

1,2-ジクロロエタンのラット及びマウスを用いた
吸入によるがん原性試験報告書

APPENDIX

(C1-1～C11-2)

13Week STUDY NO. 0055 ; 0056

APPENDIX C 1-1

CLINICAL OBSERVATION (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day													
		0-0	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	7	-	-	-	-	-	-	-	-	-	-	-	-
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	2	-	-	-	-	-	-	-	-	-	-	-	-
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	1	-	-	-	-	-	-	-	-	-	-	-	-
ATAXIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	1	-	-	-	-	-	-	-	-	-	-	-	-
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	1	-	-	-	-	-	-	-	-	-	-	-	-

STUDY NO. : 0055
 ANIMAL : RAT F344
 REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 2

Clinical sign	Group Name	Administration Week-day													
		0-0	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
GUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	0	-	-	-	-	-	-	-	-	-	-	-	-
SORE OF SOLE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	0	-	-	-	-	-	-	-	-	-	-	-	-
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	1	-	-	-	-	-	-	-	-	-	-	-	-
LOOSE STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	320 ppm	0	0	-	-	-	-	-	-	-	-	-	-	-	-

(HAN190)

BAIS 2

APPENDIX C 1-2

CLINICAL OBSERVATION (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 3

Clinical sign	Group Name	Administration Week-day													
		0-0	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-
COLORED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	1	0	0	0	1	1
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	160 ppm	0	0	0	0	0	0	0	0	2	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-
LACRYMATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-

STUDY NO. : 0055
 ANIMAL : RAT F344
 REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 4

Clinical sign	Group Name	Administration Week-day													
		0-0	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
EYE HEMORRHAGIC DISCHA	Control	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-
SORE OF SOLE	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	2
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-
NOSE HEMORRHAGIC DISCHA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-
LOOSE STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-

(HAN190)

BAIS 2

APPENDIX C 1-3

CLINICAL OBSERVATION (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: MALE

STUDY NO. : 0056
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day													
		0-0	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILOERECTION	Control	0	0	1	1	0	0	2	2	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	1	0	0	0	1	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	2	2	1	0	2	2	0	0	0	0	0	1
	160 ppm	0	1	1	1	0	0	0	1	0	0	0	0	0	0
LOSS OF HAIR	Control	0	0	1	0	0	0	0	0	1	2	3	3	3	4
	10 ppm	0	0	1	1	2	2	3	3	3	3	3	3	3	3
	20 ppm	0	0	0	0	0	0	0	2	2	4	4	4	4	4
	40 ppm	0	0	0	0	0	0	2	1	2	2	2	2	2	2
	80 ppm	0	0	0	0	0	0	1	2	2	1	2	3	3	4
	160 ppm	0	0	0	0	0	0	1	2	2	2	2	2	3	3
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	1	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	2	2	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS2

APPENDIX C 1-4

CLINICAL OBSERVATION (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 2

Clinical sign	Group Name	Administration Week-day													
		0-0	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	1	2	2	2	2	2	3	4	4	4	4	4	4
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	1	2	2	2	2	2	2
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	1	0	0	0	0	0	0	0	0	0	0	0
LOSS OF HAIR	Control	0	0	0	2	3	3	5	5	5	5	5	4	6	6
	10 ppm	0	0	0	1	1	3	5	5	5	6	4	5	5	5
	20 ppm	0	0	0	0	0	0	3	4	5	5	5	5	5	6
	40 ppm	0	0	0	0	0	2	3	6	7	7	6	6	6	6
	80 ppm	0	0	1	2	3	3	6	7	7	7	7	7	8	8
	160 ppm	0	0	1	1	1	1	1	2	1	2	2	2	2	2
TRAUMA	Control	0	1	1	1	1	1	1	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	1	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 3

Clinical sign	Group Name	Administration Week-day													
		0-0	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
NOSE HEMORRHAGIC DISCHA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	1	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 2

APPENDIX C 2-1

BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE

STUDY NO. : 0055
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration		week-day									
	0-0		1-7		2-7		3-7		4-7		5-7	
Control	101±	3	116±	4	130±	5	142±	5	152±	5	162±	7
20 ppm	101±	3	116±	5	131±	5	141±	8	153±	8	161±	10
40 ppm	101±	4	115±	4	129±	4	140±	5	149±	5	157±	7
80 ppm	101±	4	117±	5	134±	7	145±	8	154±	7	165±	12
160 ppm	101±	4	117±	4	129±	6	142±	7	150±	8	158±	10
320 ppm	101±	4	-		-		-		-		-	

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0055
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week-day											
	7-7		8-7		9-7		10-7		11-7		12-7	
Control	178±	6	182±	7	187±	5	191±	7	196±	5	199±	7
20 ppm	175±	11	182±	9	187±	11	191±	11	197±	13	202±	12
40 ppm	171±	8	177±	8	180±	8	187±	8	188±	8	193±	9
80 ppm	182±	15	189±	16	192±	16	200±	17	201±	17	208±	19
160 ppm	174±	12	180±	13	186±	13	190±	13	196±	13	200±	14
320 ppm	-		-		-		-		-		-	

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

Test of Dunnett

(HAN260)

BAIS 2

APPENDIX C 2-2

BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE

STUDY NO. : 0055
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration		week-day									
	0-0		1-7		2-7		3-7		4-7		5-7	
Control	118±	4	147±	5	178±	8	204±	11	227±	13	247±	15
20 ppm	118±	4	147±	8	179±	13	206±	16	229±	18	249±	22
40 ppm	118±	4	145±	6	177±	8	205±	8	230±	8	251±	9
80 ppm	118±	4	146±	5	181±	6	210±	7	235±	7	258±	6
160 ppm	118±	4	144±	8	176±	11	204±	12	229±	12	251±	14
320 ppm	118±	5	117±	0	-		-		-		-	

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0055
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day		7-7		8-7		9-7		10-7		11-7		12-7		13-7	
Control	280±	17	294±	17	305±	18	313±	18	325±	18	334±	19	343±	20		
20 ppm	282±	26	299±	27	313±	29	323±	29	331±	31	341±	29	351±	29		
40 ppm	286±	9	301±	10	316±	9	327±	9	334±	9	343±	9	351±	10		
80 ppm	293±	8	308±	9	322±	10	332±	11	341±	11	349±	11	355±	12		
160 ppm	286±	13	302±	12	317±	12	328±	13	337±	13	347±	13	357±	12		
320 ppm	-		-		-		-		-		-		-			

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

Test of Dunnett

(HAN260)

BAIS 2

APPENDIX C 2-3

BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: MALE

STUDY NO. : 0056
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration week-day						
	0-0	1-7	2-7	3-7	4-7	5-7	6-7
Control	23.8± 1.0	25.0± 0.9	26.2± 1.0	27.2± 1.3	28.1± 1.6	28.7± 1.5	29.9± 1.8
10 ppm	23.8± 0.9	25.1± 1.1	26.0± 1.0	26.5± 1.3	27.3± 1.3	27.9± 1.6	29.0± 1.7
20 ppm	23.8± 0.9	24.9± 1.0	26.0± 1.0	27.1± 1.3	27.8± 1.4	28.5± 1.6	29.1± 1.7
40 ppm	23.8± 0.9	24.8± 1.2	25.4± 1.2	26.0± 1.0	26.7± 1.2	27.4± 1.0	28.3± 1.1
80 ppm	23.8± 0.9	24.7± 0.8	25.4± 0.8	26.4± 1.2	27.2± 1.3	28.0± 1.5	28.6± 1.6
160 ppm	23.8± 0.9	24.1± 1.1	25.1± 1.1	26.2± 1.4	26.9± 1.3	27.6± 1.5	28.1± 1.6

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0056
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day						
	7-7	8-7	9-7	10-7	11-7	12-7	13-7
Control	30.7± 2.3	31.6± 2.2	32.2± 2.4	33.1± 2.4	34.0± 2.3	35.2± 2.6	35.2± 3.0
10 ppm	29.4± 1.9	30.3± 1.6	30.8± 1.9	31.7± 2.1	32.6± 2.4	34.0± 2.5	33.5± 2.4
20 ppm	30.1± 1.9	31.3± 2.2	31.8± 2.4	32.9± 2.5	33.4± 2.8	34.7± 2.9	34.7± 2.8
40 ppm	28.4± 1.6	29.7± 1.6	29.8± 1.7*	30.5± 2.0*	31.2± 2.3	32.2± 2.4*	31.9± 2.7*
80 ppm	29.1± 1.8	30.5± 2.0	30.6± 2.0	31.3± 2.0	31.8± 2.1	32.8± 2.4	32.1± 2.4
160 ppm	28.5± 1.5	29.9± 1.9	29.8± 1.7*	30.7± 1.8	31.4± 2.4	32.0± 2.5*	31.6± 3.0*

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS2

APPENDIX C 2-4

BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE

STUDY NO. : 0056
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week-day						
	0-0	1-7	2-7	3-7	4-7	5-7	6-7
Control	18.9± 0.6	20.0± 0.7	20.3± 0.3	21.5± 0.6	22.0± 1.0	22.8± 1.1	23.5± 1.0
10 ppm	18.9± 0.6	19.8± 1.1	20.9± 1.2	21.3± 0.9	22.5± 1.2	22.4± 1.0	23.7± 1.5
20 ppm	18.9± 0.7	20.0± 0.7	20.9± 0.7	21.1± 0.8	22.4± 0.9	22.7± 0.8	23.4± 0.8
40 ppm	18.9± 0.7	19.9± 0.8	20.6± 0.7	21.1± 0.6	22.1± 1.0	22.3± 0.5	23.3± 0.6
80 ppm	18.9± 0.7	19.6± 0.4	20.1± 0.8	20.6± 0.6	21.6± 0.8	22.5± 0.9	22.8± 0.8
160 ppm	18.9± 0.7	19.6± 0.5	20.2± 2.3	21.9± 1.0	22.2± 0.8	23.1± 0.7	23.0± 0.6

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BALS2

STUDY NO. : 0056
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name		Administration		week-day											
		7-7		8-7		9-7		10-7		11-7		12-7		13-7	
Control		23.8±	0.6	24.1±	1.2	24.3±	1.4	25.0±	1.4	25.6±	1.5	26.6±	1.6	25.9±	1.9
10	ppm	24.2±	1.2	24.9±	1.6	24.5±	1.6	25.4±	2.0	26.0±	2.0	26.6±	1.7	25.7±	2.0
20	ppm	23.7±	0.7	24.5±	1.1	24.0±	1.1	24.6±	0.9	24.9±	0.8	25.7±	1.1	25.2±	1.3
40	ppm	23.7±	1.1	24.4±	1.1	24.2±	1.0	24.1±	0.8	25.6±	1.1	25.3±	1.0	24.6±	1.2
80	ppm	23.5±	1.0	24.3±	1.1	24.4±	1.7	24.6±	1.1	25.0±	0.9	25.2±	1.3	24.1±	0.9*
160	ppm	23.9±	0.5	24.2±	0.8	24.6±	0.5	24.7±	0.6	25.3±	1.1*	25.9±	1.2**	24.7±	0.8**

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

Test of Dunnett

(HAN260)

BAIS 2

APPENDIX C 3-1

FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE

STUDY NO. : 0055
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration week-day(effective) 1-7(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	14.1± 0.7	16.3± 1.3	17.0± 1.8	17.4± 1.9	17.3± 1.6	17.1± 1.2	17.3± 1.2
20 ppm	14.7± 1.1	16.4± 1.5	17.1± 2.0	17.4± 2.1	17.0± 2.1	17.3± 2.1	17.4± 1.9
40 ppm	14.8± 1.1	16.7± 1.5	17.2± 1.1	17.9± 1.5	17.8± 1.3	18.1± 1.1	18.0± 1.3
80 ppm	15.2± 1.1	16.8± 1.1	18.2± 1.5	18.6± 1.6	18.7± 1.2	18.8± 1.2*	18.1± 1.1
160 ppm	15.0± 0.9	17.5± 0.9	18.4± 1.2	18.4± 1.2	19.1± 0.9*	19.4± 1.0**	18.6± 1.5
320 ppm	10.6± 0.0	-	-	-	-	-	-

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0055
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day(effective) 8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)
Control	17.3± 1.3	16.9± 1.1	17.8± 1.3	16.8± 1.1	16.6± 1.3	17.2± 1.4
20 ppm	17.6± 1.9	17.2± 1.8	17.6± 1.8	17.2± 1.6	17.1± 1.4	17.3± 1.5
40 ppm	18.2± 1.3	18.0± 1.2	18.1± 1.0	17.2± 1.0	17.1± 0.6	17.1± 1.1
80 ppm	18.0± 0.9	17.9± 1.1	17.9± 1.2	17.0± 0.9	17.3± 1.1	16.8± 0.9
160 ppm	18.5± 1.5	18.5± 1.3	18.9± 1.5	18.1± 1.2	17.8± 0.8	17.9± 0.9
320 ppm	-	-	-	-	-	-

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX C 3-2

FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE

STUDY NO. : 0055
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week-day(effective)						
	1-7(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	12.3± 0.7	12.3± 0.5	12.2± 0.7	11.9± 0.6	11.7± 0.9	11.6± 0.6	12.0± 0.6
20 ppm	12.0± 1.1	12.2± 0.8	12.2± 1.1	11.8± 0.8	11.5± 1.0	11.8± 0.9	11.3± 1.0
40 ppm	12.2± 1.0	12.4± 1.3	12.2± 0.8	11.9± 0.7	11.4± 0.9	11.6± 0.8	11.4± 1.0
80 ppm	12.2± 0.9	12.4± 0.9	12.6± 1.3	12.3± 1.1	12.3± 1.6	12.5± 1.4	12.5± 1.9
160 ppm	12.1± 1.2	11.9± 1.2	12.2± 1.2	11.6± 1.3	11.5± 1.2	11.5± 1.4	12.1± 1.5
320 ppm	-	-	-	-	-	-	-

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0055
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week-day(effective)					
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)
Control	11.3± 0.5	11.5± 0.9	11.0± 0.7	11.6± 0.7	11.4± 0.6	11.9± 0.6
20 ppm	11.1± 0.9	11.5± 1.3	11.4± 0.9	11.4± 1.1	11.9± 1.1	11.5± 1.5
40 ppm	11.3± 0.9	11.0± 0.6	11.6± 0.9	10.8± 0.6	11.0± 0.9	11.1± 0.8
80 ppm	12.6± 1.7	12.0± 1.6	12.3± 1.4	11.7± 1.4	12.1± 1.6	12.4± 1.4
160 ppm	11.5± 1.5	12.0± 1.1	11.6± 1.0	12.2± 1.1	11.6± 1.4	12.4± 1.2
320 ppm	-	-	-	-	-	-

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 2

APPENDIX C 3-3

FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: MALE

STUDY NO. : 0056
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration week-day(effective)						
	1-7(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	4.3± 0.3	4.2± 0.3	4.3± 0.3	4.0± 0.3	4.0± 0.3	4.2± 0.3	4.1± 0.4
10 ppm	4.2± 0.3	4.1± 0.4	4.1± 0.3	3.9± 0.3	4.0± 0.3	4.1± 0.3	4.0± 0.3
20 ppm	4.2± 0.2	4.2± 0.2	4.3± 0.2	4.0± 0.3	4.1± 0.2	4.1± 0.3	4.2± 0.3
40 ppm	4.3± 0.4	4.1± 0.2	4.4± 0.3	4.1± 0.3	4.2± 0.2	4.3± 0.3	4.0± 0.3
80 ppm	4.2± 0.3	4.1± 0.3	4.2± 0.3	3.9± 0.3	4.1± 0.4	4.1± 0.4	4.1± 0.4
160 ppm	4.0± 0.3	4.4± 0.4	4.5± 0.4	4.1± 0.4	4.3± 0.4	4.5± 0.5	4.4± 0.7

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0056
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration 8-7(7)	week-day(effective) 9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)
Control	4.1± 0.3	4.2± 0.3	4.2± 0.3	4.3± 0.3	4.4± 0.3	4.4± 0.2
10 ppm	4.0± 0.3	4.2± 0.4	4.1± 0.4	4.2± 0.3	4.2± 0.4	4.4± 0.4
20 ppm	4.3± 0.3	4.3± 0.3	4.3± 0.2	4.3± 0.2	4.4± 0.3	4.5± 0.3
40 ppm	4.1± 0.2	4.2± 0.3	4.2± 0.3	4.2± 0.3	4.2± 0.2	4.5± 0.4
80 ppm	4.1± 0.3	4.0± 0.2	4.1± 0.2	4.1± 0.2	4.3± 0.4	4.3± 0.4
160 ppm	4.5± 0.6	4.4± 0.5	4.5± 0.5	4.6± 0.5	4.5± 0.5	4.6± 0.6

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS2

APPENDIX C 3-4

FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE

STUDY NO. : 0056
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week-day(effective)						
	1-7(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	3.5± 0.3	3.7± 0.2	3.9± 0.2	3.8± 0.2	3.9± 0.3	4.0± 0.2	3.9± 0.3
10 ppm	3.5± 0.4	3.7± 0.3	3.7± 0.3	3.9± 0.3	3.9± 0.2	4.1± 0.2	3.9± 0.3
20 ppm	3.6± 0.2	3.8± 0.2	3.8± 0.2	3.9± 0.2	3.9± 0.2	3.9± 0.2	4.1± 0.3
40 ppm	3.4± 0.4	3.5± 0.3	3.8± 0.3	3.8± 0.3	3.8± 0.2	4.0± 0.3	4.0± 0.3
80 ppm	3.4± 0.3	3.5± 0.2	3.9± 0.3	3.7± 0.2	3.9± 0.3	3.9± 0.3	3.9± 0.2
160 ppm	3.4± 0.2	3.5± 0.5	4.1± 0.2	3.9± 0.2	4.1± 0.2	4.2± 0.2	4.3± 0.3

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0056
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week-day(effective)					
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)
Control	4.0± 0.2	4.0± 0.2	4.0± 0.2	4.2± 0.3	4.2± 0.3	4.2± 0.3
10 ppm	4.2± 0.2	4.1± 0.2	4.1± 0.2	4.2± 0.3	4.3± 0.3	4.3± 0.5
20 ppm	4.1± 0.2	4.2± 0.3	4.2± 0.3	4.2± 0.3	4.2± 0.2	4.4± 0.5
40 ppm	4.0± 0.2	4.1± 0.3	4.1± 0.4	4.2± 0.4	4.1± 0.3	4.3± 0.4
80 ppm	4.0± 0.2	4.0± 0.3	3.9± 0.4	3.9± 0.2	4.2± 0.4	4.0± 0.3
160 ppm	4.4± 0.2	4.5± 0.2	4.6± 0.4	4.6± 0.2	4.3± 0.4*	4.5± 0.3

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX C 4-1

HEMATOLOGY (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		PLATELET 10 ⁹ /μl	
Control	10	9.83±	0.26	16.4±	0.2	44.7±	1.0	45.4±	0.7	770±	61
20 ppm	10	9.75±	0.30	16.4±	0.4	44.3±	1.6	45.4±	0.8	743±	32
40 ppm	10	9.73±	0.25	16.4±	0.4	44.2±	0.9	45.4±	0.5	739±	55
80 ppm	10	9.70±	0.23	16.3±	0.3	43.8±	1.1	45.2±	0.7	743±	17
160 ppm	10	9.75±	0.16	16.2±	0.2	43.7±	0.8	44.8±	0.5	748±	37
320 ppm	00	-		-		-		-		-	

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

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC	(%) N-SEG	EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	10	4.14±	0.88	0±	0	19±	4	1±	1	0±	0	3±	1	77±	4	0±	0
20 ppm	10	4.18±	1.02	0±	0	19±	5	2±	1	0±	0	3±	1	76±	6	0±	0
40 ppm	10	4.33±	1.80	0±	0	20±	6	1±	1	0±	0	3±	1	76±	6	0±	0
80 ppm	10	4.01±	0.55	0±	0	19±	3	1±	1	0±	0	4±	1	76±	4	0±	0
160 ppm	10	5.60±	3.36	0±	0	19±	5	1±	1	0±	0	3±	1	76±	6	0±	0
320 ppm	00	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX C 4-2

HEMATOLOGY (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE

STUDY NO. : 0055
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		PLATELET 10 ⁹ /μl	
Control	10	8.85±	0.25	16.4±	0.4	43.7±	1.5	49.3±	0.6	796±	51
20 ppm	10	8.94±	0.28	16.6±	0.5	44.0±	1.3	49.2±	0.6	801±	33
40 ppm	10	8.93±	0.18	16.6±	0.4	44.1±	0.9	49.4±	0.6	802±	63
80 ppm	10	8.86±	0.26	16.2±	0.4	43.4±	1.4	48.9±	0.8	772±	35
160 ppm	10	8.96±	0.24	16.3±	0.3	43.8±	1.3	48.9±	0.3	792±	51
320 ppm	00	-	-	-	-	-	-	-	-	-	-

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

Group Name		NO. of Animals	WBC 1 0 ³ /μℓ		Differential N-BAND		WBC (%) N-SEG	EOSINO		BASO		MONO		LYMPHO		OTHER		
Control		10	3.29±	0.82	0±	0	18±	4	1±	1	0±	0	3±	1	78±	5	0±	0
20	ppm	10	3.39±	1.03	0±	0	18±	4	1±	1	0±	0	4±	1	76±	6	0±	0
40	ppm	10	2.95±	1.14	0±	0	19±	8	1±	1	0±	0	4±	1	76±	9	0±	0
80	ppm	10	2.54±	0.59	0±	0	17±	3	2±	1	0±	0	4±	1	78±	4	0±	0
160	ppm	10	2.97±	1.43	0±	0	19±	4	2±	1	0±	0	4±	2	76±	4	0±	0
320	ppm	00	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

Test of Dunnett

(JCL71A)

BAIS 2

APPENDIX C 4-3

HEMATOLOGY (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: MALE

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		PLATELET 10 ³ /μl	
Control	10	11.07±	0.40	15.4±	0.5	45.8±	1.7	41.3±	0.3	1305±	88
10 ppm	09	10.88±	0.26	15.1±	0.3	44.7±	1.1	41.1±	0.5	1310±	66
20 ppm	09	10.83±	0.33	14.9±	0.4	44.2±	1.3	40.8±	0.8	1316±	144
40 ppm	10	10.55±	0.30**	14.7±	0.5**	43.5±	1.6*	41.2±	0.5	1271±	112
80 ppm	08	10.55±	0.13**	14.6±	0.1*	43.6±	0.4*	41.3±	0.6	1354±	80
160 ppm	10	10.20±	0.41**	14.2±	0.5**	42.6±	1.8**	41.7±	0.4	1266±	109

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0056
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

HEMATOLOGY(2) (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG											
							EOSINO	BASO	MONO	LYMPHO	OTHER						
Control	10	1.92±	0.99	0±	0	14±	3	1±	1	0±	0	2±	1	84±	3	0±	0
10 ppm	09	1.74±	1.05	0±	0	14±	4	1±	0	0±	0	2±	1	82±	4	0±	0
20 ppm	09	1.72±	0.99	0±	0	14±	3	1±	1	0±	0	2±	1	83±	4	0±	0
40 ppm	10	1.70±	1.01	0±	0	15±	4	1±	1	0±	0	2±	1	82±	4	0±	0
80 ppm	08	1.08±	0.35	0±	0	16±	2	1±	0	0±	0	2±	2	81±	3	0±	0
160 ppm	10	1.26±	0.40	0±	0	14±	5	1±	1	0±	0	2±	1	82±	5	0±	0

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

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX C 4-4

HEMATOLOGY (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		PLATELET 10 ³ /μl	
Control	09	10.58±	0.28	15.0±	0.3	44.1±	1.2	41.7±	0.4	1157±	103
10 ppm	10	10.49±	0.37	14.9±	0.4	43.7±	1.4	41.6±	0.6	1169±	59
20 ppm	10	10.63±	0.28	15.0±	0.4	44.5±	1.2	41.8±	0.2	1153±	68
40 ppm	10	10.67±	0.37	15.0±	0.5	44.7±	1.7	41.9±	0.4	1179±	76
80 ppm	10	10.54±	0.35	14.9±	0.5	44.3±	1.7	42.0±	0.5	1189±	76
160 ppm	04	10.32±	0.09	14.7±	0.3	43.5±	0.7	42.1±	0.4	1252±	112

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC	(%) N-SEG	EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	09	1.51±	0.41	0±	0	12±	2	1±	1	0±	0	2±	1	85±	3	0±	0
10 ppm	10	1.25±	0.40	0±	0	15±	6	1±	1	0±	0	2±	1	82±	6	0±	0
20 ppm	10	1.54±	0.81	0±	0	15±	5	1±	1	0±	0	2±	1	82±	5	0±	0
40 ppm	10	1.21±	0.58	0±	0	15±	4	1±	1	0±	0	2±	1	81±	5	0±	0
80 ppm	10	1.16±	0.58	0±	0	13±	3	1±	1	0±	0	3±	2	84±	4	0±	0
160 ppm	04	0.80±	0.32	0±	1	15±	7	1±	1	0±	0	2±	1	81±	7	0±	0

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

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX C 5-1

BIOCHEMISTRY (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

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	6.5±	0.1	3.7±	0.1	1.3±	0.1	0.18±	0.02	197±	15	50±	3	116±	27
20 ppm	10	6.5±	0.2	3.7±	0.2	1.3±	0.1	0.15±	0.03	195±	15	49±	5	110±	40
40 ppm	10	6.7±	0.1	3.7±	0.1	1.3±	0.1	0.16±	0.03	201±	12	50±	4	106±	27
80 ppm	10	6.7±	0.2	3.7±	0.1	1.3±	0.1	0.14±	0.02	201±	13	48±	5	115±	34
160 ppm	10	6.7±	0.2	3.7±	0.1	1.2±	0.1	0.15±	0.04	212±	13	49±	1	120±	35
320 ppm	00	-		-		-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	GOT IU/ℓ		GPT IU/ℓ		LDH IU/ℓ		ALP IU/ℓ		LAP IU/ℓ		CPK IU/ℓ		UREA NITROGEN mg/dℓ	
Control	10	79±	19	28±	5	201±	79	254±	20	53±	2	126±	15	17.9±	1.5
20 ppm	10	84±	18	29±	5	206±	40	248±	21	53±	1	123±	17	17.9±	2.1
40 ppm	10	79±	11	28±	4	186±	41	244±	18	53±	1	118±	16	17.5±	1.2
80 ppm	10	71±	5	27±	2	169±	30	250±	18	53±	1	117±	18	17.7±	1.4
160 ppm	10	85±	10	33±	4	187±	32	253±	17	54±	1	118±	18	17.4±	0.8
320 ppm	00	-		-		-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0055
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 3

Group Name	NO. of Animals	CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	10	0.5±	0.1	142±	1	3.1±	0.2	104±	2	10.4±	0.1	5.2±	0.6
20 ppm	10	0.5±	0.1	141±	1	3.2±	0.3	105±	2	10.4±	0.1	5.4±	0.8
40 ppm	10	0.4±	0.1	141±	1	3.0±	0.1	104±	2	10.4±	0.2	5.1±	0.7
80 ppm	10	0.4±	0.1	141±	1	3.1±	0.1	105±	2	10.5±	0.2	5.1±	0.6
160 ppm	10	0.5±	0.1	141±	1	3.0±	0.1	105±	1	10.5±	0.2	5.2±	0.7
320 ppm	00	-		-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX C 5-2

BIOCHEMISTRY (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

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	6.5±	0.3	3.6±	0.1	1.3±	0.1	0.21±	0.02	146±	20	80±	7	48±	9
20 ppm	10	6.5±	0.1	3.6±	0.1	1.3±	0.1	0.21±	0.04	147±	10	78±	8	47±	6
40 ppm	10	6.6±	0.3	3.7±	0.1	1.3±	0.1	0.20±	0.03	145±	26	77±	5	47±	8
80 ppm	10	6.6±	0.2	3.7±	0.1	1.3±	0.1	0.20±	0.03	149±	18	78±	7	48±	11
160 ppm	10	6.6±	0.1	3.7±	0.1	1.3±	0.1	0.21±	0.02	144±	14	78±	4	42±	8
320 ppm	00	-		-		-		-		-		-		-	

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 5

Group Name	NO. of Animals	GOT I U / ℓ		GPT I U / ℓ		LDH I U / ℓ		ALP I U / ℓ		LAP I U / ℓ		CPK I U / ℓ		UREA NITROGEN mg / dl	
Control	10	83±	19	34±	14	182±	50	172±	19	54±	2	116±	28	17.4±	2.5
20 ppm	10	80±	31	33±	15	172±	44	167±	14	54±	2	110±	15	16.6±	2.2
40 ppm	10	84±	32	32±	19	193±	65	164±	14	54±	1	113±	14	16.7±	1.8
80 ppm	10	79±	26	32±	12	184±	60	171±	20	53±	3	110±	22	17.2±	2.1
160 ppm	10	73±	12	28±	7	181±	34	177±	17	54±	3	111±	9	17.0±	1.7
320 ppm	00	-		-		-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 6

Group Name	NO. of Animals	CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	10	0.4±	0.1	140±	2	3.2±	0.5	106±	3	10.4±	0.2	4.6±	1.0
20 ppm	10	0.4±	0.1	141±	1	3.2±	0.2	108±	2	10.3±	0.2	4.5±	1.0
40 ppm	10	0.4±	0.1	142±	2	3.6±	1.2	107±	3	10.3±	0.4	4.6±	0.9
80 ppm	10	0.4±	0.1	141±	1	3.1±	0.3	107±	2	10.3±	0.2	4.5±	0.7
160 ppm	10	0.5±	0.1	141±	1	3.0±	0.2	108±	1	10.3±	0.1	4.4±	0.7
320 ppm	00	-		-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX C 5-3

BIOCHEMISTRY (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: MALE

STUDY NO. : 0056
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		GOT IU/l	
Control	10	5.2±	0.2	3.0±	0.1	1.4±	0.1	0.31±	0.04	204±	34	87±	7	40±	3
10 ppm	10	5.2±	0.2	3.0±	0.1	1.4±	0.1	0.31±	0.09	222±	33	89±	9	38±	6
20 ppm	09	5.2±	0.1	2.9±	0.1	1.3±	0.1	0.27±	0.04	230±	25	88±	6	36±	1
40 ppm	10	5.0±	0.2*	2.9±	0.1	1.4±	0.1	0.29±	0.04	205±	45	80±	11	37±	5
80 ppm	08	5.1±	0.1	2.9±	0.1	1.4±	0.1	0.29±	0.03	200±	29	79±	7	37±	7
160 ppm	10	5.0±	0.1	2.9±	0.1	1.4±	0.1	0.27±	0.04	196±	46	79±	7	35±	3

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	GPT IU/ℓ		LDH IU/ℓ		ALP IU/ℓ		LAP IU/ℓ		UREA NITROGEN mg/dℓ		SODIUM mEq/ℓ		POTASSIUM mEq/ℓ	
Control	10	10±	1	294±	67	143±	7	42±	2	29.2±	2.6	150±	2	4.3±	0.3
10 ppm	10	10±	1	317±	102	140±	10	41±	3	30.3±	5.1	150±	2	4.1±	0.4
20 ppm	09	9±	1	275±	48	143±	5	43±	2	30.8±	3.6	150±	2	4.3±	0.5
40 ppm	10	10±	2	296±	97	142±	6	41±	2	29.7±	6.7	149±	2	4.0±	0.2
80 ppm	08	9±	2	331±	78	136±	5	41±	1	29.1±	2.9	150±	2	4.1±	0.3
160 ppm	10	9±	1	272±	65	145±	9	39±	2*	29.7±	4.9	150±	1	4.1±	0.3

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 3

Group Name	NO. of Animals	CHLORIDE mEq / ℓ	
Control	10	120±	2
10 ppm	10	120±	2
20 ppm	09	118±	1
40 ppm	10	118±	2
80 ppm	08	119±	2
160 ppm	10	119±	2

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX C 5-4

BIOCHEMISTRY (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 4

Group Name	NO. of Animals	TOTAL PROTEIN g / dl		ALBUMIN g / dl		A/G RATIO		T-BILIRUBIN mg / dl		GLUCOSE mg / dl		T-CHOLESTEROL mg / dl		GOT I U / l	
Control	10	5.0±	0.1	2.9±	0.1	1.4±	0.1	0.29±	0.05	166±	24	74±	6	42±	5
10 ppm	10	5.0±	0.2	2.9±	0.1	1.4±	0.0	0.31±	0.06	157±	14	77±	7	44±	4
20 ppm	10	5.1±	0.1	3.0±	0.1	1.4±	0.0	0.32±	0.05	157±	21	75±	8	51±	10
40 ppm	10	5.1±	0.2	2.9±	0.2	1.4±	0.1	0.30±	0.06	156±	20	77±	8	46±	5
80 ppm	10	5.1±	0.2	3.0±	0.1	1.4±	0.0	0.31±	0.04	140±	26	74±	7	54±	16
160 ppm	04	5.1±	0.1	3.0±	0.1	1.5±	0.1**	0.27±	0.06	151±	7	76±	4	43±	7

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 5

Group Name	NO. of Animals	GPT I U / ℓ		LDH I U / ℓ		ALP I U / ℓ		LAP I U / ℓ		UREA NITROGEN mg / dl		SODIUM mEq / ℓ		POTASSIUM mEq / ℓ	
Control	10	11±	1	296±	66	207±	13	39±	2	22.0±	2.1	149±	1	4.1±	0.4
10 ppm	10	11±	1	285±	36	208±	23	40±	1	26.0±	9.5	150±	1	4.3±	1.1
20 ppm	10	11±	2	359±	81	230±	23*	40±	1	23.8±	2.7	150±	1	4.1±	0.3
40 ppm	10	11±	2	304±	75	223±	19	41±	3	23.3±	3.4	150±	3	4.0±	0.2
80 ppm	10	12±	3	355±	74	228±	13	40±	2	23.2±	2.3	151±	2	4.3±	0.3
160 ppm	04	10±	2	261±	58	234±	15	36±	1	25.1±	1.7	150±	1	4.2±	0.3

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 6

Group Name	NO. of Animals	CHLORIDE mEq / ℓ	
Control	10	119±	2
10 ppm	10	118±	2
20 ppm	10	118±	2
40 ppm	10	119±	2
80 ppm	10	119±	2
160 ppm	04	121±	1

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX C 6-1

URINALYSIS (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE

STUDY NO. : 0055
 ANIMAL : RAT F344
 SAMPLING DATE : 013-7
 SEX : MALE

URINALYSIS

REPORT TYPE : A1

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+	-	+		2+	3+
Control		10	0	0	0	0	0	4	6		0	0	4	6	0	0		10	0	0	0	0	0		9	1	0	0		10	0	0	0	
20	ppm	10	0	0	0	0	3	7	0		0	2	5	3	0	0		10	0	0	0	0	0		8	2	0	0		10	0	0	0	
40	ppm	10	0	0	0	2	4	3	1		0	1	8	1	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
80	ppm	10	0	0	0	0	2	8	0		0	0	6	3	1	0		10	0	0	0	0	0		9	1	0	0		10	0	0	0	
160	ppm	10	0	0	0	0	3	7	0		0	0	9	1	0	0	*	10	0	0	0	0	0		10	0	0	0		10	0	0	0	
320	ppm	0	-	-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-		-	-	-	-	

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

Test of CHI SQUARE

(JCL103X)

BAIS2

STUDY NO. : 0055
ANIMAL : RAT F344
SAMPLING DATE : 013-7
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Occult blood - ± + 2+ 3+ CHI	Urobilinogen ± + 2+ 3+ 4+ CHI
Control	10	10 0 0 0 0	10 0 0 0 0
20 ppm	10	10 0 0 0 0	10 0 0 0 0
40 ppm	10	10 0 0 0 0	10 0 0 0 0
80 ppm	10	10 0 0 0 0	10 0 0 0 0
160 ppm	10	10 0 0 0 0	10 0 0 0 0
320 ppm	0	- - - - -	- - - - -

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

Test of CHI SQUARE

(JCL103X)

BAIS 2

APPENDIX C 6-2

URINALYSIS (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE

STUDY NO. : 0055

ANIMAL : RAT F344

SAMPLING DATE : 013-7

SEX : FEMALE

REPORT TYPE : A1

URINALYSIS

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+		-	+	2+	3+	
Control		10	0	0	0	0	0	7	3		0	7	3	0	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
20 ppm		10	0	0	0	0	1	7	2		1	3	6	0	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
40 ppm		10	0	0	0	0	2	8	0		0	2	8	0	0	0	*	10	0	0	0	0	0		9	1	0	0		10	0	0	0	
80 ppm		10	0	0	0	1	3	6	0		0	1	9	0	0	0	**	10	0	0	0	0	0		10	0	0	0		10	0	0	0	
160 ppm		10	0	0	0	0	1	9	0		0	1	9	0	0	0	**	10	0	0	0	0	0		10	0	0	0		10	0	0	0	
320 ppm		0	-	-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-		-	-	-	-	

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

Test of CHI SQUARE

(JCL103X)

BAIS 2

STUDY NO. : 0055

ANIMAL : RAT F344

SAMPLING DATE : 013-7

SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Occult blood					Urobilinogen						
		-	±	+	2+	3+	CHI	±	+	2+	3+	4+	CHI
Control	10	10	0	0	0	0	0	10	0	0	0	0	0
20 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
40 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
80 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
160 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of CHI SQUARE

(JCL103X)

BAIS 2

APPENDIX C 6-3

URINALYSIS (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: MALE

STUDY NO. : 0056

ANIMAL : MOUSE BDF1

SAMPLING DATE : 013-7

SEX : MALE

REPORT TYPE : A1

URINALYSIS

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+	-	±		+	2+	3+
Control		10	0	0	0	0	2	3	5		0	0	4	6	0	0		10	0	0	0	0	0		9	1	0	0		10	0	0	0	0	
10	ppm	10	0	0	0	0	3	4	3		0	0	5	5	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	0	
20	ppm	10	0	0	0	0	0	7	3		0	0	8	2	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	0	
40	ppm	10	0	0	0	0	3	5	2		0	0	7	3	0	0		10	0	0	0	0	0		9	1	0	0		9	1	0	0	0	
80	ppm	10	0	0	0	0	2	4	4		0	0	5	5	0	0		10	0	0	0	0	0		8	2	0	0		10	0	0	0	0	
160	ppm	10	0	0	0	1	0	4	5		0	0	5	5	0	0		10	0	0	0	0	0		8	2	0	0		10	0	0	0	0	

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

Test of CHI SQUARE

(JCL104X)

BAIS 2

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-7
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
10 ppm	10	10 0 0 0 0
20 ppm	10	10 0 0 0 0
40 ppm	10	10 0 0 0 0
80 ppm	10	10 0 0 0 0
160 ppm	10	10 0 0 0 0

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

Test of CHI SQUARE

(JCL104X)

BAIS2

APPENDIX C 6-4

URINALYSIS (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-7
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+	-	±		+	2+	3+
Control		10	0	0	0	4	2	3	1		0	0	8	2	0	0		10	0	0	0	0	0		8	2	0	0		10	0	0	0	0	
10	ppm	10	0	0	1	3	3	3	0		0	0	9	1	0	0		10	0	0	0	0	0		7	3	0	0		10	0	0	0	0	
20	ppm	10	0	0	0	2	6	2	0		0	0	8	2	0	0		10	0	0	0	0	0		8	2	0	0		10	0	0	0	0	
40	ppm	10	0	0	0	2	3	5	0		0	0	9	1	0	0		10	0	0	0	0	0		9	1	0	0		10	0	0	0	0	
80	ppm	10	0	0	1	2	2	5	0		0	0	7	3	0	0		10	0	0	0	0	0		7	3	0	0		10	0	0	0	0	
160	ppm	4	0	0	0	0	0	2	2		0	0	3	1	0	0		4	0	0	0	0	0		4	0	0	0		4	0	0	0	0	

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

Test of CHI SQUARE

(JCL104X)

BAIS 2

STUDY NO. : 0056

URINALYSIS

ANIMAL : MOUSE BDF1

SAMPLING DATE : 013-7

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+ CHI
Control	10	10 0 0 0 0
10 ppm	10	10 0 0 0 0
20 ppm	10	10 0 0 0 0
40 ppm	10	10 0 0 0 0
80 ppm	10	10 0 0 0 0
160 ppm	4	4 0 0 0 0

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of CHI SQUARE

(JCL104X)

BAIS2

APPENDIX C 7-1

GROSS FINDINGS (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE: DEAD AND MORIBUND ANIMALS

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 0 (%)	20 ppm 0 (%)	40 ppm 0 (%)	80 ppm 0 (%)
lung	red		- (-)	- (-)	- (-)	- (-)
	red patch/zone		- (-)	- (-)	- (-)	- (-)
thymus	red patch/zone		- (-)	- (-)	- (-)	- (-)
stomach	hemorrhage		- (-)	- (-)	- (-)	- (-)
thoracic ca	pleural fluid		- (-)	- (-)	- (-)	- (-)
whole body	wasting		- (-)	- (-)	- (-)	- (-)

(HPT080)

BAIS2

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 2

Organ	Findings	Group Name	180 ppm	320 ppm
		NO. of Animals	0 (%)	10 (%)
lung	red		- (-)	7 (70)
	red patch/zone		- (-)	1 (10)
thymus	red patch/zone		- (-)	3 (30)
stomach	hemorrhage		- (-)	4 (40)
thoracic ca	pleural fluid		- (-)	4 (40)
whole body	wasting		- (-)	2 (20)

(HPT080)

BAIS2

APPENDIX C 7-2

GROSS FINDINGS (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE: DEAD AND MORIBUND ANIMALS

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 0 (%)	20 ppm 0 (%)	40 ppm 0 (%)	80 ppm 0 (%)
lung	red		- (-)	- (-)	- (-)	- (-)
	red patch/zone		- (-)	- (-)	- (-)	- (-)
thymus	red patch/zone		- (-)	- (-)	- (-)	- (-)
stomach	hemorrhage		- (-)	- (-)	- (-)	- (-)
thoracic ca	pleural fluid		- (-)	- (-)	- (-)	- (-)

(HPT080)

BAIS2

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 4

Organ	Findings	Group Name	160 ppm	320 ppm
		NO. of Animals	0 (%)	10 (%)
lung	red		- (-)	8 (80)
	red patch/zone		- (-)	1 (10)
thymus	red patch/zone		- (-)	6 (60)
stomach	hemorrhage		- (-)	1 (10)
thoracic ca	pleural fluid		- (-)	8 (80)

(HPT080)

BAIS 2

APPENDIX C 7-3

GROSS FINDINGS (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE: SACRIFICED ANIMALS

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 1

Organ	Findings	Group Name	Control	20 ppm	40 ppm	80 ppm
		NO. of Animals	10 (%)	10 (%)	10 (%)	10 (%)
subcutis	nodule		0 (0)	0 (0)	1 (10)	0 (0)
lung	red		0 (0)	1 (10)	0 (0)	0 (0)
liver	herniation		0 (0)	0 (0)	0 (0)	1 (10)

(HPT080)

BAIS2

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 2

Organ	Findings	Group Name	160 ppm	320 ppm
		NO. of Animals	10 (%)	0 (%)
subcutis	nodule		0 (0)	- (-)
lung	red		0 (0)	- (-)
liver	herniation		0 (0)	- (-)

(HPT080)

BAIS 2

APPENDIX C 7-4

GROSS FINDINGS (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE: SACRIFICED ANIMALS

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 3

Organ	Findings	Group Name	Control	20 ppm	40 ppm	80 ppm
		NO. of Animals	9 (%)	10 (%)	9 (%)	7 (%)
lung	red		1 (11)	0 (0)	1 (11)	0 (0)
liver	nodule		0 (0)	0 (0)	1 (11)	0 (0)
	herniation		1 (11)	1 (10)	1 (11)	1 (14)
uterus	dilated lumen		0 (0)	0 (0)	1 (11)	0 (0)

(HPT080)

BAIS2

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 4

Organ	Findings	Group Name	160 ppm	320 ppm
		NO. of Animals	8 (%)	0 (%)
lung	red		0 (0)	- (-)
liver	nodule		0 (0)	- (-)
	herniation		2 (25)	- (-)
uterus	dilated lumen		0 (0)	- (-)

(HPT080)

BAIS2

APPENDIX C 7-5

GROSS FINDINGS (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE: DEAD AND MORIBUND ANIMALS

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 0 (%)	10 ppm 0 (%)	20 ppm 0 (%)	40 ppm 0 (%)
lung	red		- (-)	- (-)	- (-)	- (-)
	red patch/zone		- (-)	- (-)	- (-)	- (-)
stomach	hemorrhage		- (-)	- (-)	- (-)	- (-)
liver	pale		- (-)	- (-)	- (-)	- (-)
kidney	pale		- (-)	- (-)	- (-)	- (-)
uterus	dilated lumen		- (-)	- (-)	- (-)	- (-)
whole body	wasting		- (-)	- (-)	- (-)	- (-)

(HPT080)

BAIS 2

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13w)

PAGE : 2

Organ	Findings	Group Name	80 ppm	160 ppm
		NO. of Animals	0 (%)	6 (%)
Lung	red		- (-)	2 (33)
	red patch/zone		- (-)	1 (17)
stomach	hemorrhage		- (-)	3 (50)
liver	pale		- (-)	4 (67)
kidney	pale		- (-)	1 (17)
uterus	dilated lumen		- (-)	1 (17)
whole body	wasting		- (-)	1 (17)

(HPT080)

BAIS 2

APPENDIX C 7-6

GROSS FINDINGS (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: MALE: SACRIFICED ANIMALS

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 1

Organ_____	Findings_____	Group Name NO. of Animals	Control	10 ppm	20 ppm	40 ppm
			10 (%)	10 (%)	10 (%)	10 (%)
spleen	black patch/zone		1 (10)	1 (10)	0 (0)	0 (0)
stomach	hemorrhage		2 (20)	1 (10)	1 (10)	1 (10)
kidney	pale		0 (0)	0 (0)	0 (0)	0 (0)
	white patch/zone		1 (10)	0 (0)	1 (10)	1 (10)
	black patch/zone		0 (0)	1 (10)	0 (0)	0 (0)
	anemic		0 (0)	0 (0)	0 (0)	1 (10)
	hydronephrosis		0 (0)	0 (0)	1 (10)	1 (10)
adipose	nodule		0 (0)	0 (0)	1 (10)	0 (0)

(HPT080)

BAIS 2

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 2

Organ	Findings	Group Name	80 ppm	160 ppm
		NO. of Animals	10 (%)	10 (%)
spleen	black patch/zone		1 (10)	0 (0)
stomach	hemorrhage		0 (0)	1 (10)
kidney	pale		0 (0)	1 (10)
	white patch/zone		0 (0)	1 (10)
	black patch/zone		0 (0)	0 (0)
	anemic		0 (0)	0 (0)
	hydronephrosis		0 (0)	1 (10)
adipose	nodule		0 (0)	0 (0)

(HPT080)

BAIS 2

APPENDIX C 7-7

GROSS FINDINGS (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE: SACRIFICED ANIMALS

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 3

Organ	Findings	Group Name	Control	10 ppm	20 ppm	40 ppm
		NO. of Animals	10 (%)	10 (%)	10 (%)	10 (%)
spleen	black patch/zone		2 (20)	0 (0)	0 (0)	2 (20)
stomach	hemorrhage		0 (0)	1 (10)	1 (10)	0 (0)
liver	yellow patch/zone		0 (0)	0 (0)	0 (0)	1 (10)
uterus	dilated lumen		3 (30)	2 (20)	3 (30)	3 (30)

(HPT080)

BAIS 2

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 4

Organ_____	Findings_____	Group Name	80 ppm	160 ppm
		NO. of Animals	10 (%)	4 (%)
spleen	black patch/zone		1 (10)	3 (75)
stomach	hemorrhase		2 (20)	0 (0)
liver	yellow patch/zone		0 (0)	0 (0)
uterus	dilated lumen		3 (30)	1 (25)

(HPT080)

BAIS2

APPENDIX C 8-1

ORGAN WEIGHT (THIRTEEN-WEEK STUDIES: SUMMARY), ABSOLUTE

RAT: MALE

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	Body weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	321± 18	0.264± 0.027	0.051± 0.004	2.858± 0.094	0.901± 0.040	0.962± 0.043
20 ppm	10	328± 29	0.278± 0.036	0.050± 0.005	2.908± 0.104	0.895± 0.115	0.964± 0.042
40 ppm	10	328± 11	0.284± 0.034	0.050± 0.004	2.916± 0.104	0.911± 0.046	0.969± 0.046
80 ppm	10	332± 10	0.274± 0.034	0.052± 0.005	2.974± 0.113	0.922± 0.030	0.966± 0.039
160 ppm	10	333± 11	0.285± 0.032	0.053± 0.003	2.929± 0.068	0.934± 0.041	0.956± 0.035
320 ppm	00	-	-	-	-	-	-

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	1.798±	0.090	0.546±	0.032	8.102±	0.680	1.867±	0.023
20 ppm	10	1.814±	0.126	0.550±	0.044	8.150±	0.656	1.872±	0.039
40 ppm	10	1.816±	0.056	0.533±	0.020	8.178±	0.294	1.843±	0.057
80 ppm	10	1.834±	0.061	0.549±	0.012	8.331±	0.514	1.879±	0.040
160 ppm	10	1.836±	0.065	0.551±	0.016	8.455±	0.341	1.868±	0.032
320 ppm	00	-		-		-		-	

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX C 8-2

ORGAN WEIGHT (THIRTEEN-WEEK STUDIES: SUMMARY), ABSOLUTE

RAT: FEMALE

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 3

Group Name	NO. of Animals	Body weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	187± 7	0.214± 0.016	0.057± 0.005	0.115± 0.017	0.598± 0.024	0.707± 0.037
20 ppm	10	189± 14	0.215± 0.016	0.059± 0.004	0.112± 0.020	0.591± 0.047	0.711± 0.050
40 ppm	10	183± 12	0.219± 0.018	0.058± 0.003	0.115± 0.015	0.578± 0.032	0.703± 0.042
80 ppm	10	195± 18	0.225± 0.039	0.061± 0.006	0.128± 0.018	0.632± 0.058	0.725± 0.049
160 ppm	10	190± 14	0.230± 0.033	0.059± 0.003	0.120± 0.015	0.598± 0.036	0.699± 0.026
320 ppm	00	-	-	-	-	-	-

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

Test of Dunnett

(HCL040)

BAIS2

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 4

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	1.137±	0.071	0.374±	0.028	4.351±	0.233	1.724±	0.057
20 ppm	10	1.128±	0.081	0.375±	0.027	4.339±	0.335	1.733±	0.045
40 ppm	10	1.109±	0.074	0.366±	0.018	4.255±	0.354	1.717±	0.026
80 ppm	10	1.155±	0.071	0.375±	0.030	4.541±	0.522	1.734±	0.034
160 ppm	10	1.130±	0.051	0.366±	0.016	4.400±	0.235	1.710±	0.035
320 ppm	00	-		-		-		-	

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX C 8-3

ORGAN WEIGHT (THIRTEEN-WEEK STUDIES: SUMMARY), ABSOLUTE

MOUSE: MALE

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	Body weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	32.7± 2.9	0.042± 0.007	0.008± 0.002	0.230± 0.016	0.146± 0.015	0.146± 0.008
10 ppm	10	31.3± 2.8	0.040± 0.007	0.008± 0.002	0.225± 0.029	0.142± 0.010	0.147± 0.009
20 ppm	10	32.1± 2.5	0.041± 0.007	0.008± 0.002	0.231± 0.017	0.146± 0.009	0.149± 0.007
40 ppm	10	29.5± 2.6*	0.037± 0.006	0.009± 0.002	0.237± 0.028	0.142± 0.009	0.149± 0.007
80 ppm	10	30.0± 2.5	0.035± 0.007	0.009± 0.003	0.226± 0.030	0.147± 0.006	0.150± 0.010
160 ppm	10	29.6± 2.9	0.040± 0.005	0.008± 0.002	0.230± 0.020	0.149± 0.009	0.151± 0.011

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

Test of Dunnett

(HCL040)

BAIS2

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	0.439±	0.023	0.052±	0.008	1.187±	0.072	0.435±	0.019
10 ppm	10	0.447±	0.024	0.047±	0.004	1.141±	0.059	0.438±	0.008
20 ppm	10	0.530±	0.252	0.050±	0.006	1.168±	0.079	0.440±	0.008
40 ppm	10	0.509±	0.177	0.050±	0.007	1.111±	0.073	0.439±	0.007
80 ppm	10	0.471±	0.024	0.048±	0.004	1.121±	0.070	0.441±	0.011
160 ppm	10	0.538±	0.171**	0.052±	0.008	1.143±	0.084	0.441±	0.018

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

Test of Dunnett

(HCL040)

BAIS2

APPENDIX C 8-4

ORGAN WEIGHT (THIRTEEN-WEEK STUDIES: SUMMARY), ABSOLUTE

MOUSE: FEMALE

STUDY NO. : 0056
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 3

Group Name	NO. of Animals	Body weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	23.1± 2.1	0.042± 0.007	0.012± 0.003	0.031± 0.005	0.121± 0.010	0.146± 0.006
10 ppm	10	23.3± 2.4	0.041± 0.006	0.011± 0.003	0.037± 0.009	0.120± 0.007	0.150± 0.009
20 ppm	10	22.1± 1.4	0.041± 0.007	0.012± 0.003	0.032± 0.008	0.117± 0.006	0.148± 0.009
40 ppm	10	22.1± 1.5	0.041± 0.005	0.012± 0.002	0.031± 0.004	0.115± 0.005	0.144± 0.016
80 ppm	10	21.9± 1.3	0.046± 0.009	0.012± 0.002	0.030± 0.005	0.119± 0.006	0.150± 0.014
160 ppm	04	21.8± 1.1	0.044± 0.007	0.012± 0.002	0.031± 0.007	0.125± 0.018	0.148± 0.003

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0056
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 4

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	0.288±	0.009	0.058±	0.005	0.935±	0.043	0.462±	0.010
10 ppm	10	0.300±	0.017	0.061±	0.006	0.970±	0.094	0.460±	0.011
20 ppm	10	0.291±	0.011	0.057±	0.006	0.920±	0.044	0.463±	0.010
40 ppm	10	0.292±	0.011	0.059±	0.007	0.920±	0.050	0.458±	0.029
80 ppm	10	0.293±	0.010	0.057±	0.008	0.921±	0.046	0.457±	0.013
160 ppm	04	0.314±	0.019**	0.063±	0.004	0.922±	0.042	0.449±	0.012

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX C 9-1

ORGAN WEIGHT (THIRTEEN-WEEK STUDIES : SUMMARY) , RELATIVE

RAT : MALE

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	Body weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	321± 18	0.082± 0.008	0.016± 0.001	0.891± 0.039	0.281± 0.011	0.300± 0.012
20 ppm	10	328± 29	0.085± 0.007	0.015± 0.002	0.892± 0.067	0.273± 0.021	0.295± 0.020
40 ppm	10	328± 11	0.086± 0.009	0.015± 0.001	0.889± 0.047	0.277± 0.012	0.295± 0.011
80 ppm	10	332± 10	0.082± 0.010	0.016± 0.002	0.896± 0.045	0.278± 0.009	0.291± 0.011
160 ppm	10	333± 11	0.089± 0.010	0.016± 0.001	0.880± 0.039	0.281± 0.011	0.287± 0.014
320 ppm	00	-	-	-	-	-	-

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.560± 0.014	0.170± 0.010	2.520± 0.102	0.583± 0.028
20 ppm	10	0.555± 0.018	0.168± 0.010	2.489± 0.033	0.575± 0.048
40 ppm	10	0.553± 0.012	0.162± 0.002	2.491± 0.050	0.562± 0.022
80 ppm	10	0.553± 0.019	0.166± 0.004	2.507± 0.092	0.566± 0.022
160 ppm	10	0.551± 0.017	0.166± 0.006	2.538± 0.065	0.561± 0.020
320 ppm	00	-	-	-	-

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

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX C 9-2

ORGAN WEIGHT (THIRTEEN-WEEK STUDIES : SUMMARY) , RELATIVE

RAT : FEMALE

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 3

Group Name	NO. of Animals	Body weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	187± 7	0.115± 0.008	0.031± 0.003	0.062± 0.010	0.320± 0.010	0.378± 0.016
20 ppm	10	189± 14	0.115± 0.009	0.031± 0.002	0.060± 0.013	0.314± 0.020	0.378± 0.018
40 ppm	10	183± 12	0.120± 0.012	0.032± 0.002	0.063± 0.008	0.317± 0.020	0.386± 0.031
80 ppm	10	195± 18	0.115± 0.012	0.031± 0.002	0.066± 0.009	0.325± 0.013	0.374± 0.022
160 ppm	10	190± 14	0.122± 0.013	0.032± 0.002	0.063± 0.007	0.316± 0.020	0.370± 0.025
320 ppm	00	-	-	-	-	-	-

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.608± 0.021	0.200± 0.010	2.327± 0.089	0.923± 0.031
20 ppm	10	0.599± 0.015	0.199± 0.008	2.303± 0.080	0.923± 0.058
40 ppm	10	0.609± 0.051	0.201± 0.009	2.339± 0.245	0.944± 0.061
80 ppm	10	0.595± 0.025	0.193± 0.007	2.329± 0.102	0.897± 0.075
160 ppm	10	0.598± 0.032	0.194± 0.008	2.325± 0.082	0.906± 0.065
320 ppm	00	-	-	-	-

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

Test of Dunnett

(HCL042)

BAIS2

APPENDIX C 9-3

ORGAN WEIGHT (THIRTEEN-WEEK STUDIES: SUMMARY), RELATIVE

MOUSE: MALE

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	Body weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	32.7± 2.9	0.130± 0.017	0.026± 0.008	0.710± 0.081	0.448± 0.058	0.449± 0.031
10 ppm	10	31.3± 2.8	0.128± 0.021	0.026± 0.008	0.723± 0.104	0.456± 0.038	0.474± 0.049
20 ppm	10	32.1± 2.5	0.127± 0.015	0.025± 0.006	0.723± 0.075	0.455± 0.025	0.466± 0.039
40 ppm	10	29.5± 2.6*	0.124± 0.014	0.029± 0.006	0.812± 0.141	0.483± 0.042	0.508± 0.052*
80 ppm	10	30.0± 2.5	0.116± 0.018	0.028± 0.007	0.755± 0.088	0.494± 0.038	0.504± 0.039*
160 ppm	10	29.6± 2.9	0.136± 0.015	0.029± 0.007	0.782± 0.105	0.506± 0.054*	0.515± 0.061**

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.347± 0.077	0.158± 0.022	3.644± 0.182	1.340± 0.119
10 ppm	10	1.434± 0.099	0.150± 0.011	3.659± 0.176	1.411± 0.119
20 ppm	10	1.651± 0.769	0.157± 0.019	3.640± 0.063	1.377± 0.113
40 ppm	10	1.718± 0.540**	0.170± 0.024	3.769± 0.142	1.497± 0.122*
80 ppm	10	1.579± 0.092**	0.160± 0.014	3.750± 0.160	1.479± 0.119
160 ppm	10	1.848± 0.689**	0.179± 0.034	3.872± 0.245*	1.500± 0.148*

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

Test of Dunnett

(HCL042)

BAIS2

APPENDIX C 9-4

ORGAN WEIGHT (THIRTEEN-WEEK STUDIES: SUMMARY), RELATIVE

MOUSE: FEMALE

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 3

Group Name	NO. of Animals	Body weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	23.1± 2.1	0.184± 0.031	0.054± 0.015	0.136± 0.030	0.526± 0.057	0.635± 0.067
10 ppm	10	23.3± 2.4	0.178± 0.022	0.049± 0.014	0.160± 0.040	0.520± 0.040	0.648± 0.070
20 ppm	10	22.1± 1.4	0.185± 0.026	0.054± 0.015	0.144± 0.032	0.534± 0.047	0.674± 0.046
40 ppm	10	22.1± 1.5	0.187± 0.020	0.054± 0.013	0.142± 0.019	0.523± 0.037	0.654± 0.080
80 ppm	10	21.9± 1.3	0.207± 0.035	0.054± 0.011	0.138± 0.023	0.543± 0.038	0.687± 0.065
160 ppm	04	21.8± 1.1	0.205± 0.040	0.053± 0.011	0.141± 0.030	0.572± 0.082	0.680± 0.051

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

Test of Dunnett

(HCL042)

BAIS2

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.256± 0.119	0.250± 0.025	4.065± 0.328	2.008± 0.157
10 ppm	10	1.295± 0.109	0.262± 0.020	4.175± 0.191	1.992± 0.179
20 ppm	10	1.322± 0.079	0.257± 0.023	4.177± 0.248	2.103± 0.123
40 ppm	10	1.328± 0.093	0.266± 0.026	4.171± 0.236	2.084± 0.212
80 ppm	10	1.339± 0.072	0.259± 0.028	4.208± 0.207	2.089± 0.129
160 ppm	04	1.445± 0.083**	0.289± 0.019	4.240± 0.204	2.062± 0.055

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

Test of Dunnett

(HCL042)

BAIS2

APPENDIX C 10-1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(THIRTEEN-WEEK STUDIES : SUMMARY)

RAT : MALE : DEAD AND MORIBUND ANIMALS

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 1

Organ	Findings	Group Name	Control				20 ppm				40 ppm				80 ppm			
		No. of Animals	0				0				0				0			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]																		
nasal cavit	disarrangement:olfactory epithelium		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	atrophy:olfactory epithelium		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
lung/branch	congestion		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	bronchopneumonia		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
[Hematopoietic system]																		
thymus	hemorrhage		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	karyorrhexis		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
spleen	congestion		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
[Circulatory system]																		
heart	myocarditis		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
[Digestive system]																		
pancreas	atrophy		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

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

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 2

Organ	Findings	Group Name No. of Animals				160 ppm 0				320 ppm 10			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]													
nasal cavit	disarrangement:olfactory epithelium	-	-	-	-	7	1	0	0				
		(-)	(-)	(-)	(-)	(70)	(10)	(0)	(0)				
	atrophy:olfactory epithelium	-	-	-	-	1	9	0	0				
		(-)	(-)	(-)	(-)	(10)	(90)	(0)	(0)				
lung/branch	congestion	-	-	-	-	2	8	0	0				
		(-)	(-)	(-)	(-)	(20)	(80)	(0)	(0)				
	bronchopneumonia	-	-	-	-	1	0	0	0				
		(-)	(-)	(-)	(-)	(10)	(0)	(0)	(0)				
[Hematopoietic system]													
thymus	hemorrhage	-	-	-	-	3	3	0	0				
		(-)	(-)	(-)	(-)	(30)	(30)	(0)	(0)				
	karyorrhexis	-	-	-	-	1	0	0	0				
		(-)	(-)	(-)	(-)	(10)	(0)	(0)	(0)				
spleen	congestion	-	-	-	-	1	1	0	0				
		(-)	(-)	(-)	(-)	(10)	(10)	(0)	(0)				
[Circulatory system]													
heart	myocarditis	-	-	-	-	4	0	0	0				
		(-)	(-)	(-)	(-)	(40)	(0)	(0)	(0)				
[Digestive system]													
pancreas	atrophy	-	-	-	-	2	0	0	0				
		(-)	(-)	(-)	(-)	(20)	(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. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 3

Organ	Findings	Group Name No. of Animals	Control 0				20 ppm 0				40 ppm 0				80 ppm 0			
			<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Urinary system]																		
kidney	eosinophilic body		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
[Nervous system]																		
brain	degeneration		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

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. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 4

Organ	Findings	160 ppm				320 ppm			
		No. of Animals				No. of Animals			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Urinary system]

kidney	eosinophilic body	-	-	-	-	1	1	0	0
		(-)	(-)	(-)	(-)	(10)	(10)	(0)	(0)

[Nervous system]

brain	degeneration	-	-	-	-	3	0	0	0
		(-)	(-)	(-)	(-)	(30)	(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 C 10-2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(THIRTEEN-WEEK STUDIES : SUMMARY)

RAT : FEMALE : DEAD AND MORIBUND ANIMALS

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 5

Organ	Findings	Group Name	Control				20 ppm				40 ppm				80 ppm			
		No. of Animals	0				0				0				0			
		<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	
[Respiratory system]																		
nasal cavit	disarrangement:olfactory epithelium		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	
	atrophy:olfactory epithelium		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	
lung/branch	congestion		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	
[Hematopoietic system]																		
thymus	hemorrhage		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	
[Circulatory system]																		
heart	myocarditis		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	
[Nervous system]																		
brain	hemorrhage		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	
	degeneration		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	

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. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 6

Organ	Findings	Group Name No. of Animals				160 ppm 0				320 ppm 10			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]													
nasal cavit	disarrangement:olfactory epithelium	-	-	-	-	4	2	0	0				
		(-)	(-)	(-)	(-)	(40)	(20)	(0)	(0)				
	atrophy:olfactory epithelium	-	-	-	-	0	8	0	0				
		(-)	(-)	(-)	(-)	(0)	(80)	(0)	(0)				
lung/branch	congestion	-	-	-	-	1	8	0	0				
		(-)	(-)	(-)	(-)	(10)	(80)	(0)	(0)				
[Hematopoietic system]													
thymus	hemorrhage	-	-	-	-	6	0	0	0				
		(-)	(-)	(-)	(-)	(60)	(0)	(0)	(0)				
[Circulatory system]													
heart	myocarditis	-	-	-	-	1	0	0	0				
		(-)	(-)	(-)	(-)	(10)	(0)	(0)	(0)				
[Nervous system]													
brain	hemorrhage	-	-	-	-	1	0	0	0				
		(-)	(-)	(-)	(-)	(10)	(0)	(0)	(0)				
	degeneration	-	-	-	-	2	0	0	0				
		(-)	(-)	(-)	(-)	(20)	(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 C 10-3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(THIRTEEN-WEEK STUDIES : SUMMARY)

RAT : MALE : SACRIFICED ANIMALS

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 1

Organ	Findings	Group Name	Control				20 ppm				40 ppm				80 ppm			
		No. of Animals	10				10				10				10			
		<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	
[Respiratory system]																		
lung/branch	congestion		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)	0 (0)	0 (0)	
[Circulatory system]																		
heart	myocarditis		2 (20)	0 (0)	0 (0)	0 (0)	4 (40)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	
[Digestive system]																		
liver	herniation		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)	
pancreas	atrophy		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)	
[Urinary system]																		
kidney	eosinophilic body		0 (0)	10 (100)	0 (0)	0 (0)	1 (10)	9 (90)	0 (0)	0 (0)	5 (50)	0 (0)	0 (0)	0 (0) **	6 (60)	1 (10)	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)

BA1S2

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 2

		Group Name	160 ppm				320 ppm			
		No. of Animals	10				0			
Organ	Findings	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	
[Respiratory system]										
lung/branch	congestion	0 (0)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	
[Circulatory system]										
heart	myocarditis	2 (20)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	
[Digestive system]										
liver	herniation	0 (0)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	
pancreas	atrophy	0 (0)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	
[Urinary system]										
kidney	eosinophilic body	3 (30)	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 C 10-4

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(THIRTEEN-WEEK STUDIES : SUMMARY)

RAT : FEMALE : SACRIFICED ANIMALS

STUDY NO. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 3

Organ	Findings	Group Name No. of Animals	Control 10				20 ppm 10				40 ppm 10				80 ppm 10			
			<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
lung/branch	congestion		0 (0)	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)	
[Hematopoietic system]																		
bone marrow	granulation		1 (10)	2 (20)	0 (0)	0 (0)	3 (30)	1 (10)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	2 (20)	1 (10)	0 (0)	
[Digestive system]																		
liver	herniation		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)	
	granulation		1 (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)	
	basophilic cell focus		0 (0)	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)	
[Endocrine system]																		
thyroid	ultimobranchial body remant		0 (0)	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)	
[Reproductive system]																		
ovary	cyst		0 (0)	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)	
[Special sense organs/appandage]																		
Harder gl	lymphocytic infiltration		2 (20)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	5 (50)	0 (0)	0 (0)	0 (0)	2 (20)	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. : 0055
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 4

		Group Name	160 ppm				320 ppm			
		No. of Animals	10				0			
Organ_____	Findings_____		<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]										
Lung/branch	congestion		0 (0)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)
[Hematopoietic system]										
bone marrow	granulation		1 (10)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)
[Digestive system]										
Liver	herniation		2 (20)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)
	granulation		0 (0)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)
	basophilic cell focus		0 (0)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)
[Endocrine system]										
thyroid	ultimobranchial body remnant		0 (0)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)
[Reproductive system]										
ovary	cyst		0 (0)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)
[Special sense organs/appandage]										
Harder gl	lymphocytic infiltration		2 (20)	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

APPENDIX C 10-5

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(THIRTEEN-WEEK STUDIES : SUMMARY)

MOUSE : FEMALE : DEAD AND MORIBUND ANIMALS

STUDY NO. : 0056
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 1

Organ	Findings	Group Name	Control				10 ppm				20 ppm				40 ppm			
		No. of Animals	0				0				0				0			
		<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	
[Respiratory system]																		
lung/branch	congestion		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	
	hemorrhage		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	
[Circulatory system]																		
heart	dilatation		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	
[Digestive system]																		
stomach	erosion:glandular stomach		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	
liver	fatty change:peripheral		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	
	granulation		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	
[Reproductive system]																		
uterus	dilatation		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 2

		Group Name		80 ppm				160 ppm			
		No. of Animals		0				6			
Organ_____	Findings_____	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)		
[Respiratory system]											
Lung/branch	congestion	- (-)	- (-)	- (-)	- (-)	2 (33)	0 (0)	0 (0)	0 (0)		
	hemorrhage	- (-)	- (-)	- (-)	- (-)	0 (0)	1 (17)	0 (0)	0 (0)		
[Circulatory system]											
heart	dilatation	- (-)	- (-)	- (-)	- (-)	2 (33)	0 (0)	0 (0)	0 (0)		
[Digestive system]											
stomach	erosion:glandular stomach	- (-)	- (-)	- (-)	- (-)	2 (33)	0 (0)	0 (0)	0 (0)		
liver	fatty change:peripheral	- (-)	- (-)	- (-)	- (-)	2 (33)	0 (0)	0 (0)	0 (0)		
	granulation	- (-)	- (-)	- (-)	- (-)	1 (17)	0 (0)	0 (0)	0 (0)		
[Reproductive system]											
uterus	dilatation	- (-)	- (-)	- (-)	- (-)	1 (17)	0 (0)	0 (0)	0 (0)		

APPENDIX C 10-6

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(THIRTEEN-WEEK STUDIES : SUMMARY)

MOUSE : MALE : SACRIFICED ANIMALS

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 1

Organ	Findings	Group Name No. of Animals	Control 10				10 ppm 10				20 ppm 10				40 ppm 10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]																		
lung/branch	hemorrhage		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
[Hematopoietic system]																		
spleen	deposit of melanin		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)	
[Circulatory system]																		
heart	mineralization:papilla		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
[Digestive system]																		
stomach	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 (0)	0 (0)	
liver	granulation		1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	
[Urinary system]																		
kidney	vacuolization of proximal tubule		10 (100)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)	0 (0)	9 (90)	0 (0)	0 (0)	0 (0)	8 (80)	0 (0)	0 (0)	
	hydronephrosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	
	regeneration proximal tubule		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (20)	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. : 0056
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (13W)

PAGE : 2

		Group Name	80 ppm				160 ppm			
		No. of Animals	10				10			
Organ_____	Findings_____	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	
[Respiratory system]										
lung/branch	hemorrhage	1 (10)	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)	0 (0)	0 (0)	0 (0)	0 (0)	
[Circulatory system]										
heart	mineralization:papilla	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	
[Digestive system]										
stomach	erosion:glandular stomach	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	
liver	granulation	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	
[Urinary system]										
kidney	vacuolization of proximal tubule	8 (80)	0 (0)	0 (0)	0 (0)	6 (60)	0 (0)	0 (0)	0 (0)	
	hydronephrosis	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	
	regeneration proximal tubule	0 (0)	0 (0)	0 (0)	0 (0)	2 (20)	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. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 3

Organ_____	Findings_____	Group Name	Control				10 ppm				20 ppm				40 ppm			
		No. of Animals	10				10				10				10			
		<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	
[Endocrine system]																		
pituitary	cyst		1 (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)	
[Reproductive system]																		
testis	atrophy		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)	
[Body cavities]																		
adipose	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 (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. : 0056
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (13W)

PAGE : 4

		Group Name	80 ppm				160 ppm			
		No. of Animals	10				10			
Organ	Findings	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
[Endocrine system]										
pituitary	cyst	0	0	0	0	0	0	0	0	
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
[Reproductive system]										
testis	atrophy	0	0	0	0	0	0	0	0	
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
[Body cavities]										
adipose	granulation	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 C 10-7

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(THIRTEEN-WEEK STUDIES : SUMMARY)

MOUSE : FEMALE : SACRIFICED ANIMALS

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 5

Organ	Findings	Group Name No. of Animals	Control 10				10 ppm 10				20 ppm 10				40 ppm 10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]																		
nasal cavit	eosinophilic change:respiratory epithelium		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)	
	disarrangement:olfactory epithelium		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
	atrophy:olfactory epithelium		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
lung/branch	hemorrhage		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)	
[Hematopoietic system]																		
spleen	deposit of melanin		2 (20)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	
[Digestive system]																		
stomach	hyperplasia: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 (0)	0 (0)	
liver	granulation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	
[Reproductive system]																		
uterus	dilatation		1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	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. : 0056
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 6

Organ	Findings	Group Name No. of Animals				80 ppm 10				160 ppm 4			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]													
nasal cavit	eosinophilic change:respiratory epithelium	0	0	0	0	1	0	0	0				
		(0)	(0)	(0)	(0)	(25)	(0)	(0)	(0)				
	disarrangement:olfactory epithelium	0	0	0	0	2	0	0	0				
		(0)	(0)	(0)	(0)	(50)	(0)	(0)	(0)				
	atrophy:olfactory epithelium	0	0	0	0	2	0	0	0				
		(0)	(0)	(0)	(0)	(50)	(0)	(0)	(0)				
lung/branch	hemorrhage	0	0	0	0	0	0	0	0				
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)				
[Hematopoietic system]													
spleen	deposit of melanin	1	0	0	0	2	0	0	0				
		(10)	(0)	(0)	(0)	(50)	(0)	(0)	(0)				
[Digestive system]													
stomach	hyperplasia:glandular stomach	0	0	0	0	1	0	0	0				
		(0)	(0)	(0)	(0)	(25)	(0)	(0)	(0)				
liver	granulation	0	0	0	0	1	0	0	0				
		(0)	(0)	(0)	(0)	(25)	(0)	(0)	(0)				
[Reproductive system]													
uterus	dilatation	2	0	0	0	1	0	0	0				
		(20)	(0)	(0)	(0)	(25)	(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

APPENDIX C 11-1

CONCENTRATION OF 1, 2-DICHLOROETHANE IN INHLATION CHAMBER

(THIRTEEN-WEEK STUDIES)

CONCENTRATION OF 1,2-DICHLOROETHANE IN INHALATION CHAMBER
(RAT : THIRTEEN-WEEK STUDIES)

Group Name	Concentration(ppm)	
	Mean ±	S.D.
Control	0.0 ±	0.0
20ppm	19.9 ±	0.2
40ppm	39.9 ±	0.3
80ppm	80.2 ±	0.9
160ppm	160.3 ±	1.8
320ppm	321.2 ±	0.7

CONCENTRATION OF 1,2-DICHLOROETHANE IN INHALATION CHAMBER
(MOUSE : THIRTEEN-WEEK STUDIES)

Group Name	Concentration(ppm)	
	Mean ±	S.D.
Control	0.0 ±	0.0
10ppm	10.0 ±	0.1
20ppm	20.0 ±	0.3
40ppm	40.2 ±	0.5
80ppm	79.7 ±	0.7
160ppm	161.2 ±	1.3

APPENDIX C 11-2

ENVIRONMENT OF INHLATION CHAMBER

(THIRTEEN-WEEK STUDIES)

ENVIRONMENT OF INHALATION CHAMBER

(RAT : THIRTEEN-WEEK STUDIES)

Group Name	TEMPERATURE (°C)			HUMIDITY (%)			VENTILATION RATE (ℓ/min)			ROOM AIR CHANGE (time/h)
	MEAN	±	S.D.	MEAN	±	S.D.	MEAN	±	S.D.	MEAN
Control	24.5	±	0.2	53.9	±	2.0	264.1	±	0.6	14.9
20ppm	24.7	±	0.2	57.2	±	2.1	266.4	±	0.9	15.1
40ppm	24.9	±	0.2	55.1	±	2.7	268.6	±	0.8	15.2
80ppm	24.8	±	0.2	50.9	±	2.4	265.0	±	1.0	15.0
160ppm	24.9	±	0.2	56.3	±	2.2	264.1	±	1.3	14.9
320ppm	24.0	±	0.7	52.7	±	1.8	266.3	±	0.1	15.1

ENVIRONMENT OF INHALATION CHAMBER

(MOUSE : THIRTEEN-WEEK STUDIES)

Group Name	TEMPERATURE (°C)			HUMIDITY (%)			VENTILATION RATE (ℓ/min)			ROOM AIR CHANGE (time/h)
	MEAN	±	S.D.	MEAN	±	S.D.	MEAN	±	S.D.	MEAN
Control	24.0	±	0.1	58.2	±	2.0	131.9	±	0.7	15.1
10ppm	23.9	±	0.2	55.8	±	2.5	131.1	±	0.3	15.0
20ppm	23.7	±	0.2	58.7	±	2.1	130.7	±	0.2	15.0
40ppm	23.8	±	0.2	58.6	±	2.1	130.7	±	0.7	15.0
80ppm	24.0	±	0.2	55.7	±	2.1	130.7	±	0.3	15.0
160ppm	24.2	±	0.2	57.9	±	2.6	131.3	±	1.1	15.1