

アクリル酸=2 - ヒドロキシエチルのマウスを用いた
経口投与による 2 週間毒性試験(混水試験)報告書

試験番号：0 3 1 5

APPENDIX

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APPENDIX A 1

CLINICAL OBSERVATION : SUMMARY, MOUSE : MALE

(2-WEEK STUDY)

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day				
		1-1	1-3	1-7	2-3	2-7
DEATH	Control	0	0	0	0	1
	512 ppm	0	0	0	0	0
	1280 ppm	0	0	0	0	0
	3200 ppm	0	0	0	0	0
	8000 ppm	0	0	0	0	1
	20000 ppm	0	0	0	2	7
HUNCHBACK POSITION	Control	0	0	0	0	0
	512 ppm	0	0	0	0	0
	1280 ppm	0	0	0	0	0
	3200 ppm	0	0	0	0	0
	8000 ppm	0	0	0	0	0
	20000 ppm	0	0	0	0	2
ATAXIC GAIT	Control	0	0	0	0	0
	512 ppm	0	0	0	0	0
	1280 ppm	0	0	0	0	0
	3200 ppm	0	0	0	0	0
	8000 ppm	0	0	0	0	0
	20000 ppm	0	0	0	0	1
PILOERECTION	Control	0	0	0	0	0
	512 ppm	0	0	0	0	0
	1280 ppm	0	0	0	0	0
	3200 ppm	0	0	0	0	0
	8000 ppm	0	0	0	2	2
	20000 ppm	0	0	7	7	3
IRREGULAR BREATHING	Control	0	0	0	0	0
	512 ppm	0	0	0	0	0
	1280 ppm	0	0	0	0	0
	3200 ppm	0	0	0	0	0
	8000 ppm	0	0	0	0	0
	20000 ppm	0	0	0	0	1
ABNORMAL RESPIRATION	Control	0	0	0	0	0
	512 ppm	0	0	0	0	0
	1280 ppm	0	0	0	0	0
	3200 ppm	0	0	0	0	0
	8000 ppm	0	0	0	0	0
	20000 ppm	0	0	0	0	1

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 2

Clinical sign	Group Name	Administration Week-day				
		1-1	1-3	1-7	2-3	2-7
SMALL STOOL	Control	0	0	0	0	0
	512 ppm	0	0	1	0	0
	1280 ppm	0	0	0	0	0
	3200 ppm	0	0	0	0	0
	8000 ppm	0	0	1	1	0
	20000 ppm	0	0	10	8	3
OLIGO-STOOL	Control	0	0	0	0	0
	512 ppm	0	0	0	0	0
	1280 ppm	0	0	0	0	0
	3200 ppm	0	0	1	1	0
	8000 ppm	0	0	1	2	2
	20000 ppm	0	10	10	8	3

(HAN190)

BAIS 3

APPENDIX A 2

CLINICAL OBSERVATION : SUMMARY, MOUSE : FEMALE
(2-WEEK STUDY)

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 3

Clinical sign	Group Name	Administration Week-day				
		1-1	1-3	1-7	2-3	2-7
DEATH	Control	0	0	0	0	0
	512 ppm	0	0	0	0	0
	1280 ppm	0	0	0	0	0
	3200 ppm	0	0	0	0	0
	8000 ppm	0	0	0	0	0
	20000 ppm	0	0	1	10	10
PILOERECTION	Control	0	0	0	0	0
	512 ppm	0	0	0	0	0
	1280 ppm	0	0	0	0	0
	3200 ppm	0	0	0	0	0
	8000 ppm	0	0	2	5	3
	20000 ppm	0	0	9	0	-
SMALL STOOL	Control	0	0	0	0	0
	512 ppm	0	0	0	0	0
	1280 ppm	0	0	0	0	0
	3200 ppm	0	0	0	0	0
	8000 ppm	0	0	0	0	0
	20000 ppm	0	0	9	0	-
OLIGO-STOOL	Control	0	0	0	0	0
	512 ppm	0	0	0	0	0
	1280 ppm	0	0	0	0	0
	3200 ppm	0	0	0	1	0
	8000 ppm	0	0	1	1	0
	20000 ppm	0	10	9	0	-

APPENDIX B 1

BODY WEIGHT CHANGES :SUMMARY, MOUSE : MALE
(2-WEEK STUDY)

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 2
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration week-day				
	0-0	1-3	1-7	2-3	2-7
Control	22.5± 0.8	22.8± 1.0	23.3± 1.1	23.0± 2.3	24.4± 1.2
512 ppm	22.5± 0.7	21.9± 2.1	22.9± 1.9	23.7± 0.9	24.6± 1.2
1280 ppm	22.5± 0.8	22.4± 0.8	23.2± 1.3	23.4± 1.2	24.1± 1.5
3200 ppm	22.5± 0.8	21.4± 1.3	22.2± 2.0	22.6± 1.8	22.8± 1.3
8000 ppm	22.5± 0.8	18.7± 0.8**	18.9± 1.9**	18.9± 2.4**	19.6± 2.1**
20000 ppm	22.5± 0.7	17.7± 0.6**	14.8± 0.8**	13.7± 0.7**	12.8± 0.2**

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

Test of Dunnett

(HAN260)

BAIS 3

APPENDIX B 2

BODY WEIGHT CHANGES : SUMMARY, MOUSE : FEMALE

(2-WEEK STUDY)

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 2
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day				
	0-0	1-3	1-7	2-3	2-7
Control	17.5± 0.5	16.7± 1.0	18.7± 0.8	18.9± 0.6	19.2± 0.9
512 ppm	17.6± 0.4	17.9± 0.5	19.1± 0.6	19.0± 0.6	19.8± 0.5
1280 ppm	17.5± 0.4	17.5± 0.4	19.1± 0.5	18.9± 0.4	19.6± 0.5
3200 ppm	17.5± 0.4	17.0± 0.5	18.2± 0.7	18.1± 1.3	19.2± 0.8
8000 ppm	17.5± 0.4	14.4± 0.6	14.5± 0.7**	15.1± 0.7**	15.6± 0.9**
20000 ppm	17.5± 0.5	13.3± 0.4**	10.7± 0.3**	-	-

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

Test of Dunnett

(HAN260)

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APPENDIX C 1

WATER CONSUMPTION CHANGES : SUMMARY, MOUSE : MALE
(2-WEEK STUDY)

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 2
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration week-day(effective)			
	1-3(3)	1-7(4)	2-3(3)	2-7(4)
Control	4.2± 0.6	4.5± 0.5	4.0± 1.3	4.5± 0.7
512 ppm	3.3± 0.8	3.2± 1.1	3.6± 0.8	3.6± 0.9
1280 ppm	3.1± 0.3	2.7± 0.5	2.7± 0.6	2.7± 0.6*
3200 ppm	2.2± 0.5**	2.0± 0.5**	1.9± 0.3*	1.8± 0.3**
8000 ppm	0.9± 0.3**	1.2± 0.3**	1.2± 0.3**	1.2± 0.3**
20000 ppm	0.4± 0.1**	0.4± 0.0**	0.3± 0.1**	0.8± 0.7**

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

Test of Dunnett

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BAIS 3

APPENDIX C 2

WATER CONSUMPTION CHANGES : SUMMARY, MOUSE : FEMALE
(2-WEEK STUDY)

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 2
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day(effective)			
	1-3(3)	1-7(4)	2-3(3)	2-7(4)
Control	3.7± 1.0	4.5± 1.0	4.1± 0.7	4.2± 0.5
512 ppm	3.6± 0.2	3.2± 0.3	3.1± 0.2	3.3± 0.4
1280 ppm	3.1± 0.3	3.0± 0.3	2.7± 0.5*	2.8± 0.6*
3200 ppm	2.4± 0.4*	2.4± 0.4**	2.1± 0.9**	2.6± 1.0**
8000 ppm	0.8± 0.2**	1.1± 0.1**	1.1± 0.1**	1.6± 1.1**
20000 ppm	0.3± 0.1**	0.3± 0.0**	-	-

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

Test of Dunnett

(HAN260)

BAIS 3

APPENDIX D 1

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : MALE (2-WEEK STUDY)

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 2
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration week-day(effective)			
	1-3(3)	1-7(4)	2-3(3)	2-7(4)
Control	3.6± 0.6	3.8± 0.5	3.5± 0.9	3.8± 0.5
512 ppm	3.5± 0.8	3.8± 0.7	4.1± 0.6	3.9± 0.3
1280 ppm	3.7± 0.2	3.6± 0.5	3.8± 0.2	3.7± 0.3
3200 ppm	3.2± 0.5	3.6± 0.6	3.8± 0.4	3.4± 0.4
8000 ppm	2.1± 0.3**	3.5± 0.7	3.3± 0.7	3.2± 0.7*
20000 ppm	1.9± 0.2**	1.6± 0.2**	2.0± 0.1**	1.9± 0.4**

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

Test of Dunnett

(HAN260)

BATS 3

APPENDIX D 2

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : FEMALE
(2-WEEK STUDY)

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 2
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day(effective)			
	1-3(3)	1-7(4)	2-3(3)	2-7(4)
Control	2.7± 0.4	3.6± 0.3	3.3± 0.4	3.3± 0.3
512 ppm	3.1± 0.3	3.6± 0.2	3.2± 0.3	3.4± 0.2
1280 ppm	2.8± 0.2	3.7± 1.2	3.1± 0.3	3.3± 0.2
3200 ppm	2.6± 0.2	3.3± 0.3	3.0± 0.3	3.3± 0.3
8000 ppm	1.6± 0.4**	2.4± 0.3**	2.8± 0.3**	2.9± 0.3**
20000 ppm	1.3± 0.2**	1.6± 0.4**	-	-

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

Test of Dunnett

APPENDIX E 1

CHEMICAL INTAKE CHANGES : SUMMARY, MOUSE : MALE

(2-WEEK STUDY)

STUDY NO. : 0315
ANIMAL : MOUSE BDF1
SEX : MALE
UNIT : g/kg/day

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration Week-Day	1-4	1-7	2-4	2-7
Control		0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000
512 ppm		0.076 ± 0.016	0.070 ± 0.024	0.078 ± 0.017	0.075 ± 0.019
1280 ppm		0.176 ± 0.021	0.149 ± 0.024	0.144 ± 0.027	0.143 ± 0.027
3200 ppm		0.320 ± 0.066	0.278 ± 0.063	0.271 ± 0.029	0.254 ± 0.041
8000 ppm		0.367 ± 0.117	0.501 ± 0.095	0.498 ± 0.068	0.503 ± 0.093
20000 ppm		0.452 ± 0.072	0.542 ± 0.077	0.405 ± 0.168	1.191 ± 1.119

APPENDIX E 2

CHEMICAL INTAKE CHANGES : SUMMARY, MOUSE : FEMALE

(2-WEEK STUDY)

STUDY NO. : 0315
ANIMAL : MOUSE BDF1
SEX : FEMALE
UNIT : g/kg/day

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration Week-Day	1-4	1-7	2-4	2-7
Control		0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000
512 ppm		0.102 ± 0.006	0.086 ± 0.007	0.083 ± 0.007	0.085 ± 0.011
1280 ppm		0.224 ± 0.023	0.203 ± 0.026	0.181 ± 0.034	0.182 ± 0.040
3200 ppm		0.451 ± 0.066	0.412 ± 0.060	0.367 ± 0.153	0.423 ± 0.153
8000 ppm		0.436 ± 0.072	0.599 ± 0.050	0.605 ± 0.062	0.807 ± 0.573
20000 ppm		0.509 ± 0.084	0.602 ± 0.082	—	—

APPENDIX F 1

HEMATOLOGY : SUMMARY, MOUSE : MALE

(2-WEEK STUDY)

STUDY NO. : 0315

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)

ALL ANIMALS (2W)

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 1 O ⁶ /μℓ		HEMOGLOBIN g/dℓ		HEMATOCRIT %		MCV f ℓ		MCH p g		MCHC g/dℓ		PLATELET 1 O ³ /μℓ	
Control	5	10.07±	0.62	15.3±	0.7	48.1±	3.1	47.8±	0.7	15.2±	0.6	31.8±	1.0	1122±	172
512 ppm	5	10.28±	0.33	15.6±	0.4	49.7±	1.0	48.4±	0.7	15.2±	0.3	31.3±	0.4	1129±	140
1280 ppm	5	10.61±	0.51	15.7±	0.4	50.1±	1.5	47.3±	1.5	14.8±	0.4	31.4±	0.4	1100±	122
3200 ppm	5	10.47±	0.34	15.8±	0.4	50.3±	2.2	48.1±	0.9	15.1±	0.3	31.5±	0.7	1018±	65
8000 ppm	5	11.14±	0.57**	16.8±	0.5**	53.3±	1.9**	47.9±	1.0	15.0±	0.5	31.5±	0.8	1183±	142
20000 ppm	3	12.08±	0.40**	18.1±	0.4**	58.2±	2.9**	48.2±	0.9	15.0±	0.2	31.2±	0.9	1099±	96

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

Test of Dunnett

(HCL070)

BAIS 3

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (2W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	5	2.61±	0.60	0±	0	14±	12	2±	1	0±	0	3±	1	81±	13	0±	0
512 ppm	5	3.59±	2.16	0±	1	10±	2	1±	1	0±	0	3±	2	86±	2	0±	0
1280 ppm	5	3.95±	1.42	1±	1	22±	11	2±	1	0±	0	3±	1	72±	11	0±	0
3200 ppm	5	3.06±	0.74	0±	0	13±	4	1±	1	0±	0	3±	1	82±	4	0±	0
8000 ppm	5	2.23±	0.86	1±	1	26±	15	1±	1	0±	0	3±	1	70±	16	0±	0
20000 ppm	3	0.23±	0.11	2±	1	47±	20*	0±	0	0±	0	3±	2	49±	19*	0±	0

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 3

APPENDIX F 2

HEMATOLOGY : SUMMARY, MOUSE : FEMALE

(2-WEEK STUDY)

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (2W)

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ³ /μl	
Control	5	10.29±	0.22	15.5±	0.4	48.2±	1.4	46.8±	0.4	15.1±	0.2	32.2±	0.4	1009±	98
512 ppm	5	10.16±	0.25	15.3±	0.3	48.3±	1.1	47.6±	0.6	15.1±	0.2	31.7±	0.4	983±	80
1280 ppm	5	10.19±	0.26	15.3±	0.5	48.4±	1.7	47.5±	0.5	15.0±	0.1	31.7±	0.3	975±	66
3200 ppm	5	10.30±	0.34	15.2±	0.3	48.6±	1.4	47.2±	0.5	14.8±	0.3	31.4±	0.5	985±	33
8000 ppm	5	11.27±	0.37**	16.8±	0.4**	52.5±	2.2**	46.5±	0.6	14.9±	0.2	32.0±	0.6	1033±	44
20000 ppm	0	-		-		-		-		-		-		-	

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

Test of Dunnett

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (2W)

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	WBC 10 ³ /μℓ		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	5	2.90±	0.92	0±	0	11±	2	2±	1	0±	0	3±	2	83±	2	0±	0
512 ppm	5	3.14±	0.88	0±	0	9±	1	2±	1	0±	0	4±	2	85±	2	0±	0
1280 ppm	5	3.46±	1.05	0±	0	13±	4	2±	2	0±	0	3±	1	83±	5	0±	0
3200 ppm	5	3.48±	0.49	0±	1	11±	4	1±	0	0±	0	5±	2	83±	6	0±	0
8000 ppm	5	1.93±	0.38	0±	0	20±	3**	2±	0	0±	0	2±	1	75±	2	0±	0
20000 ppm	0	-		-		-		-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

APPENDIX G 1

BIOCHEMISTRY : SUMMARY, MOUSE : MALE

(2-WEEK STUDY)

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (2W)

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		PHOSPHOLIPID mg/dl	
Control	5	4.9±	0.4	2.7±	0.1	1.3±	0.2	0.17±	0.01	268±	45	93±	14	187±	26
512 ppm	5	4.6±	0.2	2.7±	0.1	1.3±	0.1	0.16±	0.02	281±	22	80±	6	176±	19
1280 ppm	5	5.1±	0.7	2.8±	0.1	1.2±	0.2	0.17±	0.02	244±	51	102±	32	199±	44
3200 ppm	5	4.4±	0.0	2.5±	0.0	1.3±	0.0	0.17±	0.02	261±	24	78±	4	166±	9
8000 ppm	5	4.6±	0.5	2.6±	0.2	1.4±	0.1	0.24±	0.10	227±	68	98±	5	178±	21
20000 ppm	3	5.0±	0.3	3.0±	0.0	1.6±	0.2	0.48±	0.16	94±	60**	119±	63	137±	56

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

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (2W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	GOT I U / ℓ		GPT I U / ℓ		LDH I U / ℓ		G-GTP I U / ℓ		CPK I U / ℓ		UREA NITROGEN mg / dl		SODIUM mEq / ℓ	
Control	5	30±	2	18±	3	207±	42	2±	1	61±	27	27.5±	10.7	147±	1
512 ppm	5	36±	9	20±	3	206±	44	1±	1	78±	35	20.5±	2.2	147±	1
1280 ppm	5	33±	4	18±	5	304±	147	2±	1	57±	8	27.9±	2.5	146±	1
3200 ppm	5	34±	4	19±	2	183±	34	2±	0	65±	14	24.1±	3.8	147±	1
8000 ppm	5	50±	20*	22±	4	275±	76	3±	3	71±	20	41.0±	11.1	155±	6
20000 ppm	3	1721±	2750**	497±	790	4971±	7268*	15±	5	7077±	11922	115.2±	91.7	185±	11*

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BALS 3

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (2W)

PAGE : 3

Group Name	NO. of Animals	POTASSIUM mEq/ℓ		CHLORIDE mEq/ℓ		CALCIUM mg/dℓ		INORGANIC PHOSPHORUS mg/dℓ	
Control	5	5.4±	0.8	116±	2	9.4±	0.5	6.3±	1.0
512 ppm	5	5.1±	0.5	117±	1	9.3±	0.3	7.8±	1.0
1280 ppm	5	4.9±	0.2	113±	6	9.7±	0.7	6.9±	0.9
3200 ppm	5	5.2±	0.2	117±	1	9.1±	0.2	7.4±	1.3
8000 ppm	5	5.0±	0.5	123±	4*	9.0±	0.4	6.8±	0.4
20000 ppm	3	4.6±	0.5	143±	9**	9.4±	0.2	13.4±	8.9

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

APPENDIX G 2

BIOCHEMISTRY : SUMMARY, MOUSE : FEMALE

(2-WEEK STUDY)

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (2w)

REPORT TYPE : A1

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		PHOSPHOLIPID mg/dl	
Control	5	4.7±	0.1	3.0±	0.1	1.7±	0.1	0.18±	0.01	253±	16	69±	5	135±	5
512 ppm	5	4.6±	0.1	2.9±	0.1	1.7±	0.1	0.19±	0.03	250±	12	72±	7	140±	13
1280 ppm	5	4.6±	0.1	2.9±	0.1	1.7±	0.1	0.20±	0.03	253±	15	69±	5	141±	9
3200 ppm	5	4.4±	0.2**	2.7±	0.1	1.6±	0.1	0.17±	0.02	231±	6	78±	7	160±	14**
8000 ppm	5	4.5±	0.1*	2.7±	0.0	1.5±	0.1*	0.20±	0.06	187±	20**	103±	5**	197±	7**
20000 ppm	0	-		-		-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0315

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (2W)

PAGE : 5

Group Name	NO. of Animals	GOT I U / ℓ		GPT I U / ℓ		LDH I U / ℓ		G-GTP I U / ℓ		CPK I U / ℓ		UREA NITROGEN mg / dℓ		SODIUM mEq / ℓ	
Control	5	39±	7	24±	2	236±	55	1±	1	78±	51	21.2±	3.2	147±	0
512 ppm	5	37±	1	22±	1	260±	78	1±	0	85±	46	21.5±	3.3	147±	1
1280 ppm	5	37±	2	22±	3	287±	99	3±	4	128±	89	20.4±	3.0	147±	2
3200 ppm	5	33±	3	21±	5	216±	44	1±	2	83±	39	26.6±	5.2	146±	2
8000 ppm	5	44±	10	25±	4	328±	50	3±	2	82±	28	41.4±	5.7**	155±	4
20000 ppm	0	-		-		-		-		-		-		-	

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

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (2W)

PAGE : 6

Group Name	NO. of Animals	POTASSIUM mEq/ℓ		CHLORIDE mEq/ℓ		CALCIUM mg/dℓ		INORGANIC PHOSPHORUS mg/dℓ	
Control	5	5.0±	0.4	118±	1	9.1±	0.2	7.4±	1.0
512 ppm	5	5.0±	0.3	118±	1	9.1±	0.2	7.2±	0.7
1280 ppm	5	5.3±	0.8	118±	3	9.1±	0.3	7.1±	2.0
3200 ppm	5	5.2±	0.3	118±	2	9.2±	0.2	6.4±	1.5
8000 ppm	5	5.1±	0.2	123±	4**	9.5±	0.3	6.7±	0.9
20000 ppm	0	-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 3

APPENDIX H 1

GROSS FINDINGS : SUMMARY, MOUSE : MALE ALL ANIMALS
(2-WEEK STUDY)

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 10 (%)	512 ppm 10 (%)	1280 ppm 10 (%)	3200 ppm 10 (%)
thymus	atrophic		0 (0)	0 (0)	0 (0)	0 (0)
spleen	black zone		0 (0)	1 (10)	1 (10)	0 (0)
kidney	white zone		1 (10)	0 (0)	0 (0)	0 (0)
	hydronephrosis		1 (10)	1 (10)	2 (20)	1 (10)

(HPT080)

BAIS 3

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name	8000 ppm	20000 ppm
		NO. of Animals	10 (%)	10 (%)
thymus	atrophic		2 (20)	10 (100)
spleen	black zone		1 (10)	1 (10)
kidney	white zone		0 (0)	0 (0)
	hydronephrosis		0 (0)	0 (0)

(HPT080)

BAIS 3

APPENDIX H 2

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE ALL ANIMALS
(2-WEEK STUDY)

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 3

Organ	Findings	Group Name	Control	512 ppm	1280 ppm	3200 ppm
		NO. of Animals	10 (%)	10 (%)	10 (%)	10 (%)
thymus	atrophic		0 (0)	0 (0)	0 (0)	0 (0)
spleen	black zone		0 (0)	1 (10)	0 (0)	0 (0)
kidney	hydronephrosis		0 (0)	0 (0)	0 (0)	1 (10)

(HPT080)

BAIS 3

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 4

Organ	Findings	Group Name	8000 ppm		20000 ppm	
		NO. of Animals	10	(%)	10	(%)
thymus	atrophic		0	(0)	10	(100)
spleen	black zone		0	(0)	0	(0)
kidney	hydronephrosis		0	(0)	0	(0)

(HPT080)

BAIS 3

APPENDIX H 3

GROSS FINDINGS : SUMMARY, MOUSE : MALE

DEAD AND MORIBUND ANIMALS

(2-WEEK STUDY)

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 1 (%)	512 ppm 0 (%)	1280 ppm 0 (%)	3200 ppm 0 (%)
thymus	atrophic		0 (0)	- (-)	- (-)	- (-)
kidney	white zone		1 (100)	- (-)	- (-)	- (-)

(HPT080)

BAIS 3

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name	8000 ppm	20000 ppm
		NO. of Animals	1 (%)	7 (%)
thymus	atrophic		1 (100)	7 (100)
kidney	white zone		0 (0)	0 (0)

(HPT080)

BAIS 3

APPENDIX H 4

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE

DEAD AND MORIBUND ANIMALS

(2-WEEK STUDY)

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 0 (%)	512 ppm 0 (%)	1280 ppm 0 (%)	3200 ppm 0 (%)
thymus	atrophic		- (-)	- (-)	- (-)	- (-)

(HPT080)

BAIS 3

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 4

Organ	Findings	Group Name NO. of Animals	8000 ppm 0 (%)	20000 ppm 10 (%)
thymus	atrophic		- (-)	10 (100)

(HPT080)

BAIS 3

APPENDIX H 5

GROSS FINDINGS : SUMMARY, MOUSE : MALE : SACRIFICED ANIMALS
(2-WEEK STUDY)

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 9 (%)	512 ppm 10 (%)	1280 ppm 10 (%)	3200 ppm 10 (%)
thymus	atrophic		0 (0)	0 (0)	0 (0)	0 (0)
spleen	black zone		0 (0)	1 (10)	1 (10)	0 (0)
kidney	hydronephrosis		1 (11)	1 (10)	2 (20)	1 (10)

(HPT080)

BAIS 3

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 2

Organ	Findings	Group Name	8000 ppm	20000 ppm
		NO. of Animals	9 (%)	3 (%)
thymus	atrophic		1 (11)	3 (100)
spleen	black zone		1 (11)	1 (33)
kidney	hydronephrosis		0 (0)	0 (0)

(HPT080)

BAIS 3

APPENDIX H 6

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE : SACRIFICED ANIMALS
(2-WEEK STUDY)

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control	512 ppm	1280 ppm	3200 ppm
			10 (%)	10 (%)	10 (%)	10 (%)
spleen	black zone		0 (0)	1 (10)	0 (0)	0 (0)
kidney	hydronephrosis		0 (0)	0 (0)	0 (0)	1 (10)

(HPT080)

BAIS 3

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	8000 ppm	20000 ppm
			10 (%)	0 (%)
spleen	black zone		0 (0)	- (-)
kidney	hydronephrosis		0 (0)	- (-)

(HPT080)

BAIS 3

APPENDIX I 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : MALE

(2-WEEK STUDY)

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 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	24.6± 1.4	0.059± 0.007	0.010± 0.002	0.194± 0.044	0.135± 0.011	0.155± 0.008
512 ppm	5	24.8± 0.9	0.059± 0.005	0.011± 0.007	0.203± 0.039	0.144± 0.013	0.144± 0.008
1280 ppm	5	23.3± 1.4	0.049± 0.012	0.009± 0.002	0.174± 0.020	0.133± 0.014	0.140± 0.017
3200 ppm	5	22.3± 0.6*	0.048± 0.005	0.009± 0.001	0.176± 0.011	0.124± 0.010	0.135± 0.010*
8000 ppm	5	19.0± 2.1**	0.029± 0.010*	0.008± 0.001	0.156± 0.027	0.102± 0.012**	0.123± 0.007**
20000 ppm	3	12.8± 0.2**	0.004± 0.001**	0.006± 0.001	0.127± 0.013*	0.066± 0.004**	0.107± 0.014**

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

Test of Dunnett

(HCL040)

BAIS 3

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 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	0.482±	0.198	0.062±	0.012	1.244±	0.174	0.428±	0.016
512 ppm	5	0.364±	0.022	0.054±	0.007	1.216±	0.087	0.425±	0.023
1280 ppm	5	0.498±	0.171	0.073±	0.026	1.164±	0.124	0.411±	0.022
3200 ppm	5	0.386±	0.019	0.048±	0.009	1.126±	0.097	0.431±	0.007
8000 ppm	5	0.345±	0.010	0.034±	0.007*	0.854±	0.175**	0.401±	0.007
20000 ppm	3	0.233±	0.025*	0.009±	0.002**	0.450±	0.036**	0.373±	0.015**

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

Test of Dunnett

(HCL040)

BAIS 3

APPENDIX I 2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : FEMALE

(2-WEEK STUDY)

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
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	18.9± 0.9	0.072± 0.011	0.011± 0.003	0.021± 0.005	0.104± 0.006	0.140± 0.011
512 ppm	5	19.5± 0.3	0.074± 0.007	0.010± 0.002	0.022± 0.005	0.107± 0.010	0.146± 0.017
1280 ppm	5	19.5± 0.7	0.077± 0.007	0.011± 0.004	0.021± 0.005	0.113± 0.008	0.137± 0.015
3200 ppm	5	19.2± 1.0	0.068± 0.008	0.010± 0.002	0.021± 0.002	0.108± 0.009	0.130± 0.009
8000 ppm	5	15.9± 0.9**	0.037± 0.011**	0.008± 0.002	0.013± 0.003*	0.088± 0.009*	0.118± 0.008*
20000 ppm	0	-	-	-	-	-	-

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

Test of Dunnett

(HCL040)

BAIS 3

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 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	0.243±	0.010	0.053±	0.006	0.862±	0.078	0.434±	0.008
512 ppm	5	0.257±	0.005	0.054±	0.009	0.940±	0.026	0.419±	0.013
1280 ppm	5	0.270±	0.020	0.057±	0.001	0.985±	0.047**	0.435±	0.015
3200 ppm	5	0.417±	0.268**	0.055±	0.006	0.980±	0.061*	0.429±	0.016
8000 ppm	5	0.255±	0.021	0.031±	0.007	0.722±	0.059**	0.407±	0.015*
20000 ppm	0	-		-		-		-	

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

Test of Dunnett

(HCL040)

BAIS 3

APPENDIX J 1

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : MALE

(2-WEEK STUDY)

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 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	24.6± 1.4	0.238± 0.017	0.041± 0.010	0.790± 0.166	0.550± 0.031	0.631± 0.066
512 ppm	5	24.8± 0.9	0.237± 0.015	0.046± 0.027	0.819± 0.145	0.579± 0.049	0.583± 0.033
1280 ppm	5	23.3± 1.4	0.208± 0.037	0.041± 0.009	0.751± 0.105	0.573± 0.082	0.604± 0.081
3200 ppm	5	22.3± 0.6*	0.217± 0.019	0.040± 0.007	0.791± 0.059	0.557± 0.049	0.605± 0.047
8000 ppm	5	19.0± 2.1**	0.151± 0.042**	0.043± 0.008	0.837± 0.207	0.537± 0.025	0.657± 0.082
20000 ppm	3	12.8± 0.2**	0.034± 0.004**	0.050± 0.004	0.988± 0.112	0.517± 0.029	0.832± 0.118**

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

Test of Dunnett

(HCL042)

BAIS 3

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
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	2.002± 0.980	0.253± 0.066	5.043± 0.522	1.746± 0.138
512 ppm	5	1.467± 0.066	0.216± 0.023	4.904± 0.191	1.716± 0.085
1280 ppm	5	2.168± 0.861	0.318± 0.132	4.986± 0.385	1.763± 0.065
3200 ppm	5	1.732± 0.103	0.214± 0.039	5.043± 0.306	1.932± 0.054**
8000 ppm	5	1.842± 0.251	0.178± 0.025*	4.454± 0.496	2.138± 0.267**
20000 ppm	3	1.811± 0.168	0.073± 0.011**	3.507± 0.224**	2.909± 0.103**

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

Test of Dunnett

(HCL042)

BAIS 3

APPENDIX J 2

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : FEMALE

(2-WEEK STUDY)

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 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	18.9± 0.9	0.379± 0.041	0.057± 0.013	0.110± 0.020	0.550± 0.020	0.739± 0.072
512 ppm	5	19.5± 0.3	0.378± 0.037	0.049± 0.010	0.111± 0.028	0.551± 0.052	0.749± 0.088
1280 ppm	5	19.5± 0.7	0.394± 0.045	0.058± 0.016	0.105± 0.025	0.580± 0.036	0.704± 0.087
3200 ppm	5	19.2± 1.0	0.354± 0.040	0.052± 0.011	0.111± 0.012	0.566± 0.051	0.679± 0.062
8000 ppm	5	15.9± 0.9**	0.229± 0.064**	0.049± 0.009	0.080± 0.014	0.553± 0.056	0.744± 0.076
20000 ppm	0	-	-	-	-	-	-

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

Test of Dunnett

(HCL042)

BAIS 3

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 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	1.283± 0.063	0.280± 0.034	4.553± 0.374	2.296± 0.083
512 ppm	5	1.323± 0.009	0.280± 0.045	4.834± 0.162	2.154± 0.082
1280 ppm	5	1.386± 0.070*	0.292± 0.013	5.054± 0.246*	2.230± 0.097
3200 ppm	5	2.222± 1.552**	0.285± 0.020	5.111± 0.098**	2.242± 0.064
8000 ppm	5	1.604± 0.088**	0.194± 0.040**	4.538± 0.191	2.568± 0.142**
20000 ppm	0	-	-	-	-

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

Test of Dunnett

(HCL042)

BAIS 3

APPENDIX K 1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : MALE : ALL ANIMALS

(2-WEEK STUDY)

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDf1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 2W)

PAGE : 1

Organ	Findings	Control				512 ppm				1280 ppm				3200 ppm			
		No. of Animals on Study				2				2				2			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																	
bone marrow		< 3>				< 2>				< 2>				< 2>			
	congestion	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)
thymus		< 3>				< 2>				< 2>				< 2>			
	atrophy	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(33)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
spleen		< 3>				< 2>				< 2>				< 2>			
	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)
	deposit of melanin	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)
{Circulatory system}																	
heart		< 3>				< 2>				< 2>				< 2>			
	necrosis	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(33)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Digestive system}																	
liver		< 3>				< 2>				< 2>				< 2>			
	necrosis: single cell	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 : Number of animals with lesion
(c) c : b / a * 100

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 2#)

PAGE : 2

		Group Name				8000 ppm				20000 ppm			
		No. of Animals on Study				2				3			
Organ_____	Findings_____	Grade				1	2	3	4	1	2	3	4
						(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}													
bone marrow		< 2>				< 3>							
	congestion	0	0	0	0	3	0	0	0	(100)	(0)	(0)	(0)
		(0)	(0)	(0)	(0)								
thymus		< 2>				< 3>							
	atrophy	0	0	0	0	0	0	3	0	(0)	(0)	(100)	(0)
		(0)	(0)	(0)	(0)								
spleen		< 2>				< 3>							
	atrophy	0	0	0	0	2	0	0	0	(67)	(0)	(0)	(0)
		(0)	(0)	(0)	(0)								
	deposit of melanin	0	0	0	0	1	0	0	0	(33)	(0)	(0)	(0)
		(0)	(0)	(0)	(0)								
{Circulatory system}													
heart		< 2>				< 3>							
	necrosis	0	0	0	0	0	0	0	0	(0)	(0)	(0)	(0)
		(0)	(0)	(0)	(0)								
{Digestive system}													
liver		< 2>				< 3>							
	necrosis: single cell	0	0	0	0	1	0	0	0	(33)	(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

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 2%)

PAGE : 3

		Group Name	Control				512 ppm				1280 ppm				3200 ppm			
		No. of Animals on Study	3				2				2				2			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ	Findings		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney			< 3>				< 2>				< 2>				< 2>			
	hydronephrosis		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(33)	(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																	

(HPT150)

BAIS3

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 2W)

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study	8000 ppm				20000 ppm			
			2				3			
			1	2	3	4	1	2	3	4
			Grade	(%)	(%)	(%)	(%)	(%)	(%)	(%)

(Urinary system)

kidney	hydronephrosis	< 2>				< 3>			
		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

(HPT150)

BAIS3

APPENDIX K 2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : FEMALE: ALL ANIMALS

(2-WEEK STUDY)

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 2%)

PAGE : 5

Organ	Findings	Group Name	Control				512 ppm				1280 ppm				3200 ppm			
		No. of Animals on Study	2				2				2				2			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																		
bone marrow			< 2>				< 2>				< 2>				< 2>			
	congestion		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)
thymus			< 2>				< 2>				< 2>				< 2>			
	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)
spleen			< 2>				< 2>				< 2>				< 2>			
	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)
			< 2>				< 2>				< 2>				< 2>			
	deposit of melanin		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(50)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Digestive system}																		
stomach			< 2>				< 2>				< 2>				< 2>			
	ulcer:forestomach		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			< 2>				< 2>				< 2>				< 2>			
	hydronephrosis		0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(50)	(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																	

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 2%)

PAGE : 6

Organ_____	Findings_____	Group Name	8000 ppm				20000 ppm				
		No. of Animals on Study	2				2				
		Grade	1	2	3	4	1	2	3	4	
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]											
bone marrow			< 2>				< 2>				
	congestion		0	0	0	0	1	1	0	0	
			(0)	(0)	(0)	(0)	(50)	(50)	(0)	(0)	
thymus			< 2>				< 1>				
	atrophy		0	0	0	0	0	0	1	0	
			(0)	(0)	(0)	(0)	(0)	(0)	(100)	(0)	
spleen			< 2>				< 2>				
	atrophy		0	0	0	0	2	0	0	0	
			(0)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	
	deposit of melanin		0	0	0	0	0	0	0	0	
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
[Digestive system]											
stomach			< 2>				< 2>				
	ulcer:forestomach		0	2	0	0	0	0	0	0	
			(0)	(100)	(0)	(0)	(0)	(0)	(0)	(0)	
[Urinary system]											
kidney			< 2>				< 2>				
	hydronephrosis		0	0	0	0	0	0	0	0	
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100

APPENDIX K 3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : MALE : DEAD AND MORIBUND ANIMALS

(2-WEEK STUDY)

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 2W)

PAGE : 1

Organ	Findings	Group Name No. of Animals on Study Grade	Control 1				512 ppm 0				1280 ppm 0				3200 ppm 0			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																		
bone marrow	congestion		< 1>				< 0>				< 0>				< 0>			
			0	0	0	0	-	-	-	-	-	-	-	-	-	-	-	-
			(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
thymus	atrophy		< 1>				< 0>				< 0>				< 0>			
			0	0	1	0	-	-	-	-	-	-	-	-	-	-	-	-
			(0)	(0)	(100)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
spleen	atrophy		< 1>				< 0>				< 0>				< 0>			
			0	0	0	0	-	-	-	-	-	-	-	-	-	-	-	-
			(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	deposit of melanin		< 1>				< 0>				< 0>				< 0>			
			0	0	0	0	-	-	-	-	-	-	-	-	-	-	-	-
			(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
{Circulatory system}																		
heart	necrosis		< 1>				< 0>				< 0>				< 0>			
			0	1	0	0	-	-	-	-	-	-	-	-	-	-	-	-
			(0)	(100)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
{Urinary system}																		
kidney	hydronephrosis		< 1>				< 0>				< 0>				< 0>			
			0	1	0	0	-	-	-	-	-	-	-	-	-	-	-	-
			(0)	(100)	(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

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 2W)

PAGE : 2

Organ	Findings	8000 ppm				20000 ppm			
		0				1			
		1	2	3	4	1	2	3	4
Grade		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Hematopoietic system)									
bone marrow		< 0>				< 1>			
	congestion	-	-	-	-	1	0	0	0
		(-)	(-)	(-)	(-)	(100)	(0)	(0)	(0)
thymus		< 0>				< 1>			
	atrophy	-	-	-	-	0	0	1	0
		(-)	(-)	(-)	(-)	(0)	(0)	(100)	(0)
spleen		< 0>				< 1>			
	atrophy	-	-	-	-	1	0	0	0
		(-)	(-)	(-)	(-)	(100)	(0)	(0)	(0)
	deposit of melanin	-	-	-	-	1	0	0	0
		(-)	(-)	(-)	(-)	(100)	(0)	(0)	(0)
(Circulatory system)									
heart		< 0>				< 1>			
	necrosis	-	-	-	-	0	0	0	0
		(-)	(-)	(-)	(-)	(0)	(0)	(0)	(0)
(Urinary system)									
kidney		< 0>				< 1>			
	hydronephrosis	-	-	-	-	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

APPENDIX K 4

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : FEMALE : DEAD AND MORIBUND ANIMALS

(2-WEEK STUDY)

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 2W)

PAGE : 3

		Group Name	Control				512 ppm				1280 ppm				3200 ppm			
		No. of Animals on Study	0				0				0				0			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Hematopoietic system)																		
bone marrow			< 0>				< 0>				< 0>				< 0>			
	congestion		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
thymus			< 0>				< 0>				< 0>				< 0>			
	atrophy		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
spleen			< 0>				< 0>				< 0>				< 0>			
	atrophy		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
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																	

(HPT150)

BAIS3

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 2W)

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study				8000 ppm				20000 ppm			
		Grade				0				2			
		1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Hematopoietic system)													
bone marrow	congestion	< 0>				< 2>							
		-	-	-	-	1	1	0	0				
		(-)	(-)	(-)	(-)	(50)	(50)	(0)	(0)				
thymus	atrophy	< 0>				< 1>							
		-	-	-	-	0	0	1	0				
		(-)	(-)	(-)	(-)	(0)	(0)	(100)	(0)				
spleen	atrophy	< 0>				< 2>							
		-	-	-	-	2	0	0	0				
		(-)	(-)	(-)	(-)	(100)	(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

(HPT150)

BAIS3

APPENDIX K 5

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : MALE : SACRIFICED ANIMALS

(2-WEEK STUDY)

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (2W)

PAGE : 1

Organ_____	Findings_____	Group Name No. of Animals on Study Grade	Control 2				512 ppm 2				1280 ppm 2				3200 ppm 2			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>																		
{Hematopoietic system}																		
bone marrow	congestion		< 2>				< 2>				< 2>				< 2>			
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
thymus	atrophy		< 2>				< 2>				< 2>				< 2>			
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
spleen	atrophy		< 2>				< 2>				< 2>				< 2>			
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Digestive system}																		
liver	necrosis:single cell		< 2>				< 2>				< 2>				< 2>			
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

STUDY NO. : 0315
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 2

Organ	Findings	Group Name No. of Animals on Study				8000 ppm				20000 ppm			
		Grade				2				2			
		1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}													
bone marrow		< 2>				< 2>				< 2>			
	congestion	0	0	0	0	2	0	0	0	(100)	(0)	(0)	(0)
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
thymus		< 2>				< 2>				< 2>			
	atrophy	0	0	0	0	0	0	2	0	(0)	(0)	(100)	(0)
		(0)	(0)	(0)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(0)	(0)
spleen		< 2>				< 2>				< 2>			
	atrophy	0	0	0	0	1	0	0	0	(50)	(0)	(0)	(0)
		(0)	(0)	(0)	(0)	(50)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Digestive system}													
liver		< 2>				< 2>				< 2>			
	necrosis: single cell	0	0	0	0	1	0	0	0	(50)	(0)	(0)	(0)
		(0)	(0)	(0)	(0)	(50)	(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

(HPT150)

BAIS3

APPENDIX K 6

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : FEMALE : SACRIFICED ANIMALS

(2-WEEK STUDY)

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (2#)

PAGE : 3

		Group Name	Control				512 ppm				1280 ppm				3200 ppm			
		No. of Animals on Study	2				2				2				2			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ_____	Findings_____		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>																		
{Hematopoietic system}																		
spleen			< 2>				< 2>				< 2>				< 2>			
	deposit of melanin		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(50)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
<hr/>																		
{Digestive system}																		
stomach			< 2>				< 2>				< 2>				< 2>			
	ulcer:forestomach		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)
<hr/>																		
{Urinary system}																		
kidney			< 2>				< 2>				< 2>				< 2>			
	hydronephrosis		0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(50)	(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

(HPT150)

BAIS3

STUDY NO. : 0315
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (2#)

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study Grade	8000 ppm				20000 ppm			
			2				0			
			1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}										
spleen	deposit of melanin		< 2>				< 0>			
			0	0	0	0	-	-	-	-
			(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)
{Digestive system}										
stomach	ulcer:forestomach		< 2>				< 0>			
			0	2	0	0	-	-	-	-
			(0)	(100)	(0)	(0)	(-)	(-)	(-)	(-)
{Urinary system}										
kidney	hydronephrosis		< 2>				< 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

(HPT150)

BAIS3

APPENDIX L 1

IDENTITY AND IMPURITY OF 2 - HYDROXYETHYL ACRYLATE IN THE 2-WEEK DRINKING WATER STUDY

IDENTITY AND IMPURITY OF 2-HYDROXYETHYL ACRYLATE IN THE 2-WEEK DRINKING WATER STUDY

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

Lot No. : SKR5565

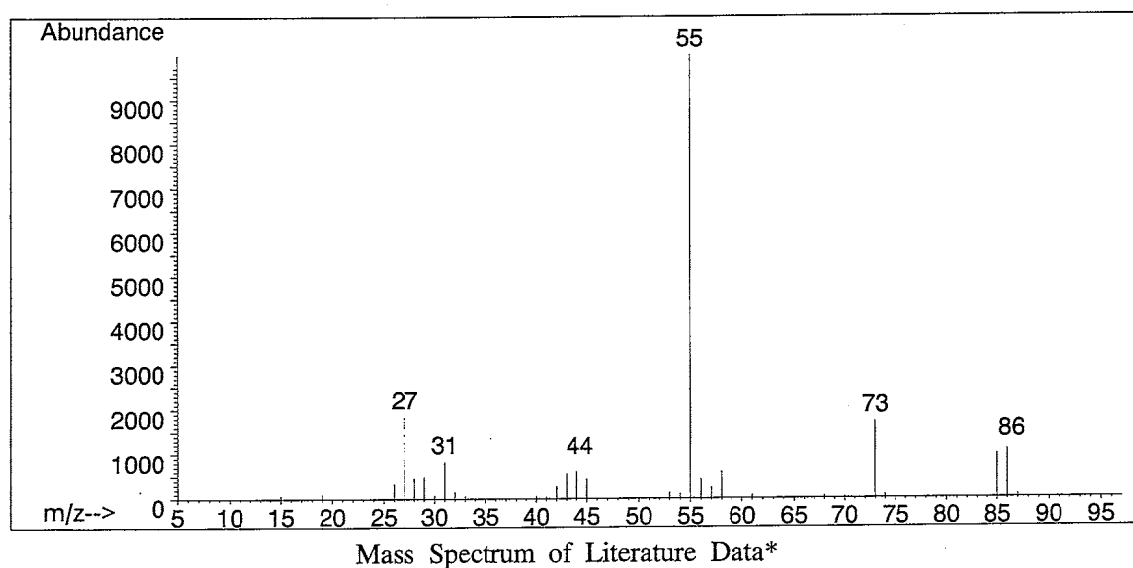
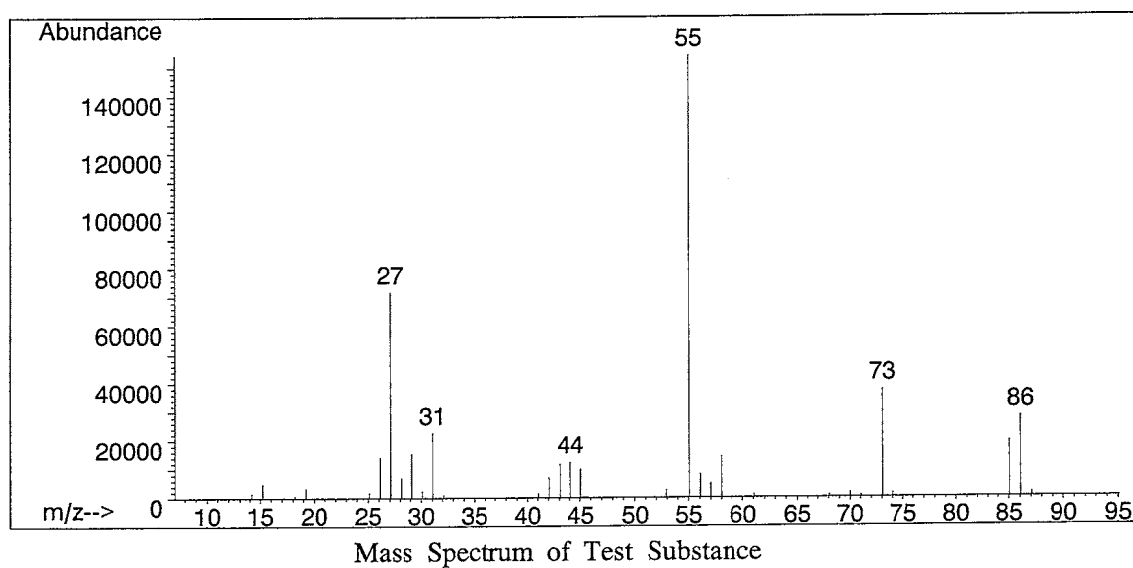
1. Spectral Data

Mass Spectrometry

Instrument : Hewlett Packard 5989B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



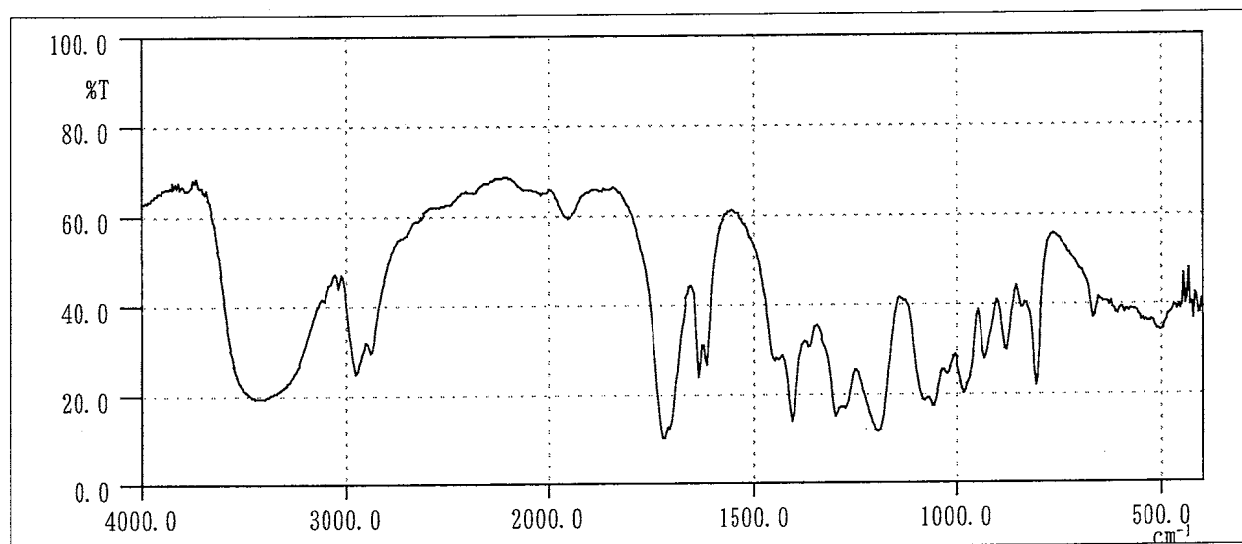
Results: The mass spectrum was consistent with literature spectrum.

(*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition.
John Wiley and Sons, Inc. (U.S.), Entry Number 12762)

Infrared Spectrometry

Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 2 cm^{-1} 

Infrared Spectrum of Test Substance

<u>Determined Values</u>	<u>Literature Values</u> *
Wave Number (cm^{-1})	Wave Number (cm^{-1})
650~ 680	650~ 680
770~ 850	770~ 850
850~ 910	850~ 910
910~ 950	910~ 950
950~1010	950~1010
1010~1140	1010~1140
1140~1250	1140~1250
1250~1350	1250~1350
1350~1550	1350~1550
1580~1660	1580~1660
1660~1850	1660~1850
1920~2000	1920~2000
2750~3020	2750~3020
3060~3700	3060~3700

Results: The infrared spectrum was consistent with literature spectrum.

(*Performed by Wako Pure Chemical Industries, Ltd.)

2. Impurity

Instrument : Hewlett Packard 5890A Gas Chromatograph
Column : FFAP (0.53 mm ϕ \times 30 m)
Column Temperature : 180 °C
Flow Rate : 3 mL/min
Detector : FID (Flame Ionization Detector)
Injection Volume : 1 μ L

Sample Name	Peak No.	Area (%)	Peak Name
Test Substance	1	0.843	Acrylic Acid
	2	96.338	2-Hydroxyethyl Acrylate
	3	2.766	Material which cannot be identified
	4	0.054	p-Methoxyphenol

Results: Gas chromatography indicated one major peak (peak No.2) and three impurities. It was identified only by comparing gas chromatograph with that of acrylic acid (peak No.1), material which cannot be identified (peak No.3) and p-methoxyphenol (peak No.4) in the 2-hydroxyethyl acrylate, the amount in the test substance were 0.843%, 2.766% and 0.054%.

3. Conclusions: The test substance was identified as 2-hydroxyethyl acrylate by the mass spectrum and the infrared spectrum. Gas chromatography indicated one major peak (peak No.2) and three impurities. It was identified only by comparing gas chromatograph with that of acrylic acid, material which cannot be identified and p-methoxyphenol, the amount in the test substance were 0.843%, 2.766% and 0.054%.

APPENDIX L 2

STABILITY OF 2 - HYDROXYETHYL ACRYLATE IN THE 2-WEEK DRINKING WATER STUDY

STABILITY OF 2-HYDROXYETHYL ACRYLATE IN THE 2-WEEK DRINKING WATER STUDY

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

Lot No. : SKR5565

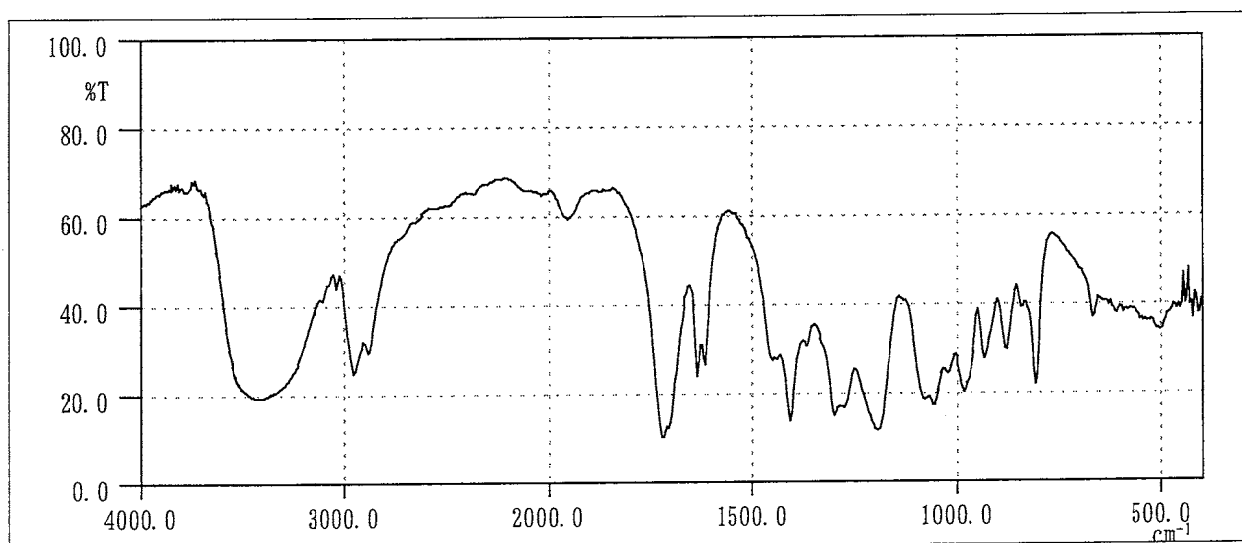
1. Sample : This lot was used from 1996.7.23 to 1996.8.6. Test substance was stored at room temperature.

2. Infrared Spectrometry

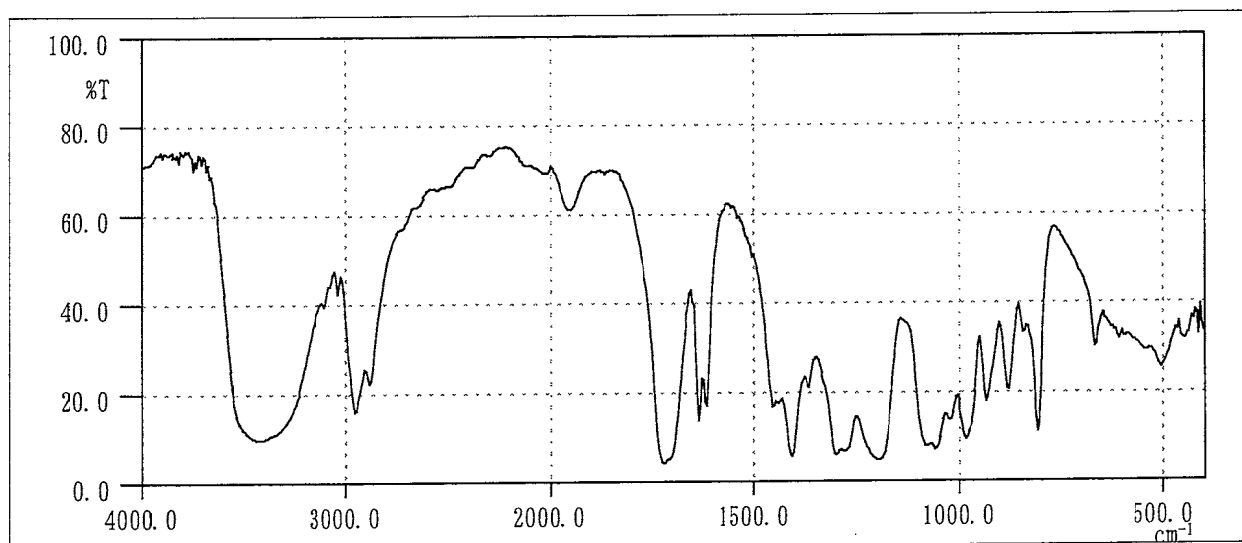
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 2 cm^{-1}



Infrared Spectrum of Test Substance (date analyzed : 1996.07.09)



Infrared Spectrum of Test Substance (date analyzed : 1996.08.13)

Results: The results of infrared spectrum did not change before and after the study.

3. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : FFAP (0.53 mm ϕ \times 30 m)

Column Temperature : 180 °C

Flow Rate : 3 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
1996.07.05	1	2.750	0.843
	2	3.477	96.338
	3	7.748	2.766
	4	20.975	0.054
1996.08.13	1	2.726	0.841
	2	3.449	96.315
	3	7.687	2.793
	4	20.824	0.051

Results: Gas chromatography indicated one major peak (peak No.2) and three impurities (peaks No.1, No.3 and No.4 < 4% of total area) analyzed on 1996.7.5 and one major peak (peak No.2) and three impurities (peaks No.1, No.3 and No.4 < 4% of total area) analyzed on 1996.8.13. No new trace impurity peak in the test substance analyzed on 1996.8.13 was detected.

4. Conclusions: The test substance was stable for about 1 month at room temperature.

APPENDIX L 3

CONCENTRATION OF 2 - HYDROXYETHYL ACRYLATE IN FORMULATED
WATER IN THE 2-WEEK DRINKING WATER STUDY

CONCENTRATION OF 2-HYDROXYETHYL ACRYLATE IN FORMULATED WATER IN THE 2-WEEK DRINKING WATER STUDY

Date Analyzed	Target Concentration				
	512 ^a	1280	3200	8000	20000
1996.07.22	506 (98.8) ^b	1250 (97.7)	3260 (102)	8150 (102)	20200 (101)

^a ppm

^b %

Analytical Method : The samples were analyzed by gas chromatography.

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : FFAP (0.53 mm ϕ \times 30 m)

Column Temperature : 180 °C

Flow Rate : 3 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

APPENDIX L 4

STABILITY OF 2 - HYDROXYETHYL ACRYLATE IN FORMULATED
WATER IN THE 2-WEEK DRINKING WATER STUDY

STABILITY OF 2-HYDROXYETHYL ACRYLATE IN FORMULATED WATER IN THE 2-WEEK DRINKING WATER STUDY

Date Prepared	Date Analyzed	Target Concentration	
		512 ^a	20000
1996.07.05	1996.07.05	519 (100) ^b	20000 (100)
	1996.07.12 ^c	477 (91.9)	18700 (93.5)

^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 : FFAP (0.53 mm ϕ \times 30 m)

Column Temperature : 180 °C

Flow Rate : 3 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

APPENDIX M 1

METHODS FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK DRINKING WATER STUDY OF 2 - HYDROXYETHYL ACRYLATE

METHODS FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK
DRINKING WATER STUDY OF 2-HYDROXYETHYL ACRYLATE

Item	Method
Hematology	
Red blood cell (RBC)	Light scattering method ¹⁾
Hemoglobin (Hgb)	Cyanmethemoglobin method ¹⁾
Hematocrit (Hct)	Calculated as $RBC \times MCV / 10$ ¹⁾
Mean corpuscular volume (MCV)	Light scattering method ¹⁾
Mean corpuscular hemoglobin (MCH)	Calculated as $Hgb / RBC \times 10$ ¹⁾
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as $Hgb / Hct \times 100$ ¹⁾
Platelet	Light scattering method ¹⁾
White blood cell (WBC)	Light scattering method ¹⁾
Differential WBC	Pattern recognition method ²⁾ (May-Grunwald-Giemsa staining)
Biochemistry	
Total protein (TP)	Biuret method ³⁾
Albumin (Alb)	BCG method ³⁾
A/G ratio	Calculated as $Alb / (TP - Alb)$ ³⁾
T-bilirubin	Alkaline azobilirubin method ³⁾
Glucose	Enzymatic method (GLK · G-6-PDH) ³⁾
T-cholesterol	Enzymatic method (CE · COD · POD) ³⁾
Phospholipid	Enzymatic method (PLD · COD · POD) ³⁾
Glutamic oxaloacetic transaminase (GOT)	IFCC method ³⁾
Glutamic pyruvic transaminase (GPT)	IFCC method ³⁾
Lactate dehydrogenase (LDH)	Wroblewski-LaDue method ³⁾
γ -Glutamyl transpeptidase (γ -GTP)	L- γ -Glutamyl-p-nitroanilide method ³⁾
Creatine phosphokinase (CPK)	GSCC method ³⁾
Urea nitrogen	Enzymatic method (Urease · GLDH) ³⁾
Sodium	Ion selective electrode method ³⁾
Potassium	Ion selective electrode method ³⁾
Chloride	Ion selective electrode method ³⁾
Calcium	OCPC method ³⁾
Inorganic phosphorus	Enzymatic method (PNP · XOD · POD) ³⁾

1) Automatic blood cell analyzer (Technicon H·1 : Technicon Instruments Corporation)

2) Automatic blood cell differential analyzer (Hitachi 8200 : Hitachi,Ltd.)

3) Automatic analyzer (Hitachi 7070 : Hitachi,Ltd.)

APPENDIX M 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE
2-WEEK DRINKING WATER STUDY OF 2 - HYDROXYETHYL ACRYLATE

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY
IN THE 2-WEEK DRINKING WATER STUDY OF 2-HYDROXYETHYL ACRYLATE

Item	Unit	Decimal place
Hematology		
Red blood cell (RBC)	$\times 10^6 / \mu\text{L}$	2
Hemoglobin	g/dL	1
Hematocrit	%	1
Mean corpuscular volume (MCV)	fL	1
Mean corpuscular hemoglobin (MCH)	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	g/dL	1
Platelet	$\times 10^3 / \mu\text{L}$	0
White blood cell (WBC)	$\times 10^3 / \mu\text{L}$	2
Differential WBC	%	0
Biochemistry		
Total protein	g/dL	1
Albumin	g/dL	1
A/G ratio	—	1
T-bilirubin	mg/dL	2
Glucose	mg/dL	0
T-cholesterol	mg/dL	0
Phospholipid	mg/dL	0
Glutamic oxaloacetic transaminase (GOT)	IU/L	0
Glutamic pyruvic transaminase (GPT)	IU/L	0
Lactate dehydrogenase (LDH)	IU/L	0
γ -Glutamyl transpeptidase (γ -GTP)	IU/L	0
Creatine phosphokinase (CPK)	IU/L	0
Urea nitrogen	mg/dL	1
Sodium	mEq/L	0
Potassium	mEq/L	1
Chloride	mEq/L	0
Calcium	mg/dL	1
Inorganic phosphorus	mg/dL	1