１，１，１－トリ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 予 備 試 験 報 告 書

APPENDIX

（B1-1～C2）
13 週間試験：ラット/0166；マウス/0167

APPENDIXES (CONTINUED)

APPENDIX B 1-1 CLINICAL OBSERVATION (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:MALE

APPENDIX B 1-2 CLINICAL OBSERVATION (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:FEMALE

APPENDIX B 2-1 BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:MALE

APPENDIX B 2-2 BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:FEMALE

APPENDIX B 2-3 BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:MALE

APPENDIX B 2-4 BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:FEMALE

APPENDIX B 3-1 FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:MALE

APPENDIX B 3-2 FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:FEMALE

APPENDIX B 3-3 FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:MALE

APPENDIX B 3-4 FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:FEMALE

APPENDIX B 4-1 HEMATOLOGY (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:MALE

APPENDIX B 4-2 HEMATOLOGY (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:FEMALE

APPENDIX B 4-3 HEMATOLOGY (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:MALE

APPENDIX B 4-4 HEMATOLOGY (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:FEMALE

APPENDIXES (CONTINUED)

APPENDIX B 5-1 BIOCHEMISTRY (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:MALE

APPENDIX B 5-2 BIOCHEMISTRY (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:FEMALE

APPENDIX B 5-3 BIOCHEMISTRY (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:MALE

APPENDIX B 5-4 BIOCHEMISTRY (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:FEMALE

APPENDIX B 6-1 URINALYSIS (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:MALE

APPENDIX B 6-2 URINALYSIS (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:FEMALE

APPENDIX B 6-3 URINALYSIS (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:MALE

APPENDIX B 6-4 URINALYSIS (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:FEMALE

APPENDIX B 7-1 GROSS FINDINGS (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:MALE:SACRIFICED ANIMALS

APPENDIX B 7-2 GROSS FINDINGS (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:FEMALE:SACRIFICED ANIMALS

APPENDIX B 7-3 GROSS FINDINGS (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:MALE:DEAD AND MORIBUND ANIMALS

APPENDIX B 7-4 GROSS FINDINGS (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:MALE:SACRIFICED ANIMALS

APPENDIX B 7-5 GROSS FINDINGS (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:FEMALE:SACRIFICED ANIMALS

APPENDIX B 7-6 GROSS FINDINGS (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:MALE:DEAD AND MORIBUND ANIMALS

APPENDIX B 7-7 GROSS FINDINGS (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:FEMALE:DEAD AND MORIBUND ANIMALS

APPENDIXES (CONTINUED)

APPENDIX B 8-1 ORGAN WEIGHT (THIRTEEN-WEEK STUDY:SUMMARY),ABSOLUTE
RAT:MALE

APPENDIX B 8-2 ORGAN WEIGHT (THIRTEEN-WEEK STUDY:SUMMARY),ABSOLUTE
RAT:FEMALE

APPENDIX B 8-3 ORGAN WEIGHT (THIRTEEN-WEEK STUDY:SUMMARY),ABSOLUTE
MOUSE:MALE

APPENDIX B 8-4 ORGAN WEIGHT (THIRTEEN-WEEK STUDY:SUMMARY),ABSOLUTE
MOUSE:FEMALE

APPENDIX B 9-1 ORGAN WEIGHT (THIRTEEN-WEEK STUDY:SUMMARY),RELATIVE
RAT:MALE

APPENDIX B 9-2 ORGAN WEIGHT (THIRTEEN-WEEK STUDY:SUMMARY),RELATIVE
RAT:FEMALE

APPENDIX B 9-3 ORGAN WEIGHT (THIRTEEN-WEEK STUDY:SUMMARY),RELATIVE
MOUSE:MALE

APPENDIX B 9-4 ORGAN WEIGHT (THIRTEEN-WEEK STUDY:SUMMARY),RELATIVE
MOUSE:FEMALE

APPENDIX B 10-1 HISTOLOGICAL FINDINGS:NON-NEOPLASTIC LESIONS (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:MALE:SACRIFICED ANIMALS

APPENDIX B 10-2 HISTOLOGICAL FINDINGS:NON-NEOPLASTIC LESIONS (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:FEMALE:SACRIFICED ANIMALS

APPENDIX B 10-3 HISTOLOGICAL FINDINGS:NON-NEOPLASTIC LESIONS (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:MALE:DEAD AND MORIBUND ANIMALS

APPENDIX B 10-4 HISTOLOGICAL FINDINGS:NON-NEOPLASTIC LESIONS (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:MALE:SACRIFICED ANIMALS

APPENDIX B 10-5 HISTOLOGICAL FINDINGS:NON-NEOPLASTIC LESIONS (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:FEMALE:SACRIFICED ANIMALS

APPENDIX B 10-6 HISTOLOGICAL FINDINGS:NON-NEOPLASTIC LESIONS (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:MALE:DEAD AND MORIBUND ANIMALS

APPENDIX B 10-7 HISTOLOGICAL FINDINGS:NON-NEOPLASTIC LESIONS (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:FEMALE:DEAD AND MORIBUND ANIMALS

APPENDIXES (CONTINUED)

APPENDIX B 11-1 IDENTITY AND PURITY OF 1,1,1-TRICHLOROETHANE (THIRTEEN-WEEK STUDIES)

APPENDIX B 11-2 STABILITY OF 1,1,1-TRICHLOROETHANE (THIRTEEN-WEEK STUDIES)

APPENDIX B 12-1 CONCENTRATION OF 1,1,1-TRICHLOROETHANE IN INHALATION CHAMBER (THIRTEEN-WEEK STUDIES)

APPENDIX B 12-2 ENVIRONMENT OF INHALATION CHAMBER (THIRTEEN-WEEK STUDIES)

APPENDIX C 1 METHODS FOR HEMATOLOGY,BIOCHEMISTRY AND URINALYSIS

APPENDIX C 2 UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY

APPENDIX B 1-1

CLINICAL OBSERVATION : SUMMARY, MOSUE : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
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
LOSS OF HAIR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	6700 ppm	0	0	0	0	0	0	0	0	0	1	1	1	0	0
	10000 ppm	0	0	-	-	-	-	-	-	-	-	-	-	-	-
	15000 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-

APPENDIX B 1-2

CLINICAL OBSERVATION : SUMMARY, MOSUE: FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
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	0	0	0	0	0	0	2	2	3	3	3	3	3
	3000 ppm	0	0	0	0	0	0	0	1	1	1	1	1	0	0
	4400 ppm	0	0	0	0	0	0	0	0	1	1	1	1	0	0
	6700 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-
	15000 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-

APPENDIX B 2-1

BODY WEIGHT CHANGES :SUMMARY, RAT : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
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	132± 5	163± 8	195± 11	221± 12	242± 12	257± 15	273± 18
2000 ppm	132± 5	159± 7	189± 11	216± 11	235± 12	252± 13	266± 12
3000 ppm	131± 6	158± 10	189± 13	217± 15	238± 17	256± 18	270± 18
4400 ppm	132± 5	153± 8*	182± 9	202± 10**	219± 11**	233± 10**	244± 9**
6700 ppm	132± 5	145± 8**	171± 13**	193± 16**	211± 20**	225± 21**	233± 21**
10000 ppm	132± 5	131± 5**	144± 7**	159± 8**	173± 11**	184± 14**	191± 16**

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

STUDY NO. : 0166
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	288± 18	304± 19	315± 18	322± 18	329± 17	337± 20	343± 19
2000 ppm	278± 12	293± 12	303± 13	310± 14	317± 14	323± 16	332± 16
3000 ppm	283± 20	297± 24	305± 27	315± 30	318± 31	328± 30	333± 32
4400 ppm	255± 11**	268± 12**	275± 12**	282± 13**	287± 12**	296± 13**	299± 13**
6700 ppm	245± 23**	253± 23**	262± 23**	270± 23**	276± 23**	282± 23**	287± 24**
10000 ppm	199± 16**	207± 17**	218± 17**	225± 19**	233± 19**	239± 19**	243± 19**

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

APPENDIX B 2-2

BODY WEIGHT CHANGES : SUMMARY, RAT : FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
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	105± 4	121± 5	133± 5	141± 7	147± 6	154± 7	162± 8
2000 ppm	106± 5	120± 6	134± 7	146± 8	154± 11	159± 11	166± 12
3000 ppm	105± 5	119± 6	132± 6	143± 8	151± 8	154± 9	160± 10
4400 ppm	106± 5	117± 8	131± 10	143± 10	149± 10	156± 10	161± 10
6700 ppm	105± 5	113± 4*	127± 6	139± 6	146± 6	152± 7	157± 8
10000 ppm	105± 5	109± 8**	119± 9**	128± 10**	137± 10	143± 11*	149± 11*

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

STUDY NO. : 0166
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	168± 8	177± 9	181± 9	184± 8	186± 9	191± 9	194± 10
2000 ppm	170± 12	175± 12	180± 14	181± 14	186± 16	188± 15	189± 17
3000 ppm	164± 10	168± 12	172± 12	175± 14	178± 14	181± 13	181± 14
4400 ppm	163± 12	168± 11	171± 12	175± 13	177± 12	179± 12	179± 12
6700 ppm	162± 8	165± 8	168± 8*	170± 7*	171± 9*	174± 9*	176± 9*
10000 ppm	154± 11*	157± 12**	161± 12**	165± 12**	169± 13*	170± 13**	173± 15**

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

APPENDIX B 2-3

BODY WEIGHT CHANGES :SUMMARY, MOSUE : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
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	23.7± 0.8	25.1± 0.9	25.9± 0.8	26.6± 1.0	27.5± 0.9	28.4± 1.1	29.4± 1.1
3000 ppm	23.7± 0.8	25.0± 1.2	25.6± 1.1	25.8± 1.4	26.0± 1.3*	27.0± 1.3*	27.5± 1.5**
4400 ppm	23.7± 0.8	24.6± 0.9	25.9± 0.8	26.4± 0.9	26.8± 1.0	27.7± 1.0	28.2± 1.1
6700 ppm	23.7± 0.8	23.4± 1.0**	25.1± 0.8	25.9± 0.7	26.3± 0.8*	27.2± 1.0	27.8± 0.9**
10000 ppm	23.7± 0.8	22.1± 1.2 ?	-	-	-	-	-
15000 ppm	23.7± 0.8	-	-	-	-	-	-

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

? : Significant test is not applied,because No. of data in this group is less than 3.

STUDY NO. : 0167
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	30.1± 1.2	30.9± 1.5	31.4± 1.5	32.4± 1.9	33.3± 1.7	34.4± 1.8	34.9± 1.8
3000 ppm	27.7± 1.4**	28.6± 1.5**	29.2± 1.4**	29.9± 1.5**	30.7± 1.4**	31.2± 1.3**	32.2± 1.3**
4400 ppm	28.5± 1.2*	29.3± 1.3*	30.0± 1.5	30.8± 1.7	31.2± 1.6**	32.2± 1.7**	32.4± 1.8**
6700 ppm	28.3± 1.2**	28.9± 1.0**	29.6± 0.8*	29.9± 0.9**	30.4± 1.2**	31.2± 1.3**	31.4± 1.4**
10000 ppm	-	-	-	-	-	-	-
15000 ppm	-	-	-	-	-	-	-

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

APPENDIX B 2-4

BODY WEIGHT CHANGES : SUMMARY, MOSUE: FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
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	19.1± 0.6	20.8± 0.7	21.8± 1.1	22.0± 1.1	22.8± 0.6	23.1± 0.8	24.4± 1.1
3000 ppm	19.1± 0.6	20.3± 0.5	21.2± 1.6	22.1± 0.7	22.9± 0.8	23.7± 0.9	24.4± 0.5
4400 ppm	19.1± 0.6	20.1± 0.7	21.5± 0.7	22.1± 1.0	22.5± 0.7	23.3± 0.9	23.7± 1.0
6700 ppm	19.1± 0.6	19.7± 0.7**	21.2± 1.0	22.5± 1.1	23.4± 0.9	24.0± 1.1	24.6± 1.1
10000 ppm	19.1± 0.6	-	-	-	-	-	-
15000 ppm	19.1± 0.6	-	-	-	-	-	-

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

STUDY NO. : 0167
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	24.3± 0.9	25.0± 0.8	25.4± 1.4	25.5± 1.0	26.3± 1.3	26.4± 0.7	26.9± 1.3
3000 ppm	24.6± 0.9	24.9± 1.0	25.2± 1.0	25.7± 1.1	26.5± 1.2	27.0± 1.0	26.9± 1.3
4400 ppm	24.6± 0.6	25.0± 1.0	25.5± 1.2	25.9± 1.3	25.9± 1.2	26.8± 1.1	26.9± 1.2
6700 ppm	25.0± 1.3	25.5± 1.2	26.1± 0.8	26.5± 1.0	27.2± 1.0	27.1± 1.4	27.4± 1.1
10000 ppm	-	-	-	-	-	-	-
15000 ppm	-	-	-	-	-	-	-

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

APPENDIX B 3-1

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
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	16.0± 1.1	17.7± 1.2	18.8± 1.3	18.0± 1.2	17.6± 1.1	18.1± 1.6	18.1± 1.4
2000 ppm	15.2± 0.8	17.1± 1.2	18.7± 1.8	18.6± 1.7	18.5± 1.4	18.1± 1.1	17.6± 0.9
3000 ppm	15.5± 1.0	17.3± 1.0	19.4± 1.3	18.6± 1.1	18.6± 1.4	18.0± 1.3	18.2± 1.1
4400 ppm	14.3± 0.6**	16.5± 1.0	17.9± 0.9	16.9± 0.8	17.2± 0.7	17.2± 0.3	17.2± 0.6
6700 ppm	12.7± 0.5**	15.2± 1.3**	16.6± 1.2**	16.8± 1.6	17.2± 1.4	16.4± 1.0*	16.9± 1.2
10000 ppm	10.7± 0.6**	12.1± 0.7**	13.0± 0.9**	13.5± 1.3**	14.3± 1.5**	13.9± 1.7**	14.2± 1.5**

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

STUDY NO. : 0166
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	18.2± 1.6	18.1± 1.2	18.3± 1.0	18.3± 1.0	17.5± 1.3	18.2± 0.9
2000 ppm	17.9± 1.0	17.9± 1.0	18.1± 1.3	17.9± 1.2	17.0± 1.5	17.8± 1.3
3000 ppm	18.5± 1.5	18.6± 1.9	18.5± 1.5	18.2± 1.7	17.7± 1.9	17.7± 1.7
4400 ppm	17.1± 0.9	17.0± 0.9	17.6± 1.0	17.0± 0.7	16.6± 0.8	16.7± 0.6
6700 ppm	16.6± 1.0*	16.6± 1.0	17.1± 1.1	16.7± 1.0*	16.6± 1.2	16.6± 1.3*
10000 ppm	14.6± 1.8**	14.6± 1.9**	14.7± 2.0**	14.7± 1.4**	15.2± 1.3**	14.8± 1.6**

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

APPENDIX B 3-2

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
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	12.5± 0.7	12.9± 0.6	12.4± 0.8	12.7± 0.5	12.7± 0.6	12.4± 0.7	12.4± 0.8
2000 ppm	11.9± 0.8	12.7± 0.9	13.0± 1.0	13.5± 1.3	13.2± 1.4	12.4± 1.1	12.4± 1.0
3000 ppm	11.9± 0.6	12.5± 0.9	13.1± 1.0	12.6± 0.8	12.2± 1.0	11.8± 0.9	11.7± 1.3
4400 ppm	11.6± 0.6*	12.7± 0.7	13.1± 1.0	12.2± 0.8	12.7± 0.5	12.0± 0.6	11.7± 0.7
6700 ppm	10.6± 0.3**	12.0± 0.6	12.5± 0.9	12.1± 0.6	12.2± 0.6	12.0± 0.6	11.9± 0.5
10000 ppm	9.7± 0.8**	10.7± 1.0**	11.4± 1.2	11.7± 0.7	11.8± 1.0	11.8± 0.8	11.8± 0.7

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

STUDY NO. : 0166
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	12.9± 1.0	12.7± 0.8	12.3± 1.3	12.9± 1.7	12.4± 0.6	13.1± 1.4
2000 ppm	12.3± 1.1	12.4± 1.4	12.1± 1.1	12.3± 1.3	12.5± 1.3	12.1± 1.3
3000 ppm	12.0± 1.2	11.9± 1.1	11.7± 1.3	11.7± 1.4	11.7± 1.5	10.9± 1.3*
4400 ppm	11.8± 0.6*	12.0± 0.7	12.3± 0.8	11.7± 0.9	11.7± 0.7	11.2± 0.6*
6700 ppm	12.0± 0.4	11.8± 0.5	12.1± 0.5	11.3± 0.8	11.7± 0.9	11.6± 0.6
10000 ppm	11.8± 0.6*	11.5± 0.5**	11.9± 0.7	11.8± 0.7	11.6± 0.9	11.2± 0.9**

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

APPENDIX B 3-3

FOOD CONSUMPTION CHANGES : SUMMARY, MOSUE : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
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	4.5± 0.2	4.3± 0.2	4.4± 0.2	4.6± 0.3	4.7± 0.2	4.8± 0.2	4.7± 0.3
3000 ppm	4.5± 0.3	4.4± 0.3	4.4± 0.3	4.6± 0.4	4.6± 0.3	4.9± 0.4	4.7± 0.3
4400 ppm	4.6± 0.3	4.5± 0.3	4.4± 0.3	4.6± 0.3	4.7± 0.2	4.6± 0.1	4.6± 0.2
6700 ppm	4.1± 0.3*	4.4± 0.1	4.4± 0.2	4.5± 0.2	4.6± 0.3	4.5± 0.1*	4.4± 0.3
10000 ppm	4.7± 0.9	5.6± 0.7 ?	-	-	-	-	-
15000 ppm	-	-	-	-	-	-	-

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

? : Significant test is not applied,because No. of data in this group is less than 3.

STUDY NO. : 0167
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	4.8± 0.3	4.9± 0.2	5.0± 0.3	4.9± 0.2	5.0± 0.2	4.9± 0.3
3000 ppm	4.8± 0.5	5.2± 0.4	5.3± 0.5	5.2± 0.4	5.2± 0.4	5.1± 0.4
4400 ppm	4.7± 0.2	5.1± 0.2	5.2± 0.4	5.1± 0.8	5.2± 0.2	5.0± 0.2
6700 ppm	4.6± 0.1	4.9± 0.2	4.9± 0.2	4.8± 0.2	4.9± 0.2	4.7± 0.2
10000 ppm	-	-	-	-	-	-
15000 ppm	-	-	-	-	-	-

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

APPENDIX B 3-4

FOOD CONSUMPTION CHANGES : SUMMARY, MOSUE : FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
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	4.0± 0.3	4.1± 0.3	4.2± 0.4	4.6± 0.3	4.7± 0.3	4.8± 0.4	4.9± 0.3
3000 ppm	4.2± 0.2	4.0± 0.4	4.3± 0.3	4.5± 0.4	4.6± 0.3	4.8± 0.4	4.8± 0.4
4400 ppm	4.1± 0.1	4.0± 0.2	4.0± 0.2	4.3± 0.2	4.4± 0.2	4.5± 0.3	4.6± 0.2
6700 ppm	3.8± 0.7	4.1± 0.3	4.2± 0.2	4.4± 0.2	4.5± 0.2	4.5± 0.3	4.5± 0.2*
10000 ppm	4.5± 0.5	-	-	-	-	-	-
15000 ppm	-	-	-	-	-	-	-

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

STUDY NO. : 0167
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	4.9± 0.4	5.1± 0.4	5.1± 0.3	5.0± 0.3	4.8± 0.3	5.0± 0.3
3000 ppm	4.9± 0.3	5.2± 0.5	5.1± 0.4	5.0± 0.5	5.2± 0.6	5.1± 0.6
4400 ppm	4.7± 0.2	5.0± 0.4	5.2± 0.4	4.9± 0.4	5.1± 0.4	5.0± 0.3
6700 ppm	4.5± 0.3*	5.0± 0.3	5.0± 0.2	5.0± 0.3	4.9± 0.4	4.7± 0.3
10000 ppm	-	-	-	-	-	-
15000 ppm	-	-	-	-	-	-

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

APPENDIX B 4-1

HEMATOLOGY : SUMMARY, RAT : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (14)

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	9.39± 0.20	16.0± 0.3	44.0± 1.0	46.8± 0.7	17.1± 0.4	36.5± 0.5	713± 37
2000 ppm	10	9.48± 0.21	15.9± 0.3	43.8± 1.1	46.2± 0.5	16.8± 0.4	36.3± 0.7	740± 24
3000 ppm	10	9.42± 0.15	15.8± 0.3	43.5± 0.8	46.1± 0.6*	16.8± 0.3	36.4± 0.8	764± 79
4400 ppm	8	9.43± 0.28	16.0± 0.4	43.8± 1.4	46.4± 0.5	16.9± 0.5	36.4± 1.0	716± 59
6700 ppm	10	9.40± 0.30	16.2± 0.4	44.3± 1.5	47.1± 0.6	17.2± 0.4	36.5± 0.7	733± 38
10000 ppm	7	9.24± 0.23	16.0± 0.2	43.3± 0.7	46.9± 0.6	17.3± 0.4	36.8± 0.7	707± 46

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

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (14)

Group Name	NO. of Animals	WBC $10^3/\mu\ell$	Differential WBC (%) N-BAND	N-SEG	EOSINO	BASO	MONO	LYMPHO	OTHERS
Control	10	4.12± 1.50	0± 0	14± 4	2± 1	0± 0	2± 2	82± 5	0± 0
2000 ppm	10	4.41± 1.23	0± 0	14± 4	2± 1	0± 0	3± 1	82± 4	0± 0
3000 ppm	10	4.76± 1.72	0± 0	16± 5	1± 1	0± 0	4± 1	79± 5	0± 0
4400 ppm	8	3.60± 1.80	0± 0	15± 4	2± 2	0± 0	3± 0	80± 5	0± 0
6700 ppm	10	5.24± 1.94	0± 0	14± 4	1± 1	0± 0	2± 1	83± 4	0± 0
10000 ppm	7	3.29± 0.37	0± 0	23± 9**	1± 1	0± 0	3± 1	74± 9*	0± 0

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

APPENDIX B 4-2

HEMATOLOGY : SUMMARY, RAT : FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (14)

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	8.60± 0.38	15.9± 0.6	43.4± 1.8	50.4± 0.9	18.5± 0.4	36.6± 0.8	695± 119
2000 ppm	10	8.67± 0.42	15.7± 0.5	43.0± 2.5	49.5± 0.8	18.1± 0.4	36.6± 1.1	748± 73
3000 ppm	9	8.69± 0.25	15.8± 0.4	42.4± 1.2	48.8± 0.6**	18.1± 0.5	37.2± 0.7	758± 56
4400 ppm	10	8.70± 0.22	15.9± 0.3	42.6± 1.1	49.0± 0.6**	18.3± 0.3	37.4± 0.5	758± 86
6700 ppm	9	8.80± 0.29	15.8± 0.4	42.8± 1.6	48.6± 0.6**	18.0± 0.3	37.0± 0.8	760± 88
10000 ppm	10	8.93± 0.34	15.7± 0.2	42.3± 0.7	47.4± 1.3**	17.6± 0.7**	37.1± 0.8	716± 126

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

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (14)

Group Name	NO. of Animals	WBC $10^3/\mu\ell$	Differential WBC (%) N-BAND	N-SEG	EOSINO	BASO	MONO	LYMPHO	OTHERS
Control	10	2.33± 1.17	0± 0	15± 3	2± 1	0± 0	3± 1	81± 3	0± 0
2000 ppm	10	2.16± 0.76	0± 0	16± 5	2± 1	0± 0	3± 1	79± 5	0± 0
3000 ppm	9	2.85± 2.00	0± 0	13± 2	2± 1	0± 0	3± 2	82± 3	0± 0
4400 ppm	10	1.98± 0.63	0± 0	15± 7	2± 1	0± 0	3± 1	81± 8	0± 0
6700 ppm	9	2.11± 0.66	0± 0	17± 5	2± 1	0± 0	3± 1	78± 4	0± 0
10000 ppm	10	2.36± 0.82	0± 0	17± 5	2± 1	0± 0	3± 1	78± 5	0± 0

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

APPENDIX B 4-3

HEMATOLOGY : SUMMARY, MOSUE : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (14)

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	11.15± 0.20	16.3± 0.3	49.2± 0.9	44.2± 0.7	14.6± 0.2	33.1± 0.5	1514± 91
3000 ppm	10	11.15± 0.44	16.4± 0.6	49.7± 2.3	44.6± 1.3	14.7± 0.1	33.0± 1.0	1497± 106
4400 ppm	10	11.13± 0.27	16.5± 0.4	49.4± 1.3	44.4± 0.6	14.8± 0.2	33.4± 0.2	1561± 123
6700 ppm	9	11.07± 0.21	16.4± 0.3	49.8± 1.3	45.0± 0.6	14.8± 0.2	33.0± 0.5	1527± 99
10000 ppm	0	-	-	-	-	-	-	-
15000 ppm	0	-	-	-	-	-	-	-

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

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (14)

Group Name	NO. of Animals	WBC $10^3/\mu\ell$	Differential WBC (%) N-BAND	N-SEG	EOSINO	BASO	MONO	LYMPHO	OTHERS
Control	9	1.47± 0.73	0± 0	18± 3	2± 1	0± 0	2± 1	78± 4	0± 0
3000 ppm	10	1.70± 0.88	0± 0	16± 3	2± 1	0± 0	3± 1	79± 2	0± 0
4400 ppm	10	1.64± 0.95	0± 0	17± 3	2± 1	0± 0	2± 2	79± 4	0± 0
6700 ppm	9	1.40± 0.62	0± 0	16± 4	2± 1	0± 0	2± 2	80± 5	0± 0
10000 ppm	0	-	-	-	-	-	-	-	-
15000 ppm	0	-	-	-	-	-	-	-	-

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

(HCL071)

APPENDIX B 4-4

HEMATOLOGY : SUMMARY, MOSUE : FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (14)

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	10.84± 0.26	16.2± 0.4	47.0± 1.1	43.4± 0.3	14.9± 0.3	34.4± 0.8	1357± 107
3000 ppm	10	10.99± 0.29	16.3± 0.5	47.7± 1.5	43.4± 0.7	14.9± 0.2	34.3± 0.6	1324± 92
4400 ppm	10	10.81± 0.33	16.5± 0.4	47.0± 1.9	43.5± 0.8	15.3± 0.3*	35.2± 0.9	1385± 80
6700 ppm	8	10.95± 0.19	16.7± 0.3*	48.3± 1.1	44.1± 0.6	15.2± 0.2	34.6± 0.7	1320± 179
10000 ppm	0	-	-	-	-	-	-	-
15000 ppm	0	-	-	-	-	-	-	-

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

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (14)

Group Name	NO. of Animals	WBC $10^3/\mu\ell$	Differential WBC (%) N-BAND	N-SEG	EOSINO	BASO	MONO	LYMPHO	OTHERS
Control	10	1.39± 0.82	0± 0	22± 6	1± 1	0± 0	2± 1	75± 6	0± 0
3000 ppm	10	1.66± 1.09	0± 0	18± 5	2± 1	0± 0	2± 1	79± 5	0± 0
4400 ppm	10	1.72± 1.02	0± 0	18± 5	2± 1	0± 0	2± 1	79± 6	0± 0
6700 ppm	8	1.51± 0.61	0± 0	19± 3	2± 1	0± 0	2± 2	77± 4	0± 0
10000 ppm	0	-	-	-	-	-	-	-	-
15000 ppm	0	-	-	-	-	-	-	-	-

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

APPENDIX B 5-1

BIOCHEMISTRY : SUMMARY, RAT : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (14)

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	7.0± 0.2	3.9± 0.1	1.3± 0.1	0.23± 0.04	187± 18	62± 5	109± 22
2000 ppm	10	6.9± 0.2	3.9± 0.1	1.3± 0.1	0.24± 0.05	180± 11	65± 4	110± 35
3000 ppm	10	7.0± 0.3	3.9± 0.1	1.3± 0.1	0.22± 0.03	170± 13	65± 8	94± 24
4400 ppm	8	7.0± 0.3	3.9± 0.2	1.3± 0.1	0.24± 0.02	175± 12	57± 5	85± 30
6700 ppm	10	7.1± 0.2	3.9± 0.1	1.2± 0.1	0.23± 0.02	175± 18	63± 6	80± 20
10000 ppm	7	6.9± 0.3	3.9± 0.1	1.3± 0.1	0.23± 0.05	158± 13**	67± 10	55± 11**

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

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (14)

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	120± 8	78± 10	28± 5	150± 29	301± 21	1± 1	86± 15
2000 ppm	10	122± 11	84± 16	31± 10	163± 31	279± 15*	1± 1	84± 9
3000 ppm	10	119± 10	75± 21	24± 7	163± 57	269± 14**	1± 1	86± 16
4400 ppm	8	106± 9*	69± 8	23± 3	153± 30	265± 13**	1± 1	89± 14
6700 ppm	10	114± 10	57± 5**	19± 2**	154± 62	263± 22**	1± 1	95± 22
10000 ppm	7	119± 15	56± 6**	19± 4*	154± 44	273± 14**	1± 1	94± 19

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

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (14)

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	18.8± 1.1	0.5± 0.1	144± 2	3.6± 0.3	105± 1	10.4± 0.2	5.5± 1.2
2000 ppm	10	18.4± 2.2	0.5± 0.1	144± 1	3.8± 0.3	104± 1	10.5± 0.2	5.6± 0.8
3000 ppm	10	17.3± 1.1	0.5± 0.0	143± 1	3.7± 0.3	104± 1	10.5± 0.3	5.5± 0.7
4400 ppm	8	17.8± 1.5	0.5± 0.0	143± 1	3.6± 0.3	105± 1	10.3± 0.3	5.8± 0.9
6700 ppm	10	16.8± 1.4*	0.5± 0.0	144± 1	3.8± 0.3	106± 2	10.5± 0.2	6.1± 1.1
10000 ppm	7	15.9± 1.5**	0.4± 0.0	144± 1	3.9± 0.5	107± 1	10.4± 0.3	6.1± 0.8

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

APPENDIX B 5-2

BIOCHEMISTRY : SUMMARY, RAT : FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (14)

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	0.27± 0.14	131± 13	78± 8	40± 6
2000 ppm	10	6.5± 0.3	3.6± 0.2	1.3± 0.1	0.25± 0.10	134± 11	80± 7	39± 5
3000 ppm	9	6.4± 0.1	3.5± 0.1	1.2± 0.1	0.24± 0.06	139± 9	73± 6	38± 7
4400 ppm	10	6.4± 0.2	3.5± 0.1	1.2± 0.1	0.24± 0.04	137± 6	72± 6	38± 6
6700 ppm	9	6.4± 0.2	3.5± 0.1*	1.2± 0.1	0.27± 0.07	133± 10	71± 7	36± 7
10000 ppm	10	6.4± 0.2	3.5± 0.1	1.2± 0.1	0.27± 0.10	129± 11	73± 14	35± 5

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

(HCL074)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (14)

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	144± 17	71± 22	24± 13	270± 164	220± 23	1± 1	110± 35
2000 ppm	10	147± 11	65± 12	19± 6	273± 183	206± 22	1± 1	119± 49
3000 ppm	9	138± 13	63± 7	21± 5	194± 46	208± 20	2± 1	98± 14
4400 ppm	10	135± 9	57± 4	16± 2	164± 41	212± 19	1± 1	89± 16
6700 ppm	9	132± 13	54± 5*	15± 2*	190± 54	224± 25	1± 1	98± 23
10000 ppm	10	132± 25	56± 4	14± 1**	284± 90	226± 32	2± 1	123± 23

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

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (14)

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	18.3± 1.9	0.5± 0.0	143± 2	3.7± 0.6	108± 2	10.0± 0.5	5.1± 1.6
2000 ppm	10	17.2± 1.6	0.5± 0.0	144± 2	3.6± 0.4	109± 2	9.9± 0.3	4.8± 0.8
3000 ppm	9	16.9± 1.9	0.4± 0.1	143± 1	3.6± 0.2	108± 1	9.8± 0.2	5.2± 0.8
4400 ppm	10	17.0± 2.1	0.5± 0.1	143± 1	3.5± 0.3	108± 1	9.8± 0.2	4.8± 0.8
6700 ppm	9	17.1± 2.2	0.5± 0.1	144± 1	3.8± 0.1	109± 1	9.9± 0.1	5.0± 1.0
10000 ppm	10	16.4± 2.5	0.4± 0.1	144± 2	4.0± 0.4	109± 2	9.9± 0.3	5.9± 1.2

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

APPENDIX B 5-3

BIOCHEMISTRY : SUMMARY, MOSUE : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (14)

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	9	5.3± 0.2	2.8± 0.1	1.1± 0.1	0.33± 0.12	231± 42	81± 8	63± 14
3000 ppm	10	5.2± 0.3	2.8± 0.2	1.2± 0.1	0.30± 0.06	179± 45	72± 10	42± 6**
4400 ppm	10	5.3± 0.2	2.8± 0.1	1.2± 0.0	0.30± 0.05	206± 42	78± 7	49± 11*
6700 ppm	9	5.4± 0.1	2.9± 0.1	1.2± 0.0	0.33± 0.08	200± 37	80± 9	45± 7**
10000 ppm	0	-	-	-	-	-	-	-
15000 ppm	0	-	-	-	-	-	-	-

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

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (14)

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	9	46± 4	10± 1	245± 71	183± 16	74± 45	28.1± 6.9	155± 3
3000 ppm	10	51± 9	12± 1	241± 45	195± 14	74± 50	29.1± 4.1	156± 2
4400 ppm	10	44± 4	11± 2	228± 36	183± 14	54± 21	26.8± 4.0	157± 4
6700 ppm	9	50± 17	12± 1	261± 46	181± 14	74± 28	27.4± 2.7	157± 3
10000 ppm	0	-	-	-	-	-	-	-
15000 ppm	0	-	-	-	-	-	-	-

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

(HCL074)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (14)

Group Name	NO. of Animals	POTASSIUM mEq/ℓ	CHLORIDE mEq/ℓ	CALCIUM mg/dℓ	INORGANIC PHOSPHORUS mg/dℓ
Control	9	4.8± 0.6	123± 1	8.7± 0.3	7.6± 1.2
3000 ppm	10	4.7± 0.8	124± 2	8.8± 0.5	7.4± 1.6
4400 ppm	10	4.5± 0.6	123± 3	8.6± 0.3	6.7± 1.2
6700 ppm	9	4.5± 0.4	124± 2	8.6± 0.3	6.9± 1.1
10000 ppm	0	-	-	-	-
15000 ppm	0	-	-	-	-

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

APPENDIX B 5-4

BIOCHEMISTRY : SUMMARY, MOSUE : FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (14)

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± 0.2	3.1± 0.1	1.3± 0.1	0.28± 0.09	167± 21	75± 8	46± 11
3000 ppm	10	5.3± 0.1	3.0± 0.1	1.4± 0.1	0.32± 0.08	164± 16	74± 12	51± 13
4400 ppm	10	5.4± 0.2	3.0± 0.1	1.3± 0.1	0.29± 0.09	172± 21	84± 11	50± 10
6700 ppm	9	5.6± 0.3	3.2± 0.1	1.3± 0.1	0.32± 0.12	151± 31	81± 8	42± 10
10000 ppm	0	-	-	-	-	-	-	-
15000 ppm	0	-	-	-	-	-	-	-

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

(HCL074)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (14)

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	64±	18	15±	5	264±	42	285±	39	72±	17	20.5±	2.2	156±	3
3000 ppm	10	61±	14	14±	1	261±	42	289±	45	62±	27	21.2±	1.6	155±	2
4400 ppm	10	58±	12	13±	2	256±	78	290±	36	62±	25	20.1±	2.2	155±	2
6700 ppm	9	58±	8	14±	2	299±	123	288±	29	63±	26	19.1±	2.2	156±	3
10000 ppm	0	-		-		-		-		-		-		-	
15000 ppm	0	-		-		-		-		-		-		-	

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

(HCL074)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (14)

Group Name	NO. of Animals	POTASSIUM mEq/ℓ	CHLORIDE mEq/ℓ	CALCIUM mg/dℓ	INORGANIC PHOSPHORUS mg/dℓ
Control	10	4.6± 0.3	123± 3	8.7± 0.2	6.3± 1.0
3000 ppm	10	4.3± 0.6	123± 3	8.8± 0.3	5.8± 1.1
4400 ppm	10	4.5± 0.5	122± 2	8.7± 0.3	5.8± 0.8
6700 ppm	9	4.9± 0.5	124± 2	9.0± 0.3	5.9± 1.1
10000 ppm	0	-	-	-	-
15000 ppm	0	-	-	-	-

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

APPENDIX B 6-1

URINALYSIS : SUMMARY, RAT : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
ANIMAL : RAT F344
SAMPLING DATE : 013-6
SEX : MALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	pH							CHI	Protein						CHI	Glucose						CHI	Ketone body						CHI	Bilirubin				CHI
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		−	±	+	2+	3+	4+		−	±	+	2+	3+	4+		−	±	+	2+	3+	4+		−	+	2+	3+	
Control	10	0	0	0	0	2	7	1		0	0	6	4	0	0		10	0	0	0	0	0		4	6	0	0	0	0		10	0	0	0	
2000 ppm	10	0	0	0	0	4	6	0		0	2	5	3	0	0		10	0	0	0	0	0		4	6	0	0	0	0		10	0	0	0	
3000 ppm	10	0	0	0	0	2	8	0		0	4	4	2	0	0		10	0	0	0	0	0		6	4	0	0	0	0		10	0	0	0	
4400 ppm	10	0	0	0	0	3	7	0		0	3	7	0	0	0	*	10	0	0	0	0	0		7	3	0	0	0	0		10	0	0	0	
6700 ppm	10	0	0	0	1	2	7	0		0	3	7	0	0	0	*	10	0	0	0	0	0		7	3	0	0	0	0		10	0	0	0	
10000 ppm	7	0	0	0	0	3	4	0		0	4	3	0	0	0	*	7	0	0	0	0	0		5	2	0	0	0	0		7	0	0	0	

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

STUDY NO. : 0166
ANIMAL : RAT F344
SAMPLING DATE : 013-6
SEX : MALE 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	
2000 ppm	10	10	0	0	0	0		10	0	0	0	0	
3000 ppm	10	10	0	0	0	0		10	0	0	0	0	
4400 ppm	10	9	0	0	0	1		10	0	0	0	0	
6700 ppm	10	10	0	0	0	0		10	0	0	0	0	
10000 ppm	7	7	0	0	0	0		7	0	0	0	0	

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

APPENDIX B 6-2

URINALYSIS : SUMMARY, RAT : FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
ANIMAL : RAT F344
SAMPLING DATE : 013-6
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+	4+	CHI	Bilirubin −	+	2+	3+	CHI
Control	10	0	0	0	0	1	9	0		0	10	0	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
2000 ppm	10	0	0	0	0	2	7	1		0	10	0	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
3000 ppm	10	0	0	0	0	0	9	1		0	9	1	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
4400 ppm	10	0	0	0	0	2	7	1		0	8	2	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
6700 ppm	10	0	0	0	1	0	8	1		0	10	0	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
10000 ppm	10	0	0	0	0	5	5	0		0	10	0	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	

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

STUDY NO. : 0166
ANIMAL : RAT F344
SAMPLING DATE : 013-6
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	
2000 ppm	10	10	0	0	0	0		10	0	0	0	0	
3000 ppm	10	10	0	0	0	0		10	0	0	0	0	
4400 ppm	10	10	0	0	0	0		10	0	0	0	0	
6700 ppm	10	10	0	0	0	0		10	0	0	0	0	
10000 ppm	10	10	0	0	0	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

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-5
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+	4+	CHI	Occult blood −	±	+	2+	3+	CHI
Control	10	0	0	0	1	6	3	0		0	0	9	1	0	0		10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	0	
3000 ppm	10	0	0	1	6	3	0	0	*	0	0	10	0	0	0		10	0	0	0	0	0		0	4	6	0	0	0	**	10	0	0	0	0	
4400 ppm	10	0	0	3	0	5	2	0		0	0	9	1	0	0		10	0	0	0	0	0		0	2	4	3	1	0	**	10	0	0	0	0	
6700 ppm	10	0	0	0	0	7	3	0		0	0	7	3	0	0		10	0	0	0	0	0		0	0	2	7	1	0	**	10	0	0	0	0	
10000 ppm	0	-	-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	
15000 ppm	0	-	-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	

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

STUDY NO. : 0167 URINALYSIS
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-5
SEX : MALE REPORT TYPE : A1

Group Name	NO. of Animals	Urobilinogen ±	+	2+	3+	4+	CHI
Control	10	10	0	0	0	0	
3000 ppm	10	10	0	0	0	0	
4400 ppm	10	10	0	0	0	0	
6700 ppm	10	10	0	0	0	0	
10000 ppm	0	-	-	-	-	-	
15000 ppm	0	-	-	-	-	-	

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

APPENDIX B 6-4

URINALYSIS : SUMMARY, MOSUE : FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-5
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+	4+	CHI	Occult blood −	±	+	2+	3+	CHI
Control	10	0	0	1	1	5	3	0		0	1	8	1	0	0		10	0	0	0	0	0		2	6	2	0	0	0		10	0	0	0	0	
3000 ppm	10	0	0	0	5	4	1	0		0	5	5	0	0	0		10	0	0	0	0	0		1	9	0	0	0	0		10	0	0	0	0	
4400 ppm	10	0	0	0	4	4	2	0		0	2	8	0	0	0		10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	0	
6700 ppm	9	0	0	1	1	4	3	0		0	1	6	2	0	0		9	0	0	0	0	0		1	7	1	0	0	0		9	0	0	0	0	
10000 ppm	0	-	-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	
15000 ppm	0	-	-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	

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

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-5
SEX : FEMALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	Urobilinogen ±	+	2+	3+	4+	CHI
Control	10	10	0	0	0	0	
3000 ppm	10	10	0	0	0	0	
4400 ppm	10	10	0	0	0	0	
6700 ppm	9	9	0	0	0	0	
10000 ppm	0	-	-	-	-	-	
15000 ppm	0	-	-	-	-	-	

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

(JCL101)

APPENDIX B 7-1

GROSS FINDINGS : SUMMARY, RAT : MALE : SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

Organ	Findings	Group Name NO. of Animals	Control 10 (%)	2000 ppm 10 (%)	3000 ppm 10 (%)	4400 ppm 10 (%)
thymus	red zone		1 (10)	1 (10)	0 (0)	0 (0)
liver	herniation		0 (0)	2 (20)	0 (0)	0 (0)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

Organ	Findings	Group Name NO. of Animals	6700 ppm 10 (%)	10000 ppm 7 (%)
thymus	red zone		0 (0)	0 (0)
liver	herniation		0 (0)	1 (14)

APPENDIX B 7-2

GROSS FINDINGS : SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

Organ	Findings	Group Name NO. of Animals	Control 10 (%)	2000 ppm 10 (%)	3000 ppm 10 (%)	4400 ppm 10 (%)
gl stomach	ulcer		0 (0)	0 (0)	0 (0)	0 (0)
liver	herniation		0 (0)	1 (10)	0 (0)	0 (0)
ovary	fluid:red		1 (10)	0 (0)	0 (0)	0 (0)
brain	deformed		0 (0)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

Organ	Findings	Group Name NO. of Animals	6700 ppm 10 (%)	10000 ppm 10 (%)
gl stomach	ulcer		0 (0)	1 (10)
liver	herniation		0 (0)	0 (0)
ovary	fluid:red		0 (0)	0 (0)
brain	deformed		0 (0)	1 (10)

APPENDIX B 7-3

GROSS FINDINGS : SUMMARY,RAT: MALE :DEAD AND MORIBUND ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 14W)

Organ	Findings	Group Name NO. of Animals	Control 0 (%)	2000 ppm 0 (%)	3000 ppm 0 (%)	4400 ppm 0 (%)
lung	voluminus		- (-)	- (-)	- (-)	- (-)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 14W)

Organ	Findings	Group Name NO. of Animals	6700 ppm 0 (%)	10000 ppm 3 (%)
lung	voluminus		- (-)	1 (33)

APPENDIX B 7-4

GROSS FINDINGS : SUMMARY, MOSUE : MALE : SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

Organ	Findings	Group Name NO. of Animals	Control 10 (%)	3000 ppm 10 (%)	4400 ppm 10 (%)	6700 ppm 10 (%)
spleen	black zone		1 (10)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

Organ	Findings	Group Name NO. of Animals	10000 ppm 0 (%)	15000 ppm 0 (%)
spleen	black zone		- (-)	- (-)

APPENDIX B 7-5

GROSS FINDINGS : SUMMARY, MOSUE : FEMALE : SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

Organ	Findings	Group Name NO. of Animals	Control 10 (%)	3000 ppm 10 (%)	4400 ppm 10 (%)	6700 ppm 9 (%)
spleen	black zone		1 (10)	1 (10)	1 (10)	0 (0)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

Organ	Findings	Group Name	10000 ppm	15000 ppm
		NO. of Animals	0 (%)	0 (%)
spleen	black zone		- (-)	- (-)

APPENDIX B 7-6

GROSS FINDINGS : SUMMARY, MOUSE: MALE :DEAD AND MORIBUND ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 14W)

Organ	Findings	Group Name NO. of Animals	Control 0 (%)	3000 ppm 0 (%)	4400 ppm 0 (%)	6700 ppm 0 (%)
lung	red zone		- (-)	- (-)	- (-)	- (-)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 14W)

Organ	Findings	Group Name	10000 ppm	15000 ppm
		NO. of Animals	10 (%)	10 (%)
lung	red zone		0 (0)	1 (10)

APPENDIX B 7-7

GROSS FINDINGS : SUMMARY, MOUSE: FEMALE :DEAD AND MORIBUND ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 14W)

Organ	Findings	Group Name NO. of Animals	Control 0 (%)	3000 ppm 0 (%)	4400 ppm 0 (%)	6700 ppm 1 (%)
lung	red zone		- (-)	- (-)	- (-)	0 (0)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 14W)

Organ	Findings	Group Name	10000 ppm	15000 ppm
		NO. of Animals	10 (%)	10 (%)
lung	red zone		1 (10)	2 (20)

APPENDIX B 8-1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	323± 18	0.339± 0.131	0.057± 0.009	2.974± 0.051	0.943± 0.045	1.006± 0.040
2000 ppm	10	311± 15	0.276± 0.030	0.052± 0.006	2.781± 0.662	0.926± 0.050	1.007± 0.038
3000 ppm	10	312± 30	0.278± 0.053	0.054± 0.006	3.010± 0.108	0.950± 0.107	1.026± 0.079
4400 ppm	10	280± 14**	0.243± 0.037*	0.062± 0.012	3.006± 0.093	0.895± 0.042	0.967± 0.048
6700 ppm	10	269± 22**	0.208± 0.026**	0.059± 0.005	2.804± 0.275	0.848± 0.064*	0.955± 0.037
10000 ppm	7	227± 18**	0.185± 0.030**	0.064± 0.005	2.809± 0.119	0.783± 0.060**	0.885± 0.037**

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

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.947± 0.076	0.531± 0.030	8.451± 0.605	1.902± 0.027
2000 ppm	10	1.970± 0.116	0.527± 0.031	8.348± 0.488	1.885± 0.046
3000 ppm	10	2.008± 0.205	0.534± 0.039	8.238± 0.884	1.884± 0.052
4400 ppm	10	1.863± 0.046	0.496± 0.031	7.630± 0.456*	1.865± 0.024
6700 ppm	10	1.800± 0.129*	0.474± 0.045**	7.269± 0.449**	1.844± 0.033**
10000 ppm	7	1.609± 0.083**	0.413± 0.037**	6.266± 0.525**	1.788± 0.032**

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

APPENDIX B 8-2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	182± 10	0.219± 0.020	0.061± 0.007	0.128± 0.056	0.622± 0.026	0.778± 0.052
2000 ppm	10	178± 15	0.204± 0.026	0.065± 0.008	0.100± 0.013	0.611± 0.044	0.753± 0.053
3000 ppm	10	171± 14	0.204± 0.013	0.060± 0.011	0.097± 0.019	0.591± 0.055	0.766± 0.046
4400 ppm	10	170± 13	0.199± 0.036	0.059± 0.005	0.107± 0.015	0.602± 0.047	0.757± 0.044
6700 ppm	10	165± 9*	0.179± 0.020**	0.062± 0.006	0.114± 0.027	0.594± 0.041	0.744± 0.029
10000 ppm	10	162± 13**	0.179± 0.028**	0.067± 0.006	0.103± 0.023	0.591± 0.035	0.741± 0.049

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

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.219± 0.063	0.369± 0.021	4.379± 0.249	1.728± 0.034
2000 ppm	10	1.236± 0.082	0.366± 0.039	4.405± 0.325	1.764± 0.029
3000 ppm	10	1.239± 0.071	0.363± 0.039	4.227± 0.426	1.745± 0.043
4400 ppm	10	1.230± 0.077	0.365± 0.046	4.195± 0.318	1.737± 0.049
6700 ppm	10	1.233± 0.050	0.350± 0.024	4.214± 0.257	1.704± 0.033
10000 ppm	10	1.208± 0.084	0.336± 0.033	4.294± 0.287	1.670± 0.066*

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

APPENDIX B 8-3

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	30.9± 2.1	0.040± 0.007	0.011± 0.004	0.208± 0.022	0.153± 0.010	0.158± 0.010
3000 ppm	10	28.1± 1.2**	0.034± 0.004*	0.010± 0.003	0.215± 0.023	0.154± 0.008	0.161± 0.009
4400 ppm	10	28.7± 1.8*	0.035± 0.004	0.009± 0.002	0.210± 0.025	0.149± 0.010	0.160± 0.008
6700 ppm	10	27.9± 1.3**	0.033± 0.003*	0.010± 0.002	0.216± 0.018	0.153± 0.010	0.156± 0.007
10000 ppm	0	-	-	-	-	-	-
15000 ppm	0	-	-	-	-	-	-

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

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.468± 0.019	0.044± 0.005	1.190± 0.070	0.443± 0.013
3000 ppm	10	0.461± 0.026	0.046± 0.005	1.150± 0.060	0.450± 0.014
4400 ppm	10	0.466± 0.020	0.043± 0.005	1.191± 0.077	0.437± 0.010
6700 ppm	10	0.449± 0.029	0.042± 0.004	1.172± 0.057	0.444± 0.010
10000 ppm	0	-	-	-	-
15000 ppm	0	-	-	-	-

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

APPENDIX B 8-4

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	22.3± 1.1	0.039± 0.006	0.012± 0.002	0.025± 0.005	0.138± 0.005	0.156± 0.008
3000 ppm	10	22.7± 1.5	0.042± 0.008	0.014± 0.002	0.023± 0.007	0.135± 0.007	0.158± 0.013
4400 ppm	10	22.7± 0.8	0.043± 0.006	0.013± 0.001	0.026± 0.003	0.133± 0.006	0.157± 0.008
6700 ppm	9	22.7± 1.3	0.042± 0.006	0.012± 0.001	0.026± 0.004	0.140± 0.007	0.157± 0.010
10000 ppm	0	-	-	-	-	-	-
15000 ppm	0	-	-	-	-	-	-

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

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.326± 0.009	0.054± 0.005	0.994± 0.064	0.465± 0.010
3000 ppm	10	0.322± 0.025	0.056± 0.010	1.026± 0.123	0.463± 0.017
4400 ppm	10	0.326± 0.012	0.053± 0.004	1.058± 0.053	0.455± 0.013
6700 ppm	9	0.325± 0.023	0.050± 0.009	1.036± 0.080	0.456± 0.012
10000 ppm	0	-	-	-	-
15000 ppm	0	-	-	-	-

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

APPENDIX B 9-1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	323± 18	0.105± 0.041	0.018± 0.004	0.925± 0.054	0.293± 0.015	0.312± 0.012
2000 ppm	10	311± 15	0.089± 0.008	0.017± 0.002	0.893± 0.211	0.298± 0.017	0.324± 0.015
3000 ppm	10	312± 30	0.089± 0.009	0.018± 0.002	0.971± 0.072	0.304± 0.006	0.330± 0.015
4400 ppm	10	280± 14**	0.087± 0.011	0.022± 0.004**	1.076± 0.049**	0.320± 0.015**	0.346± 0.015**
6700 ppm	10	269± 22**	0.077± 0.009**	0.022± 0.003*	1.046± 0.119*	0.315± 0.014**	0.356± 0.023**
10000 ppm	7	227± 18**	0.082± 0.016	0.029± 0.003**	1.241± 0.102**	0.344± 0.010**	0.390± 0.021**

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

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.605± 0.018	0.165± 0.009	2.619± 0.073	0.591± 0.034
2000 ppm	10	0.634± 0.026	0.170± 0.007	2.687± 0.075	0.608± 0.028
3000 ppm	10	0.644± 0.022*	0.172± 0.008	2.640± 0.076	0.608± 0.045
4400 ppm	10	0.667± 0.037**	0.177± 0.008**	2.727± 0.133	0.668± 0.038**
6700 ppm	10	0.670± 0.035**	0.176± 0.009*	2.703± 0.087	0.688± 0.054**
10000 ppm	7	0.709± 0.026**	0.182± 0.007**	2.757± 0.121*	0.791± 0.069**

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

APPENDIX B 9-2

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	182± 10	0.120± 0.007	0.034± 0.004	0.071± 0.032	0.342± 0.016	0.428± 0.027
2000 ppm	10	178± 15	0.115± 0.011	0.037± 0.005	0.057± 0.010	0.345± 0.016	0.425± 0.023
3000 ppm	10	171± 14	0.120± 0.013	0.035± 0.005	0.056± 0.008	0.345± 0.010	0.449± 0.023
4400 ppm	10	170± 13	0.116± 0.013	0.035± 0.004	0.063± 0.008	0.355± 0.012	0.446± 0.021
6700 ppm	10	165± 9*	0.108± 0.008	0.038± 0.004	0.069± 0.016	0.360± 0.015	0.452± 0.020
10000 ppm	10	162± 13**	0.110± 0.012	0.042± 0.005**	0.064± 0.013	0.367± 0.029	0.460± 0.022*

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

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.670± 0.017	0.203± 0.010	2.409± 0.087	0.952± 0.050
2000 ppm	10	0.698± 0.038	0.206± 0.014	2.484± 0.092	0.999± 0.078
3000 ppm	10	0.726± 0.036**	0.212± 0.013	2.469± 0.098	1.025± 0.071
4400 ppm	10	0.725± 0.027**	0.214± 0.015	2.470± 0.084	1.026± 0.054
6700 ppm	10	0.748± 0.022**	0.212± 0.008	2.555± 0.078**	1.036± 0.050
10000 ppm	10	0.749± 0.024**	0.208± 0.018	2.662± 0.106**	1.042± 0.113

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

APPENDIX B 9-3

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : MALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	30.9± 2.1	0.128± 0.015	0.034± 0.012	0.673± 0.071	0.496± 0.031	0.511± 0.046
3000 ppm	10	28.1± 1.2**	0.119± 0.014	0.035± 0.009	0.768± 0.097*	0.549± 0.039**	0.575± 0.039**
4400 ppm	10	28.7± 1.8*	0.124± 0.015	0.030± 0.007	0.731± 0.070	0.519± 0.020	0.560± 0.050*
6700 ppm	10	27.9± 1.3**	0.119± 0.012	0.034± 0.007	0.775± 0.075*	0.548± 0.043**	0.560± 0.042*
10000 ppm	0	-	-	-	-	-	-
15000 ppm	0	-	-	-	-	-	-

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

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.515± 0.072	0.144± 0.013	3.852± 0.171	1.436± 0.073
3000 ppm	10	1.645± 0.067**	0.163± 0.018*	4.101± 0.110**	1.606± 0.092**
4400 ppm	10	1.626± 0.076*	0.150± 0.013	4.145± 0.108**	1.526± 0.101
6700 ppm	10	1.611± 0.107*	0.149± 0.016	4.207± 0.171**	1.595± 0.075**
10000 ppm	0	-	-	-	-
15000 ppm	0	-	-	-	-

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

APPENDIX B 9-4

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	22.3± 1.1	0.173± 0.027	0.056± 0.010	0.111± 0.020	0.619± 0.033	0.700± 0.038
3000 ppm	10	22.7± 1.5	0.184± 0.022	0.060± 0.009	0.103± 0.034	0.595± 0.033	0.698± 0.044
4400 ppm	10	22.7± 0.8	0.191± 0.027	0.055± 0.006	0.114± 0.014	0.587± 0.041	0.691± 0.038
6700 ppm	9	22.7± 1.3	0.185± 0.020	0.055± 0.004	0.112± 0.017	0.618± 0.029	0.693± 0.049
10000 ppm	0	-	-	-	-	-	-
15000 ppm	0	-	-	-	-	-	-

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

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.464± 0.064	0.244± 0.016	4.448± 0.176	2.083± 0.097
3000 ppm	10	1.422± 0.060	0.246± 0.026	4.514± 0.273	2.047± 0.109
4400 ppm	10	1.436± 0.059	0.235± 0.021	4.657± 0.183	2.006± 0.086
6700 ppm	9	1.429± 0.055	0.219± 0.030	4.561± 0.176	2.014± 0.137
10000 ppm	0	-	-	-	-
15000 ppm	0	-	-	-	-

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

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name	Control				2000 ppm				3000 ppm				4400 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
nasal cavit			<10>				<10>				<10>				<10>			
	squamous cell 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)
	respiratory 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)
	inflammation:foreign body		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammation:squamous epithelium		0	0	0	0	0	0	0	0	2	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	inflammation:respiratory 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)
	nuclear enlargement: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)
	nuclear enlargement:respiratory 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)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	6700 ppm				10000 ppm			
		No. of Animals on Study	10				7			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]										
nasal cavit			<10>				< 7>			
	squamous cell metaplasia		0	0	0	0	3	1	0	0 *
			(0)	(0)	(0)	(0)	(43)	(14)	(0)	(0)
	respiratory metaplasia		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(14)	(0)	(0)	(0)
	inflammation:foreign body		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammation:squamous epithelium		2	0	0	0	1	0	0	0
			(20)	(0)	(0)	(0)	(14)	(0)	(0)	(0)
	inflammation:respiratory epithelium		0	0	0	0	5	0	0	0 **
			(0)	(0)	(0)	(0)	(71)	(0)	(0)	(0)
	atrophy:olfactory epithelium		0	0	0	0	2	5	0	0 **
			(0)	(0)	(0)	(0)	(29)	(71)	(0)	(0)
	nuclear enlargement:olfactory epithelium		0	0	0	0	6	0	0	0 **
			(0)	(0)	(0)	(0)	(86)	(0)	(0)	(0)
	nuclear enlargement:respiratory epithelium		0	0	0	0	4	0	0	0 *
			(0)	(0)	(0)	(0)	(57)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	Control				2000 ppm				3000 ppm				4400 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
lung			<10>				<10>				<10>				<10>			
	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)
	accumulation of foamy cells		0	0	0	0	0	0	0	0	0	0	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			<10>				<10>				<10>				<10>			
	granulation		2	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
[Digestive system]																		
liver			<10>				<10>				<10>				<10>			
	herniation		0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Urinary system]																		
kidney			<10>				<10>				<10>				<10>			
	basophilic change		1	0	0	0	3	0	0	0	2	0	0	0	2	0	0	0
			(10)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(20)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	6700 ppm				10000 ppm			
		No. of Animals on Study	10				7			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]										
lung			<10>				< 7>			
	granulation		0	0	0	0	0	2	0	0
			(0)	(0)	(0)	(0)	(0)	(29)	(0)	(0)
	accumulation of foamy cells		1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Circulatory system]										
heart			<10>				< 7>			
	granulation		1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Digestive system]										
liver			<10>				< 7>			
	herniation		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(14)	(0)	(0)	(0)
[Urinary system]										
kidney			<10>				< 7>			
	basophilic change		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(14)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	Control				2000 ppm				3000 ppm				4400 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Urinary system]																		
kidney			<10>				<10>				<10>				<10>			
	eosinophilic body		7	3	0	0	7	3	0	0	8	2	0	0	9	1	0	0
			(70)	(30)	(0)	(0)	(70)	(30)	(0)	(0)	(80)	(20)	(0)	(0)	(90)	(10)	(0)	(0)
[Endocrine system]																		
pituitary			< 9>				<10>				<10>				<10>			
	Rathke pouch		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(11)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
thyroid			<10>				<10>				<10>				<10>			
	ultimibranchial body remanet		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
adrenal			<10>				<10>				<10>				<10>			
	mineralization		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Reproductive system]																		
testis			<10>				<10>				<10>				<10>			
	atrophy		0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	6700 ppm				10000 ppm			
		No. of Animals on Study	10				7			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Urinary system]										
kidney			<10>				< 7>			
	eosinophilic body		8	2	0	0	7	0	0	0
			(80)	(20)	(0)	(0)	(100)	(0)	(0)	(0)
[Endocrine system]										
pituitary			<10>				< 7>			
	Rathke pouch		1	0	0	0	1	0	0	0
			(10)	(0)	(0)	(0)	(14)	(0)	(0)	(0)
thyroid			<10>				< 7>			
	ultimibranchial body remanet		1	0	0	0	1	0	0	0
			(10)	(0)	(0)	(0)	(14)	(0)	(0)	(0)
adrenal			<10>				< 7>			
	mineralization		1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Reproductive system]										
testis			<10>				< 7>			
	atrophy		0	0	1	0	0	0	0	0
			(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name	Control				2000 ppm				3000 ppm				4400 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Reproductive system]																		
prostate			<10>				<10>				<10>				<10>			
	inflammation		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
[Special sense organs/appandage]																		
eye			<10>				<10>				<10>				<10>			
	retinal atrophy		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	6700 ppm				10000 ppm			
		No. of Animals on Study	10				7			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Reproductive system]										
prostate			<10>				< 7>			
	inflammation		1	0	0	0	1	0	0	0
			(10)	(0)	(0)	(0)	(14)	(0)	(0)	(0)
[Special sense organs/appandage]										
eye			<10>				< 7>			
	retinal atrophy		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

APPENDIX B 10-2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE : SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

Organ	Findings	Group Name	Control				2000 ppm				3000 ppm				4400 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
[Respiratory system]																		
nasal cavit			<10>				<10>				<10>				<10>			
	squamous cell 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)
	respiratory 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)
	inflammation:foreign body		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)
	inflammation:squamous epithelium		2 (20)	1 (10)	0 (0)	0 (0)	3 (30)	1 (10)	0 (0)	0 (0)	2 (20)	1 (10)	0 (0)	0 (0)	3 (30)	0 (0)	0 (0)	0 (0)
	inflammation: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)
	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)
	nuclear enlargement: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)
	nuclear enlargement:respiratory 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)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	6700 ppm				10000 ppm			
		No. of Animals on Study	10				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]										
nasal cavit			<10>				<10>			
	squamous cell metaplasia		0	0	0	0	4	3	0	0 **
			(0)	(0)	(0)	(0)	(40)	(30)	(0)	(0)
	respiratory metaplasia		0	0	0	0	3	0	0	0
			(0)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
	inflammation:foreign body		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammation:squamous epithelium		3	0	0	0	4	0	0	0
			(30)	(0)	(0)	(0)	(40)	(0)	(0)	(0)
	inflammation:respiratory epithelium		0	0	0	0	5	0	0	0 *
			(0)	(0)	(0)	(0)	(50)	(0)	(0)	(0)
	atrophy:olfactory epithelium		0	0	0	0	4	5	0	0 **
			(0)	(0)	(0)	(0)	(40)	(50)	(0)	(0)
	nuclear enlargement:olfactory epithelium		0	0	0	0	7	0	0	0 **
			(0)	(0)	(0)	(0)	(70)	(0)	(0)	(0)
	nuclear enlargement:respiratory epithelium		0	0	0	0	8	0	0	0 **
			(0)	(0)	(0)	(0)	(80)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	Control				2000 ppm				3000 ppm				4400 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
[Respiratory system]																		
lung			<10>				<10>				<10>				<10>			
	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)
	accumulation of foamy cells		1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
[Hematopoietic system]																		
bone marrow			<10>				<10>				<10>				<10>			
	granulation		1	2	0	0	2	3	0	0	3	0	0	0	0	1	0	0
			(10)	(20)	(0)	(0)	(20)	(30)	(0)	(0)	(30)	(0)	(0)	(0)	(0)	(10)	(0)	(0)
[Circulatory system]																		
heart			<10>				<10>				<10>				<10>			
	granulation		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Digestive system]																		
liver			<10>				<10>				<10>				<10>			
	herniation		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	6700 ppm				10000 ppm			
		No. of Animals on Study	10				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]										
lung			<10>				<10>			
	granulation		0	1	0	0	0	0	0	0
			(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)
	accumulation of foamy cells		2	0	0	0	1	0	0	0
			(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
[Hematopoietic system]										
bone marrow			<10>				<10>			
	granulation		1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Circulatory system]										
heart			<10>				<10>			
	granulation		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Digestive system]										
liver			<10>				<10>			
	herniation		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	Control				2000 ppm				3000 ppm				4400 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
liver			<10>				<10>				<10>				<10>			
	granulation		1	0	0	0	3	0	0	0	2	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Urinary system]																		
kidney			<10>				<10>				<10>				<10>			
	basophilic change		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	mineralization:cortico-medullary junction		3	0	0	0	2	0	0	0	2	0	0	0	0	0	0	0
			(30)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Endocrine system]																		
thyroid			<10>				<10>				<10>				<10>			
	ultimibranchial body remanet		1	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Special sense organs/appandage]																		
eye			<10>				<10>				<10>				<10>			
	retinal atrophy		0	0	0	0	0	0	0	0	1	0	0	0	2	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	6700 ppm				10000 ppm			
		No. of Animals on Study	10				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]										
liver			<10>				<10>			
	granulation		2	0	0	0	2	0	0	0
			(20)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
[Urinary system]										
kidney			<10>				<10>			
	basophilic change		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	mineralization:cortico-medullary junction		1	0	0	0	2	0	0	0
			(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
[Endocrine system]										
thyroid			<10>				<10>			
	ultimibranchial body remanet		1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Special sense organs/appandage]										
eye			<10>				<10>			
	retinal atrophy		1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	Control				2000 ppm				3000 ppm				4400 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Special sense organs/appandage]																		
Harder gl			<10>				<10>				<10>				<10>			
	lymphocytic infiltration		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	6700 ppm				10000 ppm			
		No. of Animals on Study	10				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Special sense organs/appandage]										
Harder gl			<10>				<10>			
	lymphocytic infiltration		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

APPENDIX B 10-3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : DEAD AND MORIBUNDANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 14W)

Organ	Findings	Group Name	Control				2000 ppm				3000 ppm				4400 ppm			
		No. of Animals on Study	0				0				0				0			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
nasal cavit			< 0>				< 0>				< 0>				< 0>			
	squamous cell metaplasia		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	inflammation:respiratory epithelium		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	atrophy:olfactory epithelium		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	nuclear enlargement:olfactory epithelium		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
lung			< 0>				< 0>				< 0>				< 0>			
	congestion		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100

Organ	Findings	Group Name	6700 ppm				10000 ppm			
		No. of Animals on Study	0				3			
		Grade	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
[Respiratory system]										
nasal cavit			< 0>				< 3>			
	squamous cell metaplasia		- (-)	- (-)	- (-)	- (-)	1 (33)	2 (67)	0 (0)	0 (0)
	inflammation:respiratory epithelium		- (-)	- (-)	- (-)	- (-)	2 (67)	0 (0)	0 (0)	0 (0)
	atrophy:olfactory epithelium		- (-)	- (-)	- (-)	- (-)	1 (33)	1 (33)	0 (0)	0 (0)
	nuclear enlargement:olfactory epithelium		- (-)	- (-)	- (-)	- (-)	3 (100)	0 (0)	0 (0)	0 (0)
lung			< 0>				< 3>			
	congestion		- (-)	- (-)	- (-)	- (-)	0 (0)	0 (0)	3 (100)	0 (0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100

APPENDIX B 10-4

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : MALE : SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Grade	Control 10				3000 ppm 10				4400 ppm 10				6700 ppm 10			
			1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
[Respiratory system]																		
nasal cavit			<10>				<10>				<10>				<10>			
	nuclear enlargement: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)	2 (20)	0 (0)	0 (0)	0 (0)
[Hematopoietic system]																		
spleen			<10>				<10>				<10>				<10>			
	deposit of melanin		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			<10>				<10>				<10>				<10>			
	hyperplasia:forestomach		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (30)	0 (0)	0 (0)	0 (0)
liver			<10>				<10>				<10>				<10>			
	granulation		4 (40)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	4 (40)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
[Urinary system]																		
kidney			<10>				<10>				<10>				<10>			
	basophilic change		2 (20)	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)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	10000 ppm				15000 ppm			
		No. of Animals on Study	0				0			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]										
nasal cavit			< 0>				< 0>			
	nuclear enlargement:olfactory epithelium		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
[Hematopoietic system]										
spleen			< 0>				< 0>			
	deposit of melanin		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
[Digestive system]										
stomach			< 0>				< 0>			
	hyperplasia:forestomach		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
liver			< 0>				< 0>			
	granulation		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
[Urinary system]										
kidney			< 0>				< 0>			
	basophilic change		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	Control				3000 ppm				4400 ppm				6700 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Urinary system]																		
kidney			<10>				<10>				<10>				<10>			
	vacuolization of proximal tubule		9	0	0	0	8	0	0	0	8	0	0	0	1	0	0	0 **
			(90)	(0)	(0)	(0)	(80)	(0)	(0)	(0)	(80)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
[Endocrine system]																		
adrenal			<10>				<10>				<10>				<10>			
	accesory cortical nodule		2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	10000 ppm				15000 ppm			
		No. of Animals on Study	0				0			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Urinary system]										
kidney			< 0>				< 0>			
	vacuolization of proximal tubule		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
[Endocrine system]										
adrenal			< 0>				< 0>			
	accesory cortical nodule		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

APPENDIX B 10-5

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : FEMALE : SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

Organ	Findings	Group Name	Control				3000 ppm				4400 ppm				6700 ppm			
		No. of Animals on Study	10				10				10				9			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
nasal cavit			<10>				<10>				<10>				< 9>			
	eosinophilic change:respiratory epithelium		0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	nuclear enlargement:olfactory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(44)	(0)	(0)	(0)
[Hematopoietic system]																		
spleen			<10>				<10>				<10>				< 9>			
	deposit of melanin		1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Digestive system]																		
stomach			<10>				<10>				<10>				< 9>			
	hyperplasia:forestomach		0	0	0	0	0	0	0	0	0	0	0	0	6	0	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(67)	(0)	(0)	(0)
liver			<10>				<10>				<10>				< 9>			
	granulation		4	0	0	0	3	0	0	0	2	0	0	0	4	0	0	0
			(40)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(44)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	10000 ppm				15000 ppm			
		No. of Animals on Study	0				0			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]										
nasal cavit			< 0>				< 0>			
	eosinophilic change:respiratory epithelium		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	nuclear enlargement:olfactory epithelium		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
[Hematopoietic system]										
spleen			< 0>				< 0>			
	deposit of melanin		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
[Digestive system]										
stomach			< 0>				< 0>			
	hyperplasia:forestomach		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
liver			< 0>				< 0>			
	granulation		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	Control				3000 ppm				4400 ppm				6700 ppm			
		No. of Animals on Study	10				10				10				9			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Endocrine system]																		
adrenal			<10>				<10>				<10>				< 9>			
	accesory cortical nodule		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Reproductive system]																		
ovary			<10>				<10>				<10>				< 9>			
	hyaline degeneration		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(11)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	10000 ppm				15000 ppm			
		No. of Animals on Study	0				0			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Endocrine system]										
adrenal			< 0>				< 0>			
	accesory cortical nodule		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
[Reproductive system]										
ovary			< 0>				< 0>			
	hyaline degeneration		-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

APPENDIX B 10-6

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : MALE : DEAD AND MORIBUND ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 14W)

Organ	Findings	Group Name	Control				3000 ppm				4400 ppm				6700 ppm			
		No. of Animals on Study	0				0				0				0			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
liver			< 0>				< 0>				< 0>				< 0>			
	granulation		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
[Endocrine system]																		
adrenal			< 0>				< 0>				< 0>				< 0>			
	accesory cortical nodule		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100

Organ	Findings	Group Name	10000 ppm				15000 ppm			
		No. of Animals on Study	10				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]										
liver			<10>				<10>			
	granulation		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
[Endocrine system]										
adrenal			<10>				<10>			
	accesory cortical nodule		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100

APPENDIX B 10-7

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : FEMALE : DEAD AND MORIBUND ANIMALS

(THIRTEEN - WEEK STUDY)

Organ	Findings	Group Name	Control				3000 ppm				4400 ppm				6700 ppm			
		No. of Animals on Study	0				0				0				1			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
nasal cavit			< 0>				< 0>				< 0>				< 1>			
	vacuolic change:olfactory epithelium		-	-	-	-	-	-	-	-	-	-	-	-	0	0	0	0
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(0)	(0)	(0)
lung			< 0>				< 0>				< 0>				< 1>			
	congestion		-	-	-	-	-	-	-	-	-	-	-	-	0	0	0	0
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(0)	(0)	(0)
	hemorrhage		-	-	-	-	-	-	-	-	-	-	-	-	0	1	0	0
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(100)	(0)	(0)
[Digestive system]																		
stomach			< 0>				< 0>				< 0>				< 1>			
	erosion:forestomach		-	-	-	-	-	-	-	-	-	-	-	-	0	0	0	0
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(0)	(0)	(0)
liver			< 0>				< 0>				< 0>				< 1>			
	granulation		-	-	-	-	-	-	-	-	-	-	-	-	0	0	0	0
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(0)	(0)	(0)
[Endocrine system]																		
adrenal			< 0>				< 0>				< 0>				< 1>			
	accesory cortical nodule		-	-	-	-	-	-	-	-	-	-	-	-	0	0	0	0
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100

Organ	Findings	Group Name	10000 ppm				15000 ppm			
		No. of Animals on Study	10				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]										
nasal cavit			<10>				<10>			
	vacuolic change:olfactory epithelium		0	0	0	0	6	0	0	0
			(0)	(0)	(0)	(0)	(60)	(0)	(0)	(0)
lung			<10>				<10>			
	congestion		1	0	0	0	2	0	0	0
			(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
	hemorrhage		5	0	0	0	0	0	0	0
			(50)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Digestive system]										
stomach			<10>				<10>			
	erosion:forestomach		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
liver			<10>				<10>			
	granulation		0	0	0	0	2	0	0	0
			(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
[Endocrine system]										
adrenal			<10>				<10>			
	accesory cortical nodule		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100

APPENDIX B 11-1

IDENTITY AND PURITY OF 1,1,1-TRICHLOROETHANE

(THIRTEEN - WEEK STUDY)

IDENTITY OF 1,1,1-TRICHLOROETHANE(THIRTEEN-WEEK STUDIES)

A. Lot no. ECG7864

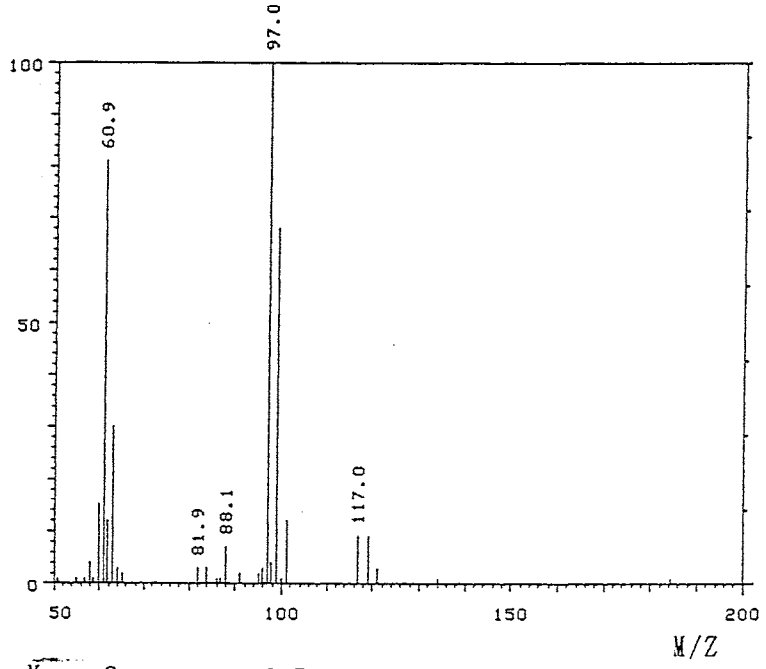
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI(Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

Results:

Determines Fragment Peak(M/Z)	Literature Values* Fragment Peak(M/Z)
60.9	61
97.0	97
117.0	117

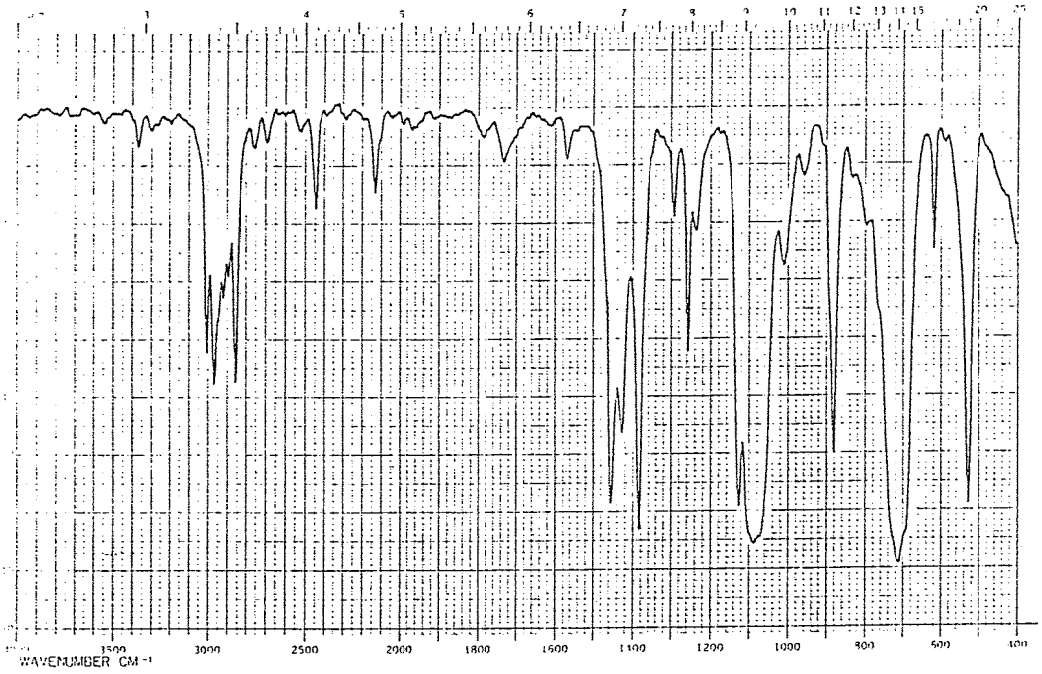
(*EPA/NIH Mass Spectral Data Base (1978) V. 1, p. 278.)

Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr

Slit : Medium



Infrared Spectrum of Test Substance

Results:

Determined Value Wave Number(cm^{-1})	Literature Values* Wave Number(cm^{-1})
510～ 550	500～ 540
600～ 640	600～ 630
660～ 760	660～ 760
850～ 900	860～ 900
1040～1110	1040～1110
1120～1150	1110～1140
1240～1270	1240～1260
1370～1400	1370～1400
1410～1440	1410～1440
1440～1480	1440～1480
2100～2170	2100～2150
2420～2480	2400～2470
2800～2880	2800～2880
2940～3050	2940～3050

(*Performed by the WAKO PURE CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The result of the mass spectrum and the infrared spectrum agreed with the literature values.
Consequently, the test substance was identified as 1,1,1-Trichloroethane.

B. Lot no. DSP4087

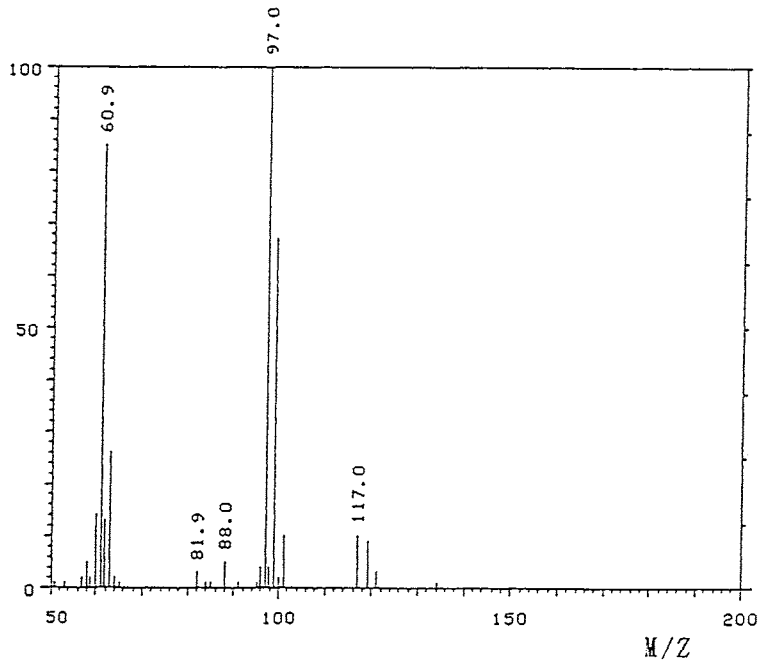
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI(Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

Results:

Determines Fragment Peak(M/Z)	Literature Values* Fragment Peak(M/Z)
60.9	61
97.0	97
117.0	117

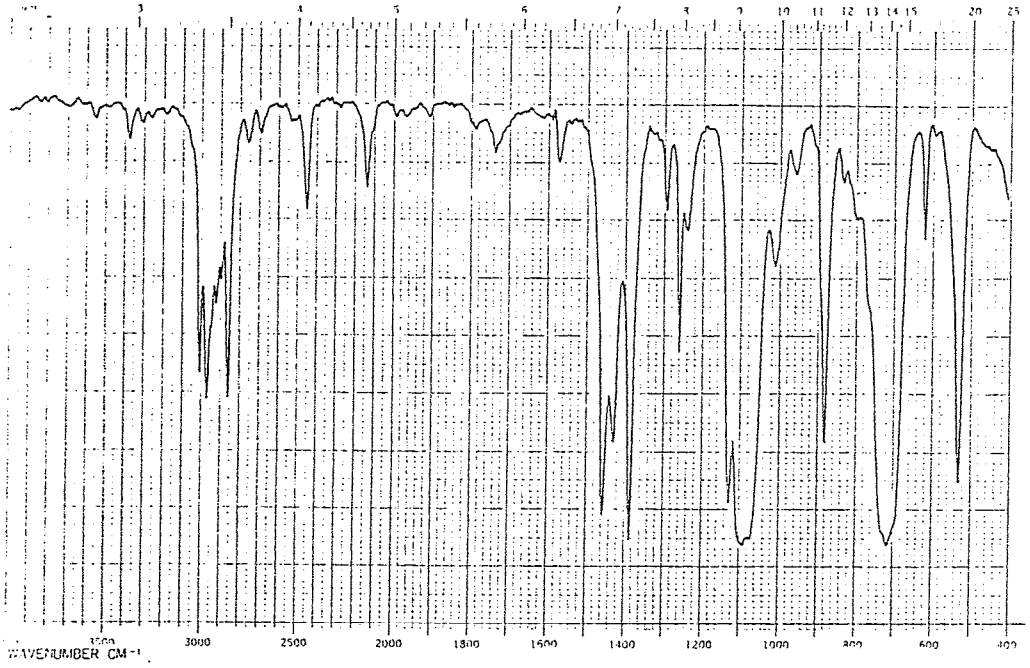
(*EPA/NIH Mass Spectral Data Base (1978) V. 1, p. 278.)

Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr

Slit : Medium



Infrared Spectrum of Test Substance

Results:

Determined Value Wave Number(cm^{-1})	Literature Values* Wave Number(cm^{-1})
510～ 550	500～ 540
600～ 640	600～ 630
660～ 760	660～ 760
850～ 900	860～ 900
1040～1110	1040～1110
1120～1150	1110～1140
1240～1270	1240～1260
1370～1400	1370～1400
1410～1440	1410～1440
1440～1480	1440～1480
2100～2170	2100～2150
2420～2480	2400～2470
2800～2880	2800～2880
2940～3050	2940～3050

(*Performed by the WAKO PURE CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The result of the mass spectrum and the infrared spectrum agreed with the literature values.
Consequently, the test substance was identified as 1,1,1-Trichloroethane.

C. Lot no. DSQ3398

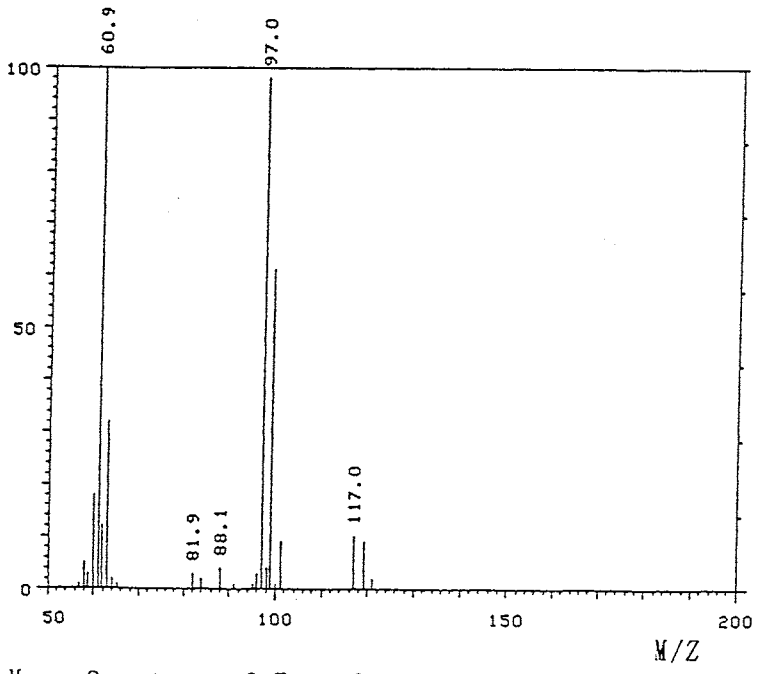
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI(Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

Results:

Determines Fragment Peak(M/Z)	Literature Values* Fragment Peak(M/Z)
60.9	61
97.0	97
117.0	117

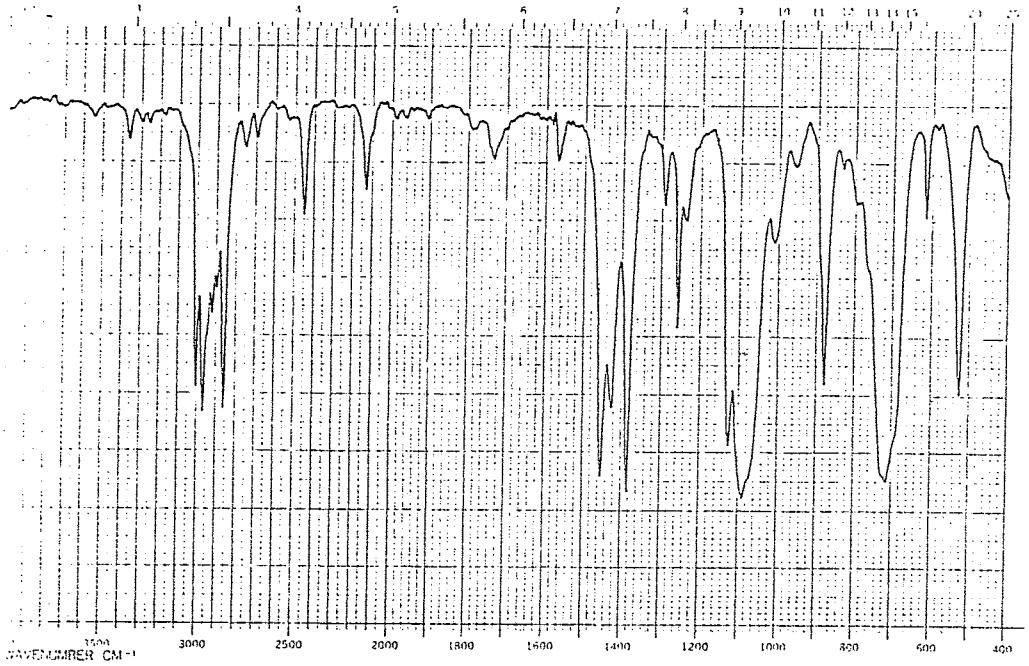
(*EPA/NIH Mass Spectral Data Base (1978) V. 1, p. 278.)

Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr

Slit : Medium



Infrared Spectrum of Test Substance

Results:	Determined Value Wave Number(cm^{-1})	Literature Values* Wave Number(cm^{-1})
	510～ 550	500～ 540
	600～ 640	600～ 630
	660～ 760	660～ 760
	850～ 900	860～ 900
	1040～1110	1040～1110
	1120～1150	1110～1140
	1240～1270	1240～1260
	1370～1400	1370～1400
	1410～1440	1410～1440
	1440～1480	1440～1480
	2100～2170	2100～2150
	2420～2480	2400～2470
	2800～2880	2800～2880
	2940～3050	2940～3050

(*Performed by the WAKO PURE CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The result of the mass spectrum and the infrared spectrum agreed with the literature values.
Consequently, the test substance was identified as 1,1,1-Trichloroethane.

APPENDIX B 11-2

STABILITY OF 1,1,1-TRICHLOROETHANE

(THIRTEEN - WEEK STUDY)

STABILITY OF 1,1,1-TRICHLOROETHANE(THIRTEEN-WEEK STUDIES)

A. Lot no. ECG7864

1. Sample: This lot was used from 1991.4.11 to 1991.4.29. Test substance was stored at room temperature.

2. Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr

Slit : Medium

Results: Infrared spectrum of the test substance agreed with before use and after use.

1991.04.03(date analyzed) Wave Number(cm^{-1})	1991.05.01(date analyzed) Wave Number(cm^{-1})
510～ 550	510～ 550
600～ 640	600～ 640
660～ 760	660～ 760
850～ 900	850～ 900
1040～1110	1040～1110
1120～1150	1120～1150
1240～1270	1240～1270
1370～1400	1370～1400
1410～1440	1410～1440
1440～1480	1440～1480
2100～2170	2100～2170
2420～2480	2420～2480
2800～2880	2800～2880
2940～3050	2940～3050

3. Gas Chromatography

Instrument: Hewlett Packard 5890A

Column: Methyl Silicone(0.2mmϕ × 50m)

Column Temperature: 80°C

Flow Rate: 1 ml/min

Detector: FID(Flame Ionization Detector)

Injection Volume: 1 μl

Results: Gas chromatography indicated one major peak(peak No.4) and four impurities(peak No.1, 2, 3, 5 < 5% of total area) analyzed at 1991.4.3 and one major peak(peak No.4) and four impurities(peak No.1, 2, 3, 5 < 5% of total area) analyzed at 1991.5.1. It was identified only by comparing its gas chromatograph with that of the 1,4-Dioxane(peak No.5) in the 1,1,1-Trichloroethane, the amount in the test substance was 3.43% at 1991.4.3. The new treace impurity peak in the test substance analyzed at 1991.5.1 was not detected.

Date	Peak No.	Retention Time(min)	AREA COUNT
1991.04.03	1	2.388	122
(date analyzed)	2	2.455	73
	3	2.54	1092
	4	2.782	145248
	5	3.093	5658
1991.05.01	1	2.387	121
(date analyzed)	2	2.453	72
	3	2.54	1090
	4	2.78	144876
	5	3.092	5646

4. Conclusions: The results indicated that the test substance did not change when stored in the dark at room temperature during this period(for about 4 weeks).

B. Lot no. DSP4087

1. Sample: This lot was used from 1991.4.29 to 1991.7.8. Test substance was stored at room temperature.

2. Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr

Slit : Medium

Results: Infrared spectrum of the test substance agreed with before use and after use.

1991.04.19(date analyzed) Wave Number(cm^{-1})	1991.07.08(date analyzed) Wave Number(cm^{-1})
510～ 550	510～ 550
600～ 640	600～ 640
660～ 760	660～ 760
850～ 900	850～ 900
1040～1110	1040～1110
1120～1150	1120～1150
1240～1270	1240～1270
1370～1400	1370～1400
1410～1440	1410～1440
1440～1480	1440～1480
2100～2170	2100～2170
2420～2480	2420～2480
2800～2880	2800～2880
2940～3050	2940～3050

3. Gas Chromatography

Instrument: Hewlett Packard 5890A

Column: Methyl Silicone(0.2mmϕ × 50m)

Column Temperature: 80°C

Flow Rate: 1 ml/min

Detector: FID(Flame Ionization Detector)

Injection Volume: 1 μl

Results: Gas chromatography indicated one major peak(peak No.4) and four impurities(peak No.1,2,3,5 < 5% of total area) analyzed at 1991.4.19 and one major peak(peak No.4) and four impurities(peak No.1,2,3,5 < 5% of total area) analyzed at 1991.7.8. It was identified only by comparing its gas chromatograph with that of the 1,4-Dioxane(peak No.5) in the 1,1,1-Trichloroethane, the amount in the test substance was 3.44% at 1991.4.19. The new treace impurity peak in the test substance analyzed at 1991.7.8 was not detected.

Date	Peak No.	Retention Time(min)	Area Count
1991.04.19	1	2.388	129
(date analyzed)	2	2.455	94
	3	2.54	1088
	4	2.782	143663
	5	3.093	5570
1991.07.08	1	2.387	130
(date analyzed)	2	2.453	95
	3	2.538	1094
	4	2.78	144718
	5	3.092	5610

4. Conclusions: The results indicated that the test substance did not change when stored in the dark at room temperature during this period(for about 11 weeks).

C. Lot no. DSQ3398

1. Sample: This lot was used from 1991.7.8 to 1991.7.17. Test substance was stored at room temperature.

2. Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr

Slit : Medium

Results: Infrared spectrum of the test substance agreed with before use and after use.

1991.07.03(date analyzed) Wave Number(cm^{-1})	1991.07.30(date analyzed) Wave Number(cm^{-1})
510～ 550	510～ 550
600～ 640	600～ 640
660～ 760	660～ 760
850～ 900	850～ 900
1040～1110	1040～1110
1120～1150	1120～1150
1240～1270	1240～1270
1370～1400	1370～1400
1410～1440	1410～1440
1440～1480	1440～1480
2100～2170	2100～2170
2420～2480	2420～2480
2800～2880	2800～2880
2940～3050	2940～3050

3. Gas Chromatography

Instrument: Hewlett Packard 5890A

Column: Methyl Silicone(0.2mmϕ × 50m)

Column Temperature: 80°C

Flow Rate: 1 ml/min

Detector: FID(Flame Ionization Detector)

Injection Volume: 1 μl

Results: Gas chromatography indicated one major peak(peak No.4) and four impurities(peak No.1,2,3,5 < 5% of total area) analyzed at 1991.7.3 and one major peak(peak No.4) and four impurities(peak No.1,2,3,5 < 5% of total area) analyzed at 1991.7.30. It was identified only by comparing its gas chromatograph with that of the 1,4-Dioxane(peak No.5) in the 1,1,1-Trichloroethane, the amount in the test substance was 3.49% at 1991.7.3. The new treace impurity peak in the test substance analyzed at 1990.7.30 was not detected.

Date	Peak No.	Retention Time(min)	AREA COUNT
1991.07.03	1	2.388	130
(date analyzed)	2	2.453	93
	3	2.54	1083
	4	2.78	143204
	5	3.092	5544
1991.07.30	1	2.387	131
(date analyzed)	2	2.453	93
	3	2.54	1085
	4	2.78	144147
	5	3.092	5596

4. Conclusions: The results indicated that the test substance did not change when stored in the dark at room temperature during this period(for about 2 weeks).

APPENDIX B 12-1

CONCENTRATION OF 1,1,1-TRICHLOROETHANE IN INHALATION CHAMBER

(THIRTEEN - WEEK STUDY)

CONCENTRATION OF 1, 1, 1-TRICHLOROETANE
IN INHALTION CHAMBER
(RAT: THIRTEEN-WEEK STUDY)

Group Name	Concentration (ppm) Mean ± S.D.
Control	0.0 ± 0.0
2000ppm	2001.6 ± 12.7
3000ppm	2994.8 ± 15.4
4400ppm	4380.3 ± 31.6
6700ppm	6665.2 ± 45.5
10000ppm	10003.7 ± 81.9

CONCENTRATION OF 1, 1, 1-TRICHLOROETANE
IN INHALTION CHAMBER
(MOUSE: THIRTEEN-WEEK STUDY)

Group Name	Concentration (ppm) Mean ± S.D.
Control	0.0 ± 0.0
3000ppm	3006.0 ± 35.1
4400ppm	4388.1 ± 42.4
6700ppm	6696.1 ± 28.8
10000ppm	9997.4 ± 1.1
15000ppm	14972.9 ± 0.0

APPENDIX B 12-2

ENVIRONMENT OF INHALATION CHAMBER

(THIRTEEN - WEEK STUDY)

METHODS FOR HEMATOLOGY,BIOCHEMISTRY AND URINALYSIS

Item	Method	Unit
Hematology		
Red blood cell	Light scattering method [1]	$\times 10^6 / \mu L$
Hemoglobin	Cyanmethemoglobin method [1]	g/dL
Hematocrit	Calculated as RBC × MCV/10 [1]	%
Mean corpuscular volume (MCV)	Light scattering method [1]	fL
Mean corpuscular hemoglobin (MCH)	Calculated as Hgb/RBC × 10 [1]	pg
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as Hgb/Hct × 10 [1]	g/dL
Platelet	Light scattering method [1]	$\times 10^3 / \mu L$
White blood cell (WBC)	Light scattering method [1]	$\times 10^3 / \mu L$
Differential WBC	Pattern recognition method [2] (May−Grunwald−Giemsa staining)	%
Biochemistry		
Total protein	Biuret method [3]	g/dL
Albumin	BCG method [3]	g/dL
A/G ratio	Calculated as Alb/(TP−Alb) [3]	
T−bilirubin	Michaelson method [3]	mg/dL
Glucose	Enzymatic method (HK·G−6−PDH) [3]	mg/dL
T−cholesterol	Enzymatic method (CEH·COD·POD) [3]	mg/dL
Triglyceride	Enzymatic method (GK·GPO·POD) [3]	mg/dL
Phospholipid	Enzymatic method (PLD·COD·POD) [3]	mg/dL
Glutamic oxaloacetic transaminase (GOT)	Karmen method [3]	IU/L
Glutamic pyruvic transaminase(GPT)	Karmen method [3]	IU/L
Lactate dehydrogenase (LDH)	Wroblewski−LaDue method [3]	IU/L
Alkaline phosphatase (ALP)	GSCC method [3]	IU/L
γ −Glutamyl transpeptidase (G−GTP)	L− γ −Glutamyl−p−nitroanilide substrate method [3]	IU/L
Creatine phosphokinase (CPK)	GSCC method [3]	IU/L
Urea nitrogen	Enzymatic method (Urease ·GLDH) [3]	mg/dL
Creatinine	Jaffe metod [3]	mg/dL
Sodium	Flame photometry [4]	mEq/L
Potassium	Flame photometry [4]	mEq/L
Chloride	Coulometric titration [4]	mEq/L
Calcium	OCPC method 3)	mg/dL
Inorganic phosphorus	Enzymatic method (SPL·PGM·G−6−PDH) [3]	mg/dL
Urinalysis		
pH,Protein,Glucose,Ketone body, Bilirubin, Occult Blood,Urobilinogen	Urinalysis reagent paper metod [5]	

1) Automatic blood cell analyzer (Technicon H·1 : Technicon Instruments Corporation,USA)
2) Automatic blood cell differential analyzer (Hitachi 8200 : Hitachi ,Ltd.,Japan)
3) Automatic analyzer (Hitachi 705 : Hitachi ,Ltd.,Japan)
4) Flame photometer (Hitachi 750 : Hitachi ,Ltd.,Japan)
5) Ames reagent strips for urinalysis (Multistix,Uro−Labstix : Miles Sankyo Co.,Ltd.,Japan)

APPENDIX C 1

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS

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

Group Name	Temperature(℃) Mean ± S.D.	Humidity(%) Mean ± S.D.	Ventilation Rate(L/min) Mean ± S.D.	Room Air Change(time/h) Mean
Control	22.6 ± 0.2	60.2 ± 3.1	208.6 ± 11.5	11.8
2000ppm	22.5 ± 0.2	55.4 ± 2.4	208.9 ± 11.0	11.8
3000ppm	22.8 ± 0.2	57.7 ± 1.7	208.1 ± 11.0	11.8
4400ppm	22.2 ± 0.2	55.0 ± 1.6	207.9 ± 10.4	11.8
6700ppm	22.8 ± 0.3	51.3 ± 1.0	207.9 ± 10.7	11.8
10000ppm	22.6 ± 0.2	53.0 ± 1.3	208.8 ± 10.3	11.8

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

Group Name	Temperature(℃) Mean ± S.D.	Humidity(%) Mean ± S.D.	Ventilation Rate(L/min) Mean ± S.D.	Room Air Change(time/h) Mean
Control	21.2 ± 0.2	60.5 ± 2.6	102.3 ± 5.8	11.8
3000ppm	21.2 ± 0.2	60.0 ± 2.9	104.1 ± 0.6	12.0
4400ppm	21.3 ± 0.2	55.2 ± 2.9	104.7 ± 0.7	12.1
6700ppm	21.3 ± 0.4	56.0 ± 3.0	102.7 ± 5.2	11.9
10000ppm	20.9 ± 0.6	54.4 ± 5.8	103.6 ± 0.7	12.0
15000ppm	21.5 ± 0.0	48.0 ± 0.0	103.3 ± 0.0	11.9

APPENDIX C 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY

	TEST ITEM	DECIMAL PLACE	UNIT
HEMATOLOGY	Red blood cell	2	$\times 10^6/\mu L$
	Hemoglobin	1	g/dL
	Hematocrit	1	%
	MCV	1	fL
	MCH	1	pg
	MCHC	1	g/dL
	Platelet	0	$\times 10^3/\mu L$
	White blood cell	2	$\times 10^3/\mu L$
	Differential WBC	0	%
BIOCHEMISTRY	Total protein	1	g/dL
	Albumin	1	g/dL
	A/G ratio	1	—
	T-bilirubin	2	mg/dL
	Glucose	0	mg/dL
	T-cholesterol	0	mg/dL
	Triglyceride	0	mg/dL
	Phospholipid	0	mg/dL
	GOT	0	IU/L
	GPT	0	IU/L
	LDH	0	IU/L
	ALP	0	IU/L
	G-GTP	0	IU/L
	CPK	0	IU/L
	Urea nitrogen	1	mg/dL
	Creatinine	1	mg/dL
	Sodium	0	mEq/L
	Potassium	1	mEq/L
	Chloride	0	mEq/L
	Calcium	1	mg/dL
	Inorganic phosphorus	1	mg/dL