テトラクロロエチレンのラット及びマウスを用いた
吸 入 に よ る が ん 原 性 試 験 報 告 書

APPENDIX

(F1～K4)

がん原性試験 NO.　0104 ; 0105

APPENDIXES (CONTINUED)

APPENDIXES (CONTINUED)

APPENDIX F 1

HEMATOLOGY : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV fℓ	MCH pg	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	37	7.82± 1.82	13.6± 3.1	40.5± 8.0	52.7± 8.0	17.5± 2.2	33.4± 1.8	900± 377
50 ppm	33	8.28± 1.28	14.3± 2.7	41.8± 7.2	50.4± 2.6	17.1± 1.4	34.0± 1.4	886± 265
200 ppm	30	7.70± 1.42	13.6± 2.4	40.2± 6.3	52.7± 4.4	17.8± 1.5	33.8± 1.3	856± 250
600 ppm	28	7.27± 2.20	13.0± 3.4	38.8± 8.6	56.1± 13.1	18.3± 2.7	33.2± 2.7	865± 274

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

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	WBC $10^3/\mu\ell$	Differential WBC (%) N-BAND	N-SEG	EOSINO	BASO	MONO	LYMPHO	OTHER
Control	37	8.07± 6.07	3± 2	45± 13	2± 2	0± 0	4± 3	37± 11	9± 17
50 ppm	33	7.72± 5.07	2± 2	48± 13	2± 2	0± 0	6± 3	33± 10	8± 13
200 ppm	30	11.33± 16.77	2± 2	46± 16	2± 1	0± 0	5± 3	35± 13	11± 20
600 ppm	28	30.41± 72.32	2± 1	44± 19	1± 1	0± 0	4± 3	32± 14	17± 26

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

APPENDIX F 2

HEMATOLOGY : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV fℓ	MCH pg	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	42	7.84± 1.38	14.6± 2.2	42.3± 6.0	55.0± 7.4	18.9± 1.9	34.5± 1.2	621± 124
50 ppm	34	7.67± 1.12	14.5± 1.9	41.9± 4.5	55.3± 6.0	19.0± 1.0	34.5± 1.6	626± 161
200 ppm	33	7.59± 1.65	14.3± 3.0	41.2± 7.7	55.4± 5.8	19.0± 1.1	34.5± 2.2	622± 166
600 ppm	34	7.54± 1.34	14.5± 1.7	41.7± 4.1	56.8± 9.5	19.5± 2.3**	34.6± 1.4	643± 178

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

(HCL070)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	WBC $10^3/\mu\ell$	Differential WBC (%) N-BAND	N-SEG	EOSINO	BASO	MONO	LYMPHO	OTHER
Control	42	8.05± 24.44	3± 2	39± 13	1± 1	0± 0	5± 3	43± 13	9± 18
50 ppm	34	8.36± 25.78	3± 3	40± 15	2± 1	0± 0	4± 3	41± 16	9± 20
200 ppm	33	14.67± 47.15	3± 2	38± 14	2± 1	0± 0	4± 3	41± 14	11± 23
600 ppm	34	8.02± 17.35	3± 2	37± 13	2± 2	0± 0	5± 3	44± 14	9± 19

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

APPENDIX F 3

HEMATOLOGY : SUMMARY, MOSUE : MALE

(2-YEAR STUDY)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV fℓ	MCH pg	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	30	9.08± 0.79	13.3± 1.2	38.6± 3.2	42.6± 2.2	14.6± 0.8	34.4± 1.0	1875± 531
10 ppm	34	9.07± 0.94	13.2± 1.2	38.9± 3.2	43.0± 2.2	14.6± 0.6	34.0± 1.1	1996± 398
50 ppm	28	9.32± 1.36	13.4± 1.7	39.5± 4.8	42.6± 2.0	14.5± 0.7	34.0± 1.1	1741± 395
250 ppm	21	10.95± 2.18**	14.2± 2.7	42.6± 8.4*	39.1± 2.2**	13.0± 0.8**	33.4± 1.2**	1346± 518**

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

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	WBC $10^3/\mu\ell$	Differential WBC (%) N-BAND	N-SEG	EOSINO	BASO	MONO	LYMPHO	OTHER
Control	30	2.68± 1.54	2± 2	39± 17	1± 2	0± 0	4± 3	51± 17	2± 2
10 ppm	34	2.67± 1.72	3± 3	36± 14	1± 2	0± 0	4± 2	54± 15	2± 2
50 ppm	28	2.65± 1.66	3± 3	39± 13	1± 2	0± 0	4± 2	49± 15	4± 4
250 ppm	21	3.49± 1.73	3± 3	42± 13	1± 3	0± 0	4± 3	46± 16	4± 3*

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

(JCL71A)

APPENDIX F 4

HEMATOLOGY : SUMMARY, MOSUE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV fℓ	MCH pg	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	31	8.99± 1.18	13.3± 1.7	38.2± 4.2	42.7± 2.2	14.8± 0.5	34.7± 1.2	1093± 304
10 ppm	26	9.05± 1.34	13.5± 1.8	38.8± 5.0	43.1± 2.6	15.0± 0.8	34.7± 1.5	1057± 307
50 ppm	22	8.95± 0.92	13.2± 1.4	38.3± 3.2	42.9± 1.6	14.8± 0.6	34.5± 1.7	917± 382
250 ppm	16	10.12± 1.73*	14.8± 1.6**	42.3± 5.2**	42.1± 3.2	14.7± 1.2	35.0± 1.1	899± 332

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

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	WBC $10^3/\mu\ell$	Differential WBC (%) N-BAND	N-SEG	EOSINO	BASO	MONO	LYMPHO	OTHER
Control	31	3.95± 5.23	2± 2	26± 13	1± 1	0± 0	4± 3	60± 13	6± 7
10 ppm	26	2.94± 4.27	2± 2	37± 17*	1± 1	0± 0	5± 3	49± 17*	5± 6
50 ppm	22	8.74± 23.09	1± 1	27± 13	2± 4	0± 0	5± 3	59± 15	6± 5
250 ppm	16	4.50± 10.45	3± 2	37± 16	1± 1	0± 0	5± 2	47± 15**	8± 15

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

APPENDIX G 1

BIOCHEMISTRY : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	TOTAL PROTEIN g/dℓ	ALBUMIN g/dℓ	A/G RATIO	T-BILIRUBIN mg/dℓ	GLUCOSE mg/dℓ	T-CHOLESTEROL mg/dℓ	TRIGLYCERIDE mg/dℓ
Control	37	6.8± 0.5	3.2± 0.3	0.9± 0.1	0.32± 0.18	151± 23	163± 44	251± 136
50 ppm	33	7.0± 0.5	3.3± 0.2	0.9± 0.1	0.27± 0.07	147± 24	176± 50	258± 188
200 ppm	30	6.8± 0.5	3.2± 0.3	0.9± 0.1	0.28± 0.09	147± 19	171± 39	236± 122
600 ppm	28	6.8± 0.4	3.2± 0.3	0.9± 0.1	0.54± 0.97	137± 30	178± 54	251± 132

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

(HCL074)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

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	37	263± 77	85± 64	21± 10	227± 82	234± 146	6± 5	78± 25
50 ppm	33	284± 93	80± 44	26± 20	227± 55	266± 485	6± 4	79± 17
200 ppm	30	273± 66	83± 50	23± 8	236± 97	204± 77	6± 4	111± 155
600 ppm	28	291± 90	192± 300	45± 62**	638± 1586	285± 224	7± 6	108± 75

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

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

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	37	23.3± 6.7	0.7± 0.1	141± 2	3.7± 0.3	106± 2	10.7± 0.4	4.2± 0.9
50 ppm	33	25.2± 11.8	0.8± 0.2	141± 2	3.6± 0.3	105± 2	10.9± 0.5	4.1± 0.9
200 ppm	30	24.1± 3.7	0.7± 0.1	141± 2	3.7± 0.4	106± 2	10.7± 0.4	4.2± 0.8
600 ppm	28	27.6± 11.4	0.8± 0.3	142± 3	3.7± 0.5	107± 3	10.9± 0.7	5.1± 2.4

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

APPENDIX G 2

BIOCHEMISTRY : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

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	42	7.3± 0.6	3.8± 0.3	1.1± 0.1	0.32± 0.19	150± 18	139± 39	192± 188
50 ppm	33	7.2± 0.6	3.7± 0.3	1.1± 0.2	0.41± 0.72	148± 25	147± 60	191± 216
200 ppm	33	7.3± 0.5	3.9± 0.3	1.1± 0.1	0.36± 0.56*	146± 19	151± 35	140± 80
600 ppm	34	7.1± 0.4	3.7± 0.3	1.1± 0.1	0.36± 0.42	148± 16	146± 42	127± 100*

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

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

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	42	266± 85	119± 82	33± 14	342± 399	147± 64	4± 3	77± 15
50 ppm	33	276± 120	169± 226	42± 22	362± 479	148± 93	4± 3	86± 49
200 ppm	33	276± 67	253± 481	53± 57*	831± 2871	232± 446	5± 11	121± 202
600 ppm	34	261± 74	209± 211	65± 44**	349± 170	186± 127	4± 2	101± 54

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

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

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	42	16.3± 2.6	0.5± 0.1	140± 2	3.6± 0.5	104± 2	10.6± 0.5	3.5± 0.9
50 ppm	33	17.0± 2.3	0.5± 0.1	139± 2	3.5± 0.5	104± 2	10.5± 0.4	3.6± 1.1
200 ppm	33	18.3± 2.8**	0.5± 0.1	140± 2	3.6± 0.6	104± 2	10.6± 0.3	3.5± 0.9
600 ppm	34	19.0± 2.3**	0.5± 0.1	140± 2	3.8± 0.3**	105± 2	10.5± 0.3	3.9± 0.8

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

APPENDIX G 3

BIOCHEMISTRY : SUMMARY, MOSUE : MALE

(2-YEAR STUDY)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

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	30	5.4± 0.5	2.8± 0.4	1.1± 0.2	0.27± 0.10	186± 45	101± 21	71± 32
10 ppm	34	5.7± 0.9	3.0± 0.5	1.1± 0.2	0.26± 0.12	174± 53	109± 38	62± 32
50 ppm	28	5.7± 0.7	2.9± 0.4	1.0± 0.2	0.27± 0.13	167± 59	110± 51	61± 27
250 ppm	21	6.1± 0.9**	3.1± 0.5	1.0± 0.1	0.51± 0.46**	125± 44**	139± 44**	47± 12**

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

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

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	30	113± 167	40± 68	367± 296	175± 81	49± 28	25.8± 8.7	155± 2
10 ppm	34	108± 125	55± 130	438± 441	192± 147	62± 54	29.2± 12.7	155± 2
50 ppm	28	443± 1179*	118± 269*	1272± 3082	249± 164	64± 77	24.1± 7.9	155± 2
250 ppm	21	1718± 2908**	525± 636**	3140± 3611**	701± 441**	51± 26	20.7± 3.8*	154± 2

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

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	POTASSIUM mEq/ℓ	CHLORIDE mEq/ℓ	CALCIUM mg/dℓ	INORGANIC PHOSPHORUS mg/dℓ
Control	30	4.3± 0.4	122± 3	9.0± 0.3	6.6± 0.9
10 ppm	34	4.2± 0.5	121± 3	9.1± 0.7	6.6± 1.0
50 ppm	28	4.1± 0.4	121± 3	9.1± 0.7	6.4± 0.7
250 ppm	21	4.0± 0.5	118± 2**	9.6± 0.7**	6.5± 1.0

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

APPENDIX G 4

BIOCHEMISTRY : SUMMARY, MOSUE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

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	31	5.2± 0.8	2.8± 0.3	1.3± 0.2	0.29± 0.10	136± 33	71± 18	64± 19
10 ppm	26	5.2± 0.4	2.9± 0.3	1.2± 0.2	0.33± 0.16	132± 36	70± 19	76± 28
50 ppm	22	5.4± 0.8	2.9± 0.2	1.3± 0.2	0.25± 0.06	139± 32	70± 17	59± 19
250 ppm	16	5.6± 1.0	3.1± 0.6	1.2± 0.2	0.55± 0.75*	113± 35	95± 64	52± 24

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

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

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	31	100± 63	27± 19	428± 327	253± 93	53± 57	20.5± 15.7	152± 2
10 ppm	26	434± 1286	94± 204	1206± 2280	272± 110	55± 35	17.2± 4.9	153± 3
50 ppm	22	252± 535	81± 218	833± 1826	329± 266	87± 123	21.2± 19.1	153± 4
250 ppm	16	338± 211**	84± 36**	897± 1347**	514± 460*	58± 46	17.5± 5.3	153± 2

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

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	POTASSIUM mEq/ℓ	CHLORIDE mEq/ℓ	CALCIUM mg/dℓ	INORGANIC PHOSPHORUS mg/dℓ
Control	31	4.2± 0.7	122± 2	9.1± 0.6	6.3± 0.9
10 ppm	26	4.0± 0.4	122± 3	9.2± 0.4	6.3± 1.0
50 ppm	22	4.1± 0.6	122± 4	9.3± 1.1	6.6± 1.3
250 ppm	16	3.8± 0.3**	118± 4**	9.7± 1.5	6.2± 1.2

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

APPENDIX H 1

URINALYSIS : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0104
ANIMAL : RAT F344
SAMPLING DATE : 104-4
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	Bilirubin −	+	2+	3+	CHI
Control	39	0	2	7	8	17	5	0		0	0	0	0	9	30		39	0	0	0	0	0		39	0	0	0	0	0		38	0	0	1	
50 ppm	35	0	0	9	5	15	6	0		0	0	0	0	8	27		35	0	0	0	0	0		35	0	0	0	0	0		34	1	0	0	
200 ppm	32	1	0	2	8	13	8	0		0	0	0	2	5	25		32	0	0	0	0	0		32	0	0	0	0	0		32	0	0	0	
600 ppm	30	0	2	2	10	6	9	0		0	0	0	0	5	24		29	0	0	0	0	0		29	0	0	0	0	0		28	1	0	0	

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

STUDY NO. : 0104 URINALYSIS
ANIMAL : RAT F344
SAMPLING DATE : 104-4
SEX : MALE REPORT TYPE : A1

Group Name	NO. of Animals	Occult blood −	±	+	2+	3+	CHI	Urobilinogen ±	+	2+	3+	4+	CHI
Control	39	32	5	2	0	0		38	0	0	0	1	
50 ppm	35	33	2	0	0	0		34	1	0	0	0	
200 ppm	32	31	1	0	0	0		32	0	0	0	0	
600 ppm	30	27	1	0	1	0		29	0	0	0	0	

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

APPENDIX H 2

URINALYSIS : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0104
ANIMAL : RAT F344
SAMPLING DATE : 104-4
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	45	0	3	4	4	19	14	1		0	2	1	15	18	9		45	0	0	0	0	0		41	3	0	0	1	0		45	0	0	0	
50 ppm	35	0	1	3	7	13	11	0		0	0	1	12	11	11		35	0	0	0	0	0		34	1	0	0	0	0		34	0	1	0	
200 ppm	35	0	2	2	3	15	13	0		0	0	2	10	16	7		35	0	0	0	0	0		34	1	0	0	0	0		35	0	0	0	
600 ppm	34	0	0	3	3	9	17	2		0	0	4	7	16	7		34	0	0	0	0	0		33	1	0	0	0	0		34	0	0	0	

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

Test of CHI SQUARE

STUDY NO. : 0104
ANIMAL : RAT F344
SAMPLING DATE : 104-4
SEX : FEMALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	Occult blood −	±	+	2+	3+	CHI	Urobilinogen ±	+	2+	3+	4+	CHI
Control	45	43	2	0	0	0		43	1	0	1	0	
50 ppm	35	31	3	0	0	1		33	0	1	1	0	
200 ppm	35	33	1	1	0	0		35	0	0	0	0	
600 ppm	34	31	2	0	1	0		34	0	0	0	0	

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

APPENDIX H 3

URINALYSIS : SUMMARY, MOSUE : MALE

(2-YEAR STUDY)

STUDY NO. : 0105 URINALYSIS
ANIMAL : MOUSE BDF1
SAMPLING DATE : 104-4
SEX : MALE REPORT TYPE : A1

Group Name	NO. of Animals	pH 5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	Protein −	±	+	2+	3+	4+	CHI	Glucose −	±	+	2+	3+	4+	CHI	Ketone body −	±	+	2+	3+	4+	CHI	Occult blood −	±	+	2+	3+	CHI
Control	32	0	3	15	9	3	2	0		0	0	13	19	0	0		32	0	0	0	0	0		25	7	0	0	0	0		26	4	2	0	0	
10 ppm	35	0	2	14	13	6	0	0		0	1	11	20	3	0		35	0	0	0	0	0		28	7	0	0	0	0		29	2	4	0	0	
50 ppm	28	0	4	12	7	4	1	0		0	1	10	15	2	0		28	0	0	0	0	0		22	6	0	0	0	0		25	3	0	0	0	
250 ppm	24	0	4	15	3	2	0	0		0	0	9	13	2	0		24	0	0	0	0	0		16	8	0	0	0	0		18	4	1	1	0	

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

STUDY NO. : 0105 URINALYSIS
ANIMAL : MOUSE BDF1
SAMPLING DATE : 104-4
SEX : MALE REPORT TYPE : A1

Group Name	NO. of Animals	Urobilinogen ±	+	2+	3+	4+	CHI
Control	32	32	0	0	0	0	
10 ppm	35	35	0	0	0	0	
50 ppm	28	28	0	0	0	0	
250 ppm	24	24	0	0	0	0	

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

APPENDIX H 4

URINALYSIS : SUMMARY, MOSUE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0105 URINALYSIS

△ ANIMAL : MOUSE BDF1

SAMPLING DATE : 104-4

SEX : FEMALE REPORT TYPE : A1

Group Name	NO. of Animals	pH 5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	Protein −	±	+	2+	3+	4+	CHI	Glucose −	±	+	2+	3+	4+	CHI	Ketone body −	±	+	2+	3+	4+	CHI	Occult blood −	±	+	2+	3+	CHI
Control	37	1	4	9	12	7	2	1		0	5	25	6	0	0		36	0	0	0	0	0		30	6	0	0	0	0		31	1	2	2	0	
10 ppm	28	0	1	5	7	12	2	0		0	10	11	6	0	0		27	0	0	0	0	0		25	2	0	0	0	0		24	1	1	0	1	
50 ppm	24	0	2	6	6	8	1	0		0	6	11	6	0	0		23	0	0	0	0	0		22	1	0	0	0	0		16	1	5	1	0	
250 ppm	18	0	5	3	6	2	2	0		0	3	9	6	0	0		18	0	0	0	0	0		13	5	0	0	0	0		12	1	1	1	3	

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

STUDY NO. : 0105 URINALYSIS
ANIMAL : MOUSE BDF1
SAMPLING DATE : 104-4
SEX : FEMALE REPORT TYPE : A1

Group Name	NO. of Animals	Urobilinogen ±	+	2+	3+	4+	CHI
Control	37	35	1	0	0	0	
10 ppm	28	27	0	0	0	0	
50 ppm	24	23	0	0	0	0	
250 ppm	18	18	0	0	0	0	

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

APPENDIX I 1

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

(2-YEAR STUDY)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 13 (%)	50 ppm 16 (%)	200 ppm 20 (%)	600 ppm 22 (%)
skin/app	nodule		0 (0)	1 (6)	0 (0)	0 (0)
subcutis	edema		0 (0)	0 (0)	0 (0)	2 (9)
	jaundice		0 (0)	1 (6)	2 (10)	2 (9)
	mass		2 (15)	4 (25)	5 (25)	5 (23)
	cyst		0 (0)	0 (0)	0 (0)	1 (5)
lung	white		0 (0)	1 (6)	0 (0)	0 (0)
	red		2 (15)	2 (13)	0 (0)	5 (23)
	white zone		0 (0)	0 (0)	0 (0)	1 (5)
	red zone		0 (0)	0 (0)	1 (5)	2 (9)
	yellow zone		0 (0)	0 (0)	1 (5)	0 (0)
	edema		0 (0)	0 (0)	0 (0)	1 (5)
	nodule		1 (8)	0 (0)	2 (10)	1 (5)
	voluminus		0 (0)	1 (6)	0 (0)	0 (0)
lymph node	enlarged		0 (0)	2 (13)	3 (15)	3 (14)
thymus	enlarged		0 (0)	0 (0)	2 (10)	0 (0)
	red		0 (0)	1 (6)	0 (0)	0 (0)
	red zone		0 (0)	1 (6)	0 (0)	0 (0)
	nodule		0 (0)	1 (6)	0 (0)	0 (0)
spleen	enlarged		2 (15)	7 (44)	10 (50)	13 (59)
	white zone		0 (0)	1 (6)	0 (0)	3 (14)
	nodule		0 (0)	1 (6)	1 (5)	0 (0)
heart	white		0 (0)	1 (6)	0 (0)	1 (5)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 13 (%)	50 ppm 16 (%)	200 ppm 20 (%)	600 ppm 22 (%)
heart	elevated		0 (0)	0 (0)	1 (5)	0 (0)
	dilated		0 (0)	0 (0)	2 (10)	0 (0)
	fluid:red		1 (8)	0 (0)	0 (0)	0 (0)
artery/aort	induration		0 (0)	1 (6)	0 (0)	0 (0)
oral cavity	ulcer		1 (8)	0 (0)	0 (0)	0 (0)
tongue	nodule		0 (0)	0 (0)	0 (0)	1 (5)
forestomach	nodule		0 (0)	0 (0)	1 (5)	1 (5)
	ulcer		3 (23)	1 (6)	2 (10)	3 (14)
	erosion		1 (8)	0 (0)	0 (0)	1 (5)
gl stomach	white zone		1 (8)	0 (0)	0 (0)	1 (5)
	red zone		0 (0)	0 (0)	1 (5)	0 (0)
	black zone		1 (8)	0 (0)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	0 (0)	1 (5)
	ulcer		2 (15)	2 (13)	3 (15)	3 (14)
	erosion		0 (0)	0 (0)	1 (5)	1 (5)
	scarred		0 (0)	1 (6)	0 (0)	0 (0)
	fluid:black		1 (8)	0 (0)	0 (0)	1 (5)
stomach	fluid:black		1 (8)	0 (0)	0 (0)	0 (0)
small intes	gas		1 (8)	0 (0)	0 (0)	0 (0)
large intes	gas		1 (8)	0 (0)	0 (0)	0 (0)
liver	enlarged		1 (8)	4 (25)	2 (10)	4 (18)
	pale		2 (15)	1 (6)	2 (10)	0 (0)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 13	(%)	50 ppm 16	(%)	200 ppm 20	(%)	600 ppm 22	(%)
liver	brown patch/zone		0	(0)	1	(6)	0	(0)	0	(0)
	brown zone		0	(0)	0	(0)	0	(0)	1	(5)
	nodule		1	(8)	0	(0)	1	(5)	2	(9)
	rough		0	(0)	0	(0)	0	(0)	2	(9)
	granular		1	(8)	2	(13)	4	(20)	3	(14)
	herniation		0	(0)	1	(6)	0	(0)	0	(0)
	accentuation of lobular structure		0	(0)	1	(6)	0	(0)	0	(0)
pancreas	nodule		1	(8)	0	(0)	1	(5)	1	(5)
kidney	enlarged		0	(0)	0	(0)	2	(10)	0	(0)
	green		1	(8)	0	(0)	0	(0)	0	(0)
	black		0	(0)	0	(0)	0	(0)	1	(5)
	white zone		0	(0)	0	(0)	2	(10)	0	(0)
	nodule		0	(0)	0	(0)	2	(10)	2	(9)
	granular		3	(23)	6	(38)	5	(25)	9	(41)
urin bladd	urine:marked retention		1	(8)	0	(0)	1	(5)	0	(0)
pituitary	enlarged		4	(31)	2	(13)	8	(40)	3	(14)
	red zone		0	(0)	0	(0)	1	(5)	1	(5)
	nodule		2	(15)	2	(13)	2	(10)	1	(5)
thyroid	enlarged		0	(0)	1	(6)	2	(10)	0	(0)
	nodule		0	(0)	1	(6)	0	(0)	0	(0)
adrenal	enlarged		1	(8)	0	(0)	1	(5)	1	(5)
testis	enlarged		0	(0)	2	(13)	1	(5)	2	(9)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 13 (%)	50 ppm 16 (%)	200 ppm 20 (%)	600 ppm 22 (%)
testis	atrophic		3 (23)	4 (25)	6 (30)	4 (18)
	nodule		9 (69)	11 (69)	12 (60)	20 (91)
epididymis	enlarged		0 (0)	0 (0)	0 (0)	1 (5)
semin ves	enlarged		0 (0)	0 (0)	1 (5)	1 (5)
prostate	red		0 (0)	0 (0)	0 (0)	1 (5)
	black		0 (0)	0 (0)	1 (5)	0 (0)
eye	turbid		0 (0)	3 (19)	1 (5)	0 (0)
	white		0 (0)	0 (0)	1 (5)	0 (0)
	red		0 (0)	0 (0)	0 (0)	1 (5)
Zymbal gl	nodule		0 (0)	1 (6)	1 (5)	0 (0)
	adhesion		0 (0)	0 (0)	1 (5)	0 (0)
muscle	mass		1 (8)	0 (0)	0 (0)	2 (9)
bone	nodule		0 (0)	1 (6)	0 (0)	0 (0)
	adhesion		0 (0)	1 (6)	0 (0)	0 (0)
mediastinum	mass		0 (0)	2 (13)	0 (0)	0 (0)
peritoneum	nodule		1 (8)	1 (6)	0 (0)	1 (5)
	adhesion		0 (0)	0 (0)	0 (0)	1 (5)
retroperit	mass		0 (0)	1 (6)	0 (0)	0 (0)
	cyst		0 (0)	0 (0)	1 (5)	0 (0)
abdominal c	hemorrhage		0 (0)	1 (6)	0 (0)	2 (9)
	mass		0 (0)	1 (6)	0 (0)	0 (0)
	ascites		0 (0)	0 (0)	0 (0)	1 (5)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 13 (%)	50 ppm 16 (%)	200 ppm 20 (%)	600 ppm 22 (%)
mesenterium	nodule		1 (8)	0 (0)	0 (0)	0 (0)
adipose	nodule		0 (0)	0 (0)	0 (0)	3 (14)
thoracic ca	hemorrhage		1 (8)	1 (6)	0 (0)	2 (9)
	pleural fluid		1 (8)	1 (6)	4 (20)	3 (14)
other	nodule		0 (0)	0 (0)	1 (5)	0 (0)
whole body	anemic		1 (8)	1 (6)	1 (5)	1 (5)
	jaundice		0 (0)	1 (6)	0 (0)	3 (14)
	wasting		1 (8)	0 (0)	0 (0)	0 (0)

APPENDIX I 2

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

(2-YEAR STUDY)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 8 (%)	50 ppm 16 (%)	200 ppm 16 (%)	600 ppm 16 (%)
skin/app	nodule		0 (0)	1 (6)	0 (0)	1 (6)
subcutis	edema		0 (0)	0 (0)	1 (6)	0 (0)
	jaundice		0 (0)	5 (31)	4 (25)	3 (19)
	mass		0 (0)	6 (38)	1 (6)	2 (13)
lung	red		1 (13)	2 (13)	1 (6)	1 (6)
	white zone		0 (0)	1 (6)	0 (0)	0 (0)
	red zone		1 (13)	2 (13)	1 (6)	0 (0)
	nodule		0 (0)	0 (0)	1 (6)	0 (0)
	nodular		0 (0)	1 (6)	0 (0)	0 (0)
	voluminus		0 (0)	1 (6)	0 (0)	0 (0)
lymph node	enlarged		0 (0)	0 (0)	2 (13)	2 (13)
	red		0 (0)	0 (0)	0 (0)	1 (6)
thymus	enlarged		0 (0)	0 (0)	0 (0)	1 (6)
spleen	enlarged		4 (50)	8 (50)	9 (56)	11 (69)
	nodule		1 (13)	2 (13)	1 (6)	1 (6)
heart	enlarged		0 (0)	0 (0)	0 (0)	1 (6)
	pale		0 (0)	1 (6)	0 (0)	0 (0)
	white		0 (0)	1 (6)	0 (0)	1 (6)
	dilated		0 (0)	1 (6)	0 (0)	0 (0)
forestomach	ulcer		0 (0)	1 (6)	1 (6)	1 (6)
gl stomach	black patch/zone		0 (0)	0 (0)	0 (0)	1 (6)
	hemorrhage		0 (0)	0 (0)	0 (0)	1 (6)

Organ	Findings	Group Name / NO. of Animals	Control 8 (%)	50 ppm 16 (%)	200 ppm 16 (%)	600 ppm 16 (%)
gl stomach	ulcer		0 (0)	1 (6)	2 (13)	2 (13)
	fluid:black		0 (0)	0 (0)	0 (0)	1 (6)
stomach	fluid:black		0 (0)	1 (6)	0 (0)	1 (6)
small intes	nodule		0 (0)	0 (0)	1 (6)	0 (0)
liver	enlarged		0 (0)	1 (6)	1 (6)	0 (0)
	yellow		0 (0)	0 (0)	0 (0)	1 (6)
	white zone		0 (0)	1 (6)	0 (0)	0 (0)
	brown zone		1 (13)	0 (0)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	1 (6)	0 (0)
	granular		3 (38)	4 (25)	5 (31)	4 (25)
	herniation		0 (0)	1 (6)	0 (0)	1 (6)
pancreas	nodule		0 (0)	3 (19)	0 (0)	0 (0)
	nodular		0 (0)	0 (0)	1 (6)	0 (0)
kidney	enlarged		0 (0)	0 (0)	1 (6)	0 (0)
	black		1 (13)	0 (0)	0 (0)	2 (13)
	white patch/zone		0 (0)	1 (6)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	0 (0)	1 (6)
	granular		1 (13)	1 (6)	0 (0)	2 (13)
urin bladd	red zone		0 (0)	0 (0)	0 (0)	1 (6)
	urine:marked retention		0 (0)	0 (0)	1 (6)	0 (0)
pituitary	enlarged		3 (38)	3 (19)	4 (25)	4 (25)
	red patch/zone		0 (0)	0 (0)	2 (13)	1 (6)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 8 (%)	50 ppm 16 (%)	200 ppm 16 (%)	600 ppm 16 (%)
pituitary	white zone		0 (0)	1 (6)	0 (0)	0 (0)
	red zone		0 (0)	3 (19)	2 (13)	3 (19)
	brown zone		0 (0)	0 (0)	0 (0)	1 (6)
	black zone		0 (0)	2 (13)	0 (0)	0 (0)
	hemorrhage		1 (13)	0 (0)	0 (0)	1 (6)
	nodule		0 (0)	4 (25)	1 (6)	3 (19)
	cyst		1 (13)	0 (0)	0 (0)	1 (6)
thyroid	enlarged		1 (13)	2 (13)	0 (0)	0 (0)
adrenal	enlarged		0 (0)	1 (6)	0 (0)	1 (6)
ovary	cyst		0 (0)	0 (0)	0 (0)	1 (6)
uterus	nodule		0 (0)	1 (6)	2 (13)	1 (6)
	mass		0 (0)	0 (0)	0 (0)	1 (6)
	dilated lumen		0 (0)	1 (6)	0 (0)	0 (0)
vagina	mass		0 (0)	0 (0)	1 (6)	0 (0)
brain	enlarged		0 (0)	0 (0)	1 (6)	0 (0)
spinal cord	red zone		0 (0)	0 (0)	0 (0)	1 (6)
eye	white		0 (0)	0 (0)	0 (0)	1 (6)
Zymbal gl	nodule		1 (13)	0 (0)	0 (0)	0 (0)
muscle	mass		0 (0)	0 (0)	0 (0)	1 (6)
mediastinum	nodule		0 (0)	0 (0)	0 (0)	1 (6)
peritoneum	nodule		0 (0)	0 (0)	1 (6)	1 (6)
	nodular		0 (0)	1 (6)	0 (0)	0 (0)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 8 (%)	50 ppm 16 (%)	200 ppm 16 (%)	600 ppm 16 (%)
retroperit	nodule		0 (0)	0 (0)	0 (0)	1 (6)
abdominal c	hemorrhage		1 (13)	1 (6)	3 (19)	0 (0)
	ascites		1 (13)	0 (0)	0 (0)	0 (0)
mesenterium	nodular		0 (0)	1 (6)	0 (0)	0 (0)
adipose	nodule		1 (13)	0 (0)	0 (0)	0 (0)
thoracic ca	pleural fluid		2 (25)	1 (6)	3 (19)	2 (13)
whole body	anemic		1 (13)	4 (25)	1 (6)	2 (13)
	jaundice		1 (13)	0 (0)	0 (0)	0 (0)
	wasting		0 (0)	2 (13)	1 (6)	1 (6)

APPENDIX I 3

GROSS FINDINGS : SUMMARY, RAT : MALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / NO. of Animals	Control 37	(%)	50 ppm 34	(%)	200 ppm 30	(%)	600 ppm 28	(%)
skin/app	nodule		0	(0)	0	(0)	0	(0)	1	(4)
subcutis	jaundice		0	(0)	0	(0)	0	(0)	1	(4)
	mass		3	(8)	7	(21)	9	(30)	9	(32)
lung	red zone		1	(3)	0	(0)	0	(0)	0	(0)
	nodule		2	(5)	2	(6)	2	(7)	1	(4)
lymph node	enlarged		1	(3)	0	(0)	0	(0)	1	(4)
thymus	nodule		0	(0)	1	(3)	0	(0)	0	(0)
spleen	enlarged		5	(14)	1	(3)	6	(20)	7	(25)
	nodule		0	(0)	0	(0)	1	(3)	0	(0)
	adhesion		1	(3)	0	(0)	0	(0)	0	(0)
	scarred		1	(3)	0	(0)	0	(0)	0	(0)
forestomach	nodule		0	(0)	1	(3)	0	(0)	1	(4)
	ulcer		1	(3)	0	(0)	0	(0)	0	(0)
liver	white zone		2	(5)	1	(3)	1	(3)	0	(0)
	red zone		1	(3)	0	(0)	0	(0)	0	(0)
	nodule		2	(5)	1	(3)	0	(0)	2	(7)
	granular		3	(8)	1	(3)	5	(17)	6	(21)
	nodular		3	(8)	0	(0)	0	(0)	2	(7)
	herniation		1	(3)	2	(6)	0	(0)	2	(7)
kidney	nodule		1	(3)	0	(0)	0	(0)	1	(4)
	cyst		1	(3)	0	(0)	1	(3)	0	(0)
	granular		24	(65)	26	(76)	24	(80)	24	(86)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / NO. of Animals	Control 37 (%)	50 ppm 34 (%)	200 ppm 30 (%)	600 ppm 28 (%)
pituitary	enlarged		4 (11)	4 (12)	3 (10)	5 (18)
	red zone		3 (8)	6 (18)	4 (13)	4 (14)
	nodule		0 (0)	0 (0)	1 (3)	0 (0)
	cyst		0 (0)	1 (3)	0 (0)	0 (0)
thyroid	enlarged		1 (3)	2 (6)	3 (10)	0 (0)
	nodule		0 (0)	2 (6)	0 (0)	0 (0)
adrenal	enlarged		1 (3)	1 (3)	1 (3)	0 (0)
testis	atrophic		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		36 (97)	34 (100)	29 (97)	28 (100)
prostate	enlarged		1 (3)	0 (0)	0 (0)	0 (0)
brain	black zone		0 (0)	0 (0)	1 (3)	0 (0)
eye	white		1 (3)	0 (0)	0 (0)	0 (0)
Zymbal gl	nodule		1 (3)	0 (0)	0 (0)	0 (0)
bone	rough		0 (0)	0 (0)	1 (3)	0 (0)
mediastinum	mass		1 (3)	0 (0)	0 (0)	0 (0)
peritoneum	nodule		0 (0)	0 (0)	1 (3)	0 (0)
retroperit	mass		0 (0)	1 (3)	1 (3)	0 (0)
abdominal c	ascites		1 (3)	0 (0)	0 (0)	0 (0)
adipose	nodule		0 (0)	1 (3)	1 (3)	0 (0)
thoracic ca	pleural fluid		0 (0)	0 (0)	0 (0)	1 (4)
whole body	anemic		1 (3)	0 (0)	0 (0)	0 (0)

APPENDIX I 4

GROSS FINDINGS : SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / NO. of Animals	Control 42 (%)	50 ppm 34 (%)	200 ppm 34 (%)	600 ppm 34 (%)
skin/app	nodule		0 (0)	1 (3)	0 (0)	0 (0)
subcutis	mass		6 (14)	10 (29)	4 (12)	1 (3)
lung	white patch/zone		0 (0)	1 (3)	0 (0)	0 (0)
	nodule		2 (5)	0 (0)	1 (3)	0 (0)
lymph node	enlarged		0 (0)	1 (3)	0 (0)	0 (0)
spleen	enlarged		2 (5)	4 (12)	3 (9)	2 (6)
	scarred		0 (0)	0 (0)	0 (0)	1 (3)
liver	nodule		1 (2)	1 (3)	2 (6)	2 (6)
	granular		2 (5)	3 (9)	2 (6)	2 (6)
	nodular		1 (2)	2 (6)	2 (6)	6 (18)
	herniation		4 (10)	3 (9)	0 (0)	3 (9)
kidney	granular		7 (17)	9 (26)	6 (18)	5 (15)
pituitary	enlarged		11 (26)	11 (32)	8 (24)	3 (9)
	red zone		11 (26)	5 (15)	10 (29)	8 (24)
	nodule		0 (0)	0 (0)	1 (3)	0 (0)
thyroid	enlarged		1 (2)	1 (3)	0 (0)	0 (0)
	nodule		1 (2)	1 (3)	0 (0)	0 (0)
adrenal	enlarged		0 (0)	0 (0)	1 (3)	1 (3)
ovary	fluid:transparent		1 (2)	3 (9)	1 (3)	0 (0)
uterus	nodule		8 (19)	2 (6)	4 (12)	1 (3)
eye	white		2 (5)	0 (0)	0 (0)	3 (9)
muscle	nodule		1 (2)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name	Control	50 ppm	200 ppm	600 ppm
		NO. of Animals	42 (%)	34 (%)	34 (%)	34 (%)
adipose	nodule		0 (0)	0 (0)	0 (0)	1 (3)

APPENDIX I 5

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

(2-YEAR STUDY)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 19 (%)	10 ppm 15 (%)	50 ppm 22 (%)	250 ppm 28 (%)
skin/app	nodule		0 (0)	0 (0)	1 (5)	1 (4)
	scab		0 (0)	0 (0)	1 (5)	0 (0)
subcutis	edema		1 (5)	0 (0)	0 (0)	0 (0)
	mass		2 (11)	2 (13)	2 (9)	2 (7)
lung	red		2 (11)	0 (0)	0 (0)	2 (7)
	red patch/zone		0 (0)	0 (0)	0 (0)	1 (4)
	red zone		2 (11)	2 (13)	3 (14)	3 (11)
	nodule		2 (11)	3 (20)	4 (18)	5 (18)
lymph node	enlarged		4 (21)	1 (7)	1 (5)	1 (4)
thymus	enlarged		0 (0)	1 (7)	1 (5)	0 (0)
spleen	enlarged		3 (16)	3 (20)	2 (9)	2 (7)
	pale		0 (0)	0 (0)	1 (5)	0 (0)
	black zone		0 (0)	0 (0)	1 (5)	0 (0)
	nodule		0 (0)	0 (0)	2 (9)	3 (11)
heart	pale		1 (5)	0 (0)	0 (0)	0 (0)
	elevated		0 (0)	0 (0)	1 (5)	0 (0)
	dilated		0 (0)	0 (0)	1 (5)	1 (4)
salivary gl	enlarged		0 (0)	0 (0)	0 (0)	1 (4)
forestomach	nodule		0 (0)	0 (0)	0 (0)	1 (4)
	ulcer		0 (0)	1 (7)	0 (0)	0 (0)
gl stomach	ulcer		1 (5)	0 (0)	0 (0)	0 (0)
	thick		0 (0)	0 (0)	0 (0)	1 (4)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 19 (%)	10 ppm 15 (%)	50 ppm 22 (%)	250 ppm 28 (%)
gl stomach	fluid:black		1 (5)	0 (0)	0 (0)	0 (0)
stomach	fluid:red		0 (0)	1 (7)	0 (0)	0 (0)
jejunum	nodule		0 (0)	0 (0)	0 (0)	1 (4)
	adhesion		0 (0)	0 (0)	0 (0)	1 (4)
colon	red zone		1 (5)	0 (0)	0 (0)	0 (0)
liver	enlarged		1 (5)	0 (0)	0 (0)	0 (0)
	pale		1 (5)	0 (0)	0 (0)	1 (4)
	white zone		1 (5)	0 (0)	0 (0)	1 (4)
	red zone		0 (0)	0 (0)	1 (5)	2 (7)
	nodule		5 (26)	7 (47)	13 (59)	25 (89)
	nodular		1 (5)	0 (0)	0 (0)	0 (0)
	adhesion		1 (5)	0 (0)	0 (0)	0 (0)
pancreas	nodule		2 (11)	0 (0)	0 (0)	0 (0)
	mass		1 (5)	0 (0)	0 (0)	0 (0)
	nodular		1 (5)	0 (0)	0 (0)	0 (0)
kidney	enlarged		1 (5)	0 (0)	0 (0)	0 (0)
	atrophic		0 (0)	0 (0)	0 (0)	1 (4)
	pale		0 (0)	0 (0)	0 (0)	1 (4)
	white zone		0 (0)	0 (0)	0 (0)	1 (4)
	elevated		0 (0)	1 (7)	0 (0)	0 (0)
	nodule		1 (5)	0 (0)	3 (14)	2 (7)
	deformed		1 (5)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 19 (%)	10 ppm 15 (%)	50 ppm 22 (%)	250 ppm 28 (%)
kidney	nodular		0 (0)	0 (0)	1 (5)	0 (0)
	hydronephrosis		1 (5)	0 (0)	1 (5)	1 (4)
ureter	dilated		0 (0)	0 (0)	1 (5)	0 (0)
urin bladd	white		0 (0)	0 (0)	1 (5)	0 (0)
	nodule		0 (0)	0 (0)	0 (0)	3 (11)
	urine:marked retention		5 (26)	5 (33)	6 (27)	1 (4)
	urine:turbid		0 (0)	0 (0)	0 (0)	1 (4)
pituitary	red		1 (5)	0 (0)	0 (0)	0 (0)
testis	enlarged		0 (0)	0 (0)	0 (0)	1 (4)
	nodule		1 (5)	0 (0)	0 (0)	0 (0)
semin ves	enlarged		4 (21)	3 (20)	7 (32)	0 (0)
	atrophic		1 (5)	0 (0)	0 (0)	0 (0)
	red		0 (0)	0 (0)	1 (5)	0 (0)
	brown		0 (0)	0 (0)	3 (14)	1 (4)
	black		3 (16)	0 (0)	0 (0)	0 (0)
	red zone		0 (0)	0 (0)	1 (5)	0 (0)
prep/cli gl	nodule		1 (5)	0 (0)	2 (9)	0 (0)
brain	hemorrhage		1 (5)	0 (0)	0 (0)	0 (0)
periph nerv	cyst		0 (0)	0 (0)	0 (0)	1 (4)
Harder gl	enlarged		0 (0)	0 (0)	1 (5)	1 (4)
	nodule		0 (0)	0 (0)	0 (0)	2 (7)
bone	nodule		0 (0)	0 (0)	1 (5)	0 (0)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 19 (%)	10 ppm 15 (%)	50 ppm 22 (%)	250 ppm 28 (%)
pleura	adhesion		1 (5)	0 (0)	0 (0)	0 (0)
peritoneum	nodule		1 (5)	1 (7)	0 (0)	0 (0)
retroperit	nodule		0 (0)	1 (7)	0 (0)	0 (0)
	mass		1 (5)	0 (0)	3 (14)	0 (0)
abdominal c	hemorrhage		2 (11)	0 (0)	4 (18)	7 (25)
	ascites		0 (0)	1 (7)	3 (14)	2 (7)
mesenterium	nodule		0 (0)	0 (0)	2 (9)	1 (4)
	mass		1 (5)	0 (0)	0 (0)	0 (0)
adipose	nodule		2 (11)	1 (7)	1 (5)	2 (7)
thoracic ca	hemorrhage		0 (0)	1 (7)	1 (5)	1 (4)
	mass		2 (11)	0 (0)	0 (0)	0 (0)
	pleural fluid		2 (11)	3 (20)	3 (14)	2 (7)
	ascites		1 (5)	0 (0)	0 (0)	0 (0)
other	ear:nodule		1 (5)	0 (0)	0 (0)	0 (0)
	hindlimb:swollen		1 (5)	0 (0)	1 (5)	0 (0)
whole body	anemic		1 (5)	0 (0)	1 (5)	0 (0)

APPENDIX I 6

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

(2-YEAR STUDY)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 18	(%)	10 ppm 20	(%)	50 ppm 27	(%)	250 ppm 33	(%)
skin/app	reduced		1	(6)	0	(0)	1	(4)	1	(3)
	nodule		0	(0)	0	(0)	1	(4)	1	(3)
subcutis	edema		8	(44)	3	(15)	7	(26)	1	(3)
	mass		1	(6)	1	(5)	2	(7)	3	(9)
	adhesion		0	(0)	0	(0)	0	(0)	1	(3)
lung	white		0	(0)	0	(0)	1	(4)	0	(0)
	red		1	(6)	1	(5)	2	(7)	1	(3)
	white zone		0	(0)	0	(0)	1	(4)	0	(0)
	red zone		0	(0)	1	(5)	2	(7)	3	(9)
	edema		0	(0)	3	(15)	0	(0)	1	(3)
	nodule		1	(6)	1	(5)	1	(4)	0	(0)
lymph node	enlarged		7	(39)	4	(20)	8	(30)	8	(24)
thymus	nodule		0	(0)	1	(5)	0	(0)	0	(0)
spleen	enlarged		6	(33)	3	(15)	13	(48)	4	(12)
	pale		0	(0)	0	(0)	1	(4)	0	(0)
	nodule		0	(0)	1	(5)	0	(0)	0	(0)
	deformed		0	(0)	0	(0)	1	(4)	0	(0)
heart	nodule		0	(0)	0	(0)	0	(0)	1	(3)
	cyst		0	(0)	0	(0)	1	(4)	0	(0)
	dilated		1	(6)	1	(5)	0	(0)	2	(6)
forestomach	nodule		0	(0)	0	(0)	0	(0)	1	(3)
	ulcer		1	(6)	0	(0)	0	(0)	0	(0)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 18	(%)	10 ppm 20	(%)	50 ppm 27	(%)	250 ppm 33	(%)
gl stomach	black zone		1	(6)	0	(0)	0	(0)	1	(3)
	nodule		1	(6)	0	(0)	1	(4)	0	(0)
	ulcer		0	(0)	0	(0)	1	(4)	0	(0)
	thick		0	(0)	0	(0)	0	(0)	1	(3)
liver	enlarged		5	(28)	2	(10)	7	(26)	2	(6)
	pale		0	(0)	0	(0)	0	(0)	1	(3)
	white zone		5	(28)	1	(5)	7	(26)	3	(9)
	red zone		0	(0)	0	(0)	0	(0)	2	(6)
	nodule		5	(28)	8	(40)	2	(7)	24	(73)
	deformed		0	(0)	0	(0)	0	(0)	1	(3)
	rough		1	(6)	1	(5)	0	(0)	0	(0)
	nodular		0	(0)	0	(0)	1	(4)	1	(3)
	adhesion		0	(0)	2	(10)	1	(4)	2	(6)
gall bladd	nodule		0	(0)	1	(5)	0	(0)	0	(0)
	dilated		0	(0)	0	(0)	0	(0)	1	(3)
pancreas	nodule		3	(17)	2	(10)	0	(0)	3	(9)
	nodular		0	(0)	2	(10)	0	(0)	0	(0)
	thick		0	(0)	1	(5)	0	(0)	0	(0)
kidney	enlarged		1	(6)	2	(10)	0	(0)	0	(0)
	pale		0	(0)	1	(5)	0	(0)	2	(6)
	white zone		1	(6)	1	(5)	0	(0)	0	(0)
	black zone		0	(0)	1	(5)	0	(0)	0	(0)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 18 (%)	10 ppm 20 (%)	50 ppm 27 (%)	250 ppm 33 (%)
kidney	nodule		0 (0)	1 (5)	0 (0)	2 (6)
	cyst		0 (0)	1 (5)	0 (0)	0 (0)
	granular		1 (6)	0 (0)	0 (0)	0 (0)
	hydronephrosis		0 (0)	1 (5)	0 (0)	1 (3)
urin bladd	urine:marked retention		0 (0)	1 (5)	1 (4)	0 (0)
	urine:red		0 (0)	1 (5)	0 (0)	0 (0)
pituitary	enlarged		3 (17)	2 (10)	1 (4)	4 (12)
	red zone		0 (0)	0 (0)	1 (4)	0 (0)
	hemorrhage		0 (0)	0 (0)	0 (0)	1 (3)
	nodule		1 (6)	0 (0)	1 (4)	2 (6)
thyroid	enlarged		0 (0)	0 (0)	0 (0)	1 (3)
adrenal	enlarged		0 (0)	1 (5)	0 (0)	0 (0)
ovary	enlarged		4 (22)	2 (10)	5 (19)	3 (9)
	hemorrhage		0 (0)	0 (0)	0 (0)	1 (3)
	cyst		0 (0)	1 (5)	1 (4)	0 (0)
	fluid:red		0 (0)	1 (5)	1 (4)	0 (0)
	fluid:black		1 (6)	0 (0)	0 (0)	0 (0)
	fluid:transparent		2 (11)	0 (0)	5 (19)	1 (3)
uterus	enlarged		0 (0)	0 (0)	1 (4)	0 (0)
	nodule		8 (44)	8 (40)	8 (30)	11 (33)
	adhesion		0 (0)	1 (5)	0 (0)	0 (0)
	dilated lumen		1 (6)	0 (0)	0 (0)	1 (3)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 18 (%)	10 ppm 20 (%)	50 ppm 27 (%)	250 ppm 33 (%)
brain	red zone		0 (0)	0 (0)	1 (4)	0 (0)
	black zone		0 (0)	0 (0)	1 (4)	0 (0)
	hemorrhage		1 (6)	0 (0)	0 (0)	0 (0)
muscle	nodule		0 (0)	0 (0)	0 (0)	1 (3)
mediastinum	nodule		2 (11)	0 (0)	4 (15)	0 (0)
	mass		1 (6)	0 (0)	2 (7)	1 (3)
	adhesion		0 (0)	0 (0)	1 (4)	0 (0)
peritoneum	nodule		1 (6)	0 (0)	1 (4)	1 (3)
	mass		1 (6)	2 (10)	0 (0)	1 (3)
	nodular		0 (0)	1 (5)	0 (0)	0 (0)
	adhesion		0 (0)	1 (5)	0 (0)	0 (0)
retroperit	nodule		1 (6)	0 (0)	0 (0)	1 (3)
	mass		1 (6)	1 (5)	1 (4)	1 (3)
abdominal c	hemorrhage		3 (17)	5 (25)	1 (4)	5 (15)
	mass		0 (0)	1 (5)	0 (0)	0 (0)
	ascites		6 (33)	4 (20)	8 (30)	1 (3)
mesenterium	nodule		0 (0)	0 (0)	1 (4)	0 (0)
	nodular		0 (0)	1 (5)	0 (0)	0 (0)
adipose	nodule		1 (6)	0 (0)	1 (4)	0 (0)
thoracic ca	hemorrhage		0 (0)	0 (0)	1 (4)	0 (0)
	mass		0 (0)	1 (5)	2 (7)	2 (6)
	pleural fluid		10 (56)	9 (45)	12 (44)	9 (27)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 18 (%)	10 ppm 20 (%)	50 ppm 27 (%)	250 ppm 33 (%)
other	absence		1 (6)	1 (5)	0 (0)	0 (0)
whole body	anemic		0 (0)	3 (15)	2 (7)	2 (6)

APPENDIX I 7

GROSS FINDINGS : SUMMARY, MOSUE : MALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / NO. of Animals	Control 31	(%)	10 ppm 35	(%)	50 ppm 28	(%)	250 ppm 22	(%)
skin/app	nodule		0	(0)	0	(0)	1	(4)	0	(0)
subcutis	mass		0	(0)	1	(3)	0	(0)	0	(0)
brown fat	red zone		0	(0)	1	(3)	0	(0)	0	(0)
lung	congestion		0	(0)	0	(0)	0	(0)	1	(5)
	nodule		12	(39)	9	(26)	6	(21)	4	(18)
lymph node	enlarged		1	(3)	3	(9)	2	(7)	3	(14)
spleen	enlarged		2	(6)	2	(6)	1	(4)	0	(0)
	black zone		0	(0)	3	(9)	1	(4)	0	(0)
	nodule		1	(3)	2	(6)	1	(4)	3	(14)
forestomach	nodule		0	(0)	0	(0)	1	(4)	0	(0)
gl stomach	nodule		0	(0)	0	(0)	1	(4)	0	(0)
duodenum	nodule		1	(3)	0	(0)	0	(0)	0	(0)
small intes	nodule		1	(3)	0	(0)	0	(0)	2	(9)
liver	nodule		13	(42)	17	(49)	19	(68)	22	(100)
pancreas	nodule		0	(0)	0	(0)	2	(7)	0	(0)
kidney	white		0	(0)	1	(3)	0	(0)	0	(0)
	nodule		0	(0)	0	(0)	1	(4)	0	(0)
	adhesion		0	(0)	0	(0)	1	(4)	0	(0)
	induration		0	(0)	0	(0)	0	(0)	1	(5)
	hydronephrosis		0	(0)	1	(3)	1	(4)	0	(0)
pituitary	enlarged		0	(0)	0	(0)	2	(7)	0	(0)
testis	induration		1	(3)	0	(0)	0	(0)	0	(0)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / NO. of Animals	Control 31 (%)	10 ppm 35 (%)	50 ppm 28 (%)	250 ppm 22 (%)
epididymis	enlarged		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		0 (0)	1 (3)	1 (4)	0 (0)
semin ves	enlarged		24 (77)	27 (77)	19 (68)	3 (14)
	atrophic		0 (0)	1 (3)	0 (0)	0 (0)
prep/cli gl	nodule		0 (0)	3 (9)	0 (0)	0 (0)
Harder gl	nodule		2 (6)	0 (0)	0 (0)	3 (14)
abdominal c	ascites		0 (0)	1 (3)	0 (0)	0 (0)
mesenterium	nodule		0 (0)	0 (0)	1 (4)	0 (0)
adipose	nodule		2 (6)	5 (14)	1 (4)	3 (14)
thoracic ca	pleural fluid		0 (0)	1 (3)	0 (0)	0 (0)
other	tail:nodule		0 (0)	0 (0)	0 (0)	1 (5)
	ear:nodule		0 (0)	1 (3)	0 (0)	0 (0)

APPENDIX I 8

GROSS FINDINGS : SUMMARY, MOSUE : FEMALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / NO. of Animals	Control 32 (%)	10 ppm 27 (%)	50 ppm 22 (%)	250 ppm 17 (%)
subcutis	mass		3 (9)	1 (4)	0 (0)	0 (0)
lung	white zone		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		2 (6)	3 (11)	2 (9)	5 (29)
lymph node	enlarged		1 (3)	3 (11)	1 (5)	1 (6)
spleen	enlarged		3 (9)	5 (19)	3 (14)	0 (0)
	black zone		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	1 (5)	0 (0)
tongue	nodule		0 (0)	0 (0)	0 (0)	1 (6)
forestomach	nodule		0 (0)	0 (0)	2 (9)	1 (6)
liver	white		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		10 (31)	10 (37)	10 (45)	15 (88)
kidney	white		0 (0)	1 (4)	0 (0)	0 (0)
	white zone		1 (3)	0 (0)	1 (5)	0 (0)
	nodule		0 (0)	1 (4)	0 (0)	0 (0)
	hydronephrosis		1 (3)	0 (0)	1 (5)	0 (0)
pituitary	enlarged		1 (3)	1 (4)	0 (0)	2 (12)
	red		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		4 (13)	3 (11)	0 (0)	0 (0)
ovary	enlarged		0 (0)	0 (0)	2 (9)	0 (0)
	nodule		1 (3)	1 (4)	0 (0)	1 (6)
	fluid:transparent		14 (44)	7 (26)	9 (41)	5 (29)
uterus	nodule		2 (6)	6 (22)	1 (5)	1 (6)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / NO. of Animals	Control 32 (%)	10 ppm 27 (%)	50 ppm 22 (%)	250 ppm 17 (%)
uterus	dilated lumen		0 (0)	1 (4)	1 (5)	0 (0)
Harder gl	nodule		2 (6)	1 (4)	0 (0)	1 (6)
mediastinum	mass		3 (9)	2 (7)	2 (9)	0 (0)
peritoneum	nodule		1 (3)	0 (0)	0 (0)	0 (0)
abdominal c	ascites		5 (16)	1 (4)	3 (14)	1 (6)
adipose	nodule		2 (6)	0 (0)	0 (0)	0 (0)
thoracic ca	pleural fluid		4 (13)	2 (7)	1 (5)	0 (0)
other	ear:nodule		0 (0)	0 (0)	1 (5)	0 (0)

APPENDIX J 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	Body Weight	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	37	436± 41	0.089± 0.041	5.375± 1.588	1.283± 0.113	1.618± 0.367	2.926± 0.197
50 ppm	34	420± 54	0.091± 0.048	5.097± 1.472	1.298± 0.212	1.642± 0.519	3.002± 0.299
200 ppm	30	437± 53	0.129± 0.256	5.668± 1.775	1.293± 0.133	1.642± 0.399	3.158± 0.389**
600 ppm	28	410± 49	0.085± 0.015	5.981± 2.633	1.265± 0.125	1.767± 0.515	3.553± 1.294**

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

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	37	2.199± 2.462	13.487± 2.642	2.048± 0.061
50 ppm	34	1.449± 0.635	13.152± 1.894	2.026± 0.046
200 ppm	30	2.524± 2.652	14.442± 2.918	2.034± 0.056
600 ppm	28	2.660± 2.967	14.681± 2.307	1.998± 0.051**

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

APPENDIX J 2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	Body Weight	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	42	307± 28	0.079± 0.014	0.131± 0.032	0.920± 0.079	1.066± 0.245	1.966± 0.195
50 ppm	34	304± 34	0.080± 0.010	0.158± 0.076	0.922± 0.080	1.103± 0.311	2.001± 0.162
200 ppm	34	286± 32*	0.089± 0.049	0.129± 0.030	0.924± 0.073	1.086± 0.220	1.994± 0.176
600 ppm	34	282± 31**	0.083± 0.036	0.135± 0.029	0.931± 0.078	1.108± 0.251	2.030± 0.156

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

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	42	0.835± 0.912	7.734± 1.283	1.835± 0.054
50 ppm	34	1.397± 2.379	8.584± 1.613*	1.827± 0.057
200 ppm	34	1.045± 1.501	8.395± 2.251	1.833± 0.043
600 ppm	34	1.293± 2.067	8.563± 1.827*	1.804± 0.050

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

APPENDIX J 3

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : MALE

(2-YEAR STUDY)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	Body Weight	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	31	46.0± 9.1	0.011± 0.002	0.222± 0.038	0.220± 0.020	0.214± 0.032	0.654± 0.052
10 ppm	35	45.0± 8.1	0.011± 0.002	0.232± 0.070	0.217± 0.027	0.252± 0.175	0.757± 0.745
50 ppm	28	40.9± 8.5	0.011± 0.003	0.220± 0.035	0.215± 0.024	0.254± 0.207	0.703± 0.431
250 ppm	22	33.6± 4.1**	0.011± 0.002	0.201± 0.027	0.228± 0.028	0.233± 0.056	0.600± 0.060**

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

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	31	0.144± 0.160	1.829± 0.673	0.457± 0.010
10 ppm	35	0.121± 0.148	1.786± 0.535	0.455± 0.013
50 ppm	28	0.166± 0.336	1.861± 0.767	0.455± 0.014
250 ppm	22	0.193± 0.186**	2.789± 0.907**	0.451± 0.013

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

APPENDIX J 4

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	Body Weight	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	32	34.0± 4.9	0.014± 0.003	0.059± 0.060	0.174± 0.018	0.220± 0.049	0.486± 0.144
10 ppm	27	33.6± 5.9	0.013± 0.002	0.041± 0.037	0.185± 0.029	0.214± 0.069	0.555± 0.313
50 ppm	22	32.2± 4.5	0.013± 0.003	0.133± 0.349	0.169± 0.020	0.213± 0.043	0.477± 0.185
250 ppm	17	27.5± 3.3**	0.012± 0.002	0.050± 0.045	0.184± 0.022	0.221± 0.043	0.446± 0.046

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

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	32	0.298± 0.542	1.618± 0.525	0.483± 0.027
10 ppm	27	0.241± 0.297	1.644± 0.536	0.481± 0.013
50 ppm	22	0.248± 0.209	1.669± 0.839	0.473± 0.017
250 ppm	17	0.161± 0.112	1.477± 0.398	0.467± 0.013

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

APPENDIX K 1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	37	436± 41	0.021± 0.011	1.224± 0.349	0.298± 0.051	0.378± 0.126	0.678± 0.100
50 ppm	34	420± 54	0.022± 0.012	1.217± 0.354	0.316± 0.085	0.406± 0.196	0.730± 0.159
200 ppm	30	437± 53	0.031± 0.063	1.305± 0.411	0.298± 0.037	0.382± 0.115	0.732± 0.133*
600 ppm	28	410± 49	0.021± 0.007	1.457± 0.642	0.314± 0.059	0.446± 0.185	0.894± 0.416**

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

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	37	0.538± 0.700	3.134± 0.781	0.474± 0.057
50 ppm	34	0.344± 0.151	3.169± 0.547	0.491± 0.077
200 ppm	30	0.601± 0.732	3.343± 0.853	0.470± 0.044
600 ppm	28	0.717± 1.017	3.673± 1.038**	0.495± 0.060

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

APPENDIX K 2

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	42	307± 28	0.026± 0.005	0.043± 0.011	0.302± 0.036	0.349± 0.084	0.643± 0.064
50 ppm	34	304± 34	0.027± 0.005	0.053± 0.029	0.307± 0.042	0.373± 0.149	0.665± 0.091
200 ppm	34	286± 32*	0.031± 0.016*	0.046± 0.012	0.327± 0.047*	0.388± 0.116*	0.702± 0.070**
600 ppm	34	282± 31**	0.030± 0.014	0.048± 0.011	0.334± 0.041**	0.400± 0.114**	0.729± 0.097**

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

STUDY NO. : 0104
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	42	0.274± 0.303	2.524± 0.387	0.602± 0.058
50 ppm	34	0.503± 0.933	2.878± 0.772	0.608± 0.069
200 ppm	34	0.396± 0.634	2.985± 0.988**	0.649± 0.083*
600 ppm	34	0.482± 0.838	3.074± 0.764**	0.648± 0.070*

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

APPENDIX K 3

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : MALE

(2-YEAR STUDY)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	31	46.0± 9.1	0.024± 0.005	0.500± 0.123	0.495± 0.103	0.486± 0.132	1.484± 0.361
10 ppm	35	45.0± 8.1	0.025± 0.006	0.524± 0.152	0.499± 0.111	0.618± 0.686	1.764± 1.889
50 ppm	28	40.9± 8.5	0.028± 0.008	0.550± 0.078	0.549± 0.139	0.698± 0.835	1.784± 1.117
250 ppm	22	33.6± 4.1**	0.032± 0.007**	0.609± 0.117**	0.685± 0.077**	0.700± 0.148**	1.800± 0.177**

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

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	31	0.312± 0.322	4.129± 1.950	1.037± 0.233
10 ppm	35	0.286± 0.360	4.090± 1.493	1.047± 0.213
50 ppm	28	0.451± 0.942	4.863± 2.837	1.162± 0.254
250 ppm	22	0.576± 0.520**	8.328± 2.691**	1.362± 0.172**

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

APPENDIX K 4

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	32	34.0± 4.9	0.041± 0.007	0.176± 0.173	0.516± 0.051	0.660± 0.167	1.468± 0.599
10 ppm	27	33.6± 5.9	0.041± 0.008	0.119± 0.080	0.574± 0.171	0.666± 0.290	1.757± 1.237
50 ppm	22	32.2± 4.5	0.040± 0.006	0.404± 1.007	0.532± 0.078	0.686± 0.231	1.542± 0.874
250 ppm	17	27.5± 3.3**	0.043± 0.006	0.175± 0.142	0.676± 0.090**	0.817± 0.197**	1.639± 0.204**

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

STUDY NO. : 0105
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	32	0.950± 1.989	4.781± 1.403	1.448± 0.221
10 ppm	27	0.774± 1.017	4.990± 1.785	1.479± 0.283
50 ppm	22	0.827± 0.778	5.429± 3.835	1.494± 0.198
250 ppm	17	0.577± 0.397	5.435± 1.613	1.725± 0.216**

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