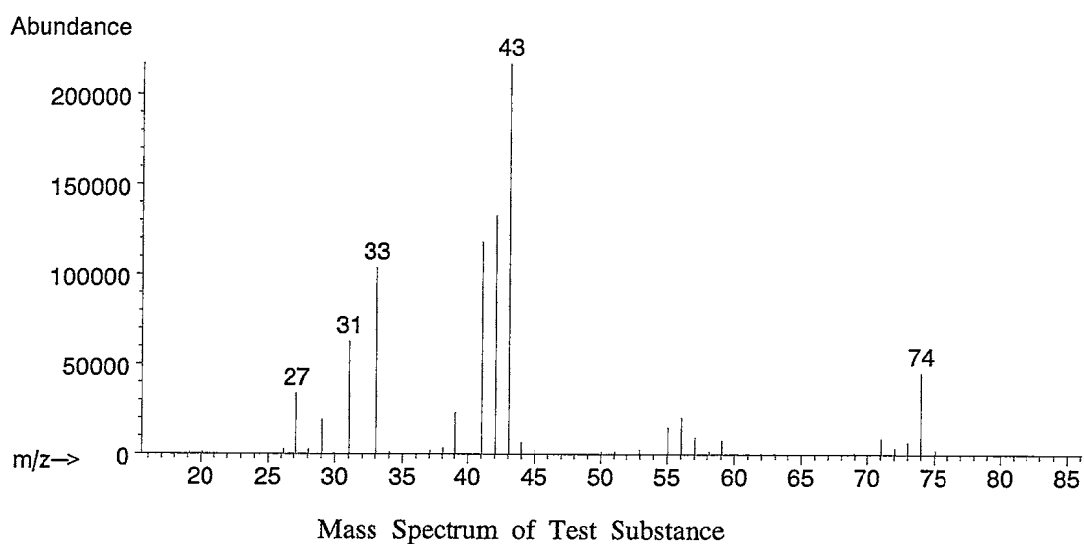
1. Spectral Data

Mass Spectrometry

Instrument : Hewlett Packard 5989B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Result: The mass spectrum was consistent with literature spectrum.

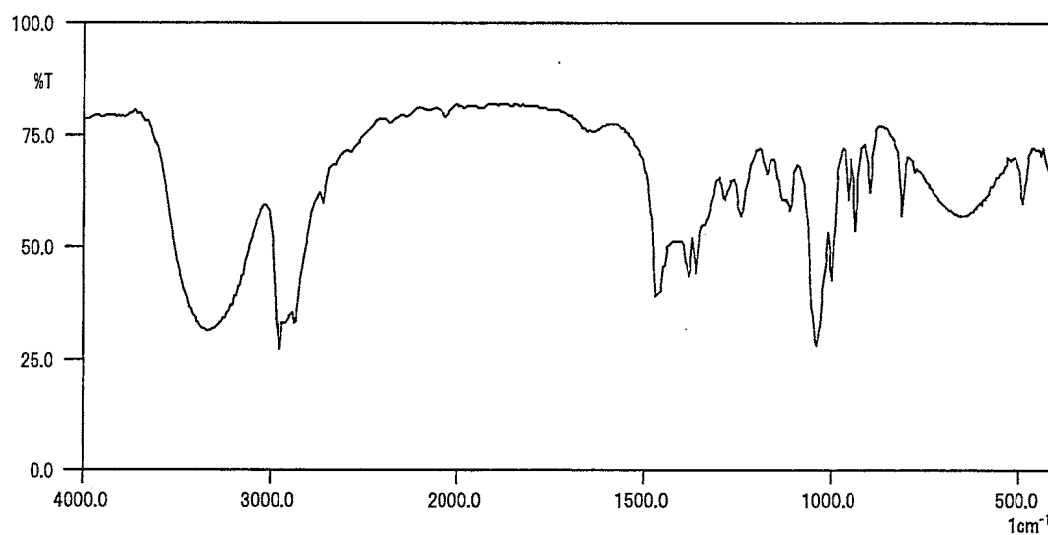
(*McLafferty FW, ed. 1994. Wiley Registry of Mass Spectral Data. 6th ed.
New York, NY : John Wiley and Sons.)

Infrared Spectrometry

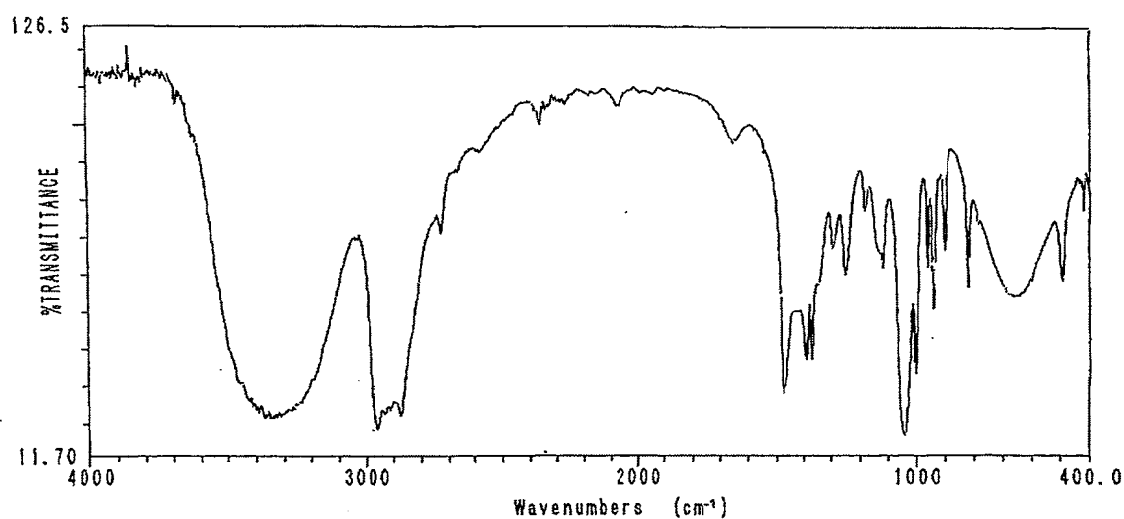
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 2 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 mm ϕ \times 50 m)
Column Temperature : 80 °C (1 min) \rightarrow (10 °C/min) \rightarrow 200 °C
Flow Rate : 1 mL/min
Detector : FID (Flame Ionization Detector)
Injection Volume : 1 μ L

Sample Name	Peak No.	Area (%)	Peak Name
Test Substance	1	0.026	Diisobutyl ether
	2	99.935	2-Methyl-1-propanol
	3	0.039	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 0.026% (The quantity value by the standard sample was 0.025%.) for diisobutyl ether and 0.039% (The quantity value by the standard sample was 0.039%.) 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 13-WEEK DRINKING WATER STUDY

STABILITY OF 2-METHYL-1-PROPANOL IN THE 13-WEEK DRINKING WATER STUDY

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

Lot No. : KLH5528

1. Sample : This lot was used from 2005.1.17 to 2005.4.20. Test substance was stored in a dark place at room temperature.

2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : INNOWAX (0.2 mm ϕ \times 50 m)

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

Flow Rate : 1 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
2005.01.13	1	3.743	0.026
	2	5.229	99.935
	3	5.559	0.039
2005.05.11	1	3.743	0.026
	2	5.232	99.935
	3	5.560	0.039

Result: Gas chromatography indicated one major peak (peak No.2) and two impurities (peak No.1 and No.3 < 0.1% of total area) analyzed on 2005.1.13 and one major peak (peak No.2) and two impurities (peak No.1 and No.3 < 0.1% of total area) analyzed on 2005.5.11. No new trace impurity peak in the test substance analyzed on 2005.5.11 was detected.

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

APPENDIX A 3

CONCENTRATION OF 2-METHYL-1-PROPANOL IN FORMULATED WATER IN THE 13-WEEK DRINKING WATER STUDY

CONCENTRATION OF 2-METHYL-1-PROPANOL IN FORMULATED WATER IN THE 13-WEEK DRINKING WATER STUDY

Date Analyzed	Target Concentration				
	2500 ^a	5000	10000	20000	40000
2005.01.17	2450 (98.0) ^b	4810 (96.2)	10100 (101)	19900 (99.5)	41800 (105)

^a ppm

^b %

Analytical method : The samples were analyzed by gas chromatography.

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : INNOWAX (0.2 mm ϕ \times 50 m)

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

Flow Rate : 1 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

APPENDIX A 4

STABILITY OF 2-METHYL-1-PROPANOL IN FORMULATED WATER

STABILITY OF 2-METHYL-1-PROPANOL IN FORMULATED WATER

Date Prepared	Date Analyzed	Target Concentration	
		2500 ^a	40000
2004.08.12	2004.08.12	2450 (100) ^b	40800 (100)
	2004.08.16 ^c	2250 (91.8)	38300 (93.9)

^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 mm ϕ \times 50 m)

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

Flow Rate : 1 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

APPENDIX B 1

CLINICAL OBSERVATION : MALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 1

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
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	2500 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1
	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
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	40000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
NON REMARKABLE	Control	10	10	10	10	10	10	10	10	10	10	10	10	10
	2500 ppm	10	10	9	9	9	9	9	9	9	9	9	9	9
	5000 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	10000 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	20000 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	40000 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10

(HAN190)

BAIS 4

APPENDIX B 2

CLINICAL OBSERVATION : FEMALE

STUDY NO. : 0571
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 2

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
SOILED PERI-GENITALIA	Control	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
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	40000 ppm	0	0	0	0	0	2	0	0	0	0	0	0	1
NON REMARKABLE	Control	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	10	10	10	10	10	10	10	10	10	10	10	10	10
	20000 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	40000 ppm	10	10	10	10	10	8	10	10	10	10	10	10	9

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APPENDIX C 1

BODY WEIGHT CHANGES : MALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration week		1		2		3		4		5		6	
	0													
Control	129±	4	163±	8	195±	10	219±	12	239±	14	254±	15	265±	15
2500 ppm	129±	4	164±	5	199±	5	225±	7	244±	6	260±	8	267±	8
5000 ppm	129±	4	163±	5	197±	8	222±	9	240±	9	256±	10	264±	10
10000 ppm	129±	4	161±	6	195±	6	221±	6	240±	7	257±	9	269±	9
20000 ppm	129±	4	160±	7	191±	9	215±	9	236±	10	251±	11	263±	12
40000 ppm	129±	4	156±	7	187±	9	213±	9	233±	8	250±	8	259±	7

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

Test of Dunnett

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STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week						
	7	8	9	10	11	12	13
Control	280± 16	291± 18	298± 18	304± 21	312± 22	319± 23	326± 24
2500 ppm	282± 7	295± 8	303± 8	312± 7	319± 9	327± 10	335± 10
5000 ppm	278± 12	289± 13	299± 15	306± 14	315± 15	324± 15	332± 15
10000 ppm	279± 10	289± 10	297± 13	307± 12	314± 13	320± 13	327± 12
20000 ppm	272± 13	283± 14	291± 13	300± 12	308± 13	316± 13	321± 12
40000 ppm	271± 8	280± 8	286± 9	294± 9	301± 9	307± 12	313± 13
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							

(HAN260)

BAIS 4

APPENDIX C 2

BODY WEIGHT CHANGES : FEMALE

STUDY NO. : 0571
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 3

Group Name	Administration week		1		2		3		4		5		6	
	0													
Control	98±	3	114±	4	125±	5	134±	5	140±	7	147±	6	151±	6
2500 ppm	98±	3	114±	5	127±	5	137±	7	143±	9	150±	9	155±	10
5000 ppm	98±	3	114±	4	126±	5	134±	9	143±	6	150±	5	154±	5
10000 ppm	98±	3	113±	3	125±	4	136±	6	144±	6	152±	7	155±	6
20000 ppm	98±	3	114±	3	129±	5	139±	6	147±	7	152±	8	156±	8
40000 ppm	98±	3	112±	4	126±	7	136±	7	142±	6	147±	6	153±	7

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

Test of Dunnett

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BAIS 4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week		7		8		9		10		11		12		13	
Control	156±	5	157±	6	161±	6	163±	7	166±	9	169±	7	171±	7		
2500 ppm	160±	9	163±	10	166±	11	170±	12	173±	11	176±	12	177±	10		
5000 ppm	158±	5	161±	5	164±	5	167±	6	172±	5	174±	6	175±	6		
10000 ppm	159±	7	164±	8	166±	7	170±	9	174±	8	177±	7	178±	8		
20000 ppm	161±	9	165±	10	168±	10	172±	10	176±	10	179±	10	180±	10		
40000 ppm	159±	10	161±	10	163±	10	167±	9	169±	7	173±	8	175±	7		
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett																

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APPENDIX D 1

FOOD CONSUMPTION CHANGES : MALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration week						
	1	2	3	4	5	6	7
Control	14.3± 0.8	15.7± 0.9	16.5± 0.9	16.2± 0.9	15.9± 1.0	15.3± 0.9	15.4± 1.4
2500 ppm	14.1± 0.4	15.7± 0.4	16.1± 0.7	15.9± 0.7	15.8± 0.6	15.1± 0.6	15.7± 0.5
5000 ppm	13.8± 1.0	15.3± 0.7	15.3± 0.7**	15.3± 0.5*	15.3± 0.7	14.4± 0.8*	15.1± 1.1
10000 ppm	13.3± 0.7*	14.8± 0.7*	15.3± 0.6**	15.0± 0.7**	15.0± 0.7	14.6± 0.7	14.6± 0.7
20000 ppm	12.7± 0.8**	14.2± 0.9**	14.5± 0.8**	14.5± 0.8**	14.4± 0.7**	14.2± 0.8**	14.0± 0.6
40000 ppm	11.1± 0.6**	13.0± 0.6**	13.4± 0.5**	13.4± 0.4**	13.7± 0.9**	13.3± 0.5**	13.0± 0.5**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							

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BAIS 4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week					
	8	9	10	11	12	13
Control	15.5± 1.2	15.4± 1.0	15.5± 1.2	15.0± 1.4	15.2± 1.4	15.7± 1.5
2500 ppm	15.6± 0.4	15.6± 0.5	15.7± 0.5	15.3± 0.6	15.1± 0.8	15.8± 0.8
5000 ppm	15.3± 1.0	15.2± 1.1	14.9± 0.9	15.1± 0.9	15.0± 1.0	15.3± 0.9
10000 ppm	15.0± 0.7	15.0± 1.0	14.6± 0.6	14.7± 0.8	14.3± 0.8	14.8± 0.8
20000 ppm	14.4± 0.8	14.5± 0.6	14.2± 0.6	14.4± 1.0	14.1± 0.6*	14.3± 0.6**
40000 ppm	13.3± 0.6**	13.4± 0.5**	13.2± 0.4**	13.2± 0.6**	12.9± 0.8**	13.4± 0.8**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett						

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APPENDIX D 2

FOOD CONSUMPTION CHANGES : FEMALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week						
	1	2	3	4	5	6	7
Control	10.5± 0.5	10.4± 0.7	10.4± 0.6	10.4± 0.7	10.2± 0.7	10.0± 0.6	10.0± 0.5
2500 ppm	10.6± 0.6	10.7± 0.7	10.8± 0.7	10.6± 0.6	10.4± 0.6	10.1± 0.6	10.2± 0.7
5000 ppm	10.2± 0.6	10.4± 0.6	10.4± 0.9	10.4± 0.4	10.2± 0.3	9.8± 0.4	9.7± 0.4
10000 ppm	9.8± 0.4*	10.0± 0.6	10.2± 0.7	10.3± 0.7	9.9± 0.7	9.6± 0.5	9.6± 0.9
20000 ppm	9.5± 0.5**	9.9± 0.5	9.8± 0.5	9.7± 0.5*	9.4± 0.7**	9.1± 0.8**	9.2± 0.7
40000 ppm	8.7± 0.4**	9.1± 0.6**	9.3± 0.5**	9.1± 0.3**	8.6± 0.6**	8.5± 0.6**	9.0± 0.8**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							

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BAIS 4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week					
	8	9	10	11	12	13
Control	9.8± 0.6	9.7± 0.7	9.7± 0.6	9.7± 1.1	9.9± 0.7	10.1± 0.7
2500 ppm	10.1± 0.7	9.9± 0.6	10.1± 0.7	10.2± 0.6	10.2± 0.9	10.3± 0.4
5000 ppm	9.6± 0.5	9.8± 0.5	9.8± 0.4	9.9± 0.6	9.9± 0.9	9.9± 0.6
10000 ppm	9.5± 0.7	9.4± 0.7	9.3± 0.7	9.6± 0.7	9.5± 0.7	9.7± 0.7
20000 ppm	9.1± 0.8	9.2± 0.8	9.2± 0.7	9.4± 0.7	9.6± 0.6	9.5± 0.5
40000 ppm	8.8± 0.7*	8.4± 0.6**	8.7± 0.5**	8.9± 0.5	8.9± 0.5*	8.8± 0.4**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett						

(HAN260)

BAIS 4

APPENDIX E 1

WATER CONSUMPTION CHANGES : MALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration week						
	1	2	3	4	5	6	7
Control	17.9± 1.2	19.2± 1.3	20.1± 1.4	20.2± 1.6	20.4± 3.9	18.9± 1.2	18.9± 1.9
2500 ppm	17.8± 0.9	20.1± 1.1	19.9± 1.3	20.0± 1.4	19.4± 1.8	19.4± 2.0	19.9± 1.5
5000 ppm	17.5± 1.3	19.1± 1.3	19.2± 1.4	18.9± 1.7	17.4± 1.4	17.0± 1.6	18.4± 1.9
10000 ppm	15.3± 0.8**	16.6± 1.0**	17.5± 1.5	17.2± 0.9*	16.0± 0.7**	16.0± 0.8**	17.0± 1.4
20000 ppm	14.9± 0.8**	15.7± 0.9**	15.5± 0.9**	15.8± 1.0**	15.2± 0.7**	15.1± 0.8**	15.5± 1.6**
40000 ppm	13.8± 1.1**	14.4± 0.6**	14.0± 0.5**	14.2± 0.6**	15.0± 1.2**	15.8± 2.3**	15.8± 2.2**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							

(HAN260)

BAIS 4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week					
	8	9	10	11	12	13
Control	19.2± 2.0	18.9± 2.3	18.7± 2.5	18.5± 2.7	18.3± 2.5	18.5± 2.7
2500 ppm	19.7± 1.1	20.0± 1.8	18.9± 0.9	18.0± 0.9	18.3± 0.7	18.2± 1.3
5000 ppm	17.9± 1.9	18.2± 1.9	19.4± 3.3	17.5± 2.0	17.5± 2.5	17.3± 2.5
10000 ppm	17.7± 1.6	17.6± 0.8	16.7± 0.6	18.3± 4.3	15.6± 0.6*	16.1± 3.1
20000 ppm	16.2± 1.6**	17.4± 2.3	17.3± 2.9	15.1± 1.2**	15.0± 1.0**	14.1± 0.8**
40000 ppm	15.2± 1.7**	15.5± 1.3**	14.6± 1.1**	14.3± 1.0**	14.0± 1.3**	13.2± 1.2**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett						

(HAN260)

BAIS 4

APPENDIX E 2

WATER CONSUMPTION CHANGES : FEMALE

STUDY NO. : 0571
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 3

Group Name	Administration week						
	1	2	3	4	5	6	7
Control	15.0± 1.4	18.1± 6.6	16.9± 5.8	18.5± 5.3	16.7± 4.0	20.2± 8.5	19.1± 5.9
2500 ppm	15.0± 1.2	17.4± 6.0	17.4± 5.1	16.1± 3.2	17.1± 5.4	15.7± 2.9	16.4± 3.5
5000 ppm	16.2± 4.5	17.2± 3.6	15.4± 2.4	17.6± 5.2	16.7± 5.1	16.1± 5.2	16.4± 5.9
10000 ppm	12.2± 1.3*	13.0± 2.9	13.2± 3.0	13.4± 3.0	13.3± 3.1	12.7± 3.0	12.1± 2.0
20000 ppm	11.7± 1.1**	12.0± 0.9*	12.7± 1.9	12.0± 1.3*	10.8± 1.0**	10.7± 0.7**	10.6± 0.8**
40000 ppm	11.3± 1.5**	10.5± 0.5**	10.2± 0.5**	9.6± 0.5**	9.3± 0.4**	9.7± 1.0**	9.6± 0.5**

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week					
	8	9	10	11	12	13
Control	19.7± 5.9	17.0± 4.6	16.6± 4.7	17.6± 6.3	18.9± 5.9	15.9± 3.3
2500 ppm	18.8± 6.8	16.6± 3.6	16.5± 3.3	19.3± 7.3	16.9± 5.1	15.2± 1.9
5000 ppm	17.7± 6.2	13.9± 1.4	15.7± 4.3	15.0± 3.9	15.9± 6.0	15.4± 3.7
10000 ppm	12.6± 2.9*	12.1± 2.1	12.2± 2.9	12.7± 2.5	12.7± 3.1*	12.6± 4.5
20000 ppm	11.2± 1.6**	10.6± 1.1**	10.5± 0.8**	10.9± 1.5*	10.7± 0.9**	10.7± 1.5**
40000 ppm	9.7± 0.8**	8.9± 0.5**	9.4± 0.7**	9.8± 1.3**	9.4± 0.7**	9.6± 0.7**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett						

(HAN260)

BAIS 4

APPENDIX F 1

CHEMICAL INTAKE CHANGES : MALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g/kg/day
 REPORT TYPE : A1 13
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration (weeks)		2	3	4	5	6	7
	1							
Control	0.000± 0.000		0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
2500 ppm	0.272± 0.013		0.253± 0.013	0.222± 0.015	0.205± 0.016	0.187± 0.020	0.182± 0.020	0.177± 0.013
5000 ppm	0.536± 0.033		0.485± 0.034	0.433± 0.032	0.394± 0.037	0.339± 0.023	0.322± 0.027	0.331± 0.031
10000 ppm	0.950± 0.037		0.849± 0.064	0.790± 0.067	0.717± 0.036	0.624± 0.019	0.593± 0.027	0.608± 0.043
20000 ppm	1.861± 0.102		1.643± 0.087	1.441± 0.075	1.341± 0.071	1.212± 0.053	1.146± 0.049	1.135± 0.077
40000 ppm	3.531± 0.231		3.080± 0.111	2.630± 0.079	2.439± 0.152	2.399± 0.259	2.447± 0.383	2.338± 0.335

(HAN300)

BAIS 4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g/kg/day
 REPORT TYPE : A1 13
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration (weeks)									
	8		9		10		11		12	13
Control	0.000± 0.000		0.000± 0.000		0.000± 0.000		0.000± 0.000		0.000± 0.000	0.000± 0.000
2500 ppm	0.167± 0.012		0.165± 0.017		0.151± 0.009		0.141± 0.006		0.140± 0.006	0.136± 0.010
5000 ppm	0.310± 0.027		0.305± 0.023		0.317± 0.049		0.278± 0.025		0.270± 0.031	0.260± 0.033
10000 ppm	0.612± 0.053		0.593± 0.034		0.546± 0.032		0.585± 0.145		0.487± 0.023	0.487± 0.078
20000 ppm	1.145± 0.078		1.189± 0.156		1.155± 0.214		0.978± 0.074		0.951± 0.057	0.882± 0.046
40000 ppm	2.177± 0.237		2.166± 0.193		1.984± 0.147		1.900± 0.132		1.824± 0.179	1.688± 0.131

(HAN300)

BAIS 4

APPENDIX F 2

CHEMICAL INTAKE CHANGES : FEMALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g/kg/day
 REPORT TYPE : A1 13
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration (weeks)									
	1	2	3	4	5	6	7			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
2500 ppm	0.330± 0.028	0.340± 0.108	0.320± 0.091	0.281± 0.055	0.286± 0.091	0.253± 0.047	0.255± 0.061			
5000 ppm	0.711± 0.201	0.682± 0.166	0.560± 0.096	0.615± 0.198	0.562± 0.187	0.526± 0.177	0.517± 0.183			
10000 ppm	1.078± 0.104	1.033± 0.208	0.966± 0.192	0.928± 0.184	0.876± 0.179	0.817± 0.175	0.755± 0.104			
20000 ppm	2.053± 0.177	1.867± 0.115	1.825± 0.241	1.632± 0.163	1.431± 0.112	1.375± 0.098	1.315± 0.087			
40000 ppm	4.018± 0.559	3.328± 0.141	3.012± 0.176	2.695± 0.169	2.531± 0.162	2.542± 0.223	2.423± 0.165			

(HAN300)

BAIS 4

STUDY NO. : 0571

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

UNIT : g/kg/day

REPORT TYPE : A1 13

SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

PAGE : 4

Group Name	Administration (weeks)									
	8	9	10	11	12	13				
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000			
2500 ppm	0.289± 0.103	0.253± 0.064	0.247± 0.058	0.279± 0.108	0.242± 0.079	0.216± 0.034				
5000 ppm	0.547± 0.192	0.425± 0.051	0.475± 0.142	0.436± 0.120	0.462± 0.188	0.444± 0.111				
10000 ppm	0.768± 0.154	0.727± 0.111	0.718± 0.157	0.729± 0.131	0.716± 0.165	0.703± 0.236				
20000 ppm	1.364± 0.168	1.262± 0.126	1.228± 0.083	1.238± 0.137	1.199± 0.092	1.185± 0.145				
40000 ppm	2.431± 0.276	2.181± 0.131	2.257± 0.202	2.320± 0.369	2.178± 0.164	2.190± 0.174				

(HAN300)

BAIS 4

APPENDIX G 1

HEMATOLOGY : MALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : MALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ⁹ /μl	
Control	10	9.46±	0.21	16.0±	0.2	46.7±	0.8	49.4±	0.5	17.0±	0.3	34.3±	0.3	711±	64
2500 ppm	10	9.41±	0.15	15.9±	0.2	46.4±	0.9	49.3±	0.4	16.9±	0.2	34.3±	0.4	706±	59
5000 ppm	10	9.39±	0.27	16.0±	0.3	46.7±	1.2	49.7±	0.5	17.1±	0.3	34.3±	0.4	723±	47
10000 ppm	10	9.40±	0.13	16.0±	0.3	46.4±	0.6	49.5±	0.3	17.0±	0.2	34.5±	0.3	699±	44
20000 ppm	10	9.45±	0.27	16.0±	0.4	46.9±	1.2	49.6±	0.4	17.0±	0.2	34.2±	0.3	698±	43
40000 ppm	10	9.30±	0.23	15.9±	0.3	46.3±	1.0	49.8±	0.4	17.1±	0.2	34.4±	0.4	661±	30

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

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0571

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)

ALL ANIMALS (14W)

PAGE : 2

Group Name	NO. of Animals	RETICULOCYTE %		PROTHROMBIN TIME s e c		APTT s e c	
Control	10	2.1±	0.2	12.8±	0.6	23.1±	1.5
2500 ppm	10	2.2±	0.1	12.8±	0.7	23.8±	1.1
5000 ppm	10	2.3±	0.1	13.0±	1.1	23.4±	1.8
10000 ppm	10	2.0±	0.2	12.7±	0.6	22.7±	1.4
20000 ppm	10	2.1±	0.2	12.7±	1.0	22.2±	1.5
40000 ppm	10	2.1±	0.3	12.2±	0.4	21.7±	1.0

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE TIME : 1
 SEX : MALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	10	6.17±	1.21	2±	1	19±	5	1±	1	0±	0	2±	1	77±	5	0±	0
2500 ppm	10	6.34±	0.85	2±	1	18±	3	1±	1	0±	0	2±	1	78±	3	0±	0
5000 ppm	10	6.18±	1.18	1±	1	19±	4	0±	1	0±	0	2±	0	78±	4	0±	0
10000 ppm	10	6.19±	1.34	1±	1	18±	4	1±	1	0±	0	2±	1	79±	4	0±	0
20000 ppm	10	6.71±	1.53	2±	1	18±	4	1±	0	0±	0	2±	1	77±	4	0±	0
40000 ppm	10	5.97±	1.12	1±	1	17±	2	1±	1	0±	0	2±	1	79±	4	0±	0

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BATS 4

APPENDIX G 2

HEMATOLOGY : FEMALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl	HEMOGLOBIN g/dl	HEMATOCRIT %	MCV fl	MCH pg	MCHC g/dl	PLATELET 10 ⁹ /μl
Control	10	8.61± 0.16	15.7± 0.3	44.5± 0.9	51.7± 0.5	18.3± 0.2	35.4± 0.3	801± 76
2500 ppm	10	8.59± 0.11	15.7± 0.2	44.4± 0.4	51.7± 0.4	18.3± 0.2	35.3± 0.4	816± 41
5000 ppm	10	8.60± 0.21	15.8± 0.3	44.5± 0.9	51.8± 0.2	18.4± 0.3	35.5± 0.5	795± 48
10000 ppm	10	8.55± 0.22	15.7± 0.4	44.4± 1.0	51.9± 0.4	18.3± 0.3	35.3± 0.5	760± 55
20000 ppm	10	8.61± 0.18	15.9± 0.2	44.8± 0.8	52.0± 0.3	18.4± 0.2	35.5± 0.2	768± 42
40000 ppm	10	8.71± 0.13	16.0± 0.3	45.1± 0.8	51.8± 0.4	18.3± 0.2	35.5± 0.4	722± 28**

Significant difference ; * : P ≤ 0.05

** : P ≤ 0.01

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0571

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE TIME : 1

SEX : FEMALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)

ALL ANIMALS (14W)

PAGE : 5

Group Name	NO. of Animals	RETICULOCYTE %		PROTHROMBIN TIME s e c		APTT s e c	
Control	10	2.1±	0.3	12.0±	0.3	18.8±	0.7
2500 ppm	10	2.0±	0.2	12.0±	0.4	19.0±	0.4
5000 ppm	10	2.1±	0.3	11.9±	0.4	18.7±	0.7
10000 ppm	10	2.1±	0.1	12.1±	0.4	18.6±	1.0
20000 ppm	10	2.0±	0.2	12.1±	0.3	19.2±	0.8
40000 ppm	10	1.9±	0.3	12.0±	0.3	19.0±	0.5

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

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE TIME : 1
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 6

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	10	3.65±	1.14	2±	1	17±	4	1±	1	0±	0	2±	1	78±	4	0±	0
2500 ppm	10	3.35±	0.68	2±	1	16±	3	1±	1	0±	0	3±	1	79±	3	0±	0
5000 ppm	10	3.62±	0.96	1±	1	18±	7	1±	1	0±	0	2±	1	78±	7	0±	0
10000 ppm	10	3.30±	1.14	2±	1	19±	5	2±	1	0±	0	2±	1	76±	5	0±	0
20000 ppm	10	3.40±	0.95	1±	1	17±	4	1±	0	0±	0	2±	1	79±	4	0±	0
40000 ppm	10	3.96±	1.07	1±	1	16±	5	1±	1	0±	0	3±	1	80±	5	0±	0

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 4

APPENDIX H 1

BIOCHEMISTRY : MALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	10	6.6±	0.2	3.6±	0.1	1.2±	0.1	0.12±	0.01	190±	12	68±	5	72±	29
2500 ppm	10	6.4±	0.2	3.6±	0.1	1.2±	0.1	0.11±	0.01	179±	14	66±	7	61±	17
5000 ppm	10	6.5±	0.1	3.6±	0.1	1.2±	0.0	0.12±	0.00	178±	13	68±	3	70±	13
10000 ppm	10	6.4±	0.1*	3.6±	0.1	1.2±	0.0	0.12±	0.01	185±	9	70±	6	61±	15
20000 ppm	10	6.3±	0.2**	3.5±	0.1**	1.3±	0.0	0.12±	0.00	188±	15	68±	4	84±	20
40000 ppm	10	6.2±	0.1**	3.5±	0.1**	1.3±	0.0	0.12±	0.01	189±	7	70±	3	55±	18

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

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		AST I U / l		ALT I U / l		LDH I U / l		ALP I U / l		G-GTP I U / l		CK I U / l	
Control	10	121±	12	108±	51	57±	18	198±	124	254±	9	1±	0	102±	8
2500 ppm	10	116±	10	104±	36	54±	12	175±	85	250±	20	1±	1	95±	7
5000 ppm	10	120±	6	103±	29	53±	12	182±	55	264±	19	1±	1	96±	11
10000 ppm	10	122±	8	119±	44	58±	15	215±	82	250±	30	1±	0	90±	12*
20000 ppm	10	124±	8	107±	50	54±	15	190±	110	255±	12	1±	0	89±	7**
40000 ppm	10	124±	7	92±	15	48±	5	149±	31	250±	23	1±	0	83±	6**

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	10	18.5±	1.3	0.5±	0.0	142±	1	3.5±	0.2	104±	1	10.3±	0.2	5.5±	0.5
2500 ppm	10	18.0±	1.0	0.5±	0.1	141±	1	3.5±	0.3	103±	1	10.2±	0.2	5.5±	0.5
5000 ppm	10	17.7±	1.9	0.5±	0.0	142±	1	3.5±	0.3	104±	1	10.2±	0.2	5.6±	0.4
10000 ppm	10	17.1±	1.3	0.5±	0.0	141±	1	3.4±	0.2	103±	1	10.2±	0.1	5.4±	0.5
20000 ppm	10	17.8±	2.3	0.5±	0.0	141±	1	3.6±	0.3	103±	1	10.0±	0.2**	5.3±	0.5
40000 ppm	10	18.6±	1.9	0.5±	0.0	140±	1**	3.6±	0.2	102±	1*	9.9±	0.3**	5.4±	0.4

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 4

APPENDIX H 2

BIOCHEMISTRY : FEMALE

STUDY NO. : 0571

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (14W)

PAGE : 4

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	10	6.1±	0.2	3.5±	0.1	1.3±	0.1	0.13±	0.01	153±	8	74±	8	14±	4
2500 ppm	10	6.1±	0.2	3.5±	0.1	1.4±	0.1	0.13±	0.01	139±	15	74±	7	14±	4
5000 ppm	10	6.2±	0.2	3.5±	0.1	1.3±	0.0	0.13±	0.01	150±	11	75±	8	12±	2
10000 ppm	10	6.0±	0.2	3.5±	0.1	1.4±	0.1	0.13±	0.01	160±	13	76±	7	15±	4
20000 ppm	10	5.9±	0.1*	3.4±	0.1*	1.4±	0.1	0.13±	0.01	162±	12	75±	5	15±	4
40000 ppm	10	5.7±	0.2**	3.3±	0.1**	1.4±	0.1	0.13±	0.01	166±	13	76±	8	16±	3

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

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 5

Group Name	NO. of Animals	PHOSPHOLIPID mg./dl		AST IU/ℓ		ALT IU/ℓ		LDH IU/ℓ		ALP IU/ℓ		G-GTP IU/ℓ		CK IU/ℓ	
Control	10	137±	12	73±	11	37±	8	178±	81	212±	30	1±	0	107±	37
2500 ppm	10	136±	10	72±	12	34±	5	186±	101	196±	19	1±	0	107±	28
5000 ppm	10	137±	12	79±	18	39±	10	186±	87	204±	14	2±	1	100±	25
10000 ppm	10	140±	12	76±	17	36±	6	191±	111	209±	20	2±	1	96±	22
20000 ppm	10	139±	7	74±	10	36±	5	155±	54	195±	24	1±	1	94±	16
40000 ppm	10	141±	13	68±	7	36±	3	151±	66	212±	31	2±	1	90±	19

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

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 6

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	10	19.5±	2.0	0.5±	0.1	142±	1	3.5±	0.3	105±	1	9.8±	0.2	4.7±	0.9
2500 ppm	10	17.4±	1.2	0.6±	0.1	141±	1	3.5±	0.3	105±	1	9.8±	0.2	5.0±	0.8
5000 ppm	10	18.9±	1.7	0.5±	0.0	141±	2	3.4±	0.4	105±	1	9.8±	0.2	4.9±	1.0
10000 ppm	10	19.6±	1.0	0.5±	0.0	141±	1	3.5±	0.5	104±	2	9.8±	0.2	4.8±	1.0
20000 ppm	10	19.0±	2.0	0.5±	0.0	140±	1	3.6±	0.3	104±	2	9.6±	0.3	4.7±	0.9
40000 ppm	10	17.8±	2.6	0.5±	0.0	139±	1**	3.7±	0.3	103±	1	9.5±	0.3**	5.0±	0.6

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 4

APPENDIX I 1

URINALYSIS : MALE

STUDY NO. : 0571
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
MEASURE. TIME : 1
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body					CHI	Bilirubin				CHI			
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	±	+		2+	3+	4+	-		+	2+	3+
Control	10	0	0	0	0	0	4	6		0	1	6	3	0	0		10	0	0	0	0	0		3	7	0	0	0	0		10	0	0	0	
2500 ppm	10	0	0	0	0	2	3	5		0	1	7	2	0	0		10	0	0	0	0	0		1	8	1	0	0	0		10	0	0	0	
5000 ppm	10	0	0	0	0	0	5	5		0	0	9	1	0	0		10	0	0	0	0	0		0	7	3	0	0	0	*	10	0	0	0	
10000 ppm	10	0	0	0	0	1	7	2		0	0	4	6	0	0		10	0	0	0	0	0		0	4	6	0	0	0	**	10	0	0	0	
20000 ppm	10	0	0	0	1	1	7	1		0	0	4	6	0	0		10	0	0	0	0	0		1	3	5	1	0	0	*	10	0	0	0	
40000 ppm	10	0	0	2	0	2	5	1		0	0	3	7	0	0		10	0	0	0	0	0		0	5	5	0	0	0	*	10	0	0	0	

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

Test of CHI SQUARE

(HCL101)

BAIS 4

STUDY NO. : 0571

URINALYSIS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE TIME : 1

SEX : MALE

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Occult blood					Urobilinogen				
		-	±	+	2+	3+	±	+	2+	3+	4+
Control	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	9	1	0	0	0	10	0	0	0	0
10000 ppm	10	10	0	0	0	0	10	0	0	0	0
20000 ppm	10	10	0	0	0	0	10	0	0	0	0
40000 ppm	10	10	0	0	0	0	10	0	0	0	0

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

Test of CHI SQUARE

(HCL101)

BAIS 4

APPENDIX I 2

URINALYSIS : FEMALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body					CHI	Bilirubin				CHI			
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	±	+		2+	3+	4+	-		+	2+	3+
Control	10	0	0	0	0	0	7	3		0	1	8	1	0	0		10	0	0	0	0	0		3	7	0	0	0	0		10	0	0	0	
2500 ppm	10	0	0	0	0	0	6	4		0	2	8	0	0	0		10	0	0	0	0	0		1	9	0	0	0	0		10	0	0	0	
5000 ppm	10	0	0	0	0	0	7	3		0	1	8	1	0	0		10	0	0	0	0	0		1	9	0	0	0	0		10	0	0	0	
10000 ppm	10	0	0	0	0	0	6	4		0	0	6	4	0	0		10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	
20000 ppm	10	0	0	0	1	2	6	1		0	0	5	5	0	0		10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	
40000 ppm	10	0	3	2	0	0	5	0	*	0	0	3	7	0	0	*	10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	

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

Test of CHI SQUARE

(HCL101)

BAIS 4

STUDY NO. : 0571

URINALYSIS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE TIME : 1

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Occult blood					Urobilinogen				
		-	±	+	2+	3+	CHI	±	+	2+	3+ 4+
Control	10	10	0	0	0	0	0	10	0	0	0
2500 ppm	10	10	0	0	0	0	0	10	0	0	0
5000 ppm	10	10	0	0	0	0	0	10	0	0	0
10000 ppm	10	10	0	0	0	0	0	10	0	0	0
20000 ppm	10	10	0	0	0	0	0	10	0	0	0
40000 ppm	10	10	0	0	0	0	0	10	0	0	0

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

Test of CHI SQUARE

(HCL101)

BAIS 4

APPENDIX J 1

GROSS FINDINGS : MALE

STUDY NO. : 0571
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control		2500 ppm		5000 ppm		10000 ppm	
			10	(%)	10	(%)	10	(%)	10	(%)
liver	herniation		3	(30)	2	(20)	1	(10)	1	(10)
kidney	nodule		0	(0)	0	(0)	1	(10)	0	(0)
testis	small		1	(10)	0	(0)	0	(0)	0	(0)
epididymis	small		1	(10)	0	(0)	0	(0)	0	(0)
semin ves	small		1	(10)	0	(0)	0	(0)	0	(0)
eye	turbid		0	(0)	1	(10)	0	(0)	0	(0)
whole body	situs inversus		1	(10)	0	(0)	0	(0)	0	(0)

(HPT080)

BAIS 4

STUDY NO. : 0571
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name NO. of Animals	20000 ppm	40000 ppm
			10 (%)	10 (%)
liver	herniation		1 (10)	2 (20)
kidney	nodule		0 (0)	0 (0)
testis	small		0 (0)	0 (0)
epididymis	small		0 (0)	0 (0)
semin ves	small		0 (0)	0 (0)
eye	turbid		0 (0)	0 (0)
whole body	situs inversus		0 (0)	0 (0)

(HPT080)

BAIS 4

APPENDIX J 2

GROSS FINDINGS : FEMALE

STUDY NO. : 0571
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 3

Organ	Findings	Group Name		Control		2500 ppm		5000 ppm		10000 ppm	
		NO. of Animals		10	(%)	10	(%)	10	(%)	10	(%)
liver	herniation			2	(20)	3	(30)	2	(20)	4	(40)

(HPT080)

BAIS 4

STUDY NO. : 0571
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 4

Organ_____	Findings_____	Group Name NO. of Animals	20000 ppm 10 (%)	40000 ppm 10 (%)
<hr/>				
liver	herniation		2 (20)	1 (10)

(HPT080)

BAIS 4

APPENDIX K 1

ORGAN WEIGHT, ABSOLUTE : MALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

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

PAGE : 1

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	305± 23	0.206± 0.031	0.045± 0.003	3.048± 0.352	0.887± 0.054	0.960± 0.055
2500 ppm	10	312± 10	0.206± 0.022	0.046± 0.005	3.089± 0.135	0.926± 0.051	0.999± 0.046
5000 ppm	10	310± 14	0.208± 0.027	0.046± 0.005	3.137± 0.119	0.915± 0.041	0.999± 0.047
10000 ppm	10	308± 13	0.215± 0.018	0.046± 0.003	3.168± 0.122	0.913± 0.042	1.014± 0.053
20000 ppm	10	303± 12	0.204± 0.015	0.046± 0.002	3.173± 0.067	0.903± 0.034	0.970± 0.041
40000 ppm	10	297± 12	0.186± 0.022	0.047± 0.004	3.272± 0.454	0.880± 0.038	0.966± 0.040

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

Test of Dunnett

(HCL040)

BAIS 4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCr-j]
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	1.831±	0.129	0.573±	0.041	7.525±	0.678	1.888±	0.045
2500 ppm	10	1.924±	0.078	0.600±	0.033	7.628±	0.355	1.917±	0.052
5000 ppm	10	2.141±	0.762	0.590±	0.035	7.614±	0.369	1.914±	0.038
10000 ppm	10	1.945±	0.094	0.579±	0.037	7.564±	0.475	1.926±	0.042
20000 ppm	10	1.942±	0.055	0.564±	0.026	7.629±	0.378	1.913±	0.025
40000 ppm	10	1.981±	0.086	0.570±	0.034	7.391±	0.331	1.891±	0.035
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett									

(HCL040)

BAIS 4

APPENDIX K 2

ORGAN WEIGHT, ABSOLUTE : FEMALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

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

PAGE : 3

Group Name	NO. of Animals	Body Weight		THYMUS		ADRENALS		OVARIES		HEART		LUNGS	
Control	10	158±	6	0.162±	0.014	0.051±	0.003	0.092±	0.006	0.569±	0.025	0.694±	0.017
2500 ppm	10	164±	10	0.167±	0.017	0.050±	0.004	0.092±	0.011	0.583±	0.029	0.704±	0.041
5000 ppm	10	163±	6	0.157±	0.016	0.049±	0.003	0.095±	0.015	0.574±	0.026	0.700±	0.025
10000 ppm	10	167±	7	0.167±	0.013	0.048±	0.006	0.095±	0.016	0.578±	0.045	0.709±	0.038
20000 ppm	10	169±	10	0.167±	0.012	0.050±	0.004	0.093±	0.012	0.576±	0.023	0.711±	0.036
40000 ppm	10	167±	7	0.158±	0.008	0.049±	0.003	0.092±	0.024	0.587±	0.029	0.697±	0.041

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

Test of Dunnett

(HCL040)

BAIS 4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	1.116±	0.045	0.365±	0.012	3.850±	0.208	1.759±	0.024
2500 ppm	10	1.126±	0.045	0.388±	0.028	3.958±	0.316	1.774±	0.032
5000 ppm	10	1.130±	0.066	0.376±	0.021	3.918±	0.163	1.764±	0.043
10000 ppm	10	1.176±	0.065	0.382±	0.025	3.897±	0.211	1.743±	0.036
20000 ppm	10	1.206±	0.064**	0.386±	0.023	4.032±	0.212	1.738±	0.045
40000 ppm	10	1.261±	0.049**	0.375±	0.021	4.035±	0.113	1.735±	0.041

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

Test of Dunnett

(HCL040)

BAIS 4

APPENDIX L 1

ORGAN WEIGHT, RELATIVE : MALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE
 UNIT: %

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

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	305± 23	0.067± 0.006	0.015± 0.001	0.998± 0.095	0.291± 0.015	0.315± 0.015
2500 ppm	10	312± 10	0.066± 0.006	0.015± 0.002	0.992± 0.040	0.297± 0.009	0.321± 0.011
5000 ppm	10	310± 14	0.067± 0.006	0.015± 0.002	1.013± 0.045	0.295± 0.005	0.322± 0.010
10000 ppm	10	308± 13	0.070± 0.005	0.015± 0.001	1.028± 0.034	0.296± 0.012	0.329± 0.013
20000 ppm	10	303± 12	0.067± 0.004	0.015± 0.001	1.048± 0.049	0.298± 0.012	0.320± 0.010
40000 ppm	10	297± 12	0.063± 0.008	0.016± 0.001	1.103± 0.155	0.296± 0.010	0.325± 0.014

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

Test of Dunnett

(HCL042)

BAIS 4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE
 UNIT: %

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.600± 0.017	0.188± 0.007	2.463± 0.077	0.621± 0.040
2500 ppm	10	0.618± 0.014	0.193± 0.005	2.448± 0.091	0.616± 0.024
5000 ppm	10	0.688± 0.228	0.190± 0.004	2.457± 0.055	0.618± 0.028
10000 ppm	10	0.631± 0.018*	0.188± 0.007	2.452± 0.100	0.625± 0.022
20000 ppm	10	0.641± 0.021**	0.186± 0.010	2.516± 0.093	0.632± 0.022
40000 ppm	10	0.667± 0.022**	0.192± 0.008	2.489± 0.086	0.637± 0.028

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

Test of Dunnett

(HCL042)

BAIS 4

APPENDIX L 2

ORGAN WEIGHT, RELATIVE : FEMALE

STUDY NO. : 0571
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE : 3

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	158± 6	0.102± 0.008	0.032± 0.002	0.058± 0.004	0.359± 0.016	0.439± 0.016
2500 ppm	10	164± 10	0.102± 0.006	0.031± 0.002	0.056± 0.006	0.356± 0.014	0.429± 0.014
5000 ppm	10	163± 6	0.096± 0.008	0.031± 0.002	0.058± 0.009	0.353± 0.015	0.431± 0.011
10000 ppm	10	167± 7	0.100± 0.008	0.029± 0.003*	0.057± 0.009	0.347± 0.019	0.425± 0.014
20000 ppm	10	169± 10	0.099± 0.004	0.030± 0.004	0.055± 0.007	0.342± 0.021	0.422± 0.028
40000 ppm	10	167± 7	0.095± 0.007	0.030± 0.002	0.056± 0.015	0.352± 0.008	0.418± 0.016

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

Test of Dunnett

(HCL042)

BAIS 4

STUDY NO. : 0571
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.705± 0.023	0.231± 0.010	2.432± 0.076	1.113± 0.051
2500 ppm	10	0.688± 0.025	0.237± 0.010	2.412± 0.081	1.085± 0.060
5000 ppm	10	0.695± 0.025	0.231± 0.011	2.408± 0.049	1.085± 0.034
10000 ppm	10	0.705± 0.025	0.229± 0.010	2.336± 0.060	1.047± 0.040*
20000 ppm	10	0.715± 0.034	0.229± 0.006	2.390± 0.104	1.033± 0.072**
40000 ppm	10	0.756± 0.027**	0.225± 0.014	2.420± 0.089	1.041± 0.031**

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

Test of Dunnett

(HCL042)

BAIS 4

APPENDIX M 1

HISTOPATHOLOGICAL FINDINGS :
NON-NEOPLASTIC LESIONS : MALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name No. of Animals on Study Grade				Control 10				2500 ppm 10				5000 ppm 10				10000 ppm 10			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
liver	herniation	<10>				<10>				<10>				<10>				<10>			
		3	0	0	0	2	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0
		(30)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Urinary system}																					
kidney	malformation	<10>				<10>				<10>				<10>				<10>			
		0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)
	eosinophilic body	<10>				<10>				<10>				<10>				<10>			
		10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
		(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
{Endocrine system}																					
pituitary	Rathke pouch	<10>				<10>				<10>				<10>				<10>			
		0	0	0	0	1	0	0	0	0	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)
thyroid	ultimibranchial body remanet	<10>				<10>				<10>				<10>				<10>			
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name No. of Animals on Study Grade				20000 ppm 10				40000 ppm 10			
		1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}													
liver	herniation	<10>				<10>							
		1	0	0	0	2	0	0	0	0	0	0	0
		(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Urinary system}													
kidney	malformation	<10>				<10>							
		0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	eosinophilic body	<10>				<10>							
		10	0	0	0	10	0	0	0	0	0	0	0
		(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Endocrine system}													
pituitary	Rathke pouch	<10>				<10>							
		0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
thyroid	ultimibranchial body remanet	<10>				<10>							
		0	0	0	0	1	0	0	0	0	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 : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study Grade	Control 10				2500 ppm 10				5000 ppm 10				10000 ppm 10			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
testis	atrophy		<10>				<10>				<10>				<10>			
			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)	(0)	(0)
epididymis	atrophy		<10>				<10>				<10>				<10>			
			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)
	decreased sperma		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)	(0)	(0)
semin ves	atrophy		<10>				<10>				<10>				<10>			
			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)
{Special sense organs/appendage}																		
Harder gl	lymphocytic infiltration		<10>				<10>				<10>				<10>			
			1	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(10)	(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 : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

(HPT150)

BAIS4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study Grade	20000 ppm 10				40000 ppm 10			
			1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}										
testis	atrophy		<10>				<10>			
			0	0	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)
epididymis	atrophy		<10>				<10>			
			0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	decreased sperma		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
semin ves	atrophy		<10>				<10>			
			0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Special sense organs/appendage}										
Harder gl	lymphocytic infiltration		<10>				<10>			
			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 : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

(HPT150)

BAIS4

APPENDIX M 2

HISTOPATHOLOGICAL FINDINGS :
NON-NEOPLASTIC LESIONS : FEMALE

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCrI CrIj[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 5

Organ	Findings	Group Name No. of Animals on Study Grade				Control 10				2500 ppm 10				5000 ppm 10				10000 ppm 10			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
liver	herniation	<10>				<10>				<10>				<10>				<10>			
		2	0	0	0	3	0	0	0	2	0	0	0	4	0	0	0	4	0	0	0
		(20)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(40)	(0)	(0)	(0)	(40)	(0)	(0)	(0)
{Endocrine system}																					
pituitary	Rathke pouch	<10>				<10>				<10>				<10>				<10>			
		2	0	0	0	0	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)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Special sense organs/appendage}																					
Harder gl	lymphocytic infiltration	<10>				<10>				<10>				<10>				<10>			
		2	0	0	0	3	0	0	0	3	0	0	0	2	0	0	0	2	0	0	0
		(20)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(20)	(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 : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

(HPT150)

BAIS4

STUDY NO. : 0571
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 6

		Group Name	20000 ppm				40000 ppm			
		No. of Animals on Study	10				10			
Organ_____	Findings_____	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}										
liver			<10>				<10>			
	herniation		2	0	0	0	1	0	0	0
			(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Endocrine system}										
pituitary			<10>				<10>			
	Rathke pouch		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Special sense organs/appendage}										
Harder gl			<10>				<10>			
	lymphocytic infiltration		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 ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

(HPT150)

BAIS4

APPENDIX N

METHODS, UNITS AND DECIMAL PLACE FOR
HEMATOLOGY AND BIOCHEMISTRY IN THE 13-WEEK
DRINKING WATER STUDY OF 2-METHYL-1-PROPANOL

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY
IN THE 13- WEEK DRINKING WATER STUDY OF 2-METHYL-1-PROPANOL

Item	Method	Unit	Decimal place
Hematology			
Red blood cell (RBC)	Light scattering method ¹⁾	$\times 10^6/\mu\text{L}$	2
Hemoglobin(Hgb)	Cyanmethemoglobin method ¹⁾	g/dL	1
Hematocrit(Hct)	Calculated as $\text{RBC} \times \text{MCV}/10$ ¹⁾	%	1
Mean corpuscular volume(MCV)	Light scattering method ¹⁾	fL	1
Mean corpuscular hemoglobin(MCH)	Calculated as $\text{Hgb}/\text{RBC} \times 10$ ¹⁾	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as $\text{Hgb}/\text{Hct} \times 100$ ¹⁾	g/dL	1
Platelet	Light scattering method ¹⁾	$\times 10^3/\mu\text{L}$	0
Reticulocyte	Light scattering method ¹⁾	%	1
Prothrombin time	Quick one stage method ²⁾	sec	1
Activated partial thromboplastin time(APTT)	Ellagic acid activaterd method ²⁾	sec	1
White blood cell(WBC)	Light scattering method ¹⁾	$\times 10^3/\mu\text{L}$	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 $\text{Alb}/(\text{TP} - \text{Alb})$ 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.)