

クロロホルム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

(D1～I4)

がん原性試験 NO.0115 ; 0116

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APPENDIX D 1

HEMATOLOGY : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0115
 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	27	7.60±	1.59	12.9±	2.8	37.8±	7.1	50.4±	5.4	17.0±	1.7	33.8±	1.5	977±	263
10 ppm	39	8.03±	1.88	13.9±	3.0	40.8±	7.7	51.8±	7.2	17.4±	1.7	33.9±	2.4	817±	258
30 ppm	36	8.23±	1.83	14.2±	2.9	41.2±	7.4	51.0±	6.4	17.4±	1.6	34.3±	1.9	850±	277
90 ppm	38	7.90±	1.98	13.0±	3.4	37.9±	8.9	49.2±	8.2	16.6±	1.5	34.1±	2.4	849±	281

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0115
 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	27	6.19±	3.79	1±	1	54±	13	1±	1	0±	0	5±	2	37±	12	2±	3
10 ppm	39	6.11±	5.55	1±	1	50±	13	1±	1	0±	0	5±	2	39±	9	3±	9
30 ppm	36	9.94±	24.47	1±	1	50±	13	1±	1	0±	0	5±	2	38±	12	3±	11
90 ppm	38	10.74±	27.11	1±	1	55±	12	1±	1	0±	0	6±	2	34±	9	3±	8

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

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX D 2

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

STUDY NO. : 0115
 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 ³ /μl	
Control	36	7.43±	1.36	13.8±	2.4	39.6±	6.0	53.8±	3.9	18.7±	1.0	34.8±	1.5	616±	149
10 ppm	35	8.07±	0.70	15.1±	1.1*	42.5±	2.8*	52.8±	2.5	18.8±	0.7	35.5±	0.9	637±	122
30 ppm	40	7.68±	1.14	14.4±	2.1	41.1±	4.9	54.0±	4.9	18.8±	1.4	34.9±	1.9	648±	182
90 ppm	33	8.03±	1.29**	15.1±	1.9**	42.5±	5.1**	53.5±	4.1	19.0±	2.0	35.5±	2.2	655±	139

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0115
 ANIMAL : RAT F344
 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	36	4.06±	6.95	2±	2	49±	13	2±	1	0±	0	4±	2	40±	10	3±	11
10 ppm	35	2.82±	2.66	1±	1	47±	10	2±	1	0±	0	5±	2	43±	8	1±	6
30 ppm	40	7.62±	22.85	1±	2	46±	13	1±	1	0±	0	5±	2	43±	11	3±	11
90 ppm	33	15.08±	58.93	2±	2	47±	13	1±	1	0±	0	4±	2	39±	12	7±	19

Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX D 3

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

STUDY NO. : 0116
 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	33	9.57±	0.81	13.5±	1.2	42.6±	3.2	44.6±	2.1	14.1±	0.6	31.7±	0.8	1878±	568
5 ppm	38	10.15±	0.74	14.4±	1.0**	45.3±	2.8**	44.8±	1.8	14.2±	0.6	31.8±	0.7	2015±	363
30 ppm	36	9.98±	1.06	14.1±	1.5	44.7±	4.8**	44.8±	2.2	14.2±	0.7	31.6±	0.6	1946±	400
90 ppm	35	9.87±	1.10	14.2±	1.2*	44.9±	3.9*	45.7±	1.9	14.5±	0.6	31.7±	0.7	2040±	338

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0116
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

Group Name	NO. of Animals	WBC 10 ⁹ /μl		Differential N-BAND		WBC	(%) N-SEG	EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	33	2.62±	1.25	0±	0	36±	12	1±	1	0±	0	5±	3	55±	11	2±	2
5 ppm	38	2.35±	0.98	0±	0	30±	9	1±	1	0±	0	5±	2	61±	9	2±	4
30 ppm	36	3.31±	1.61	0±	0	35±	13	1±	1	0±	0	5±	2	55±	12	3±	3
90 ppm	35	3.48±	2.16	0±	0	36±	12	1±	2	0±	0	5±	2	55±	12	3±	3

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

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX D 4

HEMATOLOGY : SUMMARY, MOSUE : FEMALE
(2-YEAR STUDY)

STUDY NO. : 0116
 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	28	9.41±	1.53	13.3±	2.0	41.8±	5.3	45.1±	4.8	14.2±	0.9	31.6±	1.4	1119±	446
5 ppm	34	9.53±	1.54	13.6±	2.1	42.3±	6.4	44.8±	2.9	14.3±	0.7	32.0±	1.2	1106±	346
30 ppm	24	9.42±	1.24	13.7±	1.7	42.5±	4.1	45.5±	2.7	14.5±	0.5*	32.0±	1.2	1234±	278
90 ppm	24	9.72±	1.08	14.1±	1.5	43.6±	3.6	45.0±	2.3	14.5±	0.6*	32.3±	1.3	1235±	315

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0116
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	28	6.01±	13.22	0±	0	32±	16	1±	2	0±	0	5±	3	54±	14	7±	9
5 ppm	34	2.59±	1.64	0±	0	30±	13	2±	2	0±	0	4±	2	57±	14	6±	8
30 ppm	24	4.47±	10.13	0±	0	32±	10	1±	1	0±	0	4±	3	57±	12	5±	6
90 ppm	24	6.26±	18.98	0±	0	38±	12	1±	2	0±	0	5±	2	49±	12	7±	7

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

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX E 1

BIOCHEMISTRY : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0115
 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	27	6.7±	0.6	3.1±	0.3	0.9±	0.1	0.26±	0.08	162±	35	173±	43	222±	124
10 ppm	39	7.1±	0.5	3.5±	0.3**	1.0±	0.1	0.35±	0.37	169±	41	164±	53	167±	133
30 ppm	36	7.0±	0.3	3.5±	0.3**	1.0±	0.1*	0.32±	0.27	165±	25	153±	46	146±	89*
90 ppm	38	6.9±	0.5	3.5±	0.3**	1.0±	0.1**	0.28±	0.15	154±	33	125±	33**	87±	37**

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0115
 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		LAP IU/l		G-GTP IU/l	
Control	27	289±	71	67±	37	21±	14	164±	65	215±	281	43±	6	4±	4
10 ppm	39	268±	98	79±	57	25±	16*	239±	321	265±	295	45±	7	8±	7*
30 ppm	36	241±	73*	81±	64	24±	15	179±	106	283±	286	47±	6	10±	7**
90 ppm	38	196±	52**	98±	149*	26±	24*	311±	630	243±	201	44±	7	7±	8*

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0115
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (105)

PAGE : 3

Group Name	NO. of Animals	CPK IU / ℓ	UREA NITROGEN mg / dl	CREATININE mg / dl	SODIUM mEq / ℓ	POTASSIUM mEq / ℓ	CHLORIDE mEq / ℓ	CALCIUM mg / dl
Control	27	84 \pm 73	28.6 \pm 15.6	0.9 \pm 0.8	144 \pm 1	3.5 \pm 0.3	106 \pm 2	10.9 \pm 0.8
10 ppm	39	79 \pm 47	20.6 \pm 3.9**	0.6 \pm 0.1	144 \pm 1	3.6 \pm 0.8	105 \pm 2*	10.6 \pm 0.5
30 ppm	36	75 \pm 25	18.3 \pm 2.9**	0.6 \pm 0.1**	144 \pm 1	3.4 \pm 0.2	105 \pm 2**	10.6 \pm 0.6
90 ppm	38	107 \pm 129	23.2 \pm 18.7**	0.7 \pm 0.9**	144 \pm 2	3.4 \pm 0.5	106 \pm 4*	10.5 \pm 0.7**

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0115
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 4

Group Name	NO. of Animals	INORGANIC PHOSPHORUS mg/dl	
Control	27	5.0±	1.7
10 ppm	39	4.5±	0.9
30 ppm	36	4.4±	0.7
90 ppm	38	4.9±	1.6

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

Test of Dunnett

(HCL074)

BAIS2

APPENDIX E 2

BIOCHEMISTRY : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0115
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (105)

PAGE : 5

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	7.0±	0.7	3.8±	0.4	1.2±	0.1	0.36±	0.32	170±	28	142±	62	191±	180
10 ppm	35	7.4±	0.5*	4.1±	0.3**	1.3±	0.1*	0.28±	0.10	168±	22	131±	26	126±	71
30 ppm	40	7.3±	0.5	4.0±	0.3*	1.2±	0.1	0.37±	0.43	164±	23	135±	21	109±	40
90 ppm	34	7.2±	0.4	3.9±	0.3	1.2±	0.1	0.33±	0.22	160±	24	149±	55	94±	68**

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0115
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (105)

PAGE : 6

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT IU/l		GPT IU/l		LDH IU/l		ALP IU/l		LAP IU/l		G-GTP IU/l	
Control	37	280±	137	128±	81	37±	23	297±	129	152±	125	39±	6	4±	4
10 ppm	35	252±	58	113±	59	40±	18	245±	133	133±	41	41±	4	4±	2
30 ppm	40	255±	47	124±	137	39±	27	239±	126*	157±	84	41±	4	5±	5
90 ppm	34	271±	130	144±	143	48±	38	344±	294	174±	103	46±	7**	6±	7**

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0115
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (105)

PAGE : 7

Group Name	NO. of Animals	CPK IU/ℓ		UREA NITROGEN mg/dℓ		CREATININE mg/dℓ		SODIUM mEq/ℓ		POTASSIUM mEq/ℓ		CHLORIDE mEq/ℓ		CALCIUM mg/dℓ	
Control	37	99±	92	17.9±	2.8	0.5±	0.1	143±	2	3.4±	0.4	105±	3	10.4±	0.5
10 ppm	35	91±	80	18.5±	2.6	0.5±	0.1	142±	2	3.3±	0.3	104±	2**	10.5±	0.6
30 ppm	40	79±	24	18.5±	2.7	0.5±	0.1	143±	2	3.3±	0.4	103±	2**	10.5±	0.4
90 ppm	34	137±	204	18.6±	2.2	0.5±	0.1	142±	2	3.3±	0.5	103±	4**	10.4±	0.4

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0115
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

PAGE : 8

Group Name	NO. of Animals	INORGANIC PHOSPHORUS mg/dl	
Control	37	3.9±	1.2
10 ppm	35	3.8±	1.0
30 ppm	40	4.2±	1.0
90 ppm	34	4.7±	1.3*

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

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX E 3

BIOCHEMISTRY : SUMMARY, MOSUE : MALE

(2-YEAR STUDY)

STUDY NO. : 0116
 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	33	5.6±	0.7	2.9±	0.4	1.1±	0.2	0.29±	0.09	175±	31	111±	28	83±	22
5 ppm	38	5.8±	0.5	3.0±	0.3	1.1±	0.1	0.31±	0.10	185±	23	107±	23	82±	19
30 ppm	36	5.9±	0.6	3.0±	0.3	1.1±	0.1	0.32±	0.11	166±	46	125±	24	101±	39
90 ppm	35	6.1±	0.6**	3.1±	0.3**	1.1±	0.1	0.31±	0.09	166±	37	124±	32	80±	30

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

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0116
 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	33	85±	63	29±	33	316±	156	171±	61	45±	30	25.8±	11.6	156±	3
5 ppm	38	58±	13	16±	9	263±	74	184±	27*	54±	55	22.5±	4.3	156±	3
30 ppm	36	115±	204	40±	77	388±	410	219±	95**	62±	58	26.3±	5.6*	156±	3
90 ppm	35	111±	106*	44±	32**	390±	282	205±	41**	83±	64**	30.8±	5.1**	156±	4

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

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0116
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	33	4.7±	0.3	124±	3	9.1±	0.5	7.2±	0.7
5 ppm	38	5.1±	0.4**	124±	4	9.2±	0.5	7.4±	0.9
30 ppm	36	4.7±	0.4	124±	2	9.5±	0.4**	7.2±	0.9
90 ppm	35	4.6±	0.4	124±	4	9.7±	0.5**	7.4±	1.0

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

APPENDIX E 4

BIOCHEMISTRY : SUMMARY, MOSUE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0116
 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	27	5.5±	0.8	2.8±	0.3	1.1±	0.2	0.33±	0.11	136±	34	78±	22	82±	41
5 ppm	34	5.5±	0.7	2.8±	0.2	1.1±	0.2	0.34±	0.12	129±	39	71±	16	72±	22
30 ppm	24	5.6±	0.7	2.9±	0.3	1.1±	0.2	0.31±	0.08	140±	36	86±	34	81±	44
90 ppm	24	6.0±	0.8	3.2±	0.3**	1.2±	0.2	0.33±	0.09	156±	37	77±	16	58±	16**

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

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0116
 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	27	144±	145	28±	21	745±	1045	264±	122	102±	147	17.2±	4.8	156±	5
5 ppm	34	148±	224	47±	111	560±	988	322±	214	99±	120	21.4±	23.8	155±	5
30 ppm	24	125±	88	39±	34	1437±	5278	235±	114	128±	262	19.3±	12.1	155±	4
90 ppm	24	175±	95*	50±	25**	748±	1097	303±	109	115±	127	21.4±	5.7**	155±	4

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0116
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	27	4.7±	0.4	126±	4	9.3±	0.4	7.6±	1.3
5 ppm	34	4.7±	0.5	125±	5	9.1±	0.5	7.5±	1.7
30 ppm	24	4.5±	0.5	124±	4	9.4±	0.7	7.1±	1.1
90 ppm	24	4.5±	0.3	124±	3	9.4±	0.6	6.9±	1.2

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

APPENDIX F 1

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

STUDY NO. : 0115

ANIMAL : RAT F344

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	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	27	0	5	6	6	6	4	0		0	0	0	1	2	24		27	0	0	0	0	0		24	3	0	0	0	0		27	0	0	0
10 ppm	39	0	9	7	14	6	3	0		0	0	0	7	13	19	**	39	0	0	0	0	0		38	1	0	0	0	0		38	1	0	0
30 ppm	37	0	4	4	10	14	4	1		0	0	1	12	14	10	**	35	2	0	0	0	0		37	0	0	0	0	0	*	36	1	0	0
90 ppm	39	1	4	5	13	12	4	0		0	0	3	9	10	17	**	19	9	7	4	0	0	**	28	10	0	0	0	1		38	0	0	1

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

Test of CHI SQUARE

(JCL101)

BAIS2

STUDY NO. : 0115
ANIMAL : RAT F344
SAMPLING DATE : 104-4
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Occult blood					Urobilinogen						
		-	±	+	2+	3+	CHI	±	+	2+	3+	4+	CHI
Control	27	24	3	0	0	0		27	0	0	0	0	
10 ppm	39	33	6	0	0	0		38	1	0	0	0	
30 ppm	37	33	3	1	0	0		37	0	0	0	0	
90 ppm	39	29	8	2	0	0		38	0	1	0	0	

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

Test of CHI SQUARE

(JCL101)

BAIS 2

APPENDIX F 2

URINALYSIS : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0115
 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	41	0	0	7	12	13	6	2		0	0	5	9	22	4		38	2	0	0	0	0		40	0	0	0	0	0		39	0	0	1
10 ppm	37	0	1	13	9	9	5	0		0	2	10	10	10	5		29	5	2	1	0	0		32	5	0	0	0	0	*	37	0	0	0
30 ppm	41	0	1	10	8	14	8	0		0	5	9	13	13	1	*	12	5	14	9	1	0	**	38	3	0	0	0	0		40	0	1	0
90 ppm	34	0	1	3	8	12	9	1		0	4	12	8	9	1	**	10	7	7	10	0	0	**	31	3	0	0	0	0		34	0	0	0

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

Test of CHI SQUARE

(JCL101)

BAIS 2

STUDY NO. : 0115

ANIMAL : RAT F344

SAMPLING DATE : 104-4

SEX : FEMALE

REPORT TYPE : A1

URINALYSIS

PAGE : 4

Group Name	NO. of Animals	Occult blood					Urobilinogen						
		-	±	+	2+	3+	CHI	±	+	2+	3+	4+	CHI
Control	41	38	0	1	1	0		39	1	0	0	0	
10 ppm	37	36	0	0	0	1		37	0	0	0	0	
30 ppm	41	36	4	1	0	0		40	1	0	0	0	
90 ppm	34	32	2	0	0	0		34	0	0	0	0	

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

Test of CHI SQUARE

(JCL101)

BAIS 2

APPENDIX F 3

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

STUDY NO. : 0116
 ANIMAL : MOUSE BDF1
 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	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	33	0	3	12	11	6	1	0		0	0	21	8	4	0		33	0	0	0	0	0		18	15	0	0	0	0		28	2	1	1	1
5 ppm	39	0	1	5	5	17	11	0	**	0	3	20	16	0	0	*	39	0	0	0	0	0		24	15	0	0	0	0		37	0	0	0	2
30 ppm	38	0	5	9	9	11	4	0		0	3	11	21	3	0	**	38	0	0	0	0	0		25	13	0	0	0	0		33	3	1	1	0
90 ppm	35	0	4	3	12	12	4	0		0	1	14	18	2	0		35	0	0	0	0	0		20	14	1	0	0	0		34	1	0	0	0

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

Test of CHI SQUARE

(JCL101)

BAIS 2

STUDY NO. : 0116
ANIMAL : MOUSE BDF1
SAMPLING DATE : 104-4
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+ CHI
Control	33	33 0 0 0 0
5 ppm	39	39 0 0 0 0
30 ppm	38	38 0 0 0 0
90 ppm	35	35 0 0 0 0

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

Test of CHI SQUARE

(JCL101)

BAIS 2

APPENDIX F 4

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

STUDY NO. : 0116
 ANIMAL : MOUSE BDF1
 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	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+	3+
Control	29	0	0	6	9	12	2	0		0	3	18	8	0	0		29	0	0	0	0	0		15	12	2	0	0	0		24	3	2	0	0	
5 ppm	36	0	2	9	14	9	2	0		0	3	19	13	1	0		36	0	0	0	0	0		17	15	4	0	0	0		34	0	0	2	0	*
30 ppm	27	0	1	9	8	7	2	0		0	1	20	5	1	0		26	1	0	0	0	0		12	12	3	0	0	0		26	0	0	1	0	
90 ppm	24	0	1	6	5	8	4	0		0	1	14	8	1	0		23	1	0	0	0	0		8	14	2	0	0	0		22	1	1	0	0	

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

Test of CHI SQUARE

(JCL101)

BAIS2

STUDY NO. : 0116

ANIMAL : MOUSE BDF1

SAMPLING DATE : 104-4

SEX : FEMALE

REPORT TYPE : A1

URINALYSIS

PAGE : 4

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+	CHI
Control	29	29 0 0 0 0	
5 ppm	36	36 0 0 0 0	
30 ppm	27	27 0 0 0 0	
90 ppm	24	23 1 0 0 0	

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

Test of CHI SQUARE

(JCL101)

BAIS 2

APPENDIX G 1

GROSS FINDINGS : SUMMARY, RAT : MALE : DEAD AND MORIBUND ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0115
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	10 ppm	30 ppm	80 ppm
			23 (%)	11 (%)	13 (%)	12 (%)
subcutis	edema		1 (4)	0 (0)	0 (0)	1 (8)
	jaundice		0 (0)	0 (0)	2 (15)	2 (17)
	nodule		0 (0)	0 (0)	1 (8)	0 (0)
	mass		5 (22)	4 (36)	1 (8)	1 (8)
trachea	fluid:red		0 (0)	0 (0)	1 (8)	0 (0)
lung	red		2 (9)	1 (9)	1 (8)	1 (8)
	brown		1 (4)	0 (0)	0 (0)	0 (0)
	red patch/zone		0 (0)	0 (0)	1 (8)	0 (0)
	red zone		2 (9)	1 (9)	0 (0)	1 (8)
	yellow zone		0 (0)	1 (9)	0 (0)	0 (0)
	brown zone		0 (0)	0 (0)	1 (8)	0 (0)
	edema		1 (4)	0 (0)	0 (0)	0 (0)
	voluminous		0 (0)	1 (9)	1 (8)	0 (0)
lymph node	enlarged		1 (4)	1 (9)	2 (15)	4 (33)
spleen	enlarged		7 (30)	6 (55)	3 (23)	9 (75)
	white zone		0 (0)	2 (18)	0 (0)	0 (0)
	deformed		0 (0)	0 (0)	0 (0)	1 (8)
	adhesion		0 (0)	0 (0)	1 (8)	1 (8)
heart	enlarged		1 (4)	0 (0)	0 (0)	1 (8)
	white zone		0 (0)	1 (9)	1 (8)	0 (0)
	nodule		1 (4)	0 (0)	0 (0)	0 (0)
	dilated		0 (0)	1 (9)	1 (8)	0 (0)

STUDY NO. : 0115
 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	10 ppm	30 ppm	90 ppm
			23 (%)	11 (%)	13 (%)	12 (%)
oral cavity	nodule		1 (4)	0 (0)	0 (0)	0 (0)
forestomach	nodule		3 (13)	0 (0)	0 (0)	0 (0)
	ulcer		5 (22)	0 (0)	1 (8)	0 (0)
	erosion		1 (4)	0 (0)	0 (0)	0 (0)
	thick		1 (4)	0 (0)	0 (0)	0 (0)
	red patch/zone		1 (4)	0 (0)	0 (0)	0 (0)
gl stomach	ulcer		4 (17)	3 (27)	4 (31)	0 (0)
	erosion		1 (4)	0 (0)	0 (0)	0 (0)
	thick		1 (4)	0 (0)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	0 (0)	1 (8)
small intes	nodule		0 (0)	1 (9)	0 (0)	1 (8)
cecum	nodule		0 (0)	0 (0)	0 (0)	1 (8)
	gas		1 (4)	0 (0)	0 (0)	0 (0)
liver	enlarged		2 (9)	1 (9)	1 (8)	2 (17)
	pale		1 (4)	0 (0)	0 (0)	0 (0)
	white zone		1 (4)	0 (0)	0 (0)	0 (0)
	nodule		1 (4)	0 (0)	0 (0)	0 (0)
	rough		1 (4)	0 (0)	1 (8)	0 (0)
	granular		0 (0)	1 (9)	0 (0)	3 (25)
	adhesion		1 (4)	0 (0)	0 (0)	0 (0)
	nodule		1 (4)	0 (0)	0 (0)	2 (17)
pancreas	adhesion		1 (4)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0115
 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	10 ppm	30 ppm	90 ppm
			23 (%)	11 (%)	13 (%)	12 (%)
kidney	enlarged		1 (4)	0 (0)	0 (0)	0 (0)
	white zone		0 (0)	1 (9)	0 (0)	1 (8)
	red zone		1 (4)	0 (0)	0 (0)	0 (0)
	granular		10 (43)	0 (0)	0 (0)	0 (0)
	nodular		0 (0)	1 (9)	0 (0)	0 (0)
urin bladd	red zone		1 (4)	0 (0)	0 (0)	0 (0)
	urine:marked retention		1 (4)	1 (9)	0 (0)	0 (0)
	urine:red		2 (9)	0 (0)	2 (15)	0 (0)
pituitary	enlarged		2 (9)	2 (18)	4 (31)	0 (0)
	red zone		0 (0)	1 (9)	1 (8)	0 (0)
	brown zone		0 (0)	0 (0)	2 (15)	0 (0)
	black zone		1 (4)	0 (0)	0 (0)	1 (8)
	nodule		6 (26)	1 (9)	0 (0)	2 (17)
	mass		1 (4)	0 (0)	0 (0)	0 (0)
thyroid	enlarged		2 (9)	0 (0)	0 (0)	0 (0)
adrenal	enlarged		0 (0)	0 (0)	0 (0)	1 (8)
	mass		0 (0)	0 (0)	1 (8)	0 (0)
testis	enlarged		2 (9)	1 (9)	1 (8)	1 (8)
	atrophic		6 (26)	5 (45)	0 (0)	2 (17)
	white		1 (4)	0 (0)	0 (0)	0 (0)
	nodule		12 (52)	5 (45)	6 (46)	8 (67)
semin ves	white zone		0 (0)	0 (0)	1 (8)	0 (0)

STUDY NO. : 0115
 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	10 ppm	30 ppm	90 ppm
			23 (%)	11 (%)	13 (%)	12 (%)
brain	red zone		1 (4)	1 (9)	0 (0)	0 (0)
	brown zone		1 (4)	0 (0)	0 (0)	0 (0)
	black zone		0 (0)	0 (0)	0 (0)	1 (8)
	hemorrhage		2 (9)	0 (0)	1 (8)	1 (8)
	nodule		1 (4)	1 (9)	2 (15)	0 (0)
spinal cord	red patch/zone		0 (0)	0 (0)	1 (8)	0 (0)
	black zone		0 (0)	1 (9)	0 (0)	0 (0)
	hemorrhage		2 (9)	0 (0)	0 (0)	0 (0)
eye	red		1 (4)	0 (0)	0 (0)	0 (0)
	black		0 (0)	0 (0)	1 (8)	0 (0)
Harder gl	red		1 (4)	0 (0)	0 (0)	0 (0)
	brown		0 (0)	0 (0)	1 (8)	0 (0)
Zymbal gl	nodule		1 (4)	0 (0)	0 (0)	0 (0)
muscle	red zone		0 (0)	0 (0)	0 (0)	1 (8)
	nodule		0 (0)	1 (9)	0 (0)	0 (0)
pleura	nodule		0 (0)	0 (0)	0 (0)	1 (8)
peritoneum	nodule		1 (4)	0 (0)	1 (8)	1 (8)
abdominal c	hemorrhage		0 (0)	3 (27)	0 (0)	0 (0)
	ascites		2 (9)	0 (0)	1 (8)	3 (25)
mesenterium	nodule		0 (0)	0 (0)	0 (0)	1 (8)
adipose	nodule		0 (0)	1 (9)	0 (0)	0 (0)
thoracic ca	hemorrhage		1 (4)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0115
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	10 ppm	30 ppm	90 ppm
			23 (%)	11 (%)	13 (%)	12 (%)
thoracic ca	nodule		1 (4)	0 (0)	0 (0)	0 (0)
	pleural fluid		3 (13)	2 (18)	1 (8)	3 (25)
other	:		1 (4)	0 (0)	0 (0)	0 (0)
whole body	anemic		3 (13)	2 (18)	1 (8)	6 (50)
	wasting		1 (4)	0 (0)	0 (0)	0 (0)

(HPT080)

BATS 2

APPENDIX G 2

GROSS FINDINGS : SUMMARY, RAT : FEMALE : DEAD AND MORIBUND ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0115
 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	10 ppm	30 ppm	90 ppm
			12 (%)	14 (%)	10 (%)	15 (%)
skin/app	reduced		0 (0)	1 (7)	1 (10)	0 (0)
subcutis	edema		0 (0)	0 (0)	0 (0)	1 (7)
	jaundice		0 (0)	2 (14)	2 (20)	2 (13)
	mass		1 (8)	5 (36)	2 (20)	4 (27)
	cyst		0 (0)	0 (0)	1 (10)	0 (0)
lung	red		1 (8)	0 (0)	0 (0)	1 (7)
	white zone		0 (0)	0 (0)	0 (0)	1 (7)
	red zone		0 (0)	0 (0)	0 (0)	1 (7)
	yellow zone		0 (0)	0 (0)	0 (0)	1 (7)
	nodule		1 (8)	0 (0)	0 (0)	1 (7)
	nodular		0 (0)	0 (0)	0 (0)	1 (7)
lymph node	enlarged		3 (25)	2 (14)	1 (10)	3 (20)
spleen	enlarged		5 (42)	5 (36)	5 (50)	5 (33)
	white zone		0 (0)	0 (0)	1 (10)	0 (0)
	hemorrhage		0 (0)	1 (7)	0 (0)	0 (0)
	nodule		1 (8)	0 (0)	1 (10)	1 (7)
	deformed		1 (8)	0 (0)	0 (0)	0 (0)
heart	white zone		0 (0)	1 (7)	0 (0)	0 (0)
	dilated		0 (0)	0 (0)	0 (0)	1 (7)
salivary gl	nodule		1 (8)	0 (0)	0 (0)	0 (0)
forestomach	ulcer		1 (8)	1 (7)	1 (10)	0 (0)
	erosion		1 (8)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0115
 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	10 ppm	30 ppm	90 ppm
			12 (%)	14 (%)	10 (%)	15 (%)
gl stomach	white zone		0 (0)	0 (0)	1 (10)	0 (0)
	ulcer		3 (25)	2 (14)	2 (20)	1 (7)
	erosion		1 (8)	1 (7)	0 (0)	0 (0)
	fluid:black		0 (0)	0 (0)	1 (10)	0 (0)
stomach	fluid:red		0 (0)	1 (7)	0 (0)	0 (0)
	fluid:black		0 (0)	0 (0)	0 (0)	1 (7)
jejunum	nodule		1 (8)	0 (0)	0 (0)	0 (0)
small intes	red zone		0 (0)	0 (0)	1 (10)	0 (0)
rectum	dilated		0 (0)	0 (0)	0 (0)	1 (7)
liver	pale		0 (0)	1 (7)	0 (0)	1 (7)
	red zone		1 (8)	0 (0)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	0 (0)	3 (20)
	deformed		0 (0)	1 (7)	0 (0)	0 (0)
	rough		2 (17)	0 (0)	1 (10)	0 (0)
	granular		0 (0)	1 (7)	0 (0)	2 (13)
	nodular		0 (0)	0 (0)	2 (20)	0 (0)
	adhesion		0 (0)	0 (0)	0 (0)	1 (7)
	herniation		3 (25)	0 (0)	0 (0)	1 (7)
	pancreas		0 (0)	0 (0)	0 (0)	1 (7)
	adhesion		1 (8)	0 (0)	0 (0)	0 (0)
	neck		0 (0)	0 (0)	0 (0)	1 (7)
kidney	pale		0 (0)	0 (0)	0 (0)	1 (7)

STUDY NO. : 0115
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 8

Organ_____	Findings_____	Group Name	Control	10 ppm	30 ppm	90 ppm
		NO. of Animals	12 (%)	14 (%)	10 (%)	15 (%)
kidney	white zone		0 (0)	1 (7)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	0 (0)	1 (7)
	granular		0 (0)	0 (0)	0 (0)	1 (7)
	hydronephrosis		0 (0)	0 (0)	0 (0)	1 (7)
ureter	dilated		0 (0)	0 (0)	0 (0)	1 (7)
urin bladd	urine:marked retention		0 (0)	0 (0)	0 (0)	1 (7)
pituitary	enlarged		6 (50)	7 (50)	3 (30)	2 (13)
	red zone		0 (0)	1 (7)	0 (0)	1 (7)
	hemorrhage		0 (0)	1 (7)	0 (0)	0 (0)
	nodule		1 (8)	0 (0)	0 (0)	1 (7)
	cyst		0 (0)	1 (7)	0 (0)	0 (0)
thyroid	enlarged		0 (0)	0 (0)	2 (20)	0 (0)
adrenal	enlarged		0 (0)	0 (0)	0 (0)	2 (13)
ovary	enlarged		0 (0)	1 (7)	0 (0)	0 (0)
	fluid:transparent		0 (0)	1 (7)	0 (0)	1 (7)
uterus	red zone		0 (0)	0 (0)	0 (0)	1 (7)
	nodule		1 (8)	2 (14)	0 (0)	1 (7)
vagina	dilated lumen		1 (8)	0 (0)	0 (0)	0 (0)
	fluid:red		1 (8)	0 (0)	0 (0)	0 (0)
prep/cli gl	enlarged		0 (0)	1 (7)	0 (0)	0 (0)
brain	red zone		1 (8)	0 (0)	0 (0)	0 (0)
	hemorrhage		0 (0)	0 (0)	1 (10)	1 (7)

STUDY NO. : 0115
 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	10 ppm	30 ppm	90 ppm
			12 (%)	14 (%)	10 (%)	15 (%)
brain	adhesion		0 (0)	0 (0)	1 (10)	0 (0)
spinal cord	red zone		0 (0)	0 (0)	1 (10)	1 (7)
	hemorrhage		1 (8)	0 (0)	0 (0)	0 (0)
Zymbal gl	nodule		2 (17)	0 (0)	0 (0)	0 (0)
muscle	nodule		0 (0)	0 (0)	0 (0)	1 (7)
	mass		0 (0)	1 (7)	0 (0)	0 (0)
retroperit	mass		0 (0)	0 (0)	0 (0)	1 (7)
abdominal c	hemorrhage		0 (0)	1 (7)	0 (0)	1 (7)
	nodule		0 (0)	1 (7)	0 (0)	0 (0)
	ascites		0 (0)	0 (0)	1 (10)	1 (7)
adipose	nodule		1 (8)	0 (0)	0 (0)	0 (0)
thoracic ca	pleural fluid		1 (8)	2 (14)	2 (20)	1 (7)
whole body	anemic		1 (8)	2 (14)	1 (10)	3 (20)
	wasting		1 (8)	0 (0)	0 (0)	1 (7)

APPENDIX G 3

GROSS FINDINGS : SUMMARY, RAT : MALE : SACRIFICED ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0115
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control	10 ppm	30 ppm	90 ppm
			27 (%)	39 (%)	37 (%)	38 (%)
skin/app	nodule		1 (4)	0 (0)	2 (5)	1 (3)
subcutis	mass		6 (22)	6 (15)	8 (22)	8 (21)
lung	nodule		2 (7)	0 (0)	2 (5)	2 (5)
lymph node	enlarged		2 (7)	0 (0)	1 (3)	2 (5)
spleen	enlarged		2 (7)	4 (10)	7 (19)	3 (8)
	nodule		0 (0)	0 (0)	0 (0)	1 (3)
	deformed		0 (0)	1 (3)	0 (0)	0 (0)
	scarred		2 (7)	2 (5)	3 (8)	1 (3)
heart	white zone		0 (0)	1 (3)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	0 (0)	1 (3)
salivary gl	nodule		0 (0)	0 (0)	0 (0)	1 (3)
forestomach	nodule		0 (0)	1 (3)	0 (0)	0 (0)
	ulcer		1 (4)	0 (0)	0 (0)	0 (0)
liver	enlarged		0 (0)	0 (0)	1 (3)	0 (0)
	pale		0 (0)	0 (0)	0 (0)	1 (3)
	nodule		0 (0)	0 (0)	0 (0)	1 (3)
	cyst		2 (7)	0 (0)	0 (0)	0 (0)
	nodular		0 (0)	1 (3)	1 (3)	1 (3)
	herniation		0 (0)	4 (10)	3 (8)	2 (5)
pancreas	nodule		0 (0)	0 (0)	0 (0)	1 (3)
kidney	cyst		0 (0)	1 (3)	0 (0)	0 (0)
	granular		18 (67)	5 (13)	2 (5)	1 (3)

STUDY NO. : 0115
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control	10 ppm	30 ppm	90 ppm
			27 (%)	39 (%)	37 (%)	38 (%)
pituitary	enlarged		2 (7)	5 (13)	3 (8)	3 (8)
	red		0 (0)	0 (0)	0 (0)	1 (3)
	red zone		1 (4)	1 (3)	2 (5)	2 (5)
	nodule		4 (15)	10 (26)	8 (22)	5 (13)
thyroid	enlarged		0 (0)	1 (3)	0 (0)	0 (0)
	nodule		3 (11)	5 (13)	3 (8)	4 (11)
adrenal	enlarged		2 (7)	2 (5)	2 (5)	1 (3)
testis	atrophic		0 (0)	0 (0)	1 (3)	1 (3)
	nodule		27 (100)	36 (92)	36 (97)	36 (95)
brain	nodule		1 (4)	0 (0)	0 (0)	0 (0)
	adhesion		0 (0)	0 (0)	0 (0)	1 (3)
eye	white		1 (4)	1 (3)	1 (3)	2 (5)
Zymbal gl	nodule		1 (4)	2 (5)	0 (0)	2 (5)
muscle	nodule		0 (0)	1 (3)	0 (0)	0 (0)
mediastinum	nodule		0 (0)	0 (0)	0 (0)	1 (3)
peritoneum	nodule		0 (0)	0 (0)	0 (0)	1 (3)
abdominal c	ascites		0 (0)	0 (0)	1 (3)	0 (0)
thoracic ca	mass		1 (4)	0 (0)	0 (0)	0 (0)

APPENDIX G 4

GROSS FINDINGS : SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0115
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control	10 ppm		30 ppm		90 ppm	
			38 (%)	36 (%)	40 (%)	34 (%)	40 (%)	34 (%)	40 (%)
skin/app	nodule		0 (0)	0 (0)	2 (5)	0 (0)			
subcutis	nodule		0 (0)	0 (0)	1 (3)	0 (0)			
	mass		10 (26)	4 (11)	11 (28)	8 (24)			
lung	red patch/zone		0 (0)	0 (0)	0 (0)	1 (3)			
	nodule		0 (0)	2 (6)	1 (3)	1 (3)			
lymph node	enlarged		0 (0)	1 (3)	0 (0)	1 (3)			
spleen	enlarged		3 (8)	1 (3)	5 (13)	5 (15)			
	nodule		0 (0)	1 (3)	0 (0)	0 (0)			
	adhesion		0 (0)	1 (3)	0 (0)	0 (0)			
	ulcer		0 (0)	0 (0)	0 (0)	1 (3)			
salivary gl	nodule		0 (0)	0 (0)	0 (0)	1 (3)			
gl stomach	nodule		1 (3)	0 (0)	0 (0)	1 (3)			
	ulcer		0 (0)	0 (0)	1 (3)	0 (0)			
liver	yellow zone		0 (0)	0 (0)	1 (3)	0 (0)			
	nodule		1 (3)	1 (3)	3 (8)	3 (9)			
	cyst		1 (3)	0 (0)	1 (3)	0 (0)			
	nodular		1 (3)	1 (3)	1 (3)	3 (9)			
	herniation		2 (5)	2 (6)	4 (10)	1 (3)			
kidney	granular		2 (5)	0 (0)	0 (0)	1 (3)			
pituitary	enlarged		7 (18)	3 (8)	4 (10)	0 (0)			
	red zone		4 (11)	4 (11)	4 (10)	4 (12)			
	nodule		9 (24)	10 (28)	6 (15)	6 (18)			

STUDY NO. : 0115
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control	10 ppm	30 ppm	90 ppm
			38 (%)	36 (%)	40 (%)	34 (%)
pituitary	cyst		0 (0)	0 (0)	1 (3)	0 (0)
thyroid	nodule		2 (5)	2 (6)	1 (3)	2 (6)
adrenal	enlarged		3 (8)	2 (6)	2 (5)	3 (9)
ovary	enlarged		0 (0)	0 (0)	2 (5)	0 (0)
	fluid:transparent		2 (5)	0 (0)	2 (5)	1 (3)
uterus	atrophic		0 (0)	1 (3)	0 (0)	0 (0)
	nodule		11 (29)	4 (11)	3 (8)	7 (21)
	polyp		0 (0)	0 (0)	1 (3)	0 (0)
vagina	nodule		1 (3)	0 (0)	0 (0)	0 (0)
spinal cord	hemorrhage		0 (0)	0 (0)	0 (0)	1 (3)
eye	white		2 (5)	1 (3)	0 (0)	2 (6)
	nodule		0 (0)	0 (0)	0 (0)	1 (3)
mediastinum	mass		0 (0)	0 (0)	0 (0)	1 (3)
thoracic ca	pleural fluid		0 (0)	0 (0)	0 (0)	1 (3)
other	ear:nodule		1 (3)	0 (0)	0 (0)	0 (0)

(HPT080)

BAIS 2

APPENDIX G 5

GROSS FINDINGS : SUMMARY, MOSUE : MALE : DEAD AND MORIBUND ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0116
 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 17 (%)	5 ppm 12 (%)	30 ppm 14 (%)	90 ppm 13 (%)
skin/app	ulcer		0 (0)	1 (8)	1 (7)	0 (0)
subcutis	edema		0 (0)	1 (8)	1 (7)	1 (8)
	mass		4 (24)	1 (8)	1 (7)	0 (0)
lung	red		0 (0)	0 (0)	0 (0)	2 (15)
	white zone		1 (6)	0 (0)	0 (0)	0 (0)
	nodule		2 (12)	1 (8)	0 (0)	5 (38)
	nodular		0 (0)	1 (8)	0 (0)	0 (0)
	adhesion		1 (6)	1 (8)	0 (0)	0 (0)
lymph node	enlarged		1 (6)	0 (0)	3 (21)	0 (0)
thymus	enlarged		1 (6)	0 (0)	0 (0)	0 (0)
	nodule		0 (0)	1 (8)	0 (0)	0 (0)
spleen	enlarged		2 (12)	1 (8)	5 (36)	0 (0)
	white zone		0 (0)	0 (0)	1 (7)	0 (0)
	black zone		0 (0)	0 (0)	0 (0)	1 (8)
	hemorrhage		0 (0)	1 (8)	0 (0)	0 (0)
	nodule		1 (6)	1 (8)	1 (7)	1 (8)
	deformed		0 (0)	0 (0)	1 (7)	0 (0)
heart	white zone		0 (0)	0 (0)	1 (7)	0 (0)
stomach	nodule		0 (0)	0 (0)	1 (7)	1 (8)
small intes	nodule		0 (0)	0 (0)	1 (7)	0 (0)
	adhesion		0 (0)	0 (0)	1 (7)	0 (0)
	dilated		1 (6)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0116
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 17 (%)	5 ppm 12 (%)	30 ppm 14 (%)	80 ppm 13 (%)
large intes	red		0 (0)	0 (0)	0 (0)	1 (8)
	adhesion		0 (0)	0 (0)	1 (7)	0 (0)
Liver	enlarged		2 (12)	0 (0)	0 (0)	1 (8)
	pale		1 (6)	0 (0)	0 (0)	0 (0)
	white zone		1 (6)	0 (0)	0 (0)	0 (0)
	nodule		6 (35)	3 (25)	4 (29)	6 (46)
	rough		0 (0)	0 (0)	1 (7)	0 (0)
pancreas	nodule		0 (0)	1 (8)	0 (0)	1 (8)
kidney	enlarged		2 (12)	0 (0)	0 (0)	0 (0)
	pale		0 (0)	0 (0)	0 (0)	1 (8)
	white zone		0 (0)	1 (8)	0 (0)	0 (0)
	nodule		0 (0)	1 (8)	0 (0)	3 (23)
	cyst		0 (0)	0 (0)	0 (0)	1 (8)
	hydronephrosis		3 (18)	1 (8)	1 (7)	0 (0)
urin bladd	urine:marked retention		5 (29)	3 (25)	3 (21)	1 (8)
pituitary	red		0 (0)	0 (0)	0 (0)	1 (8)
	nodule		0 (0)	0 (0)	2 (14)	0 (0)
adrenal	nodule		0 (0)	0 (0)	0 (0)	1 (8)
epididymis	enlarged		0 (0)	1 (8)	0 (0)	1 (8)
brain	hemorrhage		0 (0)	0 (0)	0 (0)	1 (8)
	fluid:brown		0 (0)	1 (8)	0 (0)	0 (0)
muscle	nodule		0 (0)	0 (0)	0 (0)	1 (8)

STUDY NO. : 0116
 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 17 (%)	5 ppm 12 (%)	30 ppm 14 (%)	90 ppm 13 (%)
pleura	nodule		0 (0)	1 (8)	0 (0)	0 (0)
mediastinum	mass		0 (0)	0 (0)	0 (0)	1 (8)
peritoneum	nodule		1 (6)	0 (0)	0 (0)	1 (8)
retroperit	mass		0 (0)	1 (8)	1 (7)	1 (8)
abdominal c	hemorrhage		3 (18)	3 (25)	1 (7)	1 (8)
	ascites		2 (12)	1 (8)	4 (29)	1 (8)
	fluid:white		0 (0)	0 (0)	1 (7)	0 (0)
mesenterium	nodule		1 (6)	1 (8)	0 (0)	0 (0)
thoracic ca	nodule		0 (0)	0 (0)	0 (0)	1 (8)
	pleural fluid		2 (12)	4 (33)	3 (21)	4 (31)
whole body	anemic		0 (0)	1 (8)	3 (21)	2 (15)
	wasting		0 (0)	1 (8)	0 (0)	0 (0)

APPENDIX G 6

GROSS FINDINGS : SUMMARY, MOSUE : FEMALE : DEAD AND MORIBUND ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0116
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control 21 (%)	5 ppm 13 (%)	30 ppm 25 (%)	90 ppm 24 (%)
skin/app	scab		1 (5)	0 (0)	0 (0)	0 (0)
subcutis	edema		6 (29)	2 (15)	9 (36)	9 (38)
	mass		0 (0)	1 (8)	4 (16)	1 (4)
lung	red		1 (5)	1 (8)	0 (0)	0 (0)
	white zone		0 (0)	0 (0)	0 (0)	1 (4)
	red zone		0 (0)	1 (8)	1 (4)	2 (8)
	nodule		0 (0)	2 (15)	1 (4)	2 (8)
	voluminus		1 (5)	0 (0)	0 (0)	0 (0)
lymph node	enlarged		5 (24)	5 (38)	5 (20)	2 (8)
	black		0 (0)	0 (0)	1 (4)	0 (0)
spleen	enlarged		4 (19)	2 (15)	5 (20)	4 (17)
	white zone		1 (5)	0 (0)	0 (0)	0 (0)
	nodule		1 (5)	0 (0)	0 (0)	0 (0)
heart	white zone		0 (0)	0 (0)	1 (4)	0 (0)
salivary gl	nodule		0 (0)	0 (0)	1 (4)	0 (0)
forestomach	nodule		0 (0)	0 (0)	0 (0)	1 (4)
gl stomach	black zone		0 (0)	0 (0)	1 (4)	0 (0)
	ulcer		0 (0)	0 (0)	0 (0)	1 (4)
	erosion		0 (0)	1 (8)	0 (0)	0 (0)
	thick		0 (0)	0 (0)	0 (0)	2 (8)
stomach	nodule		0 (0)	0 (0)	1 (4)	0 (0)
	fluid:black		0 (0)	0 (0)	1 (4)	0 (0)

STUDY NO. : 0116
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 21 (%)	5 ppm 13 (%)	30 ppm 25 (%)	90 ppm 24 (%)
small intes	fluid:black		0 (0)	0 (0)	1 (4)	0 (0)
liver	enlarged		3 (14)	1 (8)	5 (20)	5 (21)
	white patch/zone		0 (0)	1 (8)	0 (0)	0 (0)
	white zone		4 (19)	1 (8)	3 (12)	7 (29)
	nodule		7 (33)	2 (15)	5 (20)	8 (33)
	rough		1 (5)	0 (0)	0 (0)	1 (4)
	nodular		1 (5)	0 (0)	1 (4)	0 (0)
	accentuation of lobular structure		0 (0)	0 (0)	0 (0)	1 (4)
pancreas	nodule		2 (10)	0 (0)	3 (12)	1 (4)
	nodular		0 (0)	2 (15)	1 (4)	0 (0)
kidney	pale		1 (5)	0 (0)	0 (0)	0 (0)
	white zone		0 (0)	0 (0)	2 (8)	0 (0)
	nodule		0 (0)	0 (0)	1 (4)	0 (0)
	hydronephrosis		0 (0)	0 (0)	2 (8)	3 (13)
urin bladd	urine:marked retention		0 (0)	1 (8)	2 (8)	0 (0)
pituitary	enlarged		3 (14)	1 (8)	2 (8)	0 (0)
	white patch/zone		0 (0)	0 (0)	1 (4)	0 (0)
	nodule		1 (5)	1 (8)	2 (8)	2 (8)
	adhesion		1 (5)	0 (0)	0 (0)	0 (0)
ovary	enlarged		3 (14)	1 (8)	4 (16)	5 (21)
	cyst		2 (10)	1 (8)	2 (8)	2 (8)
uterus	enlarged		1 (5)	0 (0)	1 (4)	0 (0)

STUDY NO. : 0116
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 21 (%)	5 ppm 13 (%)	30 ppm 25 (%)	90 ppm 24 (%)
uterus	nodule		8 (38)	4 (31)	6 (24)	10 (42)
	nodular		0 (0)	0 (0)	1 (4)	0 (0)
	dilated		0 (0)	0 (0)	1 (4)	0 (0)
brain	deformed		0 (0)	1 (8)	0 (0)	0 (0)
Harder gl	nodule		1 (5)	0 (0)	0 (0)	1 (4)
mediastinum	mass		2 (10)	3 (23)	0 (0)	0 (0)
peritoneum	nodule		1 (5)	0 (0)	1 (4)	1 (4)
	mass		1 (5)	0 (0)	0 (0)	0 (0)
	nodular		0 (0)	3 (23)	1 (4)	0 (0)
	adhesion		0 (0)	0 (0)	1 (4)	1 (4)
retroperit	mass		1 (5)	2 (15)	0 (0)	1 (4)
abdominal c	hemorrhage		3 (14)	1 (8)	5 (20)	2 (8)
	mass		1 (5)	0 (0)	0 (0)	0 (0)
	ascites		6 (29)	4 (31)	3 (12)	9 (38)
	fluid:white		0 (0)	1 (8)	0 (0)	0 (0)
adipose	nodule		1 (5)	0 (0)	0 (0)	0 (0)
thoracic ca	nodule		1 (5)	0 (0)	0 (0)	0 (0)
	pleural fluid		6 (29)	8 (62)	5 (20)	5 (21)
other	hemorrhage		0 (0)	0 (0)	1 (4)	0 (0)
whole body	anemic		2 (10)	2 (15)	2 (8)	2 (8)
	wasting		1 (5)	0 (0)	0 (0)	3 (13)

APPENDIX G 7

GROSS FINDINGS : SUMMARY, MOSUE : MALE : SACRIFICED ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0116
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 33 (%)	5 ppm 38 (%)	30 ppm 36 (%)	90 ppm 35 (%)
skin/app	ulcer		2 (6)	0 (0)	0 (0)	0 (0)
	erosion		0 (0)	1 (3)	0 (0)	0 (0)
subcutis	mass		0 (0)	0 (0)	2 (6)	0 (0)
lung	nodule		3 (9)	4 (11)	4 (11)	4 (11)
	adhesion		0 (0)	0 (0)	0 (0)	1 (3)
lymph node	enlarged		0 (0)	0 (0)	0 (0)	1 (3)
spleen	enlarged		0 (0)	1 (3)	1 (3)	3 (9)
	white zone		0 (0)	0 (0)	0 (0)	1 (3)
	black zone		3 (9)	8 (21)	0 (0)	0 (0)
	nodule		1 (3)	0 (0)	1 (3)	1 (3)
small intes	nodule		0 (0)	1 (3)	0 (0)	0 (0)
liver	enlarged		0 (0)	0 (0)	1 (3)	0 (0)
	white zone		1 (3)	0 (0)	2 (6)	1 (3)
	nodule		16 (48)	6 (16)	11 (31)	19 (54)
	cyst		0 (0)	0 (0)	1 (3)	0 (0)
	ulcer		1 (3)	0 (0)	0 (0)	0 (0)
pancreas	nodule		0 (0)	2 (5)	0 (0)	0 (0)
kidney	nodule		1 (3)	0 (0)	6 (17)	10 (29)
	cyst		0 (0)	0 (0)	3 (8)	2 (6)
	adhesion		1 (3)	0 (0)	0 (0)	0 (0)
	hydronephrosis		1 (3)	0 (0)	0 (0)	1 (3)
urin bladd	urine:marked retention		2 (6)	1 (3)	1 (3)	0 (0)

STUDY NO. : 0116
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 33 (%)	5 ppm 38 (%)	30 ppm 36 (%)	90 ppm 35 (%)
pituitary	enlarged		0 (0)	1 (3)	0 (0)	1 (3)
testis	enlarged		0 (0)	0 (0)	1 (3)	0 (0)
epididymis	nodule		0 (0)	0 (0)	1 (3)	0 (0)
semin ves	atrophic		1 (3)	0 (0)	1 (3)	0 (0)
prep/cli gl	enlarged		0 (0)	0 (0)	1 (3)	0 (0)
eye	turbid		0 (0)	1 (3)	1 (3)	0 (0)
Harder gl	nodule		0 (0)	3 (8)	0 (0)	0 (0)
muscle	nodule		0 (0)	0 (0)	1 (3)	0 (0)
abdominal c	fluid:white		0 (0)	0 (0)	1 (3)	0 (0)
mesenterium	nodule		1 (3)	0 (0)	0 (0)	0 (0)
thoracic ca	mass		0 (0)	0 (0)	0 (0)	1 (3)
other	nodule		0 (0)	0 (0)	1 (3)	0 (0)
	tail:nodule		1 (3)	0 (0)	2 (6)	0 (0)
	ear:nodule		0 (0)	0 (0)	1 (3)	0 (0)
whole body	anemic		0 (0)	1 (3)	1 (3)	0 (0)

APPENDIX G 8

GROSS FINDINGS : SUMMARY, MOSUE : FEMALE : SACRIFICED ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0116
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 29 (%)	5 ppm 36 (%)	30 ppm 25 (%)	90 ppm 24 (%)
subcutis	edema		0 (0)	0 (0)	1 (4)	0 (0)
	mass		0 (0)	3 (8)	1 (4)	0 (0)
lung	nodule		0 (0)	2 (6)	3 (12)	1 (4)
lymph node	enlarged		2 (7)	2 (6)	2 (8)	2 (8)
spleen	enlarged		6 (21)	6 (17)	4 (16)	4 (17)
	nodule		0 (0)	1 (3)	0 (0)	0 (0)
	deformed		0 (0)	1 (3)	0 (0)	0 (0)
small intes	nodule		0 (0)	2 (6)	0 (0)	0 (0)
liver	enlarged		1 (3)	1 (3)	1 (4)	0 (0)
	white zone		0 (0)	0 (0)	2 (8)	1 (4)
	red zone		0 (0)	2 (6)	0 (0)	0 (0)
	nodule		8 (28)	9 (25)	3 (12)	10 (42)
	ulcer		0 (0)	0 (0)	0 (0)	1 (4)
pancreas	nodule		0 (0)	1 (3)	1 (4)	2 (8)
kidney	nodule		1 (3)	1 (3)	1 (4)	0 (0)
	hydronephrosis		1 (3)	2 (6)	1 (4)	0 (0)
urin bladd	urine:marked retention		0 (0)	1 (3)	0 (0)	0 (0)
pituitary	enlarged		2 (7)	1 (3)	3 (12)	0 (0)
	nodule		0 (0)	2 (6)	5 (20)	3 (13)
ovary	enlarged		2 (7)	3 (8)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	1 (4)	0 (0)
	mass		0 (0)	0 (0)	1 (4)	0 (0)

STUDY NO. : 0116
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control	5 ppm	30 ppm	90 ppm
			29 (%)	36 (%)	25 (%)	24 (%)
ovary	cyst		9 (31)	9 (25)	9 (36)	6 (25)
uterus	nodule		4 (14)	3 (8)	6 (24)	2 (8)
eye	turbid		0 (0)	0 (0)	1 (4)	0 (0)
Harder gl	nodule		0 (0)	1 (3)	1 (4)	0 (0)
muscle	nodule		0 (0)	1 (3)	0 (0)	0 (0)
mediastinum	mass		1 (3)	0 (0)	1 (4)	0 (0)
retroperit	mass		0 (0)	1 (3)	0 (0)	0 (0)
abdominal c	hemorrhage		1 (3)	0 (0)	0 (0)	0 (0)
	ascites		4 (14)	3 (8)	3 (12)	7 (29)
mesenterium	nodule		1 (3)	1 (3)	0 (0)	0 (0)
thoracic ca	pleural fluid		3 (10)	1 (3)	3 (12)	4 (17)
other	ear:nodule		1 (3)	0 (0)	0 (0)	0 (0)
whole body	anemic		0 (0)	1 (3)	1 (4)	0 (0)

APPENDIX H 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : MALE
(2-YEAR STUDY)

STUDY NO. : 0115
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	27	420± 70	0.104±	0.089	4.941±	1.825	1.339±	0.150	1.535±	0.209	3.093±	0.381
10 ppm	39	428± 42	0.090±	0.032	4.557±	1.498	1.312±	0.143	1.563±	0.262	2.909±	0.291
30 ppm	37	441± 45*	0.086±	0.022	4.704±	1.347	1.303±	0.141	1.700±	0.582	2.976±	0.278
90 ppm	38	397± 54	0.092±	0.038	4.144±	1.571	1.243±	0.100*	1.552±	0.304	2.933±	0.320

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

Test of Dunnett

(HCL040)

BAIS2

STUDY NO. : 0115
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	27	1.297±	0.549	13.444±	2.389	1.998±	0.102
10 ppm	39	1.583±	1.775	12.735±	1.997	2.007±	0.066
30 ppm	37	2.138±	3.422	13.433±	2.823	2.036±	0.060*
90 ppm	38	1.566±	2.442	11.728±	1.706**	1.996±	0.058

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX H 2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : FEMALE
(2-YEAR STUDY)

STUDY NO. : 0115
 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	38	310± 39	0.091± 0.032	0.134± 0.043	1.002± 0.124	1.096± 0.217	2.030± 0.202
10 ppm	36	310± 35	0.086± 0.023	0.127± 0.031	0.966± 0.087	1.130± 0.275	1.854± 0.160**
30 ppm	40	300± 35	0.085± 0.028	0.404± 1.476	0.969± 0.103	1.104± 0.218	2.033± 0.203
90 ppm	34	260± 23**	0.090± 0.048	0.137± 0.071	0.905± 0.063**	1.134± 0.238	2.292± 0.333**

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0115
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	38	0.943±	1.386	8.260±	1.421	1.816±	0.049
10 ppm	36	0.760±	1.261	7.771±	1.019	1.823±	0.062
30 ppm	40	1.218±	2.593	8.098±	1.167	1.818±	0.065
90 ppm	34	1.230±	2.049	8.142±	1.681	1.822±	0.065

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX H 3

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : MALE
(2-YEAR STUDY)

STUDY NO. : 0116
 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	33	43.7± 7.4	0.010±	0.002	0.205±	0.030	0.210±	0.023	0.226±	0.114	0.630±	0.061
5 ppm	38	38.5± 5.3*	0.010±	0.003	0.206±	0.030	0.183±	0.016**	0.198±	0.015	0.509±	0.034**
30 ppm	36	36.9± 4.6**	0.009±	0.002*	0.264±	0.344	0.196±	0.024*	0.202±	0.028	0.532±	0.202**
90 ppm	35	32.7± 3.2**	0.008±	0.001**	0.206±	0.034	0.191±	0.019**	0.211±	0.064	0.836±	1.096**

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

Test of Dunnett

(HCL040)

BAIS2

STUDY NO. : 0116
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	33	0.082±	0.042	1.581±	0.350	0.450±	0.016
5 ppm	38	0.082±	0.083	1.398±	0.267*	0.459±	0.016*
30 ppm	36	0.092±	0.055	1.606±	0.597	0.457±	0.014
90 ppm	35	0.112±	0.109	1.633±	0.372	0.461±	0.014**

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

Test of Dunnett

(HCL040)

BAIS2

APPENDIX H 4

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : FEMALE
(2-YEAR STUDY)

STUDY NO. : 0116
 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	29	30.2± 3.6	0.012± 0.002	0.071± 0.107	0.161± 0.024	0.209± 0.047	0.429± 0.072
5 ppm	36	30.3± 4.1	0.013± 0.003	0.054± 0.079	0.163± 0.019	0.231± 0.173	0.681± 1.297
30 ppm	25	29.5± 5.2	0.011± 0.003	0.092± 0.252	0.181± 0.034*	0.213± 0.067	0.530± 0.361
90 ppm	24	26.4± 3.4**	0.011± 0.002	0.037± 0.037	0.166± 0.025	0.204± 0.037	0.433± 0.058

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0116
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	29	0.225±	0.293	1.554±	1.113	0.478±	0.017
5 ppm	36	0.238±	0.356	1.436±	0.408	0.473±	0.012
30 ppm	25	0.211±	0.240	1.880±	1.452	0.480±	0.012
90 ppm	24	0.213±	0.191	1.469±	0.396	0.471±	0.018

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

(HCL040)

BAIS 2

APPENDIX I 1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0115
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	27	420± 70	0.026± 0.023	1.195± 0.451	0.328± 0.067	0.371± 0.051	0.758± 0.168
10 ppm	39	428± 42	0.021± 0.008	1.053± 0.307	0.309± 0.046	0.369± 0.075	0.686± 0.105*
30 ppm	37	441± 45*	0.020± 0.009*	1.066± 0.291	0.298± 0.040	0.390± 0.149	0.682± 0.094
90 ppm	38	397± 54	0.023± 0.009	1.043± 0.385	0.318± 0.047	0.401± 0.121	0.752± 0.148

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0115
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	27	0.311± 0.120	3.239± 0.518	0.488± 0.077
10 ppm	39	0.377± 0.445	2.996± 0.545	0.473± 0.051
30 ppm	37	0.494± 0.854	3.059± 0.653	0.467± 0.054
90 ppm	38	0.430± 0.828	3.008± 0.705	0.510± 0.064

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

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX I 2

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0115
 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	38	310± 39	0.030± 0.013	0.044± 0.016	0.327± 0.054	0.359± 0.083	0.663± 0.104
10 ppm	36	310± 35	0.028± 0.006	0.041± 0.010	0.314± 0.036	0.371± 0.121	0.603± 0.072*
30 ppm	40	300± 35	0.029± 0.011	0.138± 0.519	0.326± 0.045	0.374± 0.098	0.685± 0.087
90 ppm	34	260± 23**	0.035± 0.018*	0.053± 0.029**	0.350± 0.036**	0.440± 0.112**	0.885± 0.143**

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0115
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	38	0.313± 0.476	2.682± 0.482	0.594± 0.071
10 ppm	36	0.244± 0.387	2.522± 0.335	0.594± 0.062
30 ppm	40	0.437± 0.985	2.733± 0.514	0.615± 0.076
90 ppm	34	0.500± 0.905	3.155± 0.758**	0.706± 0.072**

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

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX I 3

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : MALE
(2-YEAR STUDY)

STUDY NO. : 0116
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	33	43.7± 7.4	0.023± 0.005	0.485± 0.112	0.491± 0.077	0.557± 0.448	1.481± 0.287
5 ppm	38	38.5± 5.3*	0.026± 0.007	0.541± 0.080	0.481± 0.048	0.524± 0.081	1.340± 0.150
30 ppm	36	36.9± 4.6**	0.023± 0.004	0.708± 0.841**	0.535± 0.066*	0.552± 0.087**	1.459± 0.565
90 ppm	35	32.7± 3.2**	0.025± 0.005	0.632± 0.109**	0.587± 0.046**	0.654± 0.228**	2.572± 3.238

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0116
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	33	0.198± 0.123	3.716± 0.977	1.064± 0.215
5 ppm	38	0.216± 0.227	3.658± 0.639	1.214± 0.168**
30 ppm	36	0.253± 0.167	4.393± 1.721*	1.259± 0.164**
90 ppm	35	0.348± 0.341**	5.012± 1.157**	1.422± 0.134**

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

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX I 4

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : FEMALE
(2-YEAR STUDY)

STUDY NO. : 0116
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	29	30.2± 3.6	0.040± 0.008	0.235± 0.365	0.541± 0.109	0.703± 0.198	1.443± 0.331
5 ppm	36	30.3± 4.1	0.041± 0.007	0.200± 0.337	0.549± 0.114	0.792± 0.695	2.198± 3.800
30 ppm	25	29.5± 5.2	0.038± 0.010	0.303± 0.811	0.624± 0.117*	0.736± 0.224	1.836± 1.326*
90 ppm	24	26.4± 3.4**	0.042± 0.008	0.137± 0.120	0.631± 0.077**	0.787± 0.179**	1.647± 0.155**

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

Test of Dunnett

(HCL042)

BAIS2

STUDY NO. : 0116
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	29	0.744± 0.950	5.129± 3.377	1.607± 0.210
5 ppm	36	0.779± 1.102	4.756± 1.143	1.594± 0.232
30 ppm	25	0.702± 0.782	6.075± 2.950**	1.669± 0.248
90 ppm	24	0.797± 0.685	5.564± 1.213**	1.811± 0.209**

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

Test of Dunnett

(HCL042)

BAIS2