

ヒドラジーン-水加物のラット及びマウスを用いた
経口投与によるがん原性予備試験(混水試験)報告書

APPENDIX

(A1-1～A12-4)

2週間試験：ラット/0261；マウス/0262

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APPENDIX A 1-1

CLINICAL OBSERVATION (TWO-WEEK STUDY: SUMMARY)

RAT : MALE

STUDY NO. : 0261
 ANIMAL : RAT F344
 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
		1	1	1	1	1
DEATH	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	0	1
	800 ppm	0	0	0	0	10
HUNCHBACK POSITION	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	0	4
	800 ppm	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	0	9
	800 ppm	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	0	5
	800 ppm	0	0	0	2	0
SMALL STOOL	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	9	10	10
	800 ppm	0	0	10	10	1

STUDY NO. : 0261
ANIMAL : RAT F344
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
		1	1	1	1	1
OLIGO-STOOL	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	3	3	9	10
	800 ppm	0	10	10	10	1

(IAN190)

BATS 2

APPENDIX A 1-2

CLINICAL OBSERVATION (TWO-WEEK STUDY: SUMMARY)

RAT : FEMALE

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 3

Clinical sign	Group Name	Administration Week-day				
		1-1 1	1-3 1	1-7 1	2-3 1	2-7 1
DEATH	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	3	6
	800 ppm	0	0	1	9	-
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	1	0	1
	800 ppm	0	0	1	0	-
HUNCHBACK POSITION	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	2	1	3
	800 ppm	0	0	3	1	-
WASTING	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	1	0	0
	800 ppm	0	0	1	0	-
SOILED	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	1	1
	400 ppm	0	0	0	1	1
	800 ppm	0	0	0	0	-

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 4

Clinical sign	Group Name	Administration Week-day				
		1-1	1-3	1-7	2-3	2-7
		1	1	1	1	1
PILOERECTON	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	0	4
	800 ppm	0	0	0	0	-
SOILED PERI GENITALIA	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	2	5	7
	400 ppm	0	0	7	5	6
	800 ppm	0	2	10	3	-
NOSE HEMORRHAGIC DISCHA	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	0	0
	800 ppm	0	0	0	1	-
SMALL STOOL	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	5	6	6
	400 ppm	0	0	3	6	6
	800 ppm	0	0	5	2	-
OLIGO-STOOL	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	4	6	7
	400 ppm	0	7	9	7	6
	800 ppm	0	10	10	3	-

APPENDIX A 1-3

CLINICAL OBSERVATION (TWO-WEEK STUDY: SUMMARY)

MOSUE : MALE

STUDY NO. : 0262
 ANIMAL : MOUSE 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
		1	1	1	1	1
DEATH	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	0	0
	800 ppm	0	0	0	2	9
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	0	0
	800 ppm	0	0	0	0	1
HUNCHBACK POSITION	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	0	6
	800 ppm	0	0	2	5	1
PILOERECTION	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	4
	400 ppm	0	0	3	4	10
	800 ppm	0	0	8	6	1
IRREGULAR BREATHING	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	0	0
	800 ppm	0	0	0	0	1

STUDY NO. : 0262
ANIMAL : MOUSE 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
		1	1	1	1	1
ABNORMAL RESPIRATION	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	0	0
	800 ppm	0	0	0	0	1
OLIGO-STOOL	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	0	10
	800 ppm	0	2	5	5	1

(HAN190)

BATS2

APPENDIX A 1-4

CLINICAL OBSERVATION (TWO-WEEK STUDY: SUMMARY)

MOSUE: FEMALE

STUDY NO. : 0262
 ANIMAL : MOUSE 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
		1	1	1	1	1
DEATH	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	0	1
	800 ppm	0	0	0	3	10
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	0	0
	800 ppm	0	0	1	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	0	0	0	3
	800 ppm	0	0	2	3	0
PILOERECTION	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	1	2	3
	400 ppm	0	0	5	9	9
	800 ppm	0	0	9	7	0
OLIGO-STOOL	Control	0	0	0	0	0
	50 ppm	0	0	0	0	0
	100 ppm	0	0	0	0	0
	200 ppm	0	0	0	0	0
	400 ppm	0	1	6	6	10
	800 ppm	0	5	9	7	1

APPENDIX A 2-1

BODY WEIGHT CHANGES (TWO-WEEK STUDY: SUMMARY)

RAT : MALE

STUDY NO. : 0261
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 2
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration		week-day									
	0-0		1-1		1-3		1-7		2-3		2-7	
Control	124±	5	128±	6	135±	7	150±	9	162±	10	178±	12
50 ppm	124±	4	125±	4	130±	5	144±	6	153±	8	166±	10*
100 ppm	124±	4	122±	4*	127±	6*	144±	6	150±	7	161±	7**
200 ppm	124±	4	120±	4**	123±	6**	126±	9**	129±	9**	137±	9**
400 ppm	124±	5	117±	4**	108±	5**	89±	5**	79±	6**	68±	5**
800 ppm	124±	4	115±	4**	102±	4**	82±	3**	70±	3**	-	

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

Test of Dunnett

(HAN260)

BATS 2

APPENDIX A 2-2

BODY WEIGHT CHANGES (TWO-WEEK STUDY: SUMMARY)

RAT : FEMALE

STUDY NO. : 0261
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 2
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration		week-day									
	0-0		1-1		1-3		1-7		2-3		2-7	
Control	100±	4	100±	3	107±	4	117±	5	122±	5	129±	7
50 ppm	100±	4	96±	5*	101±	4*	108±	4**	111±	4**	117±	4**
100 ppm	99±	4	96±	3*	94±	4**	104±	4**	104±	6**	110±	7**
200 ppm	99±	4	94±	4**	87±	4**	79±	6**	74±	8**	75±	9**
400 ppm	99±	4	92±	4**	83±	4**	65±	5**	62±	3**	57±	5**
800 ppm	100±	4	91±	4**	79±	4**	62±	4**	56±	0 ?	-	

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

Test of Dunnett

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

(HAN260)

BAIS 2

APPENDIX A 2-3

BODY WEIGHT CHANGES (TWO-WEEK STUDY: SUMMARY)

MOSUE : MALE

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 2
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration week-day					
	0-0	1-1	1-3	1-7	2-3	2-7
Control	22.8± 0.9	22.3± 0.9	23.4± 0.8	24.2± 0.9	24.7± 1.0	25.2± 1.0
50 ppm	22.7± 0.9	21.5± 0.8	21.8± 0.9**	22.7± 0.9*	23.3± 1.1*	24.1± 1.2
100 ppm	22.8± 0.9	21.0± 0.8**	21.4± 0.8**	21.1± 1.5**	22.3± 0.8**	23.0± 0.9**
200 ppm	22.7± 0.9	20.5± 0.8**	19.4± 0.8**	19.0± 0.9**	18.9± 1.0**	19.0± 1.3**
400 ppm	22.7± 0.9	20.4± 0.9**	18.6± 1.0**	16.1± 1.3**	14.9± 1.4**	13.2± 1.1**
800 ppm	22.7± 0.9	20.0± 0.9**	17.8± 1.0**	14.5± 1.1**	13.3± 0.7**	12.8± 0.0 ?

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

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

APPENDIX A 2-4

BODY WEIGHT CHANGES (TWO-WEEK STUDY: SUMMARY)

MOSUE: FEMALE

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 2
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day					
	0-0	1-1	1-3	1-7	2-3	2-7
Control	18.6± 0.6	18.0± 0.4	18.7± 0.8	19.3± 0.6	19.3± 0.9	19.9± 0.7
50 ppm	18.6± 0.6	16.9± 0.6**	17.0± 1.1	18.4± 1.0*	18.4± 0.8*	19.0± 0.8
100 ppm	18.6± 0.6	16.6± 0.7**	16.1± 0.9	16.8± 1.1**	16.9± 1.0**	17.9± 1.0**
200 ppm	18.6± 0.6	16.6± 0.4**	15.4± 0.4**	14.4± 0.6**	14.1± 0.6**	13.8± 0.9**
400 ppm	18.6± 0.6	16.3± 0.4**	14.7± 0.5**	12.6± 0.7**	11.5± 0.6**	10.5± 0.4**
800 ppm	18.6± 0.6	16.1± 0.6**	14.2± 0.7**	11.7± 0.7**	10.7± 0.4**	

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

Test of Dunnett

APPENDIX A 3-1

WATER CONSUMPTION CHANGES : SUMMARY, RAT: MALE
(TWO-WEEK STUDY)

STUDY NO. : 0261
 ANIMAL : RAT F344
 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	17.4± 2.0	17.3± 1.7	17.7± 1.5	16.6± 1.2
50 ppm	11.0± 1.0	11.7± 0.8	11.9± 1.0	11.4± 1.5**
100 ppm	9.7± 1.3*	12.3± 1.2	10.8± 0.7*	11.4± 1.2**
200 ppm	8.4± 1.1**	9.5± 1.5**	9.5± 2.0**	9.6± 1.3**
400 ppm	3.9± 0.8**	2.0± 0.9**	2.4± 1.1**	2.1± 0.7**
800 ppm	1.8± 0.3**	1.3± 0.3**	1.1± 0.2**	-

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

Test of Dunnett

APPENDIX A 3-2

WATER CONSUMPTION CHANGES : SUMMARY, RAT: FEMALE
(TWO-WEEK STUDY)

STUDY NO. : 0261
 ANIMAL : RAT F344
 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	14.6± 0.8	14.7± 1.1	14.8± 1.1	13.7± 2.2
50 ppm	9.0± 0.4	9.6± 1.0	9.1± 0.7**	8.8± 0.4
100 ppm	6.3± 1.1*	9.8± 2.0	7.7± 1.5**	8.2± 1.8**
200 ppm	4.0± 0.6**	4.4± 1.4**	4.9± 1.4**	5.6± 1.7**
400 ppm	2.4± 0.5**	1.4± 0.4**	3.7± 1.4**	3.1± 1.2**
800 ppm	1.5± 0.2**	1.2± 0.1**	1.6± 0.0 ?	-

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

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

APPENDIX A 3-3

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

STUDY NO. : 0262
 ANIMAL : MOUSE 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	3.9± 0.5	4.0± 0.5	4.0± 0.5	3.8± 0.5
50 ppm	1.9± 0.3	2.0± 0.2	1.8± 0.2	1.6± 0.2
100 ppm	1.6± 0.3	1.6± 0.6*	1.7± 0.6	1.6± 0.4*
200 ppm	0.8± 0.2**	1.1± 0.1**	0.9± 0.2**	0.9± 0.3**
400 ppm	0.5± 0.1**	0.6± 0.2**	0.4± 0.2**	0.4± 0.1**
800 ppm	0.3± 0.0**	0.3± 0.1**	0.3± 0.1**	0.3± 0.0 ?

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

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

APPENDIX 3-4

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

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 2
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration 1-3(3)	week-day(effective) 1-7(4)	2-3(3)	2-7(4)
Control	3.6± 0.4	4.0± 0.3	4.1± 0.3	4.1± 0.4
50 ppm	1.6± 0.5	2.0± 0.2	1.7± 0.3	1.7± 0.3
100 ppm	1.1± 0.3*	1.6± 0.2	1.3± 0.2*	1.6± 0.3*
200 ppm	0.7± 0.1**	0.8± 0.1**	0.8± 0.1**	0.8± 0.1**
400 ppm	0.4± 0.1**	0.5± 0.1**	0.4± 0.0**	0.5± 0.1**
800 ppm	0.3± 0.1**	0.3± 0.0**	0.3± 0.1**	-

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

Test of Dunnett

(HAN260)

BAIS 2

APPENDIX A 4-1

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : MALE
(TWO-WEEK STUDY)

STUDY NO. : 0261
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 2
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration week	
	1	2
Control	12.8± 1.0	13.5± 1.0
50 ppm	11.3± 0.6	11.8± 1.1**
100 ppm	11.2± 0.7	11.7± 0.7**
200 ppm	9.4± 1.3**	9.7± 0.9**
400 ppm	4.5± 0.4**	3.5± 0.5**
800 ppm	3.5± 0.2**	-

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

Test of Dunnett

APPENDIX A 4-2

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : FEMALE
(TWO-WEEK STUDY)

STUDY NO. : 0261
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 2
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

Group Name	Administration week	
	1	2
Control	10.3± 0.7	10.1± 0.8
50 ppm	8.8± 0.4**	9.0± 0.3**
100 ppm	7.8± 0.4**	8.5± 0.7**
200 ppm	4.7± 0.6**	5.3± 0.8**
400 ppm	2.8± 0.4**	4.0± 0.6**
800 ppm	2.3± 0.3**	-

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

Test of Dunnett

(HAN260)

BAIS3

APPENDIX A 4-3

FOOD CONSUMPTION CHANGES : SUMMARY, MOSUE : MALE
(TWO-WEEK STUDY)

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 2
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration week	
	1	2
Control	3.6± 0.2	3.7± 0.2
50 ppm	3.2± 0.2**	3.7± 0.2
100 ppm	2.9± 0.3**	3.7± 0.4
200 ppm	2.4± 0.1**	3.2± 0.2**
400 ppm	1.8± 0.2**	2.1± 0.2**
800 ppm	1.6± 0.2**	1.7± 0.0 ?

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

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

APPENDIX A 4-4

FOOD CONSUMPTION CHANGES : SUMMARY, MOSUE : FEMALE
(TWO-WEEK STUDY)

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 2
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

Group Name	Administration week	
	1	2
Control	3.0± 0.2	3.4± 0.2
50 ppm	2.8± 0.3*	3.1± 0.2**
100 ppm	2.5± 0.2**	3.1± 0.3*
200 ppm	2.0± 0.2**	2.5± 0.3**
400 ppm	1.5± 0.2**	2.0± 0.2**
800 ppm	1.3± 0.2**	-

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

Test of Dunnett

(HAN260)

BAIS3

APPENDIX A 5-1

CHEMICAL INTAKE CHANGES: SUMMARY, RAT : MALE
(TWO-WEEK STUDY)

STUDY NO. :0261
ANIMAL :RAT F344
UNIT :mg/kg/day
REPORT TYPE :A1 2
SEX :MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective)			
	1-3(3)	1-7(4)	2-3(3)	2-7(4)
Control	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000
50ppm	4.213 ± 0.292	4.046 ± 0.180	3.867 ± 0.161	3.429 ± 0.252
100ppm	7.556 ± 0.711	8.572 ± 0.749	7.216 ± 0.388	7.111 ± 0.806
200ppm	13.709 ± 1.427	15.135 ± 2.130	14.744 ± 3.165	13.970 ± 1.775
400ppm	14.358 ± 2.579	8.611 ± 3.453	12.006 ± 5.000	12.045 ± 3.527
800ppm	14.289 ± 1.701	12.355 ± 2.367	12.497 ± 1.842	—

APPENDIX A 5-2

CHEMICAL INTAKE CHANGES: SUMMARY, RAT : FEMALE
(TWO-WEEK STUDY)

STUDY NO. :0261
ANIMAL :RAT F344
UNIT :mg/kg/day
REPORT TYPE :A1 2
SEX :FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective)			
	1-3(3)	1-7(4)	2-3(3)	2-7(4)
Control	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000
50ppm	4.452 ± 0.239	4.459 ± 0.520	4.118 ± 0.350	3.749 ± 0.232
100ppm	6.693 ± 1.060	9.435 ± 1.942	7.395 ± 1.327	7.420 ± 1.360
200ppm	9.111 ± 1.028	11.000 ± 2.982	13.342 ± 3.771	14.762 ± 3.802
400ppm	11.442 ± 2.106	8.619 ± 2.149	23.967 ± 8.424	21.555 ± 6.572
800ppm	15.219 ± 1.821	15.857 ± 2.083	22.857 ± 0.000	—

APPENDIX A 5-3

CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: MALE (TWO-WEEK STUDY)

STUDY NO. :0262
ANIMAL :BDF1 MOUSE
UNIT :mg/kg/day
REPORT TYPE :A1 2
SEX :MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective)			
	1-3(3)	1-7(4)	2-3(3)	2-7(4)
Control	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000
50ppm	4.458 ± 0.786	4.480 ± 0.338	3.803 ± 0.384	3.382 ± 0.284
100ppm	7.376 ± 1.175	7.215 ± 2.542	7.704 ± 2.833	6.699 ± 1.278
200ppm	7.950 ± 1.611	11.132 ± 1.139	9.385 ± 2.229	9.506 ± 1.976
400ppm	10.716 ± 2.355	13.903 ± 4.046	11.748 ± 3.933	13.438 ± 3.953
800ppm	12.637 ± 2.066	18.893 ± 3.163	18.914 ± 7.72	18.750 ± 0.000

APPENDIX A 5-4

CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: FEMALE
(TWO-WEEK STUDY)

STUDY NO. :0262
ANIMAL :BDF1 MOUSE
UNIT :mg/kg/day
REPORT TYPE :A1 2
SEX :FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective)			
	1-3(3)	1-7(4)	2-3(3)	2-7(4)
Control	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000
50ppm	4.713 ± 1.181	5.483 ± 0.317	4.493 ± 0.651	4.557 ± 0.771
100ppm	6.655 ± 1.547	9.270 ± 1.128	7.534 ± 0.981	8.889 ± 1.681
200ppm	9.492 ± 1.149	11.649 ± 0.923	11.043 ± 1.514	11.733 ± 1.720
400ppm	11.998 ± 3.094	15.217 ± 2.633	13.579 ± 1.355	18.226 ± 3.955
800ppm	16.361 ± 4.120	19.235 ± 3.076	20.497 ± 6.278	—

APPENDIX A 6-1

HEMATOLOGY (TWO-WEEK STUDY : SUMMARY)

RAT : MALE

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (2)

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 ³ /μl
Control	5	7.52± 0.09	13.8± 0.2	40.7± 0.4	54.2± 0.6	18.4± 0.2	33.9± 0.3	691± 117
50 ppm	5	7.65± 0.35	14.0± 0.4	40.5± 1.8	52.9± 0.4	18.3± 0.4	34.6± 0.9	629± 51
100 ppm	5	7.76± 0.20	13.9± 0.4	40.8± 0.9	52.6± 0.4	17.9± 0.2	34.1± 0.3	632± 67
200 ppm	5	8.07± 0.30	14.2± 0.7	41.6± 1.7	51.5± 0.4**	17.6± 0.2**	34.2± 0.2	582± 164
400 ppm	5	11.80± 0.95**	21.5± 1.8**	66.8± 7.6*	56.5± 1.9	18.2± 0.2	32.3± 1.1	153± 76**
800 ppm	0	-	-	-	-	-	-	-

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (2)

PAGE : 2

Group Name	NO. of Animals	RETICULOCYTE %		PROTHROMBIN TIME s e c		APTT s e c	
Control	5	51±	6	13.3±	0.3	18.9±	1.6
50 ppm	5	37±	9*	13.2±	0.4	19.7±	2.4
100 ppm	5	34±	7**	13.2±	0.2	19.3±	0.6
200 ppm	5	33±	10**	13.6±	0.6	19.8±	3.8
400 ppm	5	9±	4**	15.5±	1.2	20.6±	2.5
800 ppm	0	-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0261
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

HEMATOLOGY(2) (SUMMARY)
 SURVIVAL ANIMALS (2)

PAGE : 1

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		NONO		LYMPHO		OTHERS	
Control	5	2.80±	0.92	0±	0	22±	7	1±	1	0±	0	5±	1	72±	7	0±	1
50 ppm	5	2.54±	0.67	0±	1	18±	6	1±	1	0±	0	3±	2	77±	7	0±	1
100 ppm	5	2.74±	0.91	0±	0	21±	7	0±	1	0±	0	2±	1	76±	6	0±	1
200 ppm	5	2.09±	0.83	0±	0	19±	6	1±	1	0±	0	4±	2	76±	6	1±	1
400 ppm	5	1.66±	0.27	0±	1	41±	12**	1±	1	0±	0	4±	1	53±	11**	0±	0
800 ppm	0	-		-		-		-		-		-		-		-	

Significant difference ; * : P ≤ 0.05

** : P ≤ 0.01

Test of Dunnett

(HCL071)

BAIS2

APPENDIX A 6-2

HEMATOLOGY (TWO-WEEK STUDY : SUMMARY)

RAT : FEMALE

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (2)

PAGE : 2

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	9.87±	0.41	15.1±	0.2	45.2±	1.5	45.8±	0.5	15.3±	0.6	33.5±	1.0	985±	77
50 ppm	5	10.33±	0.38	15.7±	0.4	46.8±	1.6	45.3±	0.7	15.2±	0.5	33.5±	0.7	1023±	77
100 ppm	5	10.26±	0.28	15.3±	0.4	46.6±	1.4	45.4±	0.3	14.9±	0.1	32.8±	0.3	1020±	60
200 ppm	5	10.30±	0.80	15.7±	0.4	46.1±	3.5	44.7±	0.8	15.4±	1.0	34.3±	2.1	995±	99
400 ppm	5	10.94±	1.20	16.2±	1.8	49.9±	6.6	45.5±	1.1	14.8±	0.1	32.5±	0.7	1002±	164
800 ppm	0	-		-		-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
 SURVIVAL ANIMALS (2)

PAGE : 2

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	5	2.34±	1.01	0±	0	12±	3	2±	1	0±	0	1±	1	85±	3	0±	0
50 ppm	5	2.60±	0.94	1±	1	9±	3	1±	1	0±	0	1±	1	88±	3	0±	0
100 ppm	5	2.52±	0.94	0±	0	10±	2	2±	1	0±	0	0±	1	88±	3	0±	0
200 ppm	5	0.55±	0.47	1±	1	17±	8	1±	1	0±	0	2±	2	78±	7	0±	0
400 ppm	5	0.26±	0.18*	3±	2	45±	8	0±	0	0±	0	0±	0	51±	8**	0±	0
800 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL071)

BAIS 2

APPENDIX A 6-3

HEMATOLOGY (TWO-WEEK STUDY : SUMMARY)

MOUSE: MALE

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (2)

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 ⁹ /μl
Control	5	8.12± 0.10	15.0± 0.2	43.5± 0.5	53.6± 0.5	18.5± 0.1	34.6± 0.3	666± 91
50 ppm	5	8.33± 0.15	15.1± 0.3	43.7± 1.1	52.4± 0.6	18.1± 0.1**	34.6± 0.1	508± 57*
100 ppm	5	8.40± 0.40	15.2± 0.7	43.7± 1.9	52.0± 0.3*	18.0± 0.2**	34.7± 0.4	565± 85
200 ppm	5	9.20± 0.51*	16.8± 1.1	48.2± 3.1	52.4± 0.5	18.2± 0.2*	34.8± 0.4	407± 75**
400 ppm	4	10.80± 0.97**	19.8± 1.7**	60.0± 7.2**	55.4± 1.8	18.4± 0.2	33.1± 1.1	288± 130**
800 ppm	0	-	-	-	-	-	-	-

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (2)

PAGE : 4

Group Name	NO. of Animals	RETICULOCYTE %		PROTHROMBIN TIME s e c		APTT s e c	
Control	5	30±	5	13.2±	0.2	18.1±	0.6
50 ppm	5	27±	6	13.2±	0.1	18.3±	0.8
100 ppm	5	28±	4	13.3±	0.2	17.9±	1.3
200 ppm	5	9±	3**	13.5±	0.2	15.6±	0.8
400 ppm	4	7±	2**	14.8±	1.0**	18.6±	4.2
800 ppm	0	-		-		-	

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (2)

PAGE : 2

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	5	2.62±	1.30	0±	0	19±	5	2±	1	0±	0	2±	1	76±	5	0±	0
50 ppm	5	2.63±	0.54	0±	0	18±	6	2±	1	0±	0	4±	1	76±	6	0±	0
100 ppm	5	2.86±	1.19	0±	0	18±	6	1±	1	0±	0	3±	1	77±	6	1±	1
200 ppm	5	3.40±	1.54	0±	0	26±	15	2±	1	0±	0	5±	2	66±	16	0±	0
400 ppm	4	2.28±	0.54	0±	0	45±	8**	1±	1	0±	0	5±	2	50±	9**	0±	1
800 ppm	0	-		-		-		-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL071)

BAIS2

APPENDIX A 6-4

HEMATOLOGY (TWO-WEEK STUDY : SUMMARY)

MOUSE: FEMALE

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (2)

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 ³ /μl	
Control	5	10.63±	0.22	15.8±	0.4	49.0±	1.3	46.1±	0.3	14.8±	0.1	32.1±	0.4	1243±	45
50 ppm	5	10.77±	0.29	16.3±	0.5	49.7±	1.4	46.2±	0.7	15.1±	0.1	32.7±	0.5	1188±	67
100 ppm	5	10.84±	0.59	16.1±	0.8	50.0±	2.5	46.1±	0.6	14.8±	0.2	32.2±	0.3	1140±	44
200 ppm	5	11.36±	0.45	16.6±	0.7	50.5±	2.0	44.5±	0.7**	14.6±	0.2	33.0±	0.3	1099±	265
400 ppm	5	11.20±	0.95	16.8±	1.4	51.2±	5.1	45.6±	0.8	15.0±	0.8	33.0±	1.8	1045±	281
800 ppm	1	12.66±	0.00 ?	20.8±	0.0 ?	59.6±	0.0 ?	47.1±	0.0 ?	16.4±	0.0 ?	34.8±	0.0 ?	824±	0 ?

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

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

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

HEMATOLOGY(2) (SUMMARY)
 SURVIVAL ANIMALS (2)

PAGE : 1

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	5	2.15±	0.73	0±	0	9±	1	3±	2	0±	0	1±	1	87±	2	0±	0
50 ppm	5	2.23±	0.61	1±	1	9±	4	1±	2	0±	0	1±	1	88±	4	0±	0
100 ppm	5	2.08±	1.18	0±	1	10±	4	1±	1	0±	0	1±	1	88±	4	0±	0
200 ppm	5	1.85±	0.73	0±	1	17±	7	2±	1	0±	0	1±	1	80±	9	0±	0
400 ppm	5	0.29±	0.21**	4±	3	55±	22**	0±	0	0±	0	1±	1	40±	22*	0±	0
800 ppm	1	0.46±	0.00 ?	2±	0 ?	69±	0 ?	0±	0 ?	0±	0 ?	0±	0 ?	29±	0 ?	0±	0 ?

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

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

(HCL071)

BAIS2

APPENDIX A 7-1

BIOCHEMISTRY (TWO-WEEK STUDY : SUMMARY)

RAT : MALE

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (2)

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	5.9±	0.1	3.3±	0.1	1.3±	0.1	0.19±	0.05	205±	16	60±	5	121±	8
50 ppm	5	5.9±	0.1	3.4±	0.0	1.4±	0.1	0.20±	0.07	195±	11	66±	3	128±	4
100 ppm	5	5.8±	0.2	3.4±	0.1	1.4±	0.1	0.18±	0.06	199±	10	59±	3	119±	7
200 ppm	5	6.0±	0.1	3.5±	0.1	1.5±	0.1	0.23±	0.08	190±	13	59±	4	115±	7
400 ppm	5	5.3±	1.0	3.0±	0.6	1.3±	0.3	0.89±	0.50*	105±	28**	63±	23	106±	30
800 ppm	0	-		-		-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0261
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (2)

PAGE : 2

Group Name	NO. of Animals	GOT IU/ℓ		GPT IU/ℓ		LDH IU/ℓ		G-GTP IU/ℓ		CPK IU/ℓ		UREA NITROGEN mg/dℓ		CREATININE mg/dℓ	
Control	5	58±	6	19±	1	157±	13	0±	1	147±	43	14.2±	2.4	0.4±	0.1
50 ppm	5	54±	3	17±	1	176±	48	1±	1	142±	31	17.8±	2.9	0.4±	0.0
100 ppm	5	52±	4	16±	1	175±	32	0±	0	132±	5	17.9±	2.5	0.4±	0.0
200 ppm	5	57±	9	14±	1*	218±	64	0±	0	143±	32	17.5±	2.0	0.4±	0.0
400 ppm	5	565±	217	88±	34	923±	569**	1±	1	566±	452*	98.2±	66.7**	0.5±	0.2
800 ppm	0	-		-		-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0261
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (2)

PAGE : 3

Group Name	NO. of Animals	SODIUM mEq/ℓ		POTASSIUM mEq/ℓ		CHLORIDE mEq/ℓ		CALCIUM mg/dℓ		INORGANIC PHOSPHORUS mg/dℓ	
Control	5	142±	0	3.9±	0.2	106±	1	11.0±	0.5	8.3±	0.7
50 ppm	5	141±	1	4.0±	0.2	106±	1	10.9±	0.4	7.7±	0.7
100 ppm	5	141±	1	4.2±	0.1	105±	1	10.8±	0.2	7.6±	0.7
200 ppm	5	143±	2	4.8±	1.1	107±	1	10.2±	1.1	6.9±	0.6*
400 ppm	5	181±	14	4.8±	1.2	139±	12*	10.5±	0.4	11.6±	4.1
800 ppm	0	-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX A 7-2

BIOCHEMISTRY (TWO-WEEK STUDY : SUMMARY)

RAT : FEMALE

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (2)

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	5.7±	0.1	3.3±	0.0	1.4±	0.0	0.28±	0.04	199±	14	71±	3	127±	7
50 ppm	5	5.7±	0.1	3.4±	0.1	1.5±	0.1	0.34±	0.09	196±	10	74±	8	138±	9
100 ppm	5	5.8±	0.1	3.4±	0.1	1.5±	0.1	0.40±	0.12	189±	12	73±	3	133±	6
200 ppm	5	5.8±	0.3	3.5±	0.2	1.6±	0.1	0.49±	0.08	144±	20**	67±	8	127±	13
400 ppm	4	5.5±	0.4	3.1±	0.5	1.3±	0.3	0.78±	0.27**	92±	15**	92±	17	162±	16**
800 ppm	0	-		-		-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (2)

PAGE : 5

Group Name	NO. of Animals	GOT IU/ℓ		GPT IU/ℓ		LDH IU/ℓ		G-GTP IU/ℓ		CPK IU/ℓ		UREA NITROGEN mg/dℓ		CREATININE mg/dℓ	
Control	5	60±	2	19±	1	247±	84	1±	0	150±	12	17.1±	2.8	0.4±	0.1
50 ppm	5	62±	5	17±	1	252±	83	1±	0	140±	32	20.5±	2.3	0.4±	0.1
100 ppm	5	66±	5	17±	2	225±	58	1±	0	134±	32	19.7±	2.2	0.4±	0.1
200 ppm	5	112±	56*	21±	12	277±	70	2±	0	128±	27	25.6±	6.2	0.4±	0.1
400 ppm	4	223±	100**	29±	14	670±	260	3±	1	287±	99	53.4±	28.2**	0.3±	0.1**
800 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0261
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (2)

PAGE : 6

Group Name	NO. of Animals	SODIUM mEq/ℓ		POTASSIUM mEq/ℓ		CHLORIDE mEq/ℓ		CALCIUM mg/dℓ		INORGANIC PHOSPHORUS mg/dℓ	
Control	5	142±	1	3.9±	0.4	109±	2	10.3±	0.1	6.6±	0.8
50 ppm	5	142±	1	4.1±	0.2	108±	1	10.3±	0.1	7.0±	0.9
100 ppm	5	143±	1	4.4±	0.3*	109±	1	10.4±	0.3	7.1±	1.2
200 ppm	5	148±	1*	4.0±	0.1	112±	2	10.5±	0.4	6.3±	1.0
400 ppm	4	173±	17**	4.7±	0.3**	132±	13*	10.8±	0.4	9.7±	2.5**
800 ppm	0	-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX A 7-3

BIOCHEMISTRY (TWO-WEEK STUDY : SUMMARY)

MOUSE: MALE

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (2)

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		GOT I U / l	
Control	5	5.3±	0.2	3.0±	0.1	1.3±	0.0	0.36±	0.14	313±	15	101±	6	39±	11
50 ppm	5	5.0±	0.3	2.8±	0.1	1.3±	0.0	0.33±	0.09	325±	25	92±	7	41±	4
100 ppm	5	5.1±	0.2	2.9±	0.2	1.4±	0.1	0.30±	0.03	299±	18	96±	7	42±	6
200 ppm	5	5.4±	0.3	3.1±	0.2	1.3±	0.1	0.40±	0.13	264±	24*	108±	15	53±	10
400 ppm	5	5.6±	0.6	3.4±	0.4**	1.6±	0.1	0.49±	0.12	93±	38**	101±	14	251±	72**
800 ppm	1	5.4±	0.0 ?	3.3±	0.0 ?	1.6±	0.0 ?	0.54±	0.00 ?	144±	0 ?	99±	0 ?	522±	0 ?

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

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

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (2)

PAGE : 2

Group Name	NO. of Animals	GPT IU/ℓ		LDH IU/ℓ		CPK IU/ℓ		UREA NITROGEN mg/dℓ		SODIUM mEq/ℓ		POTASSIUM mEq/ℓ		CHLORIDE mEq/ℓ	
Control	5	17±	5	212±	96	92±	49	23.4±	6.6	149±	2	5.5±	0.6	114±	7
50 ppm	5	16±	3	200±	42	66±	19	27.2±	4.2	149±	0	5.1±	0.4	117±	3
100 ppm	5	18±	3	223±	21	103±	25	29.4±	6.8	149±	2	5.3±	0.5	118±	3
200 ppm	5	20±	3	233±	87	92±	57	32.4±	7.9	153±	3	5.0±	0.8	119±	3
400 ppm	5	60±	13**	568±	99**	518±	174*	67.5±	4.9**	178±	7**	4.4±	0.4	133±	5**
800 ppm	1	150±	0 ?	1722±	0 ?	3306±	0 ?	95.4±	0.0 ?	189±	0 ?	3.0±	0.0 ?	150±	0 ?

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

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

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (2)

PAGE : 3

Group Name	NO. of Animals	CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	5	9.6±	0.4	8.8±	1.1
50 ppm	5	9.3±	0.3	8.7±	1.8
100 ppm	5	9.3±	0.2	8.8±	1.4
200 ppm	5	9.7±	0.4	7.4±	1.2
400 ppm	5	9.4±	0.3	9.1±	1.8
800 ppm	1	10.8±	0.0 ?	9.0±	0.0 ?

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

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

APPENDIX A 7-4

BIOCHEMISTRY (TWO-WEEK STUDY : SUMMARY)

MOUSE: FEMALE

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (2)

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		GOT I U / l	
Control	5	4.9±	0.2	3.0±	0.1	1.6±	0.1	0.29±	0.10	263±	32	82±	7	42±	7
50 ppm	5	4.7±	0.2	2.9±	0.1	1.6±	0.1	0.25±	0.03	270±	18	84±	6	44±	7
100 ppm	5	4.9±	0.4	2.9±	0.2	1.5±	0.0*	0.33±	0.09	266±	22	89±	2	46±	7
200 ppm	5	5.6±	0.2**	3.4±	0.2**	1.5±	0.1	0.42±	0.07	147±	57**	105±	6**	95±	33
400 ppm	5	5.7±	0.4**	3.5±	0.3**	1.6±	0.1	0.53±	0.20*	45±	32**	90±	17	278±	105**
800 ppm	0	-		-		-		-		-		-		-	

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

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (2)

PAGE : 5

Group Name	NO. of Animals	GPT I U / ℓ		LDH I U / ℓ		CPK I U / ℓ		UREA NITROGEN mg / dl		SODIUM mEq / ℓ		POTASSIUM mEq / ℓ		CHLORIDE mEq / ℓ	
Control	5	18±	3	181±	42	68±	18	22.8±	4.7	148±	1	4.7±	0.7	122±	3
50 ppm	5	17±	5	204±	41	68±	23	28.2±	4.0	149±	1	5.0±	0.2	119±	4
100 ppm	5	18±	5	192±	19	66±	17	30.8±	4.0	149±	1	4.8±	0.5	119±	3
200 ppm	5	29±	10	328±	110	108±	38	48.0±	8.0*	160±	3*	4.1±	0.6	125±	5
400 ppm	5	59±	17*	945±	633**	1482±	1327**	93.4±	25.1**	184±	11**	4.1±	0.1	146±	7**
800 ppm	0	-		-		-		-		-		-		-	

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

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (2)

PAGE : 6

Group Name	NO. of Animals	CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	5	9.2±	0.2	7.8±	0.7
50 ppm	5	9.1±	0.2	7.8±	0.9
100 ppm	5	9.3±	0.2	7.3±	2.0
200 ppm	5	9.5±	0.5	8.9±	1.6
400 ppm	5	10.0±	0.8	11.3±	3.4
800 ppm	0	-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

APPENDIX A 8-1

GROSS FINDINGS (TWO-WEEK STUDY: SUMMARY)

RAT : MALE : DEAD AND MORIBUND ANIMALS

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 0 (%)	50 ppm 0 (%)	100 ppm 0 (%)	200 ppm 0 (%)
subcutis	dry		- (-)	- (-)	- (-)	- (-)
thymus	atrophic		- (-)	- (-)	- (-)	- (-)
gl stomach	hemorrhage		- (-)	- (-)	- (-)	- (-)
adrenal	red		- (-)	- (-)	- (-)	- (-)

(HPT080)

BAIS 2

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

Organ_____	Findings_____	Group Name	400 ppm	800 ppm
		NO. of Animals	1 (%)	10 (%)
subcutis	dry		1 (100)	8 (80)
thymus	atrophic		1 (100)	10 (100)
gl stomach	hemorrhage		0 (0)	7 (70)
adrenal	red		0 (0)	3 (30)

(HPT080)

BAIS 2

APPENDIX A 8-2

GROSS FINDINGS (TWO-WEEK STUDY: SUMMARY)

RAT : FEMALE : DEAD AND MORIBUND ANIMALS

STUDY NO. : 0261
ANIMAL : RAT F344
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 (%)	50 ppm 0 (%)	100 ppm 0 (%)	200 ppm 0 (%)
subcutis	dry		- (-)	- (-)	- (-)	- (-)
thymus	atrophic		- (-)	- (-)	- (-)	- (-)
	red zone		- (-)	- (-)	- (-)	- (-)
gl stomach	hemorrhage		- (-)	- (-)	- (-)	- (-)
adrenal	red		- (-)	- (-)	- (-)	- (-)

(IIP T080)

BAIS 2

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 4

Organ	Findings	Group Name	400 ppm	800 ppm
		NO. of Animals	6 (%)	10 (%)
subcutis	dry		5 (83)	9 (90)
thymus	atrophic		6 (100)	10 (100)
	red zone		1 (17)	3 (30)
gl stomach	hemorrhage		2 (33)	6 (60)
adrenal	red		2 (33)	7 (70)

(HPT080)

BAIS 2

APPENDIX A 8-3

GROSS FINDINGS (TWO-WEEK STUDY: SUMMARY)

RAT : MALE : SACRIFICED ANIMALS

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 1

Organ_____	Findings_____	Group Name NO. of Animals	Control	50 ppm	100 ppm	200 ppm
			10 (%)	10 (%)	10 (%)	10 (%)
thymus	atrophic		0 (0)	0 (0)	0 (0)	0 (0)
gl stomach	hemorrhase		0 (0)	0 (0)	0 (0)	0 (0)

(HPT080)

BAIS 2

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 2

Organ_____	Findings_____	Group Name NO. of Animals	400 ppm 9 (%)	800 ppm 0 (%)
<hr/>				
thymus	atrophic		9 (100)	- (-)
sl stomach	hemorrhage		1 (11)	- (-)

(IPT080)

BAIS 2

APPENDIX A 8-4

GROSS FINDINGS (TWO-WEEK STUDY: SUMMARY)

RAT : FEMALE : SACRIFICED ANIMALS

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 10 (%)	50 ppm 10 (%)	100 ppm 10 (%)	200 ppm 10 (%)
thymus	atrophic		0 (0)	0 (0)	0 (0)	6 (60)
	red zone		0 (0)	0 (0)	2 (20)	0 (0)
liver	herniation		1 (10)	0 (0)	0 (0)	0 (0)

(HPT080)

BAIS 2

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 4

Organ	Findings	Group Name	400 ppm	800 ppm
		NO. of Animals	4 (%)	0 (%)
thymus	atrophic		4 (100)	- (-)
	red zone		0 (0)	- (-)
Liver	herniation		0 (0)	- (-)

(HPT080)

BAIS 2

APPENDIX A 8-5

GROSS FINDINGS (TWO-WEEK STUDY: SUMMARY)

MOUSE: MALE : DEAD AND MORIBUNDANIMALS

STUDY NO. : 0262
ANIMAL : MOUSE 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 0 (%)	50 ppm 0 (%)	100 ppm 0 (%)	200 ppm 0 (%)
subcutis	dry		- (-)	- (-)	- (-)	- (-)
thymus	atrophic		- (-)	- (-)	- (-)	- (-)
gl stomach	hemorrhage		- (-)	- (-)	- (-)	- (-)

(HPT080)

BAIS 2

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name	400 ppm	800 ppm
		NO. of Animals	0 (%)	9 (%)
subcutis	dry		- (-)	5 (56)
thymus	atrophic		- (-)	9 (100)
sl stomach	hemorrhage		- (-)	2 (22)

(HPT080)

BAIS 2

APPENDIX A 8-6

GROSS FINDINGS (TWO-WEEK STUDY: SUMMARY)

MOUSE: FEMALE : DEAD AND MORIBUNDANIMALS

STUDY NO. : 0262
ANIMAL : MOUSE 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 (%)	50 ppm 0 (%)	100 ppm 0 (%)	200 ppm 0 (%)
subcutis	dry		- (-)	- (-)	- (-)	- (-)
thymus	atrophic		- (-)	- (-)	- (-)	- (-)

(HPT080)

BAIS 2

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 4

Organ_____	Findings_____	Group Name NO. of Animals	400 ppm 1 (%)	800 ppm 10 (%)
<hr/>				
subcutis	dry		0 (0)	3 (30)
thymus	atrophic		1 (100)	10 (100)

(HPT080)

BAIS 2

APPENDIX A 8-7

GROSS FINDINGS (TWO-WEEK STUDY: SUMMARY)

MOUSE: MALE : SACRIFICED ANIMALS

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 1

Organ	Findings	Group Name	Control	50 ppm	100 ppm	200 ppm
		NO. of Animals	10 (%)	10 (%)	10 (%)	10 (%)
thymus	atrophic		0 (0)	0 (0)	0 (0)	0 (0)
spleen	black zone		0 (0)	0 (0)	0 (0)	1 (10)
gl stomach	hemorrhage		0 (0)	0 (0)	0 (0)	0 (0)

(HPT080)

BATS2

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 2

Organ	Findings	Group Name	400 ppm	800 ppm
		NO. of Animals	10 (%)	1 (%)
thymus	atrophic		10 (100)	1 (100)
spleen	black zone		0 (0)	0 (0)
gl stomach	hemorrhage		1 (10)	0 (0)

(HPT080)

BAIS 2

APPENDIX A 8-8

GROSS FINDINGS (TWO-WEEK STUDY: SUMMARY)

MOUSE: FEMALE : SACRIFICED ANIMALS

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 3

Organ_____	Findings_____	Group Name NO. of Animals	Control	50 ppm	100 ppm	200 ppm
			10 (%)	10 (%)	10 (%)	10 (%)
thymus	atrophic		0 (0)	0 (0)	0 (0)	0 (0)
spleen	black zone		1 (10)	0 (0)	0 (0)	0 (0)

(IPT080)

BAIS2

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 4

Organ_____	Findings_____	Group Name	400 ppm	800 ppm
		NO. of Animals	9 (%)	0 (%)
thymus	atrophic		9 (100)	- (-)
spleen	black zone		0 (0)	- (-)

(HPT080)

BAIS2

APPENDIX A 9-1

ORGAN WEIGHT (TWO-WEEK STUDY : SUMMARY),ABSOLUTE

RAT : MALE

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

PAGE : 1

Group Name	NO. of Animals	Body Weight		THYMUS		ADRENALS		TESTES		HEART		LUNGS	
Control	5	177±	16	0.324±	0.054	0.043±	0.005	2.054±	0.233	0.649±	0.049	0.779±	0.022
50 ppm	5	161±	12	0.328±	0.027	0.041±	0.009	1.644±	0.430	0.561±	0.057*	0.714±	0.030*
100 ppm	5	164±	7	0.304±	0.028	0.046±	0.005	2.000±	0.253	0.587±	0.039	0.720±	0.027*
200 ppm	5	137±	12**	0.181±	0.026**	0.048±	0.008	1.956±	0.273	0.486±	0.030**	0.646±	0.050**
400 ppm	5	67±	6**	0.020±	0.009**	0.033±	0.004	0.610±	0.206**	0.289±	0.029**	0.521±	0.039**
800 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0261
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	5	1.308±	0.086	0.411±	0.041	6.693±	0.678	1.723±	0.026
50 ppm	5	1.284±	0.103	0.369±	0.026	5.961±	0.707	1.699±	0.019
100 ppm	5	1.399±	0.036	0.377±	0.031	6.407±	0.309	1.716±	0.048
200 ppm	5	1.324±	0.087	0.319±	0.019**	5.502±	0.540**	1.675±	0.037
400 ppm	5	0.899±	0.062**	0.087±	0.030**	2.428±	0.410**	1.573±	0.021**
800 ppm	0	-		-		-		-	

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

Test of Dunnett

(IICL040)

BAIS 2

APPENDIX A 9-2

ORGAN WEIGHT (TWO-WEEK STUDY : SUMMARY),ABSOLUTE

RAT : FEMALE

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

PAGE : 3

Group Name	NO. of Animals	Body Weight		THYMUS		ADRENALS		OVARIES		HEART		LUNGS	
Control	5	126±	5	0.295±	0.023	0.051±	0.009	0.067±	0.008	0.461±	0.019	0.605±	0.024
50 ppm	5	116±	2	0.271±	0.025	0.040±	0.007*	0.054±	0.014	0.454±	0.028	0.567±	0.039
100 ppm	5	107±	5**	0.239±	0.017**	0.042±	0.006	0.052±	0.006	0.394±	0.025**	0.573±	0.041
200 ppm	5	75±	9**	0.051±	0.029**	0.032±	0.003**	0.044±	0.005**	0.312±	0.029**	0.490±	0.034**
400 ppm	4	57±	5**	0.016±	0.007**	0.029±	0.004**	0.035±	0.010**	0.257±	0.036**	0.465±	0.048**
800 ppm	0	-		-		-		-		-		-	

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

Test of Dunnett

(HCL040)

BAIS2

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	5	0.968±	0.052	0.296±	0.015	4.261±	0.367	1.580±	0.042
50 ppm	5	1.073±	0.032*	0.280±	0.023	4.292±	0.190	1.595±	0.028
100 ppm	5	1.072±	0.053	0.256±	0.011*	4.082±	0.397	1.584±	0.020
200 ppm	5	0.893±	0.090	0.163±	0.028**	3.384±	0.396**	1.536±	0.021
400 ppm	4	0.802±	0.072**	0.098±	0.030**	2.674±	0.501**	1.450±	0.060**
800 ppm	0	-		-		-		-	

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

Test of Dunnett

(ICL040)

BAIS2

APPENDIX A 9-3

ORGAN WEIGHT (TWO-WEEK STUDY : SUMMARY),ABSOLUTE

MOUSE: MALE

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

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

PAGE : 1

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	5	24.9± 0.9	0.063± 0.008	0.014± 0.000	0.187± 0.021	0.134± 0.012	0.144± 0.012
50 ppm	5	23.1± 0.7*	0.053± 0.007	0.016± 0.003	0.182± 0.013	0.127± 0.009	0.141± 0.013
100 ppm	5	23.4± 1.1	0.050± 0.010	0.016± 0.002	0.188± 0.024	0.126± 0.011	0.152± 0.016
200 ppm	5	19.4± 1.4**	0.032± 0.013**	0.013± 0.002	0.175± 0.013	0.113± 0.011*	0.134± 0.010
400 ppm	5	13.3± 0.6**	0.008± 0.005**	0.009± 0.001*	0.159± 0.024	0.081± 0.004**	0.125± 0.020
800 ppm	1	12.8± 0.0 ?	0.003± 0.000 ?	0.006± 0.000 ?	0.156± 0.000 ?	0.083± 0.000 ?	0.117± 0.000 ?

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

Test of Dunnett

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

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	5	0.368±	0.022	0.050±	0.004	1.252±	0.182	0.451±	0.019
50 ppm	5	0.377±	0.008	0.044±	0.002	1.164±	0.056	0.443±	0.015
100 ppm	5	0.385±	0.016	0.047±	0.008	1.185±	0.113	0.436±	0.014
200 ppm	5	0.354±	0.029	0.034±	0.010**	0.967±	0.081	0.443±	0.026
400 ppm	5	0.255±	0.021**	0.014±	0.007**	0.649±	0.034**	0.401±	0.012**
800 ppm	1	0.224±	0.000 ?	0.007±	0.000 ?	0.651±	0.000 ?	0.381±	0.000 ?

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

Test of Dunnett

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

APPENDIX A 9-4

ORGAN WEIGHT (TWO-WEEK STUDY : SUMMARY),ABSOLUTE

MOUSE: FEMALE

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

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

PAGE : 3

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	5	20.0± 0.9	0.077± 0.008	0.012± 0.002	0.024± 0.009	0.118± 0.013	0.141± 0.013
50 ppm	5	19.1± 0.5	0.076± 0.006	0.012± 0.003	0.023± 0.005	0.105± 0.010	0.140± 0.019
100 ppm	5	18.3± 0.8**	0.066± 0.007	0.012± 0.002	0.023± 0.006	0.101± 0.011*	0.128± 0.019
200 ppm	5	13.9± 1.0**	0.024± 0.014**	0.009± 0.002*	0.009± 0.003**	0.087± 0.006**	0.127± 0.013
400 ppm	5	10.7± 0.5**	0.007± 0.004**	0.007± 0.001**	0.007± 0.004**	0.066± 0.006**	0.108± 0.010*
800 ppm	0	-	-	-	-	-	-

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	5	0.253±	0.012	0.054±	0.006	0.934±	0.119	0.440±	0.006
50 ppm	5	0.280±	0.011**	0.049±	0.004	0.895±	0.038	0.443±	0.011
100 ppm	5	0.273±	0.006	0.052±	0.008	0.898±	0.057	0.426±	0.015
200 ppm	5	0.246±	0.018	0.021±	0.006**	0.640±	0.060**	0.426±	0.014
400 ppm	5	0.200±	0.013**	0.009±	0.003**	0.474±	0.055**	0.390±	0.019**
800 ppm	0	-		-		-		-	

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX A 10-1

ORGAN WEIGHT (TWO-WEEK STUDY : SUMMARY),RELATIVE

RAT : MALE

STUDY NO. : 0261
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE
 UNIT: %

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

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	5	177± 16	0.183± 0.024	0.025± 0.002	1.166± 0.138	0.369± 0.036	0.442± 0.031
50 ppm	5	161± 12	0.204± 0.020	0.026± 0.006	1.011± 0.206	0.348± 0.019	0.444± 0.018
100 ppm	5	164± 7	0.185± 0.014	0.028± 0.003	1.217± 0.142	0.357± 0.021	0.438± 0.015
200 ppm	5	137± 12**	0.131± 0.008**	0.035± 0.005*	1.423± 0.098	0.356± 0.012	0.474± 0.039
400 ppm	5	67± 6**	0.030± 0.013**	0.049± 0.007**	0.898± 0.253	0.431± 0.014**	0.781± 0.074*
800 ppm	0	-	-	-	-	-	-

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	0.742± 0.028	0.232± 0.006	3.783± 0.096	0.981± 0.092
50 ppm	5	0.797± 0.014	0.229± 0.011	3.693± 0.258	1.058± 0.069
100 ppm	5	0.851± 0.024**	0.229± 0.013	3.897± 0.083	1.045± 0.048
200 ppm	5	0.968± 0.032**	0.234± 0.009	4.015± 0.097	1.230± 0.110**
400 ppm	5	1.345± 0.064**	0.128± 0.037**	3.615± 0.457	2.360± 0.187**
800 ppm	0	-	-	-	-

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

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX A 10-2

ORGAN WEIGHT (TWO-WEEK STUDY : SUMMARY),RELATIVE

RAT : FEMALE

STUDY NO. : 0261
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: %

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

PAGE : 3

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	5	126± 5	0.235± 0.018	0.040± 0.005	0.053± 0.006	0.367± 0.012	0.483± 0.030
50 ppm	5	116± 2	0.233± 0.020	0.035± 0.006	0.046± 0.013	0.390± 0.019	0.487± 0.036
100 ppm	5	107± 5**	0.224± 0.017	0.039± 0.005	0.049± 0.004	0.370± 0.017	0.539± 0.056
200 ppm	5	75± 9**	0.065± 0.028**	0.042± 0.004	0.058± 0.004	0.415± 0.025**	0.654± 0.052**
400 ppm	4	57± 5**	0.028± 0.013**	0.050± 0.003*	0.061± 0.013	0.451± 0.033**	0.818± 0.082**
800 ppm	0	-	-	-	-	-	-

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	0.771± 0.033	0.236± 0.003	3.389± 0.195	1.260± 0.066
50 ppm	5	0.922± 0.037**	0.241± 0.020	3.689± 0.199	1.370± 0.028
100 ppm	5	1.006± 0.023**	0.240± 0.006	3.823± 0.202	1.489± 0.081
200 ppm	5	1.188± 0.045**	0.216± 0.018	4.490± 0.144**	2.058± 0.214**
400 ppm	4	1.408± 0.062**	0.170± 0.041*	4.667± 0.508**	2.558± 0.228**
800 ppm	0	-	-	-	-

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

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX A 10-3

ORGAN WEIGHT (TWO-WEEK STUDY : SUMMARY),RELATIVE

MOUSE: MALE

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE
 UNIT: %

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

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	5	24.9± 0.9	0.254± 0.035	0.057± 0.002	0.752± 0.076	0.538± 0.047	0.580± 0.065
50 ppm	5	23.1± 0.7*	0.231± 0.029	0.068± 0.015	0.786± 0.051	0.548± 0.031	0.609± 0.046
100 ppm	5	23.4± 1.1	0.212± 0.033	0.068± 0.007	0.807± 0.109	0.540± 0.041	0.649± 0.064
200 ppm	5	19.4± 1.4**	0.161± 0.056**	0.065± 0.010	0.908± 0.106	0.584± 0.066	0.688± 0.029
400 ppm	5	13.3± 0.6**	0.059± 0.041**	0.065± 0.011	1.188± 0.169**	0.605± 0.030	0.939± 0.156**
800 ppm	1	12.8± 0.0 ?	0.023± 0.000 ?	0.047± 0.000 ?	1.219± 0.000 ?	0.648± 0.000 ?	0.914± 0.000 ?

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

Test of Dunnett

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

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	1.476± 0.063	0.200± 0.010	5.012± 0.557	1.815± 0.087
50 ppm	5	1.633± 0.034*	0.189± 0.005	5.034± 0.103	1.917± 0.095
100 ppm	5	1.651± 0.095*	0.202± 0.029	5.069± 0.341	1.870± 0.101
200 ppm	5	1.822± 0.098**	0.177± 0.044	4.978± 0.187	2.285± 0.076**
400 ppm	5	1.910± 0.114**	0.106± 0.052*	4.866± 0.157	3.010± 0.061**
800 ppm	1	1.750± 0.000 ?	0.055± 0.000 ?	5.086± 0.000 ?	2.977± 0.000 ?

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

Test of Dunnett

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

APPENDIX A 10-4

ORGAN WEIGHT (TWO-WEEK STUDY : SUMMARY),RELATIVE

MOUSE: FEMALE

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE : 3

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	5	20.0± 0.9	0.387± 0.043	0.062± 0.006	0.119± 0.047	0.588± 0.048	0.708± 0.088
50 ppm	5	19.1± 0.5	0.398± 0.028	0.063± 0.014	0.120± 0.025	0.552± 0.065	0.734± 0.094
100 ppm	5	18.3± 0.8**	0.358± 0.041	0.068± 0.011	0.127± 0.028	0.551± 0.052	0.699± 0.098
200 ppm	5	13.9± 1.0**	0.167± 0.088**	0.063± 0.010	0.065± 0.021*	0.623± 0.025	0.911± 0.085**
400 ppm	5	10.7± 0.5**	0.061± 0.034**	0.065± 0.010	0.069± 0.032	0.618± 0.074	1.009± 0.103**
800 ppm	0	-	-	-	-	-	-

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

Test of Dunnett

(HCL042)

BAIS2

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: %

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	1.265± 0.074	0.268± 0.028	4.655± 0.392	2.203± 0.127
50 ppm	5	1.468± 0.054*	0.255± 0.022	4.688± 0.146	2.322± 0.083
100 ppm	5	1.492± 0.071*	0.285± 0.036	4.903± 0.268	2.327± 0.143
200 ppm	5	1.774± 0.170**	0.151± 0.037**	4.588± 0.136	3.065± 0.172**
400 ppm	5	1.870± 0.156**	0.082± 0.024**	4.400± 0.335	3.630± 0.161**
800 ppm	0	-	-	-	-

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

Test of Dunnett

(HCL042)

BAIS2

APPENDIX A 11-1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(TWO-WEEK STUDY: SUMMARY)

RAT : MALE : DEAD AND MORIBUND ANIMALS

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

PAGE : 1

		Group Name No. of Animals on Study Grade	Control 0				50 ppm 0				100 ppm 0				200 ppm 0			
Organ	Findings		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		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
	decreased hematopoiesis		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
thymus			< 0>				< 0>				< 0>				< 0>			
	atrophy		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
spleen			< 0>				< 0>				< 0>				< 0>			
	atrophy		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
[Endocrine system]																		
adrenal			< 0>				< 0>				< 0>				< 0>			
	congestion		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
[Reproductive system]																		
testis			< 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																	

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

		400 ppm				800 ppm			
		No. of Animals on Study				No. of Animals on Study			
		Grade				Grade			
Organ_____	Findings_____	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>									
[Hematopoietic system]									
bone marrow		< 0>				< 2>			
	congestion	-	-	-	-	0	1	1	0
		(-)	(-)	(-)	(-)	(0)	(50)	(50)	(0)
	decreased hematopoiesis	-	-	-	-	0	2	0	0
		(-)	(-)	(-)	(-)	(0)	(100)	(0)	(0)
thymus		< 0>				< 2>			
	atrophy	-	-	-	-	0	0	2	0
		(-)	(-)	(-)	(-)	(0)	(0)	(100)	(0)
spleen		< 0>				< 2>			
	atrophy	-	-	-	-	0	2	0	0
		(-)	(-)	(-)	(-)	(0)	(100)	(0)	(0)
[Endocrine system]									
adrenal		< 0>				< 2>			
	congestion	-	-	-	-	0	2	0	0
		(-)	(-)	(-)	(-)	(0)	(100)	(0)	(0)
[Reproductive system]									
testis		< 0>				< 2>			
	atrophy	-	-	-	-	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

STUDY NO. : 0261
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 3

Organ	Findings	Group Name	Control				50 ppm				100 ppm				200 ppm			
		No. of Animals on Study	0				0				0				0			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Reproductive system]

epididymis		< 0>				< 0>				< 0>				< 0>			
	debris of spermatic elements	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

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)

BAIS2

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

PAGE : 4

Organ	Findings	400 ppm				800 ppm			
		0				2			
		1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Reproductive system]

epididymis		< 0>				< 2>			
	debris of spermatic elements	-	-	-	-	1	0	1	0
		(-)	(-)	(-)	(-)	(50)	(0)	(50)	(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)

BAIS2

APPENDIX A 11-2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(TWO-WEEK STUDY: SUMMARY)

RAT : FEMALE : DEAD AND MORIBUND ANIMALS

STUDY NO. : 0261
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 5

Organ	Findings	Group Name	Control				50 ppm				100 ppm				200 ppm			
		No. of Animals on Study	0				0				0				0			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
lung	hemorrhage		< 0>				< 0>				< 0>				< 0>			
			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
[Hematopoietic system]																		
bone marrow	congestion		< 0>				< 0>				< 0>				< 0>			
			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	decreased hematopoiesis		< 0>				< 0>				< 0>				< 0>			
			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
thymus	atrophy		< 0>				< 0>				< 0>				< 0>			
			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	congestion		< 0>				< 0>				< 0>				< 0>			
			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
spleen	atrophy		< 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																	

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 6

		Group Name	400 ppm				800 ppm			
		No. of Animals on Study	1				2			
Organ_____	Findings_____	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>										
[Respiratory system]										
lung			< 1>				< 2>			
	hemorrhage		0	0	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(0)	(50)	(0)	(0)
[Hematopoietic system]										
bone marrow			< 1>				< 2>			
	congestion		0	1	0	0	0	0	2	0
			(0)	(100)	(0)	(0)	(0)	(0)	(100)	(0)
	decreased hematopoiesis		0	1	0	0	0	2	0	0
			(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)
thymus			< 1>				< 2>			
	atrophy		0	0	1	0	0	0	2	0
			(0)	(0)	(100)	(0)	(0)	(0)	(100)	(0)
	congestion		0	0	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(0)	(50)	(0)	(0)
spleen			< 1>				< 2>			
	atrophy		1	0	0	0	0	2	0	0
			(100)	(0)	(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 : Number of animals with lesion
(c) c : b / a * 100

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 7

Organ	Findings	Group Name	Control				50 ppm				100 ppm				200 ppm			
		No. of Animals on Study	0				0				0				0			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Endocrine system]

adrenal	congestion	< 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

(IPT150)

BAIS2

STUDY NO. : 0261
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 8

Organ	Findings	400 ppm				800 ppm			
		1				2			
		1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Endocrine system]

adrenal	congestion	< 1>				< 2>			
		0	1	0	0	1	1	0	0
		(0)	(100)	(0)	(0)	(50)	(50)	(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)

BAIS2

APPENDIX A 11-3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(TWO-WEEK STUDY: SUMMARY)

RAT : MALE : SACRIFICED ANIMALS

STUDY NO. : 0261
 ANIMAL : RAT F344
 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				50 ppm 2				100 ppm 2				200 ppm 2			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
lung	hemorrhage		< 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)
[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)
	decreased hematopoiesis		< 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)
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)
[Reproductive system]																		
testis	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)

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. : 0261
 ANIMAL : RAT F344
 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 Grade	400 ppm				800 ppm			
			1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Respiratory system]

Lung	hemorrhage	< 2>				< 0>			
		0	1	0	0	-	-	-	-
		(0)	(50)	(0)	(0)	(-)	(-)	(-)	(-)

[Hematopoietic system]

bone marrow	congestion	< 2>				< 0>			
		0	2	0	0	-	-	-	-
		(0)	(100)	(0)	(0)	(-)	(-)	(-)	(-)

decreased hematopoiesis		0	2	0	0	-	-	-	-
		(0)	(100)	(0)	(0)	(-)	(-)	(-)	(-)

thymus	atrophy	< 2>				< 0>			
		0	0	2	0	-	-	-	-
		(0)	(0)	(100)	(0)	(-)	(-)	(-)	(-)

[Reproductive system]

testis	atrophy	< 2>				< 0>			
		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	b : Number of animals with lesion			
(c)	c : b / a * 100			

STUDY NO. : 0261
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 3

Organ	Findings	Group Name	Control				50 ppm				100 ppm				200 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
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Reproductive system]

epididymis		< 2>				< 2>				< 2>				< 2>			
debris of spermatic elements		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

(HPT150)

BAIS2

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

PAGE : 4

Organ_____	Findings_____	Group Name		400 ppm				800 ppm			
		No. of Animals on Study		2				0			
		Grade		1	2	3	4	1	2	3	4
				(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Reproductive system]

epididymis

debris of spermatic elements

< 2>				< 0>			
1	0	0	0	-	-	-	-
(50)	(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)

BAIS2

APPENDIX A 11-4

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(TWO-WEEK STUDY: SUMMARY)

RAT : FEMALE : SACRIFICED ANIMALS

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 5

Organ	Findings	Group Name	Control				50 ppm				100 ppm				200 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
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
lung	hemorrhage		< 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)
[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)
	decreased hematopoiesis		< 2>				< 2>				< 2>				< 2>			
			0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
thymus	atrophy		< 2>				< 2>				< 2>				< 2>			
			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)	(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)
[Digestive system]																		
liver	herniation		< 2>				< 2>				< 2>				< 2>			
			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)	(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

STUDY NO. : 0261
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 6

		400 ppm				800 ppm				
		No. of Animals on Study				0				
Organ_____	Findings_____	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>										
[Respiratory system]										
lung	hemorrhage		< 2>				< 0>			
			0	1	0	0	-	-	-	-
			(0)	(50)	(0)	(0)	(-)	(-)	(-)	(-)
 [Hematopoietic system]										
bone marrow	congestion		< 2>				< 0>			
			1	0	1	0	-	-	-	-
			(50)	(0)	(50)	(0)	(-)	(-)	(-)	(-)
	decreased hematopoiesis		0	2	0	0	-	-	-	-
			(0)	(100)	(0)	(0)	(-)	(-)	(-)	(-)
thymus	atrophy		< 2>				< 0>			
			0	0	2	0	-	-	-	-
			(0)	(0)	(100)	(0)	(-)	(-)	(-)	(-)
spleen	atrophy		< 2>				< 0>			
			1	0	0	0	-	-	-	-
			(50)	(0)	(0)	(0)	(-)	(-)	(-)	(-)
 [Digestive system]										
liver	herniation		< 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 : Number of animals with lesion
(c) c : b / a * 100

STUDY NO. : 0261
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 7

Organ_____	Findings_____	Group Name	Control				50 ppm				100 ppm				200 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
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>																		
[Digestive system]																		
liver			< 2>				< 2>				< 2>				< 2>			
	necrosis:midbral		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
 [Endocrine system]																		
pituitary			< 2>				< 2>				< 2>				< 2>			
	Rathke pouch		0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(50)	(0)	(0)	(0)	(50)	(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

(IPT150)

BAIS2

STUDY NO. : 0261
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 8

		400 ppm				800 ppm			
		2				0			
		No. of Animals on Study							
		Grade							
Organ_____	Findings_____	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Digestive system]

liver	necrosis:middral	< 2>				< 0>			
		1	0	0	0	-	-	-	-
		(50)	(0)	(0)	(0)	(-)	(-)	(-)	(-)

[Endocrine system]

pituitary	Rathke pouch	< 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)

BAIS2

APPENDIX A 11-5

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(TWO-WEEK STUDY: SUMMARY)

MOUSE: MALE : DEAD AND MORIBUNDANIMALS

STUDY NO. : 0262
 ANIMAL : MOUSE B6F1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

Organ_____	Findings_____	Group Name	Control				50 ppm				100 ppm				200 ppm			
		No. of Animals on Study	0				0				0				0			
		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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
			< 0>				< 0>				< 0>				< 0>			
	decreased hematopoiesis		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
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)

BAISZ

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

		Group Name	400 ppm				800 ppm			
		No. of Animals on Study	0				3			
Organ_____	Findings_____	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>										
[Hematopoietic system]										
bone marrow			< 0>				< 3>			
	congestion		-	-	-	-	0	3	0	0
			(-)	(-)	(-)	(-)	(0)	(100)	(0)	(0)
	decreased hematopoiesis		-	-	-	-	0	3	0	0
			(-)	(-)	(-)	(-)	(0)	(100)	(0)	(0)
thymus			< 0>				< 2>			
	atrophy		-	-	-	-	0	0	2	0
			(-)	(-)	(-)	(-)	(0)	(0)	(100)	(0)
spleen			< 0>				< 3>			
	atrophy		-	-	-	-	0	3	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

(HPT150)

BAIS2

APPENDIX A 11-6

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(TWO-WEEK STUDY: SUMMARY)

MOUSE: FEMALE : DEAD AND MORIBUNDANIMALS

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 3

Organ_____	Findings_____	Group Name	Control				50 ppm				100 ppm				200 ppm			
		No. of Animals on Study	0				0				0				0			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																		
bone marrow	congestion		< 0>				< 0>				< 0>				< 0>			
			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	decreased hematopoiesis		< 0>				< 0>				< 0>				< 0>			
			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
thymus	atrophy		< 0>				< 0>				< 0>				< 0>			
			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
spleen	atrophy		< 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)

BAIS2

STUDY NO. : 0262
 ANIMAL : MOUSE 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 Grade	400 ppm 0				800 ppm 2			
			1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]										
bone marrow			< 0>				< 2>			
	congestion		-	-	-	-	1	1	0	0
			(-)	(-)	(-)	(-)	(50)	(50)	(0)	(0)
	decreased hematopoiesis		-	-	-	-	1	1	0	0
			(-)	(-)	(-)	(-)	(50)	(50)	(0)	(0)
thymus			< 0>				< 1>			
	atrophy		-	-	-	-	0	0	1	0
			(-)	(-)	(-)	(-)	(0)	(0)	(100)	(0)
spleen			< 0>				< 2>			
	atrophy		-	-	-	-	0	1	1	0
			(-)	(-)	(-)	(-)	(0)	(50)	(50)	(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)

BAIS2

APPENDIX A 11-7

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(TWO-WEEK STUDY: SUMMARY)

MOUSE: MALE : SACRIFICED ANIMALS

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name	Control				50 ppm				100 ppm				200 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)
	decreased hematopoiesis		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	2	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(100)	(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)
[Digestive system]																		
liver			< 2>				< 2>				< 2>				< 2>			
	necrosis:midtrial		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)
	granulation		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)	(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																	

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

Organ	Findings	400 ppm				800 ppm			
		No. of Animals on Study				No. of Animals on Study			
		1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]									
bone marrow		< 2>				< 1>			
	congestion	2	0	0	0	0	1	0	0
		(100)	(0)	(0)	(0)	(0)	(100)	(0)	(0)
	decreased hematopoiesis	0	2	0	0	0	1	0	0
		(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)
thymus		< 2>				< 1>			
	atrophy	0	2	0	0	0	1	0	0
		(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)
spleen		< 2>				< 1>			
	atrophy	2	0	0	0	0	1	0	0
		(100)	(0)	(0)	(0)	(0)	(100)	(0)	(0)
[Digestive system]									
liver		< 2>				< 1>			
	necrosis:midral	0	0	0	0	0	1	0	0
		(0)	(0)	(0)	(0)	(0)	(100)	(0)	(0)
	granulation	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

APPENDIX A 11-8

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(TWO-WEEK STUDY: SUMMARY)

MOUSE: FEMALE : SACRIFICED ANIMALS

STUDY NO. : 0262
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study Grade	Control 2				50 ppm 2				100 ppm 2				200 ppm 2			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[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)
	decreased hematopoiesis		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	2	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(100)	(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)
[Digestive system]																		
liver	necrosis:focal		< 2>				< 2>				< 2>				< 2>			
			0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
	granulation		1	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			(50)	(0)	(0)	(0)	(50)	(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 b : Number of animals with lesion
 (c) c : b / a * 100

STUDY NO. : 0262
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 4

		400 ppm				800 ppm				
		No. of Animals on Study				0				
Organ_____	Findings_____	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>										
[Hematopoietic system]										
bone marrow			< 2>				< 0>			
	congestion		2 (100)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)
	decreased hematopoiesis		2 (100)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)
thymus			< 2>				< 0>			
	atrophy		0 (0)	2 (100)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)
spleen			< 2>				< 0>			
	atrophy		0 (0)	2 (100)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)
[Digestive system]										
liver			< 2>				< 0>			
	necrosis:focal		1 (50)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)
	granulation		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 A 12-1

IDENTITY OF HYDRAZINE MONOHYDRATE

(TWO-WEEK STUDIES)

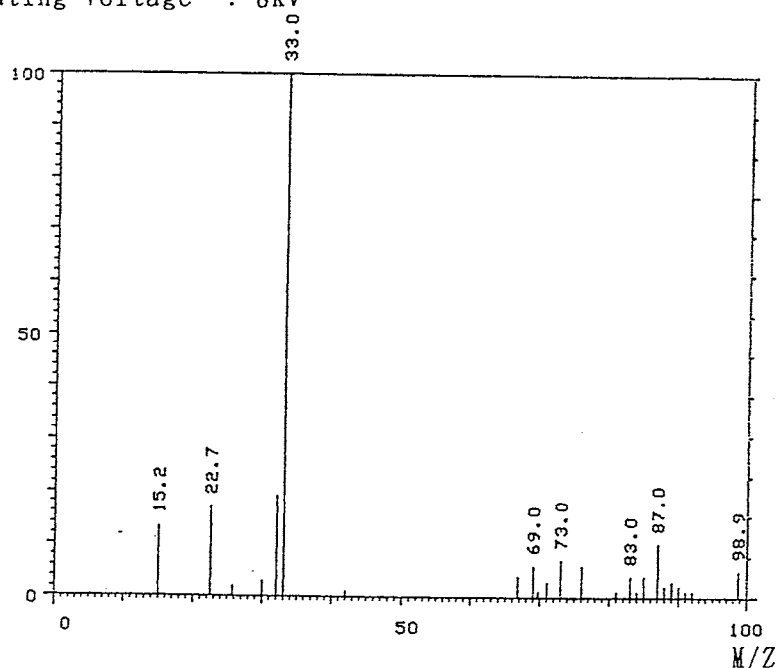
IDENTITY OF HYDRAZINE MONOHYDRATE(TWO-WEEK STUDIES)

Test Substance Lot No. APF5206

1. Spectral data

(1) Mass Spectrometry

Instrument : Hitachi M-80B
Ionization : SIMS(Secondary Ionization Mass Spectrometry)
Matrix : Glycerol
Primary Ion : Xenone⁺
Accelerating Voltage : 8kv



Result: The mass spectrum was consistent with calculated spectrum.

Quasi Molecule Ion

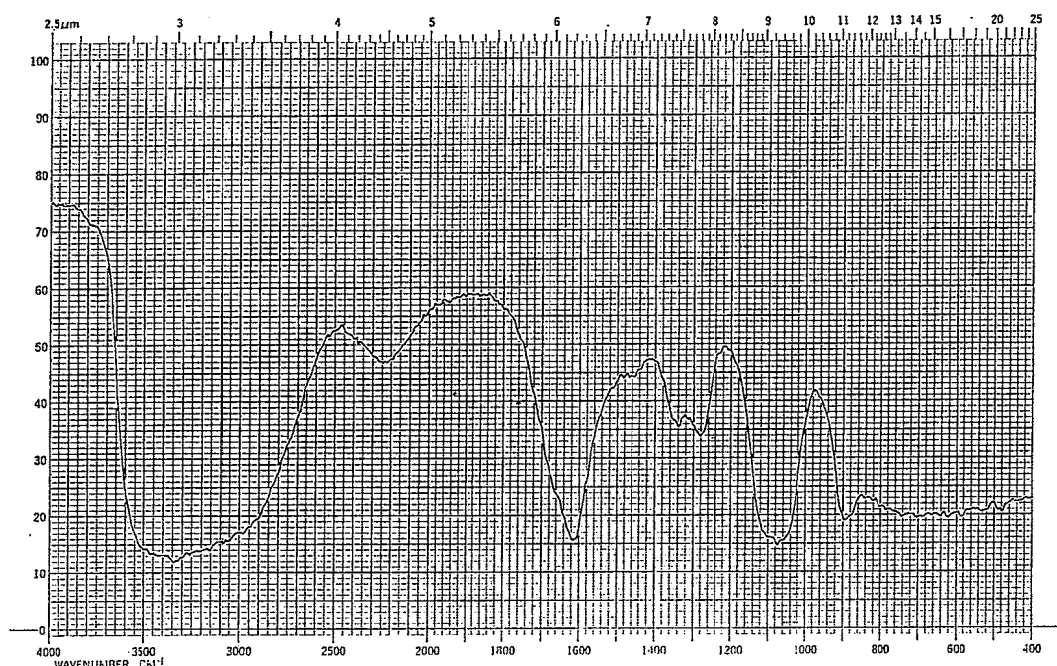
Calculated Value	33.0
(NH ₂ •NH ₂ + H ⁺)	
Determined Value	33.0

(2) Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr Liquid Cell

Slit : Medium



Infrared Spectrum of Test Substance

Results: The infrared spectrum was consistent with literature spectrum.

Determined Values
Wave Number(cm⁻¹)

Literature Values*
Wave Number(cm⁻¹)

850~ 970
970~1220
1220~1400
1500~1800
2000~2500
2500~3750

850~ 970
970~1220
1220~1400
1500~1800
2000~2500
2500~3750

(*Performed by WAKO PURE
CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The test substance was identified as Hydrazine monohydrate, by the mass spectrum and infrared spectrum.

APPENDIX A 12-2

STABILITY OF HYDRAZINE MONOHYDRATE

(TWO-WEEK STUDIES)

STABILITY OF HYDRAZINE MONOHYDRATE(TWO-WEEK STUDIES)

Test Substance Lot No. APF5206

1. Sample: This lot was used from 1994.1.25 to 1994.2.15. The test substance was stored in the dark at room temperature.

2. Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr Liquid Cell

Slit : Medium

Results: Infrared spectrum of the test substance agreed with before use and after use.

<u>1994.01.11(date analyzed)</u>	<u>1994.02.25(date analyzed)</u>
<u>Wave Number(cm^{-1})</u>	<u>Wave Number(cm^{-1})</u>
850~ 970	850~ 970
970~1220	970~1220
1220~1400	1220~1400
1500~1800	1500~1800
2000~2500	2000~2500
2500~3750	2500~3750

3. High Performance Liquid Chromatography

Instrument : Shimadzu LC-10AD(Pump)
Esa Coulochem II (Detector)Column : TSK GEL ODS-80TM(4.6mm ϕ \times 15cm)

Column Temperature : 50°C

Flow Rate : 1ml/min

Mobile Phase : Water (pH. 7.0 Phosphate Buffer Powder +
0.2mol/l Sodium Perchlorate Monohydrate)Oxidation Voltage : 600mV (Analytical Cell)
650mV (Guard Cell)

Detector : ECD(Electrochemical Detector)

Injection Volume : 10 μ l

Results: Chromatogram indicated one major peak analyzed at 1994.1.11 and one major peak analyzed at 1994.2.25. The new trace impurity peak in the test substance analyzed at 1994.2.25 was not detected.

Date	Retention Time(min)	AREA
1994.01.11 (date analyzed)	2.353	393562
1994.02.25 (date analyzed)	2.353	390976

4. Conclusions: The test substance was stable for about 6 weeks in the dark at room temperature.

APPENDIX A 12-3

CONCENTRATION HYDRAZINE MONOHYDRATE IN DRINKING WATER

(TOW-WEEK STUDIES)

CONCENTRATION OF HYDRAZINE MONOHYDRATE IN DRINKING WATER(TWO-WEEK STUDIES)

(Rat)

Date analyzed	Target Concentration(ppm)				
	50	100	200	400	800
1994.01.27	49.5(99.0)*	99.8(99.8)	204.6(102.3)	424.8(106.2)	799.4(99.9)

(Mouse)

Date analyzed	Target Concentration(ppm)				
	50	100	200	400	800
1994.02.10	50.1(100.2)	102.4(102.4)	212.0(106.0)	422.0(105.5)	846.4(105.8)

(*) % of target concentration

Analytical method: The sample were analyzed by the HPLC.

Instrument	: Shimadzu LC-10AD(Pump)	Mobile Phase	: Water(pH7.0 Phosphate Buffer Powder + 0.2mol/l Sodium Perchlorate Monohydrate)
	Esa Coulochem II (Detector)	Oxidation Voltage	: 600mv (Analytical Cell)
Column	: TSK GEL ODS-80TM(4.6mm ϕ \times 15cm)		650mv (Guard Cell)
Column Temperature:	50°C	Detector	: ECD(Electrochemical Detector)
Flow Rate	: 1ml/min	Injection Volume	: 10 μ l

APPENDIX A 12-4

STABILITY OF HYDRAZINE MONOHYDRATE IN DRINKING WATER

(TWO-WEEK STUDIES)

STABILITY OF HYDRAZINE MONOHYDRATE IN DRINKING WATER(TWO-WEEK STUDIES)

(Rat)

Date analyzed	Target Concentration(ppm)	
	50	800
1994.01.27(a)	49.5(99.0)*	799.4(99.9)
1994.02.01(b)	36.3(72.6)	707.3(88.4)

(Mouse)

Date analyzed	Target Concentration(ppm)	
	50	800
1994.02.10(a)	50.1(100.2)	846.4(105.8)
1994.02.15(b)	43.5(87.0)	716.3(89.5)

(a) Date of preparation

(b) The stability of Hydrazine monohydrate in drinking water was established for 5 days when stored at room temperature.

(*) % of target concentration

Analytical method: The sample were analyzed by the HPLC.

Instrument : Shimadzu LC-10AD(Pump)
Esa Coulochem II (Detector)
Column : TSK GEL ODS-80TM(4.6mm ϕ \times 15cm)
Column Temperature: 50°C
Flow Rate : 1ml/min

Mobile Phase : Water(pH7.0 Phosphate Buffer Powder +
0.2mol/l Sodium Perchlorate Monohydrate)
Oxidation Voltage : 600mv(Analytical Cell)
650mv(Guard Cell)
Detector : ECD(Electrochemical Detector)
Injection Volume : 10 μ l