

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

(E1～E4)

がん原性試験 NO. 0067 ; 0068

APPENDIX E 1

BODY WEIGHT CHANGES (TWO-YEAR STUDIES: SUMMARY)

RAT: MALE

STUDY NO. : 0067
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 104
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		120±	5	153±	7	187±	9	213±	10	233±	11	254±	11	272±	12
10	ppm	120±	5	151±	8	185±	9	212±	11	235±	12	256±	13	275±	14
40	ppm	120±	5	150±	7	184±	9	209±	10	232±	11	252±	12	270±	13
160	ppm	120±	5	147±	7**	180±	9**	206±	10**	230±	12	250±	13	268±	15

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 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	288±	13	305±	14	319±	15	330±	15	341±	15	349±	16	360±	17		
10 ppm	292±	15	306±	16	320±	17	330±	19	341±	19	350±	20	360±	20		
40 ppm	287±	13	302±	14	317±	14	327±	15	339±	15	347±	15	358±	16		
160 ppm	283±	15	297±	16*	311±	16*	322±	16*	332±	16*	341±	16*	350±	15**		

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week-day		14-7		16-7		18-7		20-7		22-7		24-7		26-7	
Control	367±	17	382±	18	393±	18	404±	19	414±	18	424±	20	431±	20		
10 ppm	368±	21	380±	21	392±	22	403±	22	413±	22	423±	23	431±	23		
40 ppm	365±	16	380±	17	393±	16	404±	17	413±	17	423±	17	430±	17		
160 ppm	358±	16*	371±	17*	383±	16*	394±	15*	402±	16**	412±	17**	421±	17*		

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

(HAN260)

BAIS 2

STUDY NO. : 0067
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 104
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 4

Group Name	Administration		week-day									
	28-7		30-7		32-7		34-7		36-7		38-7	
Control	436±	20	440±	21	446±	22	451±	21	457±	21	463±	21
10 ppm	435±	22	440±	23	445±	25	450±	27	457±	28	464±	28
40 ppm	432±	17	437±	17	442±	16	448±	17	455±	17	462±	18
160 ppm	423±	19**	429±	20*	433±	19*	438±	19*	443±	21*	452±	21

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

Group Name	Administration		week-day									
	42-7		44-7		46-7		48-7		50-7		52-7	
Control	473±	23	476±	23	481±	23	487±	23	488±	25	492±	26
10 ppm	472±	29	476±	29	481±	29	487±	31	488±	30	492±	30
40 ppm	472±	18	476±	18	481±	18	487±	20	489±	20	492±	19
160 ppm	462±	22	466±	25	472±	23	479±	23	481±	24	486±	23

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

(HAN260)

BAIS 2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 6

Group Name	Administration		week-day									
	56-7		58-7		60-7		62-7		64-7		66-7	
Control	495±	27	497±	29	499±	26	503±	27	505±	27	506±	29
10 ppm	499±	33	501±	36	501±	42	501±	48	502±	51	507±	36
40 ppm	501±	21	503±	20	502±	21	506±	21	506±	21	507±	25
160 ppm	493±	23	496±	23	498±	23	500±	24	500±	25	501±	24

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 7

Group Name	Administration week-day											
	70-7		72-7		74-7		76-7		78-7		80-7	
Control	506±	33	507±	37	505±	41	501±	45	506±	25	503±	26
10 ppm	508±	31	508±	32	507±	32	504±	38	507±	32	505±	33
40 ppm	509±	21	511±	21	509±	20	508±	22	507±	23	508±	22
160 ppm	502±	26	502±	32	504±	26	503±	28	502±	29	500±	30

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

Group Name	Administration week-day											
	84-7		86-7		88-7		90-7		92-7		94-7	
Control	497±	30	491±	33	485±	37	472±	46	469±	46	466±	40
10 ppm	500±	35	496±	39	495±	43	487±	50	479±	62	487±	49
40 ppm	504±	23	499±	34	498±	35	491±	48	492±	55	490±	66
160 ppm	497±	31	493±	33	490±	33	487±	35	482±	43	476±	57

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0067
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 104
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 9

Group Name	Administration week-day							
	98-7		100-7		102-7		104-7	
Control	460±	37	449±	44	447±	43	434±	46
10 ppm	468±	52	469±	47	463±	47	459±	59
40 ppm	473±	31	463±	45	456±	40	448±	41
160 ppm	477±	47	468±	64	463±	78	467±	85

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 2

APPENDIX E 2

BODY WEIGHT CHANGES (TWO-YEAR STUDIES: SUMMARY)

RAT: FEMALE

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 10

Group Name	Administration		week-day									
	0-0		1-7		2-7		3-7		4-7		5-7	
Control	100±	3	117±	5	134±	6	144±	6	152±	7	161±	8
10 ppm	100±	3	116±	4	133±	5	143±	5	153±	6	163±	6
40 ppm	100±	3	116±	4	133±	4	143±	5	153±	6	162±	7
160 ppm	100±	3	114±	4**	130±	5**	141±	7	150±	7	160±	8

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

(HAN260)

BAIS 2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 11

Group Name	Administration		week-day													
	7-7		8-7		9-7		10-7		11-7		12-7		13-7			
Control	176±	9	182±	10	189±	10	194±	10	198±	11	200±	11	205±	11		
10 ppm	177±	7	182±	8	188±	9	194±	10	197±	9	201±	10	205±	11		
40 ppm	179±	9	184±	9	190±	10	195±	11	200±	10	203±	10	207±	11		
160 ppm	175±	9	179±	9	186±	10	191±	11	197±	11	200±	11	206±	11		

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

(HAN260)

BAIS 2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 12

Group Name	Administration		week-day									
	14-7		16-7		18-7		20-7		22-7		24-7	
Control	208±	12	214±	12	221±	13	225±	13	231±	13	235±	14
10 ppm	208±	10	213±	10	220±	11	225±	10	229±	11	234±	12
40 ppm	210±	11	216±	12	221±	12	225±	12	230±	14	236±	14
160 ppm	207±	10	212±	11	219±	11	223±	12	228±	11	234±	12

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0067
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 13

Group Name	Administration		week-day									
	28-7		30-7		32-7		34-7		36-7		38-7	
Control	240±	14	242±	15	244±	15	248±	15	251±	16	258±	16
10 ppm	237±	12	240±	12	242±	12	247±	13	251±	14	257±	13
40 ppm	236±	12	238±	14	241±	15	246±	15	250±	15	256±	16
160 ppm	236±	12	239±	13	242±	13	246±	14	251±	13	256±	14

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 14

Group Name	Administration		week-day									
	42-7		44-7		46-7		48-7		50-7		52-7	
Control	264±	17	269±	18	273±	19	279±	20	281±	21	286±	21
10 ppm	262±	13	266±	15	272±	15	277±	15	277±	15	282±	17
40 ppm	262±	18	266±	18	272±	19	277±	19	279±	21	283±	22
160 ppm	261±	15	265±	14	270±	15	274±	16	276±	17	281±	19

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 15

Group Name	Administration		week-day											
	56-7		58-7		60-7		62-7		64-7		66-7		68-7	
Control	295±	24	298±	26	301±	26	305±	26	310±	29	313±	31	317±	34
10 ppm	291±	20	294±	20	296±	21	301±	21	304±	22	306±	23	311±	24
40 ppm	293±	24	297±	25	299±	26	304±	27	307±	27	310±	28	311±	28
160 ppm	288±	20	291±	22	294±	22	299±	23	301±	25	304±	26	307±	27

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 16

Group Name	Administration		week-day									
	70-7		72-7		74-7		76-7		78-7		80-7	
Control	321±	36	327±	44	330±	49	332±	56	330±	30	331±	29
10 ppm	314±	24	317±	26	318±	30	321±	31	325±	28	326±	29
40 ppm	315±	29	319±	29	320±	31	320±	30	323±	30	321±	34
160 ppm	310±	27	314±	27	317±	27	318±	27	321±	28	321±	30

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 17

Group Name	Administration week-day											
	84-7		86-7		88-7		90-7		92-7		94-7	
Control	333±	33	335±	36	338±	29	335±	31	335±	25	333±	27
10 ppm	331±	31	332±	31	330±	34	329±	36	328±	37	326±	42
40 ppm	323±	35	324±	40	330±	32	331±	32	329±	36	328±	41
160 ppm	330±	30	331±	31	332±	32	334±	33	332±	34	333±	36

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 18

Group Name	Administration		week-day					
	98-7		100-7		102-7		104-7	
Control	328±	24	322±	31	316±	46	317±	46
10 ppm	335±	34	334±	37	330±	40	329±	41
40 ppm	335±	35	338±	35	336±	40	331±	45
160 ppm	335±	44	333±	49	336±	50	336±	56

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

(HAN260)

BAIS2

APPENDIX E 3

BODY WEIGHT CHANGES (TWO-YEAR STUDIES: SUMMARY)

MOUSE: MALE

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 104
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	23.4± 0.8	25.3± 0.9	26.4± 1.1	27.4± 1.3	28.3± 1.4	29.5± 1.6	30.1± 1.8
10 ppm	23.4± 0.8	25.2± 0.9	26.1± 1.0	26.9± 1.2	27.9± 1.3	29.1± 1.7	29.9± 1.8
30 ppm	23.4± 0.8	25.1± 0.9	26.2± 1.2	27.4± 1.5	28.2± 1.6	29.2± 1.8	29.8± 2.1
90 ppm	23.4± 0.8	24.9± 1.0	26.0± 1.1	27.0± 1.2	27.7± 1.4	28.7± 1.4	29.3± 1.5

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

(HAN260)

BAIS 2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 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± 1.9	31.4± 2.0	32.1± 2.2	33.0± 2.2	33.8± 2.2	34.4± 2.4	35.0± 2.5
10 ppm	30.3± 2.0	31.2± 2.1	31.9± 2.2	32.8± 2.4	33.6± 2.6	33.9± 2.7	34.7± 2.9
30 ppm	30.3± 2.2	31.1± 2.4	31.9± 2.6	32.7± 2.8	33.5± 3.0	34.0± 3.2	35.0± 3.5
90 ppm	29.8± 1.8	30.5± 1.9	31.4± 1.9	31.7± 2.2	32.4± 2.5*	32.7± 2.6**	33.6± 2.7*

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week-day						
	14-7	16-7	18-7	20-7	22-7	24-7	26-7
Control	35.9± 2.5	36.7± 2.7	38.1± 2.8	39.0± 2.8	40.4± 2.9	41.0± 3.1	41.7± 3.3
10 ppm	35.7± 3.1	36.0± 3.4	37.3± 3.9	38.1± 4.1	40.0± 4.0	40.9± 4.0	41.6± 4.3
30 ppm	35.6± 3.7	36.4± 3.5	37.8± 3.5	38.5± 3.8	39.7± 4.1	40.6± 4.0	41.4± 4.2
90 ppm	34.3± 2.9**	34.9± 3.1*	35.8± 3.1**	36.5± 3.4**	37.7± 3.6**	38.8± 3.7**	38.9± 3.8**

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name		Administration		week-day											
		28-7		30-7		32-7		34-7		36-7		38-7		40-7	
Control		42.2±	3.3	43.3±	3.3	44.1±	3.4	45.5±	3.3	46.0±	3.3	46.7±	3.2	47.1±	3.1
10	ppm	42.3±	4.3	43.4±	4.3	44.0±	4.2	45.3±	4.3	45.8±	4.2	46.7±	4.1	46.9±	4.0
30	ppm	41.9±	4.4	42.6±	4.4	43.6±	4.5	44.9±	4.6	45.3±	4.6	45.8±	4.5	46.2±	4.5
90	ppm	40.2±	4.1*	40.5±	3.8**	41.3±	4.4**	42.7±	4.3**	42.9±	4.4**	43.6±	4.2**	44.0±	4.2**

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

Group Name	Administration week-day						
	42-7	44-7	46-7	48-7	50-7	52-7	54-7
Control	47.6± 3.3	48.8± 3.4	48.6± 3.6	49.6± 2.9	49.9± 2.8	50.6± 2.9	50.5± 2.8
10 ppm	47.4± 3.9	48.6± 4.0	48.5± 3.9	49.2± 4.5	49.4± 4.7	49.7± 5.0	49.6± 5.2
30 ppm	46.5± 4.4	47.8± 4.5	48.0± 4.4	48.6± 4.6	49.0± 4.4	49.2± 4.4	49.4± 4.5
90 ppm	44.7± 4.2**	46.0± 4.3**	46.1± 4.5**	47.0± 4.3**	47.4± 4.3**	48.1± 4.2**	48.4± 4.4

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 6

Group Name	Administration week-day						
	56-7	58-7	60-7	62-7	64-7	66-7	68-7
Control	50.8± 2.8	51.2± 2.7	51.4± 2.8	51.7± 3.1	51.5± 3.9	52.0± 3.7	52.2± 3.7
10 ppm	50.8± 3.8	50.8± 3.8	51.0± 3.8	51.5± 3.9	51.6± 3.9	51.6± 3.8	51.7± 4.0
30 ppm	50.2± 4.0	50.4± 4.1	50.8± 4.3	51.1± 4.2	51.4± 4.3	51.6± 4.4	52.0± 4.4
90 ppm	48.9± 4.3	49.3± 4.2	49.6± 4.1	50.1± 4.3	50.1± 4.7	50.2± 4.7	50.8± 4.7

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 7

Group Name		Administration		week-day											
		70-7		72-7		74-7		76-7		78-7		80-7		82-7	
Control		52.0±	4.0	52.5±	4.2	52.5±	4.5	52.3±	5.4	52.3±	5.1	52.1±	5.4	51.8±	5.9
10	ppm	51.7±	4.3	51.9±	4.7	51.7±	5.1	51.9±	5.7	51.4±	5.6	51.7±	5.2	51.1±	5.4
30	ppm	51.6±	4.5	52.3±	4.3	52.4±	4.5	52.3±	4.5	52.2±	4.6	52.7±	4.8	52.5±	4.8
90	ppm	50.5±	4.8	50.9±	5.0	50.9±	5.2	51.1±	5.6	51.2±	5.3	51.4±	5.5	51.0±	5.7

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

(HAN260)

BAIS 2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

Group Name	Administration week-day						
	84-7	86-7	88-7	90-7	92-7	94-7	96-7
Control	52.2± 6.1	51.8± 6.2	51.2± 6.4	52.3± 6.0	51.9± 6.2	51.9± 7.0	51.2± 7.7
10 ppm	51.3± 6.3	51.3± 6.1	50.9± 5.8	51.1± 5.7	50.8± 6.0	51.5± 5.7	51.2± 5.6
30 ppm	53.4± 4.9	53.1± 5.0	52.5± 4.9	52.3± 5.2	51.4± 5.5	51.2± 6.2	50.8± 6.9
90 ppm	51.2± 5.8	52.1± 6.0	51.7± 6.0	51.6± 6.2	50.9± 6.6	52.0± 6.6	52.5± 6.1

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

(HAN260)

BAIS 2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 9

Group Name	Administration week-day			
	98-7	100-7	102-7	104-7
Control	51.9± 7.0	52.0± 6.4	51.4± 6.2	50.8± 6.5
10 ppm	51.3± 6.3	51.1± 6.5	51.2± 6.9	51.7± 6.1
30 ppm	49.9± 7.5	49.8± 7.4	49.0± 7.3	48.1± 8.2
90 ppm	52.6± 6.4	52.1± 6.4	51.5± 6.6	50.7± 6.6

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

(HAN260)

BAIS 2

APPENDIX E 4

BODY WEIGHT CHANGES (TWO-YEAR STUDIES: SUMMARY)

MOUSE: FEMALE

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 10

Group Name	Administration week-day						
	0-0	1-7	2-7	3-7	4-7	5-7	6-7
Control	19.8± 0.7	20.9± 1.1	21.3± 1.0	21.8± 1.2	22.5± 1.3	23.1± 1.2	23.5± 1.1
10 ppm	19.8± 0.7	20.8± 1.0	21.1± 1.0	21.8± 1.1	22.5± 1.1	22.9± 1.1	23.3± 1.3
30 ppm	19.8± 0.7	21.0± 1.0	21.4± 1.1	22.4± 1.1*	23.1± 1.2	23.5± 1.2	24.0± 1.3
90 ppm	19.8± 0.7	20.5± 0.9	21.4± 1.0	21.8± 1.0	22.6± 1.0	22.8± 1.2	23.3± 1.2

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 11

Group Name	Administration week-day						
	7-7	8-7	9-7	10-7	11-7	12-7	13-7
Control	23.7± 1.1	24.0± 1.3	24.4± 1.4	24.7± 1.3	24.7± 1.5	25.1± 1.6	25.3± 1.3
10 ppm	23.7± 1.2	24.3± 1.4	24.5± 1.6	24.4± 1.5	24.9± 1.7	24.6± 1.6	24.8± 1.7
30 ppm	24.3± 1.4*	24.8± 1.3**	25.2± 1.6*	25.4± 1.6*	25.4± 1.8*	25.8± 1.9	26.0± 2.0
90 ppm	23.4± 1.1	24.0± 1.1	24.7± 1.2	24.2± 1.0	24.5± 1.1	24.4± 1.1	24.8± 1.3

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 12

Group Name	Administration week-day							
	14-7	16-7	18-7	20-7	22-7	24-7	26-7	
Control	25.7± 1.3	25.9± 1.4	26.8± 1.5	26.8± 1.8	28.0± 1.7	28.5± 2.1	28.6± 2.0	
10 ppm	25.2± 2.3	25.4± 1.9	26.0± 2.0*	26.4± 2.1	27.3± 2.1	28.1± 2.5	28.3± 2.4	
30 ppm	26.2± 1.8	26.5± 2.1	27.6± 2.2	27.2± 2.2	28.2± 2.7	28.9± 2.8	29.1± 2.8	
90 ppm	25.1± 1.2	25.2± 1.3	25.4± 1.4**	26.1± 1.4	26.3± 1.7**	27.3± 1.8*	27.2± 1.9**	

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

(HAN260)

BAIS2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 13

Group Name	Administration week-day	28-7	30-7	32-7	34-7	36-7	38-7	40-7
Control		28.8± 2.2	29.7± 2.3	29.5± 2.4	30.7± 3.0	30.9± 3.0	31.8± 2.9	31.5± 3.1
10 ppm		28.8± 2.5	29.2± 2.7	29.5± 3.2	30.0± 3.3	30.6± 3.2	31.1± 3.5	31.6± 3.6
30 ppm		29.4± 2.6	29.6± 2.8	30.5± 3.3	31.6± 3.8	31.3± 3.7	31.7± 3.9	32.1± 3.7
90 ppm		27.7± 1.9*	27.6± 1.9**	28.5± 2.1*	28.8± 2.4**	29.2± 2.5*	29.1± 2.5**	29.5± 2.5**

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 14

Group Name	Administration week-day							
	42-7	44-7	46-7	48-7	50-7	52-7	54-7	
Control	32.1± 3.1	32.9± 3.5	33.2± 3.7	34.3± 4.0	34.3± 3.4	34.8± 3.9	35.1± 3.7	
10 ppm	31.7± 3.9	32.3± 3.7	32.8± 3.8	33.4± 4.2	34.0± 4.0	34.4± 4.3	34.8± 4.1	
30 ppm	31.9± 4.1	33.3± 4.5	33.4± 4.4	34.0± 4.6	34.3± 4.8	35.1± 4.7	35.0± 4.9	
90 ppm	29.5± 2.7**	30.6± 2.6**	30.4± 2.7**	31.0± 3.1**	31.4± 3.3**	32.0± 3.1**	31.5± 3.2**	

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 15

Group Name		Administration		week-day											
		56-7		58-7		60-7		62-7		64-7		66-7		68-7	
Control		35.8±	3.7	35.5±	4.2	36.0±	4.3	36.3±	4.2	37.3±	4.3	36.9±	4.2	37.3±	4.8
10	ppm	35.0±	4.6	35.5±	4.7	35.6±	4.2	35.9±	4.3	36.4±	4.5	36.7±	4.5	36.8±	4.6
30	ppm	35.5±	4.9	35.6±	5.3	35.9±	5.1	36.1±	5.2	37.0±	5.3	36.8±	5.2	36.8±	5.2
90	ppm	32.1±	3.1**	33.2±	3.7**	32.5±	3.5**	33.1±	3.5**	33.2±	3.9**	33.1±	3.6**	33.7±	3.5**

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 16

Group Name		Administration		week-day											
		70-7		72-7		74-7		76-7		78-7		80-7		82-7	
Control		37.6±	4.2	37.6±	4.3	37.2±	4.4	36.6±	4.5	36.5±	3.8	37.1±	4.5	36.7±	4.6
10	ppm	36.5±	4.7	36.4±	4.4	37.0±	4.8	36.6±	4.3	36.9±	4.3	36.6±	3.9	35.8±	4.2
30	ppm	37.3±	5.7	37.4±	5.3	37.5±	5.0	36.7±	5.1	37.6±	4.4	38.3±	4.8	37.6±	5.3
90	ppm	33.4±	3.7**	34.1±	3.5**	34.5±	3.8**	34.3±	4.2**	34.1±	4.8**	34.2±	4.0**	33.5±	4.1**

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 17

Group Name	Administration week-day						
	84-7	86-7	88-7	90-7	92-7	94-7	96-7
Control	37.5± 4.9	36.6± 4.5	36.6± 4.7	36.7± 4.6	36.5± 4.5	37.8± 4.8	38.0± 5.1
10 ppm	36.7± 4.4	36.3± 4.5	36.3± 5.5	35.9± 4.4	34.8± 4.6	35.7± 4.8	36.3± 5.0
30 ppm	37.6± 5.1	38.3± 4.9	37.9± 5.1	37.4± 5.3	37.3± 4.9	38.0± 5.0	38.1± 5.4
90 ppm	34.1± 4.2**	34.4± 5.5*	34.1± 4.2*	34.1± 4.5**	33.4± 4.1**	34.5± 3.4	34.2± 4.2

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 18

Group Name	Administration week-day			
	98-7	100-7	102-7	104-7
Control	37.7± 4.8	36.9± 5.1	37.5± 4.7	36.6± 5.2
10 ppm	36.5± 5.0	36.7± 3.8	35.9± 4.4	35.8± 4.1
30 ppm	38.2± 5.7*	37.8± 5.5	37.7± 5.0*	37.4± 4.9*
90 ppm	34.8± 4.2*	34.0± 4.5**	34.1± 3.9**	34.1± 4.0

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

(HAN260)

BAIS2

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

(F1～F4)

がん原性試験 NO. 0067 ; 0068

APPENDIX F 1

FOOD CONSUMPTION CHANGES (TWO-YEAR STUDIES: SUMMARY)

RAT: MALE

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 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	15.9± 1.0	19.6± 2.1	19.5± 2.1	19.6± 2.0	20.0± 1.5	19.8± 1.4	19.9± 1.4
10 ppm	15.3± 0.9*	18.7± 1.5	18.8± 1.8	18.9± 1.6	19.6± 1.8	19.2± 1.6	19.2± 1.7
40 ppm	15.3± 1.1*	18.8± 1.9	18.7± 1.7	18.5± 1.6**	19.3± 1.7	18.6± 1.5**	18.8± 1.4**
160 ppm	15.0± 1.0**	18.5± 1.4*	19.3± 1.7	19.2± 1.7	19.9± 1.8	18.9± 1.9*	18.8± 1.7**

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 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)	14-7(7)
Control	19.4± 1.2	19.6± 1.2	19.6± 1.3	18.7± 1.1	18.4± 1.3	19.1± 1.1	18.7± 1.1
10 ppm	18.9± 1.6	19.2± 1.7	19.0± 1.5	18.1± 1.2*	18.2± 1.3	18.5± 1.4*	18.3± 1.3
40 ppm	18.6± 1.5*	19.0± 1.5	18.8± 1.4*	18.2± 1.2	18.0± 1.2	18.5± 1.3*	18.2± 1.3
160 ppm	18.3± 1.4**	18.9± 1.6	18.5± 1.5**	17.4± 1.3**	17.6± 1.3**	18.0± 1.2**	18.0± 1.2

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration 18-7(7)	week-day(effective) 22-7(7)	26-7(7)	30-7(7)	34-7(7)	38-7(7)	42-7(7)
Control	18.8± 0.9	19.7± 1.0	19.3± 0.8	18.6± 1.0	19.6± 1.0	19.1± 1.0	19.2± 0.9
10 ppm	18.2± 1.3*	19.1± 1.0*	19.0± 1.0	18.0± 1.0**	18.8± 1.2**	18.7± 1.0	18.6± 1.1*
40 ppm	18.5± 1.0	18.9± 1.1**	18.8± 1.0*	17.5± 0.9**	18.6± 1.0**	18.6± 0.9	18.7± 1.1
160 ppm	18.2± 1.1*	18.7± 1.1**	18.8± 0.9*	17.7± 1.1**	18.4± 1.1**	19.0± 1.1	18.8± 1.1

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week-day(effective) 46-7(7)	50-7(7)	52-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)
Control	19.4± 1.1	19.4± 1.0	19.1± 1.0	19.0± 1.0	19.7± 1.6	19.9± 1.0	19.9± 1.6
10 ppm	18.9± 1.0*	18.8± 1.2	18.5± 1.2*	18.9± 1.4	19.2± 2.1	18.7± 2.6**	18.5± 2.3**
40 ppm	18.9± 1.0*	18.6± 1.4**	18.6± 1.2	18.8± 1.1	19.2± 1.1	19.1± 1.8**	18.8± 1.8**
160 ppm	18.9± 1.1*	18.7± 1.2*	18.8± 0.9	18.5± 1.2	19.0± 1.0**	19.2± 1.0**	18.7± 1.1**

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

Group Name	Administration 70-7(7)	week-day(effective) 74-7(7)	78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)
Control	19.6± 1.9	19.8± 4.1	19.5± 1.3	19.4± 1.6	18.6± 2.3	18.1± 3.6	18.6± 2.9
10 ppm	18.6± 1.2**	18.7± 1.5	18.9± 1.2	18.3± 1.6**	17.9± 2.8	17.8± 3.2	18.5± 2.0
40 ppm	18.5± 1.3**	18.8± 1.3	18.9± 1.3	18.3± 2.7**	17.7± 3.3	18.1± 3.4	18.8± 2.6
160 ppm	18.7± 1.7*	19.1± 1.3	18.8± 1.6	18.7± 1.5	17.9± 1.9	18.6± 2.0	18.2± 3.4

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0067
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 104
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 6

Group Name	Administration week-day(effective)		
	98-7(7)	102-7(7)	104-7(7)
Control	19.4± 2.2	18.5± 3.4	18.1± 1.9
10 ppm	18.3± 3.9	19.0± 1.7	18.4± 3.9
40 ppm	19.0± 1.9	17.7± 3.5	18.3± 3.1
160 ppm	19.0± 2.5	17.3± 4.1	18.7± 4.6

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

(HAN260)

BAIS2

APPENDIX F 2

FOOD CONSUMPTION CHANGES (TWO-YEAR STUDIES: SUMMARY)

RAT: FEMALE

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 7

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	12.4± 0.8	13.8± 1.1	13.2± 1.2	13.2± 1.1	13.8± 1.3	13.6± 1.3	13.6± 1.1
10 ppm	12.1± 0.7	13.6± 1.2	13.2± 1.2	12.8± 1.0	13.3± 1.1	13.0± 1.0*	13.0± 0.9*
40 ppm	12.1± 0.7*	13.2± 1.0**	13.2± 1.0	12.8± 0.9	13.2± 1.1*	13.0± 1.1**	13.3± 1.1
160 ppm	11.7± 0.6**	12.8± 0.9**	12.9± 1.4	12.7± 1.2	13.1± 0.9**	12.8± 1.1**	12.8± 1.1**

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

Group Name	Administration week-day(effective) 8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	13.2± 1.1	13.4± 1.0	13.5± 1.1	12.6± 1.2	12.5± 1.1	12.9± 1.3	12.6± 1.1
10 ppm	12.7± 0.9*	12.6± 1.2**	12.7± 1.0**	12.1± 1.0	12.1± 0.9	12.5± 1.0	12.3± 0.9
40 ppm	12.7± 1.1*	12.7± 1.1**	12.6± 1.2**	12.4± 1.0	12.1± 1.0	12.4± 1.1	12.6± 1.4
160 ppm	12.4± 1.0**	12.6± 1.1**	12.8± 1.4*	12.2± 1.1	12.3± 1.3	12.6± 1.2	12.4± 1.2

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 9

Group Name	Administration 18-7(7)	week-day(effective) 22-7(7)	26-7(7)	30-7(7)	34-7(7)	38-7(7)	42-7(7)
Control	13.0± 1.1	13.5± 1.1	12.6± 1.0	13.2± 1.2	13.7± 1.1	14.0± 1.2	13.2± 0.9
10 ppm	12.9± 1.0	13.1± 1.2	12.8± 1.2	12.5± 1.1*	13.4± 1.2	13.8± 2.4	12.7± 0.9*
40 ppm	12.7± 1.4	12.9± 1.4	11.9± 1.0**	12.2± 1.3**	13.1± 1.2	13.2± 1.1**	12.6± 1.1*
160 ppm	12.8± 1.4	13.3± 1.1	12.4± 1.2	12.7± 1.3	13.2± 1.1	13.7± 1.2	12.8± 1.0

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 10

Group Name	Administration 46-7(7)	week-day(effective) 50-7(7)	52-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)
Control	13.7± 1.0	13.4± 1.1	13.8± 1.0	13.9± 1.3	14.3± 1.3	14.6± 1.2	14.3± 1.4
10 ppm	13.5± 1.1	12.7± 0.9**	13.5± 1.3	13.3± 1.2	13.9± 0.9	14.0± 1.1*	13.6± 0.9*
40 ppm	13.4± 0.9	12.8± 1.1**	13.3± 1.2	13.4± 1.1	13.8± 1.0*	14.1± 1.2	13.6± 1.5
160 ppm	13.2± 0.9*	12.6± 1.1**	13.3± 1.2	13.2± 1.0	13.4± 0.9**	13.6± 1.0**	13.5± 1.1**

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0067
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 11

Group Name	Administration 70-7(7)	week-day(effective) 74-7(7)	78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)
Control	14.5± 1.8	14.8± 3.1	15.0± 1.3	14.9± 1.7	14.7± 2.3	14.7± 2.9	15.0± 2.9
10 ppm	13.9± 0.9	13.7± 2.6	14.3± 1.5	14.4± 1.7	14.3± 2.0	14.3± 2.6	14.3± 2.8
40 ppm	13.8± 1.2	13.8± 2.0	14.0± 1.7**	13.7± 2.4	13.8± 3.4	14.5± 2.0	14.0± 3.0
160 ppm	13.7± 0.9**	13.9± 1.4	13.7± 2.4**	14.5± 1.3	14.1± 1.4*	14.5± 2.3	14.5± 1.7

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0067
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 12

Group Name	Administration week-day(effective)		
	98-7(7)	102-7(7)	104-7(7)
Control	15.3± 3.4	13.5± 4.1	14.1± 4.1
10 ppm	15.5± 1.8	15.0± 2.3	14.7± 2.0
40 ppm	15.3± 2.8	14.9± 1.6	14.4± 3.1
160 ppm	15.0± 2.4	14.5± 2.6	14.0± 3.1

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX F 3

FOOD CONSUMPTION CHANGES (TWO-YEAR STUDIES: SUMMARY)

MOUSE: MALE

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 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	4.2± 0.3	4.2± 0.3	4.2± 0.3	4.2± 0.3	3.9± 0.3
10 ppm	4.2± 0.3	4.2± 0.3	4.2± 0.3	4.4± 0.3	4.3± 0.3	4.3± 0.3	4.1± 0.3
30 ppm	4.2± 0.3	4.2± 0.3	4.2± 0.3	4.4± 0.5	4.3± 0.4	4.3± 0.5	4.1± 0.4
90 ppm	4.3± 0.2	4.2± 0.2	4.3± 0.2	4.4± 0.3*	4.3± 0.3	4.4± 0.3	4.1± 0.3*

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 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)	14-7(7)
Control	4.1± 0.3	4.1± 0.3	4.2± 0.3	4.2± 0.2	4.3± 0.3	4.3± 0.2	4.3± 0.2
10 ppm	4.3± 0.3**	4.2± 0.3	4.3± 0.3	4.3± 0.3	4.3± 0.3	4.3± 0.3	4.4± 0.3
30 ppm	4.3± 0.3**	4.2± 0.3	4.3± 0.3	4.3± 0.3	4.3± 0.3	4.4± 0.4*	4.4± 0.4
90 ppm	4.3± 0.3*	4.2± 0.3	4.2± 0.3	4.3± 0.4	4.3± 0.3	4.4± 0.3	4.4± 0.3

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

Test of Dunnett

(HAN260)

BAIS 2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration 18-7(7)	week-day(effective) 22-7(7)	26-7(7)	30-7(7)	34-7(7)	38-7(7)	42-7(7)
Control	4.6± 0.2	4.5± 0.2	4.4± 0.2	4.5± 0.3	4.7± 0.2	4.7± 0.2	4.7± 0.3
10 ppm	4.6± 0.4	4.6± 0.3	4.4± 0.3	4.4± 0.3	4.7± 0.3	4.8± 0.3	4.8± 0.3
30 ppm	4.5± 0.3	4.6± 0.3	4.4± 0.3	4.5± 0.3	4.7± 0.3	4.7± 0.4	4.7± 0.3
90 ppm	4.4± 0.3	4.5± 0.3	4.4± 0.3	4.4± 0.3	4.7± 0.4	4.7± 0.4	4.6± 0.4

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week-day(effective)						
	46-7(7)	50-7(7)	52-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)
Control	4.8± 0.3	4.8± 0.3	4.9± 0.3	4.9± 0.2	4.9± 0.3	4.9± 0.2	5.0± 0.3
10 ppm	4.8± 0.3	4.8± 0.4	4.9± 0.3	4.9± 0.4	5.0± 0.3	5.0± 0.3	5.0± 0.3
30 ppm	4.8± 0.3	4.8± 0.3	4.9± 0.3	4.9± 0.4	5.0± 0.3	5.0± 0.4	5.1± 0.4
90 ppm	4.7± 0.4	4.7± 0.3	4.9± 0.3	4.9± 0.3	4.9± 0.3	4.9± 0.3	4.9± 0.3

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

Group Name	Administration week-day(effective) 70-7(7)	74-7(7)	78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)
Control	5.0± 0.3	5.0± 0.4	5.0± 0.4	4.9± 0.3	5.1± 0.4	5.2± 0.4	5.2± 0.7
10 ppm	5.1± 0.4	5.0± 0.4	4.9± 0.4	4.9± 0.5	5.3± 0.4*	5.1± 0.9	5.2± 0.4
30 ppm	5.1± 0.4	5.1± 0.4	5.0± 0.4	4.9± 0.3	5.2± 0.4	5.1± 0.5	5.1± 0.6
90 ppm	5.0± 0.5	5.0± 0.4	4.9± 0.4	4.9± 0.4	5.3± 0.3*	5.2± 0.4	5.3± 0.5

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 104
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 6

Group Name	Administration week-day(effective)		
	98-7(7)	102-7(7)	104-7(7)
Control	5.2± 0.5	4.9± 0.4	4.8± 0.6
10 ppm	5.3± 0.6	5.1± 0.7	5.1± 0.6
30 ppm	5.1± 0.7	4.7± 0.8	4.8± 0.7
90 ppm	5.3± 0.4	4.9± 0.5	4.9± 0.7

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX F 4

FOOD CONSUMPTION CHANGES (TWO-YEAR STUDIES: SUMMARY)

MOUSE: FEMALE

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 7

Group Name	Administration 1-7(7)	week-day(effective) 2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	3.7± 0.4	3.6± 0.3	3.8± 0.3	4.0± 0.3	4.1± 0.3	4.1± 0.3	4.1± 0.3
10 ppm	3.6± 0.4	3.6± 0.3	3.8± 0.3	4.0± 0.3	4.0± 0.3	4.2± 0.3	4.0± 0.3
30 ppm	3.7± 0.3	3.8± 0.3*	3.9± 0.3	4.1± 0.4	4.1± 0.3	4.2± 0.3	4.0± 0.3
90 ppm	3.7± 0.3	3.8± 0.3**	3.8± 0.3	4.1± 0.3	4.0± 0.3	4.2± 0.3	4.0± 0.3

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

Group Name	Administration 8-7(7)	week-day(effective) 9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	4.2± 0.3	4.2± 0.3	4.2± 0.3	4.2± 0.4	4.3± 0.4	4.3± 0.3	4.4± 0.4
10 ppm	4.2± 0.3	4.2± 0.3	4.2± 0.3	4.3± 0.4	4.3± 0.3	4.3± 0.3	4.3± 0.6
30 ppm	4.3± 0.3	4.1± 0.3	4.2± 0.4	4.1± 0.4	4.2± 0.3	4.2± 0.5	4.3± 0.4
90 ppm	4.3± 0.3	4.2± 0.3	4.2± 0.3	4.2± 0.3	4.3± 0.3	4.3± 0.3	4.3± 0.3

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 9

Group Name	Administration week-day(effective)						
	18-7(7)	22-7(7)	26-7(7)	30-7(7)	34-7(7)	38-7(7)	42-7(7)
Control	4.6± 0.4	4.4± 0.4	4.3± 0.3	4.3± 0.4	4.6± 0.6	4.7± 0.5	4.7± 0.4
10 ppm	4.5± 0.4	4.4± 0.4	4.2± 0.4	4.2± 0.4	4.4± 0.5	4.5± 0.6	4.5± 0.6
30 ppm	4.4± 0.4	4.5± 0.4	4.2± 0.4	4.3± 0.4	4.6± 0.5	4.5± 0.6	4.6± 0.6
90 ppm	4.2± 0.4**	4.3± 0.5	4.1± 0.3	4.2± 0.3	4.4± 0.5	4.5± 0.5	4.4± 0.4**

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 10

Group Name	Administration 46-7(7)	week-day(effective) 50-7(7)	52-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)
Control	4.7± 0.5	4.4± 0.5	4.7± 0.6	4.7± 0.5	4.6± 0.6	4.7± 0.5	4.7± 0.5
10 ppm	4.5± 0.5	4.6± 0.5	4.7± 0.6	4.8± 0.5	4.8± 0.7	5.0± 0.7	5.0± 1.2
30 ppm	4.7± 0.4	4.6± 0.6	4.8± 0.6	4.7± 0.6	4.7± 0.6	4.7± 0.6	4.9± 0.6
90 ppm	4.5± 0.4	4.4± 0.4	4.6± 0.4	4.6± 0.6	4.8± 0.5	4.6± 0.5	4.7± 0.6

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 11

Group Name	Administration 70-7(7)	week-day(effective) 74-7(7)	78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)
Control	4.8± 0.5	4.9± 0.6	4.6± 0.6	4.5± 0.6	4.6± 0.6	4.8± 0.9	5.1± 0.8
10 ppm	4.7± 0.7	4.7± 0.6	4.7± 0.6	4.4± 0.6	4.8± 0.7	4.7± 0.7	4.8± 0.8
30 ppm	4.9± 0.6	4.8± 0.6	4.8± 0.6	4.5± 0.6	5.0± 0.5	4.7± 0.7	4.9± 0.8
90 ppm	4.7± 0.7	4.8± 0.6	4.5± 0.8	4.5± 0.6	4.8± 0.9	4.7± 0.7	4.8± 0.7

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 12

Group Name	Administration week-day(effective)		
	98-7(7)	102-7(7)	104-7(7)
Control	5.1± 0.7	4.9± 0.6	4.9± 0.8
10 ppm	5.1± 0.6	4.7± 0.7	4.7± 0.7
30 ppm	5.2± 0.5	4.9± 0.9	4.8± 0.7**
90 ppm	4.8± 0.7	4.7± 0.8	4.8± 1.0

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

Test of Dunnett

(HAN260)

BAIS2

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

(G1～G4)

がん原性試験 NO. 0067 ; 0068

APPENDIX G 1

HEMATOLOGY (TWO-YEAR STUDIES: SUMMARY)

RAT: MALE

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		PLATELET 10 ³ /μl	
Control	36	7.88±	1.51	14.4±	2.8	39.7±	7.7	50.3±	3.2	1203±	253
10 ppm	34	8.12±	1.42	14.9±	2.7	40.7±	7.6	50.1±	4.0	1151±	304
40 ppm	32	7.44±	1.65	13.6±	3.1	36.4±	9.2	49.1±	8.1	1256±	376
160 ppm	37	7.47±	1.92	13.3±	3.3	36.4±	9.2	48.8±	4.0	1255±	273

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 1

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	36	6.44±	2.29	1±	1	51±	10	1±	2	0±	0	4±	2	40±	10	2±	2
10 ppm	34	6.79±	3.75	2±	2	54±	12	1±	1	0±	0	4±	2	38±	12	2±	2
40 ppm	32	31.23±	110.32	1±	2	48±	15	1±	2	0±	0	4±	3	39±	11	7±	20
160 ppm	37	6.22±	3.21	3±	2**	52±	12	1±	1	0±	0	4±	3	38±	11	3±	6

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

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX G 2

HEMATOLOGY (TWO-YEAR STUDIES: SUMMARY)

RAT: FEMALE

STUDY NO. : 0067
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
 SURVIVAL ANIMALS (104)

PAGE : 2

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		PLATELET 10 ³ /μl	
Control	35	7.66±	1.78	15.0±	2.7	41.1±	7.6	55.6±	10.0	808±	196
10 ppm	41	7.78±	1.77	15.2±	2.6	41.7±	7.4	55.7±	11.7	763±	256
40 ppm	37	7.92±	1.45	15.5±	2.1	42.4±	5.8	54.8±	8.3	806±	205
160 ppm	36	7.74±	1.25	15.0±	1.8	40.1±	6.2	52.5±	7.3	821±	249

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0067
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
 SURVIVAL ANIMALS (104)

PAGE : 2

Group Name		NO. of Animals	WBC 1 O ³ /μℓ		Differential N-BAND		WBC (%) N-SEG	EOSINO		BASO		MONO		LYMPHO		OTHER		
Control		35	4.61±	4.19	3±	2	42±	13	1±	1	0±	0	4±	3	48±	12	2±	2
10	ppm	41	8.66±	17.59	2±	2	44±	18	1±	1	0±	0	4±	3	43±	15	6±	14
40	ppm	37	11.64±	47.17	3±	2	47±	13	1±	2	0±	0	4±	2	43±	11	2±	6
160	ppm	36	6.87±	20.78	3±	2	43±	11	1±	1	0±	0	4±	3	44±	11	4±	15

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

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX G 3

HEMATOLOGY (TWO-YEAR STUDIES: SUMMARY)

MOUSE: MALE

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		PLATELET 10 ³ /μl	
Control	38	10.36±	1.94	14.3±	2.4	43.1±	7.5	41.7±	2.7	2039±	651
10 ppm	31	10.19±	1.07	14.3±	1.3	42.9±	4.4	42.0±	1.5	2107±	364
30 ppm	35	9.91±	1.57	13.8±	1.9	41.2±	5.9	41.6±	2.4	1761±	612
90 ppm	37	10.12±	1.35	14.3±	1.7	42.7±	5.2	42.3±	2.4	1955±	429

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

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

HEMATOLOGY(2) (SUMMARY)
 SURVIVAL ANIMALS (104)

PAGE : 1

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC	(%) N-SEG	EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	38	3.56±	2.83	1±	2	37±	13	1±	2	0±	0	2±	3	58±	14	1±	1
10 ppm	31	2.53±	1.17	1±	1	36±	11	2±	1*	0±	0	2±	2	58±	13	1±	4
30 ppm	35	3.46±	4.05	2±	2	40±	15	2±	2	0±	0	1±	2	55±	16	1±	1
90 ppm	37	3.32±	1.95	1±	1	39±	10	2±	3*	0±	0	3±	2	54±	10	1±	3

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

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX G 4

HEMATOLOGY (TWO-YEAR STUDIES: SUMMARY)

MOUSE: FEMALE

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 2

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		PLATELET 10 ³ /μl	
Control	34	10.02±	0.73	14.4±	1.1	42.3±	3.5	42.2±	1.1	1428±	262
10 ppm	28	9.46±	1.30	13.6±	1.7	40.0±	5.3	42.5±	3.3	1223±	405
30 ppm	18	9.83±	0.75	14.3±	0.8	42.4±	2.3	43.1±	2.2	1322±	305
90 ppm	26	9.47±	1.57	13.7±	1.9	40.7±	5.9	43.2±	2.6	1247±	405

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
 SURVIVAL ANIMALS (104)

PAGE : 2

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC	(%) N-SEG	EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	34	3.56±	5.33	1±	1	31±	13	3±	3	0±	0	2±	2	61±	15	3±	13
10 ppm	28	2.33±	1.52	1±	2	38±	13	3±	3	0±	0	2±	2	55±	15	2±	4
30 ppm	18	3.24±	4.40	1±	1	35±	11	2±	3	0±	0	2±	2	50±	13	1±	2
90 ppm	26	4.90±	11.45	1±	2	46±	17**	1±	2	0±	0	2±	2	49±	17**	1±	1

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

Test of Dunnett

(JCL71A)

BAIS2

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

(H1～H4)

がん厳性試験 NO. 0067 ; 0068

APPENDIX H 1

BIOCHEMISTRY (TWO-YEAR STUDIES: SUMMARY)

RAT: MALE

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (104)

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	37	6.8±	0.5	3.0±	0.2	0.8±	0.1	0.24±	0.06	149±	25	204±	55	271±	175
10 ppm	35	6.8±	0.7	3.1±	0.4	0.8±	0.1	0.26±	0.06	151±	36	213±	61	311±	214
40 ppm	32	6.7±	0.5	3.0±	0.3	0.8±	0.1	0.31±	0.50	149±	26	204±	57	261±	147
160 ppm	37	6.7±	0.7	3.0±	0.4	0.8±	0.1	0.26±	0.07	150±	25	205±	59	279±	180

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 2

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT IU/l		GPT IU/l		LDH IU/l		ALP IU/l		LAP IU/l		G-GTP IU/l	
Control	37	320±	89	64±	26	21±	13	170±	49	169±	151	46±	8	5±	4
10 ppm	35	330±	102	94±	165	21±	17	220±	218	206±	398	47±	9	5±	3
40 ppm	32	319±	101	104±	196	27±	33	271±	379	180±	139	47±	9	6±	8
160 ppm	37	320±	106	74±	59	21±	11	202±	89	149±	66	45±	9	5±	3

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0067
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (104)

PAGE : 3

Group Name	NO. of Animals	CPK IU/ℓ		UREA NITROGEN mg/dℓ		CREATININE mg/dℓ		SODIUM mEq/ℓ		POTASSIUM mEq/ℓ		CHLORIDE mEq/ℓ		CALCIUM mg/dℓ	
Control	37	81±	16	29.7±	12.5	0.8±	0.4	141±	2	3.5±	0.3	105±	2	11.0±	0.5
10 ppm	35	95±	90	30.2±	15.6	0.9±	0.3	142±	2	3.8±	0.8	105±	2	11.0±	0.6
40 ppm	32	103±	77	28.3±	13.9	0.9±	0.5	141±	2	3.6±	0.5	105±	2	11.0±	0.7
160 ppm	37	82±	15	24.7±	7.0*	0.7±	0.2	141±	2	3.6±	0.3	105±	2	11.0±	0.6

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 4

Group Name	NO. of Animals	INORGANIC PHOSPHORUS mg/dl	
Control	37	4.2±	0.8
10 ppm	35	4.5±	1.9
40 ppm	32	4.2±	1.5
160 ppm	37	4.4±	0.9

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

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX H 2

BIOCHEMISTRY (TWO-YEAR STUDIES: SUMMARY)

RAT: FEMALE

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 5

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	35	6.9±	0.5	3.6±	0.4	1.1±	0.1	0.32±	0.48	153±	20	148±	50	163±	120
10 ppm	41	6.9±	0.6	3.6±	0.4	1.1±	0.1	0.50±	1.61	160±	20	149±	46	163±	107
40 ppm	37	7.1±	0.4	3.6±	0.3	1.1±	0.1	0.25±	0.09	158±	30	155±	40	166±	109
160 ppm	36	7.0±	0.7	3.6±	0.4	1.1±	0.1	0.27±	0.14	155±	22	143±	42	194±	114

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0067
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (104)

PAGE : 6

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT IU/l		GPT IU/l		LDH IU/l		ALP IU/l		LAP IU/l		G-GTP IU/l	
Control	35	270±	98	124±	164	35±	24	203±	118	152±	131	43±	4	3±	2
10 ppm	41	266±	79	146±	202	35±	21	316±	509	154±	123	44±	6	3±	2
40 ppm	37	281±	76	116±	82	36±	18	247±	270	133±	85	43±	4	4±	3
160 ppm	36	263±	92	113±	57	34±	11	267±	254	128±	66	41±	6	4±	2

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 7

Group Name	NO. of Animals	CPK IU / ℓ		UREA NITROGEN mg / dl		CREATININE mg / dl		SODIUM mEq / ℓ		POTASSIUM mEq / ℓ		CHLORIDE mEq / ℓ		CALCIUM mg / dl	
Control	35	81 $\pm$	28	17.8 $\pm$	5.1	0.5 $\pm$	0.1	140 $\pm$	2	3.5 $\pm$	0.4	105 $\pm$	2	10.6 $\pm$	0.4
10 ppm	41	90 $\pm$	48	17.5 $\pm$	4.2	0.5 $\pm$	0.1	140 $\pm$	2	3.6 $\pm$	0.5	105 $\pm$	2	10.6 $\pm$	0.4
40 ppm	37	88 $\pm$	45	18.8 $\pm$	10.0	0.6 $\pm$	0.4	140 $\pm$	2	3.4 $\pm$	0.3	104 $\pm$	2	10.7 $\pm$	0.6
160 ppm	36	112 $\pm$	177	17.9 $\pm$	8.0	0.5 $\pm$	0.1	140 $\pm$	2	3.5 $\pm$	0.4	105 $\pm$	3	10.6 $\pm$	0.5

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 8

Group Name	NO. of Animals	INORGANIC PHOSPHORUS mg/dl	
Control	35	3.4±	1.0
10 ppm	41	3.4±	1.0
40 ppm	37	3.4±	1.5
160 ppm	36	3.5±	0.9

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

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX H 3

BIOCHEMISTRY (TWO-YEAR STUDIES: SUMMARY)

MOUSE: MALE

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (104)

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	37	5.9±	0.9	3.0±	0.5	1.0±	0.1	0.33±	0.17	179±	43	116±	39	79±	55
10 ppm	31	5.8±	0.6	2.9±	0.4	1.0±	0.1	0.31±	0.09	191±	38	109±	37	71±	17
30 ppm	35	5.7±	0.8	2.9±	0.5	1.0±	0.2	0.37±	0.21	169±	58	104±	33	66±	21
90 ppm	37	5.7±	0.7	2.9±	0.3	1.0±	0.2	0.30±	0.08	187±	44	103±	32	71±	15

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (104)

PAGE : 2

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT I U/l		GPT I U/l		LDH I U/l		ALP I U/l		LAP I U/l		CPK I U/l	
Control	37	203±	60	237±	569	84±	193	1195±	3188	205±	155	71±	30	57±	18
10 ppm	31	194±	61	152±	298	50±	86	538±	539	210±	163	67±	26	62±	22
30 ppm	35	178±	58	458±	1223	170±	507	2168±	6185	348±	543	70±	36	63±	34
90 ppm	37	184±	57	125±	241	43±	82	600±	863	180±	94	64±	30	54±	20

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (104)

PAGE : 3

Group Name	NO. of Animals	UREA NITROGEN mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	37	23.9±	5.2	154±	2	4.3±	0.4	123±	3	9.2±	0.6	7.5±	1.1
10 ppm	31	23.4±	3.3	154±	1	4.3±	0.4	123±	2	9.0±	0.5	7.9±	1.1
30 ppm	35	27.3±	18.4	154±	2	4.6±	0.5	122±	3	9.0±	0.5	8.0±	1.6
90 ppm	37	22.5±	2.9	154±	2	4.4±	0.5	123±	2	9.0±	0.5	7.8±	1.2

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX H 4

BIOCHEMISTRY (TWO-YEAR STUDIES: SUMMARY)

MOUSE: FEMALE

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (104)

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	34	5.3±	0.5	2.8±	0.2	1.1±	0.2	0.32±	0.10	126±	29	78±	34	79±	48
10 ppm	28	5.5±	1.0	2.8±	0.3	1.1±	0.2	0.31±	0.09	131±	29	72±	18	74±	57
30 ppm	18	5.3±	0.4	2.7±	0.2	1.1±	0.2	0.34±	0.08	124±	25	68±	16	83±	34
90 ppm	26	5.4±	0.5	2.8±	0.2	1.1±	0.2	0.31±	0.09	127±	39	78±	20	67±	22

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (104)

PAGE : 5

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT IU/l		GPT IU/l		LDH IU/l		ALP IU/l		LAP IU/l		CPK IU/l	
Control	34	136±	55	82±	35	23±	12	351±	155	234±	126	58±	6	67±	42
10 ppm	28	130±	34	95±	37	29±	28	399±	177	233±	98	61±	11	97±	162
30 ppm	18	129±	29	107±	49*	28±	22	434±	181	243±	99	59±	8	67±	34
90 ppm	26	142±	45	98±	74	23±	17	473±	304	280±	119	57±	7	67±	46

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 6

Group Name	NO. of Animals	UREA NITROGEN mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	34	19.6±	10.5	152±	3	4.1±	0.4	124±	3	9.1±	0.5	6.9±	1.2
10 ppm	28	21.6±	14.9	151±	2	4.2±	0.5	123±	2	9.2±	0.4	7.0±	1.2
30 ppm	18	17.8±	7.4	152±	2	4.3±	0.6	124±	2	9.0±	0.3	7.5±	1.7
90 ppm	26	20.6±	12.7	152±	2	4.2±	0.6	124±	2	9.0±	0.5	6.9±	1.1

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

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

(I1～I4)

がん原性試験 NO. 0067 ; 0068

APPENDIX I 1

URINALYSIS (TWO-YEAR STUDIES: SUMMARY)

RAT: MALE

STUDY NO. : 0067
 ANIMAL : RAT F344
 SAMPLING DATE : 104-7
 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	37	0	0	12	9	12	4	0		0	0	0	1	0	36		37	0	0	0	0	0		32	5	0	0		37	0	0	0	
10 ppm	35	0	1	10	7	12	5	0		0	0	0	1	4	30		35	0	0	0	0	0		31	4	0	0		34	1	0	0	
40 ppm	32	0	1	11	8	12	0	0		0	0	0	0	13	19	**	32	0	0	0	0	0		30	2	0	0		30	1	1	0	
160 ppm	37	0	0	8	9	16	4	0		0	0	1	0	5	31		37	0	0	0	0	0		28	9	0	0		37	0	0	0	

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

Test of CHI SQUARE

(JCL103X)

BAIS 2

STUDY NO. : 0067
ANIMAL : RAT F344
SAMPLING DATE : 104-7
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	37	37	0	0	0	0		37	0	0	0	0	
10 ppm	35	32	1	0	0	2		35	0	0	0	0	
40 ppm	32	31	1	0	0	0		32	0	0	0	0	
160 ppm	37	36	1	0	0	0		37	0	0	0	0	

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

Test of CHI SQUARE

(JCL103X)

BAIS2

APPENDIX I 2

URINALYSIS (TWO-YEAR STUDIES: SUMMARY)

RAT: FEMALE

STUDY NO. : 0067
 ANIMAL : RAT F344
 SAMPLING DATE : 104-7
 SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body				CHI	Bilirubin				CHI		
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	+		2+	3+	-	+		2+	3+
Control	36	0	2	7	10	8	8	1		0	0	3	3	5	25		36	0	0	0	0	0		30	6	0	0		34	2	0	0	
10 ppm	41	0	1	5	11	17	7	0		0	0	0	4	14	23		41	0	0	0	0	0		29	12	0	0		40	0	1	0	
40 ppm	37	0	1	9	11	13	2	1		0	0	2	8	8	19		37	0	0	0	0	0		27	10	0	0		33	4	0	0	
160 ppm	40	1	1	8	8	12	7	3		0	0	1	0	7	32		40	0	0	0	0	0		12	28	0	0	**	37	2	0	1	

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

Test of CHI SQUARE

(JCL103X)

BAIS2

STUDY NO. : 0067

URINALYSIS

ANIMAL : RAT F344

SAMPLING DATE : 104-7

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	36	35	0	0	0	1		36	0	0	0	0	
10 ppm	41	40	1	0	0	0		41	0	0	0	0	
40 ppm	37	35	1	0	0	1		37	0	0	0	0	
160 ppm	40	36	3	0	0	1		39	1	0	0	0	

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

Test of CHI SQUARE

(JCL103X)

BAIS 2

APPENDIX I 3

URINALYSIS (TWO-YEAR STUDIES: SUMMARY)

MOUSE: MALE

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 SAMPLING DATE : 104-7
 SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body				CHI	Occult blood					CHI	
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	+		2+	3+	-	±	+		2+
Control	39	0	1	16	6	9	7	0		0	0	23	15	1	0		39	0	0	0	0	0		0	39	0	0		36	0	1	0	2
10 ppm	32	0	2	8	9	10	3	0		0	0	23	8	1	0		32	0	0	0	0	0		18	14	0	0	**	31	0	1	0	0
30 ppm	35	0	4	13	8	9	1	0		0	0	10	25	0	0	*	35	0	0	0	0	0		6	29	0	0	**	29	4	0	0	2
90 ppm	36	0	3	9	12	8	4	0		0	0	6	29	1	0	**	36	0	0	0	0	0		18	18	0	0	**	31	1	2	0	2

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

Test of CHI SQUARE

(JCL104X)

BAIS2

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
SAMPLING DATE : 104-7
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+ CHI
Control	39	38 0 0 0 0
10 ppm	32	32 0 0 0 0
30 ppm	35	35 0 0 0 0
90 ppm	36	36 0 0 0 0

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

Test of CHI SQUARE

(JCL104X)

BAIS2

APPENDIX I 4

URINALYSIS (TWO-YEAR STUDIES: SUMMARY)

MOUSE: FEMALE

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 SAMPLING DATE : 104-7
 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+
Control	34	0	1	2	4	11	12	4		0	0	26	7	1	0		34	0	0	0	0	0		5	29	0	0		30	1	0	2	1
10 ppm	28	0	0	3	3	16	5	1		0	1	17	9	0	1		28	0	0	0	0	0		12	16	0	0	*	22	3	2	0	1
30 ppm	20	0	2	1	5	9	3	0		0	0	11	6	3	0		20	0	0	0	0	0		2	17	1	0		16	2	0	1	1
90 ppm	26	0	1	5	4	10	6	0		1	0	11	10	4	0	*	26	0	0	0	0	0		17	9	0	0	**	22	2	1	1	0

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

Test of CHI SQUARE

(JCL104X)

BAIS 2

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
SAMPLING DATE : 104-7
SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+ CHI
Control	34	33 1 0 0 0
10 ppm	28	28 0 0 0 0
30 ppm	20	20 0 0 0 0
90 ppm	26	26 0 0 0 0

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

Test of CHI SQUARE

(JCL104X)

BAIS 2

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

(J1～J8)

がん原性試験 NO. 0067 ; 0068

APPENDIX J 1

GROSS FINDINGS (TWO-YEAR STUDIES: SUMMARY)

RAT: MALE: DEAD AND MORIBUND ANIMALS

STUDY NO. : 0067
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 13 (%)	10 ppm 15 (%)	40 ppm 18 (%)	160 ppm 13 (%)
skin/app	nodule		0 (0)	1 (7)	2 (11)	0 (0)
subcutis	mass		1 (8)	4 (27)	7 (39)	0 (0)
lung	white		0 (0)	0 (0)	0 (0)	1 (8)
	red		6 (46)	5 (33)	8 (44)	8 (62)
	white patch/zone		1 (8)	0 (0)	1 (6)	0 (0)
	red patch/zone		0 (0)	1 (7)	1 (6)	0 (0)
	congestion		0 (0)	0 (0)	0 (0)	1 (8)
	nodule		2 (15)	1 (7)	0 (0)	0 (0)
lymph node	enlarged		2 (15)	2 (13)	3 (17)	1 (8)
	red		0 (0)	1 (7)	1 (6)	1 (8)
thymus	enlarged		0 (0)	0 (0)	2 (11)	0 (0)
	atrophic		0 (0)	0 (0)	1 (6)	0 (0)
spleen	enlarged		4 (31)	1 (7)	5 (28)	2 (15)
	nodule		1 (8)	1 (7)	0 (0)	0 (0)
	deformed		0 (0)	0 (0)	0 (0)	1 (8)
heart	white		0 (0)	0 (0)	1 (6)	0 (0)
	red		1 (8)	0 (0)	0 (0)	0 (0)
	dilated		0 (0)	1 (7)	1 (6)	1 (8)
forestomach	swollen		1 (8)	0 (0)	0 (0)	0 (0)
	adhesion		0 (0)	0 (0)	1 (6)	0 (0)
	rupture		0 (0)	0 (0)	1 (6)	1 (8)
	ulcer		2 (15)	2 (13)	1 (6)	3 (23)

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 13 (%)	10 ppm 15 (%)	40 ppm 18 (%)	160 ppm 13 (%)
forestomach	thick		0 (0)	0 (0)	2 (11)	0 (0)
gl stomach	black patch/zone		0 (0)	0 (0)	1 (6)	1 (8)
	hemorrhage		0 (0)	1 (7)	1 (6)	0 (0)
	ulcer		2 (15)	0 (0)	0 (0)	1 (8)
	thick		1 (8)	0 (0)	4 (22)	1 (8)
	fluid:black		1 (8)	0 (0)	3 (17)	0 (0)
stomach	dilated		0 (0)	1 (7)	0 (0)	0 (0)
	gas		0 (0)	0 (0)	0 (0)	1 (8)
small intes	red patch/zone		1 (8)	0 (0)	0 (0)	0 (0)
	dilated		0 (0)	2 (13)	1 (6)	0 (0)
cecum	gas		0 (0)	0 (0)	0 (0)	1 (8)
large intes	red		0 (0)	0 (0)	1 (6)	0 (0)
	red patch/zone		0 (0)	0 (0)	1 (6)	0 (0)
	dilated		1 (8)	1 (7)	0 (0)	0 (0)
liver	enlarged		1 (8)	5 (33)	4 (22)	2 (15)
	pale		0 (0)	2 (13)	2 (11)	0 (0)
	white patch/zone		1 (8)	0 (0)	1 (6)	2 (15)
	nodule		0 (0)	1 (7)	0 (0)	0 (0)
	herniation		1 (8)	1 (7)	0 (0)	0 (0)
pancreas	nodule		0 (0)	0 (0)	0 (0)	1 (8)
kidney	enlarged		1 (8)	1 (7)	1 (6)	1 (8)
	white patch/zone		1 (8)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0067
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 13 (%)	10 ppm 15 (%)	40 ppm 18 (%)	160 ppm 13 (%)
kidney	red patch/zone		0 (0)	1 (7)	0 (0)	0 (0)
	cyst		0 (0)	1 (7)	0 (0)	0 (0)
	granular		2 (15)	3 (20)	4 (22)	3 (23)
	dilated		0 (0)	1 (7)	0 (0)	1 (8)
urin bladd	dilated		0 (0)	0 (0)	1 (6)	0 (0)
	urine:marked retention		2 (15)	0 (0)	0 (0)	1 (8)
pituitary	enlarged		3 (23)	5 (33)	8 (44)	4 (31)
	red patch/zone		1 (8)	0 (0)	1 (6)	0 (0)
	black patch/zone		0 (0)	0 (0)	1 (6)	0 (0)
	nodule		2 (15)	2 (13)	2 (11)	0 (0)
thyroid	enlarged		1 (8)	0 (0)	1 (6)	1 (8)
	nodule		0 (0)	1 (7)	1 (6)	1 (8)
adrenal	enlarged		1 (8)	0 (0)	1 (6)	0 (0)
testis	enlarged		1 (8)	0 (0)	0 (0)	0 (0)
	atrophic		4 (31)	0 (0)	3 (17)	0 (0)
	edema		0 (0)	0 (0)	0 (0)	1 (8)
	nodule		10 (77)	7 (47)	5 (28)	6 (46)
	fluid:red		0 (0)	0 (0)	0 (0)	1 (8)
brain	swollen		0 (0)	0 (0)	1 (6)	0 (0)
	brown patch/zone		0 (0)	1 (7)	0 (0)	0 (0)
	black patch/zone		0 (0)	0 (0)	0 (0)	1 (8)
	hemorrhage		1 (8)	0 (0)	1 (6)	0 (0)

STUDY NO. : 0067
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control 13 (%)	10 ppm 15 (%)	40 ppm 18 (%)	160 ppm 13 (%)
periph nerv	swollen		1 (8)	0 (0)	0 (0)	0 (0)
eye	white		0 (0)	1 (7)	0 (0)	0 (0)
	red		2 (15)	1 (7)	2 (11)	1 (8)
Harder gl	swollen		1 (8)	0 (0)	0 (0)	0 (0)
	black patch/zone		0 (0)	0 (0)	0 (0)	1 (8)
Zymbal gl	nodule		0 (0)	0 (0)	0 (0)	1 (8)
muscle	mass		0 (0)	0 (0)	0 (0)	1 (8)
bone	nodule		2 (15)	0 (0)	0 (0)	0 (0)
peritoneum	nodule		0 (0)	1 (7)	0 (0)	2 (15)
abdominal c	hemorrhage		1 (8)	1 (7)	0 (0)	0 (0)
	nodule		0 (0)	1 (7)	0 (0)	0 (0)
	mass		1 (8)	1 (7)	0 (0)	1 (8)
	ascites		3 (23)	1 (7)	0 (0)	3 (23)
adipose	nodule		2 (15)	1 (7)	2 (11)	0 (0)
thoracic ca	hemorrhage		0 (0)	0 (0)	1 (6)	0 (0)
	pleural fluid		2 (15)	3 (20)	2 (11)	2 (15)
other	nodule		0 (0)	1 (7)	0 (0)	0 (0)
whole body	anemic		0 (0)	0 (0)	1 (6)	0 (0)

APPENDIX J 2

GROSS FINDINGS (TWO-YEAR STUDIES: SUMMARY)

RAT:FEMALE:DEAD AND MORIBUND ANIMALS

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 5

Organ	Findings	Group Name NO. of Animals	Control 15 (%)	10 ppm 9 (%)	40 ppm 13 (%)	160 ppm 12 (%)
subcutis	jaundice		1 (7)	2 (22)	2 (15)	1 (8)
	mass		4 (27)	2 (22)	3 (23)	7 (58)
lung	red		2 (13)	4 (44)	3 (23)	1 (8)
	white patch/zone		1 (7)	1 (11)	0 (0)	0 (0)
	red patch/zone		1 (7)	0 (0)	0 (0)	0 (0)
	nodule		1 (7)	1 (11)	1 (8)	0 (0)
lymph node	enlarged		1 (7)	1 (11)	2 (15)	0 (0)
	red		0 (0)	1 (11)	0 (0)	0 (0)
thymus	enlarged		0 (0)	1 (11)	0 (0)	0 (0)
spleen	enlarged		9 (60)	4 (44)	5 (38)	2 (17)
	white patch/zone		0 (0)	1 (11)	0 (0)	0 (0)
	nodule		1 (7)	0 (0)	1 (8)	1 (8)
	adhesion		0 (0)	0 (0)	1 (8)	0 (0)
heart	white		1 (7)	0 (0)	0 (0)	1 (8)
	white patch/zone		1 (7)	0 (0)	1 (8)	1 (8)
tongue	nodule		0 (0)	1 (11)	0 (0)	0 (0)
forestomach	red		0 (0)	0 (0)	1 (8)	0 (0)
	nodule		1 (7)	0 (0)	0 (0)	0 (0)
	ulcer		4 (27)	1 (11)	3 (23)	5 (42)
	thick		0 (0)	0 (0)	0 (0)	1 (8)
gl stomach	red patch/zone		0 (0)	1 (11)	1 (8)	0 (0)
	black patch/zone		0 (0)	0 (0)	0 (0)	1 (8)

STUDY NO. : 0067
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 6

Organ	Findings	Group Name NO. of Animals	Control 15 (%)	10 ppm 9 (%)	40 ppm 13 (%)	160 ppm 12 (%)
gl stomach	ulcer		4 (27)	3 (33)	2 (15)	3 (25)
	thick		0 (0)	1 (11)	1 (8)	2 (17)
small intes	red patch/zone		1 (7)	0 (0)	0 (0)	0 (0)
	brown patch/zone		0 (0)	0 (0)	1 (8)	0 (0)
	black patch/zone		0 (0)	1 (11)	0 (0)	0 (0)
	dilated		1 (7)	0 (0)	0 (0)	0 (0)
cecum	dilated		1 (7)	0 (0)	0 (0)	0 (0)
colon	dilated		1 (7)	0 (0)	0 (0)	0 (0)
large intes	brown patch/zone		0 (0)	0 (0)	1 (8)	0 (0)
liver	enlarged		1 (7)	0 (0)	0 (0)	1 (8)
	pale		1 (7)	1 (11)	1 (8)	1 (8)
	yellow		1 (7)	0 (0)	1 (8)	1 (8)
	white patch/zone		0 (0)	1 (11)	0 (0)	1 (8)
	red patch/zone		1 (7)	0 (0)	0 (0)	1 (8)
	nodule		1 (7)	0 (0)	0 (0)	0 (0)
	rough		1 (7)	0 (0)	0 (0)	1 (8)
	granular		0 (0)	0 (0)	3 (23)	0 (0)
	herniation		1 (7)	1 (11)	1 (8)	1 (8)
kidney	enlarged		0 (0)	0 (0)	1 (8)	0 (0)
	green		0 (0)	0 (0)	0 (0)	1 (8)
	white patch/zone		0 (0)	0 (0)	1 (8)	0 (0)
	granular		0 (0)	1 (11)	0 (0)	1 (8)

STUDY NO. : 0067
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 7

Organ	Findings	Group Name NO. of Animals	Control 15 (%)	10 ppm 9 (%)	40 ppm 13 (%)	160 ppm 12 (%)
urin bladd	dilated		0 (0)	0 (0)	0 (0)	1 (8)
pituitary	enlarged		6 (40)	3 (33)	4 (31)	3 (25)
	red patch/zone		1 (7)	2 (22)	1 (8)	1 (8)
	brown patch/zone		0 (0)	0 (0)	1 (8)	0 (0)
	black patch/zone		1 (7)	0 (0)	0 (0)	0 (0)
	nodule		4 (27)	0 (0)	1 (8)	1 (8)
thyroid	nodule		1 (7)	0 (0)	0 (0)	0 (0)
adrenal	enlarged		1 (7)	0 (0)	0 (0)	0 (0)
ovary	enlarged		1 (7)	1 (11)	0 (0)	0 (0)
	fluid:transparent		1 (7)	0 (0)	0 (0)	0 (0)
uterus	enlarged		0 (0)	1 (11)	0 (0)	0 (0)
	nodule		3 (20)	2 (22)	2 (15)	1 (8)
	dilated lumen		0 (0)	0 (0)	0 (0)	1 (8)
vagina	nodule		1 (7)	0 (0)	0 (0)	0 (0)
	dilated		0 (0)	0 (0)	1 (8)	1 (8)
	dilated lumen		0 (0)	0 (0)	1 (8)	0 (0)
	fluid:red		0 (0)	0 (0)	1 (8)	1 (8)
	fluid:brown		1 (7)	0 (0)	0 (0)	0 (0)
	fluid:black		1 (7)	0 (0)	0 (0)	0 (0)
	fluid:white		1 (7)	0 (0)	1 (8)	0 (0)
prep/cli gl	nodule		0 (0)	0 (0)	0 (0)	1 (8)
brain	red patch/zone		0 (0)	0 (0)	1 (8)	1 (8)

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 8

Organ	Findings	Group Name NO. of Animals	Control 15 (%)	10 ppm 9 (%)	40 ppm 13 (%)	160 ppm 12 (%)
spinal cord	red patch/zone		1 (7)	0 (0)	0 (0)	0 (0)
eye	red		0 (0)	1 (11)	0 (0)	0 (0)
	brown		0 (0)	0 (0)	0 (0)	1 (8)
mediastinum	nodule		1 (7)	0 (0)	0 (0)	0 (0)
	mass		0 (0)	1 (11)	0 (0)	0 (0)
retroperit	mass		0 (0)	1 (11)	0 (0)	0 (0)
abdominal c	hemorrhage		1 (7)	0 (0)	1 (8)	1 (8)
	nodule		0 (0)	0 (0)	0 (0)	1 (8)
	mass		0 (0)	0 (0)	1 (8)	0 (0)
	ascites		1 (7)	0 (0)	0 (0)	0 (0)
adipose	nodule		0 (0)	1 (11)	0 (0)	1 (8)
thoracic ca	hemorrhage		0 (0)	0 (0)	0 (0)	1 (8)
	pleural fluid		3 (20)	1 (11)	3 (23)	2 (17)
other	nodule		0 (0)	0 (0)	0 (0)	1 (8)
whole body	anemic		0 (0)	0 (0)	1 (8)	1 (8)
	jaundice		1 (7)	1 (11)	1 (8)	1 (8)

APPENDIX J 3

GROSS FINDINGS (TWO-YEAR STUDIES: SUMMARY)

RAT: MALE: SACRIFICED ANIMALS

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (104W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 37 (%)	10 ppm 35 (%)	40 ppm 32 (%)	160 ppm 37 (%)
skin/app	nodule		4 (11)	4 (11)	5 (16)	3 (8)
	mass		0 (0)	0 (0)	0 (0)	1 (3)
subcutis	mass		7 (19)	9 (26)	13 (41)	18 (49)
lung	white patch/zone		1 (3)	0 (0)	3 (9)	3 (8)
	red patch/zone		0 (0)	0 (0)	0 (0)	1 (3)
	yellow patch/zone		0 (0)	0 (0)	1 (3)	0 (0)
	brown patch/zone		0 (0)	1 (3)	0 (0)	0 (0)
	nodule		1 (3)	2 (6)	0 (0)	5 (14)
	adhesion		0 (0)	1 (3)	0 (0)	0 (0)
lymph node	enlarged		0 (0)	0 (0)	0 (0)	2 (5)
spleen	enlarged		2 (5)	1 (3)	5 (16)	4 (11)
	red		0 (0)	0 (0)	1 (3)	0 (0)
	infarct		0 (0)	0 (0)	1 (3)	1 (3)
	nodule		0 (0)	1 (3)	1 (3)	2 (5)
	deformed		0 (0)	0 (0)	1 (3)	0 (0)
	accessory spleen		0 (0)	0 (0)	1 (3)	0 (0)
	scarred		0 (0)	1 (3)	0 (0)	1 (3)
tongue	nodule		0 (0)	1 (3)	1 (3)	0 (0)
salivary gl	atrophic		0 (0)	0 (0)	1 (3)	0 (0)
small intes	red patch/zone		1 (3)	0 (0)	0 (0)	0 (0)
liver	enlarged		1 (3)	1 (3)	2 (6)	0 (0)
	swollen		0 (0)	1 (3)	0 (0)	0 (0)

STUDY NO. : 0067
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (104W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 37 (%)	10 ppm 35 (%)	40 ppm 32 (%)	160 ppm 37 (%)
Liver	atrophic		1 (3)	0 (0)	0 (0)	2 (5)
	white patch/zone		0 (0)	1 (3)	0 (0)	1 (3)
	red patch/zone		0 (0)	0 (0)	0 (0)	1 (3)
	yellow patch/zone		1 (3)	2 (6)	0 (0)	1 (3)
	brown patch/zone		1 (3)	0 (0)	0 (0)	2 (5)
	nodule		1 (3)	1 (3)	1 (3)	5 (14)
	cyst		2 (5)	0 (0)	1 (3)	1 (3)
	rough		1 (3)	1 (3)	2 (6)	3 (8)
	herniation		0 (0)	0 (0)	2 (6)	4 (11)
pancreas	nodule		0 (0)	0 (0)	3 (9)	0 (0)
kidney	nodule		0 (0)	0 (0)	1 (3)	0 (0)
	cyst		1 (3)	1 (3)	0 (0)	1 (3)
	granular		33 (89)	31 (89)	26 (81)	30 (81)
urin bladd	nodule		0 (0)	1 (3)	0 (0)	0 (0)
	fluid:red		0 (0)	1 (3)	0 (0)	0 (0)
pituitary	enlarged		8 (22)	5 (14)	3 (9)	9 (24)
	red patch/zone		2 (5)	1 (3)	2 (6)	1 (3)
	nodule		4 (11)	3 (9)	5 (16)	4 (11)
	cyst		2 (5)	0 (0)	1 (3)	0 (0)
thyroid	enlarged		1 (3)	4 (11)	4 (13)	2 (5)
	red		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		2 (5)	3 (9)	0 (0)	3 (8)

STUDY NO. : 0067
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (104W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 37 (%)	10 ppm 35 (%)	40 ppm 32 (%)	160 ppm 37 (%)
adrenal	enlarged		2 (5)	1 (3)	2 (6)	3 (8)
	atrophic		0 (0)	0 (0)	0 (0)	1 (3)
testis	enlarged		0 (0)	2 (6)	1 (3)	2 (5)
	atrophic		4 (11)	4 (11)	7 (22)	10 (27)
	nodule		35 (95)	33 (94)	30 (94)	36 (97)
	cyst		0 (0)	2 (6)	0 (0)	0 (0)
semin ves	atrophic		23 (62)	21 (60)	18 (56)	24 (65)
prep/cli gl	nodule		3 (8)	1 (3)	2 (6)	1 (3)
eye	white		1 (3)	0 (0)	0 (0)	0 (0)
	white patch/zone		1 (3)	0 (0)	0 (0)	0 (0)
Zymbal gl	nodule		1 (3)	0 (0)	1 (3)	0 (0)
muscle	mass		0 (0)	1 (3)	0 (0)	0 (0)
peritoneum	nodule		1 (3)	1 (3)	2 (6)	3 (8)
	fluid:brown		0 (0)	0 (0)	0 (0)	1 (3)
abdominal c	ascites		0 (0)	1 (3)	1 (3)	3 (8)
mesenterium	nodule		0 (0)	0 (0)	0 (0)	1 (3)
	fluid:brown		0 (0)	0 (0)	0 (0)	1 (3)
adipose	nodule		1 (3)	7 (20)	7 (22)	6 (16)
thoracic ca	pleural fluid		0 (0)	0 (0)	0 (0)	1 (3)
other	swollen		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		1 (3)	0 (0)	3 (9)	0 (0)
	mass		1 (3)	0 (0)	0 (0)	1 (3)

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (104W)

PAGE : 4

Organ	Findings	Group Name	Control	10 ppm	40 ppm	160 ppm
		NO. of Animals	37 (%)	35 (%)	32 (%)	37 (%)
whole body	anemic		2 (5)	1 (3)	2 (6)	1 (3)

(HPT080)

BAIS 2

APPENDIX J 4

GROSS FINDINGS (TWO-YEAR STUDIES: SUMMARY)

RAT: FEMALE: SACRIFICED ANIMALS

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (104W)

PAGE : 5

Organ	Findings	Group Name NO. of Animals	Control 35 (%)	10 ppm 41 (%)	40 ppm 37 (%)	160 ppm 38 (%)
skin/app	nodule		1 (3)	0 (0)	1 (3)	2 (5)
subcutis	jaundice		1 (3)	1 (2)	0 (0)	0 (0)
	mass		8 (23)	10 (24)	11 (30)	23 (61)
lung	white patch/zone		1 (3)	0 (0)	0 (0)	0 (0)
	red patch/zone		0 (0)	0 (0)	0 (0)	2 (5)
	yellow patch/zone		0 (0)	0 (0)	1 (3)	2 (5)
	brown patch/zone		0 (0)	1 (2)	0 (0)	0 (0)
	nodule		1 (3)	2 (5)	0 (0)	0 (0)
lymph node	enlarged		1 (3)	1 (2)	0 (0)	0 (0)
thymus	enlarged		0 (0)	1 (2)	0 (0)	0 (0)
spleen	enlarged		2 (6)	6 (15)	3 (8)	5 (13)
	infarct		1 (3)	1 (2)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	0 (0)	1 (3)
	rough		0 (0)	0 (0)	1 (3)	0 (0)
heart	enlarged		0 (0)	1 (2)	0 (0)	0 (0)
	white		0 (0)	0 (0)	0 (0)	1 (3)
	white patch/zone		0 (0)	1 (2)	0 (0)	0 (0)
tongue	white patch/zone		0 (0)	0 (0)	1 (3)	0 (0)
	nodule		1 (3)	0 (0)	0 (0)	0 (0)
gl stomach	thick		0 (0)	0 (0)	0 (0)	1 (3)
small intes	nodule		1 (3)	0 (0)	0 (0)	1 (3)
	dilated		0 (0)	0 (0)	1 (3)	0 (0)

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (104W)

PAGE : 6

Organ	Findings	Group Name NO. of Animals	Control 35 (%)	10 ppm 41 (%)	40 ppm 37 (%)	160 ppm 38 (%)
liver	white patch/zone		0 (0)	0 (0)	1 (3)	0 (0)
	red patch/zone		1 (3)	1 (2)	1 (3)	0 (0)
	nodule		2 (6)	1 (2)	2 (5)	2 (5)
	rough		3 (9)	3 (7)	2 (5)	3 (8)
	herniation		7 (20)	3 (7)	3 (8)	7 (18)
kidney	green		0 (0)	1 (2)	0 (0)	0 (0)
	black		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		1 (3)	0 (0)	0 (0)	0 (0)
	cyst		0 (0)	0 (0)	0 (0)	1 (3)
	granular		10 (29)	8 (20)	9 (24)	7 (18)
pituitary	enlarged		6 (17)	3 (7)	3 (8)	6 (16)
	red patch/zone		6 (17)	7 (17)	10 (27)	9 (24)
	nodule		5 (14)	5 (12)	3 (8)	8 (21)
thyroid	enlarged		2 (6)	4 (10)	2 (5)	0 (0)
	black patch/zone		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		0 (0)	4 (10)	3 (8)	1 (3)
adrenal	enlarged		1 (3)	0 (0)	1 (3)	2 (5)
	brown		1 (3)	0 (0)	0 (0)	0 (0)
ovary	enlarged		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		1 (3)	0 (0)	0 (0)	0 (0)
	cyst		2 (6)	2 (5)	3 (8)	1 (3)
uterus	atrophic		1 (3)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (104W)

PAGE : 7

Organ	Findings	Group Name NO. of Animals	Control 35 (%)	10 ppm 41 (%)	40 ppm 37 (%)	160 ppm 38 (%)
uterus	nodule		5 (14)	7 (17)	2 (5)	3 (8)
	cyst		0 (0)	0 (0)	0 (0)	1 (3)
	dilated lumen		1 (3)	4 (10)	3 (8)	0 (0)
vagina	fluid:red		1 (3)	0 (0)	0 (0)	0 (0)
prep/cli gl	nodule		1 (3)	3 (7)	2 (5)	1 (3)
brain	turbid		0 (0)	1 (2)	0 (0)	0 (0)
eye	white		0 (0)	0 (0)	1 (3)	1 (3)
muscle	nodule		1 (3)	0 (0)	0 (0)	0 (0)
peritoneum	black patch/zone		1 (3)	0 (0)	0 (0)	0 (0)
abdominal c	ascites		0 (0)	1 (2)	0 (0)	0 (0)
adipose	brown		0 (0)	1 (2)	0 (0)	0 (0)
	nodule		1 (3)	2 (5)	4 (11)	2 (5)
thoracic ca	pleural fluid		1 (3)	1 (2)	0 (0)	1 (3)
other	nodule		0 (0)	1 (2)	0 (0)	0 (0)
whole body	anemic		0 (0)	2 (5)	0 (0)	1 (3)
	jaundice		0 (0)	1 (2)	0 (0)	0 (0)
	wasting		1 (3)	0 (0)	0 (0)	0 (0)

APPENDIX J 5

GROSS FINDINGS (TWO-YEAR STUDIES: SUMMARY)

MOUSE: MALE: DEAD AND MORIBUND ANIMALS

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 11 (%)	10 ppm 17 (%)	30 ppm 15 (%)	90 ppm 13 (%)
subcutis	edema		1 (9)	0 (0)	0 (0)	1 (8)
	nodule		0 (0)	1 (6)	0 (0)	0 (0)
	mass		0 (0)	0 (0)	0 (0)	1 (8)
lung	red		3 (27)	2 (12)	2 (13)	1 (8)
	white patch/zone		1 (9)	0 (0)	0 (0)	0 (0)
	red patch/zone		0 (0)	1 (6)	0 (0)	2 (15)
	hemorrhage		1 (9)	0 (0)	3 (20)	0 (0)
	nodule		1 (9)	6 (35)	5 (33)	5 (38)
lymph node	enlarged		1 (9)	3 (18)	1 (7)	2 (15)
	nodule		0 (0)	1 (6)	0 (0)	0 (0)
thymus	involution		0 (0)	0 (0)	1 (7)	0 (0)
spleen	enlarged		3 (27)	1 (6)	3 (20)	0 (0)
	atrophic		0 (0)	0 (0)	3 (20)	0 (0)
	white patch/zone		1 (9)	0 (0)	0 (0)	0 (0)
	black patch/zone		0 (0)	1 (6)	1 (7)	1 (8)
	nodule		0 (0)	4 (24)	2 (13)	2 (15)
heart	nodule		0 (0)	1 (6)	0 (0)	0 (0)
	dilated		0 (0)	1 (6)	0 (0)	0 (0)
tongue	nodule		1 (9)	0 (0)	0 (0)	0 (0)
stomach	red patch/zone		1 (9)	1 (6)	0 (0)	0 (0)
	hemorrhage		0 (0)	1 (6)	0 (0)	0 (0)
	ulcer		0 (0)	0 (0)	1 (7)	0 (0)

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 11 (%)	10 ppm 17 (%)	30 ppm 15 (%)	90 ppm 13 (%)
gl stomach	thick		0 (0)	5 (29)	2 (13)	0 (0)
	fluid:red		0 (0)	0 (0)	1 (7)	0 (0)
	fluid:black		0 (0)	0 (0)	0 (0)	1 (8)
stomach	black patch/zone		0 (0)	1 (6)	0 (0)	0 (0)
	dilated		1 (9)	0 (0)	0 (0)	0 (0)
small intes	dilated		0 (0)	0 (0)	1 (7)	0 (0)
cecum	dilated		1 (9)	0 (0)	0 (0)	0 (0)
anus	hemorrhage		0 (0)	1 (6)	0 (0)	0 (0)
large intes	hemorrhage		0 (0)	1 (6)	0 (0)	0 (0)
	dilated		1 (9)	1 (6)	1 (7)	0 (0)
liver	enlarged		1 (9)	1 (6)	1 (7)	0 (0)
	turbid		0 (0)	0 (0)	1 (7)	0 (0)
	pale		1 (9)	0 (0)	0 (0)	1 (8)
	white patch/zone		1 (9)	1 (6)	0 (0)	0 (0)
	nodule		7 (64)	7 (41)	8 (53)	9 (69)
kidney	enlarged		0 (0)	1 (6)	0 (0)	0 (0)
	hydronephrosis		0 (0)	1 (6)	1 (7)	0 (0)
urin bladd	dilated		0 (0)	2 (12)	0 (0)	0 (0)
	urine:marked retention		3 (27)	3 (18)	3 (20)	0 (0)
	fluid:white		0 (0)	1 (6)	0 (0)	0 (0)
pituitary	enlarged		0 (0)	1 (6)	0 (0)	0 (0)
testis	enlarged		0 (0)	1 (6)	0 (0)	0 (0)

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 11 (%)	10 ppm 17 (%)	30 ppm 15 (%)	90 ppm 13 (%)
epididymis	nodule		0 (0)	1 (6)	0 (0)	0 (0)
semin ves	enlarged		1 (9)	3 (18)	1 (7)	1 (8)
	brown		0 (0)	2 (12)	1 (7)	0 (0)
	red patch/zone		1 (9)	0 (0)	0 (0)	0 (0)
	nodule		0 (0)	1 (6)	0 (0)	0 (0)
prep/cli gl	nodule		1 (9)	4 (24)	3 (20)	1 (8)
spinal cord	hemorrhage		0 (0)	1 (6)	0 (0)	0 (0)
Harder gl	nodule		1 (9)	0 (0)	0 (0)	0 (0)
muscle	nodule		1 (9)	0 (0)	0 (0)	0 (0)
vertebra	nodule		0 (0)	1 (6)	0 (0)	0 (0)
retroperit	nodule		0 (0)	1 (6)	1 (7)	0 (0)
abdominal c	hemorrhage		1 (9)	2 (12)	2 (13)	3 (23)
	ascites		2 (18)	1 (6)	1 (7)	1 (8)
adipose	nodule		1 (9)	2 (12)	2 (13)	3 (23)
	mass		0 (0)	0 (0)	1 (7)	0 (0)
thoracic ca	hemorrhage		1 (9)	1 (6)	1 (7)	0 (0)
	pleural fluid		1 (9)	3 (18)	0 (0)	1 (8)
other	enlarged		1 (9)	0 (0)	0 (0)	0 (0)
	red		0 (0)	0 (0)	1 (7)	0 (0)

APPENDIX J 6

GROSS FINDINGS (TWO-YEAR STUDIES: SUMMARY)

MOUSE:FEMALE:DEAD AND MORIBUND ANIMALS

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control 15 (%)	10 ppm 22 (%)	30 ppm 31 (%)	90 ppm 24 (%)
subcutis	congestion		1 (7)	0 (0)	0 (0)	0 (0)
	edema		5 (33)	5 (23)	9 (29)	4 (17)
	mass		1 (7)	2 (9)	3 (10)	3 (13)
lung	pale		0 (0)	0 (0)	1 (3)	0 (0)
	red		4 (27)	4 (18)	7 (23)	8 (33)
	white patch/zone		0 (0)	1 (5)	1 (3)	0 (0)
	red patch/zone		1 (7)	0 (0)	2 (6)	1 (4)
	congestion		0 (0)	0 (0)	0 (0)	1 (4)
	edema		0 (0)	3 (14)	2 (6)	0 (0)
	nodule		2 (13)	1 (5)	1 (3)	5 (21)
lymph node	enlarged		6 (40)	12 (55)	17 (55)	7 (29)
	red		0 (0)	0 (0)	1 (3)	1 (4)
thymus	enlarged		0 (0)	0 (0)	0 (0)	1 (4)
	involution		0 (0)	1 (5)	0 (0)	1 (4)
spleen	enlarged		6 (40)	7 (32)	13 (42)	9 (38)
	white patch/zone		0 (0)	1 (5)	0 (0)	1 (4)
	black patch/zone		0 (0)	1 (5)	0 (0)	1 (4)
	nodule		1 (7)	1 (5)	1 (3)	3 (13)
	deformed		0 (0)	1 (5)	0 (0)	1 (4)
heart	enlarged		1 (7)	0 (0)	0 (0)	0 (0)
	white patch/zone		0 (0)	0 (0)	0 (0)	1 (4)
tongue	nodule		0 (0)	0 (0)	1 (3)	0 (0)

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 5

Organ	Findings	Group Name NO. of Animals	Control 15 (%)	10 ppm 22 (%)	30 ppm 31 (%)	90 ppm 24 (%)
forestomach	thick		0 (0)	0 (0)	1 (3)	0 (0)
	fluid:black		0 (0)	0 (0)	1 (3)	0 (0)
gl stomach	red patch/zone		0 (0)	1 (5)	0 (0)	1 (4)
	black patch/zone		2 (13)	0 (0)	0 (0)	0 (0)
	hemorrhage		0 (0)	1 (5)	0 (0)	0 (0)
	ulcer		0 (0)	0 (0)	0 (0)	1 (4)
	thick		1 (7)	1 (5)	5 (16)	2 (8)
	fluid:black		0 (0)	0 (0)	1 (3)	0 (0)
stomach	nodule		0 (0)	0 (0)	2 (6)	0 (0)
	fluid:brown		0 (0)	1 (5)	0 (0)	0 (0)
small intes	red patch/zone		0 (0)	0 (0)	0 (0)	1 (4)
	fluid:brown		0 (0)	1 (5)	0 (0)	0 (0)
	fluid:black		0 (0)	0 (0)	1 (3)	1 (4)
liver	enlarged		4 (27)	3 (14)	5 (16)	4 (17)
	swollen		1 (7)	1 (5)	0 (0)	0 (0)
	pale		1 (7)	0 (0)	0 (0)	0 (0)
	white patch/zone		3 (20)	3 (14)	7 (23)	6 (25)
	red patch/zone		0 (0)	1 (5)	0 (0)	1 (4)
	nodule		1 (7)	2 (9)	7 (23)	3 (13)
	granular		0 (0)	0 (0)	1 (3)	0 (0)
gall bladd	dilated		1 (7)	0 (0)	0 (0)	0 (0)
pancreas	nodule		0 (0)	0 (0)	1 (3)	2 (8)

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 6

Organ	Findings	Group Name NO. of Animals	Control 15 (%)	10 ppm 22 (%)	30 ppm 31 (%)	90 ppm 24 (%)
pancreas	fluid:white		0 (0)	0 (0)	1 (3)	0 (0)
kidney	enlarged		0 (0)	0 (0)	1 (3)	0 (0)
	pale		1 (7)	0 (0)	1 (3)	0 (0)
	white patch/zone		1 (7)	0 (0)	0 (0)	0 (0)
	granular		0 (0)	0 (0)	1 (3)	0 (0)
	hydronephrosis		1 (7)	3 (14)	1 (3)	1 (4)
ureter	dilated		0 (0)	3 (14)	1 (3)	2 (8)
urin bladd	dilated		0 (0)	1 (5)	0 (0)	0 (0)
	urine:marked retention		0 (0)	0 (0)	0 (0)	2 (8)
pituitary	enlarged		1 (7)	4 (18)	2 (6)	1 (4)
	white patch/zone		1 (7)	0 (0)	0 (0)	0 (0)
	nodule		3 (20)	0 (0)	4 (13)	0 (0)
adrenal	enlarged		0 (0)	0 (0)	1 (3)	0 (0)
ovary	enlarged		2 (13)	2 (9)	3 (10)	3 (13)
	hemorrhage		0 (0)	0 (0)	1 (3)	0 (0)
	nodule		0 (0)	0 (0)	1 (3)	0 (0)
	cyst		0 (0)	2 (9)	1 (3)	2 (8)
	fluid:red		0 (0)	0 (0)	1 (3)	1 (4)
	fluid:transparent		4 (27)	2 (9)	4 (13)	0 (0)
	fluid:white		0 (0)	0 (0)	1 (3)	0 (0)
	enlarged		1 (7)	0 (0)	1 (3)	0 (0)
uterus	black		0 (0)	1 (5)	0 (0)	0 (0)

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 7

Organ	Findings	Group Name NO. of Animals	Control 15 (%)	10 ppm 22 (%)	30 ppm 31 (%)	90 ppm 24 (%)
uterus	nodule		6 (40)	6 (27)	6 (19)	10 (42)
	thick		0 (0)	0 (0)	0 (0)	1 (4)
brain	red patch/zone		0 (0)	0 (0)	0 (0)	2 (8)
Harder gl	nodule		0 (0)	0 (0)	1 (3)	0 (0)
muscle	nodule		0 (0)	0 (0)	0 (0)	1 (4)
	mass		0 (0)	0 (0)	1 (3)	0 (0)
bone	mass		1 (7)	0 (0)	0 (0)	0 (0)
mediastinum	nodule		0 (0)	0 (0)	0 (0)	1 (4)
	mass		2 (13)	1 (5)	2 (6)	1 (4)
peritoneum	white patch/zone		1 (7)	0 (0)	0 (0)	0 (0)
	thick		0 (0)	0 (0)	4 (13)	0 (0)
retroperit	enlarged		0 (0)	1 (5)	0 (0)	0 (0)
abdominal c	hemorrhage		2 (13)	2 (9)	5 (16)	7 (29)
	ascites		5 (33)	8 (36)	10 (32)	1 (4)
mesenterium	thick		0 (0)	1 (5)	0 (0)	0 (0)
adipose	nodule		1 (7)	0 (0)	2 (6)	1 (4)
thoracic ca	hemorrhage		0 (0)	1 (5)	0 (0)	0 (0)
	pleural fluid		11 (73)	10 (45)	14 (45)	9 (38)
other	mass		0 (0)	0 (0)	1 (3)	0 (0)
whole body	anemic		2 (13)	2 (9)	0 (0)	1 (4)
	wasting		0 (0)	1 (5)	0 (0)	0 (0)

APPENDIX J 7

GROSS FINDINGS (TWO-YEAR STUDIES: SUMMARY)

MOUSE: MALE: SACRIFICED ANIMALS

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (104W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 39 (%)	10 ppm 32 (%)	30 ppm 35 (%)	90 ppm 37 (%)
subcutis	red patch/zone		0 (0)	0 (0)	1 (3)	0 (0)
lung	red		0 (0)	1 (3)	0 (0)	0 (0)
	white patch/zone		1 (3)	0 (0)	1 (3)	0 (0)
	red patch/zone		1 (3)	0 (0)	1 (3)	0 (0)
	nodule		15 (38)	11 (34)	17 (49)	18 (49)
	mass		1 (3)	0 (0)	0 (0)	0 (0)
lymph node	enlarged		5 (13)	8 (25)	6 (17)	11 (30)
spleen	enlarged		3 (8)	3 (9)	4 (11)	3 (8)
	red		0 (0)	1 (3)	0 (0)	0 (0)
	black		0 (0)	1 (3)	0 (0)	0 (0)
	black patch/zone		1 (3)	2 (6)	4 (11)	2 (5)
	nodule		3 (8)	1 (3)	2 (6)	5 (14)
heart	white patch/zone		0 (0)	0 (0)	1 (3)	0 (0)
	dilated		0 (0)	1 (3)	0 (0)	0 (0)
forestomach	ulcer		0 (0)	0 (0)	0 (0)	1 (3)
st stomach	red patch/zone		0 (0)	0 (0)	0 (0)	1 (3)
	ulcer		1 (3)	3 (9)	1 (3)	0 (0)
small intes	nodule		0 (0)	0 (0)	0 (0)	1 (3)
liver	enlarged		1 (3)	0 (0)	0 (0)	1 (3)
	atrophic		0 (0)	1 (3)	3 (9)	0 (0)
	pale		1 (3)	0 (0)	0 (0)	0 (0)
	red patch/zone		4 (10)	4 (13)	4 (11)	8 (22)

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (104W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 39 (%)	10 ppm 32 (%)	30 ppm 35 (%)	90 ppm 37 (%)
liver	yellow patch/zone		1 (3)	2 (6)	0 (0)	0 (0)
	nodule		26 (67)	15 (47)	19 (54)	15 (41)
	cyst		1 (3)	1 (3)	1 (3)	0 (0)
	adhesion		0 (0)	1 (3)	0 (0)	0 (0)
pancreas	nodule		1 (3)	0 (0)	0 (0)	0 (0)
urin bladd	nodule		0 (0)	2 (6)	0 (0)	0 (0)
	urine:marked retention		3 (8)	1 (3)	0 (0)	1 (3)
	urine:brown		0 (0)	1 (3)	0 (0)	0 (0)
adrenal	white patch/zone		0 (0)	1 (3)	0 (0)	0 (0)
testis	enlarged		2 (5)	1 (3)	0 (0)	1 (3)
	hard		4 (10)	4 (13)	9 (26)	15 (41)
epididymis	nodule		1 (3)	0 (0)	0 (0)	0 (0)
semin ves	enlarged		25 (64)	17 (53)	16 (46)	17 (46)
	nodule		0 (0)	0 (0)	1 (3)	0 (0)
prep/cli gl	nodule		7 (18)	8 (25)	7 (20)	8 (22)
	cyst		2 (5)	1 (3)	0 (0)	0 (0)
Harder gl	nodule		2 (5)	0 (0)	1 (3)	2 (5)
Zymbal gl	nodule		0 (0)	0 (0)	1 (3)	0 (0)
bone	nodule		0 (0)	0 (0)	1 (3)	0 (0)
mediastinum	mass		1 (3)	1 (3)	0 (0)	0 (0)
peritoneum	nodule		0 (0)	0 (0)	0 (0)	1 (3)
	adhesion		1 (3)	1 (3)	0 (0)	0 (0)

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (104W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 39 (%)	10 ppm 32 (%)	30 ppm 35 (%)	90 ppm 37 (%)
peritoneum	thick		0 (0)	0 (0)	0 (0)	1 (3)
abdominal c	hemorrhage		0 (0)	0 (0)	2 (6)	0 (0)
mesenterium	hemorrhage		0 (0)	0 (0)	1 (3)	0 (0)
	nodule		0 (0)	0 (0)	1 (3)	0 (0)
adipose	nodule		2 (5)	2 (6)	5 (14)	7 (19)
thoracic ca	pleural fluid		1 (3)	1 (3)	1 (3)	0 (0)
other	nodule		0 (0)	0 (0)	1 (3)	0 (0)

(HPT080)

BAIS 2

APPENDIX J 8

GROSS FINDINGS (TWO-YEAR STUDIES: SUMMARY)

MOUSE:FEMALE:SACRIFICED ANIMALS

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (104W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control 34 (%)	10 ppm 28 (%)	30 ppm 19 (%)	90 ppm 26 (%)
skin/app	scab		0 (0)	0 (0)	0 (0)	1 (4)
subcutis	edema		0 (0)	0 (0)	1 (5)	0 (0)
	mass		2 (6)	1 (4)	0 (0)	6 (23)
lung	atrophic		0 (0)	0 (0)	1 (5)	0 (0)
	white		0 (0)	1 (4)	0 (0)	0 (0)
	red patch/zone		0 (0)	0 (0)	1 (5)	1 (4)
	yellow patch/zone		1 (3)	0 (0)	0 (0)	0 (0)
	edema		0 (0)	0 (0)	2 (11)	0 (0)
	nodule		5 (15)	1 (4)	3 (16)	8 (31)
lymph node	enlarged		2 (6)	6 (21)	5 (26)	4 (15)
spleen	enlarged		3 (9)	9 (32)	3 (16)	3 (12)
	gray		0 (0)	0 (0)	0 (0)	1 (4)
	white patch/zone		0 (0)	0 (0)	1 (5)	0 (0)
	black patch/zone		0 (0)	2 (7)	0 (0)	0 (0)
	nodule		1 (3)	2 (7)	0 (0)	2 (8)
forestomach	ulcer		1 (3)	0 (0)	0 (0)	0 (0)
gl stomach	ulcer		1 (3)	1 (4)	1 (5)	0 (0)
small intes	nodule		1 (3)	1 (4)	0 (0)	0 (0)
large intes	nodule		1 (3)	0 (0)	0 (0)	0 (0)
liver	enlarged		0 (0)	1 (4)	1 (5)	1 (4)
	white patch/zone		1 (3)	1 (4)	1 (5)	0 (0)
	red patch/zone		2 (6)	7 (25)	10 (53)	6 (23)

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (104W)

PAGE : 5

Organ	Findings	Group Name NO. of Animals	Control 34 (%)	10 ppm 28 (%)	30 ppm 19 (%)	90 ppm 26 (%)
liver	yellow patch/zone		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		2 (6)	6 (21)	5 (26)	7 (27)
	cyst		1 (3)	1 (4)	0 (0)	0 (0)
pancreas	nodule		0 (0)	1 (4)	0 (0)	0 (0)
kidney	enlarged		0 (0)	0 (0)	0 (0)	1 (4)
	brown		0 (0)	0 (0)	1 (5)	0 (0)
	nodule		1 (3)	0 (0)	0 (0)	0 (0)
	hydronephrosis		1 (3)	1 (4)	1 (5)	0 (0)
urin bladd	enlarged		0 (0)	1 (4)	0 (0)	0 (0)
pituitary	enlarged		7 (21)	3 (11)	1 (5)	4 (15)
	red patch/zone		0 (0)	0 (0)	1 (5)	0 (0)
	nodule		7 (21)	5 (18)	4 (21)	5 (19)
ovary	enlarged		0 (0)	1 (4)	0 (0)	0 (0)
	red		0 (0)	0 (0)	1 (5)	0 (0)
	hemorrhage		0 (0)	0 (0)	1 (5)	0 (0)
	nodule		0 (0)	1 (4)	0 (0)	0 (0)
	cyst		17 (50)	19 (68)	10 (53)	15 (58)
	fluid:transparent		0 (0)	0 (0)	1 (5)	0 (0)
uterus	nodule		6 (18)	7 (25)	1 (5)	10 (38)
	nodular		0 (0)	1 (4)	0 (0)	0 (0)
	dilated lumen		4 (12)	1 (4)	1 (5)	2 (8)
prep/cli gl	nodule		0 (0)	1 (4)	0 (0)	0 (0)

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (104W)

PAGE : 6

Organ	Findings	Group Name	Control	10 ppm	30 ppm	90 ppm
		NO. of Animals	34 (%)	28 (%)	19 (%)	26 (%)
Harder gl	nodule		1 (3)	0 (0)	0 (0)	2 (8)
muscle	mass		0 (0)	0 (0)	0 (0)	1 (4)
mediastinum	mass		1 (3)	0 (0)	1 (5)	0 (0)
peritoneum	mass		0 (0)	0 (0)	1 (5)	0 (0)
retroperit	nodule		0 (0)	1 (4)	0 (0)	0 (0)
abdominal c	ascites		0 (0)	4 (14)	1 (5)	2 (8)
adipose	nodule		1 (3)	2 (7)	1 (5)	0 (0)
thoracic ca	pleural fluid		2 (6)	2 (7)	1 (5)	2 (8)
whole body	atrophic		0 (0)	1 (4)	0 (0)	0 (0)

(HPT080)

BAIS2

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

(K1～K4)

がん原性試験 NO. 0067 ; 0068

APPENDIX K 1

ORGAN WEIGHT (TWO-YEAR STUDIES: SUMMARY), ABSOLUTE

RAT: MALE

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 1

Group Name	NO. of Animals	Body weight	ADRENALS		TESTES		HEART		LUNGS		KIDNEYS	
Control	37	405± 46	0.080±	0.025	5.523±	2.327	1.285±	0.118	1.443±	0.121	3.142±	0.391
10 ppm	35	427± 56	0.092±	0.080	5.355±	1.833	1.269±	0.076	1.477±	0.238	3.172±	0.445
40 ppm	32	415± 43	0.099±	0.124	4.155±	1.669*	1.306±	0.105	1.511±	0.292	3.203±	0.439
160 ppm	37	441± 91	0.187±	0.645	5.159±	2.298	1.326±	0.160	1.506±	0.213	3.195±	0.545

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

Test of Dunnett

(HCL040)

BAIS2

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 2

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	37	1.324±	0.731	13.108±	1.947	2.045±	0.049
10 ppm	35	1.286±	0.448	13.633±	2.014	2.050±	0.055
40 ppm	32	1.650±	1.230	13.704±	2.387	2.062±	0.037
160 ppm	37	1.310±	0.621	14.161±	2.788	2.055±	0.055

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX K 2

ORGAN WEIGHT (TWO-YEAR STUDIES: SUMMARY), ABSOLUTE

RAT: FEMALE

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 3

Group Name	NO. of Animals	Body weight		ADRENALS		OVARIES		HEART		LUNGS		KIDNEYS	
Control	35	302±	31	0.363±	1.719	0.145±	0.163	0.981±	0.125	1.065±	0.284	2.056±	0.239
10 ppm	41	307±	40	0.071±	0.010	0.147±	0.212	0.973±	0.112	1.061±	0.226	2.057±	0.185
40 ppm	37	311±	45	0.131±	0.383	0.108±	0.017	0.972±	0.078	0.999±	0.136	2.055±	0.326
160 ppm	38	315±	55	0.079±	0.043	0.107±	0.028	0.977±	0.161	1.079±	0.271	2.040±	0.188

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 4

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	35	0.865±	1.019	7.665±	0.906	1.876±	0.048
10 ppm	41	1.403±	2.745	7.951±	1.281	1.872±	0.043
40 ppm	37	0.880±	0.992	7.744±	1.072	1.873±	0.037
160 ppm	38	1.119±	1.918	8.189±	1.280	1.872±	0.041

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX K 3

ORGAN WEIGHT (TWO-YEAR STUDIES: SUMMARY), ABSOLUTE

MOUSE: MALE

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 1

Group Name	NO. of Animals	Body weight	ADRENALS		TESTES		HEART		LUNGS		KIDNEYS	
Control	39	46.0± 6.9	0.007±	0.001	0.233±	0.037	0.225±	0.024	0.233±	0.068	0.657±	0.057
10 ppm	32	47.7± 6.1	0.008±	0.002	0.250±	0.034	0.230±	0.024	0.223±	0.045	0.668±	0.042
30 ppm	35	44.3± 7.9	0.008±	0.001	0.246±	0.042	0.227±	0.025	0.273±	0.202	0.674±	0.077
90 ppm	37	47.1± 6.6	0.008±	0.001	0.241±	0.036	0.228±	0.018	0.252±	0.124	0.692±	0.055

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 2

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	39	0.140±	0.172	1.956±	0.640	0.462±	0.014
10 ppm	32	0.202±	0.397	1.901±	0.554	0.460±	0.012
30 ppm	35	0.175±	0.251	1.967±	0.850	0.464±	0.012
90 ppm	37	0.152±	0.198	1.769±	0.459	0.465±	0.015

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX K 4

ORGAN WEIGHT (TWO-YEAR STUDIES: SUMMARY), ABSOLUTE

MOUSE: FEMALE

STUDY NO. : 0068
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (104)

PAGE : 3

Group Name	NO. of Animals	Body weight	ADRENALS		OVARIES		HEART		LUNGS		KIDNEYS	
Control	34	32.2± 5.2	0.011±	0.002	0.051±	0.061	0.177±	0.028	0.196±	0.015	0.506±	0.351
10 ppm	28	31.6± 4.0	0.010±	0.001	0.070±	0.064	0.170±	0.020	0.206±	0.038	0.462±	0.073
30 ppm	19	33.6± 4.5	0.011±	0.002	0.052±	0.058	0.192±	0.035	0.222±	0.060	0.505±	0.166
90 ppm	26	30.4± 4.1	0.009±	0.001**	0.265±	0.962	0.175±	0.026	0.232±	0.133	0.480±	0.220

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

Test of Dunnett

(HCL040)

BAIS2

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 4

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	34	0.134±	0.071	1.481±	0.237	0.492±	0.019
10 ppm	28	0.243±	0.235	1.703±	0.840	0.488±	0.012
30 ppm	19	0.154±	0.088	1.678±	0.529	0.490±	0.013
90 ppm	26	0.232±	0.418	1.557±	0.413	0.486±	0.014

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

Test of Dunnett

(HCL040)

BAIS 2

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

(L1～L4)

がん原性試験 NO. 0067 ; 0068

APPENDIX L 1

ORGAN WEIGHT (TWO-YEAR STUDIES: SUMMARY), RELATIVE

RAT: MALE

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 1

Group Name	NO. of Animals	Body weight (g)	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	37	405± 46	0.020± 0.006	1.361± 0.561	0.320± 0.037	0.360± 0.047	0.785± 0.129
10 ppm	35	427± 56	0.022± 0.018	1.270± 0.427	0.300± 0.029	0.351± 0.074	0.753± 0.138
40 ppm	32	415± 43	0.024± 0.032	1.015± 0.423*	0.319± 0.049	0.371± 0.103	0.780± 0.141
160 ppm	37	441± 91	0.042± 0.142	1.198± 0.557	0.309± 0.056	0.349± 0.054	0.741± 0.150

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 2

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	37	0.323± 0.167	3.252± 0.450	0.512± 0.060
10 ppm	35	0.302± 0.104	3.215± 0.479	0.487± 0.056
40 ppm	32	0.406± 0.323	3.345± 0.789	0.502± 0.053
160 ppm	37	0.208± 0.129	3.250± 0.554	0.481± 0.078

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

Test of Dunnett

(HCL042)

BAIS2

APPENDIX L 2

ORGAN WEIGHT (TWO-YEAR STUDIES: SUMMARY), RELATIVE

RAT: FEMALE

STUDY NO. : 0067
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
 SURVIVAL ANIMALS (104)

PAGE : 3

Group Name	NO. of Animals	Body weight (g)	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	35	302± 31	0.139± 0.678	0.048± 0.051	0.332± 0.090	0.366± 0.176	0.690± 0.126
10 ppm	41	307± 40	0.024± 0.005	0.051± 0.090	0.323± 0.070	0.356± 0.122	0.681± 0.106
40 ppm	37	311± 45	0.046± 0.145	0.035± 0.007	0.321± 0.071	0.333± 0.103	0.682± 0.205
160 ppm	38	315± 55	0.026± 0.015	0.034± 0.007	0.324± 0.105	0.364± 0.168	0.677± 0.191

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

Test of Dunnett

(HCL042)

BAIS2

STUDY NO. : 0067
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 4

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	35	0.321± 0.523	2.568± 0.451	0.629± 0.079
10 ppm	41	0.513± 1.148	2.639± 0.625	0.621± 0.090
40 ppm	37	0.326± 0.513	2.556± 0.640	0.618± 0.118
160 ppm	38	0.350± 0.519	2.660± 0.486	0.624± 0.188

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

Test of Dunnett

(HCL042)

BAIS2

APPENDIX L 3

ORGAN WEIGHT (TWO-YEAR STUDIES: SUMMARY), RELATIVE

MOUSE: MALE

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 1

Group Name	NO. of Animals	Body weight (g)	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	39	46.0± 6.9	0.016± 0.004	0.515± 0.105	0.500± 0.095	0.521± 0.194	1.458± 0.241
10 ppm	32	47.7± 6.1	0.017± 0.007	0.529± 0.078	0.492± 0.097	0.480± 0.136	1.422± 0.220
30 ppm	35	44.3± 7.9	0.018± 0.006	0.575± 0.145	0.531± 0.117	0.705± 0.815	1.567± 0.319
90 ppm	37	47.1± 6.6	0.016± 0.003	0.518± 0.081	0.491± 0.070	0.542± 0.260	1.493± 0.202

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

Test of Dunnett

(HCL042)

BAIS2

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 2

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	39	0.321± 0.425	4.482± 2.236	1.030± 0.183
10 ppm	32	0.464± 0.973	4.076± 1.543	0.982± 0.142
30 ppm	35	0.414± 0.577	4.649± 2.539	1.089± 0.246
90 ppm	37	0.336± 0.447	3.862± 1.494	1.007± 0.145

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

Test of Dunnett

(HCL042)

BAIS2

APPENDIX L 4

ORGAN WEIGHT (TWO-YEAR STUDIES: SUMMARY), RELATIVE

MOUSE: FEMALE

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 3

Group Name	NO. of Animals	Body weight (g)	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	34	32.2± 5.2	0.034± 0.009	0.161± 0.182	0.558± 0.094	0.627± 0.123	1.593± 1.006
10 ppm	28	31.6± 4.0	0.032± 0.005	0.227± 0.213	0.544± 0.071	0.667± 0.187	1.490± 0.353
30 ppm	19	33.6± 4.5	0.032± 0.006	0.161± 0.193	0.574± 0.088	0.667± 0.189	1.509± 0.444
90 ppm	26	30.4± 4.1	0.032± 0.006	0.788± 2.689	0.580± 0.091	0.783± 0.525*	1.600± 0.756

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

Test of Dunnett

(HCL042)

BAIS2

STUDY NO. : 0068
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (104)

PAGE : 4

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	34	0.422± 0.257	4.643± 0.574	1.578± 0.318
10 ppm	28	0.804± 0.815	5.454± 2.770	1.571± 0.219
30 ppm	19	0.454± 0.252	5.034± 1.571	1.479± 0.173
90 ppm	26	0.766± 1.382	5.144± 1.283	1.621± 0.188

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

(HCL042)

BAIS 2