

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

(B1-1～C2)

13週間試験：ラット/0146；マウス/0147

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MOUSE : MALE
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MOUSE : FEMALE

A P P E N D I X E S (CONTINUED)

APPENDIX B 5-1 CHEMICAL INTAKE CHANGES (THIRTEEN-WEEK STUDY : SUMMARY)
RAT : MALE

APPENDIX B 5-2 CHEMICAL INTAKE CHANGES (THIRTEEN-WEEK STUDY : SUMMARY)
RAT : FEMALE

APPENDIX B 5-3 CHEMICAL INTAKE CHANGES (THIRTEEN-WEEK STUDY : SUMMARY)
MOUSE : MALE

APPENDIX B 5-4 CHEMICAL INTAKE CHANGES (THIRTEEN-WEEK STUDY : SUMMARY)
MOUSE : FEMALE

APPENDIX B 6-1 HEMATOLOGY (THIRTEEN-WEEK STUDY : SUMMARY)
RAT : MALE

APPENDIX B 6-2 HEMATOLOGY (THIRTEEN-WEEK STUDY : SUMMARY)
RAT : FEMALE

APPENDIX B 6-3 HEMATOLOGY (THIRTEEN-WEEK STUDY : SUMMARY)
MOUSE : MALE

APPENDIX B 6-4 HEMATOLOGY (THIRTEEN-WEEK STUDY : SUMMARY)
MOUSE : FEMALE

APPENDIX B 7-1 BIOCHEMISTRY (THIRTEEN-WEEK STUDY : SUMMARY)
RAT : MALE

APPENDIX B 7-2 BIOCHEMISTRY (THIRTEEN-WEEK STUDY : SUMMARY)
RAT : FEMALE

APPENDIX B 7-3 BIOCHEMISTRY (THIRTEEN-WEEK STUDY : SUMMARY)
MOUSE : MALE

APPENDIX B 7-4 BIOCHEMISTRY (THIRTEEN-WEEK STUDY : SUMMARY)
MOUSE : FEMALE

APPENDIX B 8-1 URINALYSIS (THIRTEEN-WEEK STUDY : SUMMARY)
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APPENDIX B 8-2 URINALYSIS (THIRTEEN-WEEK STUDY : SUMMARY)
RAT : FEMALE

APPENDIX B 8-3 URINALYSIS (THIRTEEN-WEEK STUDY : SUMMARY)
MOUSE : MALE

APPENDIX B 8-4 URINALYSIS (THIRTEEN-WEEK STUDY : SUMMARY)
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A P P E N D I X E S (CONTINUED)

APPENDIX B 9-1 GROSS FINDINGS (THIRTEEN-WEEK STUDY : SUMMARY)
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APPENDIX B 9-2 GROSS FINDINGS (THIRTEEN-WEEK STUDY : SUMMARY)
RAT : FEMALE : SACRIFICED ANIMALS

APPENDIX B 9-3 GROSS FINDINGS (THIRTEEN-WEEK STUDY : SUMMARY)
MOUSE : FEMALE : DEAD AND MORIBUND ANIMALS

APPENDIX B 9-4 GROSS FINDINGS (THIRTEEN-WEEK STUDY : SUMMARY)
MOUSE : MALE : SACRIFICED ANIMALS

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MOUSE : FEMALE : SACRIFICED ANIMALS

APPENDIX B 10-1 ORGAN WEIGHT (THIRTEEN-WEEK STUDY : SUMMARY), ABSOLUTE
RAT : MALE

APPENDIX B 10-2 ORGAN WEIGHT (THIRTEEN-WEEK STUDY : SUMMARY), ABSOLUTE
RAT : FEMALE

APPENDIX B 10-3 ORGAN WEIGHT (THIRTEEN-WEEK STUDY : SUMMARY), ABSOLUTE
MOUSE : MALE

APPENDIX B 10-4 ORGAN WEIGHT (THIRTEEN-WEEK STUDY : SUMMARY), ABSOLUTE
MOUSE : FEMALE

APPENDIX B 11-1 ORGAN WEIGHT (THIRTEEN-WEEK STUDY : SUMMARY), RELATIVE
RAT : MALE

APPENDIX B 11-2 ORGAN WEIGHT (THIRTEEN-WEEK STUDY : SUMMARY), RELATIVE
RAT : FEMALE

APPENDIX B 11-3 ORGAN WEIGHT (THIRTEEN-WEEK STUDY : SUMMARY), RELATIVE
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APPENDIX B 11-4 ORGAN WEIGHT (THIRTEEN-WEEK STUDY : SUMMARY), RELATIVE
MOUSE : FEMALE

A P P E N D I X E S (CONTINUED)

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(THIRTEEN-WEEK STUDY : SUMMARY) RAT : MALE
SACRIFICED ANIMALS

APPENDIX B 12-2 HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS
(THIRTEEN-WEEK STUDY : SUMMARY) RAT : FEMALE
SACRIFICED ANIMALS

APPENDIX B 12-3 HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS
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DEAD AND MORIBUND ANIMALS

APPENDIX B 12-4 HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS
(THIRTEEN-WEEK STUDY : SUMMARY) MOUSE : MALE
SACRIFICED ANIMALS

APPENDIX B 12-5 HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS
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SACRIFICED ANIMALS

APPENDIX B 13-1 IDENTITY OF VINYL ACETATE
(THIRTEEN-WEEK STUDIES)

APPENDIX B 13-2 STABILITY OF VINYL ACETATE
(THIRTEEN-WEEK STUDIES)

APPENDIX B 13-3 CONCENTRATION OF VINYL ACETATE IN DRINKING WATER
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APPENDIX B 13-4 STABILITY OF VINYL ACETATE IN DRINKING WATER
(THIRTEEN-WEEK STUDIES)

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APPENDIX B 1-1

CLINICAL OBSERVATION : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day												
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
PILOERECTION	Control	1	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	1	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
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	24000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
LOSS OF HAIR	Control	2	1	1	0	0	1	1	1	1	2	1	2	2
	600 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1
	1500 ppm	0	0	0	0	0	0	0	0	1	1	0	0	0
	3800 ppm	1	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	1	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
GUM	Control	0	0	0	0	0	0	0	0	0	0	1	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0
	1500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	3800 ppm	0	0	1	0	0	0	0	0	0	1	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	24000 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0
EYE HEMORRHAGIC DISCHA	Control	0	0	0	0	0	0	0	0	0	0	1	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0
	1500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	3800 ppm	0	0	0	0	0	0	0	0	1	1	0	0	0
	10000 ppm	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
EYE OPACITY	Control	1	2	2	2	1	1	1	2	1	1	1	1	1
	600 ppm	2	1	2	2	2	2	2	2	2	2	2	2	1
	1500 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2
	3800 ppm	0	0	0	1	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	1	1	1	1	2	1	1	1	1
	24000 ppm	0	1	1	1	1	0	0	0	0	0	0	0	0

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 2

Clinical sign	Group Name	Administration Week-day												
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
CORNEAL OPACITY	Control	1	2	2	2	1	1	1	2	1	1	1	1	1
	600 ppm	1	1	2	2	2	2	2	2	2	2	2	2	1
	1500 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	1	1	1	1	2	1	1	1	1
	24000 ppm	0	1	1	1	1	0	0	0	0	0	0	0	0
ANTERIOS CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	1	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
	3800 ppm	0	0	0	1	0	0	0	0	0	0	0	0	0
	10000 ppm	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
SORE OF SOLE	Control	0	0	0	0	0	0	0	0	0	0	0	2	4
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	3
	1500 ppm	0	0	0	0	0	0	0	0	0	0	0	5	5
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	4
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1
	24000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	2
LOOSE STOOL	Control	0	0	1	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	1	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
	3800 ppm	1	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	24000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 2

APPENDIX B 1-2

CLINICAL OBSERVATION : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 3

Clinical sign	Group Name	Administration Week-day												
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	1	0	0	0	0	0	0	0	0	0	0	0	0
	1500 ppm	1	0	0	0	0	0	0	0	0	0	0	0	0
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	24000 ppm	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	1	1	0
	600 ppm	0	0	0	0	0	0	0	1	0	1	2	2	1
	1500 ppm	1	0	0	0	1	1	0	1	1	1	1	1	1
	3800 ppm	0	0	0	0	0	0	0	0	1	1	0	0	1
	10000 ppm	1	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
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	1	0
	600 ppm	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
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1
	10000 ppm	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
GUM	Control	0	0	0	0	0	0	0	0	0	0	0	1	0
	600 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0
	1500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	1	1	0
	24000 ppm	0	0	0	0	0	0	0	0	0	1	0	1	0
EYE HEMORRHAGIC DISCH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0
	1500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0
	24000 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 4

Clinical sign	Group Name	Administration Week-day												
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	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
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	1	1	1	0	0	0	0	0	0	0	0	0	0
	24000 ppm	0	0	1	1	1	1	0	0	0	0	0	0	0
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	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
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	1	1	1	0	0	0	0	0	0	0	0	0	0
	24000 ppm	0	0	1	1	1	1	0	0	0	0	0	0	0

(HAN190)

BAIS 2

APPENDIX B 1-3

CLINICAL OBSERVATION : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day												
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
EPILEPSY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	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
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	24000 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0
PILOERECTION	Control	0	1	1	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	1500 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0
	3800 ppm	1	1	0	1	0	1	1	0	0	0	0	0	0
	10000 ppm	0	1	1	2	0	1	2	1	1	2	1	1	0
	24000 ppm	1	1	1	1	1	1	0	0	0	0	0	0	0
LOSS OF HAIR	Control	0	1	1	1	2	4	3	5	5	6	6	6	7
	600 ppm	1	1	1	2	3	5	5	4	4	4	4	4	5
	1500 ppm	0	0	0	1	2	2	2	3	4	4	5	5	5
	3800 ppm	0	1	2	2	2	3	3	3	3	3	3	3	3
	10000 ppm	0	0	0	1	2	4	4	4	4	4	4	4	4
	24000 ppm	1	1	3	3	3	4	4	4	5	5	5	5	5
LACRYMATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	1	0	0	0	0	0	0	0	0	0	0	0	0
	1500 ppm	1	0	0	0	0	0	0	0	0	0	0	0	0
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	24000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	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
	3800 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0
	10000 ppm	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

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 2

Clinical sign	Group Name	Administration Week-day												
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	1	1	1	1	1	1	1	1
	1500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	2
	10000 ppm	0	0	0	0	0	1	1	1	1	1	1	1	1
	24000 ppm	0	0	0	0	0	0	0	1	1	1	0	0	0

(HAN190)

BAIS2

APPENDIX B 1-4

CLINICAL OBSERVATION : SUMMARY, MOSUE: FEMALE

(13Week STUDY)

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration		week		1		2		3		4		5		6	
	0															
Control	133±	5			165±	9			193±	13			215±	14		
600 ppm	133±	6			163±	6			188±	9			209±	11		
1500 ppm	133±	6			163±	9			190±	10			213±	12		
3800 ppm	133±	5			161±	6			187±	11			206±	13		
10000 ppm	133±	6			158±	6			183±	7			207±	10		
24000 ppm	133±	6			152±	10**			176±	14**			196±	15**		

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week		8		9		10		11		12		13	
	7													
Control	281± 17		295± 18		305± 18		315± 19		323± 19		333± 20		339± 19	
600 ppm	270± 15		283± 14		293± 14		301± 15		310± 16		318± 17		325± 17	
1500 ppm	275± 16		288± 16		299± 16		307± 14		317± 15		325± 15		331± 16	
3800 ppm	273± 14		283± 14		294± 12		302± 12		312± 13		321± 13		326± 13	
10000 ppm	264± 15*		271± 15**		282± 14**		286± 13**		294± 13**		300± 13**		304± 14**	
24000 ppm	255± 14**		267± 13**		276± 12**		282± 12**		291± 13**		299± 14**		303± 13**	

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

Test of Dunnett

(HAN260)

BAIS 2

APPENDIX B 2-1

BODY WEIGHT CHANGES :SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 3

Clinical sign	Group Name	Administration Week-day												
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
DEATH	Control	0	0	0	0	0	0	0	0	1	1	1	1	1
	600 ppm	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
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	24000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0
	1500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	24000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0
	1500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	24000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
LOSS OF HAIR	Control	1	1	1	1	2	7	5	6	5	7	7	7	7
	600 ppm	0	0	1	2	4	4	5	6	6	7	7	6	5
	1500 ppm	0	0	3	3	4	6	6	5	7	7	8	8	8
	3800 ppm	1	2	1	2	3	2	2	3	3	4	3	3	3
	10000 ppm	0	0	0	2	3	5	5	6	7	7	7	7	7
	24000 ppm	0	0	0	0	2	4	6	7	7	7	7	7	7
EROSION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	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
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	24000 ppm	0	0	0	0	0	0	0	0	0	1	1	1	0

(HAN190)

BAIS2

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 4

Clinical sign	Group Name	Administration Week-day												
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0
	1500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	3800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	24000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 2

APPENDIX B 2-2

BODY WEIGHT CHANGES : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week		1		2		3		4		5		6	
	0													
Control	108±	3	123±	4	133±	5	143±	6	151±	8	158±	8	163±	10
600 ppm	108±	3	122±	4	131±	4	142±	5	148±	7	157±	7	161±	8
1500 ppm	108±	4	121±	4	131±	6	143±	5	150±	6	158±	5	163±	6
3800 ppm	108±	3	120±	4	131±	4	142±	5	149±	6	156±	7	160±	9
10000 ppm	108±	4	120±	2	131±	4	141±	4	149±	5	158±	9	163±	9
24000 ppm	108±	4	116±	3**	128±	4	137±	3	145±	6	153±	6	157±	6

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

Test of Dunnett

(IIAN260)

BAIS2

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week		8		9		10		11		12		13	
	7													
Control	168±	9	171±	10	178±	10	180±	11	185±	11	188±	12	188±	12
600 ppm	165±	8	170±	9	176±	9	178±	10	182±	9	184±	9	187±	11
1500 ppm	169±	7	173±	7	178±	7	181±	8	186±	7	189±	7	189±	7
3800 ppm	165±	8	169±	10	173±	8	177±	10	180±	8	183±	10	184±	9
10000 ppm	167±	10	169±	8	172±	10	175±	9	178±	10	181±	10	183±	10
24000 ppm	161±	6	165±	6	168±	7	172±	6	177±	7	179±	7	181±	8

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX B 2-3

BODY WEIGHT CHANGES :SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration week						
	0	1	2	3	4	5	6
Control	23.0± 0.9	24.1± 1.0	24.9± 1.1	25.7± 1.1	26.3± 1.4	27.1± 1.3	27.9± 1.5
600 ppm	23.0± 0.9	24.0± 0.8	24.8± 0.8	25.5± 0.9	26.2± 0.9	27.1± 1.1	27.8± 1.3
1500 ppm	23.0± 0.9	23.9± 1.0	24.8± 1.3	25.4± 1.0	26.1± 1.2	26.9± 1.3	27.8± 1.4
3800 ppm	23.1± 0.8	24.5± 0.7	25.3± 1.0	26.0± 0.9	26.9± 1.0	27.8± 1.2	28.7± 1.2
10000 ppm	23.0± 0.9	24.0± 0.9	25.2± 1.2	25.8± 1.4	26.7± 1.6	27.7± 1.9	28.4± 2.0
24000 ppm	23.0± 0.9	24.1± 1.1	25.1± 1.2	26.0± 1.2	26.8± 1.4	27.5± 1.5	28.2± 1.4

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week						
	7	8	9	10	11	12	13
Control	29.2± 1.7	30.0± 2.1	30.4± 2.0	31.5± 2.2	32.2± 2.3	33.2± 2.5	33.5± 2.4
600 ppm	28.8± 1.7	29.9± 1.8	30.4± 1.9	31.2± 1.8	31.8± 2.0	32.5± 2.2	33.2± 2.2
1500 ppm	29.1± 1.7	30.3± 1.6	30.7± 1.6	31.6± 1.6	32.2± 1.7	33.0± 1.7	33.9± 1.7
3800 ppm	30.0± 1.5	30.9± 1.5	31.6± 1.7	32.5± 1.8	33.1± 1.9	34.1± 2.0	34.8± 1.9
10000 ppm	29.4± 2.3	30.0± 2.4	30.5± 2.5	31.4± 2.7	32.2± 2.9	33.0± 3.1	33.6± 2.9
24000 ppm	29.3± 1.6	30.2± 1.6	30.7± 1.8	31.4± 1.6	32.3± 1.8	33.3± 1.9	33.9± 2.0

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

(HAN260)

BAIS 2

APPENDIX B 2-4

BODY WEIGHT CHANGES : SUMMARY, MOSUE: FEMALE

(13Week STUDY)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week						
	0	1	2	3	4	5	6
Control	18.5± 0.6	19.2± 0.7	19.8± 0.7	20.4± 0.6	20.7± 0.5	21.1± 0.5	21.6± 0.8
600 ppm	18.5± 0.7	19.3± 0.5	19.9± 0.9	20.4± 0.7	21.1± 0.9	21.2± 0.9	20.8± 1.5
1500 ppm	18.5± 0.7	19.6± 0.7	20.2± 1.0	20.9± 1.0	21.4± 1.0	21.8± 1.3	22.2± 1.7
3800 ppm	18.5± 0.7	19.3± 0.6	19.9± 0.7	20.6± 0.5	20.8± 0.8	21.2± 0.7	21.3± 0.5
10000 ppm	18.5± 0.7	19.5± 1.0	20.2± 1.0	20.8± 1.2	21.3± 1.3	21.7± 1.4	21.7± 1.5
24000 ppm	18.5± 0.7	19.4± 0.8	19.8± 0.6	20.5± 0.7	20.9± 0.7	21.3± 0.7	21.6± 0.7

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week						
	7	8	9	10	11	12	13
Control	22.2± 0.9	22.3± 0.9	22.9± 1.1	22.5± 1.7	22.6± 0.9	22.7± 1.3	23.5± 1.0
600 ppm	22.0± 0.9	22.8± 1.0	22.8± 0.7	22.6± 0.9	22.7± 0.9	22.8± 0.9	23.0± 1.1
1500 ppm	22.5± 0.7	22.9± 1.3	22.9± 1.3	22.7± 1.6	23.1± 1.6	24.1± 2.0	24.0± 1.9
3800 ppm	22.3± 0.7	22.8± 1.1	22.8± 1.0	22.3± 0.6	23.1± 1.3	23.5± 1.4	23.5± 1.2
10000 ppm	22.4± 1.6	22.9± 1.8	23.3± 2.4	23.0± 1.7	23.1± 1.9	23.3± 2.0	24.0± 1.9
24000 ppm	22.6± 1.1	23.0± 1.0	23.0± 0.7	22.9± 0.9	23.5± 0.8	23.4± 1.1	24.0± 0.8

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX B 3-1

WATER CONSUMPTION CHANGES : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 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)	3-3(3)	3-7(4)	4-3(3)
Control	15.8± 0.8	18.4± 0.8	19.4± 1.4	19.9± 1.6	20.3± 2.0	20.9± 2.2	20.7± 2.2
600 ppm	14.9± 1.3	18.5± 1.1	18.3± 1.9	19.5± 1.7	19.6± 1.3	19.9± 1.7	18.0± 6.1
1500 ppm	15.0± 0.8	18.3± 1.1	17.9± 1.6	19.5± 2.0	19.3± 1.5	20.3± 1.8	20.0± 1.7
3800 ppm	13.6± 1.4*	17.7± 1.9	17.4± 2.1	18.7± 1.6	19.3± 2.0	19.7± 1.7	19.2± 1.7
10000 ppm	11.6± 1.7**	14.6± 0.9**	14.7± 1.3**	15.2± 1.1**	16.3± 1.1**	16.0± 1.2**	15.3± 1.0**
24000 ppm	11.6± 2.6**	13.1± 1.1**	14.7± 2.1**	13.3± 1.5**	14.4± 1.6**	14.0± 1.3**	14.1± 1.9**

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day(effective)						
	4-7(4)	5-3(3)	5-7(4)	6-3(3)	6-7(4)	7-3(3)	7-7(4)
Control	21.5± 1.8	20.7± 1.5	21.3± 1.8	20.5± 1.5	21.0± 1.3	20.9± 1.5	20.1± 1.8
600 ppm	21.5± 2.7	20.8± 1.9	21.1± 2.1	20.4± 1.7	20.6± 1.7	20.7± 1.3	19.6± 1.5
1500 ppm	22.0± 4.5	20.8± 4.3	21.9± 5.1	19.6± 1.5	20.8± 2.0	20.0± 1.7	20.0± 1.3
3800 ppm	20.0± 2.5	19.4± 2.0	19.5± 1.9	18.9± 2.0	19.6± 1.6	19.0± 1.2*	20.1± 2.0
10000 ppm	16.3± 0.9**	15.9± 1.2**	16.1± 0.8**	15.3± 0.7**	16.2± 0.8**	15.3± 1.0**	15.8± 1.4**
24000 ppm	14.5± 1.7**	14.9± 3.4**	14.9± 2.3**	13.8± 1.3**	14.0± 1.0**	13.9± 1.1**	14.1± 1.0**

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week-day(effective)						
	8-3(3)	8-7(4)	9-3(3)	9-7(4)	10-3(3)	10-7(4)	11-3(3)
Control	19.9± 1.9	20.2± 1.8	21.0± 1.3	21.0± 0.9	20.1± 1.0	19.9± 1.2	19.7± 1.3
600 ppm	20.0± 1.7	19.7± 1.6	20.9± 1.8	20.7± 2.3	20.1± 2.1	19.6± 1.8	19.6± 1.3
1500 ppm	19.6± 1.1	18.4± 1.1*	19.3± 1.2*	19.7± 1.3	18.7± 1.3	19.1± 2.0	18.3± 1.4
3800 ppm	18.7± 1.3	16.4± 1.1**	16.8± 0.9**	17.2± 1.0*	17.2± 0.9*	16.8± 0.9*	16.9± 1.1**
10000 ppm	15.4± 0.9**	12.9± 1.0**	14.1± 1.0**	14.7± 0.9**	13.9± 0.7**	13.7± 0.7**	13.9± 0.7**
24000 ppm	13.7± 0.8**	14.1± 1.1**	14.2± 1.0**	14.7± 0.8**	13.8± 0.6**	14.0± 1.2**	13.6± 1.2**

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week-day(effective)				
	11-7(4)	12-3(3)	12-7(4)	13-3(3)	13-7(4)
Control	20.7± 1.5	19.9± 1.3	20.8± 1.2	19.6± 1.2	20.3± 1.0
600 ppm	20.1± 1.4	19.2± 1.3	20.1± 1.4	19.2± 1.4	20.0± 1.2
1500 ppm	19.2± 1.1*	18.3± 1.0*	19.3± 1.2*	19.0± 1.2	19.3± 1.2
3800 ppm	17.6± 0.9**	16.4± 1.2**	17.6± 1.4**	16.9± 1.2**	17.8± 1.0**
10000 ppm	14.1± 0.8**	13.9± 0.6**	14.7± 0.6**	13.7± 0.8**	14.5± 0.5**
24000 ppm	14.4± 1.0**	13.8± 1.1**	14.8± 1.0**	13.4± 0.9**	15.0± 1.4**

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

Test of Dunnett

APPENDIX B 3-2

WATER CONSUMPTION CHANGES : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

Group Name	Administration week-day(effective)						
	1-3(3)	1-7(4)	2-3(3)	2-7(4)	3-3(3)	3-7(4)	4-3(3)
Control	13.6± 1.7	17.3± 2.3	16.6± 1.6	17.5± 3.1	16.4± 0.8	19.4± 6.5	23.9± 16.2
600 ppm	13.4± 0.9	16.2± 0.7	16.4± 1.1	16.6± 1.3	19.0± 6.9	20.7± 7.8	23.7± 16.1
1500 ppm	17.6± 12.0	16.3± 1.7	22.2± 16.4	20.9± 9.3	17.4± 1.0	17.5± 1.5	17.5± 2.5
3800 ppm	11.7± 0.7	14.8± 0.8	14.8± 0.6	15.6± 1.1	16.1± 1.2	16.7± 2.1	15.9± 1.8
10000 ppm	10.1± 0.8**	12.8± 0.6**	12.5± 0.8**	12.8± 0.7**	13.4± 1.1*	13.6± 1.0**	14.0± 3.5**
24000 ppm	11.2± 5.9**	10.6± 0.8**	11.9± 0.8**	11.6± 1.2**	12.3± 1.6**	11.5± 1.8**	11.4± 1.9**

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 6

Group Name	Administration 4-7(4)	week-day(effective) 5-3(3)	5-7(4)	6-3(3)	6-7(4)	7-3(3)	7-7(4)
Control	22.1± 9.8	17.9± 3.8	19.3± 4.7	17.4± 2.3	19.2± 4.5	23.7± 14.9	20.9± 7.9
600 ppm	23.6± 13.8	23.6± 14.8	19.1± 4.7	20.5± 8.4	22.5± 10.4	25.0± 15.5	25.8± 11.8
1500 ppm	18.2± 2.3	18.3± 2.5	19.4± 4.0	17.3± 2.2	20.5± 5.8	19.9± 6.2	21.4± 7.2
3800 ppm	16.1± 2.0	17.6± 4.1	18.6± 5.6	17.5± 3.0	21.0± 9.3	18.3± 5.2	17.4± 4.0
10000 ppm	13.6± 1.4**	12.8± 1.8*	14.0± 1.9	13.5± 2.6*	13.7± 2.0*	13.3± 2.1**	13.5± 2.0*
24000 ppm	12.1± 2.5**	12.1± 3.0**	13.2± 5.0*	11.3± 1.6**	12.6± 3.2**	11.4± 2.2**	13.3± 8.4**

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

Test of Dunnett

(IIAN260)

BAIS2

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 7

Group Name	Administration 8-3(3)	week-day(effective) 8-7(4)	9-3(3)	9-7(4)	10-3(3)	10-7(4)	11-3(3)
Control	20.5± 8.3	21.5± 5.9	29.6± 15.9	21.2± 6.4	23.6± 12.5	20.6± 5.1	21.3± 6.8
600 ppm	26.8± 15.8	23.2± 9.9	27.8± 17.0	20.2± 6.8	22.2± 10.7	21.8± 9.5	20.4± 5.9
1500 ppm	20.0± 6.1	16.6± 3.7	17.5± 3.5	18.0± 6.3	17.6± 6.3	16.2± 2.3	16.3± 2.6
3800 ppm	18.5± 5.1	15.0± 3.4	13.9± 2.1**	13.5± 1.3**	13.3± 1.6*	13.7± 1.8*	13.0± 1.6**
10000 ppm	13.0± 2.0*	12.7± 4.9**	11.8± 1.9**	12.0± 2.2**	11.4± 1.4**	11.7± 1.6**	11.7± 1.6**
24000 ppm	12.2± 4.8**	11.8± 3.2**	11.4± 2.2**	11.9± 3.2**	11.5± 2.4**	11.3± 1.3**	10.9± 1.5**

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

Group Name	Administration week-day(effective)				
	11-7(4)	12-3(3)	12-7(4)	13-3(3)	13-7(4)
Control	20.7± 3.9	19.6± 5.9	21.8± 4.2	21.1± 6.1	21.9± 5.8
600 ppm	21.0± 7.2	17.3± 3.8	21.2± 8.8	24.6± 13.3	20.4± 4.5
1500 ppm	16.7± 3.2	16.2± 2.2	17.2± 3.5	18.1± 3.3	18.5± 3.4
3800 ppm	13.5± 1.1**	13.0± 1.0**	14.5± 1.9*	14.1± 1.3*	14.6± 0.9*
10000 ppm	12.0± 1.6**	12.0± 2.0**	12.2± 1.8**	12.6± 2.9**	12.4± 1.7**
24000 ppm	11.6± 1.4**	11.3± 1.9**	12.9± 4.1**	11.6± 3.1**	12.5± 2.5**

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

(HAN260)

BAIS 2

APPENDIX B 3-3

WATER CONSUMPTION CHANGES : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 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)	3-3(3)	3-7(4)	4-3(3)
Control	3.8± 0.5	4.2± 0.9	4.1± 1.1	4.1± 0.9	4.0± 1.2	4.1± 1.0	3.9± 1.2
600 ppm	3.1± 1.1	4.4± 1.0	3.8± 1.0	4.1± 0.5	3.9± 0.4	4.0± 0.4	3.7± 0.4
1500 ppm	4.1± 0.6	4.1± 0.6	3.8± 1.1	4.1± 0.6	3.8± 0.6	3.9± 0.4	3.7± 0.3
3800 ppm	4.6± 1.0	4.8± 0.9	4.3± 1.1	4.4± 0.9	4.1± 0.8	4.3± 0.6	4.1± 0.7
10000 ppm	4.1± 0.5	4.5± 0.7	4.5± 0.7	4.4± 0.5	4.0± 0.5	4.3± 0.9	4.1± 0.9
24000 ppm	3.5± 0.5	4.0± 0.7	4.1± 0.8	4.0± 0.7	3.7± 0.7	3.9± 0.6	3.6± 0.7

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

Test of Dunnett

(HAN260)

BATS2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day(effective)						
	4-7(4)	5-3(3)	5-7(4)	6-3(3)	6-7(4)	7-3(3)	7-7(4)
Control	3.7± 0.3	4.0± 1.2	3.8± 1.2	3.8± 1.0	3.7± 1.0	3.8± 1.3	3.8± 1.4
600 ppm	3.5± 0.5	3.8± 0.5	3.6± 0.2	3.5± 0.2	3.6± 0.3	3.6± 0.3	3.6± 0.3
1500 ppm	3.4± 0.8	3.9± 0.9	3.7± 0.6	3.8± 0.6	3.7± 0.6	3.7± 0.7	3.8± 0.7
3800 ppm	4.0± 0.9	4.5± 1.1	4.3± 1.0	4.3± 1.1	4.3± 1.0	4.0± 0.7	4.0± 0.6
10000 ppm	3.8± 1.0	4.2± 0.9	4.1± 0.8	4.1± 0.7	4.1± 0.7	4.1± 1.0	3.8± 0.6
24000 ppm	3.6± 0.7	3.8± 0.8	3.7± 0.8	3.7± 0.6	3.6± 0.6	3.4± 0.6	3.6± 0.6

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(JIAN260)

BAIS2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week-day(effective)						
	8-3(3)	8-7(4)	9-3(3)	9-7(4)	10-3(3)	10-7(4)	11-3(3)
Control	3.8± 0.8	3.4± 0.2	3.7± 1.1	3.7± 1.3	3.8± 1.0	3.6± 0.8	3.6± 0.8
600 ppm	3.8± 0.2	3.7± 0.3	3.7± 0.3	3.6± 0.3	4.0± 0.2	3.6± 0.3	3.6± 0.3
1500 ppm	3.8± 0.6	3.8± 0.6	3.8± 0.8	3.7± 0.5	4.0± 0.5	3.8± 0.7	3.6± 0.7
3800 ppm	3.9± 0.6	4.0± 0.5	4.0± 0.8	4.0± 0.6**	4.3± 0.7**	4.0± 0.5	3.8± 0.6
10000 ppm	4.0± 1.0	4.0± 1.0	3.8± 0.9	3.8± 0.7	3.9± 0.6	3.7± 0.5	3.8± 0.6
24000 ppm	3.6± 0.6	3.5± 0.4	3.4± 0.6	3.5± 0.5	3.7± 0.5	3.5± 0.4	3.4± 0.6

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

(HAN260)

BAIS2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week-day(effective)				
	11-7(4)	12-3(3)	12-7(4)	13-3(3)	13-7(4)
Control	3.7± 0.9	3.7± 1.1	3.8± 1.2	3.5± 0.6	3.5± 0.5
600 ppm	3.8± 0.5	3.9± 0.7	3.8± 0.5	3.7± 0.3	3.6± 0.3
1500 ppm	3.7± 0.7	3.8± 0.6	3.7± 0.6	3.7± 0.7	3.7± 0.6
3800 ppm	3.9± 0.4	4.1± 0.5	4.0± 0.4*	3.8± 0.6	3.8± 0.3
10000 ppm	3.7± 0.6	3.7± 0.4	3.7± 0.5	3.5± 0.8	3.5± 0.3
24000 ppm	3.4± 0.4	3.4± 0.5	3.5± 0.4	3.3± 0.5	3.4± 0.4

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

(HAN260)

BAIS2

APPENDIX B 3-4

WATER CONSUMPTION CHANGES : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

Group Name	Administration week-day(effective)					
	1-3(3)	1-7(4)	2-3(3)	2-7(4)	3-3(3)	3-7(4)
Control	3.7± 0.3	4.1± 0.4	4.2± 0.6	4.4± 1.1	4.0± 0.6	4.5± 0.7
600 ppm	3.1± 1.2	4.4± 0.7	3.1± 1.4	4.4± 0.5	4.0± 0.3	4.6± 0.8
1500 ppm	4.0± 0.4	4.2± 0.3	3.7± 0.6	4.2± 0.5	4.0± 0.4	4.2± 0.4
3800 ppm	3.7± 0.4	4.4± 0.3	4.0± 0.6	4.3± 0.3	4.2± 0.4	4.6± 0.8
10000 ppm	3.9± 0.4	4.2± 0.3	3.8± 1.2	4.4± 0.6	3.9± 0.3	4.2± 0.4
24000 ppm	3.4± 0.2	4.0± 0.4	3.7± 0.4	4.0± 0.5	3.9± 0.5	4.4± 0.6

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 6

Group Name	Administration week-day(effective)						
	4-7(4)	5-3(3)	5-7(4)	6-3(3)	6-7(4)	7-3(3)	7-7(4)
Control	4.2± 0.6	4.2± 0.6	4.7± 1.5	5.0± 1.9	4.4± 0.6	4.7± 1.2	4.7± 1.3
600 ppm	3.9± 1.0	4.5± 0.6	4.9± 1.0	5.0± 1.3	4.8± 2.1	5.1± 1.5	4.6± 0.5
1500 ppm	4.1± 0.3	4.0± 0.3	4.1± 0.4	4.3± 0.4	4.3± 0.4	4.4± 0.5	4.3± 0.5
3800 ppm	4.1± 0.5	4.4± 0.7	4.3± 0.3	4.4± 0.5	4.4± 0.6	4.5± 0.5	4.6± 0.6
10000 ppm	4.1± 0.7	4.0± 0.5	4.1± 0.5	4.3± 0.7	4.3± 0.6	4.2± 0.6	4.2± 0.6
24000 ppm	4.1± 0.8	3.9± 0.6	4.1± 0.7	4.2± 0.8	4.2± 1.1	3.9± 0.4	3.9± 0.3*

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

Test of Dunnett

(HAN260)

BATS2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 7

Group Name	Administration week-day(effective)						
	8-3(3)	8-7(4)	9-3(3)	9-7(4)	10-3(3)	10-7(4)	11-3(3)
Control	5.7± 2.5	4.4± 0.7	4.2± 1.3	4.4± 0.5	5.0± 0.9	4.7± 0.9	5.3± 1.8
600 ppm	4.9± 0.8	4.7± 0.7	5.3± 1.1	5.1± 0.9	5.6± 1.5	4.8± 0.6	5.3± 1.4
1500 ppm	4.6± 0.4	4.4± 0.3	4.4± 0.4	4.4± 0.3	4.6± 0.5	4.4± 0.4	4.5± 0.4
3800 ppm	4.5± 0.5	4.5± 0.5	4.5± 0.5	4.6± 0.6	5.0± 0.8	4.9± 1.0	4.5± 0.4
10000 ppm	4.3± 0.5	4.2± 0.4	4.1± 0.4	4.3± 0.3	4.4± 0.5	4.2± 0.4	4.1± 0.4
24000 ppm	4.0± 0.4**	3.9± 0.3	4.2± 0.7	4.1± 0.4	4.2± 0.4	4.1± 0.4	4.2± 0.7

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

Test of Dunnett

(HAN260)

BATS2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

Group Name	Administration week-day(effective)				
	11-7(4)	12-3(3)	12-7(4)	13-3(3)	13-7(4)
Control	4.8± 0.8	5.2± 1.8	5.1± 1.4	5.0± 1.5	4.8± 0.8
600 ppm	5.2± 1.4	4.7± 1.1	4.4± 0.3	4.7± 0.7	5.4± 1.4
1500 ppm	4.4± 0.3	4.5± 0.5	4.5± 0.5	4.3± 0.4	4.4± 0.3
3800 ppm	4.5± 0.3	4.4± 0.3	4.4± 0.4	4.4± 0.5	4.5± 0.4
10000 ppm	4.1± 0.4*	4.0± 0.4	4.2± 0.5	4.1± 0.6	4.1± 0.4
24000 ppm	4.2± 0.4	4.1± 0.5	4.1± 0.6	3.9± 0.4*	4.1± 0.4

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS2

APPENDIX B 4-1

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration week						
	1	2	3	4	5	6	7
Control	15.0± 1.1	16.4± 1.7	16.5± 1.3	16.7± 1.4	17.8± 2.0	17.0± 1.3	16.9± 1.0
600 ppm	14.8± 1.0	15.4± 0.9	15.9± 0.9	15.7± 1.0	16.1± 1.3	15.8± 1.1	16.2± 0.8
1500 ppm	14.6± 1.2	15.8± 1.4	16.6± 1.5	16.6± 1.7	16.5± 1.3	16.3± 1.4	16.2± 1.2
3800 ppm	14.3± 1.1	15.5± 0.9	15.8± 1.0	15.9± 1.6	15.9± 1.4*	16.0± 1.1	16.5± 0.6
10000 ppm	13.5± 0.8*	15.0± 1.0*	15.8± 1.0	16.0± 1.2	16.0± 1.1*	15.6± 1.2	15.6± 1.2*
24000 ppm	13.0± 1.1**	14.6± 1.4**	15.2± 1.5	15.4± 1.5	15.7± 1.5**	15.4± 1.4	15.2± 1.0**

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week					
	8	9	10	11	12	13
Control	16.8± 1.5	17.1± 1.1	16.6± 1.2	16.7± 1.2	17.0± 1.2	16.8± 0.8
600 ppm	15.9± 0.7	16.2± 0.6	15.7± 1.0	16.2± 0.9	16.1± 1.1	16.2± 0.9
1500 ppm	16.3± 1.3	16.6± 1.2	15.9± 1.0	16.2± 1.1	16.2± 1.0	16.2± 0.9
3800 ppm	15.8± 0.5	15.9± 0.8	15.8± 0.7	16.1± 0.8	15.9± 0.9	16.0± 0.8
10000 ppm	14.8± 1.0**	15.3± 1.5**	14.5± 1.2**	14.9± 1.1**	15.2± 1.3**	14.8± 1.2**
24000 ppm	15.2± 0.8*	15.4± 0.7**	15.0± 0.8**	15.5± 1.0*	15.4± 0.9**	15.4± 0.7**

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

Test of Dunnett

APPENDIX B 4-2

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week						
	1	2	3	4	5	6	7
Control	11.5± 0.7	11.8± 0.7	12.6± 0.6	11.7± 0.9	12.1± 0.6	11.6± 1.0	11.6± 0.9
600 ppm	11.6± 0.4	11.5± 0.7	12.3± 0.8	11.5± 1.1	12.0± 0.6	11.5± 0.7	11.5± 0.9
1500 ppm	11.6± 0.7	12.0± 1.0	12.8± 0.7	12.4± 0.8	12.3± 0.8	12.0± 1.0	11.9± 0.8
3800 ppm	11.3± 0.4	12.0± 0.8	12.6± 0.8	11.9± 0.9	11.8± 1.0	11.5± 1.0	11.4± 0.8
10000 ppm	10.7± 0.5**	11.6± 0.7	12.3± 0.9	11.7± 0.8	11.7± 1.1	11.6± 0.9	11.2± 1.0
24000 ppm	10.2± 0.4**	11.7± 0.5	11.6± 0.4**	11.1± 0.8	11.2± 0.8	10.9± 0.6	10.7± 0.6

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0146
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 4

Group Name	Administration week					
	8	9	10	11	12	13
Control	11.4± 0.9	11.5± 0.9	11.3± 1.0	11.2± 0.9	11.3± 0.9	11.0± 0.9
600 ppm	11.5± 0.9	11.7± 0.8	11.1± 0.6	11.2± 0.7	11.2± 0.5	11.4± 0.8
1500 ppm	11.7± 0.8	11.7± 1.0	11.4± 0.9	11.4± 0.7	11.7± 0.8	11.4± 0.7
3800 ppm	11.0± 0.9	10.9± 0.8	10.7± 0.7	10.7± 0.7	10.8± 0.6	10.7± 0.4
10000 ppm	10.8± 0.8	10.6± 0.8	10.1± 0.7**	10.6± 0.7	10.6± 0.8	10.5± 0.7
24000 ppm	10.6± 0.6	10.7± 0.6	10.5± 0.6	10.6± 0.6	10.6± 0.8	10.5± 0.7

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX B 4-3

FOOD CONSUMPTION CHANGES : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration week						
	1	2	3	4	5	6	7
Control	4.0± 0.2	4.1± 0.3	3.9± 0.3	3.9± 0.3	3.9± 0.3	3.9± 0.2	4.0± 0.3
600 ppm	4.0± 0.2	4.0± 0.3	3.8± 0.2	3.8± 0.2	3.9± 0.3	3.9± 0.2	3.9± 0.3
1500 ppm	4.0± 0.2	4.1± 0.2	3.9± 0.2	3.8± 0.3	4.0± 0.3	4.0± 0.2	4.1± 0.3
3800 ppm	4.2± 0.3	4.1± 0.4	4.1± 0.3	4.0± 0.4	4.3± 0.4**	4.3± 0.3**	4.3± 0.3
10000 ppm	4.1± 0.2	4.2± 0.3	4.0± 0.3	4.1± 0.3	4.3± 0.3*	4.2± 0.3	4.6± 0.5**
24000 ppm	3.9± 0.2	4.0± 0.2	4.1± 0.3	4.1± 0.3	4.0± 0.3	4.1± 0.2	4.6± 0.3**

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

Test of Dunnett

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week					
	8	9	10	11	12	13
Control	3.9± 0.2	3.7± 0.3	4.0± 0.2	3.9± 0.3	4.2± 0.4	3.9± 0.2
600 ppm	3.9± 0.2	3.8± 0.3	3.9± 0.2	3.8± 0.2	3.9± 0.2	3.9± 0.2
1500 ppm	4.1± 0.3	3.9± 0.3	4.0± 0.3	3.9± 0.3	4.1± 0.3	4.0± 0.4
3800 ppm	4.2± 0.3	4.1± 0.4	4.2± 0.2	4.1± 0.3	4.4± 0.3	4.1± 0.2
10000 ppm	4.2± 0.6	4.0± 0.3	4.2± 0.4	4.0± 0.4	4.2± 0.4	4.0± 0.3
24000 ppm	4.0± 0.3	3.9± 0.3	4.1± 0.3	4.1± 0.3	4.2± 0.3	4.0± 0.3

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

Test of Dunnett

APPENDIX B 4-4

FOOD CONSUMPTION CHANGES : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week						
	1	2	3	4	5	6	7
Control	3.4± 0.2	3.6± 0.2	3.6± 0.2	3.7± 0.2	3.8± 0.2	3.9± 0.2	4.2± 0.4
600 ppm	3.5± 0.1	3.5± 0.3	3.6± 0.3	3.6± 0.2	3.8± 0.3	3.8± 0.5	4.1± 0.4
1500 ppm	3.6± 0.3	3.6± 0.1	3.7± 0.2	3.9± 0.2	3.8± 0.2	3.9± 0.3	4.0± 0.3
3800 ppm	3.5± 0.3	3.7± 0.2	3.7± 0.2	3.8± 0.2	3.8± 0.3	4.0± 0.2	4.2± 0.3
10000 ppm	3.5± 0.3	3.6± 0.2	3.6± 0.3	3.8± 0.3	3.8± 0.3	3.8± 0.3	3.8± 0.3
24000 ppm	3.5± 0.3	3.5± 0.2	3.5± 0.2	3.8± 0.2	3.8± 0.3	3.9± 0.3	3.9± 0.3

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

Test of Dunnett

(IAN260)

BAIS2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week					
	8	9	10	11	12	13
Control	3.9± 0.3	3.9± 0.3	3.9± 0.4	3.9± 0.3	3.9± 0.4	3.9± 0.2
600 ppm	4.0± 0.3	4.0± 0.3	4.1± 0.3	4.0± 0.2	4.0± 0.3	4.0± 0.2
1500 ppm	3.9± 0.2	3.9± 0.3	4.0± 0.3	4.0± 0.2	4.2± 0.3	4.0± 0.4
3800 ppm	4.0± 0.2	3.9± 0.4	3.9± 0.2	4.1± 0.4	4.1± 0.3	3.9± 0.4
10000 ppm	3.9± 0.4	3.9± 0.3	3.8± 0.3	3.8± 1.0	3.8± 0.4	3.9± 0.4
24000 ppm	3.9± 0.2	3.8± 0.3	3.9± 0.2	3.8± 0.3	3.9± 0.2	3.9± 0.2

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

(HAN260)

BAIS2

APPENDIX B 5-1

CHEMICAL INTAKE CHANGES: SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0146
ANIMAL : RAT F344
UNIT : g/kg/day
REPORT TYPE : A1 13
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration (weeks)						
	1	2	3	4	5	6	7
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
600 ppm	0.068± 0.003	0.062± 0.005	0.057± 0.003	0.058± 0.005	0.053± 0.002	0.048± 0.002	0.044± 0.003
1500 ppm	0.168± 0.003	0.154± 0.009	0.143± 0.008	0.142± 0.024	0.133± 0.026	0.120± 0.008	0.109± 0.007
3800 ppm	0.419± 0.040	0.381± 0.018	0.363± 0.018	0.337± 0.025	0.306± 0.024	0.291± 0.017	0.280± 0.023
10000 ppm	0.928± 0.058	0.828± 0.047	0.777± 0.057	0.727± 0.044	0.676± 0.048	0.646± 0.045	0.599± 0.046
24000 ppm	2.064± 0.081	1.816± 0.081	1.714± 0.061	1.614± 0.097	1.546± 0.198	1.389± 0.062	1.326± 0.059

(HAN300)

BAIS 2

STUDY NO. : 0146
ANIMAL : RAT F344
UNIT : g/kg/day
REPORT TYPE : A1 13
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

Group Name	Administration (weeks)					
	8	9	10	11	12	13
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
600 ppm	0.083± 0.005	0.084± 0.007	0.078± 0.005	0.078± 0.005	0.076± 0.004	0.074± 0.003
1500 ppm	0.192± 0.009	0.198± 0.008	0.187± 0.016	0.182± 0.011	0.178± 0.012	0.175± 0.010
3800 ppm	0.440± 0.025	0.446± 0.027	0.422± 0.027	0.429± 0.023	0.418± 0.035	0.415± 0.027
10000 ppm	0.953± 0.068	1.045± 0.043	0.958± 0.047	0.957± 0.050	0.979± 0.033	0.954± 0.042
24000 ppm	1.262± 0.065	1.277± 0.060	1.187± 0.073	1.187± 0.055	1.190± 0.045	1.185± 0.085

(IIN300)

BAIS 2

APPENDIX B 5-2

CHEMICAL INTAKE CHANGES: SUMMARY,RAT: FEMALE

(13Week STUDY)

STUDY NO. : 0146
 ANIMAL : RAT F344
 UNIT : g/kg/day
 REPORT TYPE : A1 13
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration (weeks)						
	1	2	3	4	5	6	7
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
600 ppm	0.080± 0.004	0.076± 0.006	0.088± 0.034	0.097± 0.060	0.073± 0.018	0.085± 0.043	0.094± 0.045
1500 ppm	0.201± 0.018	0.239± 0.100	0.184± 0.016	0.182± 0.022	0.184± 0.035	0.188± 0.048	0.189± 0.061
3800 ppm	0.469± 0.020	0.451± 0.024	0.445± 0.044	0.411± 0.043	0.452± 0.117	0.493± 0.197	0.400± 0.085
10000 ppm	1.067± 0.052	0.976± 0.049	0.960± 0.068	0.914± 0.090	0.886± 0.124	0.839± 0.127	0.809± 0.113
24000 ppm	2.198± 0.139	2.172± 0.186	2.002± 0.287	1.998± 0.378	2.072± 0.754	1.915± 0.427	1.960± 1.149

(HAN300)

BATS 2

STUDY NO. : 0146
ANIMAL : RAT F344
UNIT : g/kg/day
REPORT TYPE : A1.13
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 4

Group Name	Administration (weeks)					
	8	9	10	11	12	13
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
600 ppm	0.164± 0.071	0.139± 0.046	0.146± 0.059	0.138± 0.044	0.138± 0.057	0.132± 0.031
1500 ppm	0.288± 0.060	0.302± 0.099	0.269± 0.035	0.269± 0.050	0.274± 0.058	0.293± 0.056
3800 ppm	0.671± 0.135	0.592± 0.041	0.587± 0.053	0.572± 0.036	0.601± 0.061	0.605± 0.037
10000 ppm	1.503± 0.582	1.392± 0.252	1.333± 0.156	1.343± 0.158	1.344± 0.172	1.362± 0.178
24000 ppm	1.717± 0.412	1.685± 0.405	1.569± 0.156	1.578± 0.167	1.724± 0.526	1.649± 0.280

(HAN300)

BAIS 2

APPENDIX B 5-3

CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: MALE (13Week STUDY)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g/kg/day
 REPORT TYPE : A1 13
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration (weeks)						
	1	2	3	4	5	6	7
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
600 ppm	0.110± 0.023	0.100± 0.012	0.094± 0.009	0.081± 0.011	0.079± 0.005	0.077± 0.007	0.152± 0.017
1500 ppm	0.261± 0.046	0.250± 0.042	0.231± 0.025	0.193± 0.047	0.205± 0.031	0.199± 0.032	0.390± 0.078
3800 ppm	0.738± 0.143	0.663± 0.143	0.632± 0.098	0.570± 0.125	0.592± 0.159	0.571± 0.145	1.016± 0.174
10000 ppm	1.862± 0.326	1.757± 0.239	1.645± 0.360	1.412± 0.392	1.483± 0.328	1.439± 0.277	2.604± 0.481
24000 ppm	3.940± 0.614	3.808± 0.667	3.622± 0.524	3.224± 0.556	3.231± 0.687	3.054± 0.476	2.908± 0.422

(HAN300)

BAIS 2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g/kg/day
 REPORT TYPE : A1 13
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration (weeks)					
	8	9	10	11	12	13
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
600 ppm	0.149± 0.018	0.145± 0.019	0.141± 0.017	0.143± 0.021	0.142± 0.021	0.132± 0.016
1500 ppm	0.376± 0.065	0.362± 0.053	0.359± 0.066	0.344± 0.069	0.336± 0.056	0.324± 0.053
3800 ppm	0.989± 0.161	0.976± 0.171	0.942± 0.160	0.903± 0.122	0.895± 0.130	0.837± 0.103
10000 ppm	2.692± 0.747	2.479± 0.526	2.398± 0.363	2.327± 0.407	2.241± 0.384	2.073± 0.254
24000 ppm	2.765± 0.347	2.732± 0.336	2.709± 0.334	2.545± 0.319	2.496± 0.313	2.417± 0.282

APPENDIX B 5-4

CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: FEMALE

(13Week STUDY)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g/kg/day
 REPORT TYPE : A1 13
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration (weeks)						
	1	2	3	4	5	6	7
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
600 ppm	0.136± 0.021	0.132± 0.013	0.136± 0.023	0.110± 0.029	0.139± 0.027	0.136± 0.059	0.252± 0.029
1500 ppm	0.324± 0.023	0.310± 0.024	0.303± 0.020	0.286± 0.020	0.280± 0.015	0.289± 0.017	0.578± 0.069
3800 ppm	0.869± 0.055	0.826± 0.060	0.848± 0.159	0.752± 0.098	0.776± 0.076	0.782± 0.121	1.577± 0.219
10000 ppm	2.151± 0.130	2.166± 0.252	2.031± 0.134	1.942± 0.388	1.885± 0.265	1.974± 0.322	3.801± 0.633
24000 ppm	4.916± 0.536	4.848± 0.613	5.111± 0.721	4.684± 0.910	4.650± 0.775	4.678± 1.250	4.168± 0.300

(IIAN300)

BAIS 2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 UNIT : g/kg/day
 REPORT TYPE : A1 13
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration (weeks)					
	8	9	10	11	12	13
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
600 ppm	0.248± 0.033	0.266± 0.048	0.257± 0.036	0.277± 0.074	0.231± 0.014	0.280± 0.076
1500 ppm	0.577± 0.053	0.581± 0.052	0.582± 0.043	0.573± 0.044	0.566± 0.057	0.548± 0.049
3800 ppm	1.502± 0.175	1.544± 0.226	1.657± 0.331	1.466± 0.124	1.442± 0.159	1.448± 0.164
10000 ppm	3.637± 0.428	3.712± 0.390	3.666± 0.454	3.529± 0.410	3.620± 0.478	3.426± 0.471
24000 ppm	4.080± 0.383	4.285± 0.458	4.289± 0.397	4.272± 0.441	4.251± 0.684	4.074± 0.439

(I1AN300)

BAIS2

APPENDIX B 6-1

HEMATOLOGY : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (14)

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	9.55± 0.30	16.6± 0.3	46.6± 1.3	48.8± 1.1	17.4± 0.4	35.7± 0.8	773± 26
600 ppm	10	9.71± 0.25	16.8± 0.3	47.1± 1.2	48.5± 0.3	17.3± 0.3	35.7± 0.7	757± 27
1500 ppm	10	9.59± 0.28	16.5± 0.3	46.5± 1.2	48.6± 0.6	17.2± 0.4	35.4± 0.9	781± 22
3800 ppm	10	9.64± 0.16	16.5± 0.2	47.0± 0.8	48.8± 0.8	17.1± 0.3	35.1± 0.6	754± 46
10000 ppm	10	9.37± 0.24	16.3± 0.4	46.0± 2.0	49.1± 1.1	17.4± 0.3	35.5± 1.1	715± 41**
24000 ppm	10	9.51± 0.25	16.4± 0.4	46.5± 1.3	48.9± 0.5	17.2± 0.4	35.3± 0.9	756± 33

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

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0146
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

HEMATOLOGY(2) (SUMMARY)
 SURVIVAL ANIMALS (14)

PAGE : 1

Group Name	NO. of Animals	WBC 10 ³ /μL		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	10	5.34±	1.70	0±	0	24±	7	2±	1	0±	0	4±	3	70±	10	0±	1
600 ppm	10	5.44±	1.25	1±	1	22±	5	2±	1	0±	0	3±	1	74±	5	0±	0
1500 ppm	10	5.26±	1.51	1±	1	23±	6	2±	1	0±	0	3±	1	71±	7	0±	0
3800 ppm	10	5.42±	2.21	1±	1	24±	7	1±	1	0±	0	5±	2	69±	8	0±	0
10000 ppm	10	5.44±	2.48	0±	1	21±	5	1±	1	0±	0	4±	2	74±	6	0±	0
24000 ppm	10	5.47±	1.03	1±	1	21±	6	1±	1	0±	0	4±	2	74±	6	0±	0

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL071)

BAISZ

APPENDIX B 6-2

HEMATOLOGY : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (14)

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	8.76±	0.32	16.4±	0.5	45.5±	1.9	52.0±	0.8	18.7±	0.3	36.1±	0.6	798±	89
600 ppm	10	8.87±	0.15	16.7±	0.4	46.0±	0.7	51.9±	0.4	18.8±	0.3	36.3±	0.6	813±	33
1500 ppm	10	8.89±	0.34	16.6±	0.6	46.3±	2.1	52.1±	1.1	18.6±	0.3	35.8±	0.9	798±	85
3800 ppm	10	8.61±	0.26	16.2±	0.4	44.7±	1.2	51.9±	0.7	18.8±	0.3	36.2±	0.7	807±	70
10000 ppm	10	8.57±	0.30	16.1±	0.4	44.3±	1.5	51.7±	0.6	18.8±	0.4	36.5±	0.8	795±	62
24000 ppm	10	8.58±	0.37	16.0±	0.6	44.5±	2.1	51.9±	0.3	18.6±	0.4	35.8±	0.7	751±	100

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (14)

PAGE : 2

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	10	3.48±	1.10	1±	1	23±	8	2±	1	0±	0	3±	1	72±	9	0±	0
600 ppm	10	3.40±	1.19	1±	1	18±	5	2±	1	0±	0	4±	1	75±	7	0±	0
1500 ppm	10	2.61±	0.55	1±	1	20±	6	1±	1	0±	0	3±	2	74±	7	0±	0
3800 ppm	10	3.28±	0.82	1±	1	21±	5	1±	1	0±	0	3±	2	74±	5	0±	0
10000 ppm	10	3.00±	0.69	0±	1	19±	6	1±	1	0±	0	4±	2	75±	6	0±	0
24000 ppm	10	3.16±	1.28	0±	0	22±	8	2±	1	0±	0	4±	2	73±	8	0±	0

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL071)

BAIS2

APPENDIX B 6-3

HEMATOLOGY : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

HEMATOLOGY(1) (SUMMARY)
 SURVIVAL ANIMALS (14)

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	10.92± 0.34	16.1± 0.5	48.7± 1.8	44.6± 0.4	14.7± 0.3	33.0± 0.7	1528± 118
600 ppm	9	10.90± 0.27	15.9± 0.3	48.8± 0.9	44.8± 0.9	14.6± 0.3	32.6± 0.6	1535± 91
1500 ppm	10	11.04± 0.24	16.0± 0.4	49.7± 1.4	45.0± 0.5	14.5± 0.2	32.3± 0.4	1446± 122
3800 ppm	10	10.96± 0.21	16.1± 0.4	49.6± 1.7	45.3± 1.1	14.7± 0.2	32.4± 0.6	1452± 86
10000 ppm	10	10.99± 0.33	16.1± 0.5	49.3± 1.3	44.8± 1.1	14.6± 0.4	32.6± 0.7	1501± 122
24000 ppm	10	11.10± 0.25	16.2± 0.3	49.6± 1.2	44.7± 0.6	14.6± 0.2	32.7± 0.7	1480± 84

Significant difference ; * : P ≤ 0.05

** : P ≤ 0.01

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (14)

PAGE : 1

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential WBC N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	9	1.76±	1.12	1±	1	14±	3	2±	1	0±	0	3±	2	80±	5	1±	1
600 ppm	9	1.04±	0.31	2±	2	16±	7	2±	2	0±	0	3±	3	77±	11	0±	0
1500 ppm	10	1.35±	0.61	1±	1	19±	9	1±	1	0±	0	4±	2	75±	11	0±	0
3800 ppm	10	1.28±	0.75	0±	0	14±	5	2±	2	0±	0	4±	3	80±	7	0±	0
10000 ppm	10	1.26±	0.81	0±	1	15±	5	2±	2	0±	0	4±	3	79±	6	0±	1
24000 ppm	10	1.31±	0.72	1±	1	17±	5	1±	2	0±	0	3±	2	77±	7	0±	1

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL071)

BAIS2

APPENDIX B 6-4

HEMATOLOGY : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (14)

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	8	10.77± 0.20	16.0± 0.4	48.3± 1.5	44.8± 0.7	14.8± 0.2	33.1± 0.5	1353± 108
600 ppm	10	10.78± 0.39	16.1± 0.4	48.3± 1.6	44.9± 0.4	14.9± 0.3	33.3± 0.7	1349± 128
1500 ppm	10	10.79± 0.25	16.0± 0.3	48.4± 1.3	44.8± 0.6	14.9± 0.3	33.2± 0.6	1305± 126
3800 ppm	10	10.78± 0.26	16.1± 0.4	48.2± 1.4	44.7± 0.6	14.9± 0.2	33.4± 0.7	1345± 101
10000 ppm	10	10.79± 0.42	16.0± 0.5	48.2± 2.2	44.7± 0.6	14.8± 0.3	33.2± 0.8	1295± 85
24000 ppm	10	10.70± 0.52	16.0± 0.3	47.5± 2.9	44.4± 1.1	15.0± 0.6	33.8± 1.6	1322± 187

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
 SURVIVAL ANIMALS (14)

PAGE : 2

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	8	0.70±	0.44	1±	1	11±	4	1±	1	0±	0	2±	1	86±	5	0±	0
600 ppm	10	1.22±	1.10	1±	1	16±	11	0±	0	0±	0	1±	1	81±	11	0±	0
1500 ppm	10	1.19±	0.37	1±	1	16±	6	1±	1	0±	0	2±	1	80±	6	0±	1
3800 ppm	10	1.18±	1.16	1±	1	15±	13	1±	1	0±	0	1±	1	82±	13	0±	0
10000 ppm	10	1.23±	0.66	1±	1	14±	6	1±	1	0±	0	1±	1	83±	7	0±	0
24000 ppm	10	1.29±	0.64	1±	1	14±	5	1±	1	0±	0	2±	2	82±	5	0±	0

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL071)

BAIS2

APPENDIX B 7-1

BIOCHEMISTRY : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (14)

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	10	6.9±	0.2	4.0±	0.1	1.4±	0.1	0.21±	0.02	186±	15	53±	3	101±	28
600 ppm	10	6.9±	0.2	4.0±	0.1	1.4±	0.1	0.22±	0.03	191±	21	53±	2	113±	31
1500 ppm	10	6.8±	0.1	3.9±	0.2	1.4±	0.1	0.21±	0.03	190±	12	53±	3	106±	20
3800 ppm	10	6.8±	0.2	3.9±	0.1	1.3±	0.1	0.21±	0.02	192±	19	55±	3	107±	22
10000 ppm	10	6.7±	0.2**	3.9±	0.1	1.4±	0.1	0.20±	0.04	186±	11	53±	6	91±	18
24000 ppm	10	6.6±	0.1**	3.8±	0.1*	1.4±	0.1	0.21±	0.02	184±	12	53±	4	90±	13

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0146
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (14)

PAGE : 2

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT IU/l		GPT IU/l		LDH IU/l		ALP IU/l		G-GTP IU/l		CPK IU/l	
Control	10	107±	10	74±	10	27±	3	158±	19	309±	29	1±	1	87±	15
600 ppm	10	108±	8	69±	8	25±	3	153±	26	311±	23	1±	0	84±	8
1500 ppm	10	107±	6	68±	7	24±	3	146±	47	299±	21	1±	0	82±	17
3800 ppm	10	111±	6	70±	14	24±	5	153±	47	299±	19	1±	0	82±	8
10000 ppm	10	108±	11	66±	9	23±	3	142±	28	293±	18	1±	0	81±	13
24000 ppm	10	107±	7	67±	7	23±	3	144±	20	301±	27	1±	0	87±	14

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (14)

PAGE : 3

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	10	17.8±	1.3	0.5±	0.1	141±	1	3.7±	0.2	106±	1	10.4±	0.2	5.5±	1.3
600 ppm	10	18.1±	1.2	0.5±	0.1	140±	2	3.7±	0.4	105±	1	10.4±	0.2	5.3±	1.0
1500 ppm	10	17.1±	1.4	0.5±	0.1	140±	1	3.7±	0.2	105±	1	10.4±	0.2	5.4±	0.7
3800 ppm	10	17.2±	0.9	0.5±	0.1	139±	2	3.8±	0.3	104±	1*	10.3±	0.2	5.4±	1.2
10000 ppm	10	18.0±	1.5	0.5±	0.1	139±	1*	4.1±	0.6	103±	2**	10.3±	0.2	5.5±	1.2
24000 ppm	10	18.9±	2.1	0.5±	0.1	138±	0**	3.9±	0.4	104±	1**	10.2±	0.2	5.6±	0.9

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

Test of Dunnett

(HCL074)

BAIS2

APPENDIX B 7-2

BIOCHEMISTRY : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0146
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (14)

PAGE : 4

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	10	6.8±	0.2	3.9±	0.1	1.3±	0.1	0.32±	0.08	144±	5	70±	5	38±	5
600 ppm	10	6.7±	0.2	3.9±	0.1	1.4±	0.1	0.31±	0.03	150±	7	73±	5	36±	4
1500 ppm	10	6.8±	0.3	4.0±	0.2	1.4±	0.1	0.37±	0.16	143±	9	77±	8	39±	5
3800 ppm	10	6.6±	0.2	3.9±	0.2	1.4±	0.1	0.34±	0.05	153±	17	73±	4	41±	6
10000 ppm	10	6.4±	0.2**	3.7±	0.1	1.4±	0.1	0.32±	0.03	152±	11	68±	6	38±	6
24000 ppm	10	6.4±	0.2**	3.7±	0.2	1.4±	0.1	0.35±	0.10	148±	11	69±	6	40±	8

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

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0146
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (14)

PAGE : 5

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT IU/l		GPT IU/l		LDH IU/l		ALP IU/l		G-GTP IU/l		CPK IU/l	
Control	10	135±	9	68±	11	22±	4	218±	44	205±	12	1±	1	95±	17
600 ppm	10	140±	10	67±	4	22±	3	222±	36	215±	38	1±	0	93±	11
1500 ppm	10	146±	16	70±	12	23±	5	279±	94	188±	19	1±	1	104±	22
3800 ppm	10	142±	10	67±	9	21±	6	223±	41	198±	17	1±	1	90±	11
10000 ppm	10	131±	11	62±	7	18±	4	217±	35	192±	18	2±	1	89±	8
24000 ppm	10	132±	13	69±	12	22±	6	248±	87	197±	22	1±	0	98±	24

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0146
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (14)

PAGE : 6

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	10	19.3±	1.7	0.4±	0.1	141±	1	3.7±	0.7	108±	3	10.1±	0.3	4.8±	1.6
600 ppm	10	20.1±	1.6	0.4±	0.1	140±	1	3.7±	0.4	108±	1	10.1±	0.3	4.6±	1.1
1500 ppm	10	19.5±	2.1	0.5±	0.1	140±	1	4.1±	0.9	107±	2	10.2±	0.3	4.7±	1.5
3800 ppm	10	19.2±	2.7	0.4±	0.1	139±	1*	3.8±	0.6	107±	2	10.0±	0.3	4.5±	1.3
10000 ppm	10	18.4±	2.2	0.4±	0.1	138±	1**	3.9±	0.2	108±	1	9.9±	0.1	4.5±	1.0
24000 ppm	10	18.4±	2.0	0.4±	0.1	138±	1**	3.9±	0.7	107±	3	9.9±	0.4	4.6±	1.1

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

APPENDIX B 7-3

BIOCHEMISTRY : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (14)

PAGE : 4

Group Name	NO. of Animals	TOTAL PROTEIN g / dl		ALBUMIN g / dl		A/G RATIO		T-BILIRUBIN mg / dl		GLUCOSE mg / dl		T-CHOLESTEROL mg / dl		TRIGLYCERIDE mg / dl	
Control	8	5.6±	0.2	3.5±	0.1	1.7±	0.1	0.33±	0.12	173±	18	72±	10	45±	13
600 ppm	10	5.5±	0.2	3.4±	0.1	1.6±	0.1	0.35±	0.11	158±	22	70±	7	42±	8
1500 ppm	10	5.6±	0.2	3.4±	0.1	1.6±	0.1	0.39±	0.18	182±	22	75±	7	50±	18
3800 ppm	10	5.5±	0.2	3.4±	0.1	1.6±	0.1	0.39±	0.13	165±	21	67±	6	42±	11
10000 ppm	10	5.5±	0.2	3.4±	0.2	1.7±	0.2	0.30±	0.11	177±	25	68±	7	39±	7
24000 ppm	10	5.6±	0.3	3.5±	0.1	1.7±	0.1	0.43±	0.15	165±	21	71±	10	44±	9

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (14)

PAGE : 5

Group Name	NO. of Animals	GOT IU/ℓ		GPT IU/ℓ		LDH IU/ℓ		ALP IU/ℓ		CPK IU/ℓ		UREA NITROGEN mg/dℓ		SODIUM mEq/ℓ	
Control	8	64±	14	17±	4	273±	65	339±	34	79±	44	23.6±	3.8	151±	2
600 ppm	10	64±	12	14±	3	248±	56	342±	26	68±	29	21.7±	1.8	150±	1
1500 ppm	10	59±	9	15±	4	293±	161	314±	41	60±	16	21.0±	2.0	149±	2
3800 ppm	10	63±	24	15±	5	266±	188	324±	51	66±	41	20.8±	2.5	150±	1
10000 ppm	10	59±	14	14±	5	267±	145	310±	26	111±	163	19.7±	2.3	150±	1
24000 ppm	10	75±	44	15±	5	737±	1293	293±	24*	440±	1151	20.5±	3.4	150±	1

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

Test of Dunnett

(IICL074)

BAIS 2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (14)

PAGE : 6

Group Name	NO. of Animals	POTASSIUM mEq/ℓ		CHLORIDE mEq/ℓ		CALCIUM mg/dℓ		INORGANIC PHOSPHORUS mg/dℓ	
Control	8	4.7±	0.4	123±	1	8.8±	0.5	7.1±	0.5
600 ppm	10	4.6±	0.3	123±	2	8.8±	0.3	6.5±	0.8
1500 ppm	10	4.7±	0.5	121±	2	8.9±	0.3	6.6±	0.9
3800 ppm	10	4.6±	0.5	122±	2	8.6±	0.3	6.6±	0.6
10000 ppm	10	4.7±	0.4	121±	2	8.4±	0.4	6.2±	0.9
24000 ppm	10	4.9±	0.5	122±	2	8.7±	0.4	6.5±	0.5

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

APPENDIX B 7-4

BIOCHEMISTRY : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (14)

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g / dl		ALBUMIN g / dl		A/G RATIO		T-BILIRUBIN mg / dl		GLUCOSE mg / dl		T-CHOLESTEROL mg / dl		TRIGLYCERIDE mg / dl	
Control	9	5.5±	0.3	3.1±	0.1	1.3±	0.1	0.31±	0.09	213±	36	82±	5	77±	14
600 ppm	9	5.5±	0.1	3.2±	0.1	1.4±	0.1	0.30±	0.05	213±	37	83±	6	73±	13
1500 ppm	10	5.5±	0.2	3.2±	0.1	1.4±	0.1	0.27±	0.08	206±	47	86±	8	88±	14
3800 ppm	10	5.5±	0.3	3.2±	0.2	1.4±	0.1	0.36±	0.13	219±	39	84±	7	86±	18
10000 ppm	10	5.5±	0.2	3.2±	0.1	1.4±	0.1	0.33±	0.08	224±	68	85±	9	81±	18
24000 ppm	10	5.4±	0.2	3.2±	0.1	1.4±	0.1	0.31±	0.07	232±	53	82±	7	84±	13

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (14)

PAGE : 2

Group Name	NO. of Animals	GOT IU/ℓ		GPT IU/ℓ		LDH IU/ℓ		ALP IU/ℓ		CPK IU/ℓ		UREA NITROGEN mg/dℓ		SODIUM mEq/ℓ	
Control	9	52±	7	14±	4	291±	143	181±	10	48±	13	24.8±	3.0	151±	1
600 ppm	9	49±	6	14±	4	246±	73	177±	4	39±	10	25.3±	4.8	151±	1
1500 ppm	10	57±	11	15±	3	224±	35	187±	15	41±	12	26.6±	3.8	151±	1
3800 ppm	10	54±	10	15±	5	263±	78	181±	15	56±	28	25.0±	2.2	151±	1
10000 ppm	10	53±	12	14±	4	261±	62	180±	16	55±	26	26.4±	2.1	151±	1
24000 ppm	10	55±	18	13±	5	293±	200	186±	11	64±	66	26.0±	2.8	152±	2

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (14)

PAGE : 3

Group Name	NO. of Animals	POTASSIUM mEq/ℓ		CHLORIDE mEq/ℓ		CALCIUM mg/dℓ		INORGANIC PHOSPHORUS mg/dℓ	
Control	9	4.5±	0.5	123±	2	8.7±	0.2	7.4±	0.7
600 ppm	9	4.3±	0.4	122±	1	8.7±	0.2	7.2±	1.1
1500 ppm	10	4.5±	0.4	122±	1	8.9±	0.3	7.3±	0.7
3800 ppm	10	4.9±	0.9	120±	2	8.9±	0.4	8.0±	1.5
10000 ppm	10	4.3±	0.4	122±	3	8.9±	0.2	7.5±	1.0
24000 ppm	10	4.6±	0.2	121±	3	8.7±	0.2	7.8±	1.4

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

APPENDIX B 8-1

URINALYSIS : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0146

ANIMAL : RAT F344

SAMPLING DATE : 013-6

SEX : MALE

REPORT TYPE : A1

URINALYSIS

PAGE : 1

Group Name	NO. of Animals	pH_____							CHI	Protein_____					CHI	Glucose_____					CHI	Ketone body_____					CHI	Bilirubin_____				CHI		
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	±	+		2+	3+	4+	-		+	2+
Control	10	0	0	0	0	0	8	2		0	0	4	6	0	0		10	0	0	0	0	0		1	9	0	0	0	0		10	0	0	0
600 ppm	10	0	0	0	0	1	7	2		0	0	3	7	0	0		10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0
1500 ppm	10	0	0	0	0	0	8	2		0	0	1	9	0	0		10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0
3800 ppm	10	0	0	0	0	2	7	1		0	0	1	9	0	0		10	0	0	0	0	0		0	9	1	0	0	0		10	0	0	0
10000 ppm	10	0	0	0	0	6	3	1	*	0	0	1	9	0	0		10	0	0	0	0	0		0	8	2	0	0	0		10	0	0	0
24000 ppm	10	0	0	0	0	3	7	0		0	0	0	10	0	0	*	10	0	0	0	0	0		0	9	1	0	0	0		10	0	0	0

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

Test of CHI SQUARE

(JCL101)

BAIS2

STUDY NO. : 0146

ANIMAL : RAT F344

SAMPLING DATE : 013-6

SEX : MALE

REPORT TYPE : A1

URINALYSIS

PAGE : 2

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	10	10	0	0	0	0		10	0	0	0	0	
600 ppm	10	10	0	0	0	0		10	0	0	0	0	
1500 ppm	10	10	0	0	0	0		10	0	0	0	0	
3800 ppm	10	10	0	0	0	0		10	0	0	0	0	
10000 ppm	10	9	1	0	0	0		10	0	0	0	0	
24000 ppm	10	8	2	0	0	0		10	0	0	0	0	

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of CHI SQUARE

(JCL101)

BATS 2

APPENDIX B 8-2

URINALYSIS : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0146
 ANIMAL : RAT F344
 SAMPLING DATE : 013-6
 SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	pH							CHI	Protein						CHI	Glucose						CHI	Ketone body						CHI	Bilirubin				CHI
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+	4+		-	±	+	2+	3+	4+		-	±	+	2+	3+	4+		-	+	2+	3+	
Control	10	0	0	0	0	0	8	2		0	7	3	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
600 ppm	10	0	0	0	0	0	10	0		0	5	5	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
1500 ppm	10	0	0	0	0	4	6	0	*	1	3	6	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
3800 ppm	10	0	0	0	0	4	6	0	*	0	1	5	4	0	0	*	10	0	0	0	0	0		7	3	0	0	0	0		10	0	0	0	
10000 ppm	10	0	0	0	0	2	8	0		0	0	6	4	0	0	**	10	0	0	0	0	0		8	2	0	0	0	0		10	0	0	0	
24000 ppm	10	0	0	1	1	5	3	0	*	0	0	2	8	0	0	**	10	0	0	0	0	0		3	7	0	0	0	0	**	10	0	0	0	

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

Test of CHI SQUARE

(JCL101)

BAIS 2

STUDY NO. : 0146
ANIMAL : RAT F344
SAMPLING DATE : 013-6
SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	10	10	0	0	0	0	0	10	0	0	0	0	0
600 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
1500 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
3800 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
10000 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
24000 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0

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

Test of CHI SQUARE

(JCL101)

BAISZ

APPENDIX B 8-3

URINALYSIS : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 SAMPLING DATE : 013-6
 SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	pH_____							CHI	Protein_____					CHI	Glucose_____					CHI	Ketone body_____					CHI	Occult blood_____				CHI				
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	±	+		2+	3+	4+	-		±	+	2+	3+
Control	10	0	0	0	0	0	8	2		0	0	3	7	0	0		10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	0	
600 ppm	10	0	0	0	1	3	5	1		0	1	3	6	0	0		10	0	0	0	0	0		1	9	0	0	0	0		10	0	0	0	0	
1500 ppm	10	0	0	0	0	1	9	0		0	1	4	5	0	0		10	0	0	0	0	0		4	6	0	0	0	0	*	10	0	0	0	0	
3800 ppm	10	0	0	0	0	2	8	0		0	0	7	3	0	0		10	0	0	0	0	0		2	8	0	0	0	0		10	0	0	0	0	
10000 ppm	10	0	0	0	0	7	2	1	**	0	0	3	7	0	0		10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	0	
24000 ppm	10	0	0	1	0	8	1	0	**	0	0	2	8	0	0		10	0	0	0	0	0		1	9	0	0	0	0		10	0	0	0	0	

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

Test of CHI SQUARE

(JCL101)

BAIS 2

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-6
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+ CHI
Control	10	10 0 0 0 0
600 ppm	10	10 0 0 0 0
1500 ppm	10	10 0 0 0 0
3800 ppm	10	10 0 0 0 0
10000 ppm	10	10 0 0 0 0
24000 ppm	10	10 0 0 0 0

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

Test of CHI SQUARE

(JCL101)

BAIS2

APPENDIX B 8-4

URINALYSIS : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 SAMPLING DATE : 013-6
 SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	pH							CHI	Protein						CHI	Glucose						CHI	Ketone body						CHI	Occult blood						CHI
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+	4+		-	±	+	2+	3+	4+		-	±	+	2+	3+	4+		-	±	+	2+	3+	4+	
Control	9	0	0	2	2	3	2	0		0	0	6	3	0	0		9	0	0	0	0	0		2	7	0	0	0	0		9	0	0	0	0	0	
600 ppm	10	0	0	3	2	2	2	1		0	1	8	1	0	0		10	0	0	0	0	0		4	6	0	0	0	0		10	0	0	0	0	0	
1500 ppm	10	0	0	2	2	5	1	0		0	2	7	1	0	0		10	0	0	0	0	0		5	5	0	0	0	0		10	0	0	0	0	0	
3800 ppm	10	0	1	2	2	4	1	0		0	0	7	3	0	0		10	0	0	0	0	0		1	9	0	0	0	0		10	0	0	0	0	0	
10000 ppm	10	0	2	3	4	0	1	0		0	0	5	5	0	0		10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	0	0	
24000 ppm	10	0	1	1	4	4	0	0		0	0	5	5	0	0		10	0	0	0	0	0		1	9	0	0	0	0		10	0	0	0	0	0	

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

Test of CHI SQUARE

(JCL101)

BAIS2

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-6
SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+ CH1
Control	9	9 0 0 0 0
600 ppm	10	10 0 0 0 0
1500 ppm	10	10 0 0 0 0
3800 ppm	10	10 0 0 0 0
10000 ppm	10	10 0 0 0 0
24000 ppm	10	10 0 0 0 0

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

Test of CHI SQUARE

(JCL101)

BAIS2

APPENDIX B 9-1

GROSS FINDINGS : SUMMARY, RAT : MALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

PAGE : 1

Organ	Findings	Group Name	Control	600 ppm	1500 ppm	3800 ppm
		NO. of Animals	10 (%)	10 (%)	10 (%)	10 (%)
Liver	herniation		1 (10)	0 (0)	2 (20)	0 (0)

(HPT080)

BAIS 2

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	10000 ppm 10 (%)	24000 ppm 10 (%)
liver	herniation		0 (0)	0 (0)

(HPT080)

BAIS2

APPENDIX B 9-2

GROSS FINDINGS : SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control	600 ppm	1500 ppm	3800 ppm
			10 (%)	10 (%)	10 (%)	10 (%)
Liver	herniation		1 (10)	2 (20)	0 (0)	0 (0)

(IPT080)

BAIS2

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	10000 ppm 10 (%)	24000 ppm 10 (%)
Liver	herniation		0 (0)	1 (10)

(HPT080)

BATS 2

APPENDIX B 9-3

GROSS FINDINGS : SUMMARY, MOUSE: FEMALE :DEAD AND MORIBUND ANIMALS

(13Week STUDY)

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 14W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 1 (%)	600 ppm 0 (%)	1500 ppm 0 (%)	3800 ppm 0 (%)
thymus	atrophic		1 (100)	- (-)	- (-)	- (-)
whole body	wasting		1 (100)	- (-)	- (-)	- (-)

(HPT080)

BATS 2

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 14W)

PAGE : 2

Organ	Findings	Group Name	10000 ppm	24000 ppm
		NO. of Animals	0 (%)	0 (%)
thymus	atrophic		- (-)	- (-)
whole body	wasting		- (-)	- (-)

(IPT080)

BAIS 2

APPENDIX B 9-4

GROSS FINDINGS : SUMMARY, MOUSE: MALE :SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control	600 ppm	1500 ppm	3800 ppm
			10 (%)	10 (%)	10 (%)	10 (%)
spleen	black patch/zone		1 (10)	1 (10)	0 (0)	1 (10)
kidney	hydronephrosis		0 (0)	1 (10)	1 (10)	1 (10)
testis	atrophic		0 (0)	0 (0)	1 (10)	0 (0)

(HPT080)

BAIS 2

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

PAGE : 2

Organ	Findings	Group Name	10000 ppm		24000 ppm	
		NO. of Animals	10	(%)	10	(%)
spleen	black patch/zone		0	(0)	1	(10)
kidney	hydronephrosis		1	(10)	0	(0)
testis	atrophic		0	(0)	0	(0)

(IPT080)

BATS2

APPENDIX B 9-5

GROSS FINDINGS : SUMMARY, MOUSE: FEMALE :SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

PAGE : 3

Organ	Findings	Group Name	Control	600 ppm	1500 ppm	3800 ppm
		NO. of Animals	9 (%)	10 (%)	10 (%)	10 (%)
spleen	black patch/zone		1 (11)	0 (0)	1 (10)	0 (0)
ovary	fluid:transparent		0 (0)	0 (0)	0 (0)	0 (0)

(IPT080)

BAIS2

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

PAGE : 4

Organ	Findings	Group Name	10000 ppm		24000 ppm	
		NO. of Animals	10	(%)	10	(%)
spleen	black patch/zone		1	(10)	1	(10)
ovary	fluid:transparent		2	(20)	0	(0)

(IPT080)

BAIS2

APPENDIX B 10-1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

PAGE : 1

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	319± 19	0.253± 0.025	0.053± 0.005	2.864± 0.096	0.958± 0.064	1.020± 0.067
600 ppm	10	305± 16	0.236± 0.032	0.052± 0.004	2.890± 0.063	0.945± 0.050	0.988± 0.045
1500 ppm	10	312± 15	0.247± 0.033	0.053± 0.005	2.867± 0.073	0.958± 0.045	1.050± 0.041
3800 ppm	10	307± 13	0.254± 0.027	0.052± 0.003	2.880± 0.076	0.940± 0.060	0.997± 0.044
10000 ppm	10	289± 14**	0.236± 0.017	0.053± 0.002	2.822± 0.091	0.919± 0.041	0.970± 0.047
24000 ppm	10	287± 13**	0.213± 0.032*	0.051± 0.003	2.837± 0.087	0.922± 0.063	0.982± 0.049

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	1.935±	0.118	0.575±	0.027	8.063±	0.547	1.901±	0.030
600 ppm	10	1.880±	0.105	0.525±	0.036*	7.796±	0.380	1.906±	0.036
1500 ppm	10	1.921±	0.106	0.556±	0.041	7.912±	0.518	1.902±	0.028
3800 ppm	10	1.920±	0.087	0.556±	0.042	7.989±	0.437	1.903±	0.048
10000 ppm	10	1.915±	0.064	0.519±	0.028**	7.375±	0.450**	1.883±	0.029
24000 ppm	10	1.926±	0.095	0.516±	0.032**	7.273±	0.384**	1.872±	0.067

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX B 10-2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0146
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

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

PAGE : 3

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	177± 11	0.201± 0.024	0.059± 0.008	0.086± 0.009	0.639± 0.044	0.772± 0.056
600 ppm	10	175± 10	0.186± 0.021	0.060± 0.006	0.097± 0.017	0.628± 0.052	0.764± 0.041
1500 ppm	10	178± 7	0.203± 0.024	0.059± 0.003	0.097± 0.012	0.641± 0.043	0.786± 0.033
3800 ppm	10	174± 9	0.185± 0.020	0.058± 0.006	0.092± 0.008	0.622± 0.040	0.771± 0.033
10000 ppm	10	174± 10	0.184± 0.012	0.054± 0.004	0.086± 0.010	0.623± 0.038	0.759± 0.037
24000 ppm	10	173± 7	0.186± 0.022	0.056± 0.004	0.086± 0.012	0.624± 0.044	0.791± 0.069

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0146
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	1.206±	0.072	0.377±	0.033	4.258±	0.398	1.755±	0.056
600 ppm	10	1.199±	0.064	0.377±	0.016	4.171±	0.257	1.754±	0.040
1500 ppm	10	1.238±	0.059	0.376±	0.016	4.416±	0.229	1.766±	0.025
3800 ppm	10	1.229±	0.078	0.373±	0.028	4.226±	0.421	1.743±	0.044
10000 ppm	10	1.244±	0.081	0.386±	0.024	4.141±	0.291	1.752±	0.038
24000 ppm	10	1.284±	0.027	0.391±	0.037	4.211±	0.231	1.761±	0.033

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX B 10-3

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

PAGE : 1

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	30.5± 2.4	0.039± 0.006	0.009± 0.002	0.204± 0.014	0.156± 0.025	0.154± 0.008
600 ppm	10	30.2± 2.2	0.037± 0.006	0.009± 0.002	0.201± 0.013	0.154± 0.016	0.156± 0.009
1500 ppm	10	30.9± 1.7	0.039± 0.006	0.008± 0.002	0.194± 0.028	0.153± 0.012	0.150± 0.006
3800 ppm	10	31.7± 2.0	0.040± 0.005	0.008± 0.001	0.204± 0.014	0.156± 0.010	0.158± 0.009
10000 ppm	10	30.4± 2.8	0.040± 0.009	0.009± 0.002	0.203± 0.018	0.155± 0.013	0.154± 0.007
24000 ppm	10	30.8± 1.9	0.037± 0.006	0.008± 0.001	0.201± 0.010	0.159± 0.011	0.153± 0.010

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	0.419±	0.032	0.044±	0.004	1.123±	0.062	0.432±	0.014
600 ppm	10	0.459±	0.111	0.048±	0.005	1.132±	0.095	0.433±	0.016
1500 ppm	10	0.415±	0.028	0.046±	0.008	1.144±	0.050	0.435±	0.018
3800 ppm	10	0.505±	0.186	0.049±	0.004	1.160±	0.056	0.431±	0.008
10000 ppm	10	0.551±	0.345	0.048±	0.010	1.159±	0.068	0.436±	0.013
24000 ppm	10	0.441±	0.023	0.045±	0.004	1.150±	0.058	0.432±	0.016

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

Test of Dunnett

(HCL040)

BAIS2

APPENDIX B 10-4

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

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

PAGE : 3

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	9	20.4± 1.0	0.038± 0.004	0.011± 0.002	0.022± 0.003	0.130± 0.013	0.146± 0.010
600 ppm	10	20.2± 0.9	0.038± 0.005	0.012± 0.002	0.022± 0.002	0.120± 0.008	0.145± 0.008
1500 ppm	10	21.3± 2.0	0.038± 0.008	0.012± 0.001	0.024± 0.005	0.128± 0.009	0.147± 0.006
3800 ppm	10	20.7± 1.0	0.038± 0.006	0.011± 0.001	0.021± 0.003	0.127± 0.007	0.144± 0.008
10000 ppm	10	20.7± 1.9	0.040± 0.008	0.011± 0.001	0.023± 0.003	0.124± 0.005	0.141± 0.010
24000 ppm	10	21.1± 0.8	0.041± 0.003	0.011± 0.001	0.020± 0.004	0.125± 0.005	0.143± 0.008

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	9	0.276±	0.026	0.050±	0.007	0.880±	0.099	0.451±	0.014
600 ppm	10	0.278±	0.019	0.049±	0.007	0.858±	0.054	0.455±	0.013
1500 ppm	10	0.283±	0.016	0.057±	0.010	0.912±	0.094	0.459±	0.016
3800 ppm	10	0.290±	0.013	0.050±	0.006	0.893±	0.082	0.449±	0.012
10000 ppm	10	0.287±	0.022	0.047±	0.006	0.896±	0.086	0.450±	0.013
24000 ppm	10	0.290±	0.013	0.051±	0.006	0.909±	0.042	0.448±	0.013

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX B 11-1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	319± 19	0.079± 0.005	0.017± 0.001	0.901± 0.046	0.301± 0.012	0.320± 0.014
600 ppm	10	305± 16	0.078± 0.010	0.017± 0.001	0.950± 0.042	0.310± 0.015	0.325± 0.017
1500 ppm	10	312± 15	0.079± 0.008	0.017± 0.002	0.921± 0.047	0.307± 0.016	0.337± 0.019
3800 ppm	10	307± 13	0.083± 0.008	0.017± 0.001	0.938± 0.035	0.306± 0.019	0.325± 0.015
10000 ppm	10	289± 14**	0.082± 0.006	0.018± 0.001	0.978± 0.065**	0.318± 0.020	0.336± 0.012
24000 ppm	10	287± 13**	0.074± 0.009	0.018± 0.002	0.990± 0.039**	0.321± 0.015	0.342± 0.015**

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.607± 0.012	0.181± 0.011	2.529± 0.068	0.598± 0.035
600 ppm	10	0.617± 0.029	0.172± 0.008	2.559± 0.084	0.627± 0.027
1500 ppm	10	0.616± 0.019	0.178± 0.010	2.535± 0.082	0.611± 0.034
3800 ppm	10	0.625± 0.028	0.181± 0.011	2.599± 0.079	0.620± 0.029
10000 ppm	10	0.663± 0.027**	0.179± 0.007	2.549± 0.084	0.652± 0.035**
24000 ppm	10	0.671± 0.025**	0.180± 0.007	2.534± 0.072	0.653± 0.028**

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

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX B 11-2

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	30.5± 2.4	0.128± 0.011	0.029± 0.005	0.669± 0.053	0.511± 0.078	0.506± 0.044
600 ppm	10	30.2± 2.2	0.121± 0.016	0.030± 0.007	0.666± 0.040	0.511± 0.042	0.519± 0.034
1500 ppm	10	30.9± 1.7	0.126± 0.016	0.027± 0.006	0.629± 0.084	0.496± 0.039	0.487± 0.033
3800 ppm	10	31.7± 2.0	0.124± 0.014	0.025± 0.004	0.645± 0.053	0.492± 0.037	0.499± 0.040
10000 ppm	10	30.4± 2.8	0.130± 0.019	0.029± 0.006	0.672± 0.066	0.514± 0.042	0.512± 0.041
24000 ppm	10	30.8± 1.9	0.119± 0.018	0.027± 0.004	0.656± 0.051	0.516± 0.033	0.497± 0.022

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

Test of Dunnett

(HCL042)

BAIS2

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.375± 0.095	0.145± 0.012	3.689± 0.177	1.424± 0.112
600 ppm	10	1.541± 0.480	0.158± 0.018	3.753± 0.248	1.441± 0.108
1500 ppm	10	1.346± 0.091	0.150± 0.029	3.711± 0.205	1.410± 0.081
3800 ppm	10	1.601± 0.615	0.156± 0.018	3.663± 0.148	1.362± 0.076
10000 ppm	10	1.855± 1.275	0.161± 0.037	3.833± 0.216	1.447± 0.139
24000 ppm	10	1.434± 0.089	0.147± 0.011	3.732± 0.071	1.404± 0.084

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

Test of Dunnett

(IICL042)

BAIS 2

APPENDIX B 11-3

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE : 3

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	177± 11	0.113± 0.008	0.033± 0.004	0.054± 0.005	0.361± 0.023	0.435± 0.020
600 ppm	10	175± 10	0.112± 0.011	0.035± 0.004	0.055± 0.008	0.360± 0.024	0.438± 0.023
1500 ppm	10	178± 7	0.114± 0.013	0.033± 0.002	0.054± 0.006	0.360± 0.021	0.441± 0.021
3800 ppm	10	174± 9	0.112± 0.009	0.033± 0.003	0.053± 0.003	0.359± 0.023	0.445± 0.019
10000 ppm	10	174± 10	0.112± 0.008	0.031± 0.002	0.055± 0.005	0.359± 0.023	0.438± 0.021
24000 ppm	10	173± 7	0.114± 0.013	0.032± 0.003	0.056± 0.007	0.361± 0.021	0.459± 0.052

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

Test of Dunnett

(HCL042)

BATS2

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.680± 0.025	0.212± 0.012	2.387± 0.115	0.992± 0.058
600 ppm	10	0.687± 0.031	0.216± 0.013	2.387± 0.061	1.006± 0.057
1500 ppm	10	0.695± 0.024	0.211± 0.007	2.479± 0.133	0.992± 0.041
3800 ppm	10	0.709± 0.023	0.215± 0.009	2.433± 0.161	1.006± 0.039
10000 ppm	10	0.717± 0.030*	0.223± 0.010	2.385± 0.124	1.011± 0.047
24000 ppm	10	0.744± 0.032**	0.226± 0.017*	2.442± 0.184	1.020± 0.029

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

Test of Dunnett

(IICL042)

BAIS 2

APPENDIX B 11-4

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: %

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

PAGE : 3

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	9	20.4± 1.0	0.186± 0.016	0.056± 0.009	0.110± 0.013	0.635± 0.047	0.714± 0.028
600 ppm	10	20.2± 0.9	0.188± 0.021	0.057± 0.009	0.107± 0.012	0.595± 0.031	0.718± 0.029
1500 ppm	10	21.3± 2.0	0.179± 0.023	0.054± 0.006	0.110± 0.015	0.603± 0.040	0.694± 0.051
3800 ppm	10	20.7± 1.0	0.183± 0.025	0.052± 0.005	0.103± 0.015	0.617± 0.041	0.699± 0.022
10000 ppm	10	20.7± 1.9	0.193± 0.026	0.055± 0.006	0.109± 0.013	0.602± 0.039	0.682± 0.032
24000 ppm	10	21.1± 0.8	0.194± 0.015	0.054± 0.004	0.095± 0.023	0.593± 0.036	0.680± 0.041

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

Test of Dunnett

(HCL042)

BAIS2

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	9	1.354± 0.101	0.245± 0.029	4.306± 0.324	2.214± 0.096
600 ppm	10	1.379± 0.060	0.242± 0.026	4.254± 0.178	2.260± 0.087
1500 ppm	10	1.340± 0.095	0.267± 0.030	4.289± 0.196	2.170± 0.156
3800 ppm	10	1.406± 0.053	0.242± 0.025	4.320± 0.247	2.180± 0.125
10000 ppm	10	1.384± 0.072	0.225± 0.019	4.320± 0.204	2.185± 0.204
24000 ppm	10	1.379± 0.087	0.241± 0.028	4.318± 0.131	2.130± 0.116

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

Test of Dunnett

(HCL042)

BAIS2

APPENDIX B 12-1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (14W)

PAGE : 1

Organ	Findings	Group Name	Control				600 ppm				1500 ppm				3800 ppm			
		No. of Animals	10	10	10	10	10	10	10	10	10	10	10	10	10	10		
			<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Circulatory system]																		
heart	granulation		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Digestive system]																		
salivary gl	ectopic thymic tissue		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
liver	herniation		1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	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)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Urinary system]																		
kidney	basophilic change		1	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	eosinophilic body		0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0
			(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)
	hyaline cast		0	0	0	0	0	0	0	0	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	Rathke pouch		1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (14W)

PAGE : 2

Organ_____	Findings_____	Group Name	10000 ppm				24000 ppm			
		No. of Animals	10				10			
			<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Circulatory system]										
heart	granulation		1	0	0	0	1	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
[Digestive system]										
salivary gl	ectopic thymic tissue		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
liver	herniation		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	granulation		1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Urinary system]										
kidney	basophilic change		1	0	0	0	2	0	0	0
			(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
	eosinophilic body		1	9	0	0	1	9	0	0
			(10)	(90)	(0)	(0)	(10)	(90)	(0)	(0)
	hyaline cast		1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Endocrine system]										
pituitary	Rathke pouch		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(HPT150)

BAIS2

APPENDIX B 12-2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (14W)

PAGE : 3

Organ	Findings	Group Name	Control				600 ppm				1500 ppm				3800 ppm			
		No. of Animals	10	10	10	10	10	10	10	10	10	10	10	10	10	10		
			<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																		
bone marrow	granulation		2 (20)	0 (0)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	2 (20)	1 (10)	0 (0)	0 (0)	1 (10)	1 (10)	0 (0)	0 (0)
[Circulatory system]																		
heart	granulation		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	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		1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	granulation		3 (30)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Urinary system]																		
kidney	basophilic change		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 (10)	0 (0)	0 (0)	0 (0)
	mineralization:cortico-medullary junction		0 (0)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Endocrine system]																		
thyroid	ultimibranchial body remanet		0 (0)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	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)	1 (10)	0 (0)	0 (0)	0 (0)

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (14W)

PAGE : 4

		Group Name	10000 ppm				24000 ppm			
		No. of Animals	10				10			
Organ	Findings		<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Hematopoietic system]										
bone marrow	granulation		2 (20)	1 (10)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)
[Circulatory system]										
heart	granulation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Digestive system]										
liver	herniation		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
	granulation		3 (30)	0 (0)	0 (0)	0 (0)	3 (30)	0 (0)	0 (0)	0 (0)
[Urinary system]										
kidney	basophilic change		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	mineralization:cortico-medullary junction		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Endocrine system]										
thyroid	ultimibranchial body remanet		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	ectopic thymic tissue		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0146
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (14W)

PAGE : 5

Organ	Findings	Group Name No. of Animals				Control 10				600 ppm 10				1500 ppm 10				3800 ppm 10			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Special sense organs/appandage]																					
Harder gl	Lymphocytic infiltration	4	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		(40)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(HPT150)

BAIS2

STUDY NO. : 0146
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (14W)

PAGE : 6

Organ	Findings	Group Name No. of Animals	10000 ppm 10				24000 ppm 10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)

[Special sense organs/appandage]

Harder gl	Lymphocytic infiltration	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
-----------	--------------------------	------------	------------	------------	------------	-------------	------------	------------	------------

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(IPT150)

BAIS2

APPENDIX B 12-3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : FEMALE : DEAD AND MORIBUND ANIMALS

(13Week STUDY)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 14W)

PAGE : 1

Organ	Findings	Group Name No. of Animals	Control 1				600 ppm 0				1500 ppm 0				3800 ppm 0			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]																		
lung	congestion		1 (100)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	
[Hematopoietic system]																		
bone marrow	congestion		0 (0)	1 (100)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	
thymus	atrophy		0 (0)	1 (100)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	
spleen	atrophy		0 (0)	1 (100)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	
			<1>:Slight				<2>:Moderate				<3>:Marked				<4>:Severe			

(HPT150)

BA1S2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 14W)

PAGE : 2

		Group Name	10000 ppm				24000 ppm			
		No. of Animals	0				0			
Organ	Findings		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>										
[Respiratory system]										
lung	congestion		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
[Hematopoietic system]										
bone marrow	congestion		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
thymus	atrophy		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
spleen	atrophy		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

<1>:Slight

<2>:Moderate

<3>:Marked

<4>:Severe

(HPT150)

BAIS2

APPENDIX B 12-4

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : MALE : SACRIFICED ANIMALS

(13Week STUDY))

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (14W)

PAGE : 1

Organ	Findings	Group Name No. of Animals				Control 10				600 ppm 10				1500 ppm 10				3800 ppm 10			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																					
spleen	deposit of melanin	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
[Digestive system]																					
liver	granulation	1 (10)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
[Urinary system]																					
kidney	inflammatory polyp	0 (0)	0 (0)	0 (0)	0 (0)	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 (10)	0 (0)	0 (0)	0 (0)
	vacuolization of proximal tubule	9 (90)	0 (0)	0 (0)	0 (0)	9 (90)	0 (0)	0 (0)	0 (0)	9 (90)	0 (0)	0 (0)	0 (0)	9 (90)	0 (0)	0 (0)	0 (0)	9 (90)	0 (0)	0 (0)	0 (0)
	hydronephrosis	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(IPT150)

BAIS2

STUDY NO. : 0147
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (14W)

PAGE : 2

Organ	Findings	Group Name		10000 ppm				24000 ppm			
		No. of Animals		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
				(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]											
spleen	deposit of melanin			0	0	0	0	1	0	0	0
				(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
[Digestive system]											
liver	granulation			1	0	0	0	2	0	0	0
				(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
[Urinary system]											
kidney	inflammatory polyp			0	0	0	0	0	0	0	0
				(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	vacuolization of proximal tubule			10	0	0	0	8	0	0	0
				(100)	(0)	(0)	(0)	(80)	(0)	(0)	(0)
	hydronephrosis			1	0	0	0	0	0	0	0
				(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(IPT150)

BAIS2

APPENDIX B 12-5

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : FEMALE : SACRIFICED ANIMALS

(13Week STUDY))

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (14W)

PAGE : 3

Organ	Findings	Group Name No. of Animals	Control 9				600 ppm 10				1500 ppm 10				3800 ppm 10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]																		
lung	inflammation		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Hematopoietic system]																		
spleen	deposit of melanin		1 (11)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	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)	1 (10)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	3 (30)	0 (0)	0 (0)	0 (0)
[Urinary system]																		
kidney	basophilic change		1 (11)	0 (0)	0 (0)	0 (0)	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	Rathke pouch		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 (10)	0 (0)	0 (0)	0 (0)
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)	1 (10)	0 (0)	0 (0)	0 (0)
parathyroid	lymphocytic infiltration		0 (0)	0 (0)	0 (0)	0 (0)	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]																		
ovary	cyst		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0147
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (14W)

PAGE : 4

Organ_____	Findings_____	Group Name	10000 ppm				24000 ppm			
		No. of Animals	10				10			
		<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	
[Respiratory system]										
Lung	inflammation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Hematopoietic system]										
spleen	deposit of melanin		1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
[Digestive system]										
liver	granulation		2 (20)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
[Urinary system]										
kidney	basophilic change		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Endocrine system]										
pituitary	Rathke pouch		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
thyroid	ectopic thymic tissue		1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
parathyroid	lymphocytic infiltration		2 (20)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Reproductive system]										
ovary	cyst		2 (20)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0147
 ANIMAL : MOUSE BDF₁
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (14W)

PAGE : 5

Organ	Findings	Group Name No. of Animals				Control 9				600 ppm 10				1500 ppm 10				3800 ppm 10			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Nervous system]																					
brain	epidermal cyst	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(IIP150)

BAIS2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (14W)

[illegible][illegible]

(HPT150)

BAIS2

APPENDIX B 13-1

IDENTITY OF VINYL ACID

(13Week STUDY)

IDENTITY OF VINYL ACETATE(THIRTEEN-WEEK STUDIES)

Lot no.SAR5220

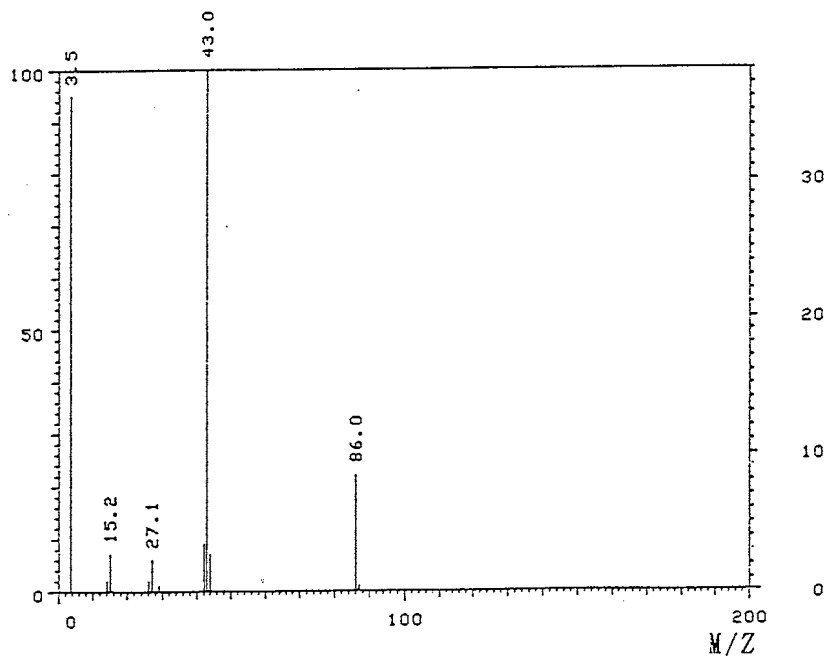
1. Spectral data

(1) Mass Spectrometry

Instrument: Hitachi M-80B Mass Spectrometer

Ionization: EI(Electron Ionization)

Ionization Voltage: 70eV



Mass Spectrum of Test Substance

Result:

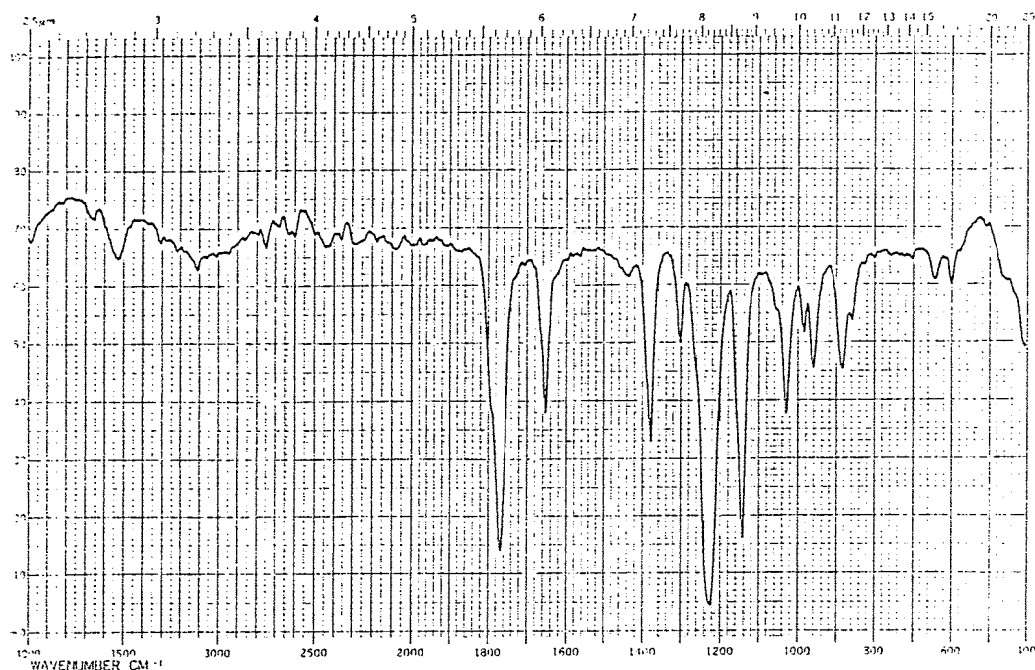
	Molecule Weight
Calculated Value	86.0
Determined Value	86.0

(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

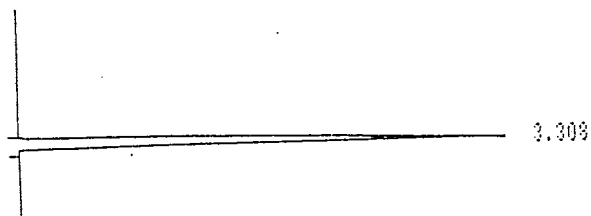
830~ 910
930~ 990
1000~1060
1110~1170
1180~1260
1280~1320
1340~1400
1630~1680
1730~1820

(*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	3.308	225559

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 B 13-2

STABILITY OF VINYL ACID

(13Week STUDY)

STABILITY OF VINYL ACETATE(THIRTEEN-WEEK STUDIES)

Lot no. SAR5220

1. Sample storage: This lot was used from 1990.03.27 to 1990.07.04. Test substance was stored at 5°C.

2. Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr

Slit : Medium

Results	<u>1990.03.27(date analyzed)</u>	<u>1990.07.03(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

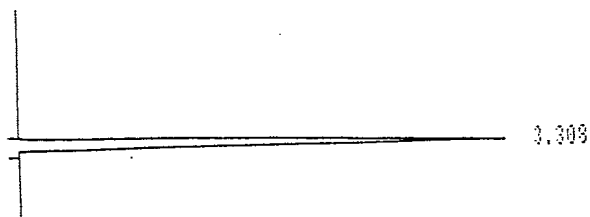
Flow Rate: 1 ml/min

Detector: FID(Flame Ionization Detector)

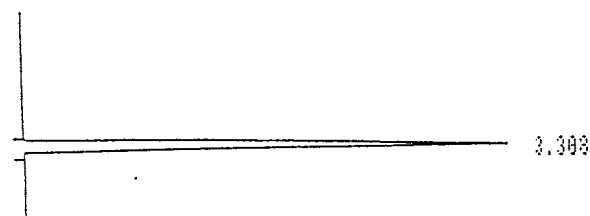
Injection Volume: 1 μ l

Results:Chromatogram indicated one major peak(peak No.1) analyzed at 1990.03.27 and one major peak(peak No.1) analyzed at 1990.07.03. The new trace impurity peak in the test substance analyzed at 1990.07.03 was not detected.

1990.03.27(date analyzed)



1990.07.03(date analyzed)



Chromatogram of Test Substance

Date	Peak No.	Retention Time(min)	AREA
1990.03.27 (date analyzed)	1	3.308	225559
1990.07.03 (date analyzed)	1	3.308	227092

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 months).

APPENDIX B 13-3

CONCENTRATION OF VINYL ACID IN DRINKING WATER

(13Week STUDY)

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

(Rat)

Date analyzed	Target Concentration(ppm)				
	600	1500	3800	10000	24000
1990.03.27	392.3(65.4)*	1259.1(83.9)	3243.8(85.4)	10249.9(102.5)	24416.6(101.7)

(Mouse)

Date analyzed	Target Concentration(ppm)				
	600	1500	3800	10000	24000
1990.04.03	504.9(84.2)	1231.3(82.1)	2974.0(78.3)	9479.8(94.8)	19490.6(81.2)

(*) % of target concentration

Analytical method: The sample were analyzed by the GC.

Instrument	: Hewlett Packard 5890A	Flow Rate	: 1ml/min
Column	: METHYL SILICONE(0.2mm ϕ \times 38m)	Detector	: FID(Flame Ionization)
Column Temperature:	40°C	Injection Volume	: 10 μ l
Carrier	: He		

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

(Rat)(Mouse)

Date analyzed	Target Concentration(ppm)				
	1200	3000	7600	20000	24000
1990.04.18	1065.6(88.8)*	2644.9(88.2)	6920.2(91.1)	17204.3(86.0)	26189.1(109.1)

(*) % of target concentration

Analytical method: The sample were analyzed by the GC.

Instrument	: Hewlett Packard 5890A	Flow Rate	: 1ml/min
Column	: METHYL SILICONE(0.2mm ϕ \times 38m)	Detector	: FID(Flame Ionization)
Column Temperature:	40°C	Injection Volume	: 10 μ l
Carrier	: He		

APPENDIX B 13-4

STABILITY OF VINYL ACID IN DRINKING WATER

(13Week STUDY)

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

(Rat)

Date analyzed	Target Concentration(ppm)				
	600	1500	3800	10000	24000
1990.03.27(a)	392.3	1259.1	3243.8	10249.9	24416.6
1990.03.31	300.2	885.8	1856.7	6067.4	14611.1

(Mouse)

Date analyzed	Target Concentration(ppm)				
	600	1500	3800	10000	24000
1990.04.03(a)	504.9	1231.3	2974.0	9479.8	19490.6
1990.04.07	277.0	815.0	2042.2	5723.4	13815.4

(a) Date of preparation

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

Analytical method: The sample were analyzed by the GC.

Instrument	: Hewlett Packard 5890A	Flow Rate	: 1ml/min
Column	: METHYL SILICONE(0.2mm ϕ \times 38m)	Detector	: FID(Flame Ionization)
Column Temperature:	40°C	Injection Volume	: 10 μ l
Carrier	: He		

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

(Rat)

Date analyzed	Target Concentration(ppm)				
	1200	3000	7600	20000	24000
1990. 04. 18(a)	1065. 6	2644. 9	6920. 2	17204. 3	26189. 1
1990. 04. 21	786. 6	2094. 4	5503. 9	13638. 8	20823. 0

(Mouse)

Date analyzed	Target Concentration(ppm)				
	1200	3000	7600	20000	24000
1990. 04. 18(a)	1065. 6	2644. 9	6920. 2	17204. 3	26189. 1
1990. 04. 21	537. 6	1590. 2	4082. 3	10182. 7	16281. 2

(a) Date of preparation

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

Analytical method: The sample were analyzed by the GC.

Instrument	: Hewlett Packard 5890A	Flow Rate	: 1ml/min
Column	: METHYL SILICONE(0.2mm ϕ \times 38m)	Detector	: FID(Flame Ionization)
Column Temperature:	40°C	Injection Volume	: 10 μ l
Carrier	: He		

APPENDIX C 1

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINARYSIS

Item	Method	Unit
Hematology		
Red blood cell (RBC)	Light scattering method ¹⁾	$\times 10^6 / \mu l$
Hemoglobin (Hgb)	Cyanmethemoglobin method ¹⁾	g/dl
Hematocrit (Hct)	Calculated as $RBC \times MCV / 10$ ¹⁾	%
Mean corpuscular volume (MCV)	Light scattering method ¹⁾	fl
Mean corpuscular hemoglobin (MCH)	Calculated as $Hgb / RBC \times 10$ ¹⁾	pg
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as $Hgb / Hct \times 10$ ¹⁾	g/dl
Platelet	Light scattering method ¹⁾	$\times 10^3 / \mu l$
White blood cell (WBC)	Light scattering method ¹⁾	$\times 10^3 / \mu l$
Differential WBC	Pattern recognition method ²⁾ (May Grunwald Giemsa staining)	%
Biochemistry		
Total protein (TP)	Biuret method ³⁾	g/dl
Albumin (Alb)	BCG method ³⁾	g/dl
A/G ratio	Calculated as $Alb / (TP - Alb)$ ³⁾	
T-bilirubin	Michaelson method ³⁾	mg/dl
Glucose	Enzymatic method (HK · G-6-PDH) ³⁾	mg/dl
T-cholesterol	Enzymatic method (CEH · COD · POD) ³⁾	mg/dl
Triglyceride	Enzymatic method (GK · GPO · POD) ³⁾	mg/dl
Phospholipid	Enzymatic method (PLD · COD · POD) ³⁾	mg/dl
Glutamic oxaloacetic transaminase (GOT)	Karmen method ³⁾	IU/l
Glutamic pyruvic transaminase (GPT)	Karmen method ³⁾	IU/l
Lactate dehydrogenase (LDH)	Wroblewski-LaDue method ³⁾	IU/l
Alkaline phosphatase (ALP)	GSCC method ³⁾	IU/l
γ -Glutamyl transpeptidase (G-GTP)	L- γ -Glutamyl p-nitroanilide substrate method ³⁾	IU/l
Creatine phosphokinase (CPK)	GSCC method ³⁾	IU/l
Urea nitrogen	Enzymatic method (Ureadse · GLDH) ³⁾	mg/dl
Creatinine	Jaffe method ³⁾	mg/dl
Sodium	Flame photometry ⁴⁾	mEq/l
Potassium	Flame photometry ⁴⁾	mEq/l
Chloride	Coulometric titration ⁴⁾	mEq/l
Calcium	OCPC method ³⁾	mg/dl
Inorganic phosphorus	Enzymatic method (SPL · PGM · G-6-PDH) ³⁾	mg/dl
Urinalysis		
pH, Protein, Glucose, Ketone body, Bilirubin, Occult Blood, Urobilinogen	Urinalysis reagent paper method ⁵⁾	

1) Automatic blood cell analyzer (Technicon H-1 : Technicon Instruments Corporation, USA)

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

3) Automatic analyzer (Hitachi 705 : Hitachi, Ltd., Japan)

4) Flame photometer (Hitachi 750 : Hitachi, Ltd., Japan)

5) Ames reagent strips for urinalysis (Multistix, Uro-Labstix : Miles Sankyo Co., Ltd., Japan)

APPENDIX C 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY

	TEST ITEM	DECIMAL PLACE	UNIT
HEMATOLOGY	Red blood cell	2	$10^6/\mu\text{l}$
	Hemoglobin	1	g/dl
	Hematocrit	1	%
	MCV	1	fl
	MCH	1	pg
	MCHC	1	g/dl
	Platelet	0	$\times 10^3/\mu\text{l}$
	White blood cell	2	$\times 10^3/\mu\text{l}$
	Differential WBC	0	%
BIOCHEMISTRY	Total protein	1	g/dl
	Albumin	1	g/dl
	A/G ratio	1	—
	T-bilirubin	2	mg/dl
	Glucose	0	mg/dl
	T-cholesterol	0	mg/dl
	Triglyceride	0	mg/dl
	Phospholipid	0	mg/dl
	GOT	0	IU/l
	GPT	0	IU/l
	LDH	0	IU/l
	ALP	0	IU/l
	γ -GTP	0	IU/l
	CPK	0	IU/l
	Urea nitrogen	1	mg/dl
	Creatinine	1	mg/dl
	Sodium	0	mEq/l
	Potassium	1	mEq/l
	Chloride	0	mEq/l
	Calcium	1	mg/dl
	Inorganic phosphorus	1	mg/dl