N,N-ジメチルホルムアミドのラット及びマウスを用いた 吸 入 に よ る が ん 原 性 予 備 試 験 報 告 書

APPENDIX

(B1-1~C1)

2週間試験:ラット/0263;マウス/0264

APPENDIXES (CONTINUED)

- APPENDIX B 1-1 BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
 RAT:MALE
- APPENDIX B 1-2 BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
 RAT:FEMALE
- APPENDIX B 1-3 BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
 MOUSE:MALE
- APPENDIX B 1-4 BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
 MOUSE:FEMALE
- APPENDIX B 2-1 FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
 RAT:MALE
- APPENDIX B 2-2 FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
 RAT:FEMALE
- APPENDIX B 2-3 FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
 MOUSE:MALE
- APPENDIX B 2-4 FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
 MOUSE:FEMALE
- APPENDIX B 3-1 HEMATOLOGY (THIRTEEN-WEEK STUDY:SUMMARY)
 RAT:MALE
- APPENDIX B 3-2 HEMATOLOGY (THIRTEEN-WEEK STUDY:SUMMARY)
 RAT:FEMALE
- APPENDIX B 3-3 HEMATOLOGY (THIRTEEN-WEEK STUDY:SUMMARY)
 MOUSE:MALE
- APPENDIX B 3-4 HEMATOLOGY (THIRTEEN-WEEK STUDY:SUMMARY)
 MOUSE:FEMALE
- APPENDIX B 4-1 BIOCHEMISTRY (THIRTEEN-WEEK STUDY: SUMMARY)
 RAT:MALE
- APPENDIX B 4-2 BIOCHEMISTRY (THIRTEEN-WEEK STUDY: SUMMARY)
 RAT: FEMALE
- APPENDIX B 4-3 BIOCHEMISTRY (THIRTEEN-WEEK STUDY: SUMMARY)
 MOUSE: MALE
- APPENDIX B 4-4 BIOCHEMISTRY (THIRTEEN-WEEK STUDY: SUMMARY)
 MOUSE: FEMALE

APPENDIXES (CONTINUED)

- APPENDIX B 5-1 URINALYSIS (THIRTEEN-WEEK STUDY:SUMMARY)
 RAT:MALE
- APPENDIX B 5-2 URINALYSIS (THIRTEEN-WEEK STUDY:SUMMARY)
 RAT:FEMALE
- APPENDIX B 5-3 URINALYSIS (THIRTEEN-WEEK STUDY:SUMMARY)
 MOUSE:MALE
- APPENDIX B 5-4 URINALYSIS (THIRTEEN-WEEK STUDY:SUMMARY)
 MOUSE:FEMALE
- APPENDIX B 6-1 GROSS FINDINGS (THIRTEEN-WEEK STUDY: SUMMARY)
 RAT:MALE:SACRIFICED ANIMALS
- APPENDIX B 6-2 GROSS FINDINGS (THIRTEEN-WEEK STUDY:SUMMARY)
 RAT:FEMALE:SACRIFICED ANIMALS
- APPENDIX B 6-3 GROSS FINDINGS (THIRTEEN-WEEK STUDY:SUMMARY)
 MOUSE:MALE:SACRIFICED ANIMALS
- APPENDIX B 6-4 GROSS FINDINGS (THIRTEEN-WEEK STUDY:SUMMARY)
 MOUSE:FEMALE:SACRIFICED ANIMALS
- APPENDIX B 7-1 ORGAN WEIGHT (THIRTEEN-WEEK STUDY: SUMMARY), ABSOLUTE RAT: MALE
- APPENDIX B 7-2 ORGAN WEIGHT (THIRTEEN-WEEK STUDY: SUMMARY), ABSOLUTE RAT: FEMALE
- APPENDIX B 7-3 ORGAN WEIGHT (THIRTEEN-WEEK STUDY: SUMMARY), ABSOLUTE MOUSE: MALE
- APPENDIX B 7-4 ORGAN WEIGHT (THIRTEEN-WEEK STUDY: SUMMARY), ABSOLUTE MOUSE: FEMALE
- APPENDIX B 8-1 ORGAN WEIGHT (THIRTEEN-WEEK STUDY: SUMMARY), RELATIVE RAT: MALE
- APPENDIX B 8-2 ORGAN WEIGHT (THIRTEEN-WEEK STUDY: SUMMARY), RELATIVE RAT: FEMALE
- APPENDIX B 8-3 ORGAN WEIGHT (THIRTEEN-WEEK STUDY: SUMMARY), RELATIVE MOUSE: MALE
- APPENDIX B 8-4 ORGAN WEIGHT (THIRTEEN-WEEK STUDY: SUMMARY), RELATIVE MOUSE: FEMALE

APPENDIXES (CONTINUED)

- APPENDIX B 9-1 HISTOLOGICAL FINDINGS:NON-NEOPLASTIC LESIONS (THIRTEEN-WEEK STUDY:SUMMARY)
 RAT:MALE:SACRIFICED ANIMALS
- APPENDIX B 9-2 HISTOLOGICAL FINDINGS:NON-NEOPLASTIC LESIONS (THIRTEEN-WEEK STUDY:SUMMARY)
 RAT:FEMALE:SACRIFICED ANIMALS
- APPENDIX B 9-3 HISTOLOGICAL FINDINGS:NON-NEOPLASTIC LESIONS (THIRTEEN-WEEK STUDY:SUMMARY)
 MOUSE:MALE:SACRIFICED ANIMALS
- APPENDIX B 9-4 HISTOLOGICAL FINDINGS:NON-NEOPLASTIC LESIONS (THIRTEEN-WEEK STUDY:SUMMARY)
 MOUSE:FEMALE:SACRIFICED ANIMALS
- APPENDIX B 10-1 IDENTITY OF N,N-DIMETHYLFORMAMIDE (THIRTEEN-WEEK STUDIES)
- APPENDIX B 10-2 STABILITY OF NN-DIMETHYLFORMAMIDE (THIRTEEN-WEEK STUDIES)
- APPENDIX B 11-1 CONCENTRATION OF N,N-DIMETHYLFORMAMIDE IN INHALATION CHAMBER (THIRTEEN-WEEK STUDIES)
- APPENDIX B 11-2 ENVIRONMENT OF INHALATION CHAMBER (THIRTEEN-WEEK STUDIES)
- APPENDIX B 12 METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS (THIRTEEN-WEEK STUDIES)
- APPENDIX C 1 UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY

APPENDIX B 1-1

BODY WEIGHT CHANGES :SUMMARY, RAT : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO.: 0275 ANIMAL : RAT F344

UNIT : g REPORT TYPE : A1 13

SEX : MALE

BODY WEIGHT CHANGES (SUMMARY) ALL ANIMALS

Nup Name	Admini	stratio	n week											
	0		1		1		2		3		4		5	
Contral	115±	4	119±	5	141±	9	169± 13		190±	14	215±	13	232±	14
50 ppm	115±	4	120±	4	143±	8	173± 12		193±	16	218±	15	237±	16
100 ppm	115±	4	119±	5	142±	7	170± 9		192±	15	213±	16	230±	18
200 ppm	115±	4	119±	4	141±	6	167± 10		189±	13	212±	14	231±	14
400 ppm	115±	4	119±	5	137±	7	160± 10		178±	13	198±	12*	215±	14
800 ppm	115±	4	119±	4	131±	5**	156± 9*		168±	11**	185±	13**	201±	14**
Significant difference;	*: P ≦ (0.05	** : P ≤ 0.()1			Test of Dunnet	t				,		

(HAN260)

BAIS 3

PAGE: 1

STUDY NO.: 0275
ANIMAL: RAT F344

BODY WEIGHT CHANGES ALL ANIMALS (SUMMARY)

UNIT : g REPORT TYPE : A1 13

SEX : MALE

PAGE: 2

oup Name	Admin	istration	week											
	6		7		8		9		10		11		12	
Control	247±	14	259±	15	271±	14	285±	17	293±	17	302±	17	311±	18
50 ppm	_251±	17	263±	18	277±	18	287±	17	295±	17	303±	18	310±	18
100 ppm	246±	17	260±	17	273±	18	283±	20	292±	21	301±	21	309±	22
200 ppm	244±	14	258±	14	270±	16	280±	15	289±	18	296±	20	304±	19
400 ppm	$227\pm$	15*	238±	15*	250±	18*	257±	18**	263±	19**	271±	20**	275±	19**
mag 008	208±	14**	219±	16**	229±	17**	235±	15**	241±	15**	249±	16**	252±	17**
					···							······································		
Significant difference	:e; *:P≦(0.05	**: P ≦ 0.0)1			Test of Du	ınnett						

(HAN260)

STUDY NO. : 0275 ANIMAL : RAT F344

UNIT : g
REPORT TYPE : A1 13

SEX : MALE

BODY WEIGHT CHANGES (SUMMARY) ALL ANIMALS

Group Name	Administration week 13		
Control	316± 17		
50 ppm	315± 17		
100 ppm	312± 22		
200 ppm	310± 20		
400 ppm	277± 18**		
Mdd 008	253± 18**		
Significant differer	nce; $*: P \le 0.05$ $**: P \le 0.01$	Test of Dunnett	

(HAN260)

BAIS 3

PAGE: 3

APPENDIX B 1-2

BODY WEIGHT CHANGES: SUMMARY, RAT: FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0275 ANIMAL : RAT F344 UNIT : g

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

REPORT TYPE : A1 13

SEX : FEMALE

PAGE: 4

oup Name	Admini	stratic	n week											
	0		1		1		2		3		4		5	
Control	96±	3	98±	3	109±	3	124±	4	132±	5	142±	6	148±	5
50 ppm	96±	3	98±	3	111±	4	126±	4	136±	5	146±	7	153±	7
100 ppm	96±	3	98土	3	110±	3	125±	4	136±	4	145±	5	152±	5
200 ppm	96±	2	97±	2	107±	3	122±	5	128±	4	137±	5	144±	5
400 ppm	96±	3	97±	3	106±	3	119±	5	124±	6**	132±	8**	140±	8*
Maja 008	96±	3	97±	2	101±	4**	113±	6**	115±	6**	120±	7**	129±	8**
												····		
Significant difference;	* : P ≦ (0.05	**: P ≤ 0.0)1			Test of Du	nnett						

(HAN260)

STUDY NO.: 0275 ANIMAL : RAT F344 BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

PAGE: 5

up Name	Admini	stration	week											
	6		7		8		9		10		11		· 12	
Control	156±	6	162±	6	166±	7	172±	8	176±	8	181±	8	183±	8
50 ppm	159±	7	166±	8	172±	8	174±	8	180±	8	185±	8	188±	9
100 ppm	159±	6	164±	4	169±	5	172±	7	177±	6	181±	8	183±	7
200 ppm	151±	7	156±	6	161±	7	165±	8	168±	9	173±	9	176±	7
400 ppm	141±	8**	147±	9**	152±	10**	154±	9**	155±	10**	161±	10**	160±	11**
nigg 008	128士	9**	132±	10**	138±	11**	137±	9**	139±	10**	147±	12**	146±	14**
Significant difference	e; *:P≦0	.05	**: P ≤ 0.0)1			Test of Dur	nett						

(HAN260)

STUDY NO.: 0275 ANIMAL: RAT F344

BODY WEIGHT CHANGES ALL ANIMALS (SUMMARY)

UNIT : g

REPORT TYPE : A1 13

SEX : FEMALE

PAGE: 6

oup Name	Administration week 13	
Control	185± 7	
50 ppm	192± 10	
100 ppm	187± 7	
200 ppm	176± 9	
400 ppm	161± 12*	
MQQ 008	142土 18**	
Significant differe	nce; *:P≤0.05 **:P≤0.01	Test of Dunnett

(HAN260)

BAISS

APPENDIX B 1-3

BODY WEIGHT CHANGES :SUMMARY, MOSUE : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0276

ANIMAL : MOUSE BDF1

UNIT : g
REPORT TYPE : A1 13

SEX : MALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

PAGE: 1

p Name	Admin	istratio	on week											
	0		1		1		2		3		4		5	-
Control	22.3±	0.8	22,5±	0.9	23.4±	1.1	24.8±	0.8	25.5±	1.0	26.1±	1.0	27.4士	1.0
50 ppm	22.3±	0.8	22.2±	0.8	22.8±	0.9	23.9±	0.9	24.5±	1.0	25.0±	0.7	26.1±	0.6*
100 ppm	22,3±	0.8	22.4±	0.7	23.1±	1.0	23.8±	0.9	24.7±	0.9	25.4±	1.2	25.9±	1.1*
200 ppm	22.3±	0.8	22.2±	1.0	22.8±	0.8	24.3±	0.9	25.3±	1.0	25.3±	1.0	25.5±	0.9**
400 ppm	22.4±	1.0	22.6±	0.9	23,6±	0,9	24.4±	1.2	25.2土	1.3	25.5±	1.4	26.2±	1.5
800 ppm	22.3±	1.1	22.4±	1.0	22.9±	1.0	23.3±	0.9**	23.6±	0,9**	24.0±	1.3**	25.4±	0.9**
Significant difference;	* ; P ≦	0.05	** ; P ≦ 0.	01	 		Test of D	unnett						

STUDY NO.: 0276

ANIMAL : MOUSE BDF1

UNIT : g
REPORT TYPE : A1 13

SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)

ALL ANIMALS

up Name	Administration	week					
	6	7	8	9	10	11	12
Control	27.7± 1.2	28.2± 1.2	28.8± 1.2	29.6± 1.4	30.5± 1.5	31.1± 1.6	31.9± 1.7
50 ppm	26.4± 1.0*	26,5± 1.1**	27.0± 1.3**	27.7± 1.2**	28.1± 1.5**	28.7± 1.6**	29.2士 1.9**
100 ppm	26.1± 1.4*	27.1± 1.2	27.0生 1.2**	27.8± 1.2*	28.7± 1.3*	29.2± 1.5*	29.9± 1.8*
200 ppm	26.2± 0.6*	26.5± 0.8**	26.6± 0.8**	27.4± 0.9**	27.7± 0.8**	28.1± 0.9**	28.8± 1.3**
400 ppm	26.5± 1.4	26.8± 1.3*	26.9± 1.4**	27.4± 1.5**	28.0± 1.5**	28.7士 2.1**	28.7± 2.0**
800 ppm	24.8± 1.1**	24.7± 1.2**	25.1± 0.9**	25.4士 1.1**	25.7± 1.3**	25.7± 1.7**	26.5± 1.2**
Significant differen	nce; *; P ≤ 0.05	** : P ≤ 0.01		Test of Dunnett			

(HAN260)

BAIS 3

PAGE: 2

STUDY NO.: 0276

ANIMAL : MOUSE BDF1

UNIT : g REPORT TYPE : A1 13

SEX : MALE

BODY WEIGHT CHANGES

(SUMMARY)

PAGE: 3

ALL ANIMALS

roup Name	Administration week		
	13		
·— ·····			
Control	32.5± 1.8		
50 ppm	29.6± 1.6**		
100 ppm	30.3± 1.8*		
200 ppm	29.5± 1.2**		
400 ppm	29.5± 2.0**		
Mqq 008	26.2± 1.5**		
Significant differ	ence; $*: P \leq 0.05$ $**: P \leq 0.01$	Test of Dunnett	
IAN260)			BAIS

APPENDIX B 1-4

BODY WEIGHT CHANGES: SUMMARY, MOSUE: FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO.: 0276

ANIMAL : MOUSE BDF1

UNIT ; g
REPORT TYPE : A1 13

SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 4

roup Name	Administratio	on week						
	0	1	1	2	3	4	5	
Cantrol	17.8± 0.8	18.0± 0.6	18.9± 0.7	20.0± 0.9	20.5± 0.9	20.9± 1.2	21.7± 1.1	
50 ppm	17.8± 0.8	17.9± 0.7	18.5± 0.9	20.2± 1.0	20.8± 1.2	21.3± 1.2	22.3± 1.3	
100 ppm	17.8± 0.8	17.9± 0.7	18.5± 0.7	20.0± 0.8	20.8± 0.7	21,8± 1.0	22.1± 0.6	
200 ppm	17.8± 0.7	18.1± 0.7	18.8± 0.8	20,2± 1.0	21.2± 0.8	21.4± 1.1	21.8± 0.8	
400 ppm	17.8± 0.9	17.6± 0.7	19.0± 0.6	20.1± 0.8	20.9± 0.7	21.9± 1.1	21.9± 0.8	
mag 008	17.9± 0.8	17.9± 0.6	18.7± 0.5	19.2± 0.6	19.7± 0.6	20.8± 0.6	22.1± 0.6	
Significant difference	; *: P ≤ 0.05	** : P ≤ 0.01		Test of Dunnett				

(IIAN260)

STUDY NO. : 0276

ANIMAL : MOUSE BDF1

UNIT : g

REPORT TYPE: A1 13

SEX : FEMALE

BODY WEIGHT CHANGES ALL ANIMALS (SUMMARY)

PAGE: 5

Jp Name	Administrat	ion week					
	6	7	8	9	10	11	12
Control	22.2± 1.0	22.6± 1.1	23.0± 1.2	23.1± 1.5	23.6± 1.3	23.7± 1.2	23.6± 1.3
50 ppm	22.8± 1.1	23.1± 1.0	23.7± 2.0	23.4± 1.1	24.2± 1.7	24.4± 1.6	24.5± 1.3
100 ppm	22.8± 0.7	23.7± 1.0	24.2± 1.3	24.1± 1.3	23.9± 1.0	24.5± 1.0	24.7± 1.0
200 ppm	22.7± 1.3	23.5± 1.4	24.2± 0.9	24.1± 1.2	24.6± 1.7	24.4± 1.4	25.5± 1.4**
400 ppm	22.8± 0.7	23.7± 0.8	24.0± 0.7	23.9± 1.0	24.5± 1.0	24.6± 0.8	24.8± 0.9
800 ppm	21.5± 0.6	21.7± 0.6	22.5± 1.0	22.5± 1.0	23.0± 0.4	23.3± 0.7	23.1± 0.8
Significant difference ;		** : P ≤ 0.01		Test of Dunnett			

(HAN260)

STUDY NO. : 0276

ANIMAL : MOUSE BDF1

UNIT : g REPORT TYPE : A1 13

BODY WEIGHT CHANGES

(SUMMARY)

ALL ANIMALS

EX : FEMALE					PAGE: 6
cup Name	Administration we 13	ek	•		
Cantrol	24.3± 1.6				
50 mag 03	25.0± 1.1				
100 ppm	24.4± 1.3				
200 ppm	25.0± 1.4				
400 ppm	25.1± 1.3				
mag 008	23.6± 0.7				
Significant difference ;	*: P ≦ 0.05 **	: P ≤ 0.01	Test of Dunnett		
MAN260)					BAIS3

APPENDIX B 2-1

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

STUDY NO.: 0275
ANIMAL: RAT F344
UNIT: g

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

REPORT TYPE : A1 13 SEX : MALE

PAGE: 1

roup Name	Administration	week					
	1	2	3	- 4	5	6	7
Contral	14.1± 0.7	15.2± 1.4	15.7± 1.6	16,2± 0.9	16.9± 1.4	16.7± 0.9	16.8± 1.2
50 ppm	14.3± 0.7	15.5± 1.1	15.9± 1.5	16.4± 1.4	16.7± 1.2	16.7± 1.2	16.6± 1.3
100 ppm	13.9± 0.6	15.5± 0.7	15.7± 1.4	16.1± 1.6	16.4± 1.4	16.1± 1.4	16.4± 1.2
200 ppm	13.4± 0.7	14.4± 0.8	15.1± 0.9	15.9± 1.2	16.9± 1.3	16.0± 1.1	16.9± 1.0
400 ppm	12.8± 0.7**	14.0± 1.1	14.5± 1.3	15.1± 1.2	15.3± 0.9*	15.4± 1.5	15.6± 1.9
Mqq 008	12,0± 0,8**	13.3± 1.3**	13.0± 1.1**	14.4± 1.3*	14.7土 1.7**	14.8士 1.8**	15.2± 1.7
Significant difference	; *: P ≤ 0,05	** ; P ≤ 0.01		Test of Dunnett			

(HAN260)

STUDY NO. : 0275 ANIMAL : RAT F344

UNIT : g
REPORT TYPE : A1 13

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE : 2

p Name	Administration	week				
	8	9	10	11	12	13
Control	16.4± 1.2	16.9± 1.2	16.5± 0.9	16.8± 1.0	16.4± 1.1	16.5± 0.8
50 ppm	16.7± 1.0	16.8± 0.9	16.4± 0.8	16.8± 0.9	16.1± 1.1	16.4± 0.7
100 ppm	16.7± 1.3	16.4± 1.4	16.3± 1.1	16.6± 0.9	16.4± 1.2	16.0± 1.1
200 ppm	16.2± 1.2	16.3± 1.4	16.1± 1.3	16.3± 1.3	15.7± 1.3	15.9± 1.2
400 ppm	15.3± 1.3	15.6± 1.4	15.6± 1.3	15.5± 1.6	15.3± 1.7	15.6± 1.5
.800 ppm	15.1± 1.1	14.7± 0.9**	14.9士 1.7*	14.9± 1.8*	14.5± 1.8*	14.3± 1.6**
Significant differer	nce; *: P ≦ 0.05	**: P ≤ 0.01		Test of Dunnett		

(HAN260)

APPENDIX B 2-2

FOOD CONSUMPTION CHANGES: SUMMARY, RAT: FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO.: 0275 ANIMAL : RAT F344

UNIT : g REPORT TYPE : A1 13

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 3

p Name	Administration	week					
	1	2	3	4	5	6	7
Control	11.4± 0.6	11.9± 0.7	11.7± 0.7	11.5± 0.7	11.8± 0.7	11.7± 1.1	11.8± 1.1
50 ppm	11.4± 0.4	12.3± 0.7	12.4± 0.5	12.2± 0.7	12.1± 0.8	12.0± 0.8	12.5± 1.1
100 ppm	11.7± 0.5	12.1± 0.7	12.2± 0.6	12.1± 0.5	12.1± 0.6	11.5± 0.6	11.8± 0.5
200 ppm	10.3± 1.2	11.4± 1.0	10.9± 0.8	10.5± 0.6	11.6± 0.9	11.0± 0.9	11.3± 1.0
400 ppm	10.1± 0.5*	10.6± 0.7**	10.2± 1.0**	10.5± 1.6	11.2± 1.0	10.4± 1.4	10.6± 1.4
800 ppm	8.8± 0.6**	9.7± 0.9**	9.0± 0.8**	8.8± 1.0**	9.8± 1.1**	9.0± 1.7**	9.0± 1.5**

(HAN260)

STUDY NO.: 0275 ANIMAL : RAT F344 UNIT : g FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

REPORT TYPE : A1 13 SEX: FEMALE

PAGE: 4

Name	Administration	week					
	8	9	10	11	12	13	
Control	11.4± 0.8	11.7± 1.1	11.4± 0.9	11.8± 0.6	11.1± 0.8	11.0± 0.7	
50 ppm	11.9± 1.1	12.1± 1.0	11.7± 0.8	12.5± 1.2	11.6± 1.3	11.6± 1.1	
100 ppm	11.4± 0.6	11.5± 0.7	11.8± 1.1	11.6± 0.7	11.3± 0.6	11.1± 0.5	
200 ppm	10.9± 0.9	10.8± 0.8	10.3± 1.2	11.3± 0.8	10.2± 0.7	10.0± 0.8	
400 ppm	10.3± 1.2	9.7± 0.9**	9.4± 1.3**	10.4± 1.2	9.2± 1.4*	9.6± 1.7	
800 ppm	9.2± 1.4**	8.1± 1.1**	8.6± 1.7**	9.9± 1.8*	9.0± 2.2*	8.5± 2.5*	
Significant difference	e; *:P≦0.05	**: P ≤ 0.01		Test of Dunnett			

(HAN260)

APPENDIX B 2-3

FOOD CONSUMPTION CHANGES: SUMMARY, MOSUE: MALE

(THIRTEEN - WEEK STUDY)

STUDY NO.: 0276

ANIMAL : MOUSE BDF1

UNIT : g

REPORT TYPE: A1 13

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 1

oup Name	Administration	Administration week							
	1	2	3	4	5	6	7		
Control	4.1± 0.2	4.1± 0.1	4.2± 0,2	4.2± 0.2	4.3± 0.1	4.2± 0.2	4.4± 0.2		
50 ppm	3.8± 0.3	4.0± 0.2	4.0± 0.2	4.1± 0.2	4.2± 0.3	4.1± 0.2	4.2± 0.3		
100 ppm	3.9± 0.3	4.0± 0.1	4.3± 0.2	4.3± 0.2	4.3± 0.2	4.3± 0.2	4.4± 0.1		
200 ppm	3.8± 0.1	4.1± 0.2	4.1± 0.1	4.0± 0.2	4.0± 0.2*	4.1± 0.2	4.2± 0.1		
400 ppm	3.6± 0.4**	4.3± 1.1	4.1± 0.4	4.1± 0.3	4.1± 0.3	4.2± 0.3	4,2± 0.3		
Maja 008	3.2± 0.3**	4.3± 1.4	3.7± 0.4**	3.6± 0.4**	3.7± 0.3**	3.5± 0.3**	3.6± 0.2**		
Significant differen	ce; *: P ≤ 0.05 *	**: P ≦ 0.01		Test of Dunnett					

(HAN260)

STUDY NO.: 0276

ANIMAL : MOUSE BDF1

UNIT : g
REPORT TYPE : A1 13

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 2

Froup Name	Λdministration	week						
	8	9	10	11	12	13		
Control	4.4± 0.2	4.5± 0.2	4.5± 0.2	4.4± 0.2	4.5± 0.2	4.4± 0.2		
50 ppm	4.2± 0.3	4.4± 0.2	4.3± 0.3	4.4± 0.3	4.4± 0.3	4,3± 0,3		
100 ppm	4.2± 0.2	4.5± 0.1	4.5± 0.2	4.4± 0.2	4.5± 0.2	4.4± 0.2		
200 ppm	4.1± 0.2**	4.5± 0.2	4.2± 0.3	4.2± 0.2	4.3± 0.2	4.3± 0.2		
400 ppm	4.2± 0.3	4.2± 0.2	4.3± 0.4	4.3± 0.3	4.2± 0.3*	4.3± 0.2		
maa 008	3.7± 0.2**	3.7± 0.3**	3.7± 0.4**	3.6± 0.3**	3.8± 0.2**	3.7± 0.3**		
Significant difference	ce; *: P ≤ 0.05	* : P ≤ 0.01		Test of Dunnett				

(HAN260)

APPENDIX B 2-4

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

STUDY NO.: 0276

ANIMAL : MOUSE BDF1

UNIT : g
REPORT TYPE : A1 13

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 3

DUD Name	Administration	week					
	1	2	3	4	5	6	7
Control	3.3± 0.2	3.5± 0.2	3.7± 0.3	3.8± 0.3	4.0± 0.2	4.1± 0.3	4.2± 0.3
50 ppm	3.3± 0.3	3.7± 0.2	3.8± 0.3	4.0± 0.2	4.1± 0.2	4.1± 0.2	4.3± 0.2
100 ppm	3.3± 0.2	3.6± 0.3	3.8± 0.3	4.0± 0.4	4.1± 0.3	4.2± 0.3	4.3± 0.3
200 ppm	3.3± 0.3	3.7± 0.3	3.9± 0.3	3.8± 0.2	4.0± 0.2	4.1± 0.3	4.2± 0.3
400 ppm	3.0± 0.4	3.8± 0.9	3.6± 0.2	3.8± 0.3	3.8± 0.2	3.9± 0.2	4.2± 0.2
800 ppm	2.8± 0.4**	3.6± 0.8	3.6± 0.2	3.6± 0.3	3.6± 0.3*	3.4± 0.3**	3.7± 0.3**
Significant differen	nce; *: $P \le 0.05$ *	$*: P \leq 0.01$		Test of Dunnett			

(HAN260)

STUDY NO.: 0276

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	4.2± 0,2	4.4± 0.2	4.3± 0.3	4.2± 0.2	4.2± 0.2	4.3± 0.3	
F0	4.4102	4 2 4 4 2	4.4.1.0.2	4.4.1.0.2	441 03	4 2 4 0 4	
50 ppm	4,4± 0.3	4.3± 0.3	4.4± 0.3	4.4± 0.3	4.4± 0.2	4.3± 0.4	
100 ppm	4.3± 0.4	4.4± 0.3	4.2± 0.2	4.3± 0.4	4.4± 0.4	4.2± 0.3	
200 ppm	4.3± 0.2	4.3± 0.2	4.3± 0.2	4.3± 0.2	4.4生 0.2	4.2± 0.4	
400 ppm	4.3± 0.2	4.2± 0.3	4.3± 0.3	4.2± 0.3	4.3± 0.3	4.4± 0,3	
mad 008	3.8± 0.2**	3.8± 0.3**	3,9± 0.2**	3.8± 0.1*	3.8± 0.1	4.0± 0.3	
Significant differen	ce; *: $P \le 0.05$ *	$*:P \leq 0.01$		Test of Dunnett			

(HAN260)

APPENDIX B 3-1

HEMATOLOGY: SUMMARY, RAT: MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0275

ANIMAL : RAT F344 SAMPLING DATE : 014-1 HEMATOLOGY (SUMMARY) SURVIVAL ANIMALS (14)

SEX : MALE

REPORT TYPE : A1

SEA . MALE REPURITIFE : AI

)	9.40±	0.42												
		V. 46	16.4±	0.4	46.2±	1.9	49.2±	0.5	17.5±	0.8	35.6±	1.4	708±	62
0	9.76±	0.15	16.2±	0.3	46.8±	1.0	48.0±	0.6**	16.7±	0.2	34.7±	0.6	795±	44**
0	9.86±	0.15*	16.2±	0.2	46.8±	0.8	47.5±	0.5**	16.5±	0.2	34.7±	0.6	822±	21**
)	9.91±	0.17**	15,9±	0.3**	46.1±	1.4	46.6±	0.8**	16.0±	0.2**	34.5±	0.8	842±	33**
)	9.70±	0.72*	15.4±	1.3**	44.6±	3.7	46.0±	0.8**	15.9±	0.2**	34.5±	0.4*	838±	51**
) 1	10.33±	0.29**	16.5±	0.4	47.8±	1.4	46.3±	0.5**	16.0±	0.3**	34.5±	0.6*	901±	35**
)		9.91± 9.70±	9.91± 0.17** 9.70± 0.72*	9.91± 0.17** 15.9± 9.70± 0.72* 15.4±	9.91± 0.17** 15.9± 0.3** 9.70± 0.72* 15.4± 1.3**	9.91± 0.17** 15.9± 0.3** 46.1± 9.70± 0.72* 15.4± 1.3** 44.6±	9.91± 0.17** 15.9± 0.3** 46.1± 1.4 9.70± 0.72* 15.4± 1.3** 44.6± 3.7	9.91± 0.17** 15.9± 0.3** 46.1± 1.4 46.6± 9.70± 0.72* 15.4± 1.3** 44.6± 3.7 46.0±	9.91± 0.17** 15.9± 0.3** 46.1± 1.4 46.6± 0.8** 9.70± 0.72* 15.4± 1.3** 44.6± 3.7 46.0± 0.8**	9.91± 0.17** 15.9± 0.3** 46.1± 1.4 46.6± 0.8** 16.0± 9.70± 0.72* 15.4± 1.3** 44.6± 3.7 46.0± 0.8** 15.9±	9.91± 0.17** 15.9± 0.3** 46.1± 1.4 46.6± 0.8** 16.0± 0.2** 9.70± 0.72* 15.4± 1.3** 44.6± 3.7 46.0± 0.8** 15.9± 0.2**	9.91± 0.17** 15.9± 0.3** 46.1± 1.4 46.6± 0.8** 16.0± 0.2** 34.5± 9.70± 0.72* 15.4± 1.3** 44.6± 3.7 46.0± 0.8** 15.9± 0.2** 34.5±	9.91 \pm 0.17** 15.9 \pm 0.3** 46.1 \pm 1.4 46.6 \pm 0.8** 16.0 \pm 0.2** 34.5 \pm 0.8 9.70 \pm 0.72* 15.4 \pm 1.3** 44.6 \pm 3.7 46.0 \pm 0.8** 15.9 \pm 0.2** 34.5 \pm 0.4*	9.91± 0.17** 15.9± 0.3** 46.1± 1.4 46.6± 0.8** 16.0± 0.2** 34.5± 0.8 842± 9.70± 0.72* 15.4± 1.3** 44.6± 3.7 46.0± 0.8** 15.9± 0.2** 34.5± 0.4* 838±

(HCL070)

BAIS3

PAGE: 1

STUDY NO.: 0275 ANIMAL : RAT F344 HEMATOLOGY (SUMMARY) SURVIVAL ANIMALS (14)

SAMPLING DATE: 014-1

SEX : MALE

REPORT TYPE : A1

PAGE: 2 Group Name NO. ⊡f RETICULOCYTE PROTHROMBIN TIME APTT Animals secsec Control 10 34士 9 17.4± 2.3 23.7± 0.9 50 ppm 10 32± 7 16.0± 1.9 24.0± 0.7 100 ppm $30 \pm$ 16.4± 2.1 24.8± 1.6 10 200 ppm 10 $33\pm$ 6 14.4± 1.2 24.2± 1.3 400 ppm 10 $34 \pm$ 10 $11.9 \pm$ 0.3** 20.1士 1.4** mqq 008 10 $30\pm$ 7 12.6± 1.3** 19.3± 2.3** Significant difference; $*: P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(IICL070)

STUDY NO.: 0275 ANIMAL : RAT F344

SAMPLING DATE : 014-1 SEX : MALE

HEMATOLOGY (SUMMARY) SURVIVAL ANIMALS (14)

: MALE		TYPE : A1									····					PAGE	•
up Name	NO. of Animals	WBC 1 O³∕		Dif N-BAND	ferentia	L WBC (% N-SEG	·)	EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	10	4.85±	2.01	0±	1	30±	9	1±	1	0±	0	3±	1	65±	9	0±	0
50 ppm	10	5.37±	1,52	1±	1	27±	4	1±	1	. 0±	0	4±	2	67±	4	0±	0
100 ppm	10	5.34±	1.87	0±	0	27±	6	1±	1	0±	0	3±	1	69±	7	0±	0
200 ppm	10	5.52±	1.54	0±	1	30±	8	1±	1	0±	0	3±	1	66±	7	0±	0
400 ppm	10	4.29±	0.98	1±	1	30±	5	1±	1	0±	0	3±	1	65±	7	0±	0
mqq 008	10	4.91±	1.60	1±	1	29±	6	2±	2	0±	0	5±	2*	63±	7	0±	0

(IICL070)

APPENDIX B 3-2

HEMATOLOGY: SUMMARY, RAT: FEMALE

ANIMAL : RAT F344 SAMPLING DATE: 014-1 HEMATOLOGY (SUMMARY) SURVIVAL ANIMALS (14)

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

up Name	NO. of Animals	RED BLO	OOD CELL	HEMOGLO g/dl		HEMATOC %	RIT	MCV f Q		MCH pg		MCHC g∕dl		PLATELE 1 Ο³ / μ	
Control	10	8,69±	0,19	16.3±	0.4	45.9±	0.7	52,8±	0,6	18.8±	0,3	35.6±	0.7	763±	59
50 ppm	10	8.68±	0.52	16.2±	0.4	45.4±	2.5	52.3±	0.6	18.8±	1.2	35.9±	2.1	819±	29
100 ppm	10	8.87±	0.13	16.3±	0.3	46.2±	1.0	52.0±	0.7	18.4±	0.2	35.2±	0.7	884±	59**
200 ppm	10	9.12±	0.11*	16.2±	0.3	46.0±	0.5	50.5±	0,6**	17.8±	0.2**	35.3±	0.4	879±	35**
400 ppm	10	9.41±	0.22**	16.6±	0,3	46.9±	1.3	49.9±	0.6**	17.6±	0.1**	35.3±	0.5	810±	40
mag 008	10	9.53±	0.46**	16.5±	1.1	46.5±	2.0	48.8±	0.9**	17.3±	0.8**	35.5±	1.6	920±	209**

(IICL070)

STUDY NO.: 0275 ANIMAL: RAT F344 SAMPLING DATE: 014-1
SEX: FEMALE HEMATOLOGY (SUMMARY) SURVIVAL ANIMALS (14)

ib Name	NO. of Animals	RETICUL	OCYTE	PROTHROI sec	MBIN TIME	APTT sec		
Control	10	31±	9	11,7±	0.4	16.4±	1.0	
50 ppm	10	31±	6	11.5±	0.3	16.8±	0.7	
100 ppm	10	34±	8	11.8±	0.4	17.3±	9,0	
200 ppm	10	34±	9	11.7±	0.6	17.5±	1.3	
400 ppm	10	30±	5	12.3±	0.5	15.9±	1.1	
mqq 008	10	34±	16	12.8±	1.2*	16.8±	1.2	

(IICL070)

ANIMAL : RAT F344

HEMATOLOGY (SUMMARY) SURVIVAL ANIMALS (14)

SAMPLING DATE: 014-1

SEX : FEMALE

REPORT TYPE : A1

Group Name NO. af WBC Differential WBC (%) Animals 1 03/με N-BAND N-SEG EOSINO BASO MONO LYMPHO OTHERS Control 10 3.06± 0.81 0± $26 \pm$ 1 $2\pm$ 1 0± 0 $5\pm$ $68 \pm$ 5 0± 1 0 50 ppm 0± 10 2.73± 0.64 0 $25\pm$ 4 $1 \pm$ 1 $0\pm$ 0 4± 1 $70 \pm$ 3 0± 0 100 ppm 10 3.03± 0.98 0± 0 $29 \pm$ 9 $1\pm$ 1 0土 0 $4\pm$ 2 67± 9 0土 0 200 ppm 10 3.11 ± 0.51 1± $26\pm$ $1\pm$ 1 0± 0 $3\pm$ 69± 2 3 $0\pm$ 0 1± $3\pm$ 400 ppm 10 3.07 ± 1.39 1土 1 $26\pm$ 1 0士 0 69± 1 $0\pm$ mag 008 10 3.34± 1.04 $0\pm$ 0 26± 7 $1\pm$ 1 0± 0 $4\pm$ 2 $69\pm$ 9 $0\pm$ 0

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

(HCL070)

BAIS 3

PAGE: 6

APPENDIX B 3-3

HEMATOLOGY: SUMMARY, MOSUE: MALE

ANIMAL : MOUSE BDF1

SAMPLING DATE: 014-1 SEX: NALE

SURVIVAL ANIMALS (14)

HEMATOLOGY (SUMNARY)

REPORT TYPE : A1

PAGE: 1

roup Name	NO. of Animals	RED BLO 1 O ⁶ /μ	OD CELL	HEMOGLC g∕dl	DBIN	11EMATO(%	CRIT	MCV f Q		MCH Pg		MCHC g∕dl		PLATELE 1 0°/µ	
Control	9	10.98±	0.28	16.2±	0.3	50.6±	1.3	46.1±	0.5	14.8±	0.1	32.1±	0.4	1397±	98
50 ppm	10	10.78±	0.33	15.9±	0.5	48.9±	1.6	45.3±	0.3*	14.8±	0.1	32.6±	0.2	1585±	98**
100 ppm	10	10.70±	0.22	15.7±	0.4	48.4±	1.5*	45.3±	0.8*	14.7±	0.1	32.5±	0.3	1612±	85**
200 ppm	10	10.81±	0.46	15.7±	0.5*	48.3±	1.8*	44.7±	0.8**	14.5±	0.4*	32.5±	0.6	1671士	142**
400 ppm	10	10.81±	0.28	15.6±	0.5*	47.8±	1.4**	44.2±	0.8**	14.4±	0,2*	32.6±	0.3	1668±	82**
mqq 008	10	10.83±	0.39	16.0±	0.6	49.3±	2.0	45.5±	0.5	14.8±	0.2	32.6±	0.4	1576±	176**
Significant	difference;	* : P ≤ 0	0.05	** : P ≤ 0.()1			Test of Dur	nett						

(IICL070)

ANIMAL : MOUSE BDF1 SAMPLING DATE: 014-1

REPORT TYPE : A1

HEMATOLOGY (SUMMARY) SURVIVAL ANIMALS (14)

SEX : MALE PAGE: 2

oup Name	NO. of Animals	WBC 1 O³∕		Dif N-BAND	ferentia	L WBC (9 N-SEG	6)	EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	9	1.55±	1.02	0±	1	15±	3	1±	1	0±	0	3±	1	80±	3	0±	0
50 ppm	10	1.30±	0,74	0±	0	17±	6	1±	1	0±	0	2±	1	79±	6	0±	0
100 ppm	10	1.16±	0,99	0±	1	13±	4	1±	1	0±	0	3±	2	83±	4	0±	0
200 ppm	10	1.23±	0.82	0±	0	16±	7	1±	1	0±	0	3±	1	80士	6	0±	0
400 ppm	10	1.01±	0.76	0±	1	14±	3	1±	1	0±	0	3±	2	82±	2	0±	0
mqq 008	10	0.39±	0.25**	0±	1	20士	12	1±	1	0±	0	2±	2	76±	12	0±	0
Significant	difference;	*: P ≦	≦ 0.05	**: P ≤	0.01			Test	of Dunr	nett					·		
CL070)										· · · · · · · · · · · · · · · · · · ·							BAIS

APPENDIX B 3-4

HEMATOLOGY: SUMMARY, MOSUE: FEMALE

STUDY NO. : 0276 ANIMAL : MOUSE BDF1 HENATOLOGY (SUMMARY) SURVIVAL ANIMALS (14)

SAMPLING DATE: 014-1

SEX : FEMALE REPORT TYPE : A1

PAGE: 3

p Name	NO. of Animals	RED BL 1 06/	OOD CELL µl	HEMOGLC g∕dl		HEMATO(%	CRIT	MCV f &		MCII pg		MCHC g∕dl		PLATELE 1 0³/J	
Control	9	10.71±	0.24	16.2±	0.4	49.2±	1.2	46.0±	0.5	15.1±	0.2	32.9±	0.6	1167±	47
50 ppm	10	10.70±	0.26	16.2±	0.3	48.8±	1,3	45.6±	0.9	15.2±	0.3	33.2±	0.6	1382±	195
100 ppm	9	10.87±	0.30	16.1±	0.5	48.7±	1.3	44.8±	0.6**	14.8±	0.3	33.0±	0.3	1476±	62**
200 ppm	10	10.95±	0.36	16.0±	0.5	48.8±	1.7	44.6±	0.8**	14.6±	0.2**	32.7±	0.3	1511±	93**
400 ppm	9	10.86±	0.20	16.0±	0.4	48.8±	1.1	45.0±	0.6*	14.7±	0.3*	32.8士	0.5	1506±	95**
800 ppm	10	11.08±	0.55	16.7±	1.0	50.3±	2,9	45.4±	0.9	15.0±	0.2	33.1±	0.6	1529±	172**

ANIMAL : MOUSE BDF1

HEMATOLOGY (SUMMARY) SURVIVAL ANIMALS (14)

SAMPLING DATE: 014-1

SEX : FEMALE

REPORT TYPE: A1

NO. of WBC Group Name Differential WBC (%) Animals 1 03/128 N-BAND N-SEG EOSINO BASO MONO LYMPHO OTHERS Control 9 0.87 ± 0.66 0± 0 $25\pm$ 8 $0\pm$ 0土 0 $2\pm$ 72± 9 0± 1 1 0 50 ppm 10 0.71 ± 0.58 $0\pm$ 0 18± 8 1± 1 0± 0 $3\pm$ 78± 7 1 0土 0 100 ppm 9 1.01± 1.26 0土 0 17士 7 0± 0± 1 0 2± 2 80土 7 0± 0 200 ppm 10 1.01± 0.92 0土 0 14± 0土 0 4** 0± 0 $2\pm$ 1 83± 4** 0± 0 400 ppm 9 0.49± 0.20 0± 0 15± 7** 0土 0 $0\pm$ 0 $3\pm$ 2 82士 7* 0 $0\pm$ 800 ppm 10 0.62± 0.57 0± 0 16± 5* 0 土 0 0± 0 $2\pm$ 1 82士 5* 0± 0

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

(HCL070)

BAIS3

PAGE: 4

APPENDIX B 4-1

BIOCHEMISTRY: SUMMARY, RAT: MALE

STUDY NO.: 0275 ANIMAL: RAT F344

SAMPLING DATE : 014-2
SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

PORT TYPE: A1	PAGE:	1

up Name	NO. of Animals	g/dl g/dl	ROTEIN	g∕d% WTBUMIN		A/G RAT	010	T-BILI mg∕dl		GLUCOSE mg/dl		T-CHOLE mg/dl	STEROL	TRIGLYC mg/dl	ER I DE
Control	10	6.5±	0.1	3.8±	0.1	1.5±	0.1	0.16±	0.01	200±	19	56±	5	89±	37
70 maga 07	10	6.7±	0.1*	3,9±	0.1	1.4±	0.1	0.16±	0.01	205±	13	89±	6**	96±	23
100 ppm	10	6.7±	0.1*	4.0±	0.1*	1.5±	0.1	0.17±	0.01	199±	14	97±	8**	82±	22
200 ppm	10	6.7±	0.2**	4.0±	0.1*	1.4±	0.1	0.17±	0.01	191±	14	111±	6**	84±	21
400 ppm	10	6.5±	0.2	3,9±	0.1	1.5±	0.1	0.18±	0.01	173±	12**	115±	12**	54±	12
800 ppm	10	6.8±	0.2**	4.1±	0.1**	1.5±	0.1	0.18±	0.01**	153±	16**	136±	9**	39±	12**

(IICLO74) BAIS 3

STUDY NO.: 0275 ANIMAL: RAT F344 BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

SAMPLING DATE : 014-2 SEX : MALE

REPORT TYPE : A1

PAGE: 2

up Name	NO. of Animals	PHOSPHO mg/dl	LIPID	GOT IU/	2	GPT IU/	Q	LDH I U/I	1	ALP IU/Q		G−GTP IU∕₽		CPK IU∕£	
Control	10	107±	9	77土	7	45±	4	136±	30	281±	28	1±	1	99±	8
50 ppm	10	159±	11**	72±	7	44±	4	120±	16	249±	20	1±	1	90±	8
100 ppm	10	169±	13**	73±	10	44±	5	136±	24	251±	21	1±	1	94±	7
200 ppm	10	182±	13**	71±	8	46±	6	136±	21	236±	14**	1±	1	89±	8
400 ppm	10	168±	13**	64±	10	51±	19	128±	19	247±	25	0±	1	82±	10**
mag 008	10	182±	16**	199±	143*	296±	264**	449±	592	256±	41	1±	0	103±	13

(IICL074)

STUDY NO.: 0275 ANIMAL : RAT F344 SAMPLING DATE: 014-2

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

SEX : MALE REPORT TYPE : A1 PAGE: 3

up Name	NO. of Animals	UREA NI mg∕dl	TROGEN	CREATIN mg/dl	INE	SODIUM mEq∕ Q		POTASSI mEq/		CHLORIDE mEq/Q		mg∕qf CVFCIAN		INORGAN mg/dl	IC PHOSPHORU
Control	10	18.6±	1.2	0.5±	0.0	144±	2	3.7±	0.2	107±	2	10.3±	0.3	5.7±	1.0
50 ppm	10	19.0±	1.0	0.5±	0.0	143±	2	3.7±	0.2	107±	2	10.5±	0.2	5.5±	1.1
100 ppm	10	18.7±	1.3	0.5±	0.0	143±	2	3.6±	0.3	107士	2	10.4±	0.2	5.4±	1.3
200 ppm	10	17.4±	1.0	0.5±	0.0	143士	2	3.7±	0.1	107±	3	10.5±	0.2	5.6±	1.1
400 ppm	10	17.3±	1.5	0.5±	0.0	141±	1**	3.9±	0.2	107±	2	10.3±	0.3	6.0±	0.8
mag 008	10	18.3±	2.3	0.5±	0.0	142±	1	3.9±	0.3	107±	2	10.5±	0.2	5.9±	1.2

(IICL074) BAIS3

APPENDIX B 4-2

BIOCHEMISTRY: SUMMARY, RAT: FEMALE

STUDY NO.: 0275 ANIMAL: RAT F344 BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

SAMPLING DATE: 014-2 SEX: FEMALE

REPORT TYPE : A1

PAGE: 4

oup Name	NO. of Animals	TOTAL F g/dl		ALBUMIN g∕dl		A/G RAT	10	T-BILI mg∕dl		GLUCOSE mg/dl		T-CHOLE mg∕dl	STEROL	TRIGLYC mg∕dl	ERIDE
Control	10	6.3±	0.2	3.7±	0.1	1.5±	0.1	0.17±	0.01	138±	14	81±	8	17±	4
50 ppm	10	6.3±	0.1	3.6±	0.1	1.4±	0.1	0.17±	0.01	142±	14	114±	11	22±	6
100 ppm	10	6.3±	0.1	3.7±	0.1	1,4±	0.1	0.17±	0.01	144土	15	118±	4	22±	5
200 ppm	10	6.2±	0.1	3.6±	0.1	1.4±	0.1	0.18±	0.01	142±	12	133±	14**	24土	4*
400 ppm	10	6.2±	0.2	3.7±	0.1	1.5±	0.0	0.19±	0.01**	134±	20	149±	9**	24±	5*
800 ppm	10	6.5±	0.4	3.9±	0.2	1.5±	0.1	0.21±	0.04**	131±	30	168±	41**	33±	11**

- ---

(HCL074)

STUDY NO.: 0275 ANIMAL : RAT F344 BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

SAMPLING DATE: 014-2

SEX: FEMALE

REPORT TYPE : A1 PAGE: 5

up Name	NO. of Animals	PHOSPHO mg/dl	LIPID	GOT IU/Q		GPT IU/	2	LDH IU/	ı	ALP IU/(G-GTP IU/s),	CPK IU/Q	1
Control	10	138±	12	69±	5	37±	6	141±	32	201±	16	1±	1	100±	15
50 ppm	10	179±	15	67±	5	36±	3	161±	20	189±	17	1±	1	101±	8
100 ppm	10	186±	5*	68±	5	37±	4	158±	43	186士	24	1±	1	103±	14
200 ppm	10	190±	15**	69±	4	39±	4	153±	27	208±	18	2±	2	102±	12
400 ppm	10	$211\pm$	12**	71±	5	45±	8*	194±	76	245±	19**	4±	1**	104±	30
mag 008	10	227±	50**	112±	52	136±	113**	333±	258**	242±	33**	16±	14**	114±	10

(HCL074)

STUDY NO.: 0275 ANIMAL: RAT F344 BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

SAMPLING DATE: 014-2

SEX : FEMALE

REPORT TYPE : A1

PAGE: 6

oup Name	NO. of Animals	UREA NI mg∕dl	TROGEN	CREATIN mg∕dl	INE	SODIUM mEq/l		POTASSI mEq/J		CHLORIDE mEq/2		CALCIU) mg/dl	1	INORGAN mg/dl	IC PHOSPHORU
Control	10	16.7±	1.6	0.6±	0.1	143±	2	3.4±	0.2	108±	2	10.1±	0.2	4.8±	1.6
50 ppm	10	16.5±	1.7	0.5±	0.1	143±	1	3.5±	0.2	108±	1	10.1±	0.2	5.2±	1.5
100 ppm	10	16.1±	1.2	0.6±	0.1	143±	2	3.3±	0.2	108±	1	10.1±	0.1	4.7±	1.6
200 ppm	10	16.2±	1.3	0.5±	0.0	143±	2	3.3±	0.2	109±	1	10.1±	0.2	5.1±	1.4
400 ppm	10	16.7±	2.9	0.6±	0.1	144±	2	3.5±	0.2	109±	2	10.0±	0.2	4.7±	1.4
800 ppm	10	20.1±	2.7	0.6±	0.1	143±	1	3.7±	0.5	107±	1	10,2±	0.3	5.2±	1,6

(HCL074)

APPENDIX B 4-3

BIOCHEMISTRY: SUMMARY, MOSUE: MALE

ANIMAL : MOUSE BDF1
SAMPLING DATE : 014-2

SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

Group Name NO. of TOTAL PROTEIN ALBUMIN A/G RATIO T-BILIRUBIN GLUCOSE T-CHOLESTEROL TRIGLYCERIDE Animals g/dl g/dl mg/dl mg/dl mg/dl mg/dl Control 10 5.2 ± 0.2 $3.0\pm$ 0.1 1.4± 0.1 0.22 ± 0.06 234士 33 80± 7 $30 \pm$ 6 50 ppm 10 5.2± 0.2 3.0± 0.1. 1.4± 0.1 0.19± 0.01 208士 24 82± 9 9 25± 100 ppm 10 $5.1\pm$ 0.2 $3.0\pm$ 0.1 1.4± 0.1 0.18± 0.02 225± 17 95± 11* 40± 12 200 ppm 10 5.1± 0.2 3.0 ± 0.1 1.4± 0.1 0.20 ± 0.06 219± 42 92± $34 \pm$ 16 400 ppm 10 5.2 ± 0.2 3.1 ± 0.1 1.5± 0.0 0.18± 0.01* 208± 36 102± 16** $33 \pm$ 20 800 ppm 10 $5.1\pm$ 0.3 3.1± 0.2 1.6± 0.1** 0.20± 0.02 190± 51 96± 24 $20 \pm$ 15 Significant defference : $*: P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

PAGE: 1

(HCL074) BAIS 3

ANIMAL : MOUSE BDF1

SAMPLING DATE: 014-2

SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

up Name	NO. of Animals	GOT IU/	1	GPT IU/,	ı	LDH I U/	Q	ALP IU/Q	ļ. 	I U/s	ļ	UREA NI mg/dl	TROGEN	SODIUM mEq/Q	
Control	10	47±	6	20±	6	261±	137	175±	9	131±	202	28.1±	2.6	155±	1
50 ppm	10	45±	8	22±	9	187±	34	160±	12	45±	20	28.9±	3.8	155±	1
100 ppm	10	42±	5	23±	7	175±	33	156±	11*	42±	15	29.1±	4.1	155±	1
200 ppm	10	52±	29	30±	15	248±	203	158±	17	73±	97	29.6±	2.7	154±	2
400 ppm	10	47±	14	38±	31	203±	62	166±	15	58±	42	29.7±	4.1	154±	2
800 ppm	10	151±	221	216±	491**	625±	1061	218±	21**	133±	144	33.1±	9.4	155±	2

PAGE: 2

(IICLO74) BAIS 3

ANIMAL : MOUSE BDF1

SAMPLING DATE: 014-2 SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

oup Name	NO. of Animals	POTASSI mEq/		CHLORIDE mEq/2		CALCIUM mg∕dl		INORGAN mg∕dl	IC PHOSPHORUS	
Control	10	4.5±	0.7	126±	3	8.7±	0.4	8.2±	1.5	
50 ppm	10	4.1±	0.4	126±	2	8.7±	0.2	7.2±	1,5	
100 ppm	10	4.0±	0.4	126±	2	8.7±	0.2	7.1±	0.9	
200 ppm	10	4.3±	0.8	125±	2	8.6±	0.2	7.5±	2.8	
400 ppm	10	4.5±	0.4	126±	2	8.8±	0.3	7.5±	1.2	
Mqq 008	10	4.1±	0.5	126±	3	8.7±	0.4	7.3±	1.1	
Significant	defference;	*: P ≦ (0.05	** : P ≤ 0.01				Test of Dun	nett	
L074)										ВА

PAGE: 3

APPENDIX B 4-4

BIOCHEMISTRY: SUMMARY, MOSUE: FEMALE

ANIMAL : MOUSE BDF1 SAMPLING DATE : 014-2

SEX : FEMALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 4

oup Name	NO. of Animals	g∕dl −	PROTEIN	ALBUMIN g∕dl		A/G RAT	10	T-BILI mg/dl		GLUCOSE mg∕dl		T-CHOLE mg∕dl	STEROL	TRIGLYCI mg∕dl	ERIDE
Control	9	5.4±	0.2	3.3±	0.1	1.6±	0.1	0.19±	0.02	176±	28	72±	6	15±	4
50 ppm	10	5.3±	0.1	3.2±	0.1	1.6±	0.1	0.19±	0.01	187±	32	91±	10*	16±	6
100 ppm	10	5.4±	0.2	3.3±	0.1	1.6±	0.1	0.18±	0.01	192±	26	96±	11**	16±	8
200 ppm	10	5.4±	0.1	3.3±	0.1	1.6±	0.1	0.18±	0.01	185士	27	100±	11**	20±	11
400 ppm	9	5.5±	0.2	3.4±	0.1	1.7±	0.1	0.20±	0.01	182±	30	100±	13**	15士	7
mqq 008	10	5.4±	0.4	3.5±	0.2	1.8±	0.1**	0.21±	0.02	170±	70	97±	24**	9±	4

(IICL074)

ANIMAL : MOUSE BDF1

SAMPLING DATE: 014-2 SEX: FEMALE REPORT TY

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

up Name	NO. of Animals	GOT IU/Q	;	GPT I U∕ Ø		LDII I U / I	Q	ALP IU/s),	CPK IU/s	,	UREA N mg∕d&	ITROGEN	SODIUM mEq/Q	
Control	9	67±	14	24±	4	236±	40	310±	31	83±	31	23,9±	3,9	154±	2
50 ppm	10	77±	29	35±	11	263±	74	264土	57	99±	54	26.2±	4.6	154±	2
100 ppm	10	72±	25	41±	24	243±	81	254±	33*	83±	41	27.0±	5,2	154±	2
200 ppm	10	77±	20	59±	44**	266±	84	243±	30**	115±	80	25.2±	5.1	154±	1
400 ppm	9	82±	27	52±	9**	349±	159	248±	35**	182±	148	30.0±	6.3	155±	2
mqq 008	10	88±	36	89±	62**	381±	167*	277±	42	189±	151	39.4±	15.9**	153±	1

PAGE: 5

(HCL074) BAIS 3

ANIMAL : MOUSE BDF1 SAMPLING DATE: 014-2

SEX: FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 6 Group Name NO. of POTASSIUM CHLORIDE CALCIUM INORGANIC PHOSPHORUS Animals mEq∕ Q mEq/Q mg∕dl mg∕dl Control 9 4.1± 0.5 126± 2 8.8± 0.2 6.1± 0.9 50 ppm 10 3.7 ± 0.5 $126 \pm$ 2 8.8± 0.3 $6.4 \pm$ 0.8 3.6± 0.5* 126± 3 100 ppm 10 8.9± 0.3 $6.5 \pm$ 0.6 200 ppm 10 3.7± 0.2 $126\pm$ 3 9.0± 0.2 $6.3 \pm$ 0.9 400 ppm 9 $3.8 \pm$ 0.4 $127 \pm$ 2 8.8± 0.4 $6.7 \pm$ 0.8 800 ppm 10 4.1± 0.6 125± 3 8.7± 0.4 7.0 ± 1.6 Significant defference; $*: P \leq 0.05$ ** : $P \le 0.01$ Test of Dunnett

(IICL074) BAIS 3

APPENDIX B 5-1

URINALYSIS: SUMMARY, RAT: MALE

URINALYSIS

ANIMAL : RAT F344 SAMPLING DATE : 015-7

SEX : MALE

REPORT TYPE : A1

PAGE: 1

NO. of	Hq.								Pr	ote	in_				-	Glu	COS	9			Ke	tone	e ba	dy			Bit	iruk	oin	
Animals	5.0	6.0	6.5	7.0	7.5	8.0	8.5	CIII		±	+	2+	3+ 4	+	CHI	_	±	+ 2	+ 3+	4+ CHI					+ 4+	CHI				CHI
10	0	1	0	0	3	6	0		(3	7	0	0	0		10	0	0	0 0	0	2	7	1	0	0 0		10	0	0 0	
10	0	0	0	1	5	3	1		. () 2	7	1	0	0		10	0	0	0 0	0	4	5	1	0	0 0		10	0	0 0	
10	0	0	0	3	4	3	0		(6	4	0	0	0		10	0	0	0 0	0	5	5	0	0	0 0		10	0	0 0	
10	0	0	1	0	1	8	0		() 6	2	2	0	0		10	0	0	0 0	0	5	3	2	0	0 0		10	0	0 0	
10	0	0	0	1	1	8	0		(0 (6	4	0	0	*	10	0	0	0 0	0	0	5	5	0	0 0		10	0	0 0	
10	0	0	6	2	1	1	0	**	() 3	5	2	0	0		10	0	0	0 0	0	0	9	0	1	0 0		10	0	0 0	
10	0	0	6	2	1	1	0	**	() 3	5	2	0	0		10	0	0	0 0	0	0	9	0	1	0 0		10	0	0 0	
	10 10 10 10 10	10 0 10 0 10 0 10 0 10 0 10 0	10 0 1 10 0 0 10 0 0 10 0 0 10 0 0	10 0 1 0 10 0 0 0 10 0 0 0 10 0 0 1 10 0 0 0	10 0 1 0 0 10 0 0 1 10 0 0 0 1 10 0 0 0	Animals 5.0 6.0 6.5 7.0 7.5 10 0 1 0 0 3 10 0 0 0 1 5 10 0 0 0 1 0 1 10 0 0 0 1 0 1 10 0 0 0	Animals 5.0 6.0 6.5 7.0 7.5 8.0 10 0 1 0 0 3 6 10 0 0 0 1 5 3 10 0 0 0 1 0 1 8 10 0 0 0 1 1 8	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 10 0 1 0 0 3 6 0 10 0 0 1 5 3 1 10 0 0 0 3 4 3 0 10 0 0 1 0 1 8 0 10 0 0 0 1 1 8 0	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII 10	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII — 10 0 1 0 0 3 6 0 0 10 0 0 0 1 5 3 1 10 0 0 0 3 4 3 0 10 0 0 1 0 1 8 0 10 0 0 0 1 1 8 0	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII — ± 10 0 1 0 0 3 6 0 0 3 10 0 0 0 1 5 3 1 0 2 10 0 0 0 3 4 3 0 0 6 10 0 0 1 0 1 8 0 0 6 10 0 0 0 1 1 8 0 0 0	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII — ± + 10 0 1 0 0 3 6 0 0 3 7 10 0 0 0 1 5 3 1 0 2 7 10 0 0 0 3 4 3 0 0 6 4 10 0 0 1 0 1 8 0 0 6 2 10 0 0 0 1 1 8 0 0 0 6	Animals $5.0 \ 6.0 \ 6.5 \ 7.0 \ 7.5 \ 8.0 \ 8.5 \ CIII \ - \pm + 2 + 2 + 2 + 2 + 2 + 2 + 2 + 2 + 2 +$	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII — ± + 2+ 3+ 4 10 0 1 0 0 3 6 0 0 3 7 0 0 10 0 0 0 1 5 3 1 0 2 7 1 0 10 0 0 0 3 4 3 0 0 6 4 0 0 10 0 0 1 0 1 8 0 0 6 2 2 0 10 0 0 0 1 1 8 0 0 0 6 4 0	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII — ± + 2+ 3+ 4+ 10 0 1 0 0 3 6 0 0 3 7 0 0 0 10 0 0 0 1 5 3 1 0 2 7 1 0 0 10 0 0 0 3 4 3 0 0 6 4 0 0 0 10 0 0 1 0 1 8 0 0 6 2 2 0 0 10 0 0 0 1 1 8 0 0 0 6 4 0 0	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII — ± + 2+ 3+ 4+ CHI 10 0 1 0 0 3 6 0 0 3 7 0 0 0 10 0 0 0 1 5 3 1 0 2 7 1 0 0 10 0 0 0 3 4 3 0 0 6 4 0 0 0 10 0 0 0 1 8 0 0 6 2 2 0 0 10 0 0 0 1 1 8 0 0 0 6 4 0 0 *	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII — ± + 2+ 3+ 4+ CHI — 10 0 1 0 0 3 6 0 0 3 7 0 0 0 10 10 0 0 0 1 5 3 1 0 0 2 7 1 0 0 10 10 0 0 0 3 4 3 0 0 6 4 0 0 0 10 10 0 0 0 1 8 0 0 6 2 2 0 0 10 10 0 0 0 1 1 8 0 0 0 6 4 0 0 * 10	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII — ± + 2+ 3+ 4+ CHI — ± 10 0 1 0 0 3 6 0 0 0 3 7 0 0 0 10 0 10 0 0 0 1 5 3 1 0 0 2 7 1 0 0 10 0 10 0 0 0 1 8 0 0 0 6 4 0 0 0 10 0 10 0 0 0 1 1 8 0 0 6 2 2 0 0 10 0 10 0 0 0 1 1 8 0 0 0 6 4 0 0 * 10 0	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII — ± + 2+ 3+ 4+ CHI — ± + 2 10 0 1 0 0 3 6 0 0 3 7 0 0 0 10 0 0 10 0 0 0 1 5 3 1 0 2 7 1 0 0 10 0 0 10 0 0 0 3 4 3 0 0 6 4 0 0 0 10 0 0 10 0 0 0 1 1 8 0 0 6 2 2 0 0 10 0 0 10 0 0 0 1 1 8 0 0 0 6 4 0 0 * 10 0 0	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII — ± + 2+ 3+ 4+ CHI — ± + 2+ 3	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII — ± + 2+ 3+ 4+ CHI — ± + 2+ 3+ 4+ CHI 10 0 1 0 0 3 6 0 0 0 3 7 0 0 0 10 0 0 0 0 0 10 0 0 0 1 5 3 1 0 0 2 7 1 0 0 10 0 0 0 0 0 10 0 0 0 1 8 0 0 0 6 4 0 0 0 10 0 0 0 0 10 0 0 0 1 1 8 0 0 0 6 4 0 0 * 10 0 0 0 0 10 0 0 0 1 1 8 0 0 0 6 4 0 0 * 10 0 0 0 0 10 0 0 0 0 1 1 8 0 0 0 6 4 0 0 * 10 0 0 0 0 10 0 0 0 0 0 0 0 0 0	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII — ± + 2+ 3+ 4+ CHI — ± + 2+ 3	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII — ± + 2+ 3+ 4+ CHI — ± + 2+ 3+ 4+ CHI — ± 10 0 1 0 0 3 6 0 0 3 7 0 0 0 10 0 0 0 0 0 2 7 10 0 0 0 1 5 3 1 0 2 7 1 0 0 10 0 0 0 0 0 0 4 5 10 0 0 0 1 0 1 8 0 0 6 2 2 0 0 10 0 0 0 0 0 5 3 10 0 0 0 1 1 8 0 0 0 6 4 0 0 * 10 0 0 0 0 0 0 0 6 5	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII — ± + 2+ 3+ 4+ CHI — ± + 2+ 3	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII - ± + 2+ 3+ 4+ CHI - ± + 2+	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII	Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CIII — ± + 2+ 3+ 4+ CHI — ± + 2+ 3

(IICL101)

URINALYSIS

ANIMAL: RAT F344 SAMPLING DATE: 015-7

SEX : MALE

REPORT TYPE : A1

Urabilinagen Group Name NO. of Occult blood Animals $-\pm+2+3+$ CHI ± + 2+ 3+ 4+ CIII Control 10 10 0 0 0 0 10 0 0 0 0 50 ppm 10 0 0 0 0 10 10 0 0 0 0 100 ppm 10 10 0 0 0 0 10 0 0 0 0 200 ppm 10 10 0 0 0 0 10 0 0 0 0 400 ppm 10 10 0 0 0 0 10 0 0 0 0 800 ppm 10 10 0 0 0 0 10 0 0 0 0 Significant difference ; $*: P \leq 0.05$ ** : $P \leq 0.01$ Test of CHI SQUARE

PAGE: 2

(HCL101) BAIS3

APPENDIX B 5-2

URINALYSIS : SUMMARY, RAT : FEMALE

URINALYSIS

ANIMAL : RAT F344 SAMPLING DATE: 015-7

SEX : FEMALE REPORT TYPE : A1 PAGE: 3

oup Name	NO. of	pll								Prote	in				Gli	ICOS	 9				Ket	one	bady			E	ilir	ubin		
	Animals	5.0	6.0	6.5	7.0	7,5	8.0	8.5	III	- ±	+	2+ 3	3+ 4+	CHI		±	+ 2	+ 3+	4+ C	CILI			+ 2+		+ CHI			2+ 3		I
Control	10	. 0	0	0	1	5	4	0		1 6	3	0	0 0		10	0	0	0 0	0		9	1	0 0	0	0	1	.0 0	0	0	
50 ppm	10	0		1	0	3	6	0					0 0					0 0					0 0					0		
100 ppm	10	0	1	0	1	7	1	0		2 6	5 2	0	0 0		10	0	0	0 0	0		10	0	0 0	0	0	1	.0 0	0	0	
200 ppm	10	0	0	0	2	6	2	0		1 5	5 3	1	0 0		10	0	0	0 0	0		9	1	0 0	0	0	1	.0 0	0	0	
400 ppm	10	0	0	2	0	4	4	0		3 4	1 3	0	0 0		10	0	0	0 0	0		7	3	0 0	0	0	1	.0 0	0	0	
mqq 008	10	0	1	3	1	4	1	0		0 7	7 1	2	0 0		10	0	0	0 0	0		6	4	0 0	0	0	1	.0 0	0	0	
Significant	difference	; *	: P ≦	≦ 0.0	5	**	: P ≦	€ 0.01						Test	t of Cl	II S	QUAF	E												
1101)																														

(HCL101) BAIS3

URINALYSIS

ANIMAL : RAT F344 SAMPLING DATE: 015-7

SEX : FEMALE

REPORT TYPE : A1

iroup Name	NO. of Animals	Occult blood — ± + 2+ 3+ CIII	Urabilinagen ± + 2+ 3+ 4+ C∏		
Control	10	10 0 0 0 0	10 0 0 0 0		
50 ppm	10	10 0 0 0 0	10 0 0 0 0		
100 ppm	10	10 0 0 0 0	10 0 0 0 0		
200 ppm	10	10 0 0 0 0	10 0 0 0 0		
400 ppm	10	10 0 0 0 0	10 0 0 0 0		
800 ppm	10	9 0 0 0 1	10 0 0 0 0		
Significant	difference	; *:P≦0.05 **	: P ≤ 0.01	Test of CHI SQUARE	
(IICL101)					RAIS

(HCL101)

BAIS3

PAGE: 4

APPENDIX B 5-3

URINALYSIS: SUMMARY, MOSUE: MALE

URINALYSIS

ANIMAL : MOUSE BDF1 SAMPLING DATE: 013-2

SEX : MALE

REPORT TYPE : A1

Group Name	NO. of	[lq									Pro	otei	n					G	Luc	ose	!					K	eta	ne	bad	y				00	cul	1 †	bli		}				_
	Animals	5.	0 6.	0	6.5	7.0	7.5	8.0	8.5	CHI				2+	3+	4+	CHI					+ 3	3+ 4	+	CHI						4+		CHI						3+	1	CHI		
											 																					•								••••			_
Control	10	0	0	•	0	0	0	9	1		0	0	3	7	0	0		1	0	0	0	0	0	0			0	4	6	0 (0	;		10) ()	0	0	0				
50 ppm	10	0	0)	1	3	2	4	0		0	0	7	3	3 0	0 (1	0	0	0	0	0	0			0	4	6	0 (0	ŀ		10) ()	0	0	0				
100 ppm	10	0	1		0	1	4	4	0		0	0	4	5	1	. 0		1	0	0	0	0	0	0			1	7	2	0 (0)		10) ()	0	0	0				
200 ppm	9	0	0)	0	4	3	1	1	**	0	0	6	1	. 1	. 1			9	0	0	0	0	0			0	5	4	0 (0)		ξ) ()	0	0	0				
400 ppm	8	0	0)	0	0	1	6	1		0	0	5	2	0) 1			8	0	0	0	0	0			1	2	3	1	0)		8	3 ()	0	0	0				
800 ppm	10	0	1		1	3	4	1	0	**	0	0	7	3	3 0	0 (1	0	0	0	0	0	0			2	6	2	0 (0)		10) ()	0	0	0				

PAGE: 1

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

(IICL101) BAIS3

URINALYSIS

ANIMAL : MOUSE BDF1 SAMPLING DATE: 013-2

REPORT TYPE : A1 SEX : MALE

Group Name NO. of Urabilinagen Animals ± + 2+ 3+ 4+ CHI 10 0 0 0 0 Control 10 50 ppm 10 10 0 0 0 0 100 ppm 10 10 0 0 0 0 200 ppm 9 0 0 0 0 400 ppm 8 8 0 0 0 0 800 ppm 10 10 0 0 0 0 Significant difference : $*:P \leq 0.05$ ** : $P \leq 0.01$ Test of CHI SQUARE

(IICL101)

BAIS3

PAGE: 2

APPENDIX B 5-4

URINALYSIS: SUMMARY, MOSUE: FEMALE

STUDY NO. : 0276

URINALYSIS

ANIMAL : MOUSE BDF1 SAMPLING DATE: 013-2

SEX : FEMALE

REPORT TYPE : A1

PAGE: 3

oup Name	NO. of					Protein	Glucose	Ketane bady	Occult bload			
	Animals	5.0	6.0	6.5	7.0	7.5	8.0	8.5 CHI	- ± + 2+ 3+ 4+		CIII — ± + 2+ 3+ 4+ CIII	- ± + 2+ 3+ CHI
Control	10	0	0	0	2	5	3	0	0 1 6 3 0 0	10 0 0 0 0	4 3 3 0 0 0	10 0 0 0 0
50 ppm	10	0	0	1	1	3	5	0	0 1 5 4 0 0	10 0 0 0 0 0	1 4 5 0 0 0	10 0 0 0 0
100 ppm	10	0	0	0	1	6	3	0	0 1 7 2 0 0	10 0 0 0 0 0	2 3 5 0 0 0	10 0 0 0 0
200 ppm	10	0	0	0	3	6	1	0	0 1 8 1 0 0	10 0 0 0 0 0	4 5 0 1 0 0	10 0 0 0 0
400 ppm	9	0	0	0	0	1	7	1	0 1 5 3 0 0	9 0 0 0 0 0	2 1 6 0 0 0	9 0 0 0 0
800 ppm	10	0	0	2	1	3	4	0	0 0 4 4 2 0	10 0 0 0 0 0	4 1 3 2 0 0	10 0 0 0 0

(HCL101)

STUDY NO.: 0276

URINALYSIS

ANIMAL : MOUSE BDF1 SAMPLING DATE: 013-2

SEX : FEMALE

REPORT TYPE : A1

Group Name NO. of Urabilinagen Animals ± + 2+ 3+ 4+ CHI Control 10 10 0 0 0 0 50 ppm 10 10 0 0 0 0 100 ppm 10 10 0 0 0 0 200 ppm 10 10 0 0 0 0 400 ppm 9 9 0 0 0 0 800 ppm 10 10 0 0 0 0 Significant difference : $*: P \leq 0.05$ ** : $P \leq 0.01$ Test of CHI SQUARE (IICL101) BAISS

PAGE: 4

APPENDIX B 6-1

GROSS FINDINGS: SUMMARY, RAT: MALE: SACRIFICED ANIMALS

STUDY NO. : 0275 ANIMAL : RAT F344 GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (14W)

REPORT TYPE : A1 SEX : MALE

PAGE: 1

Organ	Findings	Group Name Control NO. of Animals 10 (%)	50 ppm 10 (%)	100 ppm 10 (%)	200 ppm 10 (%)
ver	white zone	0 (0)	0 (0)	0 (0)	0 (0)
	red zone	0 (0)	0 (0)	0 (0)	0 (0)

(HPT080)

STUDY NO. : 0275 ANIMAL : RAT F344

REPORT TYPE : A1

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (14W)

SEX : MALE

Organ	Findings	Group Name NO, of Animals	10	400 ppm (%)	10	800 ppm (%)	
liver	white zone		0	(0)	1	(10)	
	red zone		0	(0)	1	(10)	
(HPT080)							BAIS 3

PAGE: 2

APPENDIX B 6-2

GROSS FINDINGS : SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS

STUDY NO. : 0275 ANIMAL : RAT F344 GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (14W)

REPORT TYPE : A1

SEX : FEMALE

0rgan	Findings		Control (%)	50 ppm 10 (%)	100 ppm 10 (%)	10	200 ppm (%)
.iver	white zone	0	(0)	0 (0)	0 (0)	0	(0)
	herniation	2	(20)	0 (0)	1 (10)	2	(20)
terus	absence	0	(0)	0 (0)	0 (0)	0	(0)

PAGE: 3

STUDY NO. : 0275 ANIMAL : RAT F344

REPORT TYPE : A1

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (14W)

SEX : FEMALE

0rgan	Findings	Group Name 400 p NO. of Animals 10 (%)	ppm 800 ppm 10 (%)	
liver	white zone	0 (0)	4 (40)	
	herniation	0 (0)	0 (0)	
uterus	absence	1 (10)	0 (0)	
(HPT080)				BAISS

PAGE: 4

APPENDIX B 6-3

GROSS FINDINGS : SUMMARY, MOSUE : MALE : SACRIFICED ANIMALS

STUDY NO. : 0276

ANIMAL : MOUSE BDF1

REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (14W)

Organ	Findings	Group Name (NO. of Animals 10	Control (%)	50 ppm 10 (%)	100 ppm 10 (%)	200 ppm 10 (%)
spleen	black zone		(0)	0 (0)	1 (10)	2 (20)
liver	white zone	0	(0)	0 (0)	0 (0)	0 (0)
	red zone	0	(0)	0 (0)	0 (0)	0 (0)
	brown zone	0	(0)	0 (0)	0 (0)	0 (0)
idney	hydronephrosis	0	(0)	1 (10)	0 (0)	0 (0)
estis	atrophic	1	(10)	1 (10)	0 (0)	0 (0)

(HPT080)

BAIS 3

PAGE: 1

STUDY NO. : 0276 ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : MALE GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (14W)

PAGE: 2

Organ	Findings	Group Name 44 NO. of Animals 10 (00 ppm %)	800 ppm 10 (%)	
		0 (٥)	0 (0)	
spleen	black zone	0 (0)	0 (0)	
liver	white zone	0 (0)	3 (30)	
	red zone	0 (0)	1 (10)	
	brown zone	0 (0)	1 (10)	
kidney	hydronephrasis	0 (0)	0 (0)	
testis	atrophic	0 (0)	0 (0)	

(HPT080)

APPENDIX B 6-4

GROSS FINDINGS: SUMMARY, MOSUE: FEMALE: SACRIFICED ANIMALS

STUDY NO. : 0276
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (14W)

PAGE: 3

Organ	Findings	Group Name NO. of Animals	Cantrol 10 (%)	50 ppm 10 (%)	100 ppm 10 (%)	200 ppm 10 (%)
spleen	red zane		0 (0)	0 (0)	0 (0)	0 (0)
	black zone		0 (0)	0 (0)	0 (0)	0 (0)
Jary	cyst		0 (0)	0 (0)	1 (10)	0 (0)

(HPT080) BAIS3 STUDY NO. : 0276 ANIMAL : MOUSE BDF1 GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (14W)

REPORT TYPE : A1

: FEMALE SEX

cyst

400 ppm 9 (%) 800 ppm 10 (%) Group Name NO. of Animals Organ____ Findings_ 1 (11) 0 (0) spleen red zone 0 (0) 1 (10) black zone 0 (0) 0 (0)

(HPT080)

quary

BAIS 3

PAGE: 4

APPENDIX B 7-1

ORGAN WEIGHT, ABSOLUTE: SUMMARY, RAT: MALE
(THIRTEEN - WEEK STUDY)

STUDY NO. : 0275 ANIMAL : RAT F344 REPORT TYPE : A1 ORGAN WEIGHT: ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (14)

SEX : MALE UNIT: g

PAGE: 1

up Name	NO. of Animals	Body (Weight	ТНУМ	JS	ADRE	NALS	TEST	ES	HEAR	r	LUNG	S
Control	10	293±	16	0.222±	0.019	0.050±	0.005	2.747±	0.052	0.883±	0.035	0.937±	0.043
50 ppm	10	293±	17	0.242±	0.035	0.052±	0.010	2.763±	0.108	0.895±	0.052	0,938±	0,039
100 ppm	10	290±	20	0.236±	0.032	0.051±	0.006	2.746±	0.106	0.901±	0.054	0.918±	0,037
200 ppm	10	287±	20	0.230±	0.030	0.050±	0.008	2.760±	0.101	0.891±	0.055	0.926±	0.047
400 ppm	10	259±	17**	0.183±	0.036*	0.046±	0.007	2.710±	0.144	0.814±	0.038*	0.848±	0,059**
mqq 008	10	236±	16**	0.181±	0.023*	0.045±	0.005	2,673±	0.095	0.746±	0.056**	0.837±	0.055**

(HCL040)

STUDY NO.: 0275 ANIMAL : RAT F344 REPORT TYPE : A1

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

SEX : MALE UNIT: g

NO. of KIDNEYS SPLEEN LIVER BRAIN Group Name Animals Control 10 1.756± 0.089 0.476± 0.025 7.578 ± 0.533 1.865 ± 0.031 1.788± 0.087 10 0.491± 0.034 8.503± 0.534** 1.884± 0.034 50 ppm 100 ppm 10 1.767± 0.100 0.491± 0.033 8.587± 0.623** 1.862± 0.038 200 ppm 10 1.815 ± 0.132 0.482± 0.037 8.678± 0.755** 1.868± 0.029 1.811± 0.048** 400 ppm 1.681± 0.090 0.438士 0.033* 7,905± 0.595 1.581 ± 0.135** 0.421± 0.031** 7.562 ± 0.642 1.755± 0.040** 800 ppm 10 Significant difference : $*: P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(IICL040)

BAIS3

PAGE: 2

APPENDIX B 7-2

ORGAN WEIGHT, ABSOLUTE: SUMMARY, RAT: FEMALE
(THIRTEEN - WEEK STUDY)

STUDY NO.: 0275 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : FEMALE

UNIT: g

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

PAGE: 3

up Name	NO. of Animals	Bady (Weight	ТНҮМ	JS	ADRE	NALS	OVAR	IES	HEAR	Γ	LUNG	S
Control	10	171±	7	0.204±	0.030	0.057±	0.007	0.086±	0.007	0.597±	0.025	0.706±	0.030
50 ppm	10	177±	9	0.209±	0.022	0.056±	0.005	0.092±	0.011	0.644±	0.060	0.735±	0.041
100 ppm	10	173±	6	0.204±	0.023	0.052±	0.003	0.093±	0.011	0.624±	0.027	0.730±	0.019
200 ppm	10	161±	7	0.175±	0.015*	0.049±	0.004*	0.086±	0.013	0,599±	0.040	0.705±	0.039
400 ppm	10	151±	11**	0.156±	0.015**	0.045±	0.004**	0.060±	0.013**	0.542±	0.032	0.632±	0.032**
800 ppm	10	132±	15**	0.124±	0.034**	0.048±	0.011**	0.060±	0.017**	0.506±	0.059**	0.639±	0.031**
Significant	difference;	*: P ≤ 0.	05 **	: P ≤ 0.01			Test	of Dunnett					

BAIS 3 (HCL040)

STUDY NO. : 0275 ANIMAL : RAT F344

ANIMAL : RAT F34
REPORT TYPE : A1
SEX : FEMALE

UNIT: g

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

PAGE: 4

emeN qu	NO. of Animals	KID	NEYS	SPLI	EEN	LIVI	ER	BRA		
Control	10	1.128±	0.042	0.344±	0,021	4.112±	0.220	1.706±	.077	
50 ppm	10	1.199±	0.051*	0.355±	0.030	4.532±	0.384*	1.763±	.034*	
100 ppm	10	1.188±	0.050	0.374±	0.014	4.536±	0.179*	1.730±	.045	
200 ppm	10	1.161±	0.045	0.331±	0.020	4.355±	0.286	1.739±	.033	
400 ppm	10	1.098±	0.071	0.309±	0.024	4.362±	0.407	1.680±	.041	
mag 008	10	1.127±	0.077	0,297±	0.043*	4.834±	0.495**	1,621±	.042**	

(IICL040)

APPENDIX B 7-3

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : MALE

STUDY NO. : 0276

ANIMAL : MOUSE BDF1

REPORT TYPE : A1

SEX : MALE UNIT: g

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

PAGE: 1

oup Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	28.8± 1.7	0.033± 0.007	0.011± 0.003	0.202± 0.039	0.154± 0.009	0.168± 0.010
50 ppm	10	25.7± 1.5**	0.032± 0.005	0.009± 0.003	0.212± 0.036	0.148± 0.011	0.156± 0.010
100 ppm	10	27.0± 1.8	0.033± 0.004	0.009± 0.003	0.203± 0.022	0.157± 0.013	0.160± 0.009
200 ppm	10	25.9士 1.4**	0.033± 0.004	0.010± 0.002	0.195± 0.032	0.157± 0.010	0.161± 0.014
400 ppm	10	25.8士 1.7**	0.033± 0.005	0.009± 0.002	0.220± 0.024	0.145± 0.010	0.161± 0.008
mag 008	10	22.8± 1.9**	0.028± 0.008	0.009± 0.002	0.180± 0.029	0.130± 0.012**	0.158± 0.013
Significant	difference;	*: P ≤ 0.05 **	P ≤ 0.01	Test	of Dunnett		
ር፤ ዐላቦ)					<u></u>		

(IICL040)

STUDY NO.: 0276

ANIMAL : MOUSE BDF1

REPORT TYPE : A1
SEX : MALE

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

SEX : MALE UNIT: g

To Name	NO. of Animals	KIDN	EYS	SPL	EEN	LIV	ER	BRA		
Control	10	0.446±	0.023	0.042±	0.004	1.187±	0.053	0.445±	,021	
50 ppm	10	0.437±	0.028	0.042±	0.008	1.228±	0.080	0.437±	.024	
100 ppm	10	0.446±	0.030	0.046±	0.006	1.373±	0.113**	0.441±	.012	
200 ppm	10	0.435±	0.023	0.044±	0.006	1.333±	0.080*	0.445±	.013	
400 ppm	10	0.413±	0.021	0.046±	0.006	1.340±	0.118**	0.445士	.012	
mag 008	10	0.389±	0.042**	0.037±	0.010	1.205±	0.148	0.422±	.019*	

BAIS3

PAGE: 2

(HCL040)

APPENDIX B 7-4

ORGAN WEIGHT, ABSOLUTE: SUMMARY, MOSUE: FEMALE

STUDY NO.: 0276

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : FEMALE UNIT: g ORGAN WEIGHT: ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 3

20.1± 1.1 20.6± 0.8 20.4± 1.3 21.1± 1.4	0.037± 0.005 0.038± 0.005 0.037± 0.009	0.012± 0.003 0.013± 0.002 0.012± 0.002	0.024± 0.005 0.024± 0.004 0.026± 0.010	0.119± 0.009 0.126± 0.008 0.123± 0.011	0.152± 0.010 0.157± 0.011 0.154± 0.016	
20.4± 1.3	0.037± 0.009					
		0.012± 0.002	0.026± 0.010	0.123± 0.011	0.154± 0.016	
21.1± 1.4	0.000 1 0.000					
	0.039± 0.006	0.013± 0.002	0.027± 0.005	0.128± 0.008	0.158± 0.013	
20.7± 1.0	0.036± 0.006	0.011± 0.002	0.022± 0.004	0.122± 0.012	0.150± 0.011	
19.6± 1.0	0.030± 0.008	0.011± 0.003	0,020± 0,003	0.110± 0.009	0.159± 0.009	
-	19.6± 1.0	19.6± 1.0 0.030± 0.008	19.6± 1.0 0.030± 0.008 0.011± 0.003	19.6± 1.0 0.030± 0.008 0.011± 0.003 0.020± 0.003	19.6± 1.0 0.030± 0.008 0.011± 0.003 0.020± 0.003 0.110± 0.009	19.6± 1.0 0.030± 0.008 0.011± 0.003 0.020± 0.003 0.110± 0.009 0.159± 0.009

(IICL040)

STUDY NO. : 0276

ANIMAL : MOUSE BDF1

REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

PAGE: 4

up Name	NO. of Animals	KIDNEYS	. SPL	EEN	LIVI	ER	BRA		
Control	10	0.289± 0.02	1 0.045±	0.006	0,909±	0.094	0.450±	0.014	
50 ppm	10	0.303± 0.01	3 0.050±	0.005	0.987±	0.087	0.459±	0.012	
100 ppm	10	0.301± 0.01	9 0.052±	0.009	0,999±	0.096	0.445±	0.011	
200 ppm	10	0.313± 0.01	7 0.054±	0.010	1.060±	0.122	0,450±	0.017	
Mqq 004	9	0.299土 0.03	0.052±	0.010	1.040±	0.161	0.446±	0,023	
mag 008	10	0.291± 0.00	22 0.042±	0.008	1.016±	0.155	0.433±	0,013	

(HCL040)

APPENDIX B 8-1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

STUDY NO.: 0275 ANIMAL : RAT F344

REPORT TYPE : A1

UNIT: %

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

SEX : MALE

emeN cu	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS	
Control	10	293± 16	0.076± 0.005	0.017± 0.001	0.941± 0.052	0.302± 0.006	0.320± 0.007	
50 ppm	10	293± 17	0.082± 0.013	0.018± 0.004	0.944± 0.048	0.306± 0.018	0.320± 0.012	
100 ppm	10	290± 20	0.081± 0.008	0.018± 0,003	0.950± 0.063	0.311± 0.015	0.317± 0.012	
200 ppm	10	287± 20	0.080± 0.009	0.017± 0.003	0.966± 0.042	0.311± 0.012	0.324± 0.012	
400 ppm	10	259± 17**	0.071± 0.013	0.018± 0.003	1.049± 0.060**	0.315± 0.022	0.327± 0.010	
mag 008	10	236± 16**	0.077± 0.010	0.019± 0.002	1.136± 0.062**	0.316± 0.012	0.355± 0.012**	

PAGE: 1

(HCL042)

STUDY NO.: 0275 ANIMAL: RAT F344

REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE: 2

up Name	NO. of Animals	KIDNEYS	SPLEEN	LIYER	BRAIN	
Control	10	0.601± 0.023	0.163± 0.005	2.589± 0.082	0.639± 0.030	
50 ppm	10	0.611± 0.022	0.167± 0.005	2.900± 0.036	0.645± 0.039	
100 ppm	10	0.610± 0.021	0.169± 0.005	2.960± 0.065*	0.645± 0.046	
200 ppm	10	0.634± 0.027*	0.168± 0.003	3.027± 0.099**	0.655± 0.042	
400 ppm	10	0.651± 0.032**	0.169± 0.004	3.053± 0.082**	0.702± 0.036**	
maa 008	10	0.669± 0.025**	0.179± 0.009**	3.204± 0.166**	0.747± 0.052**	

(IICL042)

APPENDIX B 8-2

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : FEMALE
(THIRTEEN - WEEK STUDY)

STUDY NO.: 0275 ANIMAL : RAT F344 REPORT TYPE : A1 SEX: FEMALE

UNIT: %

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

PAGE: 3

	NO, of Animals		eight g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS	
Control	10	171±	7	0.119± 0.014	0.034± 0.004	0.050± 0.003	0.349± 0.012	0.413± 0.024	
50 ppm	10	177±	9	0.118± 0.011	0.032± 0.003	0.052± 0.004	0.364± 0.027	0.416± 0.018	
100 ppm	10	173±	6	0.118± 0.010	0.030± 0.003	0.054± 0.006	0.361± 0.019	0.422± 0.013	
200 ppm	10	161±	7	0.108± 0.007	0.030± 0.003	0.053± 0.008	0.372± 0.018	0.438± 0.024	
400 ppm	10	151±	11**	0.104± 0.006*	0.030± 0.004	0.040± 0.007	0.360± 0.015	0.420± 0.016	
maa 008	10	132±	15**	0.092± 0.019**	0.037± 0.008	0.045± 0.011	0.384± 0.027**	0.489± 0.058**	

BAIS3 (HCL042)

STUDY NO.: 0275 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : FEMALE UNIT: %

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

PAGE: 4

Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN	
Control	10	0.659± 0.018	0.201± 0.012	2.402± 0.098	0.998± 0.063	
50 ppm	10	0.679± 0.013	0.201± 0.011	2.560± 0.118	0.999± 0.047	
100 ppm	10	0.686± 0.015	0.217± 0.009*	2.623± 0.073	1.001± 0.037	
200 ppm	10	0.721± 0.024**	0.205± 0.011	2.701± 0.097**	1.081± 0.054	
400 ppm	10	0.729± 0.039**	0.205± 0.007	2.889± 0.102**	1.119± 0.087*	
800 ppm	10	0.860± 0.083**	0.225± 0.022*	3.683± 0.388**	1.243± 0.154**	

APPENDIX B 8-3

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : MALE

STUDY NO. : 0276

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : MALE UNIT: % ORGAN WEIGHT: RELATIVE (SUMMARY)
SURVIVAL ANIMALS (14)

PAGE: 1

up Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS	
Control	10	28.8± 1.7	0.115± 0.020	0.037± 0.012	0.703± 0.140	0.535± 0.036	0.583± 0.035	
50 ppm	10	25,7± 1.5**	0.123± 0.017	0.037± 0.010	0.821± 0.120	0.573± 0.033	0.607± 0.043	
100 ppm	10	27.0± 1.8	0.122± 0.015	0.035± 0.010	0.753± 0.094	0.583± 0.030*	0.594± 0.038	
200 ppm	10	25.9± 1.4**	0.126± 0.012	0.039± 0.008	0.756± 0.123	0.610± 0.054**	0.623± 0.047	
400 ppm	10	25.8± 1.7**	0.130± 0.019	0.036± 0.006	0.854± 0.089	0.563± 0.025	0.623± 0.028	
800 ppm	10	22.8± 1.9**	0.122± 0.027	0.038± 0.010	0.795± 0.145	0.572± 0.038	0.693士 0.052**	

(IICL042)

STUDY NO. : 0276

ANIMAL : NOUSE BDF1

REPORT TYPE : A1 SEX : MALE UNIT: %

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

ems% qu	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN	
Control	10	1.549± 0.082	0.147± 0.012	4.125± 0.144	1.546± 0.097	
50 ppm	10	1.703± 0.142**	0.162± 0.032	4.770± 0.170**	1.706± 0.154**	
100 ppm	10	1.652± 0.056	0.169± 0.020	5.075± 0.151**	1.637± 0.100	
200 ppm	10	1.681± 0.079*	0.170± 0.020	5.152± 0.211**	1.722± 0.062**	
400 ppm	10	1.601± 0.087	0.178± 0.022*	5.186± 0.284**	1.729± 0.092**	
800 ppm	10	1.702± 0.106**	0.160± 0.038	5.262± 0.318**	1.856± 0.117**	

PAGE: 2

BAIS 3 (IICL042)

APPENDIX B 8-4

ORGAN WEIGHT, RELATIVE: SUMMARY, MOSUE: FEMALE

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : FEMALE UNIT: %

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

PAGE: 3

roup Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS	
Contral	10	20.1± 1.1	0.184± 0.022	0.060± 0.015	0.119± 0.026	0.591± 0.037	0.756± 0.036	
50 ppm	10	20.6± 0.8	0.184± 0.023	0.063± 0.012	0.117± 0.019	0.612± 0.038	0.763± 0.042	
100 ppm	10	20.4± 1.3	0.179± 0.034	0.056± 0.008	0.129± 0.044	0.602± 0.050	0.751± 0.048	
200 ppm	10	21.1± 1.4	0.184± 0.031	0.060± 0.008	0.130± 0.021	0.606± 0.050	0.745± 0.029	
400 ppm	9	20.7± 1.0	0.175± 0.021	0.055± 0.010	0.105± 0.015	0.591± 0.050	0.724± 0.059	
800 ppm	10	19.6± 1.0	0.152± 0.036	0.055± 0.012	0.103± 0.016	0.559± 0.041	0.810± 0.042*	
Significant	difference;	*: P ≤ 0.05 **	: P ≤ 0.01	Tes	t of Dunnett			-
ICL042)	•	<u> </u>						BAI

ANIMAL : MOUSE BDF1

REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE: 4

up Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN	
Control	10	1.439± 0.050	0.223± 0.028	4.525± 0.246	2.250± 0.147	
50 ppm	10	1.473± 0.054	0.242± 0.017	4.792± 0.316	2.234± 0.125	
100 ppm	10	1.473± 0.076	0.252± 0.030	4.888± 0.282	2.184± 0.134	
200 ppm	10	1.480± 0.054	0.256± 0.042	5.006± 0.328	2.137± 0.140	
400 ppm	9	1.443± 0.069	0.250± 0.041	4.998± 0.569	2.155± 0.121	
mag 008	10	1.485± 0.087	0.216± 0.038	5.170± 0.612	2.216± 0.125	

(IICL042)

BAIS 3

APPENDIX B 9-1

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

RAT: MALE: SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0275 ANIMAL : RAT F344 REPORT TYPE : A1

: MALE

SEX

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

PAGE: 1

Organ	Findings	Group Name No. of Animals on Study Grade 1 (%)	Control 10 2 3 (%) (%)	1 (%)	50 ppm 10 2 3 (%) (%) (1 6) 1 (%)	100 ppm 10 2 3 4 (%) (%) (%)	$\begin{array}{cccccccccccccccccccccccccccccccccccc$
[Respiratory s	system]							
nasal cavit	erosion:respiratory epithelium	(0)	<10> 0 0 (0) (0) () (0)	<10> 0 0 0 0) (0) (0 (0)	<10> 0 0 0 (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
[Digestive sys	stem]							
liver	herniation	0 (0)	<10> 0 0 (0) (0) (0 (0)((10) 0 0 0) (0) (0 (0)	<10> 0 0 0 (0) (0) (0)	2 0 0 0 (20) (0) (0) (0)
	increase in mitasis	(0)	0 0 (0 (0) (0 0 0	0 (0)	0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	necrasis:single cell	(0)	0 0 (0 (0) (0 0 0	0 (0)	0 0 0 0 (0) (0)	8 0 0 0 ** (80) (0) (0) (0)
	deposit of hemosiderin	(0)	0 0 (0 (0) (0 0 0	0 (0)	0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	granulation	0 (0)	0 0 (0) (0 (0) (0 0 0	0 (0)	0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	swelling:central	(0)	0 0 (0 (0)(0 0 0	0 (0)	0 0 0 0 (0) (0)	3 0 0 0 0 (30) (0) (0) (0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

⁽a) a: Number of animals examined at the site b

b: Number of animals with lesion

⁽c) c : b / a * 100

Significant difference ; * : $P \le 0.05$ ** : $P \le 0.01$ Test of Chi Square

STUDY NO. : 0275 ANIMAL : RAT F344 HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (14W)

REPORT TYPE : A1 : MALE

Group Name 400 ppm 800 ppm No. of Animals on Study 10 10 Findings [Respiratory system] nasal cavit <10> <10> 1 0 0 0 erosion:respiratory epithelium 0 0 0 0 (10) (0) (0) (0) (0)(0)(0)(0) [Digestive system] liver <10> <10> 0 0 0 0 herniation 0 0 0 0 (0)(0)(0)(0) (0)(0)(0)(0) increase in mitosis 4 0 0 0 (40) (0) (0) (0) (50) (0) (0) (0) necrosis:single cell 10 0 0 0 ** (100) (0) (0) (0) (20) (80) (0) (0) deposit of hemosiderin 5 0 0 0 * 10 0 0 0 ** (50) (0) (0) (0) (100) (0) (0) (0) granulation 0 1 0 0 (10) (0) (0) (0) (0)(10)(0)(0) swelling:central 0 ** (80) (0) (0) (0) (90) (0) (0) (0) Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe (a) a: Number of animals examined at the site b: Number of animals with lesion b (c) c:b/a*100Significant difference; *: $P \le 0.05$ **: $P \le 0.01$ Test of Chi Square

PAGE: 2

STUDY NO. : 0275 ANIMAL : RAT F344 HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

PAGE: 3

BA1S3

SACRIFICED ANIMALS (14W)

REPORT TYPE : A1 SEX : MALE

Group Name Control 50 ppm 100 ppm 200 ppm No. of Animals on Study 10 10 10 10 3 3 (%) Findings_ (%) (%) (%) (%) (%) (%) (%) [Urinary system] kidney <10> <10> <10> <10> eosinophilic droplet:proximal tubule 10 0 0 0 10 0 0 0 10 0 0 0 10 0 0 0 (100) (0) (0) (0) (100) (0) (0) (0) (100) (0) (0) (0) (100) (0) (0) (0) Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe (a) a: Number of animals examined at the site b b: Number of animals with lesion (c) c:b/a * 100 Significant difference; $*:P \le 0.05$ $**:P \le 0.01$ Test of Chi Square (HPT150)

STUDY NO. : 0275 ANIMAL : RAT F344

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

REPORT TYPE : A1
SEX : MALE

MAL : KAI F344 SACRIFICED ANIMAL ORT TYPE : A1

Group Name 400 ppm mqq 008 No. of Animals on Study 10 10 Organ____ Findings____ [Urinary system] kidney <10> <10> eosinophilic droplet:proximal tubule 9 0 0 0 8 0 0 0 (90) (0) (0) (0) (80) (0) (0) (0) Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe <a>> a : Number of animals examined at the site b b: Number of animals with lesion (c) c : b / a * 100Significant difference; $*:P \le 0.05$ $**:P \le 0.01$ Test of Chi Square (HPT150) BA1S3

PAGE: 4

APPENDIX B 9-2

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

RAT: FEMALE: SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0275 ANIMAL : RAT F344 HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS (14W)

REPORT TYPE : A1 SEX : FEMALE

PAGE: 5

Organ	Findings	Group Name Control No. of Animals on Study 10 Grade 1 2 3 4 (%) (%) (%) (%)	50 ppm 10 10 (%) (%) (%) (%)	100 ppm 10 1 2 3 4 (%) (%) (%) (%)	200 ppm 10 1 2 3 4 (%) (%) (%) (%)
[Hematopoieti	c system]				
bone marrow	granulation	2 0 0 0 (20) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
thymus	atrophy	0 0 0 0 (0) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
[Digestive sy	rstem]				
liver	herniation	<10> 2 0 0 0 (20) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	3 0 0 0 (30) (0) (0) (0)
	increase in mitosis	0 0 0 0 0 0 (0)	0 0 0 0 0	0 0 0 0 0 (0) (0)	4 0 0 0 (40) (0) (0) (0)
	necrosis:focal	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	necrosis:single cell	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1 0 0 0 0 (10) (10) (10)	8 0 0 0 ** (80) (0) (0) (0)
Grade (a> b (c) Significant d	1: Slight 2: Moderate a: Number of animals examined at t b: Number of animals with lesion c: b / a * 100 lifference; *: P ≤ 0.05 **:				

(HPT150)

STUDY NO. : 0275 ANIMAL : RAT F344 HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS (14W)

REPORT TYPE : A1 SEX : FEMALE

PAGE: 6

Organ	Findings	Group Name 400 ppm No. of Animals on Study 10 Grade 1 2 3 4 (%) (%) (%) (%)	800 ppm 10 1 2 3 4 (%) (%) (%) (%)	
[Nematopoietic	c system]			
bone marrow	granulation	<10> 0 0 0 0 0 0 0 0 0 0 0	(10) 0 0 0 0 (0) (0) (0) (0)	
thymus	atrophy	0 0 0 0 (0) (0) (0) (0)	(9) 1 0 0 0 (11) (0) (0) (0)	
[Digestive sys	stem]			
liver	herniation	<10> 0 0 0 0 (0) (0) (0) (0)	(10> 0 0 0 0 (0) (0) (0) (0)	
	increase in mitosis	3 0 0 0 (30) (0) (0) (0)	0 0 0 0 0 (0) (0)	
	necrosis; focal	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (0) (0)	
	necrasis:single cell	9 0 0 0 ***	5 5 0 0 ** (50) (50) (0) (0)	
(a) (c)	1: Slight 2: Moderate a: Number of animals examined at the b: Number of animals with lesion c: b / a * 100 ifference; *: P ≤ 0.05 **: P			

(HPT150)

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

ANIMAL : RAT F344
REPORT TYPE : A1

STUDY NO. : 0275

SEX : FEMALE

PAGE: 7

Organ	Group Name No. of Ant Grade	Control imals on Study 10 10 1 2 3 4 (%) (%) (%) (%)	50 ppm 10 1 2 3 4 (%) (%) (%) (%)	100 ppm 10 10 (%) (%) (%) (%)	200 ppm 10 10 (%) (%) (%) (%)
[Digestive :	system]				
Liver	deposit of hemosiderin	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	10 0 0 0 ** (100) (0) (0) (0)
	granulation	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (10) (10) (10)
	swelling:central	0 0 0 0 0 (0) (0)	0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 (0)
[Urinary sys	stem]				
kidney	hyaline cast	<10> 0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
	mineralization:cortico-medullary junction	2 0 0 0 (20) (0) (0)	2 0 0 0 0 (20) (20) (0) (0)	1 0 0 0 (10) (0) (0) (0)	1 0 0 0 0 (10) (10) (10)
	mineralization:papilla	0 0 0 0 0 (0) (0)	0 0 0 0 0	0 0 0 0 0 (0) (0)	2 0 0 0 0 (20) (0) (0) (0)
(Endocrine :	system]				
thyroid	granulation	(0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)
Grade (a> b (c)	1: Slight 2: Moderate 3: Marked a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤ 0.01	4 : Severe			

/********

Dire

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

<10>

SACRIFICED ANIMALS (14W)

<10>

REPORT TYPE : A1 : FEMALE

> Group Name 400 ppm 800 ppm No. of Animals on Study 10 10 (%) (%) Findings_

[Digestive system]

liver

de	eposit of hemosiderin		10 00)	(0		0 0)	(0 **		10 00)	(0 0)	(0	0 ** 0)
gr	ranulation		0 0)	(0 0)		0 0)		0 0)	(:	1 10)	()	2 20)	(0 0)	0 0)
sw	uelling:central	(8	8 30)	(0 0)	(0 0)	(0 ** 0)		10 00)	(0	(0 0)	0 ** 0)

[Urinary system]

kidney					<	10>							<	10>			
	hyaline cast	(0	(0 0)	(0 0)	(0 0)	(10)	(0 0)	(0)	(0 0)
	mineralization:cortico-medullary junction	(3 30)	(0 0)	(0 0)	(0	(0 0)) (0 0)	(0 0	(0 0)
	mineralization:papilla	(0 0)	(0 0)	(0 0)	(0 0)	(100) (0 0)	(() ()	(0

[Endocrine system]

thyroid					<10	>				<10	>	
granu	ılation			0	0	0	0		0	0	Q	0
		-	(0) (0) (0) (0)	(0) (0) (0) (0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

a: Number of animals examined at the site (a) b: Number of animals with lesion

(c) c:b/a*100

Significant difference; $*: P \le 0.05$ **: $P \le 0.01$ Test of Chi Square

PAGE: 8

STUDY NO. : 0275 ANIMAL : RAT F344 HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (14W)

REPORT TYPE : A1
SEX : FEMALE

PAGE: 9

0rgan	Group Name No. of Ani Grade Findings	Control mals on Study 10 10 10 10 10 10 10 10 10 10 10 10 10	50 ppm 10 10 (%) (%) (%) (%)	100 ppm 10 10 (%) (%) (%) (%)	200 ppm 10 1 2 3 4 (%) (%) (%) (%)
[Reproductive s	system]				
uterus	aplasia	0 0 0 0 (0) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
Special sense	organs/appandage]				
larder gl	granulation	3 0 0 0 (30) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	3 0 0 0 (30) (0) (0) (0)
a > a b k c) c	1: Slight 2: Moderate 3: Marked a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 fference; *: P ≤ 0.05 **: P ≤ 0.01	4 : Severe 'est of Chi Square			
		'est of Chi Square			

STUDY NO. : 0275 ANIMAL : RAT F344 HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS (14W)

REPORT TYPE : A1 SEX : FEMALE

PAGE: 10

Organ	Group Na No. of A Grade Findings	me 400 ppm unimals on Study 10 1 2 3 4 (%) (%) (%) (%) (%)	800 pipm 10 1 2 3 4 (%) (%) (%) (%)	
[Reproducti	ue system]			
uterus	aplasia	1 0 0 0 (10) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	
[Special se	ense organs/appandage]			
Narder gl	granulation	1 0 0 0 (10) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	
Grade <a>> b (c) Significant	1: Slight 2: Moderate 3: Market a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 t difference; $*: P \le 0.05$ **: $P \le 0.01$			
(HPT150)				BAIS3

APPENDIX B 9-3

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: MALE: SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0276 ANIMAL : MOUSE BDF1 HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS (14W)

REPORT TYPE : A1

X : MALE

PAGE : 1

Organ	Group No. of No. of Grade Findings	Name Control Animals on Study 10 1 2 3 4 (%) (%) (%) (%)	50 ppm 10 1 2 3 4 (%) (%) (%) (%)	100 ppm 10 10 (%) (%) (%) (%)	200 ppm 10 1 2 3 4 (%) (%) (%) (%)
(Nematopoiet	tic system]				
spleen	deposit of hemosiderin	0 0 0 0 (0) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)	2 0 0 0 (20) (0) (0) (0)
Circulatory	/ system]				
heart	necrasis	<10> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)
Digestive s	system]				
tomach	erosion:forestomach	1 0 0 0 (10) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
	ulcer:farestamach	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)
	hyperplasia:forestomach	0 0 0 0 0 (0) (0)	1 0 0 0 (10) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)
Grade <a> b (c) Significant	1: Slight 2: Moderate 3: Mark a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤ 0.01				***************************************

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

ANIMAL : MOUSE BDF1
REPORT TYPE : A1

SEX : MALE

DIOT TOLD MAINING O

PAGE: 2

Organ	Group Name No. of Ania Grade Findings	400 ppm nals on Study 10 1 2 3 4 (%) (%) (%) (%)	800 pipm 10 1 2 3 4 (%) (%) (%)	
[Nematopoie	tic system]			
spleen	deposit of hemosiderin	<10> 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 (0) (0) (0) (0)	
[Circulator:	y system]			
heart	necrosis	<10> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 (0) (0) (0) (0)	
(Digestive :	system]			
stomach	erosion:forestomach	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	
	ulcer:forestomach	1 0 0 0 0 (10) (10) (10)	0 0 0 0 0 (0) (0)	
	hyperplasia:forestomach	1 0 0 0 0 (10) (10) (10)	2 0 0 0 0 (20) (0) (0)	
Grade 〈 a 〉 b (c) Significant	1 : Slight 2 : Moderate 3 : Marked a : Number of animals examined at the site b : Number of animals with lesion c : b / a * 100 t difference ; * : $P \le 0.05$ ** : $P \le 0.01$ T	4 : Severe est of Chi Square		

(HPT150)

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

ANIMAL : MOUSE BDF1 SA

REPORT TYPE : A1
SEX : MALE

PAGE: 3

Organ	Findings	Group Name Control No. of Animals on Study 10 Grade 1 2 3 4 (%) (%) (%) (%)	50 ppm 10 1 2 3 4 (%) (%) (%) (%)	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	200 ppm 10 1 2 3 4 (%) (%) (%) (%)
[Digestive sy	stem]		÷		
liver	necrosis:central	<10> 0 0 0 0 (0) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)
	necrosis:facal	0 0 0 0 0 (0)	0 0 0 0 0 (0)	0 0 0 0 0 (0)	0 0 0 0 0 (0) (0)
	necrosis:single cell	1 1 0 0 (10) (10) (0) (0)	1 2 0 0 (10) (20) (0) (0)	2 3 0 0 (20) (30) (0) (0)	3 1 0 0 (30) (10) (0) (0)
	deposit of ceroid	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)
	depasit of hemosiderin	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	1 0 0 0 (10) (0) (0) (0)
	mineralization	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0)
	swelling:central	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
[Urinary syst	em]				
(idney	∪acuolization of proximal tubule	10 0 0 0 (100) (0) (0) (0)	10 0 0 0 (100) (0) (0) (0)	10 0 0 0 (100) (0) (0) (0)	9 0 0 0 (90) (0) (0) (0)

····

pito

ANIMAL : MOUSE BDF1

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

REPORT TYPE : A1

SEX : MALE

Organ		Group Name 400 ppm No. of Animals on Study 10 Grade 1 2 3 4 (%) (%) (%) (%)	800 ppm 10 1 2 3 4 (%) (%) (%) (%)	
[Digestive	system]			
liver	necrosis:central	<10> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<10> 0 1 0 0 (0) (10) (0) (0)	
	necrosis:focal	0 0 0 0 0 (0) (0)	2 1 0 0 (20) (10) (0) (0)	
	necrosis:single cell	2 0 1 0 (20) (0) (10) (0)	0 9 1 0 **	
	deposit of ceroid	0 0 0 0 0 (0) (0)	1 0 0 0 (10) (0) (0) (0)	
	deposit of hemosiderin	0 0 0 0 0 (0) (0)	4 0 0 0 (40) (0) (0) (0)	
	mineralization	0 0 0 0 0 (0) (0)	3 0 0 0 0 (30) (0) (0) (0)	
	swelling:central	0 0 0 0 0 (0) (0)	0 10 0 0 ** (0) (100) (0) (0)	
[Urinary s	ystem]			
kidney	vacuolization of proximal tubule	4 0 0 0 * (40) (0) (0) (0)	(10) 0 0 0 0 ** (0) (0) (0)	
Grade (a> b (c) Significan	1: Slight 2: Moderate 3 a: Number of animals examined at the si b: Number of animals with lesion c: b / a * 100 t difference; *: P ≤ 0.05 **: P ≤			

PAGE: 4

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

ANIMAL : MOUSE BDF1
REPORT TYPE : A1

REPORT TYPE : A1
SEX : MALE

PAGE: 5

Organ	No	cup Name Control . of Animals on Study 10 ade 1/2 3 4 (%) (%) (%) (%)	50 ppm 10 1 2 3 4 (%) (%) (%) (%)	100 ppm 10 10 1 2 3 4 (%) (%) (%) (%)	200 ppm 10 1 2 3 4 (%) (%) (%) (%)
[Urinary sy	rstem]				
kidney	hydranephrasis	(10) 0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)
[Reproducti	ue system]				
testis	atrophy	(10) 1 0 0 0 (10) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
	spermatogenic granuloma	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)
[Special se	ense organs/appandage]				
өуе	keratitis	(10) 0 0 0 0 (0) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)
Grade <a>> b (c) Significant	1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 tdifference; *: P ≤ 0.05 **: P ≤ 0				

(IIPT150)

BAIS3

ANIMAL : MOUSE BDF1

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

REPORT TYPE : A1 SEX : MALE

Organ	Findings	Group Name 400 ppm No. of Animals on Study 10 Grade 1 2 3 4 (%) (%) (%) (%)	800 ppm 10 1 2 3 4 (%) (%) (%) (%)	
[Urinary sy	rstem]			
kidney	hydronephrosis	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	
[Reproducti	ue system]			
testis	atrophy	0 0 0 0 (0) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)	
	spermatogenic granuloma	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	
[Special se	nse organs/appandage]			
өуө	keratitis	(0) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	
Grade (a > b (c) Significant	1: Slight 2: Moderate a: Number of animals examined at th b: Number of animals with lesion c: b / a * 100 cdifference: *: P ≤ 0.05 **:	3 : Marked 4 : Severe me site		
(HPT150)				BAIS3

PAGE: 6

APPENDIX B 9-4

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: FEMALE: SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0276 ANIMAL : MOUSE BDF1 HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS ($14\mbox{\ensuremath{\mbox{W}}})$

REPORT TYPE : A1

SEX : FEMALE

PAGE: 7

Organ		Group Name Control No. of Animals on Study 10 Grade 1 2 3 4 (%) (%) (%) (%)	10 10 1 2 3 4 (%) (%) (%) (%)	100 ppm 10 10 (%) (%) (%) (%)	200 ppm 10 1 2 3 4 (%) (%) (%)
[Respiratory	system]				
nasal cauit	desquamation:olfactory epithelium	<10> 0 0 0 0 (0) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)
[Hematopoiet	ic system]				
spleen	deposit of hemosiderin	0 0 0 0 (0) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
[Digestive s	ystem]				
stomach	ulcer:forestomach	1 0 0 0 (10) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)
	hyperplasia:forestomach	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	erosion:glandular stomach	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
Grade <a> b (c) Significant (URTISA)	1: Slight 2: Moderate 3 a: Number of animals examined at the si b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤				

(IIPT150)

SEX

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

ANIMAL. : MOUSE BDF1 REPORT TYPE : A1

: FEMALE

PAGE: 8

Organ	No	oup Name 400 ppm . of Animals on Study 9 ade 1 2 3 4 (%) (%) (%) (%)	800 ppm 10 1 2 3 4 (%) (%) (%) (%)	
[Respiratory	system] .			
nasal ca∪it	desquamation:olfactory epithelium	(9) 1 0 0 0 (11) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)	
[Hematopoiet	cic system]			
spleen	deposit of hemosiderin	(9) 1 0 0 0 (11) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	
[Digestive s	system]			
stomach	ulcer:forestomach	0 0 0 0 0 0 (0) (0)	1 0 0 0 (10) (0) (0) (0)	
	hyperplasia:forestomach	0 0 0 0 0 (0) (0)	1 0 0 0 (10) (0) (0) (0)	
	erosion:glandular stomach	0 0 0 0 0 (0) (0)	1 0 0 0 (10) (0) (0) (0)	
Grade <a>> b (c) Significant	1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; $*: P \le 0.05$ **: $P \le 0.05$			

(HPT150)

STUDY NO. : 0276 ANIMAL : MOUST HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : MOUSE BDF1
REPORT TYPE : A1

SEX : FEMALE

SACRIFICED ANIMALS (14W)

Group Name Control 50 ppm 100 ppm 200 ppm No. of Animals on Study 10 10 10 10 2 3 3 3 Findings (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) [Digestive system] liver <10> <10> <10> <10> 0 0 0 0 0 0 0 increase in mitosis 0 0 0 0 2 0 0 0 (0)(0)(0)(0) (10) (0) (0) (0) (0)(0)(0)(0) (20) (0) (0) (0) necrosis:focal 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) necrosis:single cell 0 0 0 0 3 2 0 0 * 3 4 0 0 ** 3 3 2 0 ** (0)(0)(0)(0) (30) (20) (0) (0) (30) (40) (0) (0) (30) (30) (20) (0) deposit of hemosiderin (0)(0)(0)(0) (0) (0) (0) (0) (0)(0)(0)(0) (20) (0) (0) (0) swelling:central 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) [Nervous system] brain <10> <10> <10> <10> epidermal cyst 0 0 0 0 0 0 0 0 0 0 0 0 1 0 0 0 (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (10) (0) (0) (0) Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe <a>> a: Number of animals examined at the site b b: Number of animals with lesion (c) c:b/a*100Significant difference; $*: P \le 0.05$ **: $P \le 0.01$ Test of Chi Square

PAGE: 9

STUDY NO. : 0276 ANIMAL : MOUSE BDF1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (14W)

REPORT TYPE : A1

: FEMALE SEX

> Group Name 400 ppm maa 008

Organ	Findings	No. of Animals on Study 9	10 10 1 2 3 4 (%) (%) (%) (%)	
(Digestive :	system]			
liver	increase in mitosis	1 0 0 0 (11) (0) (0) (0)	(10) 1 0 0 0 (10) (0) (0) (0)	
	necrosis:focal	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	
	necrosis:single cell	2 5 1 0 ** (22) (56) (11) (0)	1 5 4 0 ** (10) (50) (40) (0)	
	deposit of hemosiderin	1 0 0 0 (11) (0) (0) (0)	2 0 0 0 0 (20) (0) (0) (0)	
	swelling:central	0 0 0 0 0 (0) (0)	6 0 0 0 * (60) (0) (0)	
[Ner∪ous sy:	vstem]			
orain	epidermal cyst	<pre></pre>	(10) 0 0 0 0 (0) (0) (0) (0)	
Grade <a> b (c) Significant	1: Slight 2: Moderate a: Number of animals examined at t b: Number of animals with lesion c: b / a * 100 t difference; *: P ≤ 0.05 **:			

(HPT150)

BAIS3

PAGE: 10

APPENDIX B 10-1 IDENTITY OF *N,N*-DIMETHYLFORMAMIDE (THIRTEEN - WEEK STUDY)

IDENTITY OF N, N-DIMETHYLFORMAMIDE(THIRTEEN-WEEK STUDIES)

Lot no. CAL4288

1. Spectral data

Mass Spectrometry

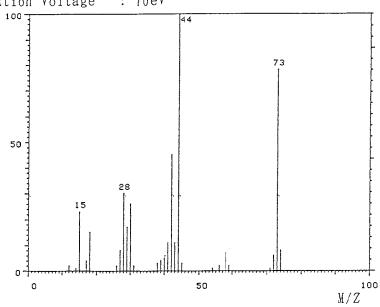
Instrument

: Hitachi M-80B Mass Spectrometer

Ionization

: EI Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

Results: The mass spectrum was consistent with literature spectrum.

Determined Values Fragment Peak(M/Z)	<u>Literature Values*</u> Fragment Peak(M/Z)
15 28 44(Base Peak) 73	15 28 44(Base Peak) 73 (*EPA/NIH Mass Spectral

Data Base (1978) Yol. 1,

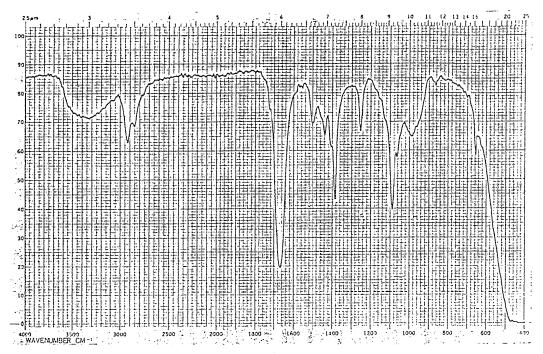
p. 20.)

Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr

Slit : Medium



Infrared Spectrum of Test Substance

Results: The infrared spectrum was consistent with literature spectrum.

Determined Values	Literature Values*
Wave Number(cm ⁻¹)	₩ave Number(cm ⁻¹)
650~ 680	650~ 680
850~ 890	850~ 890
$920 \sim 1030$	
1030~1150	1030~1150
1220~1280	1220~1280
$1350 \sim 1430$	$1350 \sim 1430$
$1430 \sim 1480$	$1430 \sim 1480$
$1480 \sim 1540$	$1480 \sim 1540$
$1600 \sim 1760$	$1600 \sim 1760$
2800~3000	2800~3000
3100~3650	3100~3700
	(*Performed by the WAKO PURE
	tuning the transfer to the terms of the term

CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The test substance was identified as N, N-Dimethylformamide, by the mass spectrum and the infrared spectrum.

APPENDIX B 10-2 STABILITY OF *N,N*-DIMETHYLFORMAMIDE (THIRTEEN - WEEK STUDY)

STABILITY OF N, N-DIMETHYLFORMAMIDE(THIRTEEN-WEEK STUDIES)

Lot no. CAL4288

1. Sample: This lot was used from 1994.9.7 to 1994.12.12. Test substance was

stored at room temperature.

2. Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr

Slit : Medium

Results: The result of infrared spectrum did not change when before and

after studies.

1994.09.06(date analyzed)	1994.12.14(date analyzed)
Wave Number(cm ⁻¹)	Wave Number(cm ⁻¹)
650~ 680	650~ 680
850~ 890	850~ 890 .
920~1030	920~1030
1030~1150	1030~1150
1220~1280	1220 ~ 1280
$1350 \sim 1430$	$1350 \sim 1430$
$1430 \sim 1480$	$1430 \sim 1480$
$1480 \sim 1540$	$1480 \sim 1540$
$1600 \sim 1760$	$1600 \sim 1760$
2800~3000	2800~3000
3100~3650	3100~3650

3. Gas Chromatography

Instrument: Hewlett Packard 5890A Gas Chromatograph

Column: INNOWax(0.2mm $\phi \times 50$ m)

Column Temperature: 150°C

Flow Rate: 1 ml/min

Detector: FID(Flame Ionization Detector)

Injection Volume: 1 μ 1

Results: Gas chromatography indicated one major peak(peak No.1) analyzed at 1994.9.6 and one major peak(peak No.1) analyzed at 1994.12.14. No new treace impurity peak in the test substance analyzed at 1994.12.14 was detected.

Date	Peak	No.	Retention Time(min)	Area Count	
1994.09.0 (date ana		1	6.013	28353	
1994.12.1 (date a.a		1	6.013	28450	

^{4.} Conclusions: The test substance was stable for about 3 months in the dark at room temperature.

APPENDIX B 11-1

CONCENTRATION OF N, N-DIMETHYLFORMAMIDE IN INHALATION CHAMBER (THIRTEEN - WEEK STUDY)

CONCENTRATION OF N, N-DIMETHYLFORMAMIDE

IN INHALTION CHAMBER (RAT: THIRTEEN-WEEK STUDY)

	Concentration (ppm)			
Group Name	Mean \pm S.D.			
Control	0.0 ± 0.0			
50ppm	49.6 ± 0.7			
100ppm	100.1 ± 0.8			
200ppm	199.5 \pm 1.9			
400ppm	399.7 ± 3.2			
800ppm	795.6 ± 9.3			

CONCENTRATION OF N, N-DIMETHYLFORMAMIDE

IN INHALTION CHAMBER

(MOUSE: THIRTEEN-WEEK STUDY)

Group Name	Concentration (ppm) Mean ± S.D.
Control	0.0 ± 0.0
50ppm	50.1 ± 0.7
100ppm	100.3 ± 1.3
200ppm	199.2 \pm 1.7
400ppm	400.2 ± 1.7
800ppm	796.3 ± 5.7

APPENDIX B 11-2 ENVIRONMENT OF INHALATION CHAMBER (THIRTEEN - WEEK STUDY)

ENVIRONMENT OF INHALATION CHAMBER (RAT: THIRTEEN-WEEK STUDY)

Group Name	Temperature(°C) Mean ± S.D.	Humidity(%) Mean ± S.D.	Ventilation Rate(L/min) Mean ± S.D.	Room Air Change(time/h) Mean
Control	22.4 ± 0.1	57.0 ± 0.4	212.0 ± 0.6	12.0
50ppm	21.8 ± 0.4	57.0 ± 0.6	211.8 ± 0.5	12.0
100ppm	22.6 ± 0.2	56.6 ± 0.8	211.1 ± 0.7	11.9
200ppm	22.3 ± 0.1	51.9 ± 0.7	211.9 ± 0.6	12.0
400ppm	22.8 ± 0.1	49.3 ± 1.0	210.9 ± 0.7	11.9
800ppm	22.6 ± 0.1	53.5 ± 1.1	212.1 ± 0.7	12.0

ENVIRONMENT OF INHALATION CHAMBER (MOUSE: THIRTEEN-WEEK STUDY)

Group Name	Temper Mean		• •	Humio Mean			Ventilatio Mean		, , ,	Room Air Change(time/h) Mean
Control	21.2	<u>±</u>	0.2	58.1	<u>+</u>	1.2	104.1	+	0.3	12.0
50ppm	21.1	\pm	0.2	53.4	<u>±</u>	0.7		<u>+</u>		12.0
100ppm	21.4	土	0.2	55.3	\pm	0.9	104.5			12.1
200ppm	21.9	\pm	0.1	54.0	\pm	1.2	103.9		0.3	12.0
400ppm	22.7	\pm	0.1	52.1	\pm	1.1	104.3		0.4	12.0
800ppm	22.1	<u>+</u>	0.1	50.2	\pm	1.2	104.4		0.3	12.0

APPENDIX B 12 METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS (THIRTEEN - WEEK STUDY)

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS (THIRTEEN WEEK STUDIES)

Item	Method					
Hematology						
Red blood cell (RBC)	Light scattering method 1)					
Hemoglobin (Hgb)	Cyanmethemoglobin method 1)					
Hematocrit (Hct)	Calculated as RBC×MCV/10 1)					
Mean corpuscular volume (MCV)	Light scattering method 1)					
Mean corpuscular hemoglobin (MCH)	Calculated as Hgb/RBC×10 1)					
Mean corpuscular hemoglobin concentration	Calculated as Hgb/Hct×100 1)					
(MCHC)						
Platelet	Light scattering method 1)					
Reticulocyte	Pattern recognition method 3)					
the distance of the	(New methyleneblue staining)					
Prothrombin time	Quick one stage method 2)					
Activated partial thromboplastin time (APTT)	Ellagic acid activated method 2)					
Activated partial antomorphism time (mill)	briagic acid accivated method					
White blood cell (WBC)	Light scattering method 1)					
Differential WBC	Pattern recognition method 3)					
DITIOI GILLIUI MDO	(May-Grunwald-Giemsa staining)					
	(ita) of direct of case of carries					
Biochemistry						
Total protein (TP)	Biuret method 4)					
Albumin (Alb)	BCG method 4)					
A/G ratio	Calculated as Alb/(TP-Alb) 4)					
T-bilirubin	Alkaline azobilirubin method 4)					
Glucose	Enzymatic method (GLK·G-6-PDH) 4)					
T-cholesterol	Enzymatic method (CE·COD·POD) 4)					
Triglyceride	Enzymatic method (LPL-GK-GPO-POD) 4)					
Phospholipid	Enzymatic method (PLD·COD·POD) 4)					
Glutamic oxaloacetic transaminase (GOT)	IFCC method 4)					
Glutamic pyruvic transaminase(GPT)	IFCC method 4)					
Lactate dehydrogenase (LDH)	Wroblewski-LaDue method 4)					
Alkaline phosphatase (ALP)	GSCC method 4)					
γ -Glutamyl transpeptidase (G-GTP)	$L-\gamma$ -Glutamyl-p-nitroanilide substrate method 4)					
Creatine phosphokinase (CPK)	GSCC method 4)					
Urea nitrogen	Enzymatic method (Urease · GLDH) 4)					
Creatinine	Jaffe metod 4)					
Sodium	Ion selective electrode method 4)					
Potassium	Ion selective electrode method 4)					
Chloride	Ion selective electrode method 4)					
Calcium	OCPC method 4)					
Inorganic phosphorus	Enzymatic method (PNP·XOD·POD) 4)					
Urinalysis						
pH, Protein, Glucose, Ketone body,	Urinalysis reagent paper metod 5)					
Bilirubin, Occult Blood,	0					
Urobilinogen						

- 1) Automatic blood cell analyzer (Technicon H·1 : Technicon Instruments Corporation, USA) 2) Automatic coagulometer (Sysmex CA-5000 : Toa Medical Electronics Co., Ltd., Japan)
- 3) Automatic blood cell differential analyzer (Hitachi 8200 : Hitachi ,Ltd., Japan)
- 4) Automatic analyzer (Hitachi 7070 : Hitachi ,Ltd.,Japan)
- 5) Ames reagent strips for urinalysis (Multistix, Uro-Labstix: Miles-Sankyo Co., Ltd., Japan)

APPENDIX C 1

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY

Item	Unit	Decimal place
Hematology		
Red blood cell (RBC)	×106/μL	2
Hemoglobin (Hgb)	g/dL	1
Hematocrit (Hct)	%	1
Mean corpuscular volume (MCV)	fL	1
Mean corpuscular hemoglobin (MCH)	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	g/dL	1
Reticulocyte	%	0
Prothrombin time	sec	1
Activated partial thromboplastin time (APTT)	sec	1
Platelet	×103/μL	0
White blood cell (WBC)	×103/μL	2
Differential WBC	%	0
Biochemistry		
Total protein	g/dL	1
Albumin	g/dL	1
A/G ratio	_	1
T-bilirubin	mg/dL	2
Glucose	mg/dL	0
T-cholesterol	mg/dL	0
Triglyceride	mg/dL	0
Phospholipid	mg/dL	0
Glutamic oxaloacetic transminase (GOT)	IU/L	0
Glutamic pyruvic transaminase (GPT)	IU/L	0
Lactate dehydrogenase (LDH)	IU/L	0
ALkaline phosphatase (ALP)	IU/L	0
γ -Glutamyl transpeptidase (G-GTP)	IU/L	0
Creatine phosphokinase (CPK)	IU/L	0
Urea nitrogen	mg/dL	1
Creatinine	mg/dL	1
Sodium	mEq/L	0
Potassium	mEq/L	1
Chloride	mEq/L	0
Calcium	mg/dL	1
Inorganic phosphorus	mg/dL	1