

酢酸ビニルのラット及びマウスを用いた  
経口投与によるがん原性試験(混水試験)報告書

## APPENDIX

(E1～K4)

がん原性：ラット/0162；マウス/0163

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## APPENDIX E 1

CHEMICAL INTAKE CHANGES : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0162  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : AI 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 1

Group Name	Administration (weeks)						
	1	2	3	4	5	6	7
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.048± 0.007	0.045± 0.010	0.038± 0.005	0.032± 0.002	0.029± 0.001	0.036± 0.002	0.032± 0.005
2000 ppm	0.226± 0.015	0.223± 0.074	0.185± 0.026	0.153± 0.009	0.146± 0.009	0.173± 0.013	0.149± 0.011
10000 ppm	0.950± 0.057	0.885± 0.085	0.768± 0.053	0.669± 0.041	0.664± 0.066	0.774± 0.106	0.639± 0.045

(HAN300)

BAIS 2

STUDY NO. : 0162  
ANIMAL : RAT F344  
UNIT : g/kg/day  
REPORT TYPE : A1 104  
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 2

Group Name	Administration		(weeks)											
	8		9		10		11		12		13		14	
Control	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000
400 ppm	0.032±	0.005	0.029±	0.004	0.029±	0.007	0.025±	0.003	0.021±	0.001	0.021±	0.001	0.022±	0.001
2000 ppm	0.146±	0.012	0.139±	0.015	0.136±	0.012	0.117±	0.009	0.103±	0.007	0.104±	0.008	0.105±	0.008
10000 ppm	0.605±	0.038	0.575±	0.037	0.575±	0.034	0.504±	0.079	0.454±	0.053	0.452±	0.026	0.459±	0.027

(HAN300)

BAIS 2

STUDY NO. : 0162  
 ANIMAL : RAT F344  
 UNIT : g/kg/d a y  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 3

Group Name	Administration (weeks)						
	16	18	20	22	24	26	28
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.023± 0.002	0.021± 0.002	0.021± 0.002	0.021± 0.002	0.020± 0.002	0.020± 0.002	0.019± 0.001
2000 ppm	0.112± 0.008	0.104± 0.011	0.101± 0.010	0.100± 0.009	0.098± 0.008	0.097± 0.010	0.096± 0.009
10000 ppm	0.476± 0.024	0.454± 0.021	0.438± 0.026	0.432± 0.025	0.425± 0.021	0.422± 0.026	0.420± 0.024

(HAN300)

BAIS 2

STUDY NO. : 0162  
 ANIMAL : RAT F344  
 UNIT : g/kg/d a y  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 4

Group Name	Administration (weeks)						
	30	32	34	36	38	40	42
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.020± 0.005	0.019± 0.001	0.018± 0.003	0.019± 0.003	0.019± 0.003	0.018± 0.001	0.018± 0.003
2000 ppm	0.092± 0.005	0.089± 0.005	0.084± 0.004	0.090± 0.005	0.090± 0.006	0.088± 0.006	0.089± 0.007
10000 ppm	0.408± 0.025	0.398± 0.023	0.376± 0.038	0.412± 0.025	0.427± 0.062	0.413± 0.028	0.407± 0.024

(HAN300)

BAIS2



STUDY NO. : 0162  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 5

Group Name	Administration (weeks)						
	44	46	48	50	52	54	56
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.016± 0.002	0.018± 0.003	0.017± 0.003	0.018± 0.002	0.017± 0.002	0.017± 0.002	0.016± 0.001
2000 ppm	0.075± 0.006	0.086± 0.005	0.080± 0.006	0.084± 0.006	0.079± 0.009	0.083± 0.005	0.079± 0.006
10000 ppm	0.364± 0.020	0.406± 0.053	0.381± 0.026	0.403± 0.025	0.388± 0.025	0.393± 0.024	0.378± 0.026

(HAN300)

BAIS2

STUDY NO. : 0162  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 6

Group Name	Administration (weeks)						
	58	60	62	64	66	68	70
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.017± 0.002	0.017± 0.001	0.017± 0.001	0.016± 0.001	0.017± 0.001	0.017± 0.002	0.017± 0.001
2000 ppm	0.082± 0.007	0.082± 0.011	0.082± 0.006	0.076± 0.007	0.081± 0.011	0.081± 0.006	0.081± 0.007
10000 ppm	0.390± 0.027	0.385± 0.032	0.394± 0.030	0.372± 0.035	0.388± 0.037	0.388± 0.045	0.381± 0.047

(HAN300)

BAIS 2

STUDY NO. : 0162  
 ANIMAL : RAT F344  
 UNIT : g/kg/d a y  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 7

Group Name	Administration (weeks)									
	72	74	76	78	80	82	84			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
400 ppm	0.017± 0.002	0.018± 0.002	0.018± 0.002	0.018± 0.002	0.018± 0.002	0.018± 0.002	0.018± 0.002	0.018± 0.002		
2000 ppm	0.082± 0.007	0.084± 0.010	0.083± 0.010	0.082± 0.014	0.089± 0.018	0.087± 0.015	0.084± 0.013			
10000 ppm	0.393± 0.046	0.410± 0.091	0.433± 0.116	0.397± 0.064	0.404± 0.079	0.401± 0.099	0.398± 0.088			

(HAN300)

BAIS 2

STUDY NO. : 0162  
 ANIMAL : RAT F344  
 UNIT : g/kg/d a y  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 8

Group Name	Administration (weeks)						
	86	88	90	92	94	96	98
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.020± 0.004	0.021± 0.003	0.022± 0.005	0.022± 0.004	0.023± 0.004	0.022± 0.004	0.023± 0.005
2000 ppm	0.089± 0.022	0.094± 0.022	0.096± 0.028	0.097± 0.020	0.100± 0.020	0.101± 0.026	0.104± 0.029
10000 ppm	0.417± 0.106	0.423± 0.135	0.452± 0.138	0.458± 0.133	0.456± 0.185	0.430± 0.079	0.440± 0.077

(HAN300)

BAIS 2

STUDY NO. : 0162  
ANIMAL : RAT F344  
UNIT : g/kg/day  
REPORT TYPE : A1 104  
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 9

Group Name	Administration (weeks)		
	100	102	104
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.023± 0.006	0.024± 0.006	0.025± 0.008
2000 ppm	0.103± 0.026	0.106± 0.029	0.107± 0.035
10000 ppm	0.448± 0.088	0.450± 0.082	0.461± 0.123

(HAN300)

BAIS2

## APPENDIX D 2

CHEMICAL INTAKE CHANGES : SUMMARY, RAT : FEMALE  
(2-YEAR STUDY)

STUDY NO. : 0162  
 ANIMAL : RAT F344  
 UNIT : g/kg/d a y  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 10

Group Name	Administration (weeks)						
	1	2	3	4	5	6	7
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.060± 0.016	0.058± 0.019	0.056± 0.018	0.052± 0.012	0.057± 0.023	0.055± 0.021	0.040± 0.009
2000 ppm	0.266± 0.018	0.257± 0.050	0.235± 0.026	0.240± 0.032	0.229± 0.034	0.225± 0.045	0.184± 0.041
10000 ppm	1.062± 0.084	0.980± 0.069	0.921± 0.055	0.902± 0.056	0.845± 0.082	0.801± 0.071	0.730± 0.050

(HAN300)

BAIS 2

STUDY NO. : 0162  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 11

Group Name	Administration		(weeks)											
	8		9		10		11		12		13		14	
Control	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000
400 ppm	0.038±	0.011	0.036±	0.011	0.038±	0.014	0.029±	0.009	0.027±	0.008	0.027±	0.006	0.030±	0.015
2000 ppm	0.172±	0.039	0.161±	0.036	0.166±	0.031	0.140±	0.018	0.135±	0.016	0.136±	0.022	0.130±	0.013
10000 ppm	0.678±	0.042	0.676±	0.045	0.689±	0.045	0.571±	0.033	0.520±	0.027	0.543±	0.041	0.548±	0.096

(HAN300)

BAIS 2



STUDY NO. : 0162  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 12

Group Name	Administration (weeks)									
	16	18	20	22	24	26	28			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
400 ppm	0.043± 0.016	0.042± 0.019	0.039± 0.017	0.040± 0.019	0.041± 0.019	0.038± 0.015	0.035± 0.010			
2000 ppm	0.185± 0.045	0.180± 0.056	0.170± 0.051	0.173± 0.049	0.172± 0.058	0.171± 0.058	0.156± 0.031			
10000 ppm	0.655± 0.048	0.617± 0.042	0.565± 0.048	0.566± 0.072	0.565± 0.037	0.557± 0.037	0.578± 0.052			

(HAN300)

BAIS 2

STUDY NO. : 0162  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 13

Group Name	Administration (weeks)		34	36	38	40	42
	30	32					
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.033± 0.010	0.036± 0.014	0.030± 0.011	0.037± 0.014	0.033± 0.009	0.034± 0.012	0.032± 0.012
2000 ppm	0.164± 0.050	0.155± 0.034	0.144± 0.039	0.173± 0.073	0.152± 0.040	0.156± 0.056	0.152± 0.047
10000 ppm	0.562± 0.043	0.554± 0.041	0.512± 0.032	0.577± 0.044	0.567± 0.040	0.600± 0.094	0.555± 0.046

(HAN300)

BAIS 2

STUDY NO. : 0162  
 ANIMAL : RAT F344  
 UNIT : g/kg/d a y  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 14

Group Name	Administration (weeks)													
	44		46		48		50		52		54		56	
Control	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000
400 ppm	0.028±	0.006	0.030±	0.009	0.031±	0.010	0.027±	0.006	0.023±	0.007	0.028±	0.009	0.027±	0.006
2000 ppm	0.137±	0.028	0.143±	0.041	0.142±	0.045	0.141±	0.034	0.109±	0.014	0.136±	0.021	0.128±	0.023
10000 ppm	0.542±	0.042	0.535±	0.044	0.545±	0.067	0.542±	0.045	0.501±	0.040	0.547±	0.061	0.537±	0.059

(HAN300)

BAIS 2

STUDY NO. : 0162  
 ANIMAL : RAT F344  
 UNIT : g/kg/d a y  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 15

Group Name	Administration (weeks)									
	58	60	62	64	66	68	70			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
400 ppm	0.026± 0.006	0.025± 0.003	0.026± 0.007	0.023± 0.006	0.026± 0.006	0.027± 0.009	0.024± 0.007			
2000 ppm	0.135± 0.041	0.131± 0.032	0.126± 0.020	0.117± 0.021	0.134± 0.042	0.139± 0.045	0.123± 0.029			
10000 ppm	0.534± 0.053	0.533± 0.054	0.528± 0.064	0.501± 0.077	0.537± 0.072	0.561± 0.077	0.497± 0.072			

(IIN300)

BAIS 2

STUDY NO. : 0162  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 16

Group Name	Administration (weeks)		74	76	78	80	82	84
	72							
Control	0.000± 0.000		0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.022± 0.004		0.026± 0.007	0.025± 0.005	0.024± 0.004	0.023± 0.003	0.024± 0.004	0.022± 0.004
2000 ppm	0.119± 0.045		0.135± 0.043	0.132± 0.026	0.126± 0.027	0.124± 0.036	0.123± 0.031	0.118± 0.024
10000 ppm	0.478± 0.091		0.544± 0.092	0.568± 0.090	0.554± 0.103	0.544± 0.129	0.546± 0.116	0.515± 0.134

(HAN300)

BAIS 2

STUDY NO. : 0162  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 17

Group Name	Administration (weeks)		88	90	92	94	96	98
	86							
Control	0.000± 0.000		0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.024± 0.004		0.025± 0.004	0.023± 0.006	0.025± 0.005	0.025± 0.005	0.025± 0.005	0.024± 0.006
2000 ppm	0.125± 0.035		0.131± 0.030	0.129± 0.027	0.129± 0.028	0.130± 0.029	0.127± 0.027	0.126± 0.025
10000 ppm	0.554± 0.162		0.574± 0.169	0.573± 0.163	0.563± 0.163	0.568± 0.171	0.552± 0.164	0.557± 0.167

(HAN300)

BAIS 2

STUDY NO. : 0162  
ANIMAL : RAT F344  
UNIT : g/kg/day  
REPORT TYPE : A1 104  
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 18

Group Name	Administration (weeks)			
	100	102	104	
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	
400 ppm	0.025± 0.005	0.028± 0.008	0.027± 0.008	
2000 ppm	0.129± 0.029	0.130± 0.034	0.133± 0.037	
10000 ppm	0.583± 0.204	0.582± 0.131	0.557± 0.146	

(HAN300)

BAIS 2

## APPENDIX E 3

CHEMICAL INTAKE CHANGES : SUMMARY, MOSUE : MALE  
(2-YEAR STUDY)



STUDY NO. : 0163  
ANIMAL : MOUSE BDF1  
UNIT : g/kg/day  
REPORT TYPE : A1 104  
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 1

Group Name	Administration (weeks)						
	1	2	3	4	5	6	7
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.085± 0.017	0.071± 0.012	0.066± 0.011	0.064± 0.012	0.058± 0.008	0.052± 0.007	0.050± 0.007
2000 ppm	0.405± 0.064	0.362± 0.049	0.342± 0.045	0.314± 0.037	0.297± 0.041	0.266± 0.034	0.255± 0.034
10000 ppm	2.081± 0.336	1.868± 0.272	1.688± 0.214	1.701± 0.616	1.484± 0.174	1.327± 0.122	1.280± 0.148

(HAN300)

BAIS 2

STUDY NO. : 0163  
ANIMAL : MOUSE BDF1  
UNIT : g/kg/day  
REPORT TYPE : A1 104  
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 2

Group Name	Administration (weeks)							
	8	9	10	11	12	13	14	
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.052± 0.009	0.046± 0.007	0.046± 0.007	0.045± 0.006	0.044± 0.006	0.044± 0.005	0.047± 0.015	
2000 ppm	0.269± 0.069	0.240± 0.031	0.228± 0.030	0.228± 0.033	0.221± 0.050	0.219± 0.022	0.223± 0.037	
10000 ppm	1.444± 1.161	1.121± 0.121	1.182± 0.161	1.148± 0.103	1.058± 0.115	1.105± 0.127	1.104± 0.176	

(HAN300)

BAIS 2

STUDY NO. : 0163  
ANIMAL : MOUSE BDF1  
UNIT : g/kg/day  
REPORT TYPE : A1 104  
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 3

Group Name	Administration (weeks)						
	16	18	20	22	24	26	28
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.045± 0.014	0.047± 0.016	0.043± 0.007	0.042± 0.012	0.040± 0.006	0.038± 0.006	0.041± 0.017
2000 ppm	0.216± 0.031	0.228± 0.051	0.198± 0.019	0.193± 0.021	0.205± 0.021	0.189± 0.021	0.183± 0.021
10000 ppm	1.039± 0.137	1.110± 0.166	1.054± 0.161	1.024± 0.190	1.059± 0.179	1.006± 0.210	1.019± 0.194

(HAN300)

BAIS2

STUDY NO. : 0163  
ANIMAL : MOUSE BDF1  
UNIT : g/kg/day  
REPORT TYPE : A1 104  
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 4

Group Name	Administration (weeks)									
	30	32	34	36	38	40	42			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
400 ppm	0.037± 0.007	0.039± 0.011	0.040± 0.004	0.036± 0.003	0.032± 0.004	0.036± 0.004	0.039± 0.006			
2000 ppm	0.189± 0.026	0.194± 0.043	0.190± 0.020	0.175± 0.020	0.248± 0.430	0.182± 0.029	0.184± 0.024			
10000 ppm	0.962± 0.190	1.017± 0.181	1.024± 0.211	0.911± 0.211	0.832± 0.156	0.974± 0.251	0.910± 0.140			

(HAN300)

BAIS2

STUDY NO. : 0163  
ANIMAL : MOUSE BDF1  
UNIT : g/kg/day  
REPORT TYPE : A1 104  
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 5

Group Name	Administration (weeks)									
	44	46	48	50	52	54	56			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
400 ppm	0.036± 0.005	0.037± 0.003	0.037± 0.005	0.035± 0.004	0.034± 0.003	0.036± 0.009	0.035± 0.004			
2000 ppm	0.167± 0.017	0.182± 0.016	0.176± 0.016	0.168± 0.015	0.177± 0.014	0.185± 0.019	0.179± 0.027			
10000 ppm	0.813± 0.162	0.943± 0.166	0.857± 0.134	0.861± 0.133	0.848± 0.135	0.879± 0.137	0.845± 0.126			

(HAN300)

BAIS2

STUDY NO. : 0163  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 6

Group Name	Administration (weeks)									
	58	60	62	64	66	68	70			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
400 ppm	0.045± 0.052	0.036± 0.008	0.036± 0.005	0.036± 0.006	0.035± 0.008	0.037± 0.010	0.038± 0.013			
2000 ppm	0.177± 0.018	0.169± 0.014	0.173± 0.017	0.170± 0.016	0.170± 0.015	0.173± 0.014	0.170± 0.015			
10000 ppm	0.818± 0.143	0.808± 0.101	0.827± 0.105	0.808± 0.105	0.826± 0.114	0.845± 0.148	0.800± 0.112			

(HAN300)

BAIS 2

STUDY NO. : 0163  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/d a y  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 7

Group Name	Administration (weeks)		74	76	78	80	82	84
	72							
Control	0.000± 0.000		0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.040± 0.015		0.039± 0.017	0.041± 0.020	0.044± 0.020	0.040± 0.015	0.040± 0.013	0.040± 0.012
2000 ppm	0.175± 0.021		0.176± 0.021	0.182± 0.024	0.183± 0.024	0.180± 0.024	0.194± 0.025	0.189± 0.049
10000 ppm	0.835± 0.179		0.841± 0.194	0.888± 0.187	0.965± 0.388	0.914± 0.365	0.944± 0.370	0.915± 0.459

(HAN300)

BAIS 2

STUDY NO. : 0163  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 8

Group Name	Administration (weeks)									
	86	88	90	92	94	96	98			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
400 ppm	0.041± 0.011	0.041± 0.012	0.042± 0.013	0.044± 0.013	0.042± 0.013	0.045± 0.015	0.047± 0.022			
2000 ppm	0.188± 0.050	0.195± 0.062	0.197± 0.076	0.209± 0.078	0.205± 0.076	0.211± 0.083	0.218± 0.090			
10000 ppm	0.912± 0.482	0.941± 0.487	0.946± 0.450	0.979± 0.201	1.004± 0.184	1.038± 0.194	1.016± 0.192			

(HAN300)

BAIS2



STUDY NO. : 0163  
ANIMAL : MOUSE BDF1  
UNIT : g/kg/day  
REPORT TYPE : A1 104  
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 9

Group Name	Administration (weeks)			
	100	102	104	
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	
400 ppm	0.050± 0.026	0.049± 0.027	0.059± 0.038	
2000 ppm	0.225± 0.094	0.231± 0.104	0.257± 0.140	
10000 ppm	1.134± 0.406	1.043± 0.242	1.070± 0.246	

(HAN300)

BAIS 2

## APPENDIX E 4

CHEMICAL INTAKE CHANGES : SUMMARY, MOSUE : FEMALE  
(2-YEAR STUDY)

STUDY NO. : 0163  
ANIMAL : MOUSE BDF1  
UNIT : g/kg/day  
REPORT TYPE : A1 104  
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 10

Group Name	Administration (weeks)						
	1	2	3	4	5	6	7
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.092± 0.010	0.081± 0.008	0.081± 0.013	0.083± 0.016	0.077± 0.012	0.081± 0.023	0.076± 0.026
2000 ppm	0.483± 0.188	0.421± 0.044	0.403± 0.037	0.403± 0.070	0.371± 0.073	0.376± 0.085	0.374± 0.080
10000 ppm	2.185± 0.231	2.078± 0.214	2.003± 0.148	2.057± 0.207	1.950± 0.207	1.850± 0.240	1.929± 0.246

(IAN300)

BAIS2

STUDY NO. : 0163  
ANIMAL : MOUSE BDF1  
UNIT : g/kg/day  
REPORT TYPE : A1 104  
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 11

Group Name	Administration (weeks)		9	10	11	12	13	14
	8							
Control	0.000± 0.000		0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.088± 0.032		0.081± 0.033	0.083± 0.036	0.081± 0.037	0.102± 0.077	0.112± 0.076	0.125± 0.132
2000 ppm	0.378± 0.066		0.363± 0.070	0.363± 0.049	0.360± 0.055	0.402± 0.159	0.464± 0.183	0.458± 0.195
10000 ppm	1.978± 0.307		1.776± 0.234	1.903± 0.300	1.938± 0.263	1.902± 0.352	1.963± 0.301	2.047± 0.320

(HAN300)

BAIS 2

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

Group Name	Administration (weeks)													
	16		18		20		22		24		26		28	
Control	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000	0.000±	0.000
400 ppm	0.094±	0.061	0.107±	0.099	0.082±	0.045	0.082±	0.040	0.075±	0.021	0.077±	0.037	0.073±	0.032
2000 ppm	0.375±	0.051	0.463±	0.466	0.377±	0.093	0.349±	0.103	0.353±	0.120	0.337±	0.096	0.334±	0.055
10000 ppm	1.829±	0.203	1.832±	0.229	1.695±	0.225	1.607±	0.204	1.736±	0.232	1.627±	0.218	1.572±	0.281

BAIS 2

STUDY NO. : 0163  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 13

Group Name	Administration (weeks)									
	30	32	34	36	38	40	42			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
400 ppm	0.070± 0.027	0.070± 0.025	0.077± 0.030	0.070± 0.026	0.059± 0.022	0.059± 0.018	0.071± 0.028			
2000 ppm	0.319± 0.052	0.322± 0.066	0.358± 0.203	0.303± 0.098	0.296± 0.176	0.281± 0.055	0.339± 0.210			
10000 ppm	1.529± 0.206	1.604± 0.266	1.631± 0.260	1.462± 0.224	1.397± 0.234	1.476± 0.249	1.562± 0.260			

(HAN300)

BAIS2

STUDY NO. : 0163  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 14

Group Name	Administration (weeks)									
	44	46	48	50	52	54	56			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
400 ppm	0.059± 0.015	0.059± 0.014	0.056± 0.019	0.060± 0.041	0.051± 0.014	0.052± 0.017	0.046± 0.012			
2000 ppm	0.306± 0.214	0.283± 0.093	0.306± 0.111	0.287± 0.121	0.261± 0.090	0.281± 0.145	0.268± 0.194			
10000 ppm	1.297± 0.237	1.490± 0.248	1.412± 0.317	1.359± 0.213	1.273± 0.216	1.308± 0.215	1.227± 0.201			

(HAN300)

BAIS2

STUDY NO. : 0163  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 15

Group Name	Administration (weeks)									
	58	60	62	64	66	68	70			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
400 ppm	0.048± 0.011	0.047± 0.009	0.049± 0.013	0.047± 0.010	0.045± 0.009	0.053± 0.015	0.050± 0.013			
2000 ppm	0.269± 0.134	0.256± 0.117	0.251± 0.131	0.230± 0.044	0.234± 0.048	0.242± 0.062	0.236± 0.060			
10000 ppm	1.217± 0.180	1.158± 0.176	1.187± 0.211	1.098± 0.161	1.106± 0.189	1.137± 0.197	1.150± 0.182			

(HAN300)

BAIS2



STUDY NO. : 0163  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/d a y  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 16

Group Name	Administration (weeks)		74	76	78	80	82	84
	72							
Control	0.000± 0.000		0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.052± 0.014		0.052± 0.012	0.052± 0.012	0.054± 0.010	0.051± 0.014	0.052± 0.012	0.053± 0.012
2000 ppm	0.235± 0.058		0.252± 0.073	0.250± 0.052	0.263± 0.054	0.249± 0.057	0.333± 0.449	0.266± 0.100
10000 ppm	1.024± 0.158		1.191± 0.183	1.112± 0.185	1.209± 0.232	1.131± 0.161	1.170± 0.217	1.117± 0.158

(HAN300)

BAIS2

STUDY NO. : 0163  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 17

Group Name	Administration (weeks)									
	86	88	90	92	94	96	98			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
400 ppm	0.055± 0.008	0.054± 0.008	0.052± 0.008	0.055± 0.008	0.052± 0.012	0.054± 0.008	0.054± 0.008	0.054± 0.008		
2000 ppm	0.270± 0.056	0.254± 0.049	0.261± 0.055	0.274± 0.057	0.267± 0.072	0.281± 0.092	0.292± 0.084			
10000 ppm	1.191± 0.179	1.181± 0.211	1.147± 0.304	1.248± 0.309	1.228± 0.197	1.270± 0.302	1.332± 0.264			

(HAN300)

BAIS 2

STUDY NO. : 0163  
ANIMAL : MOUSE BDF1  
UNIT : g/kg/day  
REPORT TYPE : A1 104  
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 18

Group Name	Administration (weeks)		
	100	102	104
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000
400 ppm	0.055± 0.015	0.052± 0.010	0.054± 0.013
2000 ppm	0.270± 0.062	0.271± 0.068	0.260± 0.063
10000 ppm	1.387± 0.357	1.409± 0.649	1.396± 0.615

(HAN300)

BAIS 2

## APPENDIX F 1

HEMATOLOGY : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0162  
 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	44	8.29±	1.44	14.9±	2.5	42.4±	6.4	51.8±	5.6	18.1±	1.7	34.9±	1.6	904±	177
400 ppm	39	8.23±	1.01	15.0±	1.6	42.3±	4.1	51.7±	2.7	18.2±	0.9	35.3±	0.8	936±	138
2000 ppm	36	8.20±	1.71	14.5±	3.0	41.5±	8.0	52.1±	9.4	18.1±	2.8	34.9±	1.5	878±	306
10000 ppm	39	8.35±	1.26	14.8±	2.6	42.4±	5.9	50.9±	2.5	17.6±	1.7	34.7±	3.1	867±	208

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BATS2

STUDY NO. : 0162  
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		OTHERS	
Control	44	5.78±	2.67	1±	1	51±	9	2±	1	0±	0	4±	2	36±	7	5±	6
400 ppm	39	6.38±	3.06	1±	1	53±	10	2±	1	0±	0	4±	2	34±	7	7±	11
2000 ppm	36	7.25±	7.22	1±	1	52±	12	1±	1	0±	0	5±	2	35±	8	6±	12
10000 ppm	39	7.27±	12.60	0±	1	51±	12	2±	1	0±	0	5±	2	36±	9	5±	13

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL071)

BAIS2

## APPENDIX F 2

HEMATOLOGY : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0162  
 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	36	7.41±	1.40	13.8±	2.6	39.5±	6.1	53.8±	5.0	18.7±	1.8	34.8±	2.9	682±	135
400 ppm	39	7.94±	0.88	15.1±	1.5*	42.4±	4.0	53.5±	2.8	19.1±	0.8*	35.7±	1.1	706±	146
2000 ppm	39	7.98±	0.73	15.0±	1.4	41.7±	3.5	52.3±	2.8	18.9±	1.4	36.0±	1.9*	675±	121
10000 ppm	36	7.56±	1.32	13.9±	2.6	39.4±	6.5	52.3±	4.1	18.3±	1.8	34.9±	2.0	694±	161

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 2



STUDY NO. : 0162  
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		OTHERS	
Control	36	5.30±	9.90	1±	1	44±	15	2±	1	0±	0	4±	2	43±	14	6±	12
400 ppm	39	3.24±	1.46	1±	1	47±	11	2±	1	0±	0	4±	2	42±	10	4±	3
2000 ppm	39	4.38±	4.22	1±	1	49±	12	1±	1	0±	0	5±	2	41±	12	3±	2
10000 ppm	36	3.18±	1.52	1±	2	49±	10	2±	1	0±	0	4±	2	40±	10	5±	4

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL071)

BAIS2

## APPENDIX F 3

HEMATOLOGY : SUMMARY, MOSUE : MALE

(2-YEAR STUDY)

STUDY NO. : 0163  
 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	35	9.48±	0.87	13.5±	1.3	40.8±	3.8	43.1±	1.3	14.2±	0.5	33.0±	0.7	1901±	311
400 ppm	40	8.86±	1.65	12.5±	2.1	38.4±	5.9	43.8±	3.8	14.2±	1.1	32.5±	1.2	1999±	372
2000 ppm	38	9.05±	0.91	12.7±	1.5	39.0±	3.8	43.1±	2.6	14.1±	0.9	32.7±	1.3	1895±	502
10000 ppm	32	9.24±	1.27	12.9±	1.6	39.1±	5.0	42.5±	1.5	14.0±	0.7	33.0±	0.8	2140±	424**

Significant difference ; \* : P ≤ 0.05

\*\* : P ≤ 0.01

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0163  
 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	35	3.36±	2.03	2±	2	33±	16	2±	2	0±	0	3±	2	58±	17	2±	2
400 ppm	40	4.41±	8.41	2±	2	34±	14	1±	1	0±	0	3±	1	56±	16	4±	5
2000 ppm	38	4.05±	7.92	2±	2	29±	13	1±	1	0±	0	4±	2	61±	13	4±	6
10000 ppm	32	2.41±	1.30	2±	2	43±	18*	1±	1	0±	0	3±	2	48±	18*	2±	2

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL071)

BAIS2

## APPENDIX F 4

HEMATOLOGY : SUMMARY, MOSUE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0163  
 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 p g		MCHC g/dℓ		PLATELET 10 <sup>3</sup> /μℓ	
Control	25	9.04±	1.11	13.3±	1.7	39.5±	4.4	43.8±	2.0	14.7±	0.6	33.5±	0.8	1248±	299
400 ppm	24	9.27±	0.76	13.6±	1.2	40.2±	3.2	43.4±	1.6	14.7±	0.8	33.8±	1.2	1157±	317
2000 ppm	25	8.95±	1.46	13.1±	2.1	39.1±	5.7	43.9±	1.9	14.7±	0.8	33.5±	1.4	1136±	344
10000 ppm	23	8.42±	1.49	12.2±	1.7	37.5±	4.4	45.3±	5.5	14.7±	1.2	32.5±	1.5*	1149±	391

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0163  
 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	25	1.61±	1.06	3±	3	31±	12	1±	1	0±	0	4±	2	56±	16	5±	5
400 ppm	24	24.10±	103.12	2±	1	27±	14	1±	1	0±	0	3±	2	60±	15	7±	12
2000 ppm	25	5.10±	14.57	2±	2	36±	18	1±	1	0±	0	4±	2	50±	18	6±	12
10000 ppm	23	1.62±	1.20	4±	4	42±	19	0±	1	0±	0	3±	2	44±	21	5±	8

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL071)

BAIS2

## APPENDIX G 1

BIOCHEMISTRY : SUMMARY, RAT : MALE

(2-YEAR STUDY)



STUDY NO. : 0162  
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	44	7.0±	0.5	3.3±	0.3	0.9±	0.1	0.27±	0.07	156±	25	195±	50	203±	143
400 ppm	39	7.0±	0.4	3.2±	0.3	0.9±	0.1	0.27±	0.06	149±	24	211±	49	255±	156
2000 ppm	36	6.9±	0.5	3.2±	0.3	0.9±	0.1	0.69±	2.51	159±	23	188±	63	219±	173
10000 ppm	39	6.9±	0.4	3.3±	0.2	1.0±	0.2*	0.27±	0.10	157±	30	158±	48**	156±	112

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0162  
 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	44	314±	98	62±	23	20±	10	169±	51	178±	69	6±	4	78±	21
400 ppm	39	342±	92	65±	31	21±	12	180±	60	174±	78	6±	3	77±	19
2000 ppm	36	305±	130	96±	130	24±	19	203±	140	228±	144	7±	7	76±	24
10000 ppm	39	255±	92*	70±	37	18±	6	195±	114	207±	81	4±	2	83±	27

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0162  
 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	44	23.3±	8.0	0.7±	0.3	144±	1	3.5±	0.3	107±	2	10.9±	0.6	4.5±	1.2
400 ppm	39	25.5±	8.2	0.7±	0.2	143±	1	3.5±	0.3	106±	2	10.9±	0.4	4.4±	1.0
2000 ppm	36	23.8±	12.9	0.7±	0.2	143±	2	3.5±	0.4	107±	2	10.8±	0.4	4.4±	1.1
10000 ppm	39	20.6±	4.7	0.6±	0.1	143±	2	3.5±	0.4	107±	2	10.6±	0.3*	4.1±	0.8

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

## APPENDIX G 2

BIOCHEMISTRY : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0162  
 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	37	7.1±	0.6	3.7±	0.4	1.1±	0.1	0.23±	0.06	155±	19	136±	44	100±	54
400 ppm	39	7.2±	0.4	3.8±	0.3	1.1±	0.1	0.25±	0.06	160±	27	142±	35	119±	79
2000 ppm	40	7.1±	0.4	3.7±	0.3	1.1±	0.1	0.24±	0.04	157±	22	141±	40	131±	125
10000 ppm	36	7.0±	0.7	3.8±	0.4	1.2±	0.1	0.30±	0.33	148±	23	127±	33	114±	85

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0162  
 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	37	254±	83	138±	121	32±	18	275±	262	158±	92	2±	1	84±	28
400 ppm	39	269±	73	125±	81	34±	22	326±	402	137±	55	3±	3	93±	59
2000 ppm	40	267±	88	119±	74	31±	15	239±	101	162±	142	2±	1	81±	14
10000 ppm	36	240±	63	158±	156	28±	14	238±	112	141±	66	2±	1	76±	16

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BATS2

STUDY NO. : 0162  
 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	37	17.1± 2.9	0.5± 0.1	143± 2	3.5± 0.4	106± 2	10.5± 0.4	3.9± 0.7
400 ppm	39	16.7± 2.1	0.5± 0.1	143± 2	3.5± 0.4	106± 2	10.5± 0.4	3.9± 1.1
2000 ppm	40	16.2± 1.8	0.5± 0.1	142± 2	3.6± 0.3	106± 2	10.5± 0.3	3.6± 0.7
10000 ppm	36	16.2± 4.7	0.5± 0.1	142± 2	3.6± 0.4	106± 2	10.5± 0.4	3.8± 0.8

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

## APPENDIX G 3

BIOCHEMISTRY : SUMMARY, MOSUE : MALE

(2-YEAR STUDY)



STUDY NO. : 0163  
 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	35	5.4±	0.4	2.7±	0.2	1.0±	0.1	0.26±	0.09	190±	40	108±	22	75±	18
400 ppm	40	5.4±	0.7	2.7±	0.4	1.0±	0.1	0.26±	0.10	162±	56*	111±	44	68±	24
2000 ppm	38	5.4±	0.6	2.7±	0.3	1.1±	0.1	0.27±	0.08	177±	45	106±	33	70±	22
10000 ppm	32	5.1±	0.7	2.7±	0.4	1.1±	0.2*	0.25±	0.07	158±	52*	90±	29**	48±	18**

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0163  
 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	35	99±	105	31±	30	327±	152	165±	57	42±	21	23.8±	7.2	156±	2
400 ppm	40	142±	190	48±	75	578±	832	159±	68	51±	46	27.0±	11.1	155±	2
2000 ppm	38	168±	267	80±	167	720±	1155	228±	377	45±	18	25.6±	7.9	155±	2
10000 ppm	32	358±	1668	127±	612	1488±	6854	184±	39*	66±	87	29.2±	35.4	156±	2

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0163  
 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	35	4.4±	0.5	122±	3	9.0±	0.4	6.4±	0.9
400 ppm	40	4.5±	0.6	123±	3	9.0±	0.6	6.3±	1.0
2000 ppm	38	4.4±	0.5	122±	3	8.9±	0.3	6.1±	0.7
10000 ppm	32	4.4±	0.7	122±	4	8.6±	0.6**	6.2±	1.5

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

## APPENDIX G 4

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

STUDY NO. : 0163  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
 SURVIVAL ANIMALS (106)

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	24	5.3±	0.7	2.7±	0.4	1.1±	0.2	0.24±	0.09	145±	26	85±	51	65±	12
400 ppm	25	5.2±	0.4	2.7±	0.2	1.1±	0.2	0.28±	0.14	139±	30	69±	13	62±	19
2000 ppm	25	5.4±	0.7	2.8±	0.2	1.1±	0.3	0.28±	0.11	121±	38	97±	101	67±	28
10000 ppm	23	5.1±	0.9	2.7±	0.4	1.2±	0.2	0.27±	0.09	106±	42**	76±	45	56±	31

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0163  
 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	24	102±	73	26±	14	348±	248	287±	112	62±	38	17.0±	3.6	154±	2
400 ppm	25	175±	386	43±	101	981±	2624	293±	109	72±	76	17.7±	6.0	153±	3
2000 ppm	25	107±	67	29±	23	638±	838	248±	112	111±	209	20.6±	9.8	154±	3
10000 ppm	23	135±	109	30±	22	710±	728	293±	145	107±	105	24.3±	15.6	154±	3

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

STUDY NO. : 0163  
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	24	4.2±	0.4	121±	3	8.9±	0.7	6.3±	0.9
400 ppm	25	4.3±	0.5	121±	3	9.1±	0.6	6.5±	1.3
2000 ppm	25	4.3±	0.5	121±	3	9.2±	0.8	6.7±	1.2
10000 ppm	23	4.3±	0.6	122±	4	9.0±	0.7	6.5±	1.1

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS2

## APPENDIX H 1

URINALYSIS : SUMMARY, RAT : MALE

(2-YEAR STUDY)



STUDY NO. : 0162

ANIMAL : RAT F344

SAMPLING DATE : 104-2

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	44	0	3	1	8	21	11	0		0	0	0	1	15	28		44	0	0	0	0	0		43	1	0	0	0	0		44	0	0	0
400 ppm	41	0	1	9	14	12	5	0	**	0	0	0	0	12	29		41	0	0	0	0	0		39	2	0	0	0	0		41	0	0	0
2000 ppm	36	0	2	2	15	11	6	0		0	0	0	0	11	25		36	0	0	0	0	0		35	1	0	0	0	0		35	0	0	1
10000 ppm	39	0	1	9	9	13	7	0	*	0	0	0	0	12	27		39	0	0	0	0	0		33	6	0	0	0	0	*	39	0	0	0

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

Test of CHI SQUARE

(JCL101)

BAIS 2

STUDY NO. : 0162  
ANIMAL : RAT F344  
SAMPLING DATE : 104-2  
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Occult blood					Urobilinogen						
		-	±	+	2+	3+	CHI	±	+	2+	3+	4+	CHI
Control	44	43	0	0	1	0		44	0	0	0	0	
400 ppm	41	41	0	0	0	0		41	0	0	0	0	
2000 ppm	36	36	0	0	0	0		35	0	1	0	0	
10000 ppm	39	33	1	1	2	2		39	0	0	0	0	

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

Test of CHI SQUARE

(JCL101)

BAIS2

## APPENDIX H 2

URINALYSIS : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0162  
 ANIMAL : RAT F344  
 SAMPLING DATE : 104-2  
 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	2	3	15	16	5		0	0	3	7	13	18		41	0	0	0	0	0		8	30	3	0	0	0		41	0	0	0
400 ppm	40	0	1	3	3	16	12	5		0	0	0	9	7	24		40	0	0	0	0	0		10	28	2	0	0	0		40	0	0	0
2000 ppm	41	0	0	3	9	13	15	1		0	0	2	3	14	22		41	0	0	0	0	0		14	26	1	0	0	0		41	0	0	0
10000 ppm	38	0	1	2	5	17	9	4		0	0	1	6	10	21		38	0	0	0	0	0		2	34	2	0	0	0		38	0	0	0

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

Test of CHI SQUARE

(JCL101)

BAIS2

STUDY NO. : 0162  
ANIMAL : RAT F344  
SAMPLING DATE : 104-2  
SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Occult blood					Urobilinogen						
		-	±	+	2+	3+	CHI	±	+	2+	3+	4+	CHI
Control	41	38	1	0	1	1		41	0	0	0	0	
400 ppm	40	36	3	1	0	0		40	0	0	0	0	
2000 ppm	41	40	1	0	0	0		41	0	0	0	0	
10000 ppm	38	33	2	1	1	1		38	0	0	0	0	

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

Test of CHI SQUARE

(JCL101)

BAIS 2

## APPENDIX H 3

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

STUDY NO. : 0163

ANIMAL : MOUSE BDF1

SAMPLING DATE : 104-3

SEX : MALE

REPORT TYPE : A1

## URINALYSIS

PAGE : 1

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body					CHI	Occult blood					CHI		
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	±	+		2+	3+	4+	-	±		+	2+
Control	35	0	4	8	12	9	1	1		0	1	24	10	0	0		35	0	0	0	0	0		21	14	0	0	0	0		29	3	2	0	1
400 ppm	40	0	5	18	14	2	0	1		0	1	26	12	1	0		40	0	0	0	0	0		32	8	0	0	0	0		32	2	2	1	3
2000 ppm	37	0	5	15	12	5	0	0		0	0	26	11	0	0		37	0	0	0	0	0		23	14	0	0	0	0		32	4	0	1	0
10000 ppm	32	0	13	16	3	0	0	0	**	0	0	9	23	0	0	**	32	0	0	0	0	0		14	14	4	0	0	0		27	1	0	1	3

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

Test of CHI SQUARE

(JCL101)

BAIS 2

STUDY NO. : 0163  
ANIMAL : MOUSE BDF1  
SAMPLING DATE : 104-3  
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+ CHI
Control	35	35 0 0 0 0
400 ppm	40	40 0 0 0 0
2000 ppm	37	37 0 0 0 0
10000 ppm	32	32 0 0 0 0

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

Test of CHI SQUARE

(JCL101)

BAIS 2



## APPENDIX H 4

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

STUDY NO. : 0163

ANIMAL : MOUSE BDF1

SAMPLING DATE : 104-3

SEX : FEMALE

REPORT TYPE : A1

## URINALYSIS

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	26	0	0	3	9	7	5	2		0	1	19	4	2	0		26	0	0	0	0	0		3	18	4	1	0	0		19	1	4	1	1	
400 ppm	27	0	0	1	10	12	4	0		0	4	14	9	0	0		27	0	0	0	0	0		4	12	11	0	0	0		23	4	0	0	0	
2000 ppm	25	0	0	5	8	7	5	0		0	1	17	6	1	0		25	0	0	0	0	0		3	10	11	1	0	0		17	5	2	0	1	
10000 ppm	24	0	2	3	8	7	3	1		0	0	7	12	5	0	**	24	0	0	0	0	0		1	3	14	6	0	0	**	22	0	2	0	0	

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

Test of CHI SQUARE

(JCL101)

BAIS2

STUDY NO. : 0163  
ANIMAL : MOUSE BDF1  
SAMPLING DATE : 104-3  
SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+ CHI
Control	26	26 0 0 0 0
400 ppm	27	27 0 0 0 0
2000 ppm	25	25 0 0 0 0
10000 ppm	24	24 0 0 0 0

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

Test of CHI SQUARE

(JCL101)

BAIS 2

## APPENDIX I 1

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

STUDY NO. : 0162  
 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	400 ppm	2000 ppm	10000 ppm
			6 (%)	10 (%)	14 (%)	11 (%)
skin/app	nodule		0 ( 0)	0 ( 0)	1 ( 7)	1 ( 9)
	scab		0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)
subcutis	jaundice		0 ( 0)	0 ( 0)	1 ( 7)	1 ( 9)
	mass		1 ( 17)	3 ( 30)	3 ( 21)	1 ( 9)
larynx	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 9)
lung	red		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
	white zone		0 ( 0)	1 ( 10)	1 ( 7)	0 ( 0)
	red zone		0 ( 0)	1 ( 10)	1 ( 7)	1 ( 9)
	nodule		0 ( 0)	1 ( 10)	0 ( 0)	1 ( 9)
	voluminous		1 ( 17)	0 ( 0)	0 ( 0)	1 ( 9)
lymph node	enlarged		0 ( 0)	1 ( 10)	0 ( 0)	1 ( 9)
thymus	nodule		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
spleen	enlarged		1 ( 17)	2 ( 20)	3 ( 21)	4 ( 36)
	nodule		0 ( 0)	0 ( 0)	1 ( 7)	1 ( 9)
forestomach	ulcer		0 ( 0)	1 ( 10)	1 ( 7)	0 ( 0)
gl stomach	ulcer		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 9)
stomach	gas		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 9)
small intes	nodule		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
	gas		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 9)
liver	enlarged		1 ( 17)	0 ( 0)	0 ( 0)	1 ( 9)
	pale		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
	nodule		1 ( 17)	0 ( 0)	1 ( 7)	0 ( 0)

STUDY NO. : 0162  
 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	400 ppm	2000 ppm	10000 ppm
			6 (%)	10 (%)	14 (%)	11 (%)
liver	cyst		0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)
	rough		0 ( 0)	1 ( 10)	1 ( 7)	1 ( 9)
	accentuation of lobular structure		0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)
pancreas	nodule		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
kidney	nodule		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
	cyst		1 ( 17)	0 ( 0)	0 ( 0)	0 ( 0)
	granular		3 ( 50)	0 ( 0)	1 ( 7)	0 ( 0)
urin bladd	urine:marked retention		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
pituitary	enlarged		2 ( 33)	3 ( 30)	4 ( 29)	1 ( 9)
	nodule		0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)
adrenal	enlarged		1 ( 17)	0 ( 0)	1 ( 7)	1 ( 9)
	nodule		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
testis	atrophic		1 ( 17)	1 ( 10)	3 ( 21)	5 ( 45)
	nodule		1 ( 17)	2 ( 20)	7 ( 50)	6 ( 55)
brain	black zone		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
	hemorrhage		0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)
spinal cord	brown zone		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
	black zone		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
	hemorrhage		0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)
eye	white		1 ( 17)	1 ( 10)	0 ( 0)	0 ( 0)
	red		1 ( 17)	0 ( 0)	0 ( 0)	0 ( 0)
Zymbal gl	nodule		0 ( 0)	1 ( 10)	1 ( 7)	0 ( 0)

STUDY NO. : 0162  
 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	400 ppm	2000 ppm	10000 ppm
			6 (%)	10 (%)	14 (%)	11 (%)
muscle	nodule		0 ( 0)	1 ( 10)	0 ( 0)	1 ( 9)
vertebra	nodule		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
pleura	nodule		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
peritoneum	nodule		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
retroperit	mass		0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)
abdominal c	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 9)
	ascites		0 ( 0)	1 ( 10)	1 ( 7)	1 ( 9)
thoracic ca	pleural fluid		0 ( 0)	1 ( 10)	2 ( 14)	3 ( 27)
other	lower jaw:nodule		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 18)
whole body	anemic		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)

(HPT080)

BAIS 2

## APPENDIX I 2

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



STUDY NO. : 0162  
ANIMAL : RAT F344  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control				400 ppm				2000 ppm				10000 ppm			
			9	(%)			10	(%)			9	(%)			13	(%)		
subcutis	jaundice		1	( 11)			0	( 0)			2	( 22)			1	( 8)		
	mass		4	( 44)			2	( 20)			3	( 33)			3	( 23)		
lung	red		1	( 11)			0	( 0)			0	( 0)			0	( 0)		
	red patch/zone		0	( 0)			0	( 0)			1	( 11)			0	( 0)		
	nodule		0	( 0)			1	( 10)			1	( 11)			1	( 8)		
lymph node	enlarged		0	( 0)			0	( 0)			0	( 0)			2	( 15)		
spleen	enlarged		2	( 22)			3	( 30)			3	( 33)			4	( 31)		
	white zone		0	( 0)			0	( 0)			0	( 0)			1	( 8)		
heart	white zone		0	( 0)			0	( 0)			1	( 11)			0	( 0)		
	fluid:red		0	( 0)			1	( 10)			0	( 0)			0	( 0)		
esophagus	infarct		0	( 0)			0	( 0)			0	( 0)			1	( 8)		
forestomach	ulcer		0	( 0)			2	( 20)			0	( 0)			0	( 0)		
gl stomach	hemorrhage		0	( 0)			1	( 10)			0	( 0)			0	( 0)		
	ulcer		1	( 11)			0	( 0)			1	( 11)			0	( 0)		
liver	pale		0	( 0)			1	( 10)			0	( 0)			0	( 0)		
	red zone		0	( 0)			0	( 0)			1	( 11)			0	( 0)		
	nodule		0	( 0)			2	( 20)			2	( 22)			0	( 0)		
	rough		1	( 11)			0	( 0)			1	( 11)			1	( 8)		
	herniation		0	( 0)			0	( 0)			1	( 11)			0	( 0)		
pancreas	nodule		1	( 11)			0	( 0)			0	( 0)			0	( 0)		
kidney	white zone		0	( 0)			0	( 0)			0	( 0)			1	( 8)		
	nodule		0	( 0)			0	( 0)			0	( 0)			1	( 8)		

STUDY NO. : 0162  
 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		400 ppm		2000 ppm		10000 ppm	
			9	(%)	10	(%)	9	(%)	13	(%)
urin bladd	urine:marked retention		0	( 0)	0	( 0)	1	( 11)	0	( 0)
	urine:red		0	( 0)	1	( 10)	0	( 0)	0	( 0)
pituitary	enlarged		1	( 11)	6	( 60)	2	( 22)	2	( 15)
	red zone		0	( 0)	1	( 10)	2	( 22)	1	( 8)
	nodule		0	( 0)	0	( 0)	1	( 11)	1	( 8)
adrenal	enlarged		0	( 0)	0	( 0)	0	( 0)	1	( 8)
ovary	cyst		0	( 0)	0	( 0)	0	( 0)	1	( 8)
uterus	enlarged		0	( 0)	0	( 0)	2	( 22)	0	( 0)
	nodule		3	( 33)	2	( 20)	2	( 22)	2	( 15)
	dilated lumen		0	( 0)	0	( 0)	0	( 0)	1	( 8)
	invagination		0	( 0)	0	( 0)	1	( 11)	0	( 0)
prep/cli gl	nodule		0	( 0)	0	( 0)	1	( 11)	0	( 0)
spinal cord	hemorrhage		0	( 0)	1	( 10)	0	( 0)	0	( 0)
eye	red		0	( 0)	0	( 0)	0	( 0)	2	( 15)
vertebra	mass		0	( 0)	0	( 0)	0	( 0)	1	( 8)
mediastinum	mass		1	( 11)	0	( 0)	0	( 0)	0	( 0)
peritoneum	nodule		1	( 11)	0	( 0)	0	( 0)	0	( 0)
	nodular		1	( 11)	0	( 0)	0	( 0)	0	( 0)
retroperit	mass		1	( 11)	0	( 0)	2	( 22)	0	( 0)
abdominal c	ascites		1	( 11)	0	( 0)	0	( 0)	0	( 0)
mesenterium	mass		1	( 11)	0	( 0)	0	( 0)	0	( 0)
adipose	nodule		1	( 11)	0	( 0)	0	( 0)	0	( 0)

STUDY NO. : 0162  
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		400 ppm		2000 ppm		10000 ppm	
			9	(%)	10	(%)	9	(%)	13	(%)
thoracic ca	pleural fluid		2	( 22)	1	( 10)	0	( 0)	2	( 15)
other	forelimb:nodule		1	( 11)	0	( 0)	0	( 0)	0	( 0)
	hindlimb:nodule		0	( 0)	1	( 10)	0	( 0)	0	( 0)
	lower jaw:nodule		0	( 0)	0	( 0)	0	( 0)	1	( 8)
whole body	anemic		0	( 0)	0	( 0)	2	( 22)	1	( 8)

(HPT080)

BAIS 2

## APPENDIX I 3

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

STUDY NO. : 0162  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 1

Organ	Findings	Group Name	Control	400 ppm	2000 ppm	10000 ppm
		NO. of Animals	44 (%)	40 (%)	36 (%)	39 (%)
skin/app	nodule		3 ( 7)	5 ( 13)	7 ( 19)	5 ( 13)
subcutis	jaundice		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	nodule		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	mass		9 ( 20)	6 ( 15)	13 ( 36)	3 ( 8)
lung	white zone		0 ( 0)	2 ( 5)	1 ( 3)	0 ( 0)
	nodule		5 ( 11)	1 ( 3)	1 ( 3)	1 ( 3)
lymph node	enlarged		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
spleen	enlarged		1 ( 2)	2 ( 5)	4 ( 11)	2 ( 5)
	deformed		1 ( 2)	1 ( 3)	2 ( 6)	0 ( 0)
heart	white zone		0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)
tongue	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
salivary gl	nodule		1 ( 2)	1 ( 3)	0 ( 0)	0 ( 0)
forestomach	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	ulcer		0 ( 0)	1 ( 3)	1 ( 3)	1 ( 3)
	thick		2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
gl stomach	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	ulcer		0 ( 0)	1 ( 3)	1 ( 3)	1 ( 3)
	thick		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
small intes	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
liver	black zone		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		1 ( 2)	1 ( 3)	0 ( 0)	1 ( 3)
	rough		2 ( 5)	0 ( 0)	3 ( 8)	0 ( 0)

STUDY NO. : 0162  
ANIMAL : RAT F344  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS (105W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control	400 ppm	2000 ppm	10000 ppm
			44 (%)	40 (%)	36 (%)	39 (%)
Liver	herniation		3 ( 7)	0 ( 0)	4 ( 11)	1 ( 3)
pancreas	nodule		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
kidney	granular		13 ( 30)	18 ( 45)	10 ( 28)	6 ( 15)
pituitary	enlarged		4 ( 9)	2 ( 5)	1 ( 3)	0 ( 0)
	red		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	red zone		2 ( 5)	3 ( 8)	4 ( 11)	2 ( 5)
	nodule		2 ( 5)	4 ( 10)	4 ( 11)	4 ( 10)
thyroid	enlarged		2 ( 5)	7 ( 18)	1 ( 3)	1 ( 3)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
adrenal	enlarged		1 ( 2)	1 ( 3)	0 ( 0)	0 ( 0)
testis	nodule		38 ( 86)	32 ( 80)	30 ( 83)	36 ( 92)
	absence		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
epididymis	absence		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
spinal cord	red zone		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
eye	white		2 ( 5)	7 ( 18)	5 ( 14)	2 ( 5)
	red		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
peritoneum	nodule		0 ( 0)	0 ( 0)	1 ( 3)	1 ( 3)
thoracic ca	pleural fluid		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
other	lower jaw:nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)

## APPENDIX I 4

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

STUDY NO. : 0162  
ANIMAL : RAT F344  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS (105W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control		400 ppm		2000 ppm		10000 ppm	
			41	(%)	40	(%)	41	(%)	37	(%)
skin/app	nodule		0	( 0)	0	( 0)	2	( 5)	0	( 0)
	scab		0	( 0)	1	( 3)	0	( 0)	1	( 3)
subcutis	mass		10	( 24)	9	( 23)	7	( 17)	15	( 41)
lung	nodule		2	( 5)	1	( 3)	1	( 2)	1	( 3)
lymph node	enlarged		0	( 0)	0	( 0)	1	( 2)	0	( 0)
spleen	enlarged		3	( 7)	0	( 0)	2	( 5)	1	( 3)
	nodule		1	( 2)	0	( 0)	0	( 0)	0	( 0)
	deformed		0	( 0)	1	( 3)	0	( 0)	0	( 0)
heart	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 3)
tooth	white		0	( 0)	0	( 0)	0	( 0)	1	( 3)
salivary gl	nodule		0	( 0)	0	( 0)	1	( 2)	0	( 0)
gl stomach	nodule		0	( 0)	1	( 3)	1	( 2)	0	( 0)
liver	white zone		0	( 0)	2	( 5)	0	( 0)	0	( 0)
	red zone		1	( 2)	0	( 0)	0	( 0)	0	( 0)
	nodule		0	( 0)	1	( 3)	2	( 5)	2	( 5)
	rough		1	( 2)	0	( 0)	1	( 2)	2	( 5)
	herniation		2	( 5)	2	( 5)	1	( 2)	3	( 8)
kidney	white zone		0	( 0)	0	( 0)	0	( 0)	1	( 3)
	cyst		0	( 0)	1	( 3)	0	( 0)	0	( 0)
	deformed		0	( 0)	1	( 3)	0	( 0)	0	( 0)
	granular		3	( 7)	3	( 8)	2	( 5)	1	( 3)
pituitary	enlarged		3	( 7)	3	( 8)	3	( 7)	5	( 14)



STUDY NO. : 0162  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control		400 ppm		2000 ppm		10000 ppm	
			41	(%)	40	(%)	41	(%)	37	(%)
pituitary	red		0	( 0)	1	( 3)	0	( 0)	0	( 0)
	red zone		5	( 12)	2	( 5)	7	( 17)	2	( 5)
	nodule		3	( 7)	2	( 5)	3	( 7)	2	( 5)
thyroid	enlarged		0	( 0)	0	( 0)	1	( 2)	1	( 3)
	red		1	( 2)	0	( 0)	0	( 0)	0	( 0)
adrenal	enlarged		0	( 0)	0	( 0)	1	( 2)	2	( 5)
ovary	cyst		3	( 7)	4	( 10)	3	( 7)	4	( 11)
uterus	nodule		7	( 17)	6	( 15)	8	( 20)	5	( 14)
prep/cli gl	nodule		2	( 5)	1	( 3)	2	( 5)	0	( 0)
eye	white		4	( 10)	6	( 15)	6	( 15)	4	( 11)
	red		1	( 2)	0	( 0)	0	( 0)	0	( 0)
Zymbal gl	nodule		0	( 0)	0	( 0)	1	( 2)	0	( 0)
other	lower jaw:nodule		0	( 0)	1	( 3)	0	( 0)	0	( 0)

(HPT080)

BAIS 2

## APPENDIX J 1

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

STUDY NO. : 0162  
 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	44	424± 53	0.091±	0.025	3.770±	1.422	1.239±	0.127	1.496±	0.264	2.976±	0.435
400 ppm	40	424± 44	0.089±	0.014	3.618±	1.196	1.262±	0.111	1.505±	0.201	3.167±	0.443
2000 ppm	36	433± 40	0.087±	0.014	3.484±	1.334	1.266±	0.104	1.547±	0.312	2.917±	0.308
10000 ppm	39	397± 34**	0.085±	0.018	3.770±	1.359	1.195±	0.107	1.445±	0.257	2.743±	0.272**

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0162  
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	44	1.152±	0.376	12.795±	2.081	2.034±	0.059
400 ppm	40	1.280±	0.909	13.479±	1.931	2.037±	0.064
2000 ppm	36	1.412±	1.115	12.699±	1.595	2.018±	0.074
10000 ppm	39	1.148±	0.602	11.500±	1.799**	2.019±	0.055

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

Test of Dunnett

(HCL040)

BAIS 2

## APPENDIX J 2

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

STUDY NO. : 0162  
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	41	299± 40	0.085± 0.017	0.192± 0.284	0.957± 0.107	1.118± 0.151	2.003± 0.190
400 ppm	40	298± 37	0.083± 0.014	0.158± 0.142	0.945± 0.089	1.120± 0.241	1.974± 0.183
2000 ppm	41	300± 34	0.081± 0.017	0.141± 0.060	0.955± 0.085	1.077± 0.110	1.981± 0.227
10000 ppm	37	284± 50	0.637± 3.142	0.152± 0.154	0.932± 0.116	1.066± 0.193	2.042± 0.210

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

Test of Dunnett

(HCL040)

BAIS2

STUDY NO. : 0162  
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	41	1.457±	3.350	8.049±	1.363	1.868±	0.049
400 ppm	40	0.624±	0.224	7.616±	1.123	1.862±	0.049
2000 ppm	41	0.753±	0.623	7.679±	1.066	1.868±	0.053
10000 ppm	37	0.667±	0.415	7.616±	1.744	1.862±	0.066

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

(HCL040)

BAIS 2

## APPENDIX J 3

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : MALE

(2-YEAR STUDY)



STUDY NO. : 0163  
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	35	47.5± 5.7	0.016±	0.005	0.217±	0.034	0.222±	0.023	0.238±	0.053	0.652±	0.051
400 ppm	42	44.8± 7.4	0.017±	0.006	0.215±	0.042	0.226±	0.025	0.235±	0.082	0.664±	0.060
2000 ppm	38	46.4± 6.9	0.052±	0.225	0.223±	0.028	0.227±	0.022	0.231±	0.038	0.684±	0.058
10000 ppm	33	33.2± 6.7**	0.014±	0.005	0.215±	0.026	0.190±	0.025**	0.212±	0.048**	0.569±	0.072**

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

Test of Dunnett

(HCL040)

BA1S2

STUDY NO. : 0163  
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	35	0.107±	0.105	1.747±	0.692	0.450±	0.015
400 ppm	42	0.138±	0.195	1.885±	1.327	0.449±	0.015
2000 ppm	38	0.141±	0.187	1.899±	0.642	0.450±	0.012
10000 ppm	33	0.087±	0.103	1.403±	0.598**	0.444±	0.012

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

(HCL040)

BAIS2

## APPENDIX J 4

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

STUDY NO. : 0163  
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	26	31.9± 4.3	0.016±	0.004	0.097±	0.144	0.176±	0.028	0.204±	0.021	0.450±	0.083
400 ppm	27	32.1± 3.4	0.018±	0.004	0.084±	0.140	0.184±	0.039	0.220±	0.047	0.454±	0.065
2000 ppm	25	33.3± 5.8	0.017±	0.005	0.065±	0.057	0.178±	0.029	0.226±	0.064	0.465±	0.068
10000 ppm	23	26.2± 4.3**	0.014±	0.004	0.148±	0.410	0.162±	0.028	0.223±	0.097	0.463±	0.094

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0163  
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	26	0.198±	0.349	1.444±	0.371	0.480±	0.034
400 ppm	27	0.247±	0.351	1.541±	0.503	0.473±	0.022
2000 ppm	25	0.273±	0.520	1.521±	0.349	0.476±	0.016
10000 ppm	23	0.150±	0.132	1.254±	0.298	0.475±	0.041

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

(HCL040)

BAIS 2

## APPENDIX I 5

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

STUDY NO. : 0163  
 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	400 ppm	2000 ppm	10000 ppm
			15 (%)	8 (%)	12 (%)	17 (%)
skin/app	ulcer		1 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)
	erosion		1 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)
subcutis	dry		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
	mass		0 ( 0)	1 ( 13)	0 ( 0)	3 ( 18)
larynx	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 6)
lung	nodule		2 ( 13)	0 ( 0)	3 ( 25)	5 ( 29)
lymph node	enlarged		1 ( 7)	4 ( 50)	2 ( 17)	1 ( 6)
thymus	mass		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 6)
spleen	enlarged		3 ( 20)	1 ( 13)	0 ( 0)	0 ( 0)
	black zone		1 ( 7)	0 ( 0)	0 ( 0)	1 ( 6)
	nodule		0 ( 0)	0 ( 0)	3 ( 25)	0 ( 0)
heart	white		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 6)
oral cavity	mass		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 6)
salivary gl	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 6)
esophagus	dilated		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
forestomach	nodule		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
gl stomach	nodule		0 ( 0)	1 ( 13)	0 ( 0)	1 ( 6)
	ulcer		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
	thick		1 ( 7)	0 ( 0)	1 ( 8)	0 ( 0)
small intes	nodule		0 ( 0)	1 ( 13)	0 ( 0)	0 ( 0)
liver	yellow		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
	white zone		1 ( 7)	0 ( 0)	1 ( 8)	0 ( 0)

STUDY NO. : 0163  
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	400 ppm	2000 ppm	10000 ppm
			15 (%)	8 (%)	12 (%)	17 (%)
liver	nodule		4 ( 27)	3 ( 38)	4 ( 33)	4 ( 24)
gall bladd	dilated		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 6)
pancreas	nodule		0 ( 0)	2 ( 25)	1 ( 8)	0 ( 0)
kidney	white zone		1 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	1 ( 8)	1 ( 6)
	hydronephrosis		2 ( 13)	0 ( 0)	0 ( 0)	1 ( 6)
ureter	dilated		1 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)
urin bladd	nodule		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
	urine:marked retention		4 ( 27)	1 ( 13)	1 ( 8)	2 ( 12)
pituitary	enlarged		2 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)
adrenal	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 6)
testis	nodule		1 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)
semin ves	nodule		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
prep/cli gl	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 6)
	nodule		1 ( 7)	0 ( 0)	1 ( 8)	2 ( 12)
brain	red zone		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
periph nerv	nodule		1 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)
harder gl	nodule		0 ( 0)	1 ( 13)	2 ( 17)	0 ( 0)
vertebra	brown		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
mediastinum	nodule		1 ( 7)	0 ( 0)	1 ( 8)	1 ( 6)
peritoneum	nodule		1 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)
retroperit	mass		1 ( 7)	0 ( 0)	1 ( 8)	0 ( 0)



STUDY NO. : 0163  
 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	400 ppm	2000 ppm	10000 ppm
			15 (%)	8 (%)	12 (%)	17 (%)
abdominal c	hemorrhage		2 ( 13)	0 ( 0)	1 ( 8)	0 ( 0)
	mass		0 ( 0)	1 ( 13)	0 ( 0)	0 ( 0)
	pleural fluid		0 ( 0)	1 ( 13)	0 ( 0)	0 ( 0)
	ascites		4 ( 27)	1 ( 13)	3 ( 25)	3 ( 18)
thoracic ca	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 6)
	pleural fluid		1 ( 7)	2 ( 25)	3 ( 25)	1 ( 6)
other	hindlimb:nodule		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
	upper jaw:nodule		0 ( 0)	0 ( 0)	0 ( 0)	3 ( 18)
	lower jaw:nodule		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 12)
whole body	anemic		1 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)

(HPT080)

BAIS2

## APPENDIX I 6

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

STUDY NO. : 0163  
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	400 ppm	2000 ppm	10000 ppm
			24 (%)	23 (%)	25 (%)	26 (%)
subcutis	anemic		1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
	edema		4 ( 17)	7 ( 30)	5 ( 20)	3 ( 12)
	jaundice		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	mass		3 ( 13)	5 ( 22)	1 ( 4)	2 ( 8)
lung	red		1 ( 4)	0 ( 0)	3 ( 12)	2 ( 8)
	red zone		1 ( 4)	1 ( 4)	0 ( 0)	2 ( 8)
	edema		1 ( 4)	0 ( 0)	1 ( 4)	0 ( 0)
	nodule		2 ( 8)	2 ( 9)	0 ( 0)	1 ( 4)
lymph node	enlarged		7 ( 29)	5 ( 22)	9 ( 36)	4 ( 15)
thymus	enlarged		1 ( 4)	1 ( 4)	0 ( 0)	0 ( 0)
spleen	enlarged		5 ( 21)	9 ( 39)	5 ( 20)	5 ( 19)
	white zone		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
heart	dilated		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
tongue	nodule		1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
forestomach	nodule		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
	ulcer		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	thick		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 8)
gl stomach	red patch/zone		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	thick		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
stomach	gas		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)

STUDY NO. : 0163  
 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		400 ppm		2000 ppm		10000 ppm	
			24	(%)	23	(%)	25	(%)	26	(%)
small intes	gas		0	( 0)	0	( 0)	0	( 0)	1	( 4)
large intes	gas		0	( 0)	0	( 0)	0	( 0)	1	( 4)
liver	enlarged		1	( 4)	4	( 17)	3	( 12)	1	( 4)
	pale		0	( 0)	0	( 0)	0	( 0)	1	( 4)
	white zone		7	( 29)	6	( 26)	5	( 20)	4	( 15)
	red zone		1	( 4)	1	( 4)	0	( 0)	2	( 8)
	black zone		0	( 0)	1	( 4)	0	( 0)	0	( 0)
	nodule		1	( 4)	2	( 9)	0	( 0)	3	( 12)
	rough		1	( 4)	0	( 0)	0	( 0)	1	( 4)
gall bladd	dilated		0	( 0)	1	( 4)	0	( 0)	0	( 0)
pancreas	nodule		0	( 0)	1	( 4)	1	( 4)	2	( 8)
kidney	enlarged		0	( 0)	0	( 0)	1	( 4)	0	( 0)
	pale		2	( 8)	0	( 0)	0	( 0)	1	( 4)
	white zone		0	( 0)	0	( 0)	1	( 4)	0	( 0)
	nodule		2	( 8)	1	( 4)	0	( 0)	1	( 4)
	hydronephrosis		2	( 8)	0	( 0)	2	( 8)	3	( 12)
urin bladd	urine:marked retention		1	( 4)	0	( 0)	2	( 8)	0	( 0)
pituitary	enlarged		4	( 17)	1	( 4)	1	( 4)	1	( 4)
	nodule		2	( 8)	0	( 0)	0	( 0)	0	( 0)
ovary	enlarged		4	( 17)	2	( 9)	4	( 16)	4	( 15)
	red		0	( 0)	1	( 4)	0	( 0)	0	( 0)
	nodule		1	( 4)	1	( 4)	0	( 0)	0	( 0)

STUDY NO. : 0163  
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		400 ppm		2000 ppm		10000 ppm	
			24	(%)	23	(%)	25	(%)	26	(%)
ovary	cyst		0	( 0)	2	( 9)	2	( 8)	3	( 12)
uterus	nodule		9	( 38)	10	( 43)	8	( 32)	7	( 27)
	mass		0	( 0)	1	( 4)	0	( 0)	0	( 0)
	dilated lumen		0	( 0)	0	( 0)	0	( 0)	1	( 4)
brain	red zone		1	( 4)	0	( 0)	0	( 0)	0	( 0)
	hemorrhage		1	( 4)	0	( 0)	0	( 0)	1	( 4)
periph nerv	nodule		0	( 0)	0	( 0)	1	( 4)	0	( 0)
muscle	mass		0	( 0)	0	( 0)	1	( 4)	0	( 0)
mediastinum	nodule		0	( 0)	1	( 4)	0	( 0)	0	( 0)
	mass		0	( 0)	1	( 4)	2	( 8)	2	( 8)
peritoneum	nodule		0	( 0)	1	( 4)	1	( 4)	0	( 0)
abdominal c	hemorrhage		1	( 4)	1	( 4)	1	( 4)	1	( 4)
	ascites		7	( 29)	11	( 48)	6	( 24)	8	( 31)
thoracic ca	hemorrhage		0	( 0)	0	( 0)	1	( 4)	0	( 0)
	mass		0	( 0)	1	( 4)	0	( 0)	0	( 0)
	pleural fluid		10	( 42)	8	( 35)	12	( 48)	11	( 42)
other	hemorrhage		0	( 0)	0	( 0)	0	( 0)	1	( 4)
	ear:nodule		1	( 4)	0	( 0)	0	( 0)	0	( 0)
	lower jaw:nodule		0	( 0)	0	( 0)	0	( 0)	3	( 12)
whole body	anemic		1	( 4)	1	( 4)	0	( 0)	0	( 0)

## APPENDIX I 7

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

STUDY NO. : 0163  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control	400 ppm	2000 ppm	10000 ppm
			35 (%)	42 (%)	38 (%)	33 (%)
skin/app	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	ulcer		0 ( 0)	1 ( 2)	1 ( 3)	0 ( 0)
	erosion		0 ( 0)	3 ( 7)	0 ( 0)	0 ( 0)
	scab		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
subcutis	mass		2 ( 6)	1 ( 2)	3 ( 8)	1 ( 3)
larynx	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
lung	nodule		7 ( 20)	7 ( 17)	8 ( 21)	4 ( 12)
lymph node	enlarged		3 ( 9)	1 ( 2)	3 ( 8)	5 ( 15)
thymus	enlarged		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
spleen	enlarged		0 ( 0)	0 ( 0)	2 ( 5)	1 ( 3)
	black zone		0 ( 0)	0 ( 0)	2 ( 5)	2 ( 6)
	nodule		1 ( 3)	2 ( 5)	0 ( 0)	0 ( 0)
	accentuation of white pulp		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
forestomach	nodule		1 ( 3)	0 ( 0)	0 ( 0)	3 ( 9)
	thin		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	thick		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 6)
gl stomach	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	ulcer		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	thick		11 ( 31)	19 ( 45)	14 ( 37)	3 ( 9)
liver	white zone		0 ( 0)	3 ( 7)	1 ( 3)	1 ( 3)
	red zone		1 ( 3)	2 ( 5)	0 ( 0)	2 ( 6)
	nodule		22 ( 63)	20 ( 48)	17 ( 45)	12 ( 36)

STUDY NO. : 0163  
ANIMAL : MOUSE BDF1  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS (105W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control		400 ppm		2000 ppm		10000 ppm	
			35	(%)	42	(%)	38	(%)	33	(%)
pancreas	nodule		2	( 6)	1	( 2)	0	( 0)	0	( 0)
kidney	white zone		1	( 3)	0	( 0)	0	( 0)	0	( 0)
	cyst		1	( 3)	1	( 2)	1	( 3)	0	( 0)
ureter	dilated		0	( 0)	1	( 2)	0	( 0)	0	( 0)
urin bladd	urine:marked retention		2	( 6)	8	( 19)	4	( 11)	0	( 0)
	urine:turbid		1	( 3)	0	( 0)	0	( 0)	0	( 0)
pituitary	nodule		0	( 0)	1	( 2)	0	( 0)	0	( 0)
thyroid	enlarged		0	( 0)	0	( 0)	1	( 3)	0	( 0)
parathyroid	nodule		1	( 3)	0	( 0)	0	( 0)	0	( 0)
testis	red zone		0	( 0)	0	( 0)	1	( 3)	0	( 0)
	nodule		0	( 0)	1	( 2)	0	( 0)	0	( 0)
semin ves	nodule		0	( 0)	0	( 0)	1	( 3)	0	( 0)
prostate	nodule		0	( 0)	1	( 2)	0	( 0)	0	( 0)
prep/cli gl	nodule		15	( 43)	12	( 29)	19	( 50)	9	( 27)
eye	turbid		1	( 3)	1	( 2)	0	( 0)	0	( 0)
	white		0	( 0)	1	( 2)	0	( 0)	0	( 0)
Harder gl	enlarged		2	( 6)	2	( 5)	1	( 3)	1	( 3)
	nodule		1	( 3)	0	( 0)	1	( 3)	0	( 0)
abdominal c	ascites		0	( 0)	0	( 0)	0	( 0)	1	( 3)
mesenterium	red zone		0	( 0)	1	( 2)	0	( 0)	0	( 0)
adipose	nodule		1	( 3)	0	( 0)	0	( 0)	0	( 0)
other	tail:nodule		0	( 0)	0	( 0)	0	( 0)	1	( 3)



STUDY NO. : 0163  
ANIMAL : MOUSE BDF1  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS (105W)

PAGE : 3

Organ_____	Findings_____	Group Name NO. of Animals	Control		400 ppm		2000 ppm		10000 ppm	
			35	(%)	42	(%)	38	(%)	33	(%)
other	Lip:nodule		0	( 0)	0	( 0)	0	( 0)	1	( 3)
	ear:nodule		0	( 0)	1	( 2)	0	( 0)	0	( 0)

(IPT080)

BAIS 2

## APPENDIX I 8

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

STUDY NO. : 0163  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control	400 ppm	2000 ppm	10000 ppm
			26 (%)	27 (%)	25 (%)	23 (%)
skin/app	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
subcutis	mass		1 ( 4)	0 ( 0)	1 ( 4)	2 ( 9)
lung	white zone		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
	nodule		1 ( 4)	3 ( 11)	3 ( 12)	2 ( 9)
lymph node	enlarged		3 ( 12)	3 ( 11)	3 ( 12)	2 ( 9)
spleen	enlarged		1 ( 4)	4 ( 15)	1 ( 4)	2 ( 9)
	nodule		1 ( 4)	0 ( 0)	2 ( 8)	1 ( 4)
	nodular		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
forestomach	thick		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
gl stomach	ulcer		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	thick		5 ( 19)	5 ( 19)	2 ( 8)	1 ( 4)
liver	white patch/zone		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	red zone		0 ( 0)	2 ( 7)	0 ( 0)	6 ( 26)
	nodule		8 ( 31)	8 ( 30)	7 ( 28)	2 ( 9)
	cyst		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
pancreas	nodule		1 ( 4)	0 ( 0)	0 ( 0)	2 ( 9)
kidney	atrophic		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	red zone		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
	cyst		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
	rough		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
	hydronephrosis		0 ( 0)	0 ( 0)	1 ( 4)	2 ( 9)
pituitary	enlarged		1 ( 4)	1 ( 4)	3 ( 12)	3 ( 13)

STUDY NO. : 0163  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 5

Organ	Findings	Group Name NO. of Animals	Control	400 ppm	2000 ppm	10000 ppm
			26 (%)	27 (%)	25 (%)	23 (%)
pituitary	red zone		1 ( 4)	1 ( 4)	0 ( 0)	0 ( 0)
	nodule		1 ( 4)	0 ( 0)	1 ( 4)	3 ( 13)
	mass		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
thyroid	enlarged		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
ovary	enlarged		0 ( 0)	1 ( 4)	0 ( 0)	3 ( 13)
	nodule		0 ( 0)	0 ( 0)	1 ( 4)	1 ( 4)
	cyst		9 ( 35)	6 ( 22)	4 ( 16)	1 ( 4)
	deformed		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
uterus	nodule		2 ( 8)	2 ( 7)	0 ( 0)	5 ( 22)
vagina	nodule		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
harder gl	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	nodule		0 ( 0)	3 ( 11)	1 ( 4)	0 ( 0)
bone	nodule		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
mediastinum	nodule		0 ( 0)	2 ( 7)	0 ( 0)	0 ( 0)
retroperit	cyst		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
abdominal c	ascites		1 ( 4)	2 ( 7)	4 ( 16)	1 ( 4)
adipose	nodule		0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
thoracic ca	pleural fluid		1 ( 4)	3 ( 11)	1 ( 4)	0 ( 0)
other	upper jaw:nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	lower jaw:nodule		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 9)

## APPENDIX K 2

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

STUDY NO. : 0162  
 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	41	299± 40	0.029± 0.007	0.064± 0.084	0.326± 0.061	0.381± 0.078	0.683± 0.120
400 ppm	40	298± 37	0.028± 0.007	0.053± 0.044	0.320± 0.038	0.381± 0.093	0.671± 0.109
2000 ppm	41	300± 34	0.027± 0.007	0.048± 0.024	0.323± 0.045	0.363± 0.041	0.669± 0.104
10000 ppm	37	284± 50	0.301± 1.564	0.055± 0.060	0.335± 0.070	0.387± 0.124	0.736± 0.155

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

Test of Dunnett

(HCL042)

BA1S2

STUDY NO. : 0162  
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	41	0.528± 1.237	2.736± 0.559	0.637± 0.090
400 ppm	40	0.211± 0.079	2.562± 0.303	0.633± 0.080
2000 ppm	41	0.257± 0.221	2.581± 0.376	0.632± 0.077
10000 ppm	37	0.246± 0.183	2.699± 0.583	0.670± 0.095

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

Test of Dunnett

(HCL042)

BAIS 2

## APPENDIX K 3

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



STUDY NO. : 0163  
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	35	47.5± 5.7	0.035± 0.011	0.459± 0.069	0.473± 0.074	0.506± 0.121	1.394± 0.231
400 ppm	42	44.8± 7.4	0.037± 0.012	0.487± 0.095	0.518± 0.096	0.537± 0.185	1.532± 0.354
2000 ppm	38	46.4± 6.9	0.115± 0.498	0.490± 0.096	0.499± 0.090	0.509± 0.125	1.511± 0.302
10000 ppm	33	33.2± 6.7**	0.042± 0.014	0.669± 0.150**	0.582± 0.077**	0.664± 0.220**	1.739± 0.166**

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0163  
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	35	0.228± 0.216	3.745± 1.671	0.963± 0.143
100 ppm	42	0.322± 0.441	4.374± 3.509	1.033± 0.195
2000 ppm	38	0.305± 0.396	4.209± 1.797	0.992± 0.168
10000 ppm	33	0.275± 0.369	4.253± 1.622**	1.385± 0.266**

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

(HCL042)

BAIS 2

## APPENDIX K 1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0162  
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	44	424± 53	0.022± 0.006	0.894± 0.355	0.295± 0.043	0.358± 0.086	0.717± 0.184
400 ppm	40	424± 44	0.021± 0.004	0.860± 0.287	0.300± 0.036	0.359± 0.058	0.760± 0.166
2000 ppm	36	433± 40	0.020± 0.004	0.806± 0.302	0.295± 0.041	0.362± 0.095	0.680± 0.103
10000 ppm	39	397± 34**	0.022± 0.005	0.944± 0.324	0.302± 0.032	0.366± 0.066	0.693± 0.071

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0162  
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	44	0.272± 0.087	3.033± 0.444	0.486± 0.057
400 ppm	40	0.308± 0.224	3.225± 0.627	0.486± 0.057
2000 ppm	36	0.340± 0.305	2.955± 0.470	0.470± 0.051
10000 ppm	39	0.288± 0.145	2.896± 0.404	0.512± 0.047

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

Test of Dunnett

(HCL042)

BAIS 2

## APPENDIX K 4

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

STUDY NO. : 0163  
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	26	31.9± 4.3	0.049± 0.012	0.312± 0.470	0.561± 0.115	0.652± 0.120	1.428± 0.267
400 ppm	27	32.1± 3.4	0.055± 0.014	0.279± 0.530	0.573± 0.109	0.695± 0.173	1.424± 0.231
2000 ppm	25	33.3± 5.8	0.051± 0.018	0.189± 0.141	0.549± 0.134	0.695± 0.225	1.427± 0.307
10000 ppm	23	26.2± 4.3**	0.055± 0.013	0.510± 1.375	0.627± 0.097	0.865± 0.337**	1.806± 0.441**

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

Test of Dunnett

(HCL042)

BAIS2

STUDY NO. : 0163  
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	26	0.608± 1.064	4.535± 1.028	1.534± 0.259
400 ppm	27	0.747± 1.019	4.780± 1.390	1.489± 0.172
2000 ppm	25	0.799± 1.459	4.641± 1.077	1.466± 0.248
10000 ppm	23	0.549± 0.441	4.799± 0.876	1.888± 0.509**

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

(HCL042)

BATS 2