テトラクロロエチレ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

(B1-1～B12-2)

1 3 Week　STUDY　NO.　0085 ; 0086

APPENDIXES

APPENDIXES (CONTINUED)

APPENDIXES (CONTINUED)

APPENDIX B 1-1

CLINICAL OBSERVATION : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Administration Week-day 0-0 1	1-7 1	2-7 1	3-7 1	4-7 1	5-7 1	6-7 1	7-7 1	8-7 1	9-7 1	10-7 1	11-7 1	12-7 1	13-7 1
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	50 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	115 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	265 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	609 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1400 ppm	0	0	4	4	4	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	50 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	115 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	265 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	609 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SORE OF SOLE	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	3
	50 ppm	0	0	0	0	0	0	0	0	0	0	0	0	2	3
	115 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	265 ppm	0	0	0	0	0	0	0	0	1	1	1	1	2	2
	609 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOOSE STOOL	Control	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	50 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	115 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	265 ppm	0	1	1	0	0	0	0	0	0	0	0	0	0	0
	609 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1400 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0

APPENDIX B 1-2

CLINICAL OBSERVATION : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0085
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
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	50 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	115 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	265 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	609 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1400 ppm	0	0	2	2	2	1	1	1	1	1	1	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	1	1	0	0	0	0
	50 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	115 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	265 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	609 ppm	0	0	0	0	0	0	0	1	1	1	1	0	0	0
	1400 ppm	0	0	1	0	0	0	0	0	0	0	0	0	0	0
LACRYMATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	50 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	115 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	265 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	609 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	1400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GUM	Control	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	50 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	115 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	265 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	609 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
LOOSE STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	50 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	115 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	265 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	609 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1400 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0

APPENDIX B 1-3

CLINICAL OBSERVATION : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0086
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	1	1	1	1	1	1	1	1	1	1	1	1	0
	50 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	115 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	265 ppm	0	0	1	1	1	1	1	1	2	2	2	3	3	4
	609 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOSS OF HAIR	Control	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	50 ppm	0	0	0	0	0	1	1	1	1	3	2	1	1	2
	115 ppm	0	1	1	1	1	3	3	3	3	3	4	4	4	4
	265 ppm	0	0	1	1	1	1	1	1	1	2	2	2	2	2
	609 ppm	0	0	0	0	0	0	0	1	4	5	5	6	7	7
	1400 ppm	0	0	0	0	0	0	0	0	1	2	2	2	4	4
SOILED PERI GENITALIA	Control	0	1	0	1	1	0	0	0	0	0	0	0	0	0
	50 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	115 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	265 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	609 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

APPENDIX B 1-4

CLINICAL OBSERVATION : SUMMARY, MOSUE: FEMALE

(13Week STUDY)

STUDY NO. : 0086
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
LOSS OF HAIR	Control	0	1	1	1	2	2	4	6	6	7	8	8	9	10
	50 ppm	0	0	0	0	1	3	3	5	5	6	6	6	6	6
	115 ppm	0	0	0	0	1	2	3	5	6	6	6	7	7	7
	265 ppm	0	0	1	1	4	5	5	5	7	7	7	7	7	7
	609 ppm	0	0	1	0	1	3	5	5	7	8	8	8	8	8
	1400 ppm	0	0	0	2	2	2	3	4	6	6	6	6	7	7
LOOSE STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	50 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	115 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	265 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	609 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

APPENDIX B 2-1

BODY WEIGHT CHANGES :SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0085
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 0	1	2	3	4	5	6
Control	131± 4	164± 6	200± 7	227± 6	252± 8	272± 9	288± 9
50 ppm	131± 4	159± 8	192± 9	219± 11	243± 13	262± 14	278± 15
115 ppm	131± 4	162± 8	194± 10	221± 11	244± 11	263± 11	278± 10
265 ppm	131± 4	162± 6	195± 8	222± 7	246± 8	267± 9	283± 8
609 ppm	131± 4	160± 9	195± 11	221± 13	246± 12	265± 12	281± 13
1400 ppm	131± 4	150± 10**	181± 12**	207± 12**	231± 12**	250± 12**	265± 13**

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

STUDY NO. : 0085
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 7	8	9	10	11	12	13
Control	305± 11	320± 12	335± 12	345± 11	355± 12	361± 12	368± 13
50 ppm	295± 16	308± 18	321± 18	331± 18	340± 18	348± 19	355± 18
115 ppm	294± 11	309± 12	321± 10	330± 12	339± 13	349± 15	357± 16
265 ppm	298± 10	314± 10	330± 12	339± 13	349± 11	357± 13	367± 13
609 ppm	298± 14	314± 16	328± 16	337± 16	346± 16	357± 15	366± 15
1400 ppm	280± 14**	294± 15**	307± 15**	316± 15**	327± 14**	337± 16**	345± 15**

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

APPENDIX B 2-2

BODY WEIGHT CHANGES : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0085
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 0	1	2	3	4	5	6
Control	104± 3	120± 4	136± 5	147± 6	157± 7	167± 6	171± 8
50 ppm	104± 3	119± 5	134± 6	146± 7	155± 8	164± 8	171± 9
115 ppm	104± 3	118± 5	132± 6	143± 8	153± 10	160± 10	166± 11
265 ppm	104± 3	118± 4	132± 3	144± 4	152± 4	160± 5	166± 7
609 ppm	104± 3	118± 4	132± 6	144± 7	152± 8	161± 9	168± 10
1400 ppm	104± 3	114± 6	131± 5	144± 7	155± 8	164± 8	171± 9

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

STUDY NO. : 0085
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 7	8	9	10	11	12	13
Control	179± 8	186± 10	192± 10	199± 9	203± 11	208± 9	210± 10
50 ppm	177± 10	181± 11	189± 11	194± 12	198± 12	202± 13	204± 12
115 ppm	172± 12	178± 12	183± 13	189± 14	193± 14	198± 14	199± 15
265 ppm	173± 7	181± 7	186± 8	189± 8	194± 8	197± 8	199± 9
609 ppm	173± 12	181± 16	186± 16	193± 17	199± 18	204± 18	208± 20
1400 ppm	178± 9	184± 9	190± 10	196± 12	200± 12	206± 12	207± 12

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

APPENDIX B 2-3

BODY WEIGHT CHANGES :SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 0	1	2	3	4	5	6
Control	22.7± 0.9	24.3± 1.1	25.5± 1.2	26.7± 1.6	27.5± 1.5	28.9± 1.7	29.8± 1.9
50 ppm	22.7± 0.9	24.4± 0.9	26.0± 1.1	27.1± 1.2	28.1± 1.5	29.1± 1.5	29.9± 1.8
115 ppm	22.7± 1.0	24.3± 0.9	25.8± 1.2	26.9± 1.5	27.9± 1.6	29.1± 1.6	29.6± 1.7
265 ppm	22.7± 1.0	23.9± 1.4	25.4± 1.4	26.6± 1.6	27.4± 1.9	28.4± 2.0	29.2± 2.2
609 ppm	22.7± 1.0	24.6± 1.1	26.0± 1.5	26.8± 1.3	26.8± 1.3	27.3± 1.5	27.1± 1.3**
1400 ppm	22.7± 1.0	22.8± 1.1*	22.2± 1.6**	23.7± 1.5**	24.5± 1.6**	24.5± 1.9**	24.9± 1.5**

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

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 7	8	9	10	11	12	13
Control	30.7± 1.9	31.4± 1.9	32.8± 2.1	33.5± 2.3	34.3± 2.1	35.0± 2.5	35.9± 2.7
50 ppm	31.1± 1.8	32.1± 2.1	32.9± 1.9	33.7± 2.2	34.7± 2.2	35.3± 2.5	36.1± 2.3
115 ppm	30.9± 1.7	31.9± 1.8	32.8± 2.0	33.6± 2.1	34.4± 2.2	35.2± 2.3	35.9± 2.6
265 ppm	29.7± 2.5	30.6± 2.6	31.3± 2.5	32.0± 2.8	32.5± 2.6	33.0± 2.9	33.1± 3.4
609 ppm	27.6± 1.4**	27.8± 1.7**	28.3± 1.7**	29.2± 1.7**	28.9± 1.9**	28.9± 2.0**	29.1± 2.1**
1400 ppm	25.7± 1.0**	26.2± 1.0**	26.5± 1.0**	28.0± 1.3**	26.5± 1.6**	27.6± 1.0**	27.7± 1.1**

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

APPENDIX B 2-4

BODY WEIGHT CHANGES : SUMMARY, MOSUE: FEMALE

(13Week STUDY)

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 0	1	2	3	4	5	6
Control	19.0± 0.7	20.1± 0.5	20.7± 0.5	21.5± 0.7	22.1± 0.5	22.8± 0.9	23.8± 1.1
50 ppm	19.0± 0.8	19.9± 0.9	20.6± 1.0	21.5± 1.2	22.2± 1.4	23.1± 1.3	23.9± 1.7
115 ppm	19.0± 0.8	19.8± 0.9	20.5± 1.1	21.4± 0.7	22.5± 1.2	23.1± 1.1	23.6± 1.0
265 ppm	19.0± 0.8	20.2± 0.6	21.2± 0.9	21.9± 1.0	22.3± 1.0	22.9± 0.9	23.4± 1.0
609 ppm	19.0± 0.8	20.1± 0.6	20.8± 1.0	21.6± 1.0	22.3± 1.1	22.9± 1.1	23.6± 1.1
1400 ppm	19.0± 0.8	19.3± 1.1	20.3± 1.1	21.2± 1.2	22.1± 1.2	22.4± 1.2	22.9± 1.2

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

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 7	8	9	10	11	12	13
Control	24.5± 1.2	25.3± 1.4	25.9± 1.3	26.7± 1.6	27.4± 2.1	27.3± 2.0	28.0± 2.1
50 ppm	24.8± 1.8	25.5± 2.0	26.2± 2.2	26.5± 2.0	26.6± 2.2	27.5± 2.6	28.0± 3.0
115 ppm	24.7± 1.4	25.2± 1.1	25.2± 1.2	26.4± 2.0	26.4± 1.2	27.0± 1.4	27.3± 1.7
265 ppm	24.2± 1.0	25.3± 1.1	25.4± 1.2	25.7± 1.3	26.2± 1.4	26.8± 1.7	27.6± 1.7
609 ppm	24.1± 1.1	24.5± 1.4	25.0± 1.5	25.6± 1.8	25.2± 1.8*	25.6± 2.3	26.0± 2.0
1400 ppm	23.4± 1.3	23.5± 1.0*	24.4± 1.1	25.2± 1.1	24.3± 1.4**	25.1± 1.0*	25.3± 1.1*

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

APPENDIX B 3-1

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0085
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 1	2	3	4	5	6	7
Control	15.5± 1.0	17.0± 0.8	17.6± 0.8	18.1± 1.1	17.9± 1.1	17.8± 1.4	18.2± 1.8
50 ppm	15.1± 1.5	16.9± 2.1	17.9± 2.3	18.2± 2.2	17.9± 2.0	17.3± 1.7	17.3± 2.0
115 ppm	14.9± 1.1	16.6± 1.3	18.1± 1.7	18.2± 1.0	17.8± 1.0	17.0± 0.7	16.9± 0.9
265 ppm	15.2± 0.7	16.6± 1.1	17.7± 0.9	18.0± 1.0	18.4± 1.3	18.0± 1.2	18.3± 1.0
609 ppm	14.5± 1.0	16.3± 1.2	16.9± 1.2	17.6± 1.1	17.3± 1.1	17.4± 1.1	17.8± 0.9
1400 ppm	12.6± 1.6**	15.6± 1.3	16.3± 0.9	17.3± 1.1	17.3± 1.1	16.9± 0.9	17.2± 0.8

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

STUDY NO. : 0085
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 8	9	10	11	12	13
Control	18.1± 1.7	18.6± 1.6	17.6± 1.6	17.2± 2.3	16.9± 1.4	17.0± 1.9
50 ppm	17.4± 1.6	17.4± 1.6	16.4± 1.4	16.6± 1.2	16.3± 0.9	16.3± 1.3
115 ppm	17.0± 1.0	17.4± 1.0	16.4± 1.0	16.7± 1.0	16.7± 1.4	16.6± 1.1
265 ppm	18.0± 1.4	18.4± 1.0	17.2± 0.9	17.7± 0.8	16.8± 0.7	17.0± 0.8
609 ppm	17.4± 1.2	17.9± 1.1	17.2± 1.0	17.3± 1.1	17.2± 1.0	17.0± 0.9
1400 ppm	17.3± 0.9	17.4± 0.8	16.8± 0.9	17.2± 0.5	17.6± 0.6	17.2± 0.9

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

APPENDIX B 3-2

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0085
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 1	2	3	4	5	6	7
Control	11.9± 0.4	12.0± 0.4	12.2± 0.7	12.1± 0.7	11.8± 0.8	11.5± 0.8	11.5± 1.0
50 ppm	11.6± 0.8	11.7± 0.8	11.9± 0.7	11.7± 0.7	11.6± 0.9	11.5± 1.4	11.2± 0.9
115 ppm	11.6± 1.3	12.0± 0.9	11.7± 0.8	11.7± 0.9	11.2± 0.7	11.1± 1.1	11.3± 1.0
265 ppm	11.1± 0.8	11.5± 0.7	11.6± 0.7	11.4± 0.5	10.9± 0.6	10.7± 0.7	11.2± 1.1
609 ppm	11.2± 1.0	11.7± 0.7	11.7± 1.0	11.5± 1.0	11.5± 1.0	11.3± 1.1	11.4± 1.4
1400 ppm	10.6± 1.4**	11.6± 0.6	12.1± 0.5	12.3± 0.8	11.8± 0.8	12.1± 1.0	12.0± 0.8

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

STUDY NO. : 0085
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 8	9	10	11	12	13
Control	12.0± 1.0	12.2± 1.4	11.6± 0.7	11.5± 0.7	11.5± 0.8	11.1± 1.1
50 ppm	10.9± 1.3	11.8± 1.2	11.3± 1.1	11.3± 0.8	11.1± 1.1	11.1± 0.9
115 ppm	10.9± 1.0	11.1± 1.0	11.3± 1.4	11.0± 0.8	11.2± 0.7	10.4± 0.9
265 ppm	11.0± 0.8	11.2± 0.6	10.7± 0.7	11.0± 0.9	10.7± 0.8	10.2± 1.0
609 ppm	11.4± 1.9	11.7± 1.4	11.5± 1.4	11.7± 1.1	12.1± 0.7	11.5± 1.1
1400 ppm	11.8± 1.0	12.2± 1.1	11.8± 1.0	12.1± 1.1	12.3± 1.2	11.7± 1.0

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

APPENDIX B 3-3

FOOD CONSUMPTION CHANGES : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 1	2	3	4	5	6	7
Control	3.7± 0.3	3.7± 0.2	3.7± 0.3	3.8± 0.3	4.0± 0.3	4.1± 0.3	4.0± 0.3
50 ppm	3.8± 0.2	3.8± 0.2	3.7± 0.2	3.8± 0.2	3.9± 0.2	4.0± 0.2	4.1± 0.2
115 ppm	3.9± 0.2	3.8± 0.2	3.8± 0.3	3.9± 0.3	4.1± 0.3	4.1± 0.3	4.0± 0.5
265 ppm	3.8± 0.4	3.8± 0.2	3.8± 0.3	3.8± 0.3	4.0± 0.3	4.1± 0.4	4.0± 0.3
609 ppm	4.0± 0.4	4.1± 0.2**	4.2± 0.5	4.4± 0.9	4.5± 0.4	4.4± 0.7	4.3± 0.6
1400 ppm	3.9± 0.7	4.0± 0.8	4.1± 0.8	4.4± 0.7*	4.3± 0.7	4.1± 0.6	4.2± 0.5

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

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 8	9	10	11	12	13
Control	4.0± 0.2	4.0± 0.2	4.0± 0.3	4.0± 0.2	4.0± 0.2	4.0± 0.3
50 ppm	4.1± 0.2	4.1± 0.2	4.0± 0.2	4.0± 0.2	4.0± 0.3	4.0± 0.2
115 ppm	4.1± 0.3	4.1± 0.3	4.1± 0.3	4.1± 0.3	4.2± 0.2	4.1± 0.3
265 ppm	4.0± 0.4	4.0± 0.3	4.0± 0.2	3.9± 0.3	3.9± 0.3	4.0± 0.3
609 ppm	4.0± 0.5	3.9± 0.4	4.0± 0.5	3.5± 0.4**	3.8± 0.6	3.7± 0.4
1400 ppm	4.0± 0.4	3.8± 0.2	3.9± 0.2	3.4± 0.2**	3.9± 0.4	3.8± 0.3

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

APPENDIX B 3-4

FOOD CONSUMPTION CHANGES : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 1	2	3	4	5	6	7
Control	3.3± 0.3	3.2± 0.2	3.2± 0.2	3.3± 0.2	3.7± 0.3	3.9± 0.3	3.9± 0.2
50 ppm	3.2± 0.2	3.2± 0.4	3.4± 0.3	3.5± 0.3	3.9± 0.3	3.9± 0.4	4.1± 0.3
115 ppm	3.2± 0.2	3.3± 0.4	3.5± 0.3	3.6± 0.3	3.8± 0.4	4.0± 0.3	4.0± 0.4
265 ppm	3.4± 0.2	3.4± 0.3	3.3± 0.3	3.4± 0.2	3.8± 0.6	3.9± 0.2	3.8± 0.3
609 ppm	3.3± 0.2	3.3± 0.3	3.3± 0.3	3.5± 0.3	3.7± 0.3	3.9± 0.4	3.9± 0.4
1400 ppm	3.1± 0.4	3.7± 0.5**	4.0± 0.6**	4.0± 0.7*	3.9± 0.4	4.0± 0.4	3.9± 0.4

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

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week 8	9	10	11	12	13
Control	4.0± 0.3	3.9± 0.3	3.9± 0.2	3.8± 0.3	3.7± 0.4	3.8± 0.4
50 ppm	4.0± 0.4	4.1± 0.4	3.9± 0.4	3.7± 0.4	3.8± 0.4	3.9± 0.6
115 ppm	4.1± 0.3	4.0± 0.3	4.2± 0.6	3.9± 0.4	4.0± 0.4	4.0± 0.5
265 ppm	4.0± 0.3	3.9± 0.3	3.7± 0.3	3.7± 0.2	3.7± 0.2	3.9± 0.3
609 ppm	3.9± 0.4	3.8± 0.3	3.8± 0.4	3.6± 0.4	3.7± 0.4	3.7± 0.4
1400 ppm	3.8± 0.3	3.8± 0.3	3.9± 0.2	3.6± 0.4	3.9± 0.3	3.8± 0.3

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

APPENDIX B 4-1

HEMATOLOGY : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0085
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	MCH p g	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	10	9.91± 0.33	17.5± 0.3	47.4± 1.5	47.8± 0.3	17.7± 0.3	37.0± 0.8	876± 55
50 ppm	10	9.85± 0.27	17.7± 0.3	47.4± 1.4	48.1± 0.5	18.0± 0.3	37.3± 0.7	873± 47
115 ppm	10	9.79± 0.31	17.5± 0.3	46.9± 1.6	47.9± 0.5	17.9± 0.4	37.3± 0.8	892± 50
265 ppm	10	9.50± 0.41	17.1± 0.5*	45.8± 1.9	48.2± 0.3	18.0± 0.4	37.3± 0.8	852± 101
609 ppm	10	9.78± 0.24	17.6± 0.4	47.6± 1.2	48.6± 0.6**	18.0± 0.4	37.0± 0.6	871± 66
1400 ppm	10	9.65± 0.34	17.4± 0.5	46.8± 1.8	48.4± 0.6*	18.1± 0.4	37.3± 0.7	892± 43

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

STUDY NO. : 0085
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	6.17± 0.91	0± 0	18± 4	1± 1	0± 0	4± 2	77± 5	0± 0
50 ppm	10	6.25± 1.09	0± 0	23± 5	2± 1	0± 0	4± 1	72± 6	0± 0
115 ppm	10	6.03± 1.35	0± 0	21± 2	1± 1	0± 0	5± 2	73± 3	0± 0
265 ppm	10	5.72± 2.05	0± 0	22± 7	1± 1	0± 0	3± 1	73± 7	0± 0
609 ppm	10	6.27± 1.32	0± 0	20± 5	2± 1	0± 0	3± 1	75± 7	0± 0
1400 ppm	10	6.12± 1.42	0± 0	21± 4	1± 1	0± 0	4± 2	74± 5	0± 1

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

APPENDIX B 4-2

HEMATOLOGY : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0085
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	MCH p g	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	10	9.01± 0.33	17.5± 0.5	46.6± 1.6	51.7± 0.3	19.5± 0.3	37.6± 0.6	969± 80
50 ppm	10	8.94± 0.25	17.4± 0.5	46.3± 1.2	51.8± 0.5	19.5± 0.4	37.6± 0.7	954± 54
115 ppm	10	8.86± 0.37	17.3± 0.5	46.2± 1.9	52.0± 0.4	19.5± 0.4	37.4± 0.6	948± 54
265 ppm	10	8.75± 0.24	17.1± 0.4	45.3± 1.3	51.7± 0.6	19.5± 0.3	37.7± 0.5	972± 69
609 ppm	10	8.90± 0.25	17.4± 0.4	46.4± 1.2	52.1± 0.6	19.6± 0.4	37.5± 0.8	901± 109
1400 ppm	10	8.87± 0.30	17.4± 0.5	46.1± 1.7	51.9± 0.6	19.6± 0.3	37.7± 0.5	992± 66

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

STUDY NO. : 0085
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	3.57± 0.91	0± 0	20± 5	1± 1	0± 0	3± 1	77± 6	0± 0
50 ppm	10	3.39± 0.64	0± 0	20± 5	1± 1	0± 0	2± 1	76± 5	0± 0
115 ppm	10	3.61± 1.09	0± 0	18± 4	1± 1	0± 0	4± 1	78± 6	0± 0
265 ppm	10	3.89± 0.90	0± 0	19± 4	2± 1*	0± 0	3± 1	75± 5	0± 0
609 ppm	10	3.82± 0.94	0± 0	20± 3	1± 1	0± 0	4± 2	76± 3	0± 0
1400 ppm	10	4.05± 1.24	0± 0	19± 4	1± 1	0± 0	3± 1	76± 5	0± 0

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

APPENDIX B 4-3

HEMATOLOGY : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0086
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 fℓ	MCH pg	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	10	11.04± 0.38	16.2± 0.5	47.8± 1.7	43.2± 0.4	14.7± 0.3	33.9± 0.6	1694± 153
50 ppm	10	11.07± 0.38	16.3± 0.5	48.0± 1.7	43.3± 0.4	14.7± 0.3	34.0± 0.6	1699± 79
115 ppm	10	11.13± 0.60	16.4± 0.8	48.2± 2.5	43.2± 0.6	14.7± 0.2	34.0± 0.7	1498± 350
265 ppm	10	10.96± 0.51	16.1± 0.6	47.2± 1.9	43.0± 0.4	14.7± 0.3	34.2± 0.6	1514± 216
609 ppm	9	10.55± 0.55	15.5± 0.7	45.4± 2.2*	43.0± 0.9	14.7± 0.3	34.2± 0.6	1641± 337
1400 ppm	8	10.29± 0.37**	15.4± 0.6*	45.2± 1.8*	43.8± 0.3*	15.0± 0.2	34.1± 0.7	1769± 82

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

STUDY NO. : 0086
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	1.07± 0.66	1± 1	18± 5	1± 1	0± 0	2± 1	79± 4	0± 0
50 ppm	10	1.26± 0.61	0± 0	14± 2	1± 1	0± 0	2± 1	82± 3	0± 0
115 ppm	10	1.44± 0.71	0± 0	18± 8	1± 1	0± 0	2± 1	79± 8	0± 1
265 ppm	10	1.22± 0.49	0± 1	16± 6	1± 1	0± 0	2± 1	80± 6	0± 1
609 ppm	9	1.00± 0.49	0± 0	16± 5	1± 1	0± 0	2± 1	81± 6	0± 0
1400 ppm	8	1.58± 0.59	0± 0	15± 7	1± 1	0± 0	2± 1	83± 6	0± 0

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

APPENDIX B 4-4

HEMATOLOGY : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0086
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	MCH p g	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	9	10.88± 0.33	16.2± 0.3	47.3± 1.7	43.4± 0.4	14.9± 0.3	34.3± 0.7	1454± 95
50 ppm	9	11.06± 0.38	16.5± 0.5	48.1± 1.7	43.4± 1.0	14.9± 0.3	34.3± 0.5	1539± 103
115 ppm	7	10.78± 0.37	16.2± 0.5	47.1± 1.8	43.6± 0.4	15.1± 0.2	34.5± 0.6	1561± 263
265 ppm	9	10.69± 0.32	16.2± 0.3	46.7± 1.7	43.6± 0.5	15.1± 0.3	34.6± 0.7	1480± 104
609 ppm	9	10.72± 0.32	16.1± 0.4	46.5± 1.6	43.3± 0.5	15.0± 0.2	34.6± 0.7	1498± 84
1400 ppm	10	10.67± 0.43	16.1± 0.5	46.9± 2.1	43.9± 0.5	15.1± 0.2	34.3± 0.6	1523± 112

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

STUDY NO. : 0086
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	9	1.36± 0.99	1± 1	15± 4	1± 1	0± 0	2± 1	81± 5	0± 0
50 ppm	9	1.43± 0.87	0± 0	16± 7	2± 1	0± 0	2± 1	79± 7	0± 1
115 ppm	7	1.36± 0.67	0± 1	18± 8	1± 1	0± 0	2± 1	78± 7	0± 0
265 ppm	9	0.98± 0.33	0± 0	19± 7	1± 1	0± 0	2± 1	78± 6	0± 1
609 ppm	9	1.32± 0.75	0± 0	19± 7	1± 1	0± 0	2± 2	77± 7	0± 1
1400 ppm	10	1.78± 1.17	0± 0	17± 6	1± 1	0± 0	2± 2	80± 6	0± 0

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

APPENDIX B 5-1

BIOCHEMISTRY : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0085
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	6.9± 0.2	4.0± 0.1	1.4± 0.1	0.19± 0.02	214± 17	54± 4	128± 35
50 ppm	10	7.0± 0.2	4.0± 0.1	1.3± 0.0	0.19± 0.02	201± 19	55± 5	124± 30
115 ppm	10	7.0± 0.2	4.0± 0.1	1.4± 0.1	0.19± 0.02	213± 15	58± 4	124± 23
265 ppm	10	6.9± 0.3	4.0± 0.1	1.4± 0.1	0.19± 0.02	212± 20	57± 4	123± 26
609 ppm	10	6.9± 0.1	4.0± 0.1	1.4± 0.1	0.18± 0.02	206± 16	60± 5**	121± 28
1400 ppm	10	6.9± 0.2	4.0± 0.2	1.4± 0.1	0.18± 0.02	202± 15	59± 4*	95± 19

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

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

Group Name	NO. of Animals	PHOSPHOLIPID mg/dℓ	GOT IU/ℓ	GPT IU/ℓ	LDH IU/ℓ	ALP IU/ℓ	G-GTP IU/ℓ	CPK IU/ℓ
Control	10	113± 8	73± 14	25± 4	137± 35	269± 12	0± 0	88± 8
50 ppm	10	111± 11	70± 8	24± 2	131± 34	286± 15	0± 0	92± 9
115 ppm	10	115± 7	81± 19	27± 5	150± 47	284± 25	0± 0	91± 14
265 ppm	10	112± 9	78± 14	26± 3	162± 57	285± 15	0± 0	94± 9
609 ppm	10	115± 6	80± 26	27± 6	163± 53	266± 16	0± 0	94± 12
1400 ppm	10	109± 8	74± 12	23± 4	151± 41	288± 29	0± 0	97± 14

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

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

Group Name	NO. of Animals	UREA NITROGEN mg/dℓ	CREATININE mg/dℓ	SODIUM mEq/ℓ	POTASSIUM mEq/ℓ	CHLORIDE mEq/ℓ	CALCIUM mg/dℓ	INORGANIC PHOSPHORUS mg/dℓ
Control	10	18.7± 1.2	0.6± 0.1	143± 1	3.1± 0.2	105± 2	10.5± 0.2	4.8± 0.6
50 ppm	10	18.4± 1.8	0.6± 0.1	144± 1	3.1± 0.1	105± 1	10.6± 0.2	4.6± 0.7
115 ppm	10	18.5± 0.8	0.6± 0.1	143± 1	3.0± 0.2	105± 1	10.6± 0.3	4.7± 0.7
265 ppm	10	18.7± 1.2	0.5± 0.1	143± 1	3.2± 0.2	105± 1	10.5± 0.3	4.9± 0.6
609 ppm	10	18.9± 2.0	0.6± 0.0	143± 1	3.1± 0.2	105± 1	10.5± 0.2	4.6± 0.8
1400 ppm	10	20.2± 1.8	0.6± 0.1	142± 1	3.3± 0.7	105± 1	10.6± 0.4	5.2± 1.2

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

APPENDIX B 5-2

BIOCHEMISTRY : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0085
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	6.9± 0.3	4.0± 0.1	1.4± 0.1	0.21± 0.01	147± 15	75± 4	49± 9
50 ppm	10	6.9± 0.2	4.1± 0.1	1.4± 0.0	0.20± 0.03	152± 15	72± 5	47± 11
115 ppm	10	6.8± 0.3	4.1± 0.2	1.5± 0.1	0.20± 0.02	147± 17	73± 4	49± 8
265 ppm	10	6.9± 0.3	4.1± 0.2	1.5± 0.1	0.20± 0.02	152± 10	73± 7	48± 8
609 ppm	10	7.0± 0.2	4.2± 0.2	1.5± 0.1	0.20± 0.02	156± 9	76± 4	49± 7
1400 ppm	10	6.8± 0.2	4.1± 0.1	1.5± 0.1	0.21± 0.02	143± 15	74± 5	42± 8

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

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

Group Name	NO. of Animals	PHOSPHOLIPID mg/dℓ	GOT IU/ℓ	GPT IU/ℓ	LDH IU/ℓ	ALP IU/ℓ	G-GTP IU/ℓ	CPK IU/ℓ
Control	10	151± 10	74± 19	26± 11	143± 30	196± 11	1± 1	93± 11
50 ppm	10	145± 11	75± 16	29± 11	144± 51	178± 15	1± 1	89± 8
115 ppm	10	144± 10	82± 26	28± 11	160± 51	184± 15	0± 0	95± 21
265 ppm	10	145± 13	72± 18	26± 13	136± 38	184± 15	0± 1	91± 12
609 ppm	10	151± 10	70± 21	26± 17	126± 31	175± 18*	1± 1	88± 10
1400 ppm	10	146± 12	58± 4	17± 2	120± 33	172± 18**	0± 0	86± 5

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

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

Group Name	NO. of Animals	UREA NITROGEN mg/dℓ	CREATININE mg/dℓ	SODIUM mEq/ℓ	POTASSIUM mEq/ℓ	CHLORIDE mEq/ℓ	CALCIUM mg/dℓ	INORGANIC PHOSPHORUS mg/dℓ
Control	10	19.2± 2.1	0.6± 0.1	143± 2	2.9± 0.2	107± 1	10.3± 0.3	4.1± 1.5
50 ppm	10	19.9± 2.2	0.5± 0.1	142± 2	3.0± 0.3	107± 1	10.4± 0.4	4.4± 1.4
115 ppm	10	19.3± 1.8	0.6± 0.1	143± 2	3.1± 0.6	107± 3	10.4± 0.2	4.8± 1.9
265 ppm	10	20.2± 2.1	0.6± 0.1	143± 2	3.0± 0.4	107± 1	10.4± 0.3	4.3± 1.3
609 ppm	10	19.3± 2.6	0.5± 0.1	143± 1	2.8± 0.2	107± 1	10.3± 0.3	4.0± 1.0
1400 ppm	10	19.4± 1.2	0.5± 0.1	143± 1	2.8± 0.1	108± 1	10.2± 0.3	4.1± 1.1

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

APPENDIX B 5-3

BIOCHEMISTRY : SUMMARY, MOSUE : MALE

(13Week　STUDY)

STUDY NO. : 0086
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	TRIGLYCERIDE mg/dℓ
Control	10	5.4± 0.3	3.0± 0.2	1.2± 0.0	0.58± 0.18	245± 33	80± 9	74± 11
50 ppm	10	5.5± 0.2	3.0± 0.1	1.2± 0.0	0.46± 0.15	248± 36	97± 7	71± 15
115 ppm	10	5.6± 0.3	3.1± 0.1	1.2± 0.0	0.56± 0.29	256± 29	111± 6**	76± 12
265 ppm	10	5.4± 0.2	3.0± 0.1	1.3± 0.1	0.59± 0.22	202± 57*	102± 19**	66± 16
609 ppm	10	5.3± 0.3	3.0± 0.1	1.3± 0.1	0.36± 0.12	184± 32**	98± 9	57± 10*
1400 ppm	10	5.4± 0.2	3.1± 0.1	1.3± 0.1*	0.48± 0.12	204± 23	114± 10**	87± 10

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

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
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	CPK IU/ℓ	UREA NITROGEN mg/dℓ	SODIUM mEq/ℓ
Control	10	47± 9	12± 2	487± 176	164± 8	58± 17	32.1± 2.0	153± 5
50 ppm	10	42± 8	11± 2	368± 150	171± 9	52± 11	30.8± 2.4	152± 2
115 ppm	10	47± 13	12± 2	485± 255	173± 11	73± 24	31.6± 3.6	154± 4
265 ppm	10	47± 12	13± 3	448± 193	192± 15*	70± 21	32.4± 4.4	152± 3
609 ppm	10	44± 10	16± 1**	350± 131	244± 23**	75± 18	33.3± 4.6	153± 3
1400 ppm	10	49± 9	20± 2**	381± 121	280± 25**	101± 25**	28.7± 2.2	153± 4

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

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

Group Name	NO. of Animals	POTASSIUM mEq/ℓ	CHLORIDE mEq/ℓ	CALCIUM mg/dℓ	INORGANIC PHOSPHORUS mg/dℓ
Control	10	3.9± 0.4	123± 3	8.6± 0.4	6.9± 1.2
50 ppm	10	3.8± 0.1	123± 2	8.8± 0.2	7.0± 1.6
115 ppm	10	4.1± 0.3	123± 4	8.8± 0.3	7.2± 1.3
265 ppm	10	3.8± 0.3	121± 2	8.5± 0.2	7.5± 1.0
609 ppm	10	4.0± 0.4	123± 2	8.5± 0.3	8.3± 1.0*
1400 ppm	10	3.7± 0.4	123± 3	8.7± 0.1	8.1± 1.0

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

APPENDIX B 5-4

BIOCHEMISTRY : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0086
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	TRIGLYCERIDE mg/dl
Control	10	5.4± 0.4	3.1± 0.2	1.4± 0.1	0.67± 0.29	184± 34	80± 9	65± 14
50 ppm	10	5.4± 0.3	3.2± 0.2	1.5± 0.1	0.52± 0.19	171± 30	83± 9	55± 12
115 ppm	9	5.4± 0.4	3.2± 0.2	1.4± 0.1	0.62± 0.30	182± 30	80± 13	53± 16
265 ppm	10	5.4± 0.3	3.2± 0.1	1.4± 0.1	0.51± 0.19	179± 30	89± 9	59± 11
609 ppm	10	5.5± 0.3	3.3± 0.1	1.5± 0.1	0.64± 0.40	161± 31	77± 5	62± 9
1400 ppm	10	5.4± 0.3	3.2± 0.2	1.4± 0.1	0.51± 0.19	174± 25	84± 9	69± 17

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

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
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	CPK IU/ℓ	UREA NITROGEN mg/dℓ	SODIUM mEq/ℓ
Control	10	58± 11	14± 1	488± 250	238± 29	53± 14	23.5± 3.0	153± 3
50 ppm	10	53± 11	13± 3	383± 155	240± 25	57± 18	22.8± 3.1	153± 4
115 ppm	9	65± 24	15± 2	504± 298	262± 44	85± 38*	23.6± 2.9	152± 3
265 ppm	10	56± 8	15± 3	412± 185	247± 36	64± 24	23.5± 3.1	152± 3
609 ppm	10	65± 14	18± 3*	518± 374	261± 41	68± 21	22.2± 2.3	153± 2
1400 ppm	10	62± 17	19± 5**	431± 177	270± 37	77± 17*	22.8± 1.8	154± 5

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

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

Group Name	NO. of Animals	POTASSIUM mEq/ℓ	CHLORIDE mEq/ℓ	CALCIUM mg/dℓ	INORGANIC PHOSPHORUS mg/dℓ
Control	10	3.9± 0.2	122± 3	8.6± 0.6	5.6± 0.9
50 ppm	10	3.9± 0.4	123± 4	8.7± 0.3	5.4± 0.8
115 ppm	9	4.0± 0.4	122± 3	8.7± 0.4	6.1± 0.6
265 ppm	10	3.8± 0.2	122± 3	8.7± 0.3	6.0± 0.7
609 ppm	10	3.9± 0.6	122± 3	8.8± 0.4	6.0± 0.7
1400 ppm	10	3.8± 0.4	124± 5	8.8± 0.3	6.8± 1.1*

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

APPENDIX B 6-1

URINALYSIS : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0085
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	7	3	0		0	5	5	0	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
50 ppm	10	0	0	0	1	7	2	0		0	4	6	0	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
115 ppm	10	0	0	0	0	7	3	0		0	4	6	0	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
265 ppm	10	0	0	0	1	4	5	0		0	5	5	0	0	0		9	0	1	0	0	0		10	0	0	0		10	0	0	0	
609 ppm	10	0	0	0	0	4	6	0		0	4	6	0	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
1400 ppm	10	0	0	0	0	0	9	1	**	0	0	8	2	0	0	*	10	0	0	0	0	0		7	3	0	0		10	0	0	0	

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

(JCL101)

STUDY NO. : 0085
ANIMAL : RAT F344
SAMPLING DATE : 013-7
SEX : MALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	Occult blood − ± + 2+ 3+	CHI	Nitrite − +	CHI	Urobilinogen ± + 2+ 3+ 4+	CHI
Control	10	10 0 0 0 0		10 0		10 0 0 0 0	
50 ppm	10	10 0 0 0 0		10 0		10 0 0 0 0	
115 ppm	10	10 0 0 0 0		10 0		10 0 0 0 0	
265 ppm	10	10 0 0 0 0		10 0		10 0 0 0 0	
609 ppm	10	9 0 0 1 0		10 0		10 0 0 0 0	
1400 ppm	10	10 0 0 0 0		10 0		10 0 0 0 0	

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

APPENDIX B 6-2

URINALYSIS : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0085
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		3	5	2	0	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
50 ppm	10	0	0	0	0	1	8	1		1	6	3	0	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
115 ppm	10	0	0	0	0	1	9	0		1	7	1	1	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
265 ppm	10	0	0	0	0	0	9	1		0	6	4	0	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
609 ppm	10	0	0	0	0	2	7	1		2	4	4	0	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
1400 ppm	10	0	0	0	0	4	6	0	*	3	7	0	0	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	

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

STUDY NO. : 0085
ANIMAL : RAT F344
SAMPLING DATE : 013-7
SEX : FEMALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	Occult blood −	±	+	2+	3+	CHI	Nitrite −	+	CHI	Urobilinogen ±	+	2+	3+	4+	CHI
Control	10	10	0	0	0	0		10	0		10	0	0	0	0	
50 ppm	10	10	0	0	0	0		10	0		10	0	0	0	0	
115 ppm	10	10	0	0	0	0		10	0		10	0	0	0	0	
265 ppm	10	10	0	0	0	0		10	0		10	0	0	0	0	
609 ppm	10	10	0	0	0	0		10	0		10	0	0	0	0	
1400 ppm	10	9	0	0	1	0		10	0		10	0	0	0	0	

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

APPENDIX B 6-3

URINALYSIS : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0086 URINALYSIS
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-7
SEX : MALE REPORT TYPE : A1

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	3	6	1		0	0	6	4	0	0		10	0	0	0	0	0		6	4	0	0		10	0	0	0	0	
50 ppm	10	0	0	0	0	0	3	7	*	0	0	10	0	0	0	*	10	0	0	0	0	0		10	0	0	0	*	10	0	0	0	0	
115 ppm	10	0	0	0	0	2	6	2		0	0	5	5	0	0		10	0	0	0	0	0		9	1	0	0		10	0	0	0	0	
265 ppm	10	0	0	1	1	3	5	0		0	0	5	5	0	0		10	0	0	0	0	0		10	0	0	0	*	9	1	0	0	0	
609 ppm	10	0	0	1	0	2	5	2		0	0	6	4	0	0		10	0	0	0	0	0		7	3	0	0		10	0	0	0	0	
1400 ppm	10	0	0	4	4	2	0	0	**	0	0	5	5	0	0		10	0	0	0	0	0		5	5	0	0		10	0	0	0	0	

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

STUDY NO. : 0086 URINALYSIS

ANIMAL : MOUSE BDF1

SAMPLING DATE : 013-7

SEX : MALE REPORT TYPE : A1

Group Name	NO. of Animals	Urobilinogen ±	+	2+	3+	4+	CHI
Control	10	10	0	0	0	0	
50 ppm	10	10	0	0	0	0	
115 ppm	10	10	0	0	0	0	
265 ppm	10	10	0	0	0	0	
609 ppm	10	10	0	0	0	0	
1400 ppm	10	10	0	0	0	0	

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

APPENDIX B 6-4

URINALYSIS : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0086 URINALYSIS
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-7
SEX : FEMALE REPORT TYPE : A1

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	2	3	5	0		0	0	4	6	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	0	
50 ppm	10	0	0	0	0	6	3	1		0	1	5	4	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	0	
115 ppm	10	0	0	1	0	3	6	0		0	0	7	3	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	0	
265 ppm	10	0	0	1	2	4	3	0		0	0	7	2	1	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	0	
609 ppm	10	0	0	3	1	3	3	0		1	1	4	4	0	0		10	0	0	0	0	0		8	2	0	0		10	0	0	0	0	
1400 ppm	10	0	1	3	3	3	0	0		1	1	6	2	0	0		10	0	0	0	0	0		4	6	0	0	**	10	0	0	0	0	

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

STUDY NO. : 0086
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	
50 ppm	10	10	0	0	0	0	
115 ppm	10	10	0	0	0	0	
265 ppm	10	10	0	0	0	0	
609 ppm	10	10	0	0	0	0	
1400 ppm	10	10	0	0	0	0	

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

APPENDIX B 7-1

GROSS FINDINGS : SUMMARY, RAT : MALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

Organ	Findings	Group Name / NO. of Animals	Control 10 (%)	50 ppm 10 (%)	115 ppm 10 (%)	265 ppm 10 (%)
lung	yellow zone		0 (0)	0 (0)	1 (10)	0 (0)
thymus	red zone		0 (0)	0 (0)	0 (0)	1 (10)
liver	herniation		0 (0)	0 (0)	0 (0)	1 (10)

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

Organ	Findings	Group Name	609 ppm	1400 ppm
		NO. of Animals	10 (%)	10 (%)
lung	yellow zone		0 (0)	0 (0)
thymus	red zone		2 (20)	0 (0)
liver	herniation		0 (0)	0 (0)

APPENDIX B 7-2

GROSS FINDINGS : SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

Organ	Findings	Group Name / NO. of Animals	Control 10 (%)	50 ppm 10 (%)	115 ppm 10 (%)	265 ppm 10 (%)
thymus	red zone		1 (10)	0 (0)	1 (10)	0 (0)
liver	herniation		0 (0)	0 (0)	0 (0)	1 (10)

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

Organ	Findings	Group Name	609 ppm	1400 ppm
		NO. of Animals	10 (%)	10 (%)
thymus	red zone		1 (10)	0 (0)
liver	herniation		2 (20)	2 (20)

APPENDIX B 7-3

GROSS FINDINGS : SUMMARY, MOSUE : MALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

Organ	Findings	Group Name / NO. of Animals	Control 10 (%)	50 ppm 10 (%)	115 ppm 10 (%)	265 ppm 10 (%)
lung	yellow zone		0 (0)	0 (0)	1 (10)	0 (0)
spleen	black zone		0 (0)	0 (0)	0 (0)	0 (0)
liver	white zone		0 (0)	0 (0)	0 (0)	0 (0)
kidney	white zone		1 (10)	0 (0)	0 (0)	0 (0)
	hydronephrosis		0 (0)	0 (0)	0 (0)	1 (10)

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

Organ	Findings	Group Name NO. of Animals	609 ppm 10 (%)	1400 ppm 10 (%)
lung	yellow zone		0 (0)	0 (0)
spleen	black zone		1 (10)	0 (0)
liver	white zone		0 (0)	1 (10)
kidney	white zone		0 (0)	1 (10)
	hydronephrosis		0 (0)	0 (0)

APPENDIX B 7-4

GROSS FINDINGS : SUMMARY, MOSUE : FEMALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

Organ	Findings	Group Name / NO. of Animals	Control 10 (%)	50 ppm 10 (%)	115 ppm 10 (%)	265 ppm 10 (%)
lung	yellow zone		0 (0)	0 (0)	0 (0)	1 (10)
spleen	black zone		0 (0)	2 (20)	0 (0)	0 (0)
liver	white zone		0 (0)	1 (10)	0 (0)	0 (0)
ovary	cyst		0 (0)	0 (0)	1 (10)	0 (0)

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

Organ	Findings	Group Name	609 ppm	1400 ppm
		NO. of Animals	10 (%)	10 (%)
lung	yellow zone		0 (0)	0 (0)
spleen	black zone		0 (0)	0 (0)
liver	white zone		0 (0)	0 (0)
ovary	cyst		0 (0)	0 (0)

APPENDIX B 8-1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0085
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	346± 12	0.269± 0.034	0.054± 0.004	2.971± 0.087	1.016± 0.053	1.059± 0.033
50 ppm	10	329± 25	0.263± 0.038	0.055± 0.004	2.983± 0.083	0.966± 0.041	1.010± 0.053
115 ppm	10	334± 16	0.256± 0.021	0.055± 0.003	2.991± 0.078	0.969± 0.046	1.016± 0.047
265 ppm	10	345± 12	0.250± 0.030	0.056± 0.004	2.975± 0.100	0.966± 0.042	1.050± 0.047
609 ppm	10	343± 14	0.248± 0.021	0.057± 0.003	3.036± 0.104	0.995± 0.036	1.055± 0.058
1400 ppm	10	324± 13*	0.250± 0.019	0.056± 0.004	3.020± 0.155	0.989± 0.036	1.027± 0.045

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

STUDY NO. : 0085
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	1.944± 0.056	0.586± 0.027	8.645± 0.617	1.917± 0.036
50 ppm	10	1.882± 0.063	0.568± 0.041	8.289± 0.704	1.892± 0.039
115 ppm	10	1.913± 0.085	0.575± 0.026	8.521± 0.599	1.879± 0.039
265 ppm	10	1.949± 0.038	0.594± 0.020	8.884± 0.558	1.858± 0.034**
609 ppm	10	2.006± 0.097	0.606± 0.029	9.172± 0.528	1.861± 0.041*
1400 ppm	10	2.078± 0.073**	0.582± 0.034	9.056± 0.677	1.838± 0.049**

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

APPENDIX B 8-2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0085
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	194± 11	0.208± 0.016	0.060± 0.004	0.107± 0.009	0.673± 0.030	0.766± 0.033
50 ppm	10	188± 11	0.204± 0.021	0.061± 0.003	0.108± 0.014	0.661± 0.043	0.752± 0.042
115 ppm	10	185± 14	0.189± 0.023	0.058± 0.005	0.104± 0.009	0.651± 0.039	0.739± 0.038
265 ppm	10	185± 6	0.206± 0.017	0.059± 0.004	0.106± 0.010	0.658± 0.027	0.739± 0.029
609 ppm	10	193± 18	0.204± 0.032	0.059± 0.005	0.097± 0.012	0.669± 0.029	0.743± 0.027
1400 ppm	10	192± 11	0.212± 0.023	0.064± 0.005	0.113± 0.023	0.668± 0.045	0.779± 0.045

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

STUDY NO. : 0085
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	1.197± 0.034	0.397± 0.019	4.417± 0.340	1.746± 0.025
50 ppm	10	1.178± 0.068	0.382± 0.027	4.566± 0.355	1.737± 0.045
115 ppm	10	1.175± 0.062	0.376± 0.026	4.482± 0.298	1.728± 0.025
265 ppm	10	1.195± 0.045	0.376± 0.013	4.619± 0.240	1.728± 0.020
609 ppm	10	1.199± 0.053	0.372± 0.029	4.802± 0.285*	1.712± 0.025
1400 ppm	10	1.281± 0.065**	0.390± 0.028	5.042± 0.290**	1.712± 0.025

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

APPENDIX B 8-3

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0086
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	32.6± 2.6	0.041± 0.007	0.009± 0.001	0.227± 0.016	0.153± 0.013	0.143± 0.006
50 ppm	10	33.0± 2.3	0.042± 0.006	0.009± 0.002	0.224± 0.016	0.152± 0.007	0.143± 0.003
115 ppm	10	32.6± 2.5	0.040± 0.004	0.009± 0.002	0.221± 0.021	0.153± 0.007	0.149± 0.017
265 ppm	10	30.9± 3.0	0.041± 0.006	0.008± 0.001	0.218± 0.019	0.151± 0.010	0.145± 0.004
609 ppm	10	27.3± 2.1**	0.036± 0.006	0.009± 0.001	0.210± 0.025	0.140± 0.011*	0.145± 0.010
1400 ppm	10	27.1± 0.9**	0.039± 0.005	0.011± 0.002*	0.210± 0.036	0.138± 0.008**	0.148± 0.008

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

STUDY NO. : 0086
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	0.437± 0.021	0.048± 0.005	1.199± 0.076	0.439± 0.010
50 ppm	10	0.425± 0.023	0.050± 0.005	1.268± 0.073	0.439± 0.011
115 ppm	10	0.429± 0.029	0.050± 0.005	1.329± 0.084	0.438± 0.010
265 ppm	10	0.520± 0.357	0.052± 0.007	1.355± 0.158*	0.425± 0.007*
609 ppm	10	0.377± 0.022**	0.052± 0.007	1.244± 0.144	0.433± 0.008
1400 ppm	10	0.374± 0.017**	0.053± 0.006	1.493± 0.148**	0.417± 0.014**

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

APPENDIX B 8-4

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0086
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	24.3± 2.4	0.047± 0.010	0.012± 0.002	0.029± 0.008	0.125± 0.008	0.136± 0.006
50 ppm	10	24.6± 2.8	0.051± 0.009	0.013± 0.002	0.031± 0.005	0.128± 0.013	0.141± 0.007
115 ppm	10	23.3± 2.0	0.044± 0.008	0.013± 0.001	0.029± 0.004	0.128± 0.010	0.145± 0.009
265 ppm	10	23.9± 1.8	0.044± 0.007	0.013± 0.001	0.032± 0.006	0.128± 0.007	0.139± 0.005
609 ppm	10	22.3± 1.8	0.043± 0.006	0.013± 0.001	0.032± 0.007	0.124± 0.006	0.142± 0.013
1400 ppm	10	22.6± 1.0	0.046± 0.008	0.013± 0.001	0.028± 0.006	0.120± 0.004	0.141± 0.010

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

STUDY NO. : 0086
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	0.290± 0.013	0.060± 0.005	1.002± 0.062	0.448± 0.014
50 ppm	10	0.297± 0.019	0.063± 0.006	1.016± 0.100	0.447± 0.009
115 ppm	10	0.299± 0.014	0.062± 0.005	1.029± 0.080	0.448± 0.011
265 ppm	10	0.297± 0.008	0.061± 0.008	1.078± 0.095	0.447± 0.012
609 ppm	10	0.271± 0.021	0.057± 0.004	1.076± 0.120	0.441± 0.014
1400 ppm	10	0.282± 0.009	0.057± 0.005	1.178± 0.121**	0.434± 0.014

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

APPENDIX B 9-1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0085
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	346± 12	0.078± 0.009	0.016± 0.001	0.859± 0.029	0.294± 0.013	0.306± 0.007
50 ppm	10	329± 25	0.080± 0.009	0.017± 0.001	0.912± 0.072	0.295± 0.019	0.308± 0.020
115 ppm	10	334± 16	0.077± 0.005	0.016± 0.001	0.896± 0.040	0.290± 0.011	0.304± 0.006
265 ppm	10	345± 12	0.073± 0.009	0.016± 0.001	0.864± 0.028	0.280± 0.011	0.305± 0.008
609 ppm	10	343± 14	0.073± 0.007	0.017± 0.001	0.887± 0.036	0.290± 0.010	0.308± 0.015
1400 ppm	10	324± 13*	0.077± 0.005	0.018± 0.002**	0.932± 0.037**	0.305± 0.012	0.317± 0.008

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

STUDY NO. : 0085
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	0.562± 0.012	0.169± 0.006	2.496± 0.118	0.554± 0.020
50 ppm	10	0.575± 0.038	0.173± 0.011	2.523± 0.089	0.579± 0.048
115 ppm	10	0.573± 0.017	0.172± 0.008	2.548± 0.090	0.563± 0.025
265 ppm	10	0.566± 0.015	0.173± 0.005	2.575± 0.095	0.540± 0.016
609 ppm	10	0.585± 0.012*	0.177± 0.007	2.675± 0.081**	0.543± 0.018
1400 ppm	10	0.641± 0.017**	0.179± 0.008	2.790± 0.127**	0.567± 0.022

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

APPENDIX B 9-2

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0085
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	194± 11	0.107± 0.009	0.031± 0.003	0.055± 0.005	0.348± 0.027	0.395± 0.018
50 ppm	10	188± 11	0.108± 0.007	0.033± 0.002	0.058± 0.009	0.351± 0.011	0.400± 0.015
115 ppm	10	185± 14	0.102± 0.009	0.032± 0.003	0.056± 0.007	0.352± 0.012	0.400± 0.022
265 ppm	10	185± 6	0.111± 0.008	0.032± 0.003	0.058± 0.005	0.356± 0.015	0.399± 0.014
609 ppm	10	193± 18	0.106± 0.010	0.031± 0.003	0.051± 0.009	0.349± 0.022	0.388± 0.031
1400 ppm	10	192± 11	0.111± 0.010	0.033± 0.003	0.059± 0.010	0.348± 0.020	0.406± 0.017

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

STUDY NO. : 0085
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	0.618± 0.024	0.205± 0.013	2.277± 0.132	0.903± 0.056
50 ppm	10	0.627± 0.019	0.203± 0.009	2.426± 0.089*	0.926± 0.052
115 ppm	10	0.637± 0.040	0.204± 0.014	2.423± 0.102*	0.938± 0.076
265 ppm	10	0.647± 0.025	0.203± 0.010	2.498± 0.117**	0.935± 0.034
609 ppm	10	0.625± 0.039	0.195± 0.020	2.502± 0.132**	0.895± 0.074
1400 ppm	10	0.669± 0.048**	0.203± 0.011	2.628± 0.068**	0.895± 0.052

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

APPENDIX B 9-3

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0086
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	32.6± 2.6	0.127± 0.018	0.027± 0.004	0.702± 0.081	0.469± 0.029	0.440± 0.026
50 ppm	10	33.0± 2.3	0.127± 0.012	0.027± 0.005	0.680± 0.062	0.462± 0.023	0.434± 0.027
115 ppm	10	32.6± 2.5	0.123± 0.011	0.026± 0.006	0.679± 0.081	0.471± 0.031	0.458± 0.043
265 ppm	10	30.9± 3.0	0.134± 0.016	0.026± 0.006	0.708± 0.078	0.491± 0.059	0.471± 0.040
609 ppm	10	27.3± 2.1**	0.132± 0.021	0.034± 0.006*	0.772± 0.102	0.513± 0.029*	0.534± 0.026**
1400 ppm	10	27.1± 0.9**	0.145± 0.018	0.039± 0.006**	0.777± 0.132	0.511± 0.036	0.549± 0.025**

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

STUDY NO. : 0086
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	1.346± 0.097	0.150± 0.020	3.688± 0.175	1.355± 0.105
50 ppm	10	1.289± 0.061	0.152± 0.012	3.848± 0.128	1.335± 0.087
115 ppm	10	1.316± 0.077	0.153± 0.013	4.079± 0.177	1.350± 0.104
265 ppm	10	1.730± 1.335	0.170± 0.031	4.373± 0.171**	1.385± 0.135
609 ppm	10	1.387± 0.081	0.191± 0.014**	4.551± 0.267**	1.596± 0.113**
1400 ppm	10	1.385± 0.088	0.197± 0.024**	5.521± 0.548**	1.541± 0.063**

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

APPENDIX B 9-4

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0086
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	24.3± 2.4	0.191± 0.024	0.051± 0.008	0.120± 0.031	0.515± 0.041	0.563± 0.056
50 ppm	10	24.6± 2.8	0.207± 0.026	0.052± 0.009	0.125± 0.019	0.520± 0.040	0.578± 0.056
115 ppm	10	23.3± 2.0	0.188± 0.031	0.058± 0.006	0.127± 0.025	0.551± 0.039	0.624± 0.045*
265 ppm	10	23.9± 1.8	0.183± 0.022	0.054± 0.003	0.136± 0.023	0.539± 0.041	0.587± 0.051
609 ppm	10	22.3± 1.8	0.195± 0.027	0.058± 0.005	0.141± 0.031	0.557± 0.032	0.635± 0.022**
1400 ppm	10	22.6± 1.0	0.206± 0.033	0.055± 0.006	0.125± 0.029	0.531± 0.029	0.624± 0.034*

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

STUDY NO. : 0086
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	1.201± 0.101	0.247± 0.026	4.136± 0.247	1.859± 0.209
50 ppm	10	1.215± 0.094	0.257± 0.031	4.143± 0.274	1.836± 0.186
115 ppm	10	1.289± 0.082	0.267± 0.010	4.423± 0.224	1.936± 0.171
265 ppm	10	1.247± 0.097	0.258± 0.033	4.509± 0.164*	1.880± 0.142
609 ppm	10	1.216± 0.032	0.258± 0.015	4.808± 0.184**	1.983± 0.138
1400 ppm	10	1.247± 0.057	0.254± 0.021	5.203± 0.416**	1.923± 0.087

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

APPENDIX B 10-1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name	Control				50 ppm				115 ppm				265 pp			
		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	inflammation:foreign body		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	osseous metaplasia		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	capsule hyperplasia		1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Circulatory system]																		
heart	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)
[Digestive system]																		
stomach	erosion		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)
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)
[Urinary system]																		
kidney	basophilic change		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	eosinophilic body		0 (0)	4 (40)	6 (60)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)	3 (30)	7 (70)	0 (0)	1 (10)	7 (70)	2 (20)	0 (0)

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

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name	609 ppm				1400 ppm			
		No. of Animals	10				10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]										
nasal cavit	inflammation:foreign body		1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
lung	osseous metaplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Hematopoietic system]										
spleen	capsule hyperplasia		1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Circulatory system]										
heart	granulation		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
[Digestive system]										
stomach	erosion		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
liver	herniation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Urinary system]										
kidney	basophilic change		3 (30)	0 (0)	0 (0)	0 (0)	2 (20)	1 (10)	0 (0)	0 (0)
	eosinophilic body		0 (0)	8 (80)	2 (20)	0 (0)	3 (30)	3 (30)	4 (40)	0 (0)

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

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name	Control				50 ppm				115 ppm				265 pp			
		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	Rathke pouch		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)
[Special sense organs/appandage]																		
Harder gl	lymphocytic infiltration		2 (20)	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)

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

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name	609 ppm				1400 ppm			
		No. of Animals	10				10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Endocrine system]										
pituitary	Rathke pouch		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Special sense organs/appandage]										
Harder gl	lymphocytic infiltration		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)

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

APPENDIX B 10-2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

Organ	Findings	Group Name	Control				50 ppm				115 ppm				265 pp			
		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	inflammation:foreign body		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)
larynx	inflammation		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	osseous metaplasia		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)
[Hematopoietic system]																		
bone marrow	granulation		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)
lymph node	granulation		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
spleen	deposit of hemosiderin		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	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)
[Urinary system]																		
kidney	mineralization:cortex		2 (20)	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)
[Endocrine system]																		
pituitary	Rathke pouch		1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

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

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

Organ	Findings	Group Name	609 ppm				1400 ppm			
		No. of Animals	10				10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]										
nasal cavit	inflammation:foreign body		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
larynx	inflammation		1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
lung	osseous metaplasia		1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Hematopoietic system]										
bone marrow	granulation		1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
lymph node	granulation		2 (20)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
spleen	deposit of hemosiderin		0 (0)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)
[Digestive system]										
liver	herniation		2 (20)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)
[Urinary system]										
kidney	mineralization:cortex		2 (20)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Endocrine system]										
pituitary	Rathke pouch		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

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

STUDY NO. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

Organ	Findings	Group Name	Control				50 ppm				115 ppm				265 pp			
		No. of Animals	10				10				10				10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Special sense organs/appandage]																		
Harder gl	lymphocytic infiltration		4 (40)	0 (0)	0 (0)	0 (0)	3 (30)	0 (0)	0 (0)	0 (0)	3 (30)	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. : 0085
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

Organ	Findings	Group Name	609 ppm				1400 ppm			
		No. of Animals	10				10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Special sense organs/appandage]										
Harder gl	Lymphocytic infiltration		3 (30)	0 (0)	0 (0)	0 (0)	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 B 10-3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : MALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name	Control				50 ppm				115 ppm				265 pp			
		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	thrombus		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)
[Hematopoietic system]																		
spleen	melanin		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]																		
liver	pigment		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	necrosis:focal		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	basophilic cell focus		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)
	swelling:central		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	8 (80)	0 (0)	0 (0)	0 ** (0)
[Urinary system]																		
kidney	vacuolic change		6 (60)	4 (40)	0 (0)	0 (0)	9 (90)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 ** (0)	0 (0)	0 (0)	0 (0)	0 ** (0)
	hydronephrosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)
	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)

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

Organ	Findings	Group Name	609 ppm				1400 ppm			
		No. of Animals	10				10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]										
lung	thrombus		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
[Hematopoiotic system]										
spleen	melanin		1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Digestive system]										
liver	pigment		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
	necrosis:focal		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
	basophilic cell focus		1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	swelling:central		10 (100)	0 (0)	0 (0)	0 ** (0)	0 (0)	10 (100)	0 (0)	0 ** (0)
[Urinary system]										
kidney	vacuolic change		0 (0)	0 (0)	0 (0)	0 ** (0)	0 (0)	0 (0)	0 (0)	0 ** (0)
	hydronephrosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	mineralization:papilla		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. : 0086
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name	Control				50 ppm				115 ppm				265 pp			
		No. of Animals	10				10				10				10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Urinary system]																		
kidney	regeneration proximal tubule		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)
	nuclear enlargement:proximal tubule		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)
urin bladd	inflammation		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)
[Endocrine system]																		
pituitary	cyst		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Rathke pouch		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	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. : 0086
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name	609 ppm				1400 ppm			
		No. of Animals	10				10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Urinary system]										
kidney	regeneration proximal tubule		1 (10)	0 (0)	0 (0)	0 (0)	5 (50)	0 (0)	0 (0)	0 * (0)
	nuclear enlargement:proximal tubule		9 (90)	0 (0)	0 (0)	0 ** (0)	10 (100)	0 (0)	0 (0)	0 ** (0)
urin bladd	inflammation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Endocrine system]										
pituitary	cyst		2 (20)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
	Rathke pouch		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

APPENDIX B 10-4

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : FEMALE : SACRIFICED ANIMALS

(13Week STUDY))

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

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

Organ	Findings	Group Name / No. of Animals	Control 10				50 ppm 10				115 ppm 10				265 pp 10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Hematopoietic system]																		
spleen	melanin		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Digestive system]																		
liver	pigment		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)
	granulation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	swelling:central		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	5 (50)	0 (0)	0 (0)	0 * (0)
[Urinary system]																		
kidney	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)
	regeneration proximal tubule		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)
	nuclear enlargement:proximal tubule		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (30)	0 (0)	0 (0)	0 (0)
[Endocrine system]																		
pituitary	cyst		2 (20)	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)
[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)

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

STUDY NO. : 0086
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

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

Organ	Findings	Group Name	609 ppm				1400 ppm			
		No. of Animals	10				10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Hematopoietic system]										
spleen	melanin		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Digestive system]										
liver	pigment		0 (0)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)
	granulation		1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	swelling:central		9 (90)	0 (0)	0 (0)	0 (0) **	0 (0)	10 (100)	0 (0)	0 (0) **
[Urinary system]										
kidney	granulation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	regeneration proximal tubule		0 (0)	0 (0)	0 (0)	0 (0)	6 (60)	0 (0)	0 (0)	0 (0) *
	nuclear enlargement:proximal tubule		10 (100)	0 (0)	0 (0)	0 (0) **	10 (100)	0 (0)	0 (0)	0 (0) **
[Endocrine system]										
pituitary	cyst		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)

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

APPENDIX B 11-1

IDENTITY AND PURITY OF TETRACHLOROETHYLENE

PERFORMED AT THE JAPAN BIOASSAY LABORATORY

(13Week STUDY)

INDENTITY AND PURITY OF TETRACHLOROETHYLENE PERFORMED AT THE JAPANBIOASSAY LABORATORY(THIRTEEN-WEEK STUDIES)

Lot no.WEN4459

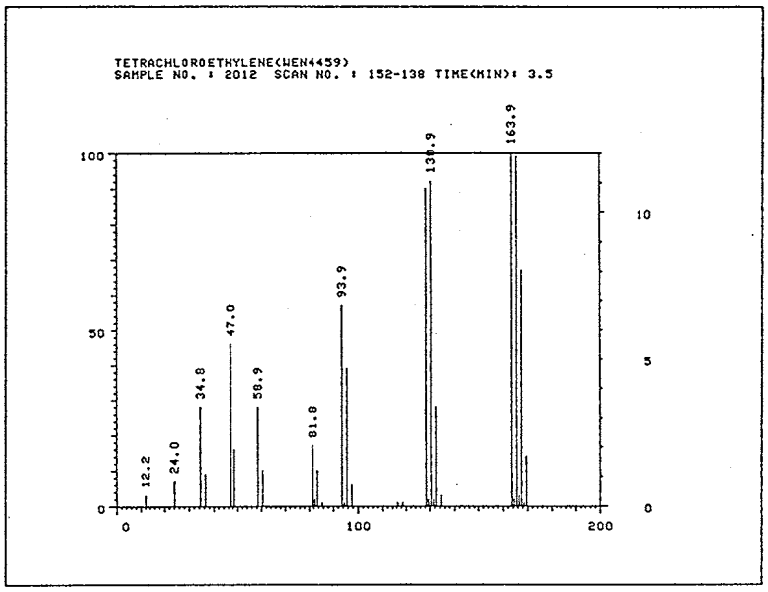
1. Spectral data

Mass Spectrometry

Instrument: Hitachi M-80B

Ionization: EI(Electron Ionization)

Ionization Voltage: 70eV



Mass Spectrum of TETRACHLOROETHYLENE

Result:

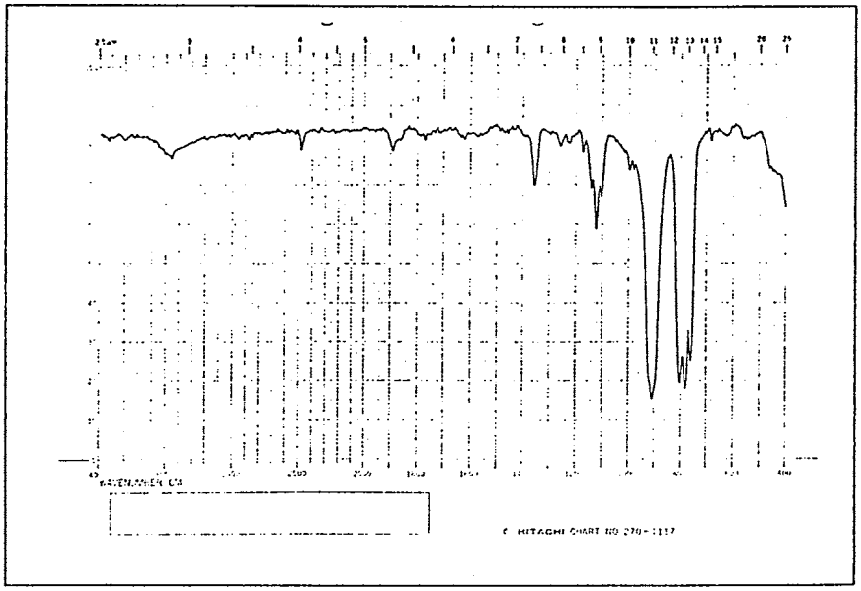
	Molecule Weight
Theory	165.8(JAPAN PHARMACOPOEIA X I)
	163.9(Calculated without isotope)
Determined	
Test Substance	163.9

Infrared

Instrument: Hitachi 270-30

Cell: Fixed Thickness Cell(NaCl)

Slit: Medium



Infrared Spectrum of TETRACHLOROETHYLENE

Results:

Determined	Literature Values
Wave Number (CM^{-1})	
Test Substance	Substance (Performed by the WAKO PURE CHEMICAL INDUSTRIES,LTD.)
750～ 820	750～ 820
860～ 950	860～ 950
1080～1180	1080～1180
1240～1280	1240～1280
1340～1380	1340～1380
1860～1920	1860～1920
2450～2500	2450～2500

2. Gas Chromatography

Instrument:	Hewlett Packard 5890A
Column:	Methyl Silicone(0.2mmϕ ×50m)
Column Temperature:	180°C
Flow Rate:	1ml/min
Detector:	FID(Hydrogen Flame Ionization)
Injection Volume:	1μl

Results: Major peak and two impurities

Peak No.	Retention Time(min)	Retention Time Relative to Maijor Peak	AREA (percent of major peak)
1	3.253	0.93	0.065
2	3.373	0.96	0.15
3	3.5	1.00	100

3. Conclusions: The results of the Mass spectra agreed with the theoretical values and the infrared spectra agreed with the Litrature values.
Gas chromtography indicated two impurities with areas totaling<0.3% of the major peak.

APPENDIX B 11-2

STABILITY OF TETRACHLOROETHYLENE AT THE JAPAN BIOASSAY LABORATORY

(13Week STUDY)

STABILITY OF TETRACHLOROETHYLENE AT THE JAPAN BIOASSAY LABORATORY
(THIRTEEN-WEEK STUDIES)

Lot no.WEN4459

1.Sample storage: Tetrachloroethylene were stored for about 4 month at 5°C.

	Previous determined of test (04/14/87)	After determined of test (08/18/87)

2.Spectral data

Infrared

Instrument: Hitachi 270-30

Cell: Fixed thickness Cell(NaCl)

Slit: Medium

Results:

Wave Number (CM^{-1})	
750～ 820	750～ 820
860～ 950	860～ 950
1080～1180	1080～1180
1240～1280	1240～1280
1340～1380	1340～1380
1860～1920	1860～1920
2450～2500	2450～2500

3.Gas Chromatography

Instrument: Hewlett Packard 5890A

Column: Methyl Silicone(0.2mmϕ ×50m)

Column Temperature: 180°C

Flow Rate: 1ml/min

Detector: FID(Hydrogen Flame Ionization)

Injection Volume: 1μl

Results: Major peak and two impurities

Date	Retention Time(min)	Retention Time Relative to Major Peak	Area (percent of Major peak)
04/14/87	3.253	0.93	0.065
	3.373	0.96	0.15
	3.5	1.00	100
08/18/87	3.247	0.93	0.062
	3.37	0.96	0.15
	3.498	1.00	100

4. Conclusions: Gas chlomatography indicates two impurities with areas totaling<0.3% of the major peak.The infrared spectra agreed with the previous determine of test values.

Consequently,Tetrachloroethylene was stable as the chemical when stored for about 4 month at temperatures to 5°C.

APPENDIX B 12-1

CONCENTRATION OF TETRACHLOROETHYLENE IN INHALATION CHAMBER

(13Week STUDY)

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

Group Name	Concentration(ppm) Mean	±	S.D.
Control	0.0	±	0.0
50ppm	50.1	±	2.1
115ppm	114.5	±	0.8
265ppm	263.7	±	1.1
609ppm	606.9	±	1.8
1400ppm	1401.2	±	11.7

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

Group Name	Concentration(ppm) Mean	±	S.D.
Control	0.0	±	0.0
50ppm	50.0	±	0.3
115ppm	115.0	±	1.0
265ppm	266.2	±	11.4
609ppm	607.4	±	4.0
1400ppm	1402.5	±	7.2

APPENDIX B 12-2

ENVIRONMENT OF INHALATION CHAMBER

(13Week STUDY)

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	24.1 ± 0.3	59.6 ± 1.0	263.4 ± 1.4	14.9
50ppm	23.8 ± 0.3	57.5 ± 0.8	262.5 ± 1.4	14.9
115ppm	24.6 ± 0.3	57.4 ± 1.5	263.3 ± 1.5	14.9
265ppm	24.5 ± 0.3	59.3 ± 1.4	266.1 ± 1.6	15.1
609ppm	24.5 ± 0.4	55.9 ± 1.7	263.3 ± 1.4	14.9
1400ppm	24.4 ± 0.3	56.7 ± 2.1	263.9 ± 1.4	14.9

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	23.1 ± 0.2	55.5 ± 2.7	131.2 ± 0.6	15.1
50ppm	23.1 ± 0.2	56.2 ± 0.9	131.2 ± 0.4	15.1
115ppm	23.2 ± 0.2	57.7 ± 1.0	130.9 ± 0.5	15.1
265ppm	23.3 ± 0.2	58.1 ± 1.1	132.1 ± 0.5	15.2
609ppm	24.0 ± 0.2	55.8 ± 1.0	130.6 ± 0.6	15.1
1400ppm	23.7 ± 0.2	56.6 ± 1.9	132.1 ± 0.7	15.2