1,2-ジクロロエタンのラット及びマウスを用いた
吸 入 に よ る が ん 原 性 試 験 報 告 書

APPENDIX

(C1-1～C11-2)

13Week　STUDY　NO.　0055 ; 0056

APPENDIX C 1-1

CLINICAL OBSERVATION (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE

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

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Administration Week-day 0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	7	-	-	-	-	-	-	-	-	-	-	-	-
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	2	-	-	-	-	-	-	-	-	-	-	-	-
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	1	-	-	-	-	-	-	-	-	-	-	-	-
ATAXIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	1	-	-	-	-	-	-	-	-	-	-	-	-
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	1	-	-	-	-	-	-	-	-	-	-	-	-

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

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Administration Week-day 0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
GUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	0	-	-	-	-	-	-	-	-	-	-	-	-
SORE OF SOLE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	0	-	-	-	-	-	-	-	-	-	-	-	-
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	1	-	-	-	-	-	-	-	-	-	-	-	-
LOOSE STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	320 ppm	0	0	-	-	-	-	-	-	-	-	-	-	-	-

APPENDIX C 1-2

CLINICAL OBSERVATION (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE

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

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Administration Week-day 0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-
COLORED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	1	0	0	0	1	1
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	160 ppm	0	0	0	0	0	0	0	0	2	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-
LACRYMATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-

Clinical sign	Group Name	Administration Week-day 0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
EYE HEMORRHAGIC DISCHA	Control	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-
SORE OF SOLE	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	2
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-
NOSE HEMORRHAGIC DISCHA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-
LOOSE STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	320 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-

APPENDIX C 1－3

CLINICAL OBSERVATION (THIRTEEN－WEEK STUDIES：SUMMARY)

MOUSE：MALE

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

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Administration Week-day 0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILOERECTION	Control	0	0	1	1	0	0	2	2	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	1	0	0	0	1	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	2	2	1	0	2	2	0	0	0	0	0	1
	160 ppm	0	1	1	1	0	0	0	1	0	0	0	0	0	0
LOSS OF HAIR	Control	0	0	1	0	0	0	0	0	1	2	3	3	3	4
	10 ppm	0	0	1	1	2	2	3	3	3	3	3	3	3	3
	20 ppm	0	0	0	0	0	0	0	2	2	4	4	4	4	4
	40 ppm	0	0	0	0	0	0	2	1	2	2	2	2	2	2
	80 ppm	0	0	0	0	0	0	1	2	2	1	2	3	3	4
	160 ppm	0	0	0	0	0	0	1	2	2	2	2	2	3	3
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	1	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	2	2	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

APPENDIX C 1-4

CLINICAL OBSERVATION (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE

Clinical sign	Group Name	Administration Week-day 0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	1	2	2	2	2	2	3	4	4	4	4	4	4
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	1	2	2	2	2	2	2
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	1	0	0	0	0	0	0	0	0	0	0	0
LOSS OF HAIR	Control	0	0	0	2	3	3	5	5	5	5	5	4	6	6
	10 ppm	0	0	0	1	1	3	5	5	5	6	4	5	5	5
	20 ppm	0	0	0	0	0	0	3	4	5	5	5	5	5	6
	40 ppm	0	0	0	0	0	2	3	6	7	7	6	6	6	6
	80 ppm	0	0	1	2	3	3	6	7	7	7	7	7	8	8
	160 ppm	0	0	1	1	1	1	1	2	1	2	2	2	2	2
TRAUMA	Control	0	1	1	1	1	1	1	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	1	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Administration Week-day 0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
NOSE HEMORRHAGIC DISCHA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	160 ppm	0	0	1	0	0	0	0	0	0	0	0	0	0	0

APPENDIX C 2-1

BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE

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

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day 0-0	1-7	2-7	3-7	4-7	5-7	6-7
Control	101± 3	116± 4	130± 5	142± 5	152± 5	162± 7	170± 6
20 ppm	101± 3	116± 5	131± 5	141± 8	153± 8	161± 10	170± 11
40 ppm	101± 4	115± 4	129± 4	140± 5	149± 5	157± 7	165± 7
80 ppm	101± 4	117± 5	134± 7	145± 8	154± 7	165± 12	174± 12
160 ppm	101± 4	117± 4	129± 6	142± 7	150± 8	158± 10	167± 10
320 ppm	101± 4	-	-	-	-	-	-

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day 7-7	8-7	9-7	10-7	11-7	12-7	13-7
Control	178± 6	182± 7	187± 5	191± 7	196± 5	199± 7	205± 8
20 ppm	175± 11	182± 9	187± 11	191± 11	197± 13	202± 12	205± 14
40 ppm	171± 8	177± 8	180± 8	187± 8	188± 8	193± 9	195± 10
80 ppm	182± 15	189± 16	192± 16	200± 17	201± 17	208± 19	211± 20
160 ppm	174± 12	180± 13	186± 13	190± 13	196± 13	200± 14	206± 14
320 ppm	-	-	-	-	-	-	-

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 2-2

BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE

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

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day 0-0	1-7	2-7	3-7	4-7	5-7	6-7
Control	118± 4	147± 5	178± 8	204± 11	227± 13	247± 15	262± 15
20 ppm	118± 4	147± 8	179± 13	206± 16	229± 18	249± 22	266± 25
40 ppm	118± 4	145± 6	177± 8	205± 8	230± 8	251± 9	270± 8
80 ppm	118± 4	146± 5	181± 6	210± 7	235± 7	258± 6	277± 8
160 ppm	118± 4	144± 8	176± 11	204± 12	229± 12	251± 14	269± 12
320 ppm	118± 5	117± 0	-	-	-	-	-

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

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

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 2-3

BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: MALE

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

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

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

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 2-4

BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE

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

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 3-1

FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE

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

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 3-2

FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE

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

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 3-3

FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: MALE

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

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

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

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 3-4

FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE

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

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

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

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 4-1

HEMATOLOGY (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE

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

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

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV f ℓ	PLATELET $10^3/\mu\ell$
Control	10	9.83± 0.26	16.4± 0.2	44.7± 1.0	45.4± 0.7	770± 61
20 ppm	10	9.75± 0.30	16.4± 0.4	44.3± 1.6	45.4± 0.8	743± 32
40 ppm	10	9.73± 0.25	16.4± 0.4	44.2± 0.9	45.4± 0.5	739± 55
80 ppm	10	9.70± 0.23	16.3± 0.3	43.8± 1.1	45.2± 0.7	743± 17
160 ppm	10	9.75± 0.16	16.2± 0.2	43.7± 0.8	44.8± 0.5	748± 37
320 ppm	00	-	-	-	-	-

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

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

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 4-2

HEMATOLOGY (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE

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

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

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV f ℓ	PLATELET $10^3/\mu\ell$
Control	10	8.85± 0.25	16.4± 0.4	43.7± 1.5	49.3± 0.6	796± 51
20 ppm	10	8.94± 0.28	16.6± 0.5	44.0± 1.3	49.2± 0.6	801± 33
40 ppm	10	8.93± 0.18	16.6± 0.4	44.1± 0.9	49.4± 0.6	802± 63
80 ppm	10	8.86± 0.26	16.2± 0.4	43.4± 1.4	48.9± 0.8	772± 35
160 ppm	10	8.96± 0.24	16.3± 0.3	43.8± 1.3	48.9± 0.3	782± 51
320 ppm	00	-	-	-	-	-

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

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

Group Name	NO. of Animals	WBC $10^3/\mu\ell$	Differential WBC (%) N-BAND	N-SEG	EOSINO	BASO	MONO	LYMPHO	OTHER
Control	10	3.29± 0.82	0± 0	18± 4	1± 1	0± 0	3± 1	78± 5	0± 0
20 ppm	10	3.38± 1.03	0± 0	18± 4	1± 1	0± 0	4± 1	76± 6	0± 0
40 ppm	10	2.95± 1.14	0± 0	19± 8	1± 1	0± 0	4± 1	76± 9	0± 0
80 ppm	10	2.54± 0.59	0± 0	17± 3	2± 1	0± 0	4± 1	78± 4	0± 0
160 ppm	10	2.97± 1.43	0± 0	19± 4	2± 1	0± 0	4± 2	76± 4	0± 0
320 ppm	00	-	-	-	-	-	-	-	-

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

APPENDIX C 4-3

HEMATOLOGY (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: MALE

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

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

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

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

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

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

APPENDIX C 4-4

HEMATOLOGY (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE

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

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

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

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

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

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

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

APPENDIX C 5-1

BIOCHEMISTRY (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

Group Name	NO. of Animals	TOTAL PROTEIN g/dl	ALBUMIN g/dl	A/G RATIO	T-BILIRUBIN mg/dl	GLUCOSE mg/dl	T-CHOLESTEROL mg/dl	TRIGLYCERIDE mg/dl
Control	10	6.5± 0.1	3.7± 0.1	1.3± 0.1	0.18± 0.02	197± 15	50± 3	116± 27
20 ppm	10	6.5± 0.2	3.7± 0.2	1.3± 0.1	0.15± 0.03	195± 15	49± 5	110± 40
40 ppm	10	6.7± 0.1	3.7± 0.1	1.3± 0.1	0.16± 0.03	201± 12	50± 4	106± 27
80 ppm	10	6.7± 0.2	3.7± 0.1	1.3± 0.1	0.14± 0.02	201± 13	48± 5	115± 34
160 ppm	10	6.7± 0.2	3.7± 0.1	1.2± 0.1	0.15± 0.04	212± 13	49± 1	120± 35
320 ppm	00	-	-	-	-	-	-	-

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 5-2

BIOCHEMISTRY (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

Group Name	NO. of Animals	TOTAL PROTEIN g/dl	ALBUMIN g/dl	A/G RATIO	T-BILIRUBIN mg/dl	GLUCOSE mg/dl	T-CHOLESTEROL mg/dl	TRIGLYCERIDE mg/dl
Control	10	6.5± 0.3	3.6± 0.1	1.3± 0.1	0.21± 0.02	146± 20	80± 7	48± 9
20 ppm	10	6.5± 0.1	3.6± 0.1	1.3± 0.1	0.21± 0.04	147± 10	78± 8	47± 6
40 ppm	10	6.6± 0.3	3.7± 0.1	1.3± 0.1	0.20± 0.03	145± 26	77± 5	47± 8
80 ppm	10	6.6± 0.2	3.7± 0.1	1.3± 0.1	0.20± 0.03	149± 18	79± 7	49± 11
160 ppm	10	6.6± 0.1	3.7± 0.1	1.3± 0.1	0.21± 0.02	144± 14	78± 4	42± 8
320 ppm	00	-	-	-	-	-	-	-

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 5-3

BIOCHEMISTRY (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: MALE

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

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

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 5-4

BIOCHEMISTRY (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

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

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 6-1

URINALYSIS (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE

STUDY NO. : 0055
ANIMAL : RAT F344
SAMPLING DATE : 013-7
SEX : MALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	pH 5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	Protein −	±	+	2+	3+	4+	CHI	Glucose −	±	+	2+	3+	4+	CHI	Ketone body −	+	2+	3+	CHI	Bilirubin −	+	2+	3+	CHI
Control	10	0	0	0	0	0	4	6		0	0	4	6	0	0		10	0	0	0	0	0		9	1	0	0		10	0	0	0	
20 ppm	10	0	0	0	0	3	7	0		0	2	5	3	0	0		10	0	0	0	0	0		8	2	0	0		10	0	0	0	
40 ppm	10	0	0	0	2	4	3	1		0	1	8	1	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
80 ppm	10	0	0	0	0	2	8	0		0	0	6	3	1	0		10	0	0	0	0	0		9	1	0	0		10	0	0	0	
160 ppm	10	0	0	0	0	3	7	0		0	0	9	1	0	0	*	10	0	0	0	0	0		10	0	0	0		10	0	0	0	
320 ppm	0	-	-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-		-	-	-	-	

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01

Test of CHI SQUARE

STUDY NO. : 0055
ANIMAL : RAT F344
SAMPLING DATE : 013-7
SEX : MALE REPORT TYPE : A1

URINALYSIS

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

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

APPENDIX C 6-2

URINALYSIS (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE

STUDY NO. : 0055
ANIMAL : RAT F344
SAMPLING DATE : 013-7
SEX : FEMALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	pH 5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	Protein −	±	+	2+	3+	4+	CHI	Glucose −	±	+	2+	3+	4+	CHI	Ketone body −	+	2+	3+	CHI	Bilirubin −	+	2+	3+	CHI
Control	10	0	0	0	0	0	7	3		0	7	3	0	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
20 ppm	10	0	0	0	0	1	7	2		1	3	6	0	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
40 ppm	10	0	0	0	0	2	8	0		0	2	8	0	0	0	*	10	0	0	0	0	0		9	1	0	0		10	0	0	0	
80 ppm	10	0	0	0	1	3	6	0		0	1	9	0	0	0	**	10	0	0	0	0	0		10	0	0	0		10	0	0	0	
160 ppm	10	0	0	0	0	1	9	0		0	1	9	0	0	0	**	10	0	0	0	0	0		10	0	0	0		10	0	0	0	
320 ppm	0	-	-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-		-	-	-	-	

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

STUDY NO. : 0055
ANIMAL : RAT F344
SAMPLING DATE : 013-7
SEX : FEMALE REPORT TYPE : A1

URINALYSIS

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

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

APPENDIX C 6-3

URINALYSIS (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: MALE

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-7
SEX : MALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	pH 5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	Protein −	±	+	2+	3+	4+	CHI	Glucose −	±	+	2+	3+	4+	CHI	Ketone body −	+	2+	3+	CHI	Occult blood −	±	+	2+	3+	CHI
Control	10	0	0	0	0	2	3	5		0	0	4	6	0	0		10	0	0	0	0	0		9	1	0	0		10	0	0	0	0	
10 ppm	10	0	0	0	0	3	4	3		0	0	5	5	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	0	
20 ppm	10	0	0	0	0	0	7	3		0	0	8	2	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	0	
40 ppm	10	0	0	0	0	3	5	2		0	0	7	3	0	0		10	0	0	0	0	0		9	1	0	0		9	1	0	0	0	
80 ppm	10	0	0	0	0	2	4	4		0	0	5	5	0	0		10	0	0	0	0	0		8	2	0	0		10	0	0	0	0	
160 ppm	10	0	0	0	1	0	4	5		0	0	5	5	0	0		10	0	0	0	0	0		8	2	0	0		10	0	0	0	0	

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-7
SEX : MALE REPORT TYPE : A1

URINALYSIS

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

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

APPENDIX C 6-4

URINALYSIS (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-7
SEX : FEMALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	pH 5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	Protein −	±	+	2+	3+	4+	CHI	Glucose −	±	+	2+	3+	4+	CHI	Ketone body −	+	2+	3+	CHI	Occult blood −	±	+	2+	3+	CHI
Control	10	0	0	0	4	2	3	1		0	0	8	2	0	0		10	0	0	0	0	0		8	2	0	0		10	0	0	0	0	
10 ppm	10	0	0	1	3	3	3	0		0	0	9	1	0	0		10	0	0	0	0	0		7	3	0	0		10	0	0	0	0	
20 ppm	10	0	0	0	2	6	2	0		0	0	8	2	0	0		10	0	0	0	0	0		8	2	0	0		10	0	0	0	0	
40 ppm	10	0	0	0	2	3	5	0		0	0	9	1	0	0		10	0	0	0	0	0		9	1	0	0		10	0	0	0	0	
80 ppm	10	0	0	1	2	2	5	0		0	0	7	3	0	0		10	0	0	0	0	0		7	3	0	0		10	0	0	0	0	
160 ppm	4	0	0	0	0	0	2	2		0	0	3	1	0	0		4	0	0	0	0	0		4	0	0	0		4	0	0	0	0	

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

STUDY NO. : 0056
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-7
SEX : FEMALE REPORT TYPE : A1

URINALYSIS

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

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

APPENDIX C 7-1

GROSS FINDINGS (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE: DEAD AND MORIBUND ANIMALS

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

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

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

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

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

Organ	Findings	Group Name NO. of Animals	160 ppm 0 (%)	320 ppm 10 (%)
lung	red		- (-)	7 (70)
	red patch/zone		- (-)	1 (10)
thymus	red patch/zone		- (-)	3 (30)
stomach	hemorrhage		- (-)	4 (40)
thoracic ca	pleural fluid		- (-)	4 (40)
whole body	wasting		- (-)	2 (20)

APPENDIX C 7-2

GROSS FINDINGS (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE: DEAD AND MORIBUND ANIMALS

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

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

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

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

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

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

APPENDIX C 7-3

GROSS FINDINGS (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: MALE: SACRIFICED ANIMALS

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

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

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

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

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

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

APPENDIX C 7-4

GROSS FINDINGS (THIRTEEN-WEEK STUDIES: SUMMARY)

RAT: FEMALE: SACRIFICED ANIMALS

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

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

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

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

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

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

APPENDIX C 7-5

GROSS FINDINGS (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE: DEAD AND MORIBUND ANIMALS

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

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

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

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

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

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

APPENDIX C 7-6

GROSS FINDINGS (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: MALE: SACRIFICED ANIMALS

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

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

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

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

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

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

APPENDIX C 7-7

GROSS FINDINGS (THIRTEEN-WEEK STUDIES: SUMMARY)

MOUSE: FEMALE: SACRIFICED ANIMALS

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

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

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

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

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

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

APPENDIX C 8-1

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

RAT : MALE

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

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

Group Name	NO. of Animals	Body weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	321± 18	0.264± 0.027	0.051± 0.004	2.858± 0.094	0.901± 0.040	0.962± 0.043
20 ppm	10	328± 29	0.278± 0.036	0.050± 0.005	2.908± 0.104	0.895± 0.115	0.964± 0.042
40 ppm	10	328± 11	0.284± 0.034	0.050± 0.004	2.916± 0.104	0.911± 0.046	0.969± 0.046
80 ppm	10	332± 10	0.274± 0.034	0.052± 0.005	2.974± 0.113	0.922± 0.030	0.966± 0.039
160 ppm	10	333± 11	0.295± 0.032	0.053± 0.003	2.929± 0.068	0.934± 0.041	0.956± 0.035
320 ppm	00	-	-	-	-	-	-

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

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

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.798± 0.090	0.546± 0.032	8.102± 0.680	1.867± 0.023
20 ppm	10	1.814± 0.126	0.550± 0.044	8.150± 0.656	1.872± 0.039
40 ppm	10	1.816± 0.056	0.533± 0.020	8.178± 0.294	1.843± 0.057
80 ppm	10	1.834± 0.061	0.549± 0.012	8.331± 0.514	1.878± 0.040
160 ppm	10	1.836± 0.065	0.551± 0.016	8.455± 0.341	1.868± 0.032
320 ppm	00	-	-	-	-

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 8-2

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

RAT : FEMALE

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

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

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

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

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

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 8-3

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

MOUSE: MALE

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

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

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

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

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 8-4

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

MOUSE : FEMALE

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

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

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

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

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 9-1

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

RAT : MALE

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

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

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

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

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 9-2

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

RAT: FEMALE

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

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

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

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

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

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 9-3

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

MOUSE: MALE

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

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

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

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

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 9-4

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

MOUSE: FEMALE

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

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

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

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

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

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

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

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX C 10-1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(THIRTEEN-WEEK STUDIES : SUMMARY)

RAT : MALE : DEAD AND MORIBUND ANIMALS

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

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

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

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

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

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

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

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

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

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

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

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

Organ	Findings	Group Name	160 ppm				320 ppm			
		No. of Animals	0				10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Urinary system]										
kidney	eosinophilic body		- (-)	- (-)	- (-)	- (-)	1 (10)	1 (10)	0 (0)	0 (0)
[Nervous system]										
brain	degeneration		- (-)	- (-)	- (-)	- (-)	3 (30)	0 (0)	0 (0)	0 (0)

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

APPENDIX C 10-2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(THIRTEEN-WEEK STUDIES : SUMMARY)

RAT : FEMALE : DEAD AND MORIBUND ANIMALS

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

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

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

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

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

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

APPENDIX C 10-3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(THIRTEEN-WEEK STUDIES : SUMMARY)

RAT : MALE : SACRIFICED ANIMALS

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

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

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

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

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

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

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

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

APPENDIX C 10-4

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(THIRTEEN-WEEK STUDIES : SUMMARY)

RAT : FEMALE : SACRIFICED ANIMALS

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

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

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

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

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

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

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

APPENDIX C 10-5

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(THIRTEEN-WEEK STUDIES : SUMMARY)

MOUSE : FEMALE : DEAD AND MORIBUND ANIMALS

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

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

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

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

APPENDIX C 10-6

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(THIRTEEN-WEEK STUDIES : SUMMARY)

MOUSE : MALE : SACRIFICED ANIMALS

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

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

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

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

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

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

Organ	Findings	Group Name	80 ppm				160 ppm			
		No. of Animals	10				10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]										
lung/bronch	hemorrhage		1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Hematopoietic system]										
spleen	deposit of melanin		1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Circulatory system]										
heart	mineralization:papilla		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
[Digestive system]										
stomach	erosion:glandular stomach		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
liver	granulation		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
[Urinary system]										
kidney	vacuolization of proximal tubule		8 (80)	0 (0)	0 (0)	0 (0)	6 (60)	0 (0)	0 (0)	0 (0)
	hydronephrosis		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
	regeneration proximal tubule		0 (0)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)

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

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

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

Organ	Findings	Group Name	Control				10 ppm				20 ppm				40 ppm			
		No. of Animals	10				10				10				10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Endocrine system]																		
pituitary	cyst		1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Reproductive system]																		
testis	atrophy		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Body cavities]																		
adipose	granulation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

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

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

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

APPENDIX C 10-7

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS

(THIRTEEN-WEEK STUDIES : SUMMARY)

MOUSE : FEMALE : SACRIFICED ANIMALS

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

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

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

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

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

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

APPENDIX C 11-1

CONCENTRATION OF 1, 2-DICHLOROETHANE IN INHLATION CHAMBER

(THIRTEEN-WEEK STUDIES)

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

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

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

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

APPENDIX C 11-2

ENVIRONMENT OF INHLATION CHAMBER

(THIRTEEN-WEEK STUDIES)

ENVIRONMENT OF INHALATION CHAMBER

(RAT : THIRTEEN-WEEK STUDIES)

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

ENVIRONMENT OF INHALATION CHAMBER

(MOUSE : THIRTEEN-WEEK STUDIES)

Group Name	TEMPERATURE(℃) MEAN ± S.D.	HUMIDITY(%) MEAN ± S.D.	VENTILATION RATE(ℓ/min) MEAN ± S.D.	ROOM AIR CHANGE(time/h) MEAN
Control	24.0 ± 0.1	58,2 ± 2.0	131.9 ± 0.7	15.1
10ppm	23.9 ± 0.2	55.8 ± 2.5	131.1 ± 0.3	15.0
20ppm	23.7 ± 0.2	58.7 ± 2.1	130.7 ± 0.2	15.0
40ppm	23.8 ± 0.2	58.6 ± 2.1	130.7 ± 0.7	15.0
80ppm	24.0 ± 0.2	55.7 ± 2.1	130.7 ± 0.3	15.0
160ppm	24.2 ± 0.2	57.9 ± 2.6	131.3 ± 1.1	15.1