

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

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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)

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ³ /μl	
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 : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

△

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

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

PAGE : 1

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) 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 : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(JCL71A)

BAIS 2

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)

PAGE : 2

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ⁹ /μl	
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 ≤ 0.05 ** : P ≤ 0.01 Test of Dunnett															

(HCL070)

BAIS2

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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 /μl		Differential N-BAND		WBC (%) 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

(JCL71A)

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)

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ³ /μl	
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

(HCL070)

BAIS2

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

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

PAGE : 1

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) 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 ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX F 4

HEMATOLOGY : SUMMARY, MOSUE : FEMALE

(2-YEAR STUDY)

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

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

PAGE : 2

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ³ /μl	
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 ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

△

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

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

PAGE : 2

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) 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 ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(JCL71A)

BAIS2

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)

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	37	6.8±	0.5	3.2±	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 ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 2

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 ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

△

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

(HCL074)

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

Test of Dunnett

(HCL074)

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

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (105)

PAGE : 5

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 ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

△

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

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (105)

PAGE : 6

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

Test of Dunnett

(HCL074)

BAIS2

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)

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	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 ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

△

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 2

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 ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

△

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 3

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 ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

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)

PAGE : 4

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	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 ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

△

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

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (105)

PAGE : 5

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±	4.8	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 ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

△

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

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 6

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

Test of Dunnett

(HCL074)

BAIS2

APPENDIX H 1

URINALYSIS : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0104
 ANIMAL : RAT F344
 SAMPLING DATE : 104-4
 SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	pH							CHI	Protein						CHI	Glucose						CHI	Ketone body						CHI	Bilirubin				CHI
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+	4+		-	±	+	2+	3+	4+		-	±	+	2+	3+	4+		-	+	2+	3+	
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	

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

Test of CHI SQUARE

(JCL101)

BAIS 2

△

STUDY NO. : 0104

URINALYSIS

ANIMAL : RAT F344

SAMPLING DATE : 104-4

SEX : MALE

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
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	

Significant difference ;

* : $P \leq 0.05$

** : $P \leq 0.01$

Test of CHI SQUARE

(JCL101)

BAIS 2

APPENDIX H 2

URINALYSIS : SUMMARY, RAT : FEMALE
(2-YEAR STUDY)

△

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

URINALYSIS

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	pH_____							CHI	Protein_____					CHI	Glucose_____					CHI	Ketone body_____					CHI	Bilirubin_____				CHI		
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	±	+		2+	3+	4+	-		+	2+
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

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

Test of CHI SQUARE

(JCL101)

BAIS2

△

STUDY NO. : 0104

URINALYSIS

ANIMAL : RAT F344

SAMPLING DATE : 104-4

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Occult blood					Urobilinogen						
		-	±	+	2+	3+	CHI	±	+	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	

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

Test of CHI SQUARE

(JCL101)

BAIS2

APPENDIX H 3

URINALYSIS : SUMMARY, MOSUE : MALE
(2-YEAR STUDY)

STUDY NO. : 0105

ANIMAL : MOUSE BDF1

SAMPLING DATE : 104-4

SEX : MALE

REPORT TYPE : A1

URINALYSIS

PAGE : 1

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body					CHI	Occult blood				CHI			
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	±	+		2+	3+	4+	-		±	+	2+
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

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

Test of CHI SQUARE

(JCL101)

BAIS2

STUDY NO. : 0105

URINALYSIS

ANIMAL : MOUSE BDF1

SAMPLING DATE : 104-4

SEX : MALE

REPORT TYPE : A1

PAGE : 2

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

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

Test of CHI SQUARE

(JCL101)

BAIS 2

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

PAGE : 3

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body					CHI	Occult blood				CHI			
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	±	+		2+	3+	4+	-		±	+	2+
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

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

Test of CHI SQUARE

(JCL101)

BAIS 2

STUDY NO. : 0105

URINALYSIS

ANIMAL : MOUSE BDF1

SAMPLING DATE : 104-4

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

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

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

Test of CHI SQUARE

(JCL101)

BAIS 2

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)

PAGE : 1

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)
	voluminous		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)

PAGE : 2

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)

PAGE : 3

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)

PAGE : 4

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)

PAGE : 5

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)

(HPT080)

BAIS 2

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)

PAGE : 6

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)
	voluminous		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)

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

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

PAGE : 7

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)

PAGE : 8

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)

PAGE : 9

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)

(HPT080)

BAIS 2

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)

PAGE : 1

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)

PAGE : 2

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)
Zymal 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)

PAGE : 3

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)

PAGE : 4

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)

(HPT080)

BAIS 2

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)

PAGE : 1

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)

PAGE : 2

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)

PAGE : 3

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)

PAGE : 4

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)

PAGE : 5

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)

PAGE : 6

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)

PAGE : 7

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)

PAGE : 8

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)

PAGE : 9

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

(HPT080)

BAIS2

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)

PAGE : 1

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)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control	10 ppm	50 ppm	250 ppm
			31 (%)	35 (%)	28 (%)	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)

(HPT080)

BAIS 2

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)

PAGE : 3

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)

PAGE : 4

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)

(HPT080)

BAIS 2

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)

PAGE : 1

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	0.081± 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 : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL040)

BAIS2

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

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

PAGE : 2

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

Test of Dunnett

(HCL040)

BAIS 2

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)

PAGE : 3

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

Test of Dunnett

(HCL040)

BAIS 2

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

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

PAGE : 4

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

Test of Dunnett

(HCL040)

BAIS 2

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)

PAGE : 1

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

Test of Dunnett

(HCL040)

BAIS2

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

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

PAGE : 2

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

Test of Dunnett

(HCL040)

BAIS2

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)

PAGE : 3

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

Test of Dunnett

(HCL040)

BAIS 2

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

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

PAGE : 4

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

Test of Dunnett

(HCL040)

BAIS2

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)

PAGE : 1

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

Test of Dunnett

(HCL042)

BAIS2

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

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

PAGE : 2

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	3.168± 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 : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL042)

BAIS 2

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)

PAGE : 3

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**	0.728± 0.097**

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

Test of Dunnett

(HCL042)

BAIS 2

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

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

PAGE : 4

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

Test of Dunnett

(HCL042)

BAIS 2

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)

PAGE : 1

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

Test of Dunnett

(HCL042)

BAIS2

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

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

PAGE : 2

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± 1.483	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± 2.681**	1.362± 0.172**

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

Test of Dunnett

(HCL042)

BAIS2

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)

PAGE : 3

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

Test of Dunnett

(HCL042)

BAIS2

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

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

PAGE : 4

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

Test of Dunnett

(HCL042)

BAIS 2