

酢酸ビニル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～A10-4)

2週間試験：ラット/0134；マウス/0135

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APPENDIX A 1-1

CLINICAL OBSERVATION : SUMMARY, RAT : MALE

(2Week STUDY)

STUDY NO. : 0134
 ANIMAL : RAT F344
 REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day													
		0-0	1-1	1-2	1-3	1-4	1-5	1-6	1-7	2-1	2-2	2-3	2-4	2-5	2-6
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	2
	1500 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	3000 ppm	0	0	1	1	1	1	1	1	3	3	3	3	3	3
	6000 ppm	0	0	0	0	0	0	0	1	1	2	2	2	2	2
	12000 ppm	0	0	2	2	2	2	2	2	2	2	2	2	2	2
	24000 ppm	0	0	0	0	1	0	1	1	1	1	1	1	1	1
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	2
	1500 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	3000 ppm	0	0	1	1	1	1	1	1	3	3	3	3	3	3
	6000 ppm	0	0	0	0	0	0	0	1	1	2	2	2	2	2
	12000 ppm	0	0	2	2	2	2	2	2	2	2	2	2	2	2
	24000 ppm	0	0	0	0	1	0	1	1	1	1	1	1	1	1
LOOSE STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1500 ppm	0	0	0	0	0	0	0	0	1	1	0	0	0	0
	3000 ppm	0	0	0	0	0	0	0	1	1	0	0	0	0	0
	6000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	12000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	24000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS2

STUDY NO. : 0134
ANIMAL : RAT F344
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 2

Clinical sign	Group Name	Administration Week-day
		2-7
		1

EYE OPACITY	Control	1
	1500 ppm	1
	3000 ppm	2
	6000 ppm	2
	12000 ppm	2
	24000 ppm	1

CORNEAL OPACITY	Control	1
	1500 ppm	1
	3000 ppm	2
	6000 ppm	2
	12000 ppm	2
	24000 ppm	1

LOOSE STOOL	Control	0
	1500 ppm	0
	3000 ppm	0
	6000 ppm	0
	12000 ppm	0
	24000 ppm	0

(HAN180)

BAIS2

APPENDIX A 1-2

CLINICAL OBSERVATION : SUMMARY, RAT : FEMALE

(2Week STUDY)

STUDY NO. : 0134
ANIMAL : RAT F344
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 3

Clinical sign	Group Name	Administration Week-day													
		0-0	1-1	1-2	1-3	1-4	1-5	1-6	1-7	2-1	2-2	2-3	2-4	2-5	2-6
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	6000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	12000 ppm	0	1	1	0	1	0	1	1	1	1	1	1	0	0
	24000 ppm	0	3	3	3	3	1	3	3	3	3	3	3	2	2
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1500 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	3000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	6000 ppm	0	0	0	0	1	1	0	0	0	0	0	0	0	0
	12000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	24000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1500 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	3000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	6000 ppm	0	0	0	0	1	1	0	0	0	0	0	0	0	0
	12000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	24000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN180)

BAIS 2

STUDY NO. : 0134
ANIMAL : RAT F344
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 4

Clinical sign	Group Name	Administration Week-day
		2-7
		1

SOILED PERI GENITALIA	Control	0
	1500 ppm	0
	3000 ppm	0
	6000 ppm	0
	12000 ppm	0
	24000 ppm	2

EYE OPACITY	Control	0
	1500 ppm	1
	3000 ppm	0
	6000 ppm	1
	12000 ppm	0
	24000 ppm	0

CORNEAL OPACITY	Control	0
	1500 ppm	1
	3000 ppm	0
	6000 ppm	1
	12000 ppm	0
	24000 ppm	0

(HAN190)

BAIS 2

APPENDIX A 1-3

CLINICAL OBSERVATION : SUMMARY, MOSUE : MALE

(2Week STUDY)

STUDY NO. : 0135
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day													
		0-0	1-1	1-2	1-3	1-4	1-5	1-6	1-7	2-1	2-2	2-3	2-4	2-5	2-6
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	375 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	750 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	6000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOSS OF HAIR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	375 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	750 ppm	0	0	0	0	0	0	0	0	0	0	0	0	2	2
	1500 ppm	0	0	0	0	0	0	0	0	0	1	1	2	1	1
	3000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	6000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BATS2

STUDY NO. : 0135
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 2

Clinical sign	Group Name	Administration Week-day
		2-7
		1
<hr/>		
PILOERECTOR	Control	0
	375 ppm	1
	750 ppm	0
	1500 ppm	0
	3000 ppm	0
	6000 ppm	0
LOSS OF HAIR	Control	0
	375 ppm	0
	750 ppm	2
	1500 ppm	1
	3000 ppm	1
	6000 ppm	0

(HAN190)

BAIS 2

APPENDIX A 1-4

CLINICAL OBSERVATION : SUMMARY, MOSUE: FEMALE

(2Week STUDY)

STUDY NO. : 0135
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 3

Clinical sign	Group Name	Administration Week-day													
		0-0	1-1	1-2	1-3	1-4	1-5	1-6	1-7	2-1	2-2	2-3	2-4	2-5	2-6
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
LOSS OF HAIR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	375 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	750 ppm	0	0	0	0	0	0	1	1	1	1	1	0	0	0
	1500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3000 ppm	0	0	0	1	1	1	1	1	1	2	2	0	1	0
	6000 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1

(HAN190)

BATS2

STUDY NO. : 0135
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 4

Clinical sign	Group Name	Administration Week-day
		2-7
		1

LOSS OF HAIR	Control	0
	375 ppm	0
	750 ppm	0
	1500 ppm	0
	3000 ppm	0
	6000 ppm	0

(HAN190)

BAIS 2

APPENDIX A 2-1

BODY WEIGHT CHANGES :SUMMARY, RAT : MALE

(2Week STUDY)

STUDY NO. : 0134
 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		1-2		1-4		1-7		2-4	
Control	131±	5	135±	7	141±	5	150±	5	165±	6	185±	5
1500 ppm	131±	5	135±	6	139±	6	149±	6	163±	8	182±	11
3000 ppm	132±	5	136±	5	140±	5	149±	6	163±	8	182±	7
6000 ppm	131±	5	135±	5	139±	5	148±	6	163±	7	181±	8
12000 ppm	131±	5	131±	6	134±	6*	144±	6*	157±	9	173±	10*
24000 ppm	132±	4	127±	4**	129±	3**	138±	4**	151±	5**	168±	7**

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

Test of Dunnett

APPENDIX A 2-2

BODY WEIGHT CHANGES : SUMMARY, RAT : FEMALE

(2Week STUDY)

STUDY NO. : 0134
 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		1-2		1-4		1-7		2-4	
Control	108±	3	110±	4	112±	4	117±	4	124±	5	133±	6
1500 ppm	108±	4	111±	4	113±	4	118±	4	125±	5	133±	5
3000 ppm	108±	4	110±	3	111±	4	117±	4	125±	5	133±	5
6000 ppm	108±	4	108±	4	112±	5	116±	5	125±	4	134±	5
12000 ppm	108±	3	104±	4**	107±	4*	112±	4*	121±	5	129±	4
24000 ppm	108±	3	101±	3**	102±	3**	108±	3**	116±	4**	126±	5**

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX A 2-3

BODY WEIGHT CHANGES :SUMMARY, MOSUE : MALE

(2Week STUDY)

STUDY NO. : 0135
 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	1-2	1-4	1-7	2-4	2-7
Control	23.1± 0.8	22.8± 1.0	22.5± 1.0	22.9± 1.0	23.4± 1.2	23.9± 1.1	23.9± 0.8
375 ppm	23.0± 0.8	22.9± 1.0	22.7± 0.9	23.1± 1.1	23.4± 1.1	23.7± 0.9	24.2± 1.0
750 ppm	23.0± 0.9	23.0± 0.9	22.7± 0.9	23.3± 0.8	23.5± 0.9	23.9± 0.7	24.1± 0.9
1500 ppm	23.1± 0.8	23.1± 0.8	22.9± 0.7	23.4± 0.6	23.6± 0.5	24.0± 0.6	24.2± 0.6
3000 ppm	23.0± 0.9	23.3± 0.6	22.9± 0.6	23.3± 0.8	23.5± 0.9	23.9± 0.7	23.9± 0.8
6000 ppm	23.1± 0.8	23.0± 0.9	22.7± 0.9	23.2± 1.1	23.2± 0.9	23.6± 1.6	23.9± 1.4

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX A 2-4

BODY WEIGHT CHANGES : SUMMARY, MOSUE: FEMALE

(2Week STUDY)

STUDY NO. : 0135
 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	1-2	1-4	1-7	2-4	2-7
Control	18.7± 0.8	18.1± 0.8	18.2± 0.9	18.6± 1.0	18.7± 0.9	19.0± 0.9	19.8± 0.9
375 ppm	18.7± 0.9	19.0± 0.9	18.6± 1.0	18.7± 0.8	19.1± 0.8	19.1± 0.9	20.0± 0.7
750 ppm	18.7± 0.9	18.8± 1.1	18.5± 0.9	18.5± 1.1	19.0± 1.0	19.3± 1.2	19.7± 1.2
1500 ppm	18.7± 0.9	18.6± 0.8	18.3± 0.7	18.7± 0.7	19.1± 0.5	19.2± 0.7	19.9± 0.6
3000 ppm	18.7± 0.9	18.6± 0.9	18.4± 1.0	18.7± 1.0	19.0± 0.8	19.4± 0.4	20.1± 0.9
6000 ppm	18.7± 0.9	18.5± 1.2	18.2± 1.1	18.3± 1.2	18.7± 0.9	19.0± 1.2	19.5± 1.3

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

Test of Dunnett

(HAN260)

BATS 2

APPENDIX A 3-1

WATER CONSUMPTION CHANGES : SUMMARY, RAT: MALE

(2Week STUDY)

STUDY NO. : 0134
 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	18.0± 1.8	19.5± 1.2	20.9± 2.0	21.9± 2.3
1500 ppm	18.1± 1.2	19.3± 1.2	20.4± 1.7	20.8± 1.9
3000 ppm	18.4± 1.5	18.9± 1.4	19.7± 1.2	20.6± 1.6
6000 ppm	16.1± 1.3	16.6± 1.2*	17.3± 1.2*	18.2± 1.3**
12000 ppm	15.1± 3.3*	16.1± 3.0**	17.5± 5.2**	15.4± 1.1**
24000 ppm	11.2± 0.9**	14.6± 1.3**	14.4± 1.4**	14.8± 1.3**

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 2

APPENDIX A 3-2

WATER CONSUMPTION CHANGES : SUMMARY, RAT: FEMALE

(2Week STUDY)

STUDY NO. : 0134
 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	16.8± 1.6	18.9± 4.2	19.1± 3.0	21.4± 7.8
1500 ppm	16.3± 0.8	17.0± 0.9	16.9± 1.6	19.2± 6.1
3000 ppm	15.3± 0.9	16.0± 1.1	16.1± 1.5	16.1± 1.2
6000 ppm	14.2± 0.5*	14.5± 0.8**	15.1± 0.8*	15.4± 0.6
12000 ppm	11.9± 1.0**	12.8± 0.6**	11.6± 0.7**	12.9± 0.9**
24000 ppm	9.9± 4.5**	13.1± 0.8**	11.2± 0.9**	12.8± 1.2**

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

APPENDIX A 3-3

WATER CONSUMPTION CHANGES : SUMMARY, MOUSE: MALE

(2Week STUDY)

STUDY NO. : 0135
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 2
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration 1-4(4)	week-day(effective) 1-7(3)	2-4(4)	2-7(3)
Control	4.1± 0.3	3.9± 0.2	3.9± 0.2	3.7± 0.3
375 ppm	4.4± 1.2	4.2± 1.0	4.3± 1.0	4.1± 0.9
750 ppm	4.2± 0.4	4.0± 0.3	3.9± 0.4	3.9± 0.3
1500 ppm	4.3± 0.4	4.1± 0.4	4.1± 0.4	4.0± 0.4
3000 ppm	4.2± 0.4	3.9± 0.3	3.7± 0.3	3.8± 0.3
6000 ppm	4.2± 0.3	4.1± 0.2	4.0± 0.4	4.0± 0.5

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 2

APPENDIX 3-4

WATER CONSUMPTION CHANGES : SUMMARY, MOUSE: MALE

(2Week STUDY)

STUDY NO. : 0135
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 2
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day(effective)			
	1-4(4)	1-7(3)	2-4(4)	2-7(3)
Control	3.8± 0.5	3.6± 1.1	4.5± 0.9	4.6± 1.1
375 ppm	4.6± 0.7**	4.4± 0.4	4.8± 0.4	5.1± 0.6
750 ppm	4.3± 0.6	4.7± 1.0	4.9± 1.0	4.8± 0.9
1500 ppm	4.4± 0.4*	4.3± 0.3	4.8± 1.4	4.9± 0.8
3000 ppm	4.2± 0.5	4.1± 0.2	4.1± 0.3	4.3± 0.3
6000 ppm	4.2± 0.3	4.3± 0.3	4.4± 0.3	4.5± 0.3

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX A 4-1

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : MALE

(2Week STUDY)

STUDY NO. : 0134
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 2
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration week-day(effective)	
	1-7(7)	2-7(7)
Control	14.7± 1.0	16.0± 0.9
1500 ppm	14.4± 0.7	15.7± 1.2
3000 ppm	14.0± 1.0	15.3± 1.0
6000 ppm	13.9± 1.0	15.3± 1.0
12000 ppm	13.4± 1.1*	14.5± 1.1*
24000 ppm	12.4± 0.7**	14.1± 0.9**

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS2

APPENDIX A 4-2

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : FEMALE

(2Week STUDY)

STUDY NO. : 0134
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 2
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

Group Name	Administration week-day(effective)	
	1-7(7)	2-7(7)
Control	11.4± 0.5	11.5± 0.7
1500 ppm	11.7± 0.8	11.5± 0.8
3000 ppm	11.5± 0.7	11.3± 0.7
6000 ppm	11.4± 0.7	11.5± 0.7
12000 ppm	10.7± 0.5*	11.1± 0.5
24000 ppm	9.6± 0.6**	10.6± 0.7*

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

Test of Dunnett

(HAN260)

BATS2

APPENDIX A 4-3

FOOD CONSUMPTION CHANGES : SUMMARY, MOSUE : MALE

(2Week STUDY)

STUDY NO. : 0135
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 2
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration week-day(effective)	
	1-7(7)	2-7(7)
Control	3.8± 0.3	3.7± 0.2
375 ppm	3.7± 0.3	3.6± 0.2
750 ppm	3.7± 0.2	3.7± 0.2
1500 ppm	3.8± 0.1	3.7± 0.2
3000 ppm	3.9± 0.2	3.6± 0.1
6000 ppm	3.8± 0.3	3.7± 0.4

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

Test of Dunnett

APPENDIX A 4-4

FOOD CONSUMPTION CHANGES : SUMMARY, MOSUE : FEMALE

(2Week STUDY)

STUDY NO. : 0135
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 2
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

Group Name	Administration week-day(effective)	
	1-7(7)	2-7(7)
Control	3.0± 0.2	3.2± 0.2
375 ppm	3.2± 0.3	3.4± 0.3
750 ppm	3.1± 0.3	3.2± 0.1
1500 ppm	3.2± 0.2	3.3± 0.2
3000 ppm	3.2± 0.2	3.2± 0.2
6000 ppm	3.1± 0.2	3.3± 0.2

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX A 5-1

CHEMICAL INTAKE CHANGES: SUMMARY, RAT : MALE

(2Week STUDY)

STUDY NO. : 0134
ANIMAL : RAT F344
UNIT : g/kg/day
REPORT TYPE : A1 2
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration (weeks)	
	1	2
Control	0.000± 0.000	0.000± 0.000
1500 ppm	0.178± 0.008	0.159± 0.009
3000 ppm	0.348± 0.014	0.314± 0.017
6000 ppm	0.611± 0.028	0.559± 0.029
12000 ppm	1.230± 0.201	0.993± 0.026
24000 ppm	2.305± 0.137	1.969± 0.114

(HAN300)

BAIS2

APPENDIX A 5-2

CHEMICAL INTAKE CHANGES: SUMMARY, RAT : FEMALE

(2Week STUDY)

STUDY NO. : 0134
ANIMAL : RAT F344
UNIT : g/kg/day
REPORT TYPE : A1 2
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

Group Name	Administration (weeks)	
	1	2
Control	0.000± 0.000	0.000± 0.000
1500 ppm	0.204± 0.012	0.207± 0.068
3000 ppm	0.382± 0.020	0.347± 0.020
6000 ppm	0.695± 0.020	0.661± 0.022
12000 ppm	1.274± 0.039	1.134± 0.060
24000 ppm	2.709± 0.118	2.325± 0.125

(HAN300)

BATS 2

APPENDIX A 5-3

CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: MALE

(2Week STUDY)

STUDY NO. : 0135
ANIMAL : MOUSE BDF1
UNIT : g/kg/day
REPORT TYPE : A1 2
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration (weeks)	
	1	2
Control	0.000± 0.000	0.000± 0.000
375 ppm	0.067± 0.015	0.064± 0.011
750 ppm	0.128± 0.009	0.122± 0.009
1500 ppm	0.261± 0.021	0.249± 0.020
3000 ppm	0.502± 0.037	0.473± 0.023
6000 ppm	1.055± 0.066	0.997± 0.128

(HAN300)

BATS2

APPENDIX A 5-4

CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: FEMALE

(2Week STUDY)

STUDY NO. : 0135
ANIMAL : MOUSE BDF1
UNIT : g/kg/day
REPORT TYPE : A1 2
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

Group Name	Administration (weeks)	
	1	2
Control	0.000± 0.000	0.000± 0.000
375 ppm	0.085± 0.008	0.096± 0.010
750 ppm	0.187± 0.043	0.182± 0.033
1500 ppm	0.339± 0.023	0.366± 0.060
3000 ppm	0.649± 0.046	0.649± 0.040
6000 ppm	1.380± 0.106	1.377± 0.105

(HAN300)

BAIS 2

APPENDIX A 6-1

HEMATOLOGY : SUMMARY, RAT : MALE

(2Week STUDY)

STUDY NO. : 0134
 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	10	7.62±	0.12	14.9±	0.3	43.6±	0.7	57.3±	0.6	19.6±	0.4	34.2±	1.0	1022±	19
1500 ppm	10	7.64±	0.12	14.9±	0.3	43.5±	0.7	56.9±	0.5	19.5±	0.2	34.2±	0.5	989±	80
3000 ppm	10	7.60±	0.13	14.8±	0.3	43.0±	0.8	56.6±	0.6	19.5±	0.3	34.5±	0.5	1006±	47
6000 ppm	10	7.62±	0.14	14.8±	0.4	43.7±	1.2	57.4±	0.7	19.4±	0.4	33.8±	0.7	991±	53
12000 ppm	10	7.70±	0.23	14.9±	0.4	43.4±	1.1	56.4±	0.8*	19.3±	0.3	34.2±	0.7	909±	100**
24000 ppm	10	7.70±	0.09	14.9±	0.3	43.5±	0.6	56.5±	0.3*	19.4±	0.3	34.3±	0.6	905±	52**

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0134
 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 WBC N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	10	5.28±	1.08	0±	0	12±	3	0±	0	0±	0	3±	1	85±	4	0±	1
1500 ppm	10	5.62±	1.87	0±	1	13±	4	0±	0	0±	0	3±	2	83±	4	1±	1
3000 ppm	10	5.16±	0.91	0±	0	13±	4	0±	1	0±	0	3±	2	83±	4	0±	1
6000 ppm	10	5.07±	1.53	1±	1	16±	6	1±	1	0±	0	3±	1	80±	7	0±	1
12000 ppm	10	4.94±	1.70	0±	1	14±	4	0±	1	0±	0	3±	2	82±	5	1±	1
24000 ppm	10	5.60±	1.72	0±	0	11±	3	1±	1	0±	0	2±	1	86±	4	0±	1

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

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX A 6-2

HEMATOLOGY : SUMMARY, RAT : FEMALE

(2Week STUDY)

STUDY NO. : 0134
ANIMAL : RAT F344
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	10	8.00± 0.14	15.8± 0.2	45.0± 0.9	56.2± 0.7	19.8± 0.4	35.2± 0.7	948± 76
1500 ppm	10	7.87± 0.24	15.6± 0.4	44.5± 1.3	56.5± 0.5	19.8± 0.5	35.0± 0.9	939± 43
3000 ppm	10	8.01± 0.25	15.8± 0.5	45.0± 1.2	56.1± 0.5	19.7± 0.3	35.1± 0.5	926± 68
6000 ppm	10	7.86± 0.23	15.5± 0.3	44.5± 1.4	56.7± 0.5	19.7± 0.4	34.9± 0.7	961± 31
12000 ppm	10	7.93± 0.18	15.6± 0.5	44.5± 1.6	56.2± 1.0	19.6± 0.4	35.0± 0.9	908± 60
24000 ppm	10	7.93± 0.22	15.6± 0.6	44.4± 1.2	56.0± 0.4	19.7± 0.4	35.2± 0.6	879± 70*

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BA1S2

STUDY NO. : 0134
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		OTHER	
Control	10	4.41±	0.71	0±	1	11±	3	1±	1	0±	0	3±	2	85±	5	0±	1
1500 ppm	10	5.14±	1.71	1±	1	14±	5	1±	1	0±	0	2±	1	82±	5	0±	0
3000 ppm	10	4.77±	1.32	0±	1	13±	4	1±	1	0±	0	4±	1	81±	4	1±	1
6000 ppm	10	5.24±	1.88	0±	1	12±	5	0±	0	0±	0	3±	1	84±	6	0±	1
12000 ppm	10	4.81±	2.30	1±	1	14±	7	0±	1	0±	0	3±	2	82±	8	0±	1
24000 ppm	10	4.46±	1.26	0±	1	12±	4	1±	1	0±	0	3±	1	84±	6	0±	0

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

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX A 6-3

HEMATOLOGY : SUMMARY, MOSUE : MALE

(2Week STUDY)

STUDY NO. : 0135
 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	9	10.79± 0.21	16.6± 0.4	51.7± 2.0	47.9± 1.2	15.4± 0.2	32.2± 0.7	1310± 73
375 ppm	10	10.66± 0.41	16.3± 0.5	50.3± 2.4	47.2± 0.7	15.3± 0.2	32.4± 0.7	1290± 75
750 ppm	10	10.77± 0.23	16.5± 0.5	51.3± 1.0	47.6± 0.5	15.3± 0.2	32.1± 0.5	1293± 88
1500 ppm	9	10.68± 0.39	16.4± 0.5	50.5± 2.0	47.3± 0.6	15.3± 0.3	32.4± 0.6	1326± 97
3000 ppm	10	10.81± 0.24	16.5± 0.5	51.3± 1.3	47.5± 0.5	15.3± 0.2	32.1± 0.4	1308± 72
6000 ppm	10	10.67± 0.39	16.3± 0.4	50.7± 1.3	47.6± 0.8	15.3± 0.3	32.2± 0.6	1323± 129

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0135
 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		OTHER	
Control	9	2.28±	1.27	2±	1	10±	3	2±	2	0±	0	2±	1	83±	5	0±	1
375 ppm	10	1.79±	0.86	3±	3	11±	6	2±	2	0±	0	2±	1	82±	8	0±	0
750 ppm	10	2.72±	1.25	3±	1	11±	3	2±	2	0±	0	2±	1	82±	4	0±	0
1500 ppm	9	2.36±	1.12	2±	1	9±	3	0±	1	0±	0	2±	1	86±	3	0±	0
3000 ppm	10	1.87±	0.63	2±	2	13±	8	1±	2	0±	0	2±	1	82±	9	1±	1
6000 ppm	10	2.04±	0.83	3±	4	13±	11	1±	1	0±	0	3±	2	80±	15	0±	1

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

Test of Dunnett

(JCL71A)

BAIS 2

APPENDIX A 6-4

HEMATOLOGY : SUMMARY, MOSUE : FEMALE

(2Week STUDY)

STUDY NO. : 0135
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	10	10.14± 0.22	15.7± 0.4	47.1± 0.9	46.5± 0.4	15.4± 0.3	33.2± 0.6	977± 218
375 ppm	10	9.92± 0.19	15.3± 0.4	46.7± 1.3	47.0± 1.1	15.4± 0.2	32.7± 0.9	976± 144
750 ppm	8	10.27± 0.28	15.9± 0.5	48.5± 1.3	47.3± 0.4	15.5± 0.3	32.9± 0.8	1037± 38
1500 ppm	10	10.15± 0.28	15.5± 0.4	47.9± 1.5	47.1± 1.1	15.3± 0.2	32.6± 0.9	1030± 151
3000 ppm	10	10.12± 0.34	15.5± 0.4	47.9± 2.4	47.3± 1.5	15.3± 0.2	32.3± 0.9	1044± 80
6000 ppm	10	9.94± 0.96	15.6± 0.6	46.7± 4.4	47.0± 1.1	15.8± 1.4	33.7± 2.6	1001± 132

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0135
 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		OTHER	
Control	10	2.11±	0.86	2±	2	11±	4	2±	2	0±	0	3±	1	82±	5	0±	0
375 ppm	10	2.25±	0.98	3±	3	14±	8	2±	1	0±	0	3±	2	78±	12	1±	1
750 ppm	8	2.40±	1.01	2±	1	9±	2	1±	1	0±	0	3±	1	84±	3	0±	0
1500 ppm	10	2.03±	0.89	2±	1	10±	2	3±	2	0±	0	3±	2	82±	3	0±	0
3000 ppm	10	1.97±	0.86	2±	1	10±	3	3±	2	0±	0	3±	1	82±	3	1±	1
6000 ppm	10	2.16±	0.85	3±	2	9±	2	2±	1	0±	0	3±	2	83±	4	0±	1

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

Test of Dunnett

(JCL71A)

BAIS 2

APPENDIX A 7-1

BIOCHEMISTRY : SUMMARY, RAT : MALE

(2Week STUDY)

STUDY NO. : 0134
 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		GOT IU/l	
Control	10	6.1±	0.1	3.6±	0.1	1.5±	0.1	0.38±	0.05	190±	14	61±	2	62±	5
1500 ppm	10	6.0±	0.2	3.6±	0.1	1.5±	0.1	0.38±	0.04	187±	21	60±	3	58±	3
3000 ppm	10	6.1±	0.1	3.6±	0.1	1.4±	0.0	0.36±	0.05	183±	15	61±	2	56±	6
6000 ppm	10	6.0±	0.1	3.6±	0.1	1.4±	0.1	0.37±	0.05	182±	12	62±	3	57±	4
12000 ppm	10	5.9±	0.1**	3.5±	0.1**	1.5±	0.0	0.39±	0.07	185±	14	59±	4	59±	5
24000 ppm	10	5.9±	0.1**	3.5±	0.1**	1.5±	0.1	0.39±	0.05	181±	10	62±	3	59±	5

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

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0134
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (2)

PAGE : 2

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	10	20 \pm	3	248 \pm	63	159 \pm	38	15.9 \pm	2.5	139 \pm	2	4.0 \pm	0.3	104 \pm	1
1500 ppm	10	18 \pm	1	240 \pm	66	155 \pm	23	15.9 \pm	2.0	138 \pm	1	3.9 \pm	0.3	103 \pm	2
3000 ppm	10	17 \pm	2*	225 \pm	48	158 \pm	37	16.2 \pm	2.1	138 \pm	2	4.0 \pm	0.1	103 \pm	2
6000 ppm	10	17 \pm	2*	193 \pm	24	143 \pm	24	16.4 \pm	2.0	138 \pm	1	4.1 \pm	0.4	103 \pm	2
12000 ppm	10	16 \pm	2**	221 \pm	42	142 \pm	14	17.0 \pm	2.4	137 \pm	1	4.0 \pm	0.3	103 \pm	2
24000 ppm	10	15 \pm	1**	223 \pm	35	141 \pm	25	17.7 \pm	2.8	137 \pm	1	4.0 \pm	0.2	104 \pm	1

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0134
ANIMAL : RAT F344
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	10	11.6±	0.4	8.1±	1.1
1500 ppm	10	11.5±	0.5	8.0±	1.2
3000 ppm	10	11.5±	0.4	8.2±	1.1
6000 ppm	10	11.4±	0.3	8.0±	1.1
12000 ppm	10	11.1±	0.4*	7.6±	1.4
24000 ppm	10	11.1±	0.2*	7.5±	1.0

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

APPENDIX A 7-2

BIOCHEMISTRY : SUMMARY, RAT : FEMALE

(2Week STUDY)

STUDY NO. : 0134
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		GOT IU/l	
Control	10	6.0±	0.1	3.6±	0.1	1.5±	0.1	0.53±	0.07	180±	9	68±	4	56±	4
1500 ppm	10	5.9±	0.1	3.5±	0.1	1.5±	0.1	0.47±	0.04	177±	12	66±	4	55±	3
3000 ppm	10	5.9±	0.1	3.5±	0.1	1.5±	0.0	0.53±	0.11	181±	11	67±	4	58±	10
6000 ppm	10	5.9±	0.1	3.5±	0.1	1.5±	0.1	0.53±	0.06	177±	18	69±	4	55±	4
12000 ppm	10	5.8±	0.2**	3.4±	0.1**	1.5±	0.1	0.52±	0.08	176±	13	71±	4	56±	4
24000 ppm	10	5.7±	0.1**	3.4±	0.1**	1.5±	0.1	0.51±	0.05	181±	9	71±	3	58±	4

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0134
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (2)

PAGE : 5

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	10	15±	2	269±	62	142±	29	15.8±	2.9	138±	2	3.8±	0.2	106±	2
1500 ppm	10	14±	1	265±	63	133±	29	15.8±	2.1	138±	1	3.7±	0.1	107±	2
3000 ppm	10	14±	1	388±	431	172±	120	16.5±	2.4	138±	2	3.8±	0.3	106±	2
6000 ppm	10	13±	1**	271±	70	153±	21	16.3±	1.7	137±	1	3.9±	0.5	106±	2
12000 ppm	10	13±	1**	286±	123	146±	35	17.4±	2.9	137±	1	3.9±	0.6	105±	3
24000 ppm	10	13±	1**	262±	60	140±	19	17.2±	2.3	136±	1*	3.9±	0.4	106±	1

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0134
ANIMAL : RAT F344
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	10	11.1±	0.4	7.2±	1.2
1500 ppm	10	11.0±	0.4	7.1±	1.4
3000 ppm	10	11.0±	0.5	7.4±	1.5
6000 ppm	10	11.0±	0.4	7.4±	1.4
12000 ppm	10	11.1±	0.5	7.3±	1.8
24000 ppm	10	10.7±	0.2	6.4±	1.2

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

APPENDIX A 7-3

BIOCHEMISTRY : SUMMARY, MOSUE : MALE

(2Week STUDY)

STUDY NO. : 0135
 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	9	5.4±	0.3	3.1±	0.2	1.4±	0.1	0.77±	0.30	305±	32	93±	7	42±	7
375 ppm	10	5.3±	0.3	3.0±	0.2	1.4±	0.1	0.61±	0.18	309±	29	91±	6	35±	4
750 ppm	10	5.4±	0.3	3.1±	0.2	1.3±	0.1	0.78±	0.29	314±	36	91±	7	35±	4
1500 ppm	9	5.4±	0.3	3.1±	0.2	1.3±	0.1	0.70±	0.26	307±	34	90±	6	36±	4
3000 ppm	10	5.3±	0.2	3.0±	0.1	1.4±	0.1	0.74±	0.15	304±	21	90±	5	37±	6
6000 ppm	10	5.4±	0.4	3.0±	0.1	1.3±	0.1	0.66±	0.19	316±	35	91±	10	39±	10

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

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0135
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (2)

PAGE : 2

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	9	16 \pm	4	244 \pm	74	93 \pm	62	22.2 \pm	5.7	149 \pm	1	4.8 \pm	0.5	120 \pm	2
375 ppm	10	15 \pm	3	213 \pm	50	59 \pm	40	22.4 \pm	5.9	148 \pm	2	4.6 \pm	0.5	119 \pm	2
750 ppm	10	14 \pm	2	201 \pm	52	66 \pm	49	21.8 \pm	4.1	149 \pm	2	4.9 \pm	0.4	119 \pm	2
1500 ppm	9	13 \pm	2	233 \pm	57	88 \pm	58	22.2 \pm	6.0	148 \pm	1	4.8 \pm	0.7	119 \pm	2
3000 ppm	10	12 \pm	2	216 \pm	62	80 \pm	64	21.1 \pm	3.7	148 \pm	1	4.8 \pm	0.5	119 \pm	1
6000 ppm	10	13 \pm	3	274 \pm	179	73 \pm	47	22.7 \pm	4.3	148 \pm	1	4.8 \pm	0.4	120 \pm	3

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0135
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	9	9.6±	0.4	8.9±	1.7
375 ppm	10	9.6±	0.7	9.0±	1.5
750 ppm	10	9.5±	0.3	9.6±	1.1
1500 ppm	9	9.5±	0.5	9.1±	1.3
3000 ppm	10	9.5±	0.5	9.3±	1.3
6000 ppm	10	9.6±	0.7	9.6±	1.8

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

APPENDIX A 7-4

BIOCHEMISTRY : SUMMARY, MOSUE : FEMALE

(2Week STUDY)

STUDY NO. : 0135
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	10	5.3±	0.3	3.3±	0.2	1.6±	0.1	0.76±	0.18	267±	21	79±	7	57±	30
375 ppm	9	5.3±	0.2	3.3±	0.2	1.7±	0.1	0.91±	0.22	256±	22	80±	4	46±	8
750 ppm	8	5.3±	0.2	3.3±	0.1	1.6±	0.1	0.83±	0.18	267±	20	80±	9	43±	4
1500 ppm	10	5.3±	0.3	3.3±	0.2	1.6±	0.1	0.85±	0.16	277±	30	83±	4	42±	6
3000 ppm	10	5.2±	0.2	3.3±	0.1	1.7±	0.1	0.85±	0.31	276±	24	81±	7	53±	23
6000 ppm	10	5.3±	0.2	3.3±	0.1	1.7±	0.1	0.87±	0.18	269±	16	80±	5	49±	6

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BATS2

STUDY NO. : 0135
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (2)

PAGE : 5

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	10	21±	16	289±	101	52±	28	19.5±	2.8	148±	2	4.7±	0.4	120±	1
375 ppm	9	16±	3	237±	61	77±	66	20.0±	2.2	148±	2	5.0±	0.4	121±	2
750 ppm	8	15±	2	210±	33	49±	15	18.8±	3.2	147±	1	5.0±	0.6	121±	2
1500 ppm	10	13±	2	253±	75	66±	38	18.9±	1.9	147±	1	4.8±	0.4	120±	1
3000 ppm	10	17±	9	296±	141	76±	60	19.3±	5.0	147±	1	4.8±	0.4	121±	2
6000 ppm	10	16±	3	226±	48	56±	37	19.1±	3.0	148±	1	4.8±	0.5	121±	1

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0135
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	10	9.5±	0.3	7.8±	0.7
375 ppm	9	9.6±	0.5	9.1±	1.4
750 ppm	8	9.5±	0.3	8.6±	1.2
1500 ppm	10	9.6±	0.5	9.1±	1.1
3000 ppm	10	9.6±	0.5	9.2±	1.2
6000 ppm	10	9.6±	0.5	8.8±	1.1

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

APPENDIX A 8-1

GROSS FINDINGS : SUMMARY, RAT : MALE :SACRIFICED ANIMALS
(2Week STUDY)

STUDY NO. : 0134
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 1

Organ	Findings	Group Name		Control		1500 ppm		3000 ppm		6000 ppm	
		NO. of Animals		10	(%)	10	(%)	10	(%)	10	(%)
thymus	red patch/zone			1	(10)	0	(0)	0	(0)	0	(0)

(IIP080)

BATS 2

STUDY NO. : 0134
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 2

Organ	Findings	Group Name	12000 ppm	24000 ppm
		NO. of Animals	10 (%)	10 (%)
thymus	red patch/zone		0 (0)	1 (10)

(HPT080)

BAIS 2

APPENDIX A 8-2

GROSS FINDINGS : SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS

(2Week STUDY)

STUDY NO. : 0135
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control		375 ppm		750 ppm		1500 ppm	
			10	(%)	10	(%)	10	(%)	10	(%)
spleen	red patch/zone		0	(0)	1	(10)	0	(0)	0	(0)
	black patch/zone		1	(10)	0	(0)	1	(10)	1	(10)
kidney	hydranephrosis		0	(0)	0	(0)	0	(0)	0	(0)

(HPT080)

BAIS 2

STUDY NO. : 0135
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	3000 ppm		6000 ppm	
			10	(%)	10	(%)
spleen	red patch/zone		0	(0)	0	(0)
	black patch/zone		2	(20)	0	(0)
kidney	hydronephrosis		0	(0)	1	(10)

(HPT080)

BAIS 2

APPENDIX A 8-3

GROSS FINDINGS : SUMMARY, MOUSE : MALE : SACRIFICED ANIMALS

(2Week STUDY)

STUDY NO. : 0134
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control		1500 ppm		3000 ppm		6000 ppm	
			10	(%)	10	(%)	10	(%)	10	(%)
Liver	herniation		0	(0)	1	(10)	0	(0)	1	(10)
uterus	dilated lumen		2	(20)	4	(40)	1	(10)	1	(10)

(HPT080)

BAIS 2

STUDY NO. : 0134
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 4

Organ	Findings	Group Name	12000 ppm		24000 ppm	
		NO. of Animals	10	(%)	10	(%)
Liver	herniation		0	(0)	0	(0)
uterus	dilated lumen		1	(10)	2	(20)

(HPT080)

BAIS2

APPENDIX A 8-4

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE : SACRIFICED ANIMALS

(2Week STUDY)

STUDY NO. : 0135
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 3

Organ	Findings	Group Name		Control		375 ppm		750 ppm		1500 ppm	
		NO. of Animals		10	(%)	10	(%)	10	(%)	10	(%)
spleen	black patch/zone			1	(10)	0	(0)	3	(30)	0	(0)
uterus	dilated lumen			5	(50)	8	(80)	5	(50)	4	(40)

(HPT080)

BAIS 2

STUDY NO. : 0135
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (2W)

PAGE : 4

Organ	Findings	Group Name	3000 ppm		6000 ppm	
		NO. of Animals	10	(%)	10	(%)
spleen	black patch/zone		1	(10)	1	(10)
uterus	dilated lumen		7	(70)	4	(40)

(HPT080)

BAIS 2

APPENDIX A 9-1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : SACRIFICED ANIMALS

(2Week STUDY)

STUDY NO. : 0134
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name	Control				1500 ppm				3000 ppm				6000 ppm			
		No. of Animals	2				2				2				2			
			<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
nasal cavit	respiratory metaplasia:gland		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)
lung	accumulation of foamy cells		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)

<1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(HPT150)

BAIS2

STUDY NO. : 0134
 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				12000 ppm				24000 ppm			
		2				2				2			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]													
nasal cavit	respiratory metaplasia:gland	1	0	0	0	0	0	0	0	0	0	0	0
		(50)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
lung	accumulation of foamy cells	0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

<1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(HPT150)

BAIS2

APPENDIX A 9-2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE : SACRIFICED ANIMALS

(2Week STUDY)

STUDY NO. : 0134
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 3

Organ	Findings	Group Name No. of Animals				Control 2				1500 ppm 2				3000 ppm 2				6000 ppm 2			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																					
nasal cavit	respiratory metaplasia:gland	0	0	0	0	0	0	0	0	1	0	0	0	0	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]																					
liver	granulation	0	0	0	0	0	0	0	0	1	0	0	0	0	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)
[Urinary system]																					
kidney	mineralization:cortico-medullary junction	0	0	0	0	0	0	0	0	1	0	0	0	0	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)
[Reproductive system]																					
uterus	dilatation	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
		(0)	(0)	(0)	(0)	(50)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(50)	(0)	(0)	(0)	(50)	(0)	(0)	(0)
		<1>:Slight				<2>:Moderate				<3>:Marked				<4>:Severe							

(HPT150)

BAIS2

STUDY NO. : 0134
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 4

Organ	Findings	Group Name No. of Animals				12000 ppm 2				24000 ppm 2			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]													
nasal cavity	respiratory metaplasia:gland	1 (50)	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	granulation	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	mineralization:cortico-medullary junction	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Reproductive system]													
uterus	dilatation	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

<1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(HPT150)

BAIS2

APPENDIX A 9-3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE: MALE : SACRIFICED ANIMALS

(2Week STUDY)

STUDY NO. : 0135
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name	Control				375 ppm				750 ppm				1500 ppm			
		No. of Animals	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																		
spleen	angiectasis		0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	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)
[Digestive system]																		
liver	granulation		1 (50)	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)
[Endocrine system]																		
thyroid	ectopic thymic tissue		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

<1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(HPT150)

BAIS2

STUDY NO. : 0135
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name No. of Animals				3000 ppm				6000 ppm			
		2				2				2			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]													
spleen	angiectasis	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	1	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]													
liver	granulation	0	0	0	0	1	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(50)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Endocrine system]													
thyroid	ectopic thymic tissue	0	0	0	0	1	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(50)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

<1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(HPT150)

BAIS2

APPENDIX A 9-4

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : FEMALE : SACRIFICED ANIMALS

(2Week STUDY)

STUDY NO. : 0135
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (20)

PAGE : 3

		Group Name No. of Animals				Control 2				375 ppm 2				750 ppm 2				1500 ppm 2			
Organ	Findings	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)				
[Hematopoietic system]																					
spleen	deposit of melanin	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
[Digestive system]																					
liver	granulation	1 (50)	0 (0)	0 (0)	0 (0)	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	cyst	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
	Rathke pouch	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
[Reproductive system]																					
uterus	dilatation	1 (50)	0 (0)	0 (0)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
		<1>:Slight				<2>:Moderate				<3>:Marked				<4>:Severe							

(HPT150)

BAIS2

STUDY NO. : 0135
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 4

		Group Name	3000 ppm				6000 ppm			
		No. of Animals	2				2			
Organ_____	Findings_____		<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
<hr/>										
[Hematopoietic system]										
spleen	deposit of melanin		1 (50)	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)
[Digestive system]										
liver	granulation		1 (50)	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)
[Endocrine system]										
pituitary	cyst		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Rathke pouch		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Reproductive system]										
uterus	dilatation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

<1>:Slight <2>:Moderate <3>:Marked <4>:Severe

APPENDIX A 10-1

IDENTITY OF VINYL ACID

(2Week STUDY)

IDENTITY OF VINYL ACETATE(TWO-WEEK STUDIES)

Lot no.CTL5987

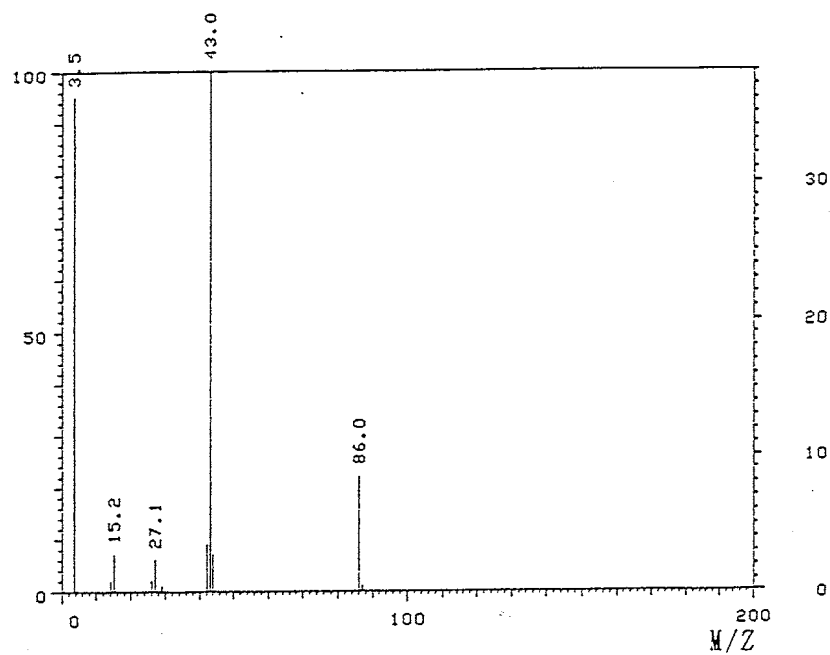
1. Spectral data

(1) Mass Spectrometry

Instrument: Hitachi M-80B Mass Spectrometer

Ionization: EI(Electron Ionization)

Ionization Voltage: 70eV



Mass Spectrum of Test Substance

Result:

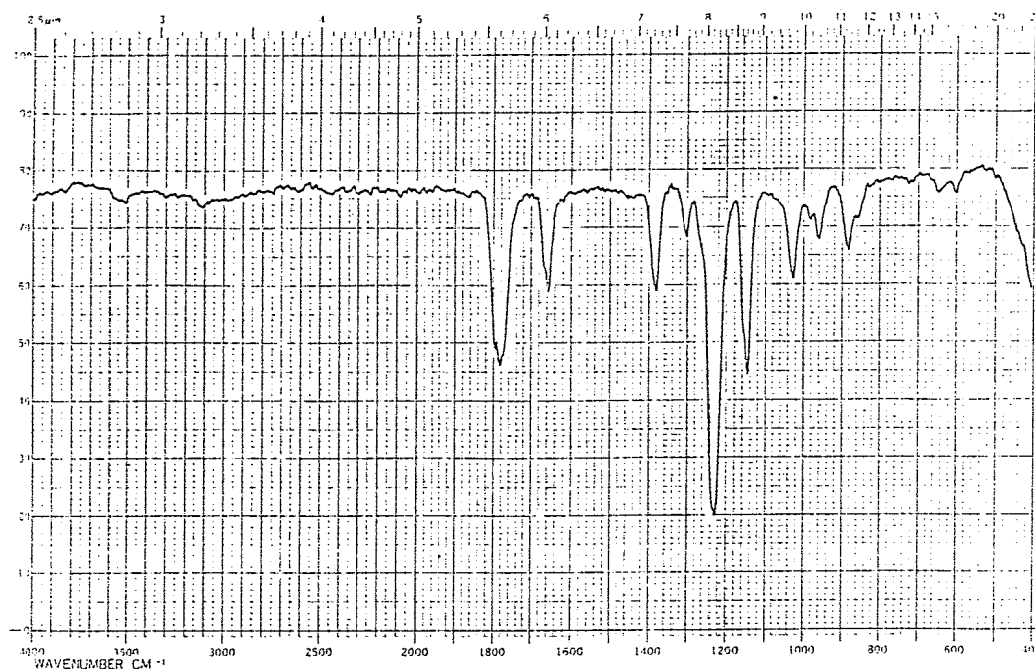
	Molecule Weight
Calculated Value	86.0
Determined Value	86.0

(2) Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr

Slit : Medium



Infrared Spectrum of Test Substance

Results

Determines
Wave Number(cm^{-1})

Literature Values*
Wave Number(cm^{-1})

840~ 920
940~1000
1000~1060
1120~1180
1200~1260
1280~1320
1360~1410
1630~1690
1740~1820

830~ 910
930~ 990
1000~1060
1110~1170
1180~1260
1280~1320
1340~1400
1630~1680
1730~1820

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

2. Gas Chromatography

Instrument: Hewlett Packard 5890A Gass Chromatograph
Column: Methyl Silicone(0.2mm ϕ \times 38m)
Column Temperature: 40°C
Flow Rate: 1 ml/min
Detector: FID(Flame Ionization Detector)
Injection Volume: 1 μ l

Results: Only major peak



Chromatogram of Test Substance

Peak No.	Retention Time(min)	AREA
1	3.315	222145

3. Conclusions: The result of the mass spectrum agreed with the calculated value and the infrared spectrum agreed with the literature values. Chromatogram indicated only the major peak. Consequently, the test substance was identified as Vinyl acetate.

APPENDIX A 10-2

STABILITY OF VINYL ACID

(2Week STUDY)

STABILITY OF VINYL ACETATE(TWO-WEEK STUDIES)

Lot no. CTL5987

1. Sample storage: This lot was used from 1989.10.02 to 1989.10.19. Test substance was stored at 5°C.

2. Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr

Slit : Medium

Results	<u>1989.10.02(date analyzed)</u>	<u>1989.10.19(date analyzed)</u>
	Wave Number(cm^{-1})	Wave Number(cm^{-1})
	840~ 920	830~ 910
	940~1000	930~ 990
	1000~1060	1000~1060
	1120~1180	1110~1170
	1200~1260	1180~1260
	1280~1320	1280~1320
	1360~1410	1340~1400
	1630~1690	1630~1680
	1740~1820	1730~1820

3. Gas Chromatography

Instrument: Hewlett Packard 5890A Gass Chromatograph

Column: Methyl Silicone(0.2mm ϕ \times 38m)

Column Temperature: 40°C

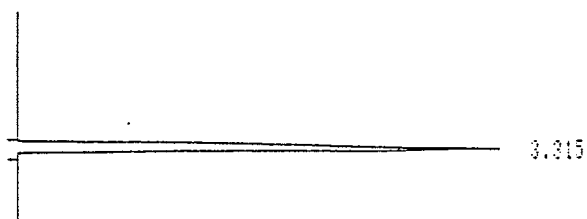
Flow Rate: 1 ml/min

Detector: FID(Flame Ionization Detector)

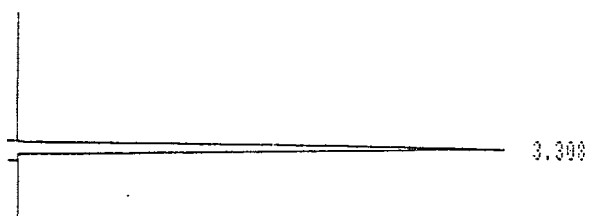
Injection Volume: 1 μ l

Results:Chromatogram indicated one major peak(peak No.1) analyzed at 1989.10.02 and one major peak(peak No.1) analyzed at 1989.10.19. The new trace impurity peak in the test substance analyzed at 1989.10.19 was not detected.

1989.10.02(date analyzed)



1989.10.19(date analyzed)



Chromatogram of Test Substance

Date	Peak No.	Retention Time(min)	AREA
1989.10.02 (date analyzed)	1	3.315	222145
1989.10.19 (date analyzed)	1	3.308	223951

4. Conclusions:The results indicated that the test substance did not change when stored in the dark at 5°C during this period(for about 3 weeks).

APPENDIX A 10-3

CONCENTRATION OF VINYL ACETAIE IN DRINKING WATER

(2Week STUDY)

CONCENTRATION OF VINYL ACETATE IN DRINKING WATER(TWO-WEEK STUDIES)

(Rat)

Date analyzed	Target Concentration(ppm)				
	1500	3000	6000	12000	24000
1989.10.02	1587.2(105.8)*	2708.6(90.3)	5417.6(90.3)	12576.3(104.8)	23972.1(99.9)

(Mouse)

Date analyzed	Target Concentration(ppm)				
	375	750	1500	3000	6000
1989.10.05	399.9(106.6)	759.0(101.2)	1350.4(90.0)	3261.4(108.7)	5939.5(99.0)

(*) % of target concentration

Analytical method: The sample were analyzed by the GC.

Instrument : Hewlett Packard 5890A
 Column : METHYL SILICONE(0.2mm ϕ \times 38m)
 Column Temperature: 40°C
 Carrier : He

Flow Rate : 1ml/min
 Detector : FID(Flame Ionization)
 Injection Volume : 10 μ l

APPENDIX A 10-4

STABILITY OF VINYL ACETATE IN DRINKING WATER

(2Week STUDY)

STABILITY OF VINYL ACETATE IN DRINKING WATER(TWO-WEEK STUDIES)

(Rat)

Date analyzed	Target Concentration(ppm)				
	1500	3000	6000	12000	24000
1989.10.02(a)	1587.2	2708.6	5417.6	12576.3	23972.1
1989.10.05(b)	1445.1	2572.1	4932.3	10620.0	18827.9

(Mouse)

Date analyzed	Target Concentration(ppm)				
	375	750	1500	3000	6000
1989.10.05(a)	399.9	759.0	1350.4	3261.4	5939.5
1989.10.09(b)	252.0	484.3	957.3	2022.6	3597.5

(a) Date of preparation

(b) The stability of vinyl acetate in drinking water was established for 3 or 4 days when stored at 25°C.

Analytical method: The sample were analyzed by the GC.

Instrument : Hewlett Packard 5890A
 Column : METHYL SILICONE(0.2mm ϕ \times 38m)
 Column Temperature: 40°C
 Carrier : He

Flow Rate : 1ml/min
 Detector : FID(Flame Ionization)
 Injection Volume : 10 μ l