

p-ジクロロベンゼ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

(D1～I4)

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## APPENDIX D 1

### HEMATOLOGY : SUMMARY, RAT : MALE (2-YEAR STUDY)

STUDY NO. : 0158  
 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 <sup>6</sup> /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 <sup>3</sup> /μl	
Control	32	6.98±	1.52	11.9±	3.1	36.3±	7.6	52.3±	5.6	17.0±	2.1	32.6±	2.4	1241±	432
20 ppm	34	7.60±	1.85	13.4±	3.0	40.0±	7.9	53.7±	7.4	17.8±	1.8	33.3±	2.3	989±	325
75 ppm	28	7.30±	1.40	12.7±	2.7	37.8±	7.0	52.0±	4.1	17.4±	1.6	33.5±	1.9	1093±	302
300 ppm	18	7.98±	1.44	13.5±	2.5	39.7±	6.6	49.9±	2.3**	16.9±	0.8	33.9±	0.9	1098±	401

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0158  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 1

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential N-BAND		WBC	(%) N-SEG	EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	32	6.71±	2.24	1±	2	56±	10	1±	1	0±	0	4±	2	32±	9	6±	4
20 ppm	34	8.53±	12.11	1±	2	52±	13	1±	1	0±	0	4±	2	33±	9	8±	14
75 ppm	28	14.65±	39.36	1±	1	58±	14	1±	1	0±	0	4±	2	29±	11	8±	16
300 ppm	18	7.56±	2.05	1±	1	53±	9	1±	1	0±	0	4±	1	34±	7	7±	6

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

Test of Dunnett

(JCL71A)

BATS 2

## APPENDIX D 2

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

STUDY NO. : 0158  
 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 <sup>6</sup> /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 <sup>3</sup> /μl	
Control	38	7.89±	0.83	14.7±	1.3	42.8±	3.1	54.5±	3.1	18.6±	0.8	34.3±	1.1	735±	122
20 ppm	34	8.04±	1.02	14.9±	1.8	43.1±	4.8	53.9±	3.0	18.5±	0.9	34.4±	1.4	720±	94
75 ppm	37	8.18±	0.64	15.0±	1.1	43.8±	2.8	53.6±	2.2	18.4±	0.7	34.3±	1.0	701±	133
300 ppm	36	7.59±	1.53	14.1±	2.5	41.1±	6.7	55.2±	6.8	18.8±	1.9	34.2±	1.1	673±	158

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2



STUDY NO. : 0158  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 2

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	38	4.02±	1.61	2±	2	51±	10	1±	1	0±	0	4±	2	40±	11	3±	3
20 ppm	34	3.54±	1.24	1±	1	51±	9	2±	1	0±	0	4±	2	39±	10	3±	3
75 ppm	37	4.10±	3.40	1±	2	48±	13	2±	1	0±	0	4±	2	40±	11	5±	14
300 ppm	36	26.08±	115.15	2±	4	45±	17	2±	1	0±	0	4±	2	36±	13	11±	22

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

Test of Dunnett

(JCL71A)

BAIS 2

## APPENDIX D 3

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

STUDY NO. : 0159  
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 <sup>6</sup> /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 <sup>3</sup> /μl	
Control	36	9.72±	1.55	13.7±	1.7	42.5±	5.2	44.0±	2.4	14.2±	0.7	32.2±	1.4	2070±	532
20ppm	28	8.98±	1.92	12.6±	2.6	39.4±	6.8	44.5±	3.5	14.1±	0.8	31.7±	2.3	2023±	619
75ppm	31	9.26±	1.54	13.3±	2.1	41.0±	5.6	44.6±	3.2	14.4±	0.7	32.3±	1.5	1977±	570
300ppm	30	9.69±	1.79	13.5±	2.0	42.1±	5.8	43.9±	4.0	14.1±	1.1	32.1±	1.0	2156±	468

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0159  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 1

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	36	2.91±	1.92	1±	2	36±	14	1±	2	0±	0	3±	1	57±	15	2±	3
20ppm	28	5.13±	11.50	2±	2	43±	20	1±	1	0±	0	3±	1	50±	20	2±	2
75ppm	31	16.79±	79.26	2±	3	42±	15	1±	1	0±	0	4±	2	48±	14	3±	7
300ppm	30	3.28±	1.82	1±	1	38±	12	1±	1	0±	0	3±	1	55±	13	2±	2

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL071)

BAIS2

## APPENDIX D 4

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

STUDY NO. : 0159  
 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 <sup>6</sup> /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 <sup>3</sup> /μl	
Control	27	9.46±	1.22	13.8±	1.7	42.2±	4.5	44.8±	3.1	14.6±	0.7	32.6±	1.4	1229±	300
20ppm	23	9.28±	1.26	13.4±	1.8	41.2±	4.6	44.6±	2.4	14.5±	0.5	32.5±	1.2	1159±	361
75ppm	20	9.44±	0.89	13.8±	1.1	42.1±	3.2	44.8±	2.4	14.6±	0.6	32.7±	0.8	1164±	335
300ppm	26	10.23±	2.76	14.1±	3.1	44.5±	8.7	44.8±	6.2	14.1±	1.5*	31.5±	1.8	1542±	597*

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0159  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 2

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	27	3.27±	4.21	1±	2	35±	15	3±	4	0±	0	4±	2	54±	16	4±	7
20ppm	23	2.38±	1.51	1±	2	32±	9	2±	1	0±	0	4±	2	57±	11	4±	8
75ppm	20	2.53±	1.74	1±	2	32±	13	2±	1	0±	0	4±	3	59±	15	3±	3
300ppm	26	3.96±	5.94	1±	1	41±	16	1±	2*	0±	0	4±	3	47±	16	5±	8

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL071)

BAIS2

## APPENDIX E 1

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



STUDY NO. : 0158  
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	32	6.6±	0.5	3.0±	0.2	0.8±	0.1	0.24±	0.12	156±	23	183±	49	220±	130
20 ppm	34	6.8±	0.7	3.0±	0.3	0.8±	0.2	0.31±	0.33	146±	24	188±	66	232±	134
75 ppm	29	6.7±	0.6	2.9±	0.3	0.8±	0.1	0.26±	0.17	138±	24*	207±	53	229±	116
300 ppm	18	6.9±	0.3	3.1±	0.1	0.8±	0.1	0.26±	0.09	160±	22	229±	40*	323±	186

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0158  
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	32	298±	81	73±	57	23±	11	199±	87	182±	60	5±	2	92±	28
20 ppm	34	302±	109	82±	85	21±	10	207±	88	173±	83	6±	3	87±	29
75 ppm	29	335±	102	68±	43	24±	12	218±	110	218±	304	5±	3	104±	60
300 ppm	18	367±	67*	58±	31	22±	9	221±	209	146±	50	6±	3	86±	25

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0158  
ANIMAL : RAT F344  
REPORT TYPE : A1  
SEX : MALE

BIOCHEMISTRY (SUMMARY)  
SURVIVAL ANIMALS (105)

PAGE : 3

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	32	26.4±	7.2	0.7±	0.2	142±	1	3.6±	0.4	106±	2	11.0±	0.5	4.7±	0.9
20 ppm	34	36.5±	32.7	1.1±	1.3	143±	2	3.7±	0.4	105±	3	11.3±	1.1	5.6±	3.2
75 ppm	29	39.8±	27.6	1.1±	0.9	142±	2	3.7±	0.4	105±	3	11.8±	1.8	6.2±	3.8
300 ppm	18	39.4±	15.8**	1.1±	0.4**	142±	2	3.6±	0.3	105±	3	11.8±	0.9**	5.8±	1.8

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. : 0158  
 ANIMAL : RAT F344  
 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	38	7.3±	0.4	3.7±	0.3	1.1±	0.1	0.24±	0.07	148±	18	165±	56	179±	152
20 ppm	34	6.9±	0.4*	3.7±	0.3	1.1±	0.1	0.22±	0.04	158±	19	146±	30	146±	62
75 ppm	37	7.1±	0.4	3.7±	0.2	1.1±	0.1	0.24±	0.04	155±	28	153±	33	162±	101
300 ppm	36	6.9±	0.5**	3.6±	0.3	1.1±	0.1	0.47±	1.18*	150±	26	168±	56	204±	138

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0158  
 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	38	312±	112	97±	44	32±	13	217±	80	131±	61	4±	3	84±	17
20 ppm	34	274±	60	96±	45	32±	17	215±	72	127±	60	4±	3	81±	14
75 ppm	37	288±	73	116±	88	41±	36	289±	371	131±	62	4±	2	86±	26
300 ppm	36	318±	112	240±	558	50±	71	276±	217	198±	197	4±	2	158±	355

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0158  
 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	38	17.0±	2.1	0.5±	0.1	141±	1	3.4±	0.3	104±	2	10.8±	0.5	3.7±	0.7
20 ppm	34	16.7±	2.3	0.5±	0.1	141±	2	3.5±	0.3	104±	2	10.7±	0.4	3.7±	0.8
75 ppm	37	16.8±	2.1	0.5±	0.1	141±	1	3.5±	0.3	103±	2	10.8±	0.4	3.9±	1.0
300 ppm	36	19.0±	2.5**	0.4±	0.1	141±	2	3.7±	0.4**	104±	2	10.8±	0.5	4.1±	1.0

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

## APPENDIX E 3

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



STUDY NO. : 0159  
 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	36	5.4±	0.7	2.7±	0.4	1.0±	0.1	0.30±	0.18	193±	57	110±	52	64±	23
20ppm	28	5.7±	1.1	2.7±	0.5	1.0±	0.2	0.32±	0.23	170±	79	134±	75	69±	25
75ppm	32	5.4±	0.7	2.7±	0.4	1.0±	0.2	0.29±	0.09	186±	51	112±	35	67±	27
300ppm	30	5.5±	0.5	2.8±	0.2	1.0±	0.1	0.30±	0.08	201±	48	157±	51**	54±	17

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0159  
 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	36	232±	573	72±	152	596±	1205	235±	243	67±	36	26.1±	10.2	155±	3
20ppm	28	645±	1967	181±	592	3686±	12061	205±	110	303±	1135	42.1±	52.6	155±	3
75ppm	32	121±	130	40±	40	578±	1113	227±	211	55±	38*	26.7±	12.4	155±	2
300ppm	30	505±	635**	227±	252**	1925±	2189**	898±	1048**	55±	19	24.0±	2.8	154±	2

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0159  
 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	36	4.3±	0.4	122±	3	9.1±	0.6	7.0±	1.2
20ppm	28	4.6±	1.0	121±	4	9.4±	0.8	8.4±	4.3
75ppm	32	4.3±	0.4	123±	3	9.3±	0.5	6.9±	1.3
300ppm	30	4.2±	0.3	122±	3	9.3±	0.4	6.9±	0.8

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. : 0159  
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	5.2±	0.7	2.6±	0.3	1.1±	0.2	0.30±	0.11	143±	33	79±	33	64±	24
20ppm	23	5.2±	0.4	2.6±	0.2	1.1±	0.2	0.31±	0.17	138±	39	79±	22	69±	20
75ppm	20	5.3±	0.5	2.7±	0.2	1.1±	0.2	0.26±	0.07	153±	32	83±	41	60±	17
300ppm	26	6.1±	1.0**	3.1±	0.4**	1.1±	0.2	0.47±	0.24**	159±	35	234±	159**	64±	41

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0159  
 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	130±	143	37±	49	455±	579	368±	409	64±	37	19.6±	12.8	153±	2
20ppm	23	249±	579	82±	216	1431±	5149	309±	339	107±	217	18.1±	11.4	153±	2
75ppm	20	135±	135	33±	27	732±	1631	261±	116	60±	17	16.1±	2.3	153±	2
300ppm	26	1448±	1960**	820±	1221**	6741±	8095**	2135±	1748**	97±	81	26.4±	7.7**	155±	2

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0159  
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	4.1±	0.5	121±	3	9.3±	0.7	6.5±	0.9
20ppm	23	4.3±	0.8	122±	2	9.3±	0.3	6.8±	1.1
75ppm	20	4.1±	0.4	122±	2	9.2±	0.5	6.4±	0.9
300ppm	26	4.2±	0.5	120±	3	10.3±	0.9**	7.4±	1.7

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. : 0158

ANIMAL : RAT F344

SAMPLING DATE : 104-5

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+	3+
Control	35	0	4	7	10	9	5	0		0	0	0	1	12	22		35	0	0	0	0	0	0		33	1	0	0	0	1		33	1	1	0
20 ppm	34	0	3	7	12	10	2	0		0	0	0	0	10	24		34	0	0	0	0	0	0		33	1	0	0	0	0		33	1	0	0
75 ppm	31	0	3	15	5	7	1	0		0	0	0	0	14	17		31	0	0	0	0	0	0		31	0	0	0	0	0		31	0	0	0
300 ppm	18	0	2	2	8	4	2	0		0	0	0	0	8	10		18	0	0	0	0	0	0		18	0	0	0	0	0		18	0	0	0

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

Test of CHI SQUARE

(JCL101)

BAIS2

STUDY NO. : 0158

ANIMAL : RAT F344

SAMPLING DATE : 104-5

SEX : MALE

REPORT TYPE : A1

URINALYSIS

PAGE : 2

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	35	34	0	0	0	1		35	0	0	0	0	
20 ppm	34	34	0	0	0	0		34	0	0	0	0	
75 ppm	31	31	0	0	0	0		31	0	0	0	0	
300 ppm	18	18	0	0	0	0		18	0	0	0	0	

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

Test of CHI SQUARE

(JCL101)

BA1S2

## APPENDIX F 2

URINALYSIS : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0158

ANIMAL : RAT F344

SAMPLING DATE : 104-5

SEX : FEMALE

REPORT TYPE : A1

## URINALYSIS

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+		3+					
Control	38	0	0	5	15	10	6	2		0	0	3	7	21	7		38	0	0	0	0	0		37	1	0	0	0	0		38	0	0	0					
20 ppm	35	0	0	3	13	8	8	3		0	0	3	4	18	10		35	0	0	0	0	0		34	1	0	0	0	0		35	0	0	0					
75 ppm	39	0	3	7	15	7	5	2		0	1	0	5	19	14		39	0	0	0	0	0		36	3	0	0	0	0		39	0	0	0					
300 ppm	39	0	2	7	8	9	11	2		0	0	5	11	21	2		39	0	0	0	0	0		36	2	0	1	0	0		38	1	0	0					

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

Test of CHI SQUARE

(JCL101)

BAIS2

STUDY NO. : 0158

ANIMAL : RAT F344

SAMPLING DATE : 104-5

SEX : FEMALE

REPORT TYPE : A1

URINALYSIS

PAGE : 4

Group Name	NO. of Animals	Occult blood					Urobilinogen						
		-	±	+	2+	3+	CHI	±	+	2+	3+	4+	CHI
Control	38	37	0	1	0	0		38	0	0	0	0	
20 ppm	35	34	0	0	1	0		35	0	0	0	0	
75 ppm	39	38	0	1	0	0		39	0	0	0	0	
300 ppm	39	38	0	0	0	1		38	1	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. : 0159  
 ANIMAL : MOUSE BDF1  
 SAMPLING DATE : 104-5  
 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	40	0	8	11	8	12	1	0		0	3	28	9	0	0		40	0	0	0	0	0		30	9	1	0	0	0		37	1	1	0	1
20ppm	33	0	8	8	13	3	1	0		0	1	21	11	0	0		33	0	0	0	0	0		24	9	0	0	0	0		30	1	0	1	1
75ppm	32	0	3	8	14	7	0	0		0	3	23	5	1	0		32	0	0	0	0	0		21	11	0	0	0	0		26	0	2	1	3
300ppm	30	0	2	7	7	12	2	0		0	6	18	6	0	0		30	0	0	0	0	0		22	8	0	0	0	0		30	0	0	0	0

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

Test of CHI SQUARE

(JCL101)

BAIS 2

STUDY NO. : 0159

ANIMAL : MOUSE BDF1

SAMPLING DATE : 104-5

SEX : MALE

REPORT TYPE : A1

URINALYSIS

PAGE : 2

Group Name	NO. of Animals	Urobilinogen					CHI
		±	+	2+	3+	4+	
Control	40	40	0	0	0	0	
20ppm	33	33	0	0	0	0	
75ppm	32	32	0	0	0	0	
300ppm	30	30	0	0	0	0	

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

Test of CHI SQUARE

(JCL101)

BAIS2



## APPENDIX F 4

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

STUDY NO. : 0159  
 ANIMAL : MOUSE BDF1  
 SAMPLING DATE : 104-5  
 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	7	9	7	4	2		0	7	16	6	0	0		29	0	0	0	0	0		20	8	1	0	0	0		28	1	0	0	0	
20ppm	25	0	0	3	11	4	7	0		0	9	14	2	0	0		25	0	0	0	0	0		16	8	1	0	0	0		23	1	0	1	0	
75ppm	23	0	0	4	4	9	4	2		0	7	10	6	0	0		23	0	0	0	0	0		14	8	1	0	0	0		17	2	3	0	1	
300ppm	26	0	0	5	8	8	5	0		2	10	10	4	0	0		26	0	0	0	0	0		23	1	2	0	0	0		24	1	1	0	0	

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

Test of CHI SQUARE

(JCL101)

BAIS2

STUDY NO. : 0159  
ANIMAL : MOUSE BDF1  
SAMPLING DATE : 104-5  
SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+ CHI
Control	29	29 0 0 0 0
20ppm	25	25 0 0 0 0
75ppm	23	23 0 0 0 0
300ppm	26	26 0 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. : 0158  
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 17 (%)	20 ppm 16 (%)	75 ppm 21 (%)	300 ppm 32 (%)
skin/app	nodule		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
subcutis	edema		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	jaundice		1 ( 6)	1 ( 6)	1 ( 5)	3 ( 9)
	nodule		0 ( 0)	1 ( 6)	0 ( 0)	1 ( 3)
	mass		3 ( 18)	0 ( 0)	0 ( 0)	12 ( 38)
lung	red		0 ( 0)	1 ( 6)	2 ( 10)	5 ( 16)
	white zone		1 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)
	yellow zone		1 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)
	edema		0 ( 0)	1 ( 6)	0 ( 0)	1 ( 3)
	nodule		0 ( 0)	1 ( 6)	1 ( 5)	1 ( 3)
lymph node	enlarged		1 ( 6)	1 ( 6)	0 ( 0)	2 ( 6)
thymus	enlarged		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
spleen	enlarged		5 ( 29)	6 ( 38)	5 ( 24)	8 ( 25)
	white zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	nodule		2 ( 12)	0 ( 0)	0 ( 0)	1 ( 3)
heart	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	white zone		2 ( 12)	0 ( 0)	1 ( 5)	1 ( 3)
oral cavity	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
forestomach	white zone		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	nodule		3 ( 18)	0 ( 0)	0 ( 0)	0 ( 0)
	rupture		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	ulcer		3 ( 18)	0 ( 0)	1 ( 5)	6 ( 19)

STUDY NO. : 0158  
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 17 (%)	20 ppm 16 (%)	75 ppm 21 (%)	300 ppm 32 (%)
forestomach	thick		1 ( 6)	0 ( 0)	0 ( 0)	1 ( 3)
gl stomach	red zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	red patch		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	nodule		1 ( 6)	1 ( 6)	0 ( 0)	0 ( 0)
	ulcer		2 ( 12)	1 ( 6)	1 ( 5)	7 ( 22)
small intes	nodule		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
liver	enlarged		0 ( 0)	2 ( 13)	0 ( 0)	1 ( 3)
	swollen		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	pale		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	white zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	red zone		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	black zone		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	rough		1 ( 6)	1 ( 6)	1 ( 5)	4 ( 13)
	herniation		1 ( 6)	1 ( 6)	0 ( 0)	3 ( 9)
pancreas	nodule		0 ( 0)	0 ( 0)	1 ( 5)	1 ( 3)
kidney	white zone		0 ( 0)	1 ( 6)	1 ( 5)	0 ( 0)
	red zone		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	cyst		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 6)
	granular		9 ( 53)	6 ( 38)	10 ( 48)	22 ( 69)
urin bladd	red zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	urine:marked retention		0 ( 0)	2 ( 13)	1 ( 5)	2 ( 6)

STUDY NO. : 0158  
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 17 (%)	20 ppm 16 (%)	75 ppm 21 (%)	300 ppm 32 (%)
urin bladd	urine:red		1 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)
pituitary	enlarged		4 ( 24)	4 ( 25)	9 ( 43)	4 ( 13)
	red zone		1 ( 6)	1 ( 6)	2 ( 10)	2 ( 6)
	black zone		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 6)
	nodule		0 ( 0)	1 ( 6)	1 ( 5)	3 ( 9)
thyroid	enlarged		1 ( 6)	0 ( 0)	1 ( 5)	1 ( 3)
adrenal	enlarged		2 ( 12)	1 ( 6)	0 ( 0)	1 ( 3)
testis	atrophic		3 ( 18)	0 ( 0)	2 ( 10)	2 ( 6)
	white		0 ( 0)	0 ( 0)	1 ( 5)	0 ( 0)
	red		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	nodule		10 ( 59)	9 ( 56)	8 ( 38)	27 ( 84)
semin ves	red		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
brain	red zone		0 ( 0)	0 ( 0)	1 ( 5)	1 ( 3)
	hemorrhage		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
spinal cord	red zone		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	black zone		1 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)
	hemorrhage		1 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)
eye	turbid		1 ( 6)	0 ( 0)	0 ( 0)	1 ( 3)
	white		2 ( 12)	0 ( 0)	0 ( 0)	1 ( 3)
Zymbal gl	nodule		0 ( 0)	1 ( 6)	0 ( 0)	1 ( 3)
muscle	mass		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
bone	nodule		0 ( 0)	0 ( 0)	1 ( 5)	0 ( 0)

STUDY NO. : 0158  
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 17 (%)	20 ppm 16 (%)	75 ppm 21 (%)	300 ppm 32 (%)
pleura	red zone		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
peritoneum	nodule		0 ( 0)	0 ( 0)	3 ( 14)	1 ( 3)
	granular		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
retroperit	mass		0 ( 0)	0 ( 0)	1 ( 5)	0 ( 0)
abdominal c	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	ascites		2 ( 12)	2 ( 13)	3 ( 14)	3 ( 9)
thoracic ca	pleural fluid		5 ( 29)	3 ( 19)	2 ( 10)	6 ( 19)
other	tail:nodule		1 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)

(HPT080)

BAIS2



## APPENDIX G 2

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

STUDY NO. : 0158  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 5

Organ	Findings	Group Name NO. of Animals	Control 12 (%)	20 ppm 16 (%)	75 ppm 12 (%)	300 ppm 14 (%)
skin/app	nodule		1 ( 8)	0 ( 0)	1 ( 8)	0 ( 0)
subcutis	jaundice		1 ( 8)	2 ( 13)	1 ( 8)	0 ( 0)
	mass		1 ( 8)	1 ( 6)	0 ( 0)	2 ( 14)
lung	red		0 ( 0)	1 ( 6)	0 ( 0)	1 ( 7)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 7)
lymph node	enlarged		0 ( 0)	3 ( 19)	1 ( 8)	0 ( 0)
	red		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
thymus	white		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	red zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 7)
spleen	enlarged		2 ( 17)	4 ( 25)	4 ( 33)	1 ( 7)
	nodule		0 ( 0)	0 ( 0)	1 ( 8)	1 ( 7)
heart	white zone		0 ( 0)	0 ( 0)	1 ( 8)	1 ( 7)
oral cavity	nodule		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
forestomach	adhesion		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 7)
gl stomach	red patch		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 7)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 7)
	erosion		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 7)
small intes	nodule		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
liver	nodule		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	rough		1 ( 8)	1 ( 6)	2 ( 17)	0 ( 0)
	granular		1 ( 8)	0 ( 0)	1 ( 8)	1 ( 7)
	herniation		3 ( 25)	3 ( 19)	2 ( 17)	1 ( 7)

STUDY NO. : 0158  
 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 12 (%)	20 ppm 16 (%)	75 ppm 12 (%)	300 ppm 14 (%)
liver	accentuation of lobular structure		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
pancreas	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 7)
kidney	enlarged		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
	granular		1 ( 8)	1 ( 6)	1 ( 8)	3 ( 21)
urin bladd	red zone		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	urine:marked retention		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
	urine:red		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
pituitary	enlarged		7 ( 58)	6 ( 38)	4 ( 33)	7 ( 50)
	white zone		1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)
	red zone		1 ( 8)	1 ( 6)	1 ( 8)	0 ( 0)
	black zone		1 ( 8)	0 ( 0)	1 ( 8)	0 ( 0)
	nodule		1 ( 8)	0 ( 0)	2 ( 17)	2 ( 14)
thyroid	enlarged		0 ( 0)	0 ( 0)	1 ( 8)	1 ( 7)
	red		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
ovary	cyst		1 ( 8)	1 ( 6)	1 ( 8)	1 ( 7)
uterus	nodule		2 ( 17)	2 ( 13)	3 ( 25)	0 ( 0)
vagina	nodule		0 ( 0)	1 ( 6)	1 ( 8)	0 ( 0)
brain	red zone		0 ( 0)	1 ( 6)	0 ( 0)	1 ( 7)
spinal cord	nodule		0 ( 0)	1 ( 6)	1 ( 8)	0 ( 0)
eye	turbid		0 ( 0)	2 ( 13)	0 ( 0)	0 ( 0)
	red		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
pleura	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 7)

STUDY NO. : 0158  
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 12 (%)	20 ppm 16 (%)	75 ppm 12 (%)	300 ppm 14 (%)
abdominal c	mass		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 7)
mesenterium	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 7)
thoracic ca	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 7)
	pleural fluid		2 ( 17)	0 ( 0)	2 ( 17)	2 ( 14)
whole body	anemic		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)

(HPT080)

BAIS 2

## APPENDIX G 3

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

STUDY NO. : 0158  
ANIMAL : RAT F344  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS (105W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 33 (%)	20 ppm 34 (%)	75 ppm 29 (%)	300 ppm 18 (%)
skin/app	nodule		3 ( 9)	5 ( 15)	1 ( 3)	2 ( 11)
subcutis	nodule		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	mass		6 ( 18)	8 ( 24)	8 ( 28)	3 ( 17)
lung	nodule		2 ( 6)	0 ( 0)	1 ( 3)	1 ( 6)
lymph node	enlarged		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
spleen	enlarged		2 ( 6)	4 ( 12)	1 ( 3)	1 ( 6)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 6)
	deformed		2 ( 6)	1 ( 3)	0 ( 0)	3 ( 17)
oral cavity	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
tongue	nodule		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
cecum	nodule		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
liver	enlarged		1 ( 3)	2 ( 6)	0 ( 0)	0 ( 0)
	white zone		1 ( 3)	0 ( 0)	0 ( 0)	1 ( 6)
	red zone		1 ( 3)	2 ( 6)	1 ( 3)	0 ( 0)
	nodule		0 ( 0)	2 ( 6)	0 ( 0)	0 ( 0)
	rough		1 ( 3)	2 ( 6)	3 ( 10)	1 ( 6)
	herniation		4 ( 12)	2 ( 6)	0 ( 0)	1 ( 6)
pancreas	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
kidney	granular		28 ( 85)	28 ( 82)	28 ( 97)	17 ( 94)
	nodular		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
pituitary	enlarged		1 ( 3)	4 ( 12)	3 ( 10)	1 ( 6)
	red zone		1 ( 3)	1 ( 3)	1 ( 3)	0 ( 0)

STUDY NO. : 0158  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 33 (%)	20 ppm 34 (%)	75 ppm 29 (%)	300 ppm 18 (%)
pituitary	black zone		4 ( 12)	5 ( 15)	4 ( 14)	5 ( 28)
	nodule		3 ( 9)	4 ( 12)	3 ( 10)	3 ( 17)
thyroid	enlarged		3 ( 9)	0 ( 0)	1 ( 3)	2 ( 11)
	nodule		1 ( 3)	1 ( 3)	3 ( 10)	0 ( 0)
adrenal	enlarged		2 ( 6)	0 ( 0)	3 ( 10)	3 ( 17)
testis	atrophic		0 ( 0)	1 ( 3)	0 ( 0)	1 ( 6)
	nodule		30 ( 91)	32 ( 94)	28 ( 97)	18 (100)
prostate	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 6)
eye	turbid		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	white		3 ( 9)	3 ( 9)	0 ( 0)	1 ( 6)
Zymbal gl	nodule		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
muscle	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
peritoneum	nodule		2 ( 6)	1 ( 3)	0 ( 0)	0 ( 0)
	cyst		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 6)
abdominal c	ascites		0 ( 0)	1 ( 3)	1 ( 3)	0 ( 0)
thoracic ca	pleural fluid		1 ( 3)	0 ( 0)	1 ( 3)	0 ( 0)
uter	tail:nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)

## APPENDIX G 4

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



STUDY NO. : 0158  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 38 (%)	20 ppm 34 (%)	75 ppm 38 (%)	300 ppm 36 (%)
skin/app	nodule		1 ( 3)	1 ( 3)	0 ( 0)	0 ( 0)
	scab		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
subcutis	jaundice		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	mass		6 ( 16)	9 ( 26)	8 ( 21)	12 ( 33)
lung	nodule		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
spleen	enlarged		1 ( 3)	0 ( 0)	2 ( 5)	4 ( 11)
	nodule		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	deformed		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
large intes	dilated		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
liver	white zone		0 ( 0)	1 ( 3)	1 ( 3)	0 ( 0)
	red zone		3 ( 8)	1 ( 3)	1 ( 3)	1 ( 3)
	nodule		0 ( 0)	2 ( 6)	2 ( 5)	3 ( 8)
	rough		2 ( 5)	0 ( 0)	1 ( 3)	2 ( 6)
	herniation		4 ( 11)	0 ( 0)	2 ( 5)	2 ( 6)
kidney	white zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	granular		10 ( 26)	11 ( 32)	10 ( 26)	15 ( 42)
pituitary	enlarged		7 ( 18)	4 ( 12)	8 ( 21)	8 ( 22)
	red zone		3 ( 8)	2 ( 6)	4 ( 11)	1 ( 3)
	black zone		12 ( 32)	11 ( 32)	9 ( 24)	8 ( 22)
	nodule		4 ( 11)	3 ( 9)	6 ( 16)	0 ( 0)
	cyst		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
thyroid	enlarged		1 ( 3)	0 ( 0)	1 ( 3)	1 ( 3)

STUDY NO. : 0158  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control 38 (%)	20 ppm 34 (%)	75 ppm 38 (%)	300 ppm 36 (%)
thyroid	nodule		0 ( 0)	2 ( 6)	0 ( 0)	0 ( 0)
adrenal	enlarged		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
ovary	enlarged		1 ( 3)	0 ( 0)	1 ( 3)	1 ( 3)
	cyst		3 ( 8)	2 ( 6)	0 ( 0)	3 ( 8)
uterus	nodule		3 ( 8)	0 ( 0)	4 ( 11)	1 ( 3)
	invagination		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
prep/cli gl	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
brain	white zone		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	black zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
periph nerv	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
eye	turbid		3 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)
	white		0 ( 0)	1 ( 3)	4 ( 11)	3 ( 8)
muscle	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
other	tail:nodule		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)

## APPENDIX G 5

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

STUDY NO. : 0159  
 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 10 (%)	20ppm 18 (%)	75ppm 18 (%)	300ppm 19 (%)
skin/app	ulcer		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
	erosion		1 ( 10)	0 ( 0)	0 ( 0)	1 ( 5)
subcutis	edema		1 ( 10)	1 ( 6)	0 ( 0)	1 ( 5)
	jaundice		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)
	mass		1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)
lung	nodule		1 ( 10)	4 ( 22)	1 ( 6)	3 ( 16)
lymph node	enlarged		1 ( 10)	2 ( 11)	3 ( 17)	2 ( 11)
thymus	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
spleen	enlarged		0 ( 0)	4 ( 22)	3 ( 17)	2 ( 11)
	atrophic		0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)
	nodule		0 ( 0)	3 ( 17)	3 ( 17)	0 ( 0)
	deformed		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
heart	white		0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)
gl stomach	thick		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
jejunum	nodule		0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)
small intes	nodule		0 ( 0)	0 ( 0)	1 ( 6)	1 ( 5)
liver	enlarged		0 ( 0)	1 ( 6)	0 ( 0)	1 ( 5)
	white zone		1 ( 10)	3 ( 17)	4 ( 22)	0 ( 0)
	nodule		4 ( 40)	6 ( 33)	8 ( 44)	14 ( 74)
	nodular		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
pancreas	nodule		1 ( 10)	1 ( 6)	1 ( 6)	0 ( 0)

STUDY NO. : 0159  
 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 10 (%)	20ppm 18 (%)	75ppm 18 (%)	300ppm 19 (%)
kidney	enlarged		1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)
	pale		0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)
	nodule		0 ( 0)	1 ( 6)	1 ( 6)	1 ( 5)
	adhesion		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	hydronephrosis		1 ( 10)	1 ( 6)	0 ( 0)	1 ( 5)
urin bladd	enlarged		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
	urine:marked retention		3 ( 30)	0 ( 0)	2 ( 11)	5 ( 26)
	urine:red		0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)
	urine:black		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	urine:turbid		1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)
pituitary	enlarged		1 ( 10)	0 ( 0)	1 ( 6)	1 ( 5)
testis	atrophic		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
epididymis	nodule		0 ( 0)	0 ( 0)	1 ( 6)	2 ( 11)
semin ves	enlarged		2 ( 20)	0 ( 0)	5 ( 28)	0 ( 0)
	black		0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)
	rupture		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
ovi d/u def	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
uterus	nodule		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
prep/cli gl	enlarged		1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	1 ( 6)	1 ( 5)
	cyst		0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)

STUDY NO. : 0159  
 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 10 (%)	20ppm 18 (%)	75ppm 18 (%)	300ppm 18 (%)
periph nerv	nodule		0 ( 0)	1 ( 6)	1 ( 6)	0 ( 0)
Harder gl	nodule		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
bone	nodule		0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)
peritoneum	nodule		0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)
	adhesion		0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)
retroperit	mass		1 ( 10)	1 ( 6)	0 ( 0)	0 ( 0)
abdominal c	hemorrhage		0 ( 0)	0 ( 0)	2 ( 11)	2 ( 11)
	mass		0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)
	pleural fluid		0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)
	ascites		0 ( 0)	5 ( 28)	2 ( 11)	2 ( 11)
mesenterium	nodule		1 ( 10)	1 ( 6)	1 ( 6)	0 ( 0)
	adhesion		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
thoracic ca	hemorrhage		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	pleural fluid		1 ( 10)	2 ( 11)	0 ( 0)	3 ( 16)
other	red		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	nodule		1 ( 10)	0 ( 0)	0 ( 0)	1 ( 5)
	tail:nodule		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 11)
whole body	anemic		1 ( 10)	0 ( 0)	0 ( 0)	1 ( 5)

## APPENDIX G 6

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

STUDY NO. : 0159  
 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 22 (%)	20ppm 25 (%)	75ppm 26 (%)	300ppm 24 (%)
skin/app	nodule		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
subcutis	edema		4 ( 18)	1 ( 4)	5 ( 19)	2 ( 8)
	nodule		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
	mass		1 ( 5)	2 ( 8)	0 ( 0)	1 ( 4)
lung	red		0 ( 0)	2 ( 8)	2 ( 8)	0 ( 0)
	nodule		0 ( 0)	1 ( 4)	2 ( 8)	4 ( 17)
lymph node	enlarged		7 ( 32)	5 ( 20)	6 ( 23)	9 ( 38)
thymus	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
spleen	enlarged		5 ( 23)	7 ( 28)	8 ( 31)	6 ( 25)
	nodule		0 ( 0)	2 ( 8)	3 ( 12)	2 ( 8)
heart	enlarged		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
	adhesion		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
forestomach	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
gl stomach	ulcer		1 ( 5)	1 ( 4)	1 ( 4)	0 ( 0)
	thick		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
anus	nodule		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
liver	enlarged		4 ( 18)	2 ( 8)	2 ( 8)	5 ( 21)
	pale		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	white zone		5 ( 23)	0 ( 0)	6 ( 23)	3 ( 13)
	red zone		1 ( 5)	2 ( 8)	0 ( 0)	0 ( 0)
	nodule		5 ( 23)	7 ( 28)	9 ( 35)	16 ( 67)
	nodular		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)



STUDY NO. : 0159  
 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 22 (%)	20ppm 25 (%)	75ppm 26 (%)	300ppm 24 (%)
pancreas	nodule		1 ( 5)	3 ( 12)	2 ( 8)	1 ( 4)
	nodular		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
kidney	enlarged		2 ( 9)	1 ( 4)	2 ( 8)	0 ( 0)
	atrophic		1 ( 5)	0 ( 0)	1 ( 4)	0 ( 0)
	pale		1 ( 5)	0 ( 0)	1 ( 4)	0 ( 0)
	white zone		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 8)
	hydronephrosis		2 ( 9)	2 ( 8)	0 ( 0)	0 ( 0)
urin bladd	white		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
	rupture		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
	thick		0 ( 0)	1 ( 4)	0 ( 0)	1 ( 4)
	urine:marked retention		2 ( 9)	2 ( 8)	0 ( 0)	0 ( 0)
	urine:red		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
pituitary	enlarged		2 ( 9)	1 ( 4)	2 ( 8)	1 ( 4)
	red		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
	red patch		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	nodule		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
ovary	enlarged		1 ( 5)	5 ( 20)	4 ( 15)	5 ( 21)
	red		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	black		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
	cyst		2 ( 9)	2 ( 8)	2 ( 8)	2 ( 8)
uterus	enlarged		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)

STUDY NO. : 0159  
 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 22 (%)	20ppm 25 (%)	75ppm 26 (%)	300ppm 24 (%)
uterus	nodule		9 ( 41)	5 ( 20)	8 ( 31)	9 ( 38)
	thick		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
vagina	nodule		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
brain	black zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
spinal cord	red zone		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
muscle	nodule		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
mediastinum	mass		3 ( 14)	3 ( 12)	3 ( 12)	2 ( 8)
peritoneum	nodule		1 ( 5)	2 ( 8)	4 ( 15)	0 ( 0)
	mass		0 ( 0)	2 ( 8)	1 ( 4)	0 ( 0)
retroperit	nodule		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	mass		0 ( 0)	3 ( 12)	0 ( 0)	1 ( 4)
abdominal c	hemorrhage		1 ( 5)	5 ( 20)	3 ( 12)	5 ( 21)
	ascites		6 ( 27)	5 ( 20)	9 ( 35)	3 ( 13)
mesenterium	red zone		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	nodule		1 ( 5)	0 ( 0)	1 ( 4)	0 ( 0)
thoracic ca	hemorrhage		2 ( 9)	2 ( 8)	1 ( 4)	1 ( 4)
	mass		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	pleural fluid		10 ( 45)	11 ( 44)	10 ( 38)	6 ( 25)
other	absence		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
whole body	anemic		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)

## APPENDIX G 7

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

STUDY NO. : 0159  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 39 (%)	20ppm 31 (%)	75ppm 32 (%)	300ppm 30 (%)
skin/app	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	erosion		2 ( 5)	1 ( 3)	3 ( 9)	0 ( 0)
subcutis	mass		0 ( 0)	2 ( 6)	1 ( 3)	1 ( 3)
brown fat	nodule		0 ( 0)	0 ( 0)	1 ( 3)	1 ( 3)
lung	nodule		7 ( 18)	5 ( 16)	7 ( 22)	5 ( 17)
lymph node	enlarged		3 ( 8)	2 ( 6)	6 ( 19)	3 ( 10)
	nodule		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
spleen	enlarged		1 ( 3)	1 ( 3)	4 ( 13)	0 ( 0)
	black zone		0 ( 0)	1 ( 3)	0 ( 0)	1 ( 3)
	nodule		2 ( 5)	2 ( 6)	0 ( 0)	1 ( 3)
	accentuation of white pulp		1 ( 3)	3 ( 10)	5 ( 16)	0 ( 0)
salivary gl	nodule		0 ( 0)	1 ( 3)	1 ( 3)	0 ( 0)
small intes	white zone		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	2 ( 6)	0 ( 0)	1 ( 3)
large intes	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
liver	white zone		0 ( 0)	3 ( 10)	3 ( 9)	3 ( 10)
	red zone		2 ( 5)	2 ( 6)	1 ( 3)	0 ( 0)
	nodule		19 ( 49)	17 ( 55)	15 ( 47)	25 ( 83)
pancreas	nodule		0 ( 0)	1 ( 3)	0 ( 0)	1 ( 3)
kidney	pale		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	1 ( 3)	1 ( 3)	0 ( 0)
	cyst		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)

STUDY NO. : 0159  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105#)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 39 (%)	20ppm 31 (%)	75ppm 32 (%)	300ppm 30 (%)
kidney	hydronephrosis		2 ( 5)	0 ( 0)	0 ( 0)	1 ( 3)
urin bladd	urine:marked retention		1 ( 3)	1 ( 3)	2 ( 6)	0 ( 0)
pituitary	enlarged		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
thyroid	enlarged		1 ( 3)	1 ( 3)	0 ( 0)	0 ( 0)
testis	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	atrophic		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	absence		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
semin ves	enlarged		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
prostate	enlarged		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
prep/cli gl	nodule		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	cyst		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
eye	turbid		0 ( 0)	0 ( 0)	2 ( 6)	0 ( 0)
liver gl	enlarged		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	nodule		2 ( 5)	1 ( 3)	0 ( 0)	2 ( 7)
mediastinum	mass		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
retroperit	mass		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
abdominal c	ascites		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
mesenterium	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
thoracic ca	mass		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	pleural fluid		0 ( 0)	0 ( 0)	1 ( 3)	1 ( 3)
other	tail:nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)

STUDY NO. : 0159  
ANIMAL : MOUSE BDF1  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS (105W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 39 (%)	20ppm 31 (%)	75ppm 32 (%)	300ppm 30 (%)
other	ear:nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)

(IPT080)

BAIS 2

## APPENDIX G 8

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

STUDY NO. : 0159  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control 28 (%)	20ppm 25 (%)	75ppm 23 (%)	300ppm 26 (%)
subcutis	mass		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
lung	red zone		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	nodule		2 ( 7)	4 ( 16)	0 ( 0)	3 ( 12)
lymph node	enlarged		3 ( 11)	1 ( 4)	0 ( 0)	4 ( 15)
spleen	enlarged		4 ( 14)	3 ( 12)	0 ( 0)	3 ( 12)
	white zone		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
	black zone		1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		1 ( 4)	0 ( 0)	0 ( 0)	1 ( 4)
	accentuation of white pulp		1 ( 4)	0 ( 0)	0 ( 0)	2 ( 8)
tongue	nodule		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
salivary gl	nodule		0 ( 0)	1 ( 4)	0 ( 0)	1 ( 4)
forestomach	nodule		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
small intes	nodule		1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
liver	enlarged		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
	white zone		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
	red zone		2 ( 7)	5 ( 20)	2 ( 9)	0 ( 0)
	yellow zone		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
	nodule		5 ( 18)	10 ( 40)	8 ( 35)	26 (100)
	rough		1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
gall bladd	dilated		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
pancreas	nodule		0 ( 0)	1 ( 4)	0 ( 0)	1 ( 4)
kidney	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)



STUDY NO. : 0159  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 5

Organ	Findings	Group Name NO. of Animals	Control 28 (%)	20ppm 25 (%)	75ppm 23 (%)	300ppm 26 (%)
kidney	atrophic		2 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	hydronephrosis		2 ( 7)	0 ( 0)	0 ( 0)	1 ( 4)
pituitary	enlarged		2 ( 7)	3 ( 12)	1 ( 4)	3 ( 12)
	nodule		0 ( 0)	4 ( 16)	2 ( 9)	1 ( 4)
ovary	enlarged		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	red		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	cyst		10 ( 36)	6 ( 24)	5 ( 22)	0 ( 0)
uterus	nodule		2 ( 7)	3 ( 12)	3 ( 13)	1 ( 4)
periph nerv	nodule		1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
eye	turbid		1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
harder gl	nodule		2 ( 7)	0 ( 0)	0 ( 0)	1 ( 4)
peritoneum	nodule		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	thick		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
retroperit	mass		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
abdominal c	mass		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	ascites		1 ( 4)	1 ( 4)	1 ( 4)	1 ( 4)
thoracic ca	mass		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	pleural fluid		3 ( 11)	0 ( 0)	3 ( 13)	0 ( 0)

## APPENDIX H 1

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

STUDY NO. : 0158  
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	33	394± 40	0.105± 0.085	4.811± 1.503	1.365± 0.155	1.596± 0.574	3.040± 0.261
20 ppm	34	406± 45	0.086± 0.014	5.318± 2.452	1.348± 0.145	1.570± 0.217	3.183± 0.590
75 ppm	29	382± 42	0.103± 0.056	4.965± 1.844	1.346± 0.148	1.538± 0.205	3.193± 0.352
300 ppm	18	382± 43	0.139± 0.171	5.571± 2.225	1.327± 0.115	1.571± 0.191	3.636± 0.493**

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0158  
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	33	1.558±	1.700	13.007±	1.669	2.028±	0.066
20 ppm	34	1.780±	1.623	14.309±	4.983	2.041±	0.053
75 ppm	29	1.754±	2.933	13.773±	2.357	2.020±	0.056
300 ppm	18	1.628±	1.221	14.957±	1.883**	2.069±	0.059

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. : 0158  
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	300± 31	0.082±	0.013	0.209±	0.410	1.007±	0.106	1.073±	0.089	2.088±	0.178
20 ppm	34	304± 40	0.084±	0.024	0.116±	0.016	0.986±	0.101	1.033±	0.089	2.042±	0.175
75 ppm	38	298± 45	0.085±	0.011	0.117±	0.058	1.014±	0.103	1.081±	0.155	2.081±	0.182
300 ppm	36	295± 42	0.081±	0.012	0.147±	0.134	1.029±	0.105	1.147±	0.253	2.172±	0.230

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0158  
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	0.737±	0.591	7.864±	0.899	1.835±	0.049
20 ppm	34	0.586±	0.168	8.032±	1.187	1.831±	0.042
75 ppm	38	0.734±	0.786	8.193±	1.378	1.839±	0.057
300 ppm	36	1.394±	2.482	9.055±	1.681**	1.852±	0.060

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

Test of Dunnett

(IICL040)

BAIS2

## APPENDIX H 3

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



STUDY NO. : 0159  
 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	39	42.5± 8.1	0.013± 0.004	0.217± 0.027	0.232± 0.034	0.266± 0.149	0.674± 0.266
20ppm	31	40.3± 8.4	0.013± 0.003	0.214± 0.039	0.235± 0.031	0.248± 0.097	0.637± 0.071
75ppm	32	41.6± 6.0	0.013± 0.004	0.218± 0.035	0.231± 0.032	0.259± 0.148	0.655± 0.064
300ppm	30	37.6± 3.9**	0.013± 0.004	0.262± 0.232	0.223± 0.024	0.233± 0.047	0.722± 0.346

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0159  
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	39	0.120±	0.105	1.700±	0.450	0.460±	0.012
20ppm	31	0.170±	0.247	1.907±	0.616	0.462±	0.011
75ppm	32	0.210±	0.323	1.984±	0.756	0.464±	0.013
300ppm	30	0.135±	0.192	3.159±	1.632**	0.463±	0.011

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

(HCL040)

BAIS 2

## APPENDIX H 4

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

STUDY NO. : 0159  
 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	28	32.4± 5.4	0.014± 0.003	0.054± 0.009	0.192± 0.034	0.220± 0.034	0.467± 0.093
20ppm	25	34.3± 6.1	0.015± 0.003	0.036± 0.017	0.197± 0.033	0.230± 0.039	0.469± 0.045
75ppm	23	31.2± 5.3	0.015± 0.004	0.063± 0.116	0.192± 0.057	0.221± 0.035	0.457± 0.062
300ppm	26	29.6± 2.3	0.014± 0.003	0.022± 0.009**	0.190± 0.027	0.230± 0.032	0.514± 0.117*

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

Test of Dunnett

(HCL040)

BAIS2

STUDY NO. : 0159  
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	28	0.245±	0.326	1.583±	0.429	0.486±	0.015
20ppm	25	0.283±	0.487	1.857±	1.283	0.483±	0.014
75ppm	23	0.156±	0.082	1.571±	0.433	0.485±	0.016
300ppm	26	0.294±	0.294	5.354±	2.955**	0.469±	0.015**

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

Test of Dunnett

(HCL040)

BAIS2

## APPENDIX I 1

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

STUDY NO. : 0158  
 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	33	394± 40	0.027± 0.023	1.230± 0.385	0.351± 0.064	0.413± 0.185	0.779± 0.108
20 ppm	34	406± 45	0.022± 0.005	1.305± 0.585	0.336± 0.052	0.393± 0.077	0.800± 0.204
75 ppm	29	382± 42	0.028± 0.021	1.315± 0.504	0.358± 0.070	0.407± 0.073	0.849± 0.165
300 ppm	18	382± 43	0.037± 0.047	1.459± 0.551	0.352± 0.051	0.415± 0.056	0.967± 0.194**

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

(HCL042)

BAIS2

STUDY NO. : 0158  
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	33	0.400± 0.443	3.331± 0.546	0.519± 0.048
20 ppm	34	0.454± 0.446	3.583± 1.375	0.509± 0.052
75 ppm	29	0.464± 0.780	3.634± 0.690	0.535± 0.067
300 ppm	18	0.441± 0.392	3.950± 0.562**	0.548± 0.062

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

Test of Dunnett

(IICL042)

BA1S2



## APPENDIX I 2

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

STUDY NO. : 0158  
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	300± 31	0.028± 0.004	0.068± 0.128	0.338± 0.034	0.361± 0.045	0.703± 0.090
20 ppm	34	304± 40	0.028± 0.011	0.039± 0.008	0.328± 0.047	0.344± 0.044	0.680± 0.093
75 ppm	38	298± 45	0.029± 0.005	0.039± 0.015	0.348± 0.060	0.374± 0.092	0.715± 0.134
300 ppm	36	295± 42	0.028± 0.006	0.048± 0.037	0.358± 0.076	0.402± 0.137	0.758± 0.186

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0158  
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	0.249± 0.211	2.644± 0.379	0.618± 0.064
20 ppm	34	0.196± 0.063	2.657± 0.330	0.612± 0.079
75 ppm	38	0.254± 0.306	2.774± 0.394	0.633± 0.103
300 ppm	36	0.543± 1.138	3.159± 0.901**	0.642± 0.105

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. : 0159  
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	39	42.5± 8.1	0.032± 0.012	0.533± 0.143	0.563± 0.124	0.683± 0.547	1.686± 1.082
20ppm	31	40.3± 8.4	0.033± 0.010	0.544± 0.111	0.610± 0.164	0.653± 0.344	1.655± 0.438
75ppm	32	41.6± 6.0	0.031± 0.009	0.532± 0.097	0.564± 0.095	0.639± 0.409	1.605± 0.283
300ppm	30	37.6± 3.9**	0.035± 0.010	0.708± 0.631**	0.595± 0.071	0.627± 0.147	1.955± 1.100**

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

Test of Dunnett

(HCL042)

BAIS2

STUDY NO. : 0159  
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	39	0.317± 0.345	4.212± 1.776	1.126± 0.228
20ppm	31	0.435± 0.580	5.062± 2.395	1.200± 0.269
75ppm	32	0.511± 0.773	4.868± 2.100	1.139± 0.178
300ppm	30	0.363± 0.508	8.606± 4.766**	1.243± 0.138**

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

(IICL042)

BAIS 2

## APPENDIX I 4

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

STUDY NO. : 0159  
 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	28	32.4± 5.4	0.045± 0.011	0.166± 0.209	0.606± 0.130	0.692± 0.137	1.474± 0.378
20ppm	25	34.3± 6.1	0.044± 0.010	0.108± 0.054	0.586± 0.114	0.688± 0.160	1.396± 0.220
75ppm	23	31.2± 5.3	0.049± 0.011	0.225± 0.444	0.618± 0.117	0.721± 0.125	1.480± 0.156
300ppm	26	29.6± 2.3	0.047± 0.010	0.075± 0.029*	0.646± 0.100	0.782± 0.123	1.749± 0.433**

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

Test of Dunnett

(HCL042)

BAIS 2



STUDY NO. : 0159  
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	28	0.807± 1.150	5.010± 1.703	1.535± 0.236
20ppm	25	0.912± 1.656	5.620± 4.412	1.442± 0.205
75ppm	23	0.503± 0.273	5.020± 0.791	1.597± 0.274
300ppm	26	1.000± 1.018	17.947± 8.830**	1.597± 0.138

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

Test of Dunnett

(HCL042)

BAIS 2