

1,4-ジオキサンのラット及びマウスを用いた  
経口(混水)投与によるがん原性試験

# APPENDIX

(A1~A4)

がん原性試験 NO. 0063 ; 0064

APPENDIX A1

CHEMICAL INTAKE CHANGES (SUMMARY)

RAT:MALE

STUDY NO. : 0063  
ANIMAL : RAT F344  
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	0.000± 0.000
200 ppm	0.024± 0.001	0.021± 0.001	0.020± 0.001	0.018± 0.001	0.017± 0.001	0.016± 0.001	0.015± 0.001	0.015± 0.001
1000 ppm	0.121± 0.007	0.109± 0.006	0.102± 0.007	0.093± 0.006	0.086± 0.007	0.081± 0.005	0.076± 0.008	0.076± 0.008
5000 ppm	0.586± 0.028	0.520± 0.031	0.491± 0.035	0.450± 0.030	0.421± 0.031	0.392± 0.024	0.365± 0.023	0.365± 0.023

(HAN300)

BAIS 2

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
200 ppm	0.014± 0.001	0.013± 0.001	0.013± 0.001	0.012± 0.001	0.012± 0.001	0.012± 0.001	0.012± 0.001	0.011± 0.001
1000 ppm	0.074± 0.007	0.068± 0.005	0.066± 0.006	0.063± 0.006	0.062± 0.005	0.060± 0.006	0.058± 0.005	
5000 ppm	0.353± 0.024	0.332± 0.018	0.321± 0.018	0.302± 0.018	0.295± 0.015	0.282± 0.014	0.276± 0.014	

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : AI 104  
 SEX : MALE

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	0.000± 0.000
200 ppm	0.011± 0.001	0.011± 0.001	0.010± 0.001	0.010± 0.000	0.010± 0.001	0.010± 0.001	0.010± 0.001	0.010± 0.001
1000 ppm	0.056± 0.005	0.054± 0.004	0.053± 0.004	0.051± 0.004	0.051± 0.004	0.048± 0.003	0.050± 0.003	
5000 ppm	0.266± 0.015	0.260± 0.015	0.252± 0.011	0.248± 0.012	0.245± 0.013	0.238± 0.012	0.242± 0.011	

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
200 ppm	0.010± 0.001	0.009± 0.001	0.009± 0.001	0.009± 0.001	0.009± 0.001	0.009± 0.001	0.009± 0.000	0.009± 0.001
1000 ppm	0.048± 0.003	0.047± 0.003	0.047± 0.003	0.046± 0.003	0.046± 0.003	0.045± 0.003	0.044± 0.003	0.044± 0.002
5000 ppm	0.236± 0.011	0.234± 0.013	0.228± 0.012	0.227± 0.014	0.227± 0.015	0.230± 0.017	0.225± 0.013	

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
200 ppm	0.009± 0.001	-	0.009± 0.000	0.009± 0.001	0.009± 0.001	0.008± 0.001	0.008± 0.001	0.008± 0.001
1000 ppm	0.044± 0.002	-	0.044± 0.003	0.044± 0.003	0.044± 0.003	0.043± 0.002	0.042± 0.003	
5000 ppm	0.223± 0.012	-	0.224± 0.012	0.224± 0.014	0.225± 0.011	0.217± 0.013	0.218± 0.014	

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
200 ppm	0.008± 0.001	0.008± 0.001	0.008± 0.001	0.008± 0.002	0.008± 0.000	0.008± 0.000	0.008± 0.001
1000 ppm	0.042± 0.003	0.041± 0.003	0.042± 0.003	0.041± 0.004	0.041± 0.005	0.041± 0.003	0.041± 0.002
5000 ppm	0.218± 0.017	0.210± 0.012	0.216± 0.013	0.212± 0.014	0.210± 0.014	0.209± 0.015	0.210± 0.017



STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
200 ppm	0.008± 0.001	0.008± 0.001	0.008± 0.001	0.008± 0.001	0.008± 0.001	0.009± 0.001	0.009± 0.001	0.009± 0.001
1000 ppm	0.042± 0.003	0.043± 0.003	0.043± 0.004	0.042± 0.005	0.042± 0.006	0.044± 0.005	0.044± 0.005	0.044± 0.005
5000 ppm	0.219± 0.020	0.219± 0.015	0.225± 0.021	0.223± 0.027	0.229± 0.058	0.234± 0.062	0.241± 0.058	

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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	-
200 ppm	0.009± 0.001	0.009± 0.001	0.009± 0.001	0.009± 0.002	0.009± 0.002	0.009± 0.001	-
1000 ppm	0.046± 0.007	0.049± 0.009	0.049± 0.009	0.049± 0.008	0.050± 0.010	0.050± 0.010	-
5000 ppm	0.247± 0.064	0.255± 0.062	0.253± 0.066	0.257± 0.067	0.260± 0.074	0.269± 0.095	-

STUDY NO. : 0063  
ANIMAL : RAT F344  
UNIT : g/kg/day  
REPORT TYPE : A1 104  
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

Group Name	Administration (weeks)		
	100	102	104
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000
200 ppm	0.010± 0.002	0.010± 0.002	0.010± 0.002
1000 ppm	0.055± 0.015	0.056± 0.017	0.058± 0.017
5000 ppm	0.296± 0.102	0.286± 0.083	0.292± 0.087

APPENDIX A2

CHEMICAL INTAKE CHANGES (SUMMARY)

RAT:FEMALE

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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	0.000± 0.000	
200 ppm	0.029± 0.002	0.028± 0.004	0.027± 0.005	0.025± 0.005	0.025± 0.006	0.024± 0.005	0.024± 0.006		
1000 ppm	0.149± 0.024	0.133± 0.016	0.132± 0.030	0.123± 0.028	0.117± 0.031	0.110± 0.017	0.105± 0.019		
5000 ppm	0.720± 0.116	0.654± 0.095	0.619± 0.098	0.562± 0.071	0.568± 0.132	0.540± 0.125	0.558± 0.202		

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
200 ppm	0.023± 0.006	0.023± 0.006	0.022± 0.006	0.022± 0.006	0.022± 0.006	0.022± 0.006	0.022± 0.006	0.020± 0.005
1000 ppm	0.107± 0.017	0.105± 0.026	0.100± 0.015	0.092± 0.013	0.097± 0.021	0.100± 0.030	0.097± 0.029	
5000 ppm	0.553± 0.147	0.518± 0.145	0.508± 0.116	0.478± 0.103	0.491± 0.114	0.473± 0.092	0.478± 0.120	

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

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
200 ppm	0.020± 0.005	0.020± 0.006	0.020± 0.005	0.019± 0.005	0.019± 0.005	0.018± 0.005	0.018± 0.004
1000 ppm	0.096± 0.028	0.090± 0.023	0.094± 0.026	0.091± 0.026	0.090± 0.030	0.084± 0.021	0.085± 0.020
5000 ppm	0.484± 0.136	0.458± 0.140	0.466± 0.121	0.463± 0.129	0.462± 0.139	0.464± 0.164	0.455± 0.141

STUDY NO. : 0063  
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)							
	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
200 ppm	0.017± 0.003	0.018± 0.005	0.016± 0.003	0.017± 0.004	0.017± 0.005	0.016± 0.004	0.016± 0.004	0.016± 0.004
1000 ppm	0.087± 0.026	0.087± 0.025	0.081± 0.019	0.079± 0.021	0.078± 0.021	0.079± 0.021	0.075± 0.017	0.075± 0.017
5000 ppm	0.430± 0.114	0.445± 0.113	0.412± 0.113	0.432± 0.114	0.437± 0.141	0.420± 0.111	0.405± 0.091	0.405± 0.091

(HAN300)

BAIS 2



STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration (weeks)		48	50	52	54	56
	44	46					
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
200 ppm	0.016± 0.004	-	0.015± 0.003	0.014± 0.003	0.014± 0.002	0.013± 0.003	0.013± 0.003
1000 ppm	0.072± 0.017	-	0.069± 0.013	0.067± 0.009	0.069± 0.016	0.066± 0.014	0.065± 0.013
5000 ppm	0.410± 0.105	-	0.390± 0.098	0.385± 0.085	0.385± 0.086	0.362± 0.090	0.338± 0.064

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
200 ppm	0.012± 0.004	0.012± 0.003	0.013± 0.003	0.013± 0.004	0.012± 0.003	0.012± 0.003	0.012± 0.003	0.012± 0.003
1000 ppm	0.060± 0.012	0.058± 0.010	0.059± 0.010	0.058± 0.010	0.058± 0.009	0.056± 0.008	0.056± 0.008	0.056± 0.008
5000 ppm	0.328± 0.070	0.315± 0.063	0.313± 0.056	0.312± 0.060	0.312± 0.055	0.315± 0.057	0.307± 0.045	

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
200 ppm	0.012± 0.003	0.013± 0.003	0.013± 0.004	0.012± 0.003	0.013± 0.003	0.013± 0.004	0.014± 0.005	
1000 ppm	0.058± 0.011	0.060± 0.014	0.063± 0.017	0.059± 0.009	0.061± 0.014	0.060± 0.013	0.062± 0.013	
5000 ppm	0.318± 0.058	0.314± 0.053	0.324± 0.057	0.322± 0.066	0.314± 0.061	0.323± 0.066	0.327± 0.056	

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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	-
200 ppm	0.013± 0.003	0.014± 0.004	0.014± 0.004	0.014± 0.005	0.015± 0.005	0.014± 0.005	0.014± 0.005	-
1000 ppm	0.063± 0.014	0.065± 0.014	0.067± 0.012	0.065± 0.014	0.067± 0.016	0.069± 0.017	0.069± 0.017	-
5000 ppm	0.332± 0.062	0.357± 0.085	0.345± 0.074	0.355± 0.067	0.373± 0.091	0.385± 0.081	0.385± 0.081	-

STUDY NO. : 0063  
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
200 ppm	0.014± 0.005	0.015± 0.005	0.014± 0.004
1000 ppm	0.071± 0.021	0.075± 0.024	0.074± 0.022
5000 ppm	0.370± 0.135	0.381± 0.107	0.395± 0.118

(HAN300)

BATS 2

APPENDIX A3

CHEMICAL INTAKE CHANGES (SUMMARY)

MOUSE:MALE

STUDY NO. : 0084  
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
500 ppm	0.094± 0.009	0.086± 0.011	0.078± 0.008	0.073± 0.010	0.069± 0.010	0.066± 0.010	0.062± 0.011
2000 ppm	0.358± 0.032	0.326± 0.037	0.300± 0.032	0.281± 0.030	0.271± 0.034	0.261± 0.037	0.241± 0.035
8000 ppm	1.086± 0.155	1.025± 0.129	0.980± 0.134	0.913± 0.127	0.903± 0.140	0.852± 0.128	0.831± 0.143

(HAN300)

BAIS 2

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
500 ppm	0.062± 0.012	0.058± 0.008	0.057± 0.009	0.054± 0.008	0.053± 0.007	0.050± 0.007	0.048± 0.006	
2000 ppm	0.235± 0.037	0.227± 0.030	0.223± 0.035	0.204± 0.033	0.205± 0.033	0.200± 0.027	0.189± 0.024	
8000 ppm	0.830± 0.148	0.776± 0.112	0.746± 0.108	0.739± 0.122	0.732± 0.109	0.716± 0.113	0.675± 0.095	



STUDY NO. : 0064  
ANIMAL : MOUSE BDF1  
UNIT : g/kg/day  
REPORT TYPE : A1 104  
SEX : MALE

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	
500 ppm	0.050± 0.008	0.047± 0.006	0.047± 0.006	0.046± 0.006	0.045± 0.006	0.045± 0.005	0.044± 0.006	
2000 ppm	0.195± 0.025	0.188± 0.028	0.179± 0.023	0.180± 0.026	0.171± 0.024	0.180± 0.022	0.170± 0.022	
8000 ppm	0.668± 0.090	0.656± 0.080	0.651± 0.081	0.649± 0.075	0.625± 0.073	0.648± 0.074	0.618± 0.066	

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : AI 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
500 ppm	0.044± 0.005	0.042± 0.005	0.044± 0.005	0.044± 0.005	0.042± 0.004	0.039± 0.005	0.037± 0.004	
2000 ppm	0.171± 0.021	0.159± 0.019	0.174± 0.024	0.170± 0.019	0.162± 0.016	0.157± 0.019	0.147± 0.021	
8000 ppm	0.618± 0.068	0.574± 0.076	0.634± 0.071	0.595± 0.080	0.581± 0.060	0.566± 0.067	0.536± 0.082	

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
500 ppm	0.037± 0.004	0.037± 0.004	0.038± 0.005	0.038± 0.004	0.038± 0.003	0.039± 0.003	0.038± 0.004	
2000 ppm	0.149± 0.020	0.144± 0.015	0.148± 0.015	0.149± 0.018	0.153± 0.017	0.148± 0.017	0.150± 0.019	
8000 ppm	0.496± 0.051	0.496± 0.061	0.513± 0.055	0.504± 0.057	0.516± 0.067	0.502± 0.067	0.497± 0.066	

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
500 ppm	0.039± 0.004	0.039± 0.003	0.039± 0.003	0.040± 0.003	0.040± 0.004	0.042± 0.004	0.041± 0.004	
2000 ppm	0.152± 0.018	0.152± 0.020	0.151± 0.020	0.157± 0.023	0.160± 0.029	0.164± 0.021	0.164± 0.029	
8000 ppm	0.502± 0.066	0.451± 0.067	0.511± 0.057	0.507± 0.072	0.521± 0.092	0.555± 0.082	0.550± 0.078	

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
500 ppm	0.041± 0.006	0.041± 0.007	0.043± 0.005	0.042± 0.006	0.043± 0.007	0.045± 0.009	0.047± 0.012	
2000 ppm	0.167± 0.029	0.168± 0.031	0.162± 0.032	0.170± 0.023	0.173± 0.032	0.180± 0.045	0.177± 0.042	
8000 ppm	0.572± 0.100	0.595± 0.108	0.589± 0.105	0.643± 0.145	0.650± 0.180	0.705± 0.232	0.676± 0.136	

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
500 ppm	0.046± 0.009	0.046± 0.007	0.047± 0.009	0.046± 0.009	0.046± 0.010	0.047± 0.011	0.046± 0.010	
2000 ppm	0.186± 0.048	0.185± 0.037	0.195± 0.069	0.181± 0.048	0.189± 0.053	0.183± 0.044	0.195± 0.048	
8000 ppm	0.717± 0.154	0.742± 0.158	0.759± 0.186	0.793± 0.181	0.772± 0.183	0.839± 0.250	0.847± 0.240	

STUDY NO. : 0064  
ANIMAL : MOUSE BDF1  
UNIT : g/kg/day  
REPORT TYPE : A1 104  
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
ALL ANIMALS

Group Name	Administration (weeks)		
	100	102	104
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000
500 ppm	0.049± 0.011	0.048± 0.008	0.046± 0.009
2000 ppm	0.206± 0.070	0.204± 0.068	0.201± 0.067
8000 ppm	0.877± 0.270	0.954± 0.400	0.886± 0.263

APPENDIX A4

CHEMICAL INTAKE CHANGES (SUMMARY)

MOUSE:FEMALE



STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
500 ppm	0.109± 0.011	0.101± 0.011	0.099± 0.012	0.092± 0.013	0.094± 0.015	0.090± 0.016	0.086± 0.016
2000 ppm	0.454± 0.036	0.418± 0.060	0.396± 0.063	0.400± 0.065	0.410± 0.074	0.383± 0.061	0.368± 0.064
8000 ppm	1.374± 0.153	1.307± 0.169	1.303± 0.246	1.255± 0.148	1.211± 0.136	1.220± 0.144	1.170± 0.150

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
500 ppm	0.080± 0.014	0.080± 0.013	0.082± 0.016	0.079± 0.013	0.080± 0.016	0.074± 0.010	0.074± 0.013	
2000 ppm	0.370± 0.084	0.353± 0.062	0.353± 0.073	0.325± 0.059	0.318± 0.060	0.294± 0.053	0.290± 0.051	
8000 ppm	1.127± 0.139	1.127± 0.121	1.108± 0.127	1.071± 0.113	1.063± 0.124	1.047± 0.153	0.992± 0.120	

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

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	0.000± 0.000
500 ppm	0.071± 0.015	0.072± 0.013	0.067± 0.013	0.071± 0.015	0.069± 0.013	0.069± 0.014	0.068± 0.017	
2000 ppm	0.299± 0.070	0.280± 0.056	0.284± 0.050	0.302± 0.063	0.284± 0.052	0.278± 0.044	0.273± 0.059	
8000 ppm	1.077± 0.215	0.964± 0.100	0.957± 0.123	0.991± 0.128	0.974± 0.110	0.989± 0.136	0.953± 0.139	

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
500 ppm	0.063± 0.013	0.061± 0.014	0.064± 0.012	0.064± 0.014	0.061± 0.011	0.063± 0.017	0.057± 0.013	
2000 ppm	0.271± 0.059	0.245± 0.043	0.262± 0.050	0.251± 0.049	0.259± 0.060	0.249± 0.058	0.224± 0.056	
8000 ppm	0.973± 0.190	0.891± 0.202	0.927± 0.185	0.932± 0.194	0.901± 0.150	0.896± 0.158	0.833± 0.137	

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
500 ppm	0.057± 0.012	0.057± 0.014	0.056± 0.016	0.057± 0.016	0.051± 0.010	0.052± 0.011	0.051± 0.011	
2000 ppm	0.232± 0.058	0.238± 0.058	0.232± 0.059	0.225± 0.046	0.195± 0.033	0.208± 0.054	0.197± 0.047	
8000 ppm	0.876± 0.216	0.825± 0.097	0.814± 0.120	0.834± 0.091	0.781± 0.094	0.794± 0.089	0.776± 0.080	

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
500 ppm	0.052± 0.014	0.052± 0.012	0.045± 0.009	0.051± 0.010	0.050± 0.011	0.051± 0.010	0.054± 0.011	
2000 ppm	0.206± 0.049	0.212± 0.057	0.192± 0.036	0.210± 0.041	0.200± 0.035	0.210± 0.043	0.214± 0.052	
8000 ppm	0.787± 0.098	0.759± 0.082	0.762± 0.078	0.808± 0.105	0.800± 0.151	0.797± 0.133	0.838± 0.164	

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration (weeks)		76	78	80	82	84
	72	74					
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
500 ppm	0.052± 0.011	0.054± 0.014	0.054± 0.016	0.056± 0.014	0.053± 0.010	0.059± 0.017	0.057± 0.017
2000 ppm	0.218± 0.055	0.233± 0.068	0.236± 0.064	0.222± 0.061	0.237± 0.060	0.246± 0.073	0.238± 0.059
8000 ppm	0.830± 0.147	0.887± 0.286	0.824± 0.097	0.807± 0.090	0.833± 0.111	0.900± 0.170	0.826± 0.220

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g/kg/day  
 REPORT TYPE : A1 104  
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)  
 ALL ANIMALS

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
500 ppm	0.061± 0.015	0.057± 0.013	0.054± 0.012	0.057± 0.013	0.056± 0.014	0.058± 0.016	0.058± 0.016	
2000 ppm	0.252± 0.064	0.250± 0.066	0.253± 0.073	0.251± 0.069	0.238± 0.071	0.254± 0.060	0.243± 0.069	
8000 ppm	0.871± 0.086	0.839± 0.071	0.828± 0.123	0.827± 0.137	0.893± 0.199	0.943± 0.205	0.973± 0.180	



STUDY NO. : 0064  
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
500 ppm	0.060± 0.014	0.057± 0.014	0.056± 0.012
2000 ppm	0.261± 0.069	0.244± 0.053	0.237± 0.036
8000 ppm	0.976± 0.258	0.993± 0.262	1.010± 0.271

(HAN300)

BAIS 2

1,4-ジオキサンのラット及びマウスを用いた  
経口(混水)投与によるがん原性試験

# APPENDIX

(B1~B4)

がん原性試験 NO. 0063 ; 0064

APPENDIX B1

BODY WEIGHT CHANGES (SUMMARY)

RAT:MALE

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration		week-day						
	0-0		1-7	2-7	3-7	4-7	5-7	6-7	
Control	134±	5	173± 7	206± 8	233± 8	253± 9	271± 10	283± 11	
200 ppm	134±	5	172± 7	205± 8	231± 9	251± 9	268± 8	279± 9	
1000 ppm	134±	5	171± 7	204± 8	231± 9	250± 10	268± 10	281± 11	
5000 ppm	135±	5	171± 7	202± 8	229± 8	248± 9*	264± 9**	276± 9**	

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration		week-day					
	7-7	8-7	9-7	10-7	11-7	12-7	13-7	
Control	296± 12	309± 12	320± 12	327± 12	334± 13	340± 13	346± 13	
200 ppm	293± 9	305± 9	316± 10	322± 10	330± 11	335± 11	342± 11	
1000 ppm	293± 12	305± 13	317± 13	323± 13	331± 14	336± 15	343± 15	
5000 ppm	287± 9**	297± 10**	310± 10**	316± 10**	323± 10**	328± 10**	334± 11**	

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day							
	14-7	16-7	18-7	20-7	22-7	24-7	26-7	
Control	350± 13	359± 14	367± 15	375± 15	384± 16	390± 17	395± 17	
200 ppm	345± 12	353± 12	361± 13	369± 13	377± 15	383± 15	390± 15	
1000 ppm	347± 16	357± 16	365± 18	373± 18	380± 18	386± 18	393± 18	
5000 ppm	338± 11**	347± 11**	355± 12**	363± 12**	370± 13**	376± 14**	381± 14**	

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration		week-day		30-7		32-7		34-7		36-7		38-7		40-7	
	28-7															
Control	400±	18	407±	18	413±	18	420±	18	425±	19	429±	19	433±	19		
200 ppm	394±	15	401±	15	407±	16	412±	16	417±	17	422±	18	425±	18		
1000 ppm	398±	19	404±	20	412±	20	417±	21	421±	21	426±	21	430±	22		
5000 ppm	385±	14**	392±	14**	399±	15**	404±	16**	406±	16**	410±	16**	414±	17**		

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration		week-day		46-7	48-7	50-7	52-7	54-7
	42-7	44-7	44-7	46-7					
Control	436± 19	443± 20	449± 20	453± 21	456± 21	460± 21	464± 22		
200 ppm	430± 18	436± 19	442± 20	445± 20	450± 20	453± 21	457± 21		
1000 ppm	434± 22	440± 22	445± 22	449± 23	453± 22	456± 22	460± 22		
5000 ppm	417± 17**	423± 17**	430± 18**	432± 18**	435± 19**	439± 19**	443± 19**		

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



STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration		week-day		60-7	62-7	64-7	66-7	68-7
	56-7	58-7							
Control	468± 23	473± 23	477± 25	480± 26	483± 28	486± 24	488± 24		
200 ppm	462± 21	464± 24	469± 23	472± 24	472± 26	475± 29	481± 24		
1000 ppm	465± 22	468± 24	473± 25	475± 24	476± 24	478± 25	479± 26		
5000 ppm	448± 20**	452± 20**	456± 20**	459± 20**	459± 21**	461± 21**	462± 22**		

Significant difference : \* : P ≤ 0.05    \*\* : P ≤ 0.01    Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration		week-day											
	70-7		72-7	74-7	76-7	78-7	80-7	82-7						
Control	490±	24	490±	24	492±	23	492±	23	493±	23	493±	23	492±	23
200 ppm	482±	26	484±	24	484±	24	484±	25	484±	25	484±	26	483±	26
1000 ppm	481±	26	481±	27	481±	27	481±	28	479±	29*	479±	31*	478±	34*
5000 ppm	461±	22**	461±	24**	459±	25**	459±	26**	456±	29**	454±	34**	451±	34**

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day							
	84-7	86-7	88-7	90-7	92-7	94-7	96-7	
Control	489± 29	488± 27	486± 32	484± 37	479± 46	473± 52	468± 57	
200 ppm	479± 32	481± 27	480± 28	478± 31	478± 29	477± 28	475± 24	
1000 ppm	480± 30	479± 29	477± 28	476± 28	472± 32	465± 43	463± 39	
5000 ppm	451± 35**	445± 39**	442± 45**	441± 39**	442± 37**	440± 42**	434± 54**	

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day							
	98-7		100-7		102-7		104-7	
Control	460±	63	462±	41	463±	34	458±	37
200 ppm	471±	26	468±	27	466±	28	462±	32
1000 ppm	450±	54	451±	48	443±	54	440±	55
5000 ppm	428±	73**	423±	47**	416±	60**	413±	66**

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

APPENDIX B2

BODY WEIGHT CHANGES (SUMMARY)

RAT:FEMALE

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration		week-day		1-7		2-7		3-7		4-7		5-7		6-7	
	0-0															
Control	105±	3	123±	4	138±	5	149±	6	159±	7	167±	7	173±	8		
200 ppm	105±	3	123±	4	138±	4	149±	6	159±	6	168±	7	173±	7		
1000 ppm	105±	3	123±	4	137±	4	149±	5	158±	6	167±	6	173±	6		
5000 ppm	105±	3	121±	4**	135±	4*	146±	5**	155±	5**	164±	6*	170±	6*		

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration		week-day		7-7		8-7		9-7		10-7		11-7		12-7		13-7	
Control	179±	9	185±	9	189±	9	193±	9	197±	10	200±	9	202±	10				
200 ppm	180±	8	184±	7	190±	8	193±	8	197±	8	199±	8	202±	8				
1000 ppm	180±	7	183±	7	190±	8	192±	8	197±	8	199±	8	202±	7				
5000 ppm	175±	7*	179±	7**	184±	7**	187±	7**	191±	7**	192±	7**	195±	7**				

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration		week-day		14-7	16-7	18-7	20-7	22-7	24-7	26-7			
Control	203±	10	207±	11	211±	11	215±	12	217±	11	220±	12	222±	12
200 ppm	203±	8	208±	9	212±	10	215±	10	218±	10	222±	10	224±	10
1000 ppm	203±	8	207±	8	211±	9	214±	9	217±	10	220±	10	223±	10
5000 ppm	196±	7**	199±	8**	202±	9**	204±	9**	207±	9**	209±	9**	212±	10**

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

Test of Dunnett



STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day							
	28-7	30-7	32-7	34-7	36-7	38-7	40-7	
Control	226± 13	229± 13	232± 13	235± 13	238± 14	240± 15	242± 16	
200 ppm	226± 10	229± 11	231± 12	235± 13	238± 14	240± 15	242± 15	
1000 ppm	224± 10	228± 11	231± 12	234± 12	235± 12	238± 13	241± 13	
5000 ppm	215± 10**	218± 11**	220± 11**	223± 12**	226± 12**	229± 13**	231± 13**	

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day							
	42-7	44-7	46-7	48-7	50-7	52-7	54-7	
Control	247± 17	252± 17	257± 17	259± 18	263± 19	268± 20	273± 21	
200 ppm	245± 15	250± 17	255± 17	259± 18	263± 19	266± 20	271± 20	
1000 ppm	243± 13	248± 14	253± 14	255± 14	260± 15	263± 15	268± 15	
5000 ppm	233± 14**	237± 14**	244± 15**	246± 16**	250± 16**	253± 18**	260± 19**	

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration		week-day		60-7	62-7	64-7	66-7	68-7
	56-7	58-7							
Control	278± 21	282± 23	287± 24	291± 25	296± 26	300± 26	303± 28		
200 ppm	277± 21	281± 22	285± 22	289± 22	294± 23	297± 24	301± 24		
1000 ppm	275± 19	278± 17	283± 17	286± 17	291± 18	295± 19	298± 19		
5000 ppm	265± 20**	269± 20*	273± 22*	278± 22*	281± 22*	284± 22**	286± 23**		

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration		week-day		74-7	76-7	78-7	80-7	82-7
	70-7		72-7						
Control	306±	29	311±	28	313± 29	316± 29	319± 29	321± 29	323± 30
200 ppm	304±	24	307±	24	308± 25	310± 27	312± 29	312± 31	314± 35
1000 ppm	300±	19	301±	19	303± 18	306± 19	307± 22	309± 27	312± 21
5000 ppm	288±	23**	287±	26**	291± 23**	291± 24**	294± 23**	294± 24**	292± 34**

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration		week-day		84-7		86-7		88-7		90-7		92-7		94-7		96-7	
Control	323±	30	323±	33	322±	39	330±	33	329±	33	329±	35	329±	38				
200 ppm	319±	33	321±	32	320±	36	321±	39	323±	37	320±	42	318±	47				
1000 ppm	315±	20	317±	21	317±	22	317±	23	319±	24	320±	26	319±	29				
5000 ppm	297±	31**	293±	28**	290±	32**	290±	37**	283±	39**	282±	39**	278±	42**				

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day							
	98-7		100-7		102-7		104-7	
Control	330±	34	332±	33	331±	35	326±	41
200 ppm	320±	41	315±	45	314±	48	320±	40
1000 ppm	319±	32	321±	36	325±	40	317±	30
5000 ppm	275±	41**	270±	43**	270±	43**	264±	45**

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

APPENDIX B3

BODY WEIGHT CHANGES (SUMMARY)

MOUSE:MALE

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day						
	0-0	1-7	2-7	3-7	4-7	5-7	6-7
Control	23.9± 0.9	25.7± 1.0	27.0± 1.1	27.9± 1.2	29.3± 1.4	30.0± 1.4	31.5± 1.7
500 ppm	23.9± 0.9	25.7± 1.1	26.9± 1.4	27.7± 1.5	29.1± 1.7	30.1± 1.9	31.1± 2.0
2000 ppm	23.9± 0.9	25.5± 1.0	26.7± 1.1	27.7± 1.2	28.8± 1.5	29.9± 1.7	31.0± 2.0
8000 ppm	23.9± 0.9	25.4± 0.9	26.5± 1.0	27.3± 1.1	28.4± 1.2**	29.4± 1.4	30.0± 1.7**

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



STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day						
	7-7	8-7	9-7	10-7	11-7	12-7	13-7
Control	32.2± 1.7	33.0± 1.8	34.0± 2.0	34.8± 2.1	35.4± 2.2	36.2± 2.3	37.3± 2.4
500 ppm	32.2± 2.3	32.7± 2.3	33.8± 2.6	34.6± 2.6	35.4± 2.9	36.2± 3.0	37.2± 3.1
2000 ppm	32.0± 2.2	32.6± 2.3	33.5± 2.4	34.6± 2.5	35.5± 2.7	36.3± 2.9	36.9± 3.1
8000 ppm	30.8± 1.8**	31.1± 1.8**	32.8± 1.9*	33.5± 2.0*	33.9± 2.0**	33.9± 2.2**	35.3± 2.2**

Significant difference : \* : P ≤ 0.05    \*\* : P ≤ 0.01    Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day						
	14-7	16-7	18-7	20-7	22-7	24-7	26-7
Control	38.4± 2.5	38.9± 2.8	40.5± 2.9	41.4± 3.5	42.5± 3.2	43.5± 3.2	45.0± 3.1
500 ppm	38.0± 3.2	38.9± 3.4	40.4± 3.5	41.3± 3.8	42.4± 3.8	43.6± 4.0	44.5± 4.2
2000 ppm	37.9± 3.2	38.7± 3.6	40.2± 3.9	41.2± 3.9	42.1± 4.0	43.4± 4.1	44.0± 4.2
8000 ppm	36.2± 2.2**	36.9± 2.4**	38.1± 2.5**	38.8± 2.7**	39.9± 2.9**	40.7± 3.0**	41.6± 3.1**

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day						
	28-7	30-7	32-7	34-7	36-7	38-7	40-7
Control	45.6± 3.1	46.4± 3.3	46.6± 3.1	47.1± 3.0	47.3± 3.0	48.1± 3.3	48.6± 3.3
500 ppm	44.7± 4.1	45.9± 4.3	46.5± 4.3	47.0± 4.4	47.2± 4.2	47.9± 4.3	48.1± 4.0
2000 ppm	44.6± 4.1	45.5± 4.0	46.2± 4.2	46.6± 4.0	46.9± 4.0	47.8± 4.1	47.9± 3.9
8000 ppm	41.8± 3.3**	43.0± 3.1**	43.3± 3.3**	43.8± 3.3**	44.2± 3.5**	44.7± 3.4**	45.3± 3.6**

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

STUDY NO. : 0084  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day						
	42-7	44-7	46-7	48-7	50-7	52-7	54-7
Control	49.5± 3.9	50.0± 3.9	50.5± 4.1	50.6± 4.2	50.8± 4.0	51.7± 4.1	51.8± 4.0
500 ppm	49.4± 4.0	50.5± 3.9	50.5± 4.0	50.5± 4.1	51.5± 3.6	51.8± 3.6	52.3± 3.5
2000 ppm	49.5± 4.2	50.1± 4.0	50.2± 4.0	50.5± 4.1	50.6± 3.8	51.4± 3.9	51.6± 3.8
8000 ppm	46.6± 3.5**	47.3± 3.3**	47.3± 3.1**	47.5± 3.2**	47.6± 3.3**	47.8± 3.3**	47.9± 3.5**

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day						
	56-7	58-7	60-7	62-7	64-7	66-7	68-7
Control	52.0± 3.9	52.1± 3.9	52.3± 3.9	52.3± 4.2	52.1± 4.1	52.3± 3.6	52.5± 3.8
500 ppm	52.4± 3.5	52.2± 3.2	52.4± 3.1	52.4± 3.3	53.0± 3.4	53.0± 3.2	53.0± 3.2
2000 ppm	51.8± 3.9	52.1± 3.9	52.2± 3.9	52.8± 3.9	52.8± 3.8	53.0± 3.9	53.0± 3.9
8000 ppm	48.3± 4.2**	48.0± 5.0**	48.2± 3.7**	48.1± 3.9**	48.0± 4.3**	47.2± 5.2**	46.7± 5.4**

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day						
	70-7	72-7	74-7	76-7	78-7	80-7	82-7
Control	52.9± 3.8	53.2± 3.8	53.7± 3.7	53.6± 3.8	54.0± 4.2	53.9± 4.5	53.7± 5.1
500 ppm	53.5± 3.4	53.4± 3.5	53.5± 4.7	53.8± 3.9	54.0± 4.1	53.9± 4.7	53.5± 5.3
2000 ppm	53.2± 4.1	53.5± 3.9	53.5± 4.3	53.7± 4.8	53.3± 4.7	53.1± 5.0	52.9± 4.7
8000 ppm	46.9± 4.9**	46.5± 5.2**	45.9± 5.3**	45.6± 4.2**	43.8± 4.5**	42.6± 4.9**	40.9± 5.2**

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day						
	84-7	86-7	88-7	90-7	92-7	94-7	96-7
Control	53.6± 5.5	53.3± 6.0	53.1± 7.0	53.1± 6.4	53.8± 5.2	53.1± 5.5	52.4± 6.2
500 ppm	53.2± 6.3	52.4± 6.2	53.5± 4.7	53.6± 5.2	53.0± 5.5	52.6± 5.6	52.4± 5.9
2000 ppm	52.7± 5.0	51.5± 5.7	50.7± 6.8	49.6± 8.0*	48.7± 8.8*	49.0± 7.8*	48.8± 6.9*
8000 ppm	39.6± 5.1**	37.9± 5.5**	37.0± 5.7**	36.4± 5.9**	35.7± 5.5**	34.9± 5.0**	33.3± 4.8**

Significant difference : \* : P ≤ 0.05    \*\* : P ≤ 0.01    Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day			
	98-7	100-7	102-7	104-7
Control	51.9± 6.4	52.6± 5.9	52.1± 7.0	52.9± 6.3
500 ppm	51.6± 6.4	51.7± 6.6	51.2± 7.3	51.5± 6.8
2000 ppm	48.6± 7.6	48.1± 7.1	48.2± 7.5	48.3± 7.4
8000 ppm	32.9± 4.1**	31.9± 3.8**	31.2± 3.3**	30.3± 3.4**

Significant difference : \* : P ≤ 0.05    \*\* : P ≤ 0.01    Test of Dunnett



APPENDIX B4

BODY WEIGHT CHANGES (SUMMARY)

MOUSE:FEMALE

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day						
	0-0	1-7	2-7	3-7	4-7	5-7	6-7
Control	19.3± 0.7	20.3± 0.9	21.7± 0.8	22.4± 1.0	23.2± 1.1	23.8± 1.2	24.9± 1.2
500 ppm	19.3± 0.7	20.8± 0.9*	21.7± 1.0	22.5± 1.1	23.4± 1.3	24.1± 1.4	24.8± 1.7
2000 ppm	19.3± 0.7	20.4± 0.9	21.5± 0.8	22.4± 0.9	22.9± 1.0	24.0± 1.1	24.4± 1.4
8000 ppm	19.3± 0.7	20.3± 0.9	21.6± 1.0	21.9± 1.2	22.6± 1.3*	23.3± 1.3	23.8± 1.4**

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day						
	7-7	8-7	9-7	10-7	11-7	12-7	13-7
Control	24.8± 1.4	25.7± 1.6	25.7± 2.1	26.6± 1.9	27.2± 2.2	27.4± 2.1	28.2± 2.3
500 ppm	25.0± 1.7	26.6± 1.7*	26.6± 1.8*	27.2± 1.9	27.3± 2.2	27.3± 2.4	28.1± 2.7
2000 ppm	24.8± 1.4	25.7± 1.6	26.2± 1.6	26.9± 1.9	27.3± 2.0	27.7± 2.2	28.2± 2.1
8000 ppm	23.9± 1.3**	24.6± 1.5**	25.2± 1.8	25.8± 1.7	26.0± 1.8*	26.3± 2.0*	26.4± 2.0**

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day						
	14-7	16-7	18-7	20-7	22-7	24-7	26-7
Control	28.9± 2.5	28.7± 2.6	30.3± 2.8	30.9± 2.9	31.4± 2.9	31.6± 3.2	32.0± 3.0
500 ppm	28.8± 2.8	29.2± 3.3	30.2± 3.1	30.1± 3.3	31.5± 3.4	31.8± 3.5	32.2± 3.8
2000 ppm	29.0± 2.6	29.1± 3.0	30.3± 2.8	30.1± 2.8	31.2± 3.3	31.5± 3.3	32.0± 3.4
8000 ppm	27.3± 2.2**	27.2± 2.4*	28.3± 2.5**	28.2± 2.5**	28.8± 2.7**	29.2± 2.5**	29.5± 2.7**

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day							
	28-7	30-7	32-7	34-7	36-7	38-7	40-7	
Control	32.5± 3.0	33.0± 3.4	33.7± 3.7	33.6± 3.7	33.8± 3.3	34.9± 3.6	34.6± 3.9	
500 ppm	32.7± 3.9	33.2± 4.1	34.1± 4.3	34.1± 4.3	34.1± 4.2	34.2± 4.2	34.4± 3.9	
2000 ppm	32.4± 4.0	32.9± 4.6	33.2± 4.5	33.1± 4.8	33.4± 4.7	33.7± 5.2	33.7± 4.7	
8000 ppm	29.7± 2.9**	30.3± 3.3**	30.7± 3.4**	30.2± 3.3**	30.2± 3.3**	30.3± 3.2**	30.0± 3.0**	

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day						
	42-7	44-7	46-7	48-7	50-7	52-7	54-7
Control	36.0± 3.9	36.0± 3.8	36.6± 4.0	37.1± 4.3	37.3± 4.3	38.9± 4.4	38.2± 4.3
500 ppm	35.6± 4.4	35.9± 4.3	36.6± 4.5	36.8± 4.5	36.8± 4.5	38.6± 4.7	38.6± 4.6
2000 ppm	35.4± 5.3	36.0± 5.1	36.1± 5.2	36.8± 5.2	37.2± 4.6	38.8± 4.8	38.3± 4.9
8000 ppm	30.3± 3.4**	30.5± 3.2**	30.2± 3.2**	30.0± 3.0**	29.8± 3.0**	30.3± 3.1**	29.4± 2.8**

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day						
	56-7	58-7	60-7	62-7	64-7	66-7	68-7
Control	38.5± 4.8	39.0± 4.4	39.3± 4.6	39.5± 5.1	40.0± 5.0	40.3± 4.7	40.7± 4.5
500 ppm	38.7± 4.8	39.1± 4.9	39.5± 4.4	39.7± 4.8	40.3± 4.7	40.0± 4.9	40.1± 5.1
2000 ppm	38.6± 5.1	38.9± 4.6	39.1± 4.7	39.8± 5.1	39.7± 5.1	39.7± 5.4	39.6± 5.1
8000 ppm	29.0± 2.8**	28.9± 2.9**	28.7± 3.2**	28.5± 2.8**	28.4± 2.6**	28.0± 2.7**	27.3± 2.7**

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day						
	70-7	72-7	74-7	76-7	78-7	80-7	82-7
Control	40.2± 4.8	40.8± 4.6	40.6± 4.9	41.0± 5.0	40.4± 4.6	40.9± 4.9	40.7± 5.2
500 ppm	40.1± 5.2	39.8± 5.8	40.2± 5.6	40.2± 5.4	40.4± 4.9	40.9± 4.6	39.7± 4.2
2000 ppm	38.9± 5.3	39.3± 5.0	39.2± 5.1	39.4± 5.1	38.8± 4.9	37.8± 5.3*	37.6± 4.6*
8000 ppm	26.9± 2.4**	26.5± 2.8**	25.9± 2.5**	25.9± 2.5**	25.1± 2.8**	25.2± 2.6**	24.8± 2.6**

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



STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day						
	84-7	86-7	88-7	90-7	92-7	94-7	96-7
Control	40.3± 4.9	40.6± 5.1	40.2± 5.3	39.8± 5.3	40.1± 6.0	39.7± 5.0	39.2± 5.0
500 ppm	39.5± 4.4	39.4± 3.9	39.5± 4.4	38.8± 4.2	38.4± 4.6	38.3± 5.0	38.8± 5.9
2000 ppm	36.9± 4.8*	36.1± 4.9**	34.9± 4.9**	34.6± 4.9**	34.2± 5.4**	34.9± 4.9**	34.5± 4.2**
8000 ppm	24.7± 2.3**	24.9± 1.7**	24.7± 2.1**	24.4± 2.5**	23.1± 2.7**	22.6± 2.8**	21.7± 2.6**

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day			
	98-7	100-7	102-7	104-7
Control	38.4± 6.3	38.7± 3.9	39.2± 5.2	38.5± 4.7
500 ppm	37.5± 6.6	37.8± 5.5	37.8± 6.0	37.3± 6.4
2000 ppm	34.5± 3.7*	33.8± 4.0*	33.1± 4.7*	32.6± 5.4**
8000 ppm	22.1± 3.0**	21.4± 2.7**	21.7± 2.9**	21.3± 2.9**

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

1,4-ジオキサンのラット及びマウスを用いた  
経口(混水)投与によるがん原性試験

# APPENDIX

(C1~C4)

がん原性試験 NO. 0063 ; 0064

APPENDIX C1

FOOD CONSUMPTION CHANGES (SUMMARY)

RAT:MALE

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	1-7(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	16.4± 0.8	17.5± 1.0	17.7± 0.9	17.9± 0.9	17.7± 0.9	17.5± 0.9	17.5± 1.1
200 ppm	16.4± 0.9	17.4± 0.9	17.6± 0.8	17.7± 0.8	17.5± 0.8	17.2± 0.8	17.3± 0.8
1000 ppm	16.3± 1.0	17.3± 0.9	17.6± 0.8	18.0± 0.9	17.6± 0.8	17.7± 1.0	17.4± 0.9
5000 ppm	15.9± 0.9*	16.9± 0.9**	17.0± 0.9**	17.4± 0.9*	17.3± 0.9	17.0± 0.9*	17.0± 1.0*

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

\*\* :  $P \leq 0.01$

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	17.5± 1.0	17.6± 0.9	17.1± 0.9	16.8± 0.9	16.5± 1.0	16.3± 0.8	16.1± 0.9
200 ppm	17.3± 0.9	17.5± 0.8	16.8± 0.8	16.6± 0.8	16.4± 0.9	16.2± 1.0	16.0± 1.0
1000 ppm	17.4± 1.0	17.6± 0.7	17.2± 0.8	17.0± 0.8	16.7± 0.9	16.5± 0.8	16.3± 0.9
5000 ppm	16.9± 0.7**	17.4± 0.8	17.0± 0.7	16.7± 0.8	16.3± 0.8	16.2± 0.8	16.0± 0.9

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	18-7(7)	22-7(7)	26-7(7)	30-7(7)	34-7(7)	38-7(7)	42-7(7)
Control	16.3± 1.0	15.8± 1.0	16.0± 1.0	16.4± 1.0	16.4± 0.9	16.1± 0.8	16.1± 1.0
200 ppm	16.1± 0.9	15.8± 1.0	16.2± 0.8	16.3± 0.8	16.3± 0.9	16.1± 1.0	16.0± 0.9
1000 ppm	16.5± 0.9	16.0± 0.8	16.2± 0.9	16.4± 0.9	16.5± 0.8	16.3± 0.8	16.2± 1.0
5000 ppm	16.0± 1.0	15.6± 1.1	16.1± 0.9	16.2± 0.9	16.2± 0.9	15.8± 1.0	15.6± 0.9*

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	46-7(7)	50-7(7)	52-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)
Control	16.4± 1.0	16.4± 0.9	16.5± 1.0	16.6± 1.2	16.6± 1.0	17.0± 1.2	17.0± 1.0
200 ppm	16.2± 0.9	16.3± 0.9	16.1± 0.8	16.4± 0.9	16.2± 1.8	16.9± 1.1	17.2± 1.5
1000 ppm	16.4± 1.0	16.9± 0.8	16.6± 0.9	16.9± 0.9	16.7± 1.2	16.9± 0.8	17.1± 1.1
5000 ppm	16.0± 0.9	16.0± 1.0*	15.8± 1.0**	16.2± 1.2	16.3± 1.0	16.7± 1.0	16.8± 1.1

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

Test of Dunnett



STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	70-7(7)	74-7(7)	78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)
Control	17.1± 1.0	16.9± 1.2	16.7± 1.1	16.7± 0.9	16.4± 1.6	16.4± 2.0	15.7± 2.4
200 ppm	16.8± 2.0	16.6± 1.1	16.4± 1.5	16.5± 1.4	16.6± 1.4	16.2± 1.6	15.9± 1.9
1000 ppm	17.1± 1.2	16.6± 1.0	16.1± 1.4	16.3± 2.5	16.9± 1.0	16.5± 1.3	15.8± 2.8
5000 ppm	16.7± 1.3	16.5± 1.2	16.4± 1.5	15.8± 3.4	16.2± 2.7	15.7± 2.9	15.4± 2.1

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

STUDY NO. : 0063  
ANIMAL : RAT F344  
UNIT : g  
REPORT TYPE : A1 104  
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 6

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Group Name	Administration week-day(effective)		
	98-7(7)	102-7(7)	104-7(7)
Control	15.9± 2.5	16.5± 1.5	16.2± 2.2
200 ppm	16.4± 1.3	16.4± 1.3	16.4± 1.4
1000 ppm	15.7± 3.1	16.0± 2.4	16.0± 2.0
5000 ppm	15.9± 2.8	16.4± 2.6	15.4± 4.7

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX C2

FOOD CONSUMPTION CHANGES (SUMMARY)

RAT:FEMALE

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	1-7(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	12.3± 0.6	12.4± 0.6	12.3± 0.7	12.2± 0.8	12.2± 0.7	12.2± 0.8	12.1± 0.8
200 ppm	12.5± 0.7	12.5± 0.6	12.4± 0.8	12.4± 0.7	12.4± 0.8	12.2± 0.8	12.3± 0.9
1000 ppm	12.4± 0.5	12.5± 0.5	12.2± 0.6	12.4± 0.7	12.3± 0.6	12.4± 0.7	12.4± 0.7
5000 ppm	12.0± 0.7*	12.2± 0.6	12.1± 0.6	12.1± 0.6	12.2± 0.7	12.0± 0.6	12.2± 0.7

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	11.9± 0.9	12.3± 0.8	12.1± 0.7	12.0± 0.7	12.0± 0.8	11.8± 0.8	11.6± 0.7
200 ppm	11.9± 1.0	12.5± 0.8	12.4± 0.7	12.3± 0.7	12.2± 0.7	12.1± 0.7	11.9± 0.9
1000 ppm	12.0± 0.7	12.5± 0.6	12.3± 0.7	12.2± 0.6	12.0± 0.7	12.1± 0.5	11.8± 0.6
5000 ppm	11.9± 0.7	12.2± 0.8	12.1± 0.8	12.2± 0.8	11.8± 0.8	12.0± 0.8	11.7± 0.7

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	18-7(7)	22-7(7)	26-7(7)	30-7(7)	34-7(7)	38-7(7)	42-7(7)
Control	11.8± 0.9	11.2± 0.8	11.5± 0.9	11.8± 0.7	12.0± 0.8	11.7± 0.9	12.0± 0.9
200 ppm	12.0± 0.7	11.7± 0.6**	11.9± 0.7	12.1± 0.8	12.3± 0.8	12.0± 0.9	12.0± 1.0
1000 ppm	11.8± 0.7	11.5± 0.6	11.8± 0.6	11.8± 0.7	11.9± 0.7	11.9± 0.7	11.7± 0.8
5000 ppm	11.9± 0.7	11.5± 0.7	11.8± 0.8	12.0± 0.8	12.2± 0.8	12.1± 0.7	11.8± 0.8

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	46-7(7)	50-7(7)	52-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)
Control	12.1± 0.9	12.1± 0.8	12.3± 0.9	12.6± 0.8	12.3± 1.0	12.9± 0.9	13.1± 1.0
200 ppm	12.4± 1.0	12.4± 1.0	12.5± 0.9	12.8± 0.9	12.7± 0.8	13.2± 0.8	13.2± 1.1
1000 ppm	12.3± 0.8	12.1± 0.8	12.1± 1.0	12.5± 0.8	12.4± 0.7	12.9± 0.8	13.0± 0.9
5000 ppm	13.0± 1.0**	12.5± 0.8	12.6± 0.8	13.1± 0.9*	12.8± 0.8*	13.2± 0.9	13.6± 1.2

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	70-7(7)	74-7(7)	78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)
Control	13.2± 1.2	13.3± 1.1	13.8± 1.1	13.7± 1.0	13.4± 1.9	14.1± 1.7	13.8± 1.7
200 ppm	13.5± 1.2	13.2± 1.2	14.0± 1.4	13.8± 2.4	14.1± 1.8	13.9± 3.1	13.6± 2.7
1000 ppm	13.0± 1.2	12.6± 2.4	13.9± 1.3	13.4± 1.4	13.7± 1.3	13.7± 1.9	13.5± 2.0
5000 ppm	13.5± 1.2	13.2± 1.2	14.0± 1.7	13.6± 3.2	13.7± 1.9	12.9± 2.8	13.3± 2.7

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

\*\* :  $P \leq 0.01$

Test of Dunnett



STUDY NO. : 0063  
ANIMAL : RAT F344  
UNIT : g  
REPORT TYPE : A1 104  
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

Group Name	Administration week-day(effective)		
	98-7(7)	102-7(7)	104-7(7)
Control	14.3± 1.3	14.4± 1.7	14.3± 2.4
200 ppm	13.9± 1.9	13.7± 3.4	14.0± 2.9
1000 ppm	13.9± 2.6	14.3± 2.2	14.4± 2.0
5000 ppm	13.5± 3.6	13.3± 3.3	13.3± 3.8

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

\*\* :  $P \leq 0.01$

Test of Dunnett

APPENDIX C3

FOOD CONSUMPTION CHANGES (SUMMARY)

MOUSE:MALE

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	1-7(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	4.2± 0.2	4.2± 0.2	4.0± 0.2	4.1± 0.2	4.0± 0.2	4.3± 0.3	4.2± 0.3
500 ppm	4.2± 0.2	4.1± 0.3	4.0± 0.3	4.1± 0.3	4.1± 0.3	4.2± 0.3	4.0± 0.5
2000 ppm	4.1± 0.3	4.1± 0.2	3.9± 0.3	4.0± 0.3	4.0± 0.3	4.2± 0.3	4.1± 0.3
8000 ppm	4.0± 0.2**	4.0± 0.2**	3.9± 0.2	4.0± 0.2	3.9± 0.2	4.1± 0.3**	4.0± 0.3

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	4.3± 0.2	4.1± 0.2	4.3± 0.2	4.1± 0.3	4.3± 0.3	4.2± 0.3	4.4± 0.3
500 ppm	4.3± 0.3	4.2± 0.3	4.2± 0.3	4.2± 0.3	4.3± 0.3	4.2± 0.3	4.4± 0.3
2000 ppm	4.2± 0.4	4.2± 0.3	4.3± 0.3	4.2± 0.3	4.3± 0.3	4.1± 0.3	4.3± 0.3
8000 ppm	4.1± 0.2*	4.1± 0.2	4.2± 0.3	4.0± 0.2	4.1± 0.3	4.1± 0.2	4.2± 0.2

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	18-7(7)	22-7(7)	26-7(7)	30-7(7)	34-7(7)	38-7(7)	42-7(7)
Control	4.1± 0.3	4.3± 0.2	4.6± 0.3	4.5± 0.3	4.5± 0.3	4.5± 0.3	4.4± 0.3
500 ppm	4.2± 0.3	4.4± 0.3	4.6± 0.3	4.5± 0.3	4.5± 0.3	4.4± 0.3	4.4± 0.3
2000 ppm	4.2± 0.3	4.3± 0.3	4.5± 0.3	4.4± 0.3	4.3± 0.3*	4.4± 0.3	4.4± 0.3
8000 ppm	4.0± 0.2	4.3± 0.3	4.4± 0.3**	4.4± 0.3	4.2± 0.3**	4.3± 0.3*	4.3± 0.3

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	46-7(7)	50-7(7)	52-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)
Control	4.3± 0.3	4.5± 0.3	4.5± 0.3	4.5± 0.2	4.4± 0.3	4.5± 0.4	4.9± 0.3
500 ppm	4.4± 0.5	4.5± 0.3	4.6± 0.3	4.4± 0.3	4.4± 0.3	4.5± 0.3	4.9± 0.3
2000 ppm	4.2± 0.3*	4.3± 0.3*	4.5± 0.3	4.3± 0.3	4.4± 0.3	4.5± 0.3	4.8± 0.3
8000 ppm	4.1± 0.3**	4.3± 0.3**	4.3± 0.4	4.2± 0.4**	4.2± 0.6**	4.3± 0.3**	4.4± 0.7**

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	70-7(7)	74-7(7)	78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)
Control	4.9± 0.3	4.7± 0.4	4.9± 0.5	4.9± 0.5	4.8± 0.6	4.7± 0.5	4.9± 0.5
500 ppm	4.8± 0.3	4.7± 0.7	4.9± 0.4	4.9± 0.5	4.7± 0.8	4.9± 0.5	4.8± 0.4
2000 ppm	4.8± 0.4	4.8± 0.6	4.8± 0.5	4.9± 0.5	4.7± 0.4	4.6± 0.6	4.7± 0.4
8000 ppm	4.5± 0.4**	4.3± 0.4**	4.2± 0.5**	4.2± 0.6**	4.0± 0.6**	3.8± 0.5**	3.8± 0.4**

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

Test of Dunnett

STUDY NO. : 0084  
ANIMAL : MOUSE BDF1  
UNIT : g  
REPORT TYPE : A1 104  
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 6

Group Name	Administration week-day(effective)		
	98-7(7)	102-7(7)	104-7(7)
Control	4.8± 0.6	4.9± 0.7	4.6± 0.5
500 ppm	4.6± 0.8	4.9± 0.7	4.6± 0.6
2000 ppm	4.8± 0.5	4.9± 0.5	4.6± 0.4
8000 ppm	3.9± 0.4**	4.1± 0.5**	3.8± 0.6**

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

Test of Dunnett

(HAN260)

BAIS2



APPENDIX C4

FOOD CONSUMPTION CHANGES (SUMMARY)

MOUSE:FEMALE

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	1-7(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	3.7± 0.2	3.7± 0.2	3.7± 0.2	3.9± 0.2	3.8± 0.3	4.0± 0.3	3.9± 0.3
500 ppm	3.8± 0.3	3.7± 0.2	3.7± 0.2	3.8± 0.3	3.8± 0.3	4.0± 0.3	3.8± 0.3
2000 ppm	3.8± 0.3	3.7± 0.2	3.7± 0.2	3.9± 0.2	3.9± 0.3*	4.1± 0.3	4.0± 0.3
8000 ppm	3.7± 0.2	3.8± 0.2	3.7± 0.3	3.8± 0.3	3.8± 0.2	4.0± 0.2	3.9± 0.3

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	4.0± 0.3	4.0± 0.3	4.1± 0.3	4.2± 0.4	4.2± 0.4	4.1± 0.4	4.3± 0.4
500 ppm	4.0± 0.4	4.0± 0.3	4.1± 0.4	4.1± 0.4	4.2± 0.4	4.0± 0.4	4.2± 0.4
2000 ppm	4.1± 0.3	4.1± 0.3	4.2± 0.3*	4.2± 0.3	4.3± 0.3	4.0± 0.3	4.4± 0.4
8000 ppm	4.0± 0.3	4.0± 0.3	4.1± 0.3	4.0± 0.3	4.2± 0.3	3.8± 0.3**	4.2± 0.3

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	18-7(7)	22-7(7)	26-7(7)	30-7(7)	34-7(7)	38-7(7)	42-7(7)
Control	4.1± 0.4	4.1± 0.4	4.3± 0.4	4.3± 0.5	4.1± 0.5	4.2± 0.4	4.1± 0.4
500 ppm	4.0± 0.4	4.2± 0.3	4.1± 0.5	4.2± 0.4	4.0± 0.4	3.9± 0.4*	4.2± 0.4
2000 ppm	4.1± 0.4	4.3± 0.4*	4.3± 0.5	4.4± 0.5	4.0± 0.5	4.1± 0.4	4.2± 0.5
8000 ppm	4.0± 0.3	4.1± 0.3	4.1± 0.4	4.3± 0.4	3.9± 0.4	3.8± 0.4**	3.8± 0.4**

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	46-7(7)	50-7(7)	52-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)
Control	4.1± 0.4	4.1± 0.5	4.3± 0.6	4.0± 0.6	4.1± 0.4	4.1± 0.6	4.4± 0.5
500 ppm	4.2± 0.5	4.0± 0.5	4.2± 0.5	4.2± 0.4	4.2± 0.5	4.2± 0.6	4.2± 0.6
2000 ppm	4.2± 0.5	4.2± 0.5	4.3± 0.6	4.1± 0.9	4.2± 0.5	4.4± 0.7	4.4± 0.4
8000 ppm	3.7± 0.5**	3.6± 0.3**	3.7± 0.5**	3.4± 0.4**	3.5± 0.5**	3.5± 0.4**	3.6± 0.5**

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	70-7(7)	74-7(7)	78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)
Control	4.4± 0.5	4.4± 0.8	4.3± 0.9	4.6± 0.8	4.3± 0.7	4.3± 0.7	4.5± 0.9
500 ppm	4.6± 1.0	4.4± 0.7	4.3± 0.5	4.5± 0.7	4.5± 0.5	4.3± 0.6	4.3± 0.7
2000 ppm	4.3± 0.7	4.4± 0.6	4.5± 0.5	4.5± 0.6	4.3± 0.5	4.2± 0.4	4.2± 0.6
8000 ppm	3.7± 0.4**	3.5± 0.5**	3.6± 0.5**	3.6± 0.6**	3.6± 0.4**	3.5± 0.6**	3.3± 0.4**

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

Test of Dunnett

STUDY NO. : 0064  
ANIMAL : MOUSE BDF1  
UNIT : g  
REPORT TYPE : A1 104  
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

Group Name	Administration week-day(effective)		
	98-7(7)	102-7(7)	104-7(7)
Control	4.2± 0.6	4.7± 0.7	4.3± 0.7
500 ppm	4.5± 0.9	4.7± 0.7	4.4± 0.8
2000 ppm	4.3± 1.0	4.7± 0.9	4.4± 0.8
8000 ppm	3.4± 0.5**	3.8± 0.6**	3.6± 0.6**

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

1,4-ジオキサンのラット及びマウスを用いた  
経口(混水)投与によるがん原性試験

# APPENDIX

(D1~D4)

がん原性試験 NO. 0063 ; 0064



APPENDIX D1

WATER CONSUMPTION CHANGES (SUMMARY)

RAT:MALE

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day (effective)						
	1-7(4)	2-7(4)	3-7(4)	4-7(4)	5-7(4)	6-7(4)	7-7(4)
Control	20.3± 1.2	22.0± 1.7	22.9± 1.4	22.6± 1.3	22.2± 1.5	21.9± 1.2	21.4± 2.4
200 ppm	20.4± 1.3	21.9± 1.3	23.1± 1.5	23.0± 1.3	22.4± 1.3	21.9± 1.4	21.4± 1.4
1000 ppm	20.8± 1.3	22.3± 1.5	23.4± 1.5	23.4± 1.6*	23.0± 1.7*	22.7± 1.3*	22.2± 1.9*
5000 ppm	20.0± 1.3	21.1± 1.6*	22.5± 1.9	22.3± 1.7	22.2± 1.7	21.6± 1.4	20.9± 1.4

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	8-7(4)	9-7(4)	10-7(4)	11-7(4)	12-7(4)	13-7(4)	14-7(4)
Control	21.7± 2.0	20.9± 1.3	20.6± 1.6	20.2± 1.6	20.0± 1.3	19.6± 1.1	19.7± 1.1
200 ppm	21.8± 1.4	21.0± 1.4	20.5± 1.2	20.5± 1.2	20.5± 1.7	20.0± 1.2	19.8± 1.2
1000 ppm	22.5± 1.6**	21.5± 1.4	21.3± 1.7*	20.9± 1.7*	20.7± 1.6	20.4± 1.8*	20.0± 1.6
5000 ppm	21.0± 1.5	20.5± 1.3	20.3± 1.2	19.5± 1.2*	19.3± 1.0*	18.8± 1.0*	18.6± 1.1**

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	16-7(4)	18-7(4)	20-7(4)	22-7(4)	24-7(4)	26-7(4)	28-7(4)
Control	19.5± 2.5	19.1± 1.6	19.2± 2.2	19.5± 3.1	19.3± 2.3	19.0± 1.9	19.7± 1.7
200 ppm	19.1± 1.2	19.1± 1.1	19.2± 1.0	19.1± 1.1	19.1± 1.3	19.0± 1.1	19.2± 1.4
1000 ppm	19.9± 1.5	19.7± 1.5	19.7± 1.5	19.4± 1.4	19.6± 1.5	19.0± 1.3	19.7± 1.3
5000 ppm	18.5± 1.2**	18.5± 1.1*	18.3± 0.9**	18.4± 1.0**	18.4± 1.1**	18.1± 1.0**	18.6± 1.0**

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	30-7(4)	32-7(4)	34-7(4)	36-7(4)	38-7(4)	40-7(4)	42-7(4)
Control	19.3± 1.4	19.3± 1.2	19.2± 1.1	19.2± 1.1	19.0± 1.1	19.2± 1.3	19.1± 1.1
200 ppm	19.2± 1.0	19.1± 1.2	19.2± 1.0	19.1± 1.2	19.1± 1.3	19.0± 1.1	19.0± 1.1
1000 ppm	19.5± 1.3	19.4± 1.1	19.4± 1.2	19.3± 1.1	19.5± 1.3	19.4± 1.2	19.1± 1.1
5000 ppm	18.5± 1.0**	18.7± 1.0*	18.4± 1.0**	18.4± 1.0**	18.6± 1.2	19.0± 1.4	18.8± 1.1

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	44-7(4)	48-7(4)	50-7(4)	52-7(4)	54-7(4)	56-7(4)	58-7(4)
Control	19.2± 1.1	19.6± 1.3	19.6± 1.0	20.1± 1.2	19.3± 1.3	19.8± 1.2	19.1± 1.2
200 ppm	19.0± 1.2	19.3± 1.1	19.4± 1.1	19.5± 1.1*	19.2± 1.2	19.5± 1.1	18.7± 2.4
1000 ppm	19.4± 1.2	19.5± 1.2	19.9± 1.4	20.1± 1.3	19.7± 1.2	19.6± 1.4	19.5± 1.5
5000 ppm	18.9± 1.0	19.3± 1.1	19.5± 1.3	19.7± 1.0	19.2± 1.2	19.5± 1.3	19.7± 1.5

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	60-7(4)	62-7(4)	64-7(4)	66-7(4)	68-7(4)	70-7(4)	72-7(4)
Control	19.5± 1.4	19.8± 1.2	19.8± 1.4	19.6± 1.2	19.5± 1.4	19.7± 1.3	20.2± 1.6
200 ppm	19.2± 1.6	19.5± 2.0	19.6± 3.3	19.5± 1.4	19.4± 1.3	19.1± 2.7	20.1± 1.6
1000 ppm	19.3± 1.6	19.9± 1.5	19.6± 2.0	19.7± 2.0	19.6± 1.3	19.7± 1.5	20.0± 1.7
5000 ppm	19.1± 1.2	19.8± 1.2	19.4± 1.2	19.4± 1.4	19.3± 1.4	19.4± 1.5	20.1± 1.6

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	74-7(4)	76-7(4)	78-7(4)	80-7(4)	82-7(4)	84-7(4)	86-7(4)
Control	20.7± 1.8	20.8± 1.9	20.9± 2.2	21.3± 2.2	21.2± 2.2	21.6± 2.6	21.6± 3.3
200 ppm	20.3± 1.7	20.4± 1.5	20.3± 2.0	20.1± 1.8*	20.6± 1.9	21.0± 2.7	21.2± 2.6
1000 ppm	20.6± 1.6	20.5± 2.0	20.2± 2.3	20.0± 2.9	21.1± 2.1	21.2± 2.2	22.1± 2.8
5000 ppm	20.1± 1.5	20.6± 1.7	20.3± 1.9	20.6± 3.4	20.9± 4.0	21.4± 3.3	21.7± 4.0

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



STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : AI 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	88-7(4)	90-7(4)	92-7(4)	94-7(4)	96-7(4)	100-7(4)	102-7(4)
Control	22.4± 3.1	22.6± 4.5	23.0± 5.0	22.5± 3.8	22.6± 4.9	23.5± 5.8	24.5± 5.0
200 ppm	22.1± 3.1	22.1± 2.8	22.7± 3.3	22.2± 3.6	22.4± 3.7	23.8± 4.8	23.7± 4.1
1000 ppm	23.2± 3.6	23.1± 3.8	22.9± 3.2	23.2± 3.9	23.0± 3.9	24.5± 4.2	24.4± 5.2
5000 ppm	22.2± 3.6	22.1± 4.1	22.4± 4.5	22.5± 4.3	22.8± 5.6	24.7± 6.3	24.2± 6.9

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

STUDY NO. : 0063  
ANIMAL : RAT F344  
UNIT : g  
REPORT TYPE : A1 104  
SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

---

Group Name	Administration week-day(effective)
	104-7(4)

---

Control	23.5± 5.1
200 ppm	23.5± 4.4
1000 ppm	24.8± 5.5
5000 ppm	24.3± 6.5

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

APPENDIX D2

WATER CONSUMPTION CHANGES (SUMMARY)

RAT:FEMALE

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : AI 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	1-7(4)	2-7(4)	3-7(4)	4-7(4)	5-7(4)	6-7(4)	7-7(4)
Control	17.6± 2.3	19.1± 5.1	19.1± 4.9	19.7± 5.8	18.4± 2.6	19.5± 5.2	19.2± 5.7
200 ppm	17.9± 1.3	19.0± 2.4	19.9± 3.7*	20.1± 4.3	20.7± 5.3	20.4± 4.7	21.2± 5.9
1000 ppm	18.2± 3.0	18.3± 2.2	19.7± 4.2	19.4± 4.3	19.5± 5.0	19.1± 2.9	19.0± 3.4
5000 ppm	17.4± 2.8	17.7± 2.6	18.1± 2.7	17.4± 2.2*	18.6± 4.2	18.3± 4.1	19.5± 6.7

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	8-7(4)	9-7(4)	10-7(4)	11-7(4)	12-7(4)	13-7(4)	14-7(4)
Control	20.4± 5.7	18.6± 3.5	18.9± 5.2	19.2± 5.9	19.6± 5.5	20.7± 7.6	18.8± 5.6
200 ppm	21.4± 5.7	21.9± 6.2	21.4± 6.1	21.3± 5.9	22.3± 6.2*	22.6± 6.6*	20.8± 5.3
1000 ppm	19.7± 3.1	19.9± 4.8	19.2± 2.7	18.2± 2.5	19.3± 3.9	20.2± 5.9	19.7± 5.5
5000 ppm	19.8± 5.0	19.1± 5.4	19.0± 4.4	18.2± 3.7	18.9± 4.4	18.4± 3.5	18.7± 4.6

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	16-7(4)	18-7(4)	20-7(4)	22-7(4)	24-7(4)	26-7(4)	28-7(4)
Control	19.2± 5.0	18.7± 4.9	19.3± 6.3	18.1± 3.3	19.1± 5.2	17.6± 4.1	18.2± 3.5
200 ppm	20.9± 5.6	21.4± 6.0	21.2± 5.7	21.0± 5.2	20.5± 5.4	20.3± 5.0	20.5± 4.9
1000 ppm	19.9± 5.8	19.1± 4.9	20.1± 5.4	19.6± 5.7	19.8± 6.5	18.6± 4.5	19.0± 4.3
5000 ppm	19.2± 5.4	18.5± 5.5	19.0± 4.8	19.2± 5.3	19.3± 5.8	19.6± 6.7	19.5± 6.0

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	30-7(4)	32-7(4)	34-7(4)	36-7(4)	38-7(4)	40-7(4)	42-7(4)
Control	17.9± 4.0	18.2± 4.6	17.7± 4.0	17.9± 5.1	17.9± 3.4	17.6± 3.5	18.4± 4.7
200 ppm	19.3± 4.1	21.0± 5.9	19.2± 3.7	19.9± 5.0	20.4± 6.0	19.8± 5.0	19.2± 4.5
1000 ppm	19.8± 5.9	20.2± 5.7	18.9± 4.4	18.4± 4.8	18.7± 5.1	18.9± 4.9	18.2± 3.9
5000 ppm	18.7± 4.6	19.5± 4.9	18.4± 4.8	19.4± 4.7	20.0± 6.1	19.3± 4.8	18.8± 4.0

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 14

Group Name	Administration week-day(effective)						
	44-7(4)	48-7(4)	50-7(4)	52-7(4)	54-7(4)	56-7(4)	58-7(4)
Control	17.9± 4.8	17.8± 4.2	17.5± 4.2	17.7± 3.0	16.6± 2.0	16.7± 2.2	16.1± 3.1
200 ppm	19.3± 4.6	19.0± 3.9	18.4± 4.4	18.3± 2.8	18.3± 3.8*	18.0± 3.6	17.1± 3.7
1000 ppm	17.9± 3.9	17.6± 3.1	17.3± 2.1	18.2± 4.0	17.6± 3.7	17.7± 3.6	16.6± 3.2
5000 ppm	19.3± 4.5	19.0± 4.2	19.1± 3.8**	19.4± 4.0	18.7± 4.3*	17.8± 2.8	17.5± 3.1

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

(HAN260)

BAIS 2



STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	60-7(4)	62-7(4)	64-7(4)	66-7(4)	68-7(4)	70-7(4)	72-7(4)
Control	16.4± 2.3	16.3± 2.0	16.6± 3.3	17.0± 3.2	17.1± 2.5	17.2± 4.0	18.1± 2.5
200 ppm	17.3± 3.6	17.9± 3.9	18.6± 5.2	17.7± 4.0	17.9± 4.0	18.4± 4.2	18.9± 4.0
1000 ppm	16.4± 2.6	16.8± 2.8	16.9± 2.6	17.1± 2.4	16.7± 2.2	16.9± 2.1	17.3± 2.8
5000 ppm	17.1± 2.7	17.3± 2.4	17.4± 2.9	17.6± 2.7	17.9± 3.0	17.6± 2.4	18.1± 3.0

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	74-7(4)	76-7(4)	78-7(4)	80-7(4)	82-7(4)	84-7(4)	86-7(4)
Control	18.6± 3.6	18.7± 2.2	18.7± 2.7	18.6± 2.4	19.4± 3.5	20.0± 3.2	20.1± 3.2
200 ppm	19.3± 4.5	19.6± 4.7	19.3± 4.1	19.3± 4.0	20.3± 4.9	21.6± 5.6	20.9± 4.7
1000 ppm	18.0± 4.0	19.1± 4.4	18.2± 2.4	18.5± 2.7	18.8± 3.4	19.3± 3.3	19.9± 3.7
5000 ppm	18.2± 2.7	18.8± 3.0	18.8± 3.6	18.3± 3.3	18.9± 4.3	19.3± 3.4	19.3± 3.3

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	88-7(4)	90-7(4)	92-7(4)	94-7(4)	96-7(4)	100-7(4)	102-7(4)
Control	20.7± 5.0	21.3± 3.6	21.2± 3.4	21.5± 4.1	21.5± 4.6	24.3± 5.7	24.7± 5.0
200 ppm	21.6± 5.9	22.3± 5.7	22.3± 6.7	23.5± 5.6	22.3± 4.7	21.9± 6.3	22.9± 6.5
1000 ppm	20.5± 3.4	21.2± 3.1	20.7± 3.5	21.1± 4.3	21.6± 3.9	22.4± 5.4	24.0± 5.9
5000 ppm	20.6± 4.9	19.6± 4.5	19.9± 3.6	20.8± 4.6	20.0± 4.3	19.8± 6.9	20.5± 6.0

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

STUDY NO. : 0063  
ANIMAL : RAT F344  
UNIT : g  
REPORT TYPE : A1 104  
SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 18

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Group Name	Administration week-day(effective)
	104-7(4)

---

Control	23.6± 4.9
200 ppm	23.1± 6.6
1000 ppm	23.3± 5.4
5000 ppm	20.6± 6.0

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

(HAN260)

BAIS 2

APPENDIX D3

WATER CONSUMPTION CHANGES (SUMMARY)

MOUSE:MALE

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	1-7(4)	2-7(4)	3-7(4)	4-7(4)	5-7(4)	6-7(4)	7-7(4)
Control	4.8± 0.7	4.7± 0.7	4.4± 0.5	4.3± 0.5	4.3± 0.5	4.2± 0.4	4.1± 0.5
500 ppm	4.8± 0.5	4.6± 0.6	4.3± 0.4	4.3± 0.5	4.2± 0.6	4.1± 0.5	4.0± 0.6
2000 ppm	4.6± 0.5	4.4± 0.5*	4.2± 0.5*	4.0± 0.5**	4.0± 0.5	4.0± 0.5	3.8± 0.5
8000 ppm	3.4± 0.5**	3.4± 0.5**	3.4± 0.5**	3.2± 0.5**	3.3± 0.6**	3.2± 0.5**	3.2± 0.5**

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	8-7(4)	9-7(4)	10-7(4)	11-7(4)	12-7(4)	13-7(4)	14-7(4)
Control	4.1± 0.6	3.9± 0.4	3.9± 0.5	3.8± 0.3	3.8± 0.4	3.7± 0.4	3.6± 0.4
500 ppm	4.0± 0.7	3.9± 0.5	4.0± 0.5	3.8± 0.4	3.8± 0.4	3.7± 0.4	3.7± 0.4
2000 ppm	3.8± 0.5	3.8± 0.5	3.9± 0.6	3.6± 0.5*	3.7± 0.5	3.7± 0.4	3.6± 0.4
8000 ppm	3.2± 0.6**	3.2± 0.5**	3.1± 0.4**	3.1± 0.5**	3.1± 0.5**	3.2± 0.5**	3.0± 0.4**

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	16-7(4)	18-7(4)	20-7(4)	22-7(4)	24-7(4)	26-7(4)	28-7(4)
Control	3.9± 0.4	3.7± 0.3	3.8± 0.6	3.8± 0.4	3.9± 0.5	4.1± 0.5	3.8± 0.4
500 ppm	3.9± 0.6	3.8± 0.4	3.9± 0.4	3.9± 0.4	3.9± 0.4	4.0± 0.4	3.9± 0.4
2000 ppm	3.8± 0.4	3.7± 0.4	3.7± 0.4	3.8± 0.5	3.7± 0.4	3.9± 0.4	3.8± 0.4
8000 ppm	3.1± 0.4**	3.1± 0.4**	3.1± 0.3**	3.2± 0.4**	3.2± 0.3**	3.4± 0.4**	3.2± 0.4**

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



STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	30-7(4)	32-7(4)	34-7(4)	36-7(4)	38-7(4)	40-7(4)	42-7(4)
Control	4.0± 0.4	3.9± 0.4	4.1± 0.6	4.1± 0.5	4.0± 0.5	3.9± 0.5	3.8± 0.4
500 ppm	4.0± 0.3	3.8± 0.4	4.1± 0.4	4.1± 0.4	4.0± 0.4	3.8± 0.4	3.6± 0.3
2000 ppm	3.9± 0.4	3.7± 0.4**	4.0± 0.5	4.0± 0.4	3.9± 0.4	3.8± 0.4	3.6± 0.5
8000 ppm	3.3± 0.3**	3.1± 0.4**	3.5± 0.3**	3.3± 0.5**	3.2± 0.3**	3.2± 0.4**	3.1± 0.5**

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	44-7(4)	46-7(4)	48-7(4)	50-7(4)	52-7(4)	54-7(4)	56-7(4)
Control	3.9± 0.5	3.8± 0.5	3.9± 0.4	3.9± 0.4	4.0± 0.4	4.0± 0.4	4.1± 0.3
500 ppm	3.8± 0.4	3.7± 0.4	3.8± 0.3	3.9± 0.5	4.0± 0.4	4.0± 0.4	4.0± 0.4
2000 ppm	3.7± 0.5	3.6± 0.4*	3.7± 0.4	3.7± 0.4	3.9± 0.5	3.8± 0.5	3.9± 0.5*
8000 ppm	2.9± 0.3**	2.9± 0.3**	3.0± 0.3**	3.0± 0.3**	3.1± 0.4**	3.0± 0.4**	3.0± 0.5**

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	58-7(4)	60-7(4)	62-7(4)	64-7(4)	66-7(4)	68-7(4)	70-7(4)
Control	4.1± 0.4	4.1± 0.4	4.2± 0.5	4.3± 0.6	4.3± 0.5	4.6± 0.6	4.5± 0.6
500 ppm	4.0± 0.4	4.0± 0.4	4.1± 0.4	4.2± 0.4	4.2± 0.4	4.4± 0.4	4.4± 0.4
2000 ppm	4.0± 0.5	4.0± 0.5	4.0± 0.5	4.1± 0.6	4.2± 0.7	4.3± 0.6	4.4± 0.7
8000 ppm	3.0± 0.5**	2.7± 0.4**	3.1± 0.3**	3.0± 0.4**	3.0± 0.5**	3.2± 0.4**	3.2± 0.4**

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	72-7(4)	74-7(4)	76-7(4)	78-7(4)	80-7(4)	82-7(4)	84-7(4)
Control	4.7± 0.6	4.5± 0.7	4.6± 0.7	4.7± 0.6	4.8± 0.8	4.8± 0.7	4.9± 0.8
500 ppm	4.4± 0.6	4.4± 0.7	4.6± 0.5	4.5± 0.5	4.6± 0.7	4.8± 0.9	4.9± 1.1
2000 ppm	4.4± 0.7	4.5± 0.7	4.4± 0.9	4.5± 0.6	4.6± 0.8	4.7± 1.0	4.6± 1.0
8000 ppm	3.3± 0.5**	3.4± 0.4**	3.3± 0.5**	3.5± 0.7**	3.4± 0.8**	3.6± 1.0**	3.3± 0.5**

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	86-7(4)	88-7(4)	90-7(4)	92-7(4)	94-7(4)	96-7(4)	98-7(4)
Control	4.9± 0.8	4.7± 0.9	4.7± 0.8	5.0± 0.8	5.0± 0.7	5.0± 0.9	5.1± 0.9
500 ppm	4.8± 1.0	4.9± 0.7	5.0± 0.9	4.8± 0.8	4.8± 0.8	4.9± 1.0	4.7± 1.0
2000 ppm	4.7± 1.0	4.7± 0.9	4.8± 1.2	4.5± 1.1	4.7± 0.9	4.5± 0.7	4.8± 0.8
8000 ppm	3.4± 0.7**	3.4± 0.6**	3.4± 0.6**	3.5± 0.6**	3.3± 0.5**	3.4± 0.7**	3.4± 0.8**

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

Test of Dunnett

STUDY NO. : 0064  
ANIMAL : MOUSE BDF1  
UNIT : g  
REPORT TYPE : A1 104  
SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

Group Name	Administration week-day(effective)		
	100-7(4)	102-7(4)	104-7(4)
Control	5.1± 0.6	5.1± 1.0	5.1± 0.6
500 ppm	5.0± 0.8	4.9± 0.7	4.7± 0.6
2000 ppm	4.8± 1.1	4.8± 1.1	4.7± 1.0
8000 ppm	3.5± 0.9**	3.7± 1.3**	3.3± 0.9**

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

APPENDIX D4

WATER CONSUMPTION CHANGES (SUMMARY)

MOUSE : FEMALE

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	1-7(4)	2-7(4)	3-7(4)	4-7(4)	5-7(4)	6-7(4)	7-7(4)
Control	4.5± 0.4	4.4± 0.7	4.3± 0.6	4.2± 0.5	4.4± 0.7	4.3± 0.8	4.3± 0.6
500 ppm	4.5± 0.4	4.4± 0.5	4.4± 0.5	4.3± 0.6	4.5± 0.6	4.4± 0.7	4.3± 0.7
2000 ppm	4.6± 0.4	4.5± 0.6	4.4± 0.7	4.6± 0.7	4.9± 0.9	4.7± 0.8	4.6± 0.7
8000 ppm	3.5± 0.4**	3.5± 0.5**	3.6± 0.7**	3.5± 0.4**	3.5± 0.4**	3.6± 0.4**	3.5± 0.5**

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

Test of Dunnett



STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration 8-7(4)	week-day(effective) 9-7(4)	10-7(4)	11-7(4)	12-7(4)	13-7(4)	14-7(4)
Control	4.3± 0.5	4.4± 0.6	4.4± 0.6	4.5± 0.8	4.5± 0.9	4.3± 0.7	4.3± 0.6
500 ppm	4.3± 0.7	4.3± 0.7	4.4± 0.9	4.3± 0.6	4.3± 0.8	4.1± 0.5	4.2± 0.7
2000 ppm	4.8± 1.0	4.6± 0.8	4.7± 0.9	4.4± 0.8	4.4± 0.8	4.1± 0.7	4.2± 0.7
8000 ppm	3.5± 0.4**	3.5± 0.4**	3.6± 0.4**	3.5± 0.4**	3.5± 0.4**	3.4± 0.5**	3.4± 0.4**

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	16-7(4)	18-7(4)	20-7(4)	22-7(4)	24-7(4)	26-7(4)	28-7(4)
Control	4.3± 0.8	4.3± 0.5	4.0± 0.5	4.4± 0.5	4.4± 0.7	4.5± 0.6	4.3± 0.6
500 ppm	4.1± 0.7	4.3± 0.5	4.0± 0.5	4.5± 0.8	4.3± 0.7	4.4± 0.7	4.4± 0.9
2000 ppm	4.3± 0.8	4.4± 0.8	4.2± 0.6	4.7± 0.9	4.4± 0.7	4.4± 0.6	4.4± 0.9
8000 ppm	3.6± 0.7**	3.4± 0.3**	3.4± 0.3**	3.5± 0.3**	3.5± 0.2**	3.6± 0.5**	3.5± 0.4**

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	30-7(4)	32-7(4)	34-7(4)	36-7(4)	38-7(4)	40-7(4)	42-7(4)
Control	4.3± 0.6	4.2± 0.6	4.4± 0.8	4.2± 0.6	4.3± 0.7	4.1± 0.6	3.9± 0.5
500 ppm	4.1± 0.6	4.1± 0.7	4.3± 0.5	4.3± 0.7	4.1± 0.5	4.2± 0.9	4.0± 0.9
2000 ppm	4.4± 0.8	4.0± 0.7	4.3± 0.8	4.2± 0.8	4.3± 1.0	4.1± 0.8	3.9± 0.8
8000 ppm	3.6± 0.6**	3.4± 0.6**	3.5± 0.5**	3.5± 0.6**	3.4± 0.4**	3.3± 0.4**	3.1± 0.4**

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	44-7(4)	46-7(4)	48-7(4)	50-7(4)	52-7(4)	54-7(4)	56-7(4)
Control	4.0± 0.7	4.0± 0.6	3.9± 0.6	3.9± 0.6	3.9± 0.5	4.0± 0.8	3.9± 0.5
500 ppm	4.0± 0.7	4.1± 0.8	4.0± 0.9	4.1± 0.8	3.9± 0.6	4.0± 0.5	3.9± 0.7
2000 ppm	4.1± 0.8	4.2± 0.8	4.2± 1.0	4.1± 0.7	3.7± 0.5	3.9± 1.0	3.8± 0.8
8000 ppm	3.3± 0.6**	3.1± 0.2**	3.0± 0.3**	3.1± 0.3**	2.9± 0.3**	2.9± 0.3**	2.8± 0.3**

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	58-7(4)	60-7(4)	62-7(4)	64-7(4)	66-7(4)	68-7(4)	70-7(4)
Control	4.0± 0.6	4.0± 0.5	3.7± 0.8	4.3± 0.6	4.1± 0.6	4.3± 0.8	4.2± 0.5
500 ppm	4.0± 0.9	4.0± 0.7	3.5± 0.6	4.1± 0.7	4.0± 0.7	4.0± 0.6	4.2± 0.6
2000 ppm	3.9± 0.7	4.1± 0.8	3.8± 0.7	4.1± 0.7	3.9± 0.6	4.1± 0.7	4.1± 1.0
8000 ppm	2.8± 0.3**	2.7± 0.3**	2.7± 0.3**	2.9± 0.4**	2.8± 0.5**	2.7± 0.4**	2.8± 0.4**

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	72-7(4)	74-7(4)	76-7(4)	78-7(4)	80-7(4)	82-7(4)	84-7(4)
Control	4.3± 0.7	4.3± 0.8	4.5± 0.8	4.3± 0.9	4.3± 0.7	4.5± 0.8	4.5± 0.8
500 ppm	4.1± 0.7	4.3± 0.9	4.2± 0.9	4.4± 1.0	4.3± 0.7	4.6± 1.1	4.5± 1.2
2000 ppm	4.2± 0.9	4.5± 1.0	4.6± 1.0	4.2± 1.0	4.4± 1.0	4.5± 1.1	4.3± 0.8
8000 ppm	2.7± 0.4**	2.8± 0.7**	2.7± 0.4**	2.5± 0.3**	2.6± 0.3**	2.7± 0.3**	2.5± 0.6**

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)						
	86-7(4)	88-7(4)	90-7(4)	92-7(4)	94-7(4)	96-7(4)	98-7(4)
Control	4.5± 0.8	4.6± 0.9	4.5± 1.0	4.6± 1.2	4.4± 1.0	4.6± 0.9	4.7± 0.9
500 ppm	4.7± 0.9	4.5± 1.0	4.2± 0.9	4.3± 0.8	4.2± 1.0	4.5± 1.0	4.3± 1.0
2000 ppm	4.5± 0.9	4.3± 0.8	4.3± 0.9	4.2± 0.8	4.0± 0.9	4.3± 0.7	4.2± 1.0
8000 ppm	2.7± 0.3**	2.6± 0.3**	2.5± 0.3**	2.4± 0.3**	2.5± 0.4**	2.5± 0.4**	2.6± 0.3**

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

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

Group Name	Administration week-day(effective)		
	100-7(4)	102-7(4)	104-7(4)
Control	4.6± 1.0	4.5± 1.1	4.6± 1.1
500 ppm	4.5± 0.8	4.2± 0.9	4.1± 0.9
2000 ppm	4.4± 1.1	4.0± 0.9	3.8± 0.7**
8000 ppm	2.6± 0.5**	2.6± 0.5**	2.6± 0.6**

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



1,4-ジオキサンのラット及びマウスを用いた  
経口(混水)投与によるがん原性試験

# APPENDIX

(E1~E4)

がん原性試験 NO. 0063 ; 0064

APPENDIX E1

HEMATOLOGY (SUMMARY)

RAT:MALE

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE

HEMATOLOGY(1) (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	RED BLOOD CELL 10 <sup>6</sup> /μℓ		HEMOGLOBIN g/dℓ		HEMATOCRIT %		MCV fℓ		PLATELET 10 <sup>3</sup> /μℓ	
Control	39	9.31±	1.17	17.0±	2.1	46.2±	5.9	49.5±	1.9	898±	164
200 ppm	45	9.09±	1.37	16.5±	2.3	44.8±	6.6	49.3±	2.7	957±	145
1000 ppm	35	8.34±	1.79*	14.9±	3.1**	40.6±	8.7**	48.8±	4.5	1045±	203**
5000 ppm	22	7.91±	1.78**	13.1±	2.3**	35.7±	6.4**	45.8±	4.2**	1005±	280**

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE

HEMATOLOGY(2) (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO	BASO	MONO	Lympho	OTHER					
Control	39	7.83±	7.31	0±	0	48±	10	1±	1	0±	0	8±	2	42±	9	1±	2
200 ppm	45	7.69±	5.55	0±	0	47±	9	2±	1*	0±	0	7±	2	42±	8	1±	2
1000 ppm	35	9.20±	14.88	0±	1	50±	12	1±	1	0±	0	7±	2	39±	10	2±	3
5000 ppm	22	21.69±	62.81	0±	1	51±	19	1±	1	0±	0	6±	3	37±	14	4±	11

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

Test of Dunnett

APPENDIX E2

HEMATOLOGY (SUMMARY)

RAT:FEMALE

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	RED BLOOD CELL 10 <sup>6</sup> /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		PLATELET 10 <sup>3</sup> /μl	
Control	38	7.99±	1.34	15.9±	1.7	43.0±	4.8	54.9±	8.2	732±	174
200 ppm	36	7.89±	1.60	15.5±	2.7	41.8±	7.3	54.1±	7.4	755±	138
1000 ppm	38	7.98±	1.36	15.6±	2.0	42.3±	5.8	53.6±	4.6	753±	121
5000 ppm	23	7.94±	1.80	13.6±	2.4**	37.3±	6.4**	48.9±	9.9**	931±	264**

Significant difference ; \* : P ≤ 0.05

\*\* : P ≤ 0.01

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential N-BAND	WBC	(% N-SEG		EOSINO	BASO	MONO	LYMPHO	OTHER					
Control	38	6.44±	7.92	0±	1	45±	13	2±	1	0±	0	6±	2	46±	13	1±	2
200 ppm	36	9.18±	27.27	0±	1	43±	11	2±	1	0±	0	6±	2	46±	8	2±	6
1000 ppm	38	7.29±	12.65	0±	1	42±	14	1±	1*	0±	0	6±	2	48±	12	3±	9
5000 ppm	23	10.12±	16.89	0±	1	47±	14	1±	1*	0±	0	6±	2	42±	10	4±	9

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

Test of Dunnett

(JCL71A)

BAIS 2

APPENDIX E3

HEMATOLOGY (SUMMARY)

MOUSE:MALE



STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE

HEMATOLOGY(1) (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	RED BLOOD CELL		HEMOGLOBIN		HEMATOCRIT		MCV		PLATELET	
		$10^6/\mu\ell$		$g/d\ell$		%		$f\ell$		$10^9/\mu\ell$	
Control	31	9.63±	1.68	13.9±	2.0	40.2±	6.2	41.9±	2.1	1874±	556
500 ppm	33	9.84±	1.07	13.9±	1.3	40.0±	4.3	40.6±	2.0	2096±	422
2000 ppm	24	10.22±	1.55	14.3±	2.0	41.2±	5.3	40.4±	2.8	2069±	491
8000 ppm	26	10.88±	1.70**	15.4±	2.2*	45.5±	7.2**	41.8±	3.1	1601±	760

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

\*\* :  $P \leq 0.01$

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE

HEMATOLOGY(2) (SUMMARY)  
 SURVIVAL ANIMALS (104)

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	31	3.43±	2.01	0±	0	37±	10	1±	1	0±	0	5±	3	55±	10	1±	1
500 ppm	33	3.46±	1.32	0±	0	36±	14	1±	1	0±	0	6±	2	56±	14	1±	1
2000 ppm	24	4.15±	2.23	0±	0	34±	11	1±	1	0±	0	6±	3	58±	10	1±	1
8000 ppm	26	3.13±	1.27	0±	1	47±	20	0±	1**	0±	0	5±	3	47±	19	1±	1

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

Test of Dunnett

(JCL71A)

BAIS 2

APPENDIX E4

HEMATOLOGY (SUMMARY)

MOUSE:FEMALE

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	RED BLOOD CELL		HEMOGLOBIN		HEMATOCRIT		MCV		PLATELET	
		$10^6/\mu\ell$		$g/dl$		%		$f\ell$		$10^3/\mu\ell$	
Control	24	9.98±	0.69	14.8±	0.9	42.7±	2.8	42.8±	1.4	1326±	387
500 ppm	28	9.81±	1.22	14.5±	1.6	41.7±	4.9	42.5±	1.5	1215±	377
2000 ppm	16	9.77±	1.83	14.6±	2.6	42.7±	7.6	43.9±	2.7	901±	435**
8000 ppm	04	10.62±	1.24	16.4±	1.8	48.2±	4.9	45.4±	2.6	520±	317**

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μℓ		Differential N-BAND		WBC (%) N-SEG	EOSINO	BASO	MONO	LYMPHO	OTHER						
Control	24	2.85±	1.67	0±	1	37±	13	1±	1	0±	0	6±	2	54±	15	2±	2
500 ppm	28	2.58±	1.40	0±	1	32±	14	1±	1	0±	0	5±	3	61±	15	1±	1
2000 ppm	16	3.30±	1.30	1±	1	39±	17	1±	2	0±	0	6±	3	52±	18	1±	2
8000 ppm	04	1.95±	0.30	1±	2	45±	22	1±	1	0±	0	4±	2	48±	23	0±	1

Significant difference : \* : P ≤ 0.05    \*\* : P ≤ 0.01    Test of Dunnett

1,4-ジオキサンのラット及びマウスを用いた  
経口(混水)投与によるがん原性試験

# APPENDIX

(F1~F4)

がん原性試験 NO. 0053 ; 0054

APPENDIX F1

BIOCHEMISTRY (SUMMARY)

RAT:MALE

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE

BIOCHEMISTRY (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	TOTAL PROTEIN		ALBUMIN		A/G RATIO		T-BILIRUBIN		GLUCOSE		T-CHOLESTEROL		TRIGLYCERIDE	
		g/dl		g/dl				mg/dl		mg/dl		mg/dl		mg/dl	
Control	40	6.8±	0.5	3.3±	0.3	0.9±	0.1	0.24±	0.04	170±	22	161±	37	179±	114
200 ppm	45	6.9±	0.3	3.3±	0.2	0.9±	0.1	0.26±	0.08	167±	19	166±	66	208±	234
1000 ppm	35	6.7±	0.4	3.2±	0.3	0.9±	0.1	0.23±	0.04	161±	25	161±	51	166±	127
5000 ppm	22	6.5±	0.6**	3.0±	0.3**	0.9±	0.1	0.41±	0.54	149±	23**	192±	72	170±	164

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

Test of Dunnett



STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE

BIOCHEMISTRY (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	PHOSPHOLIPID		GOT		GPT		LDH		ALP		LAP		G-GTP	
		mg/dl		I U/l		I U/l		I U/l		I U/l		I U/l		I U/l	
Control	40	245±	58	67±	23	18±	6	158±	38	218±	271	50±	7	6±	2
200 ppm	45	251±	108	68±	26	19±	9	175±	67	188±	99	50±	6	7±	4
1000 ppm	35	247±	78	68±	24	20±	9	172±	115	199±	93	49±	8	8±	5
5000 ppm	22	309±	128*	172±	125**	68±	72**	293±	286*	307±	192**	53±	10	57±	29**

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE

BIOCHEMISTRY (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	CPK		UREA NITROGEN		CREATININE		SODIUM		POTASSIUM		CHLORIDE		CALCIUM	
		I U / l		mg / dl		mg / dl		mEq / l		mEq / l		mEq / l		mg / dl	
Control	40	77 ±	21	24.9 ±	15.8	0.7 ±	0.2	141 ±	2	3.7 ±	0.3	107 ±	2	10.6 ±	0.3
200 ppm	45	75 ±	15	22.0 ±	4.8	0.7 ±	0.2	141 ±	1	3.7 ±	0.3	107 ±	2	10.7 ±	0.4
1000 ppm	35	76 ±	19	22.2 ±	3.8	0.7 ±	0.1	141 ±	1	3.8 ±	0.3	107 ±	2	10.7 ±	0.5
5000 ppm	22	99 ±	46*	22.9 ±	6.6	0.7 ±	0.2	141 ±	2	3.9 ±	0.4*	107 ±	2	10.7 ±	0.5

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

Test of Dunnett

STUDY NO. : 0063  
ANIMAL : RAT F344  
REPORT TYPE : A1  
SEX : MALE

BIOCHEMISTRY (SUMMARY)  
SURVIVAL ANIMALS (104)

PAGE : 4

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Group Name	NO. of Animals	INORGANIC PHOSPHORUS mg/dl	
Control	40	3.9±	1.2
200 ppm	45	3.9±	0.7
1000 ppm	35	3.9±	0.7
5000 ppm	22	4.5±	0.6**

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

Test of Dunnett

(HCL074)

BAIS2

APPENDIX F2

BIOCHEMISTRY (SUMMARY)

RAT:FEMALE

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
 SURVIVAL ANIMALS (104)

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	7.1±	0.4	3.7±	0.3	1.1±	0.1	0.28±	0.26	166±	19	144±	37	147±	131
200 ppm	36	7.0±	0.5	3.7±	0.4	1.1±	0.1	0.22±	0.04	160±	26	138±	26	163±	181
1000 ppm	38	7.0±	0.5	3.6±	0.3	1.1±	0.1	0.22±	0.08	163±	17	137±	22	122±	74
5000 ppm	23	7.0±	1.0	3.4±	0.5	1.0±	0.1**	0.50±	0.86**	143±	23**	241±	68**	186±	159

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

\*\* :  $P \leq 0.01$

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT IU/l		GPT IU/l		LDH IU/l		ALP IU/l		LAP IU/l		G-GTP IU/l	
Control	38	258±	69	122±	72	32±	17	211±	107	149±	103	44±	6	4±	6
200 ppm	36	250±	55	117±	75	32±	18	201±	106	144±	117	43±	6	4±	2
1000 ppm	38	247±	45	118±	66	34±	17	239±	268	130±	55	45±	5	5±	8
5000 ppm	23	419±	113**	813±	1514**	244±	345**	712±	1270**	338±	244**	71±	33**	70±	39**

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	CPK		UREA NITROGEN		CREATININE		SODIUM		POTASSIUM		CHLORIDE		CALCIUM	
		I U / ℓ		mg / dl		mg / dl		mEq / ℓ		mEq / ℓ		mEq / ℓ		mg / dl	
Control	38	73±	23	18.9±	4.4	0.5±	0.1	140±	2	3.6±	0.4	105±	3	10.6±	0.4
200 ppm	36	78±	27	17.6±	3.6	0.5±	0.1	140±	2	3.6±	0.4	105±	2	10.5±	0.3
1000 ppm	38	79±	29	17.4±	2.3	0.5±	0.1**	140±	1	3.7±	0.5	105±	2	10.6±	0.5
5000 ppm	23	138±	85**	21.4±	6.4	0.5±	0.1	139±	3	4.0±	0.5*	107±	3	10.8±	0.5

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

\*\* :  $P \leq 0.01$

Test of Dunnett

STUDY NO. : 0063  
ANIMAL : RAT F344  
REPORT TYPE : A1  
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
SURVIVAL ANIMALS (104)

PAGE : 8

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Group Name	NO. of Animals	INORGANIC PHOSPHORUS mg/dl	
Control	38	3.7±	1.2
200 ppm	36	3.6±	0.7
1000 ppm	38	3.7±	0.8
5000 ppm	23	3.8±	1.2

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

Test of Dunnett

(HCL074)

BAIS2



APPENDIX F3

BIOCHEMISTRY (SUMMARY)

MOUSE:MALE

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE

BIOCHEMISTRY (SUMMARY)  
 SURVIVAL ANIMALS (104)

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	30	5.6±	0.7	2.9±	0.3	1.1±	0.2	0.54±	0.16	171±	39	116±	49	95±	93
500 ppm	33	5.8±	0.7	2.9±	0.4	1.1±	0.2	0.54±	0.16	163±	38	125±	46	78±	22
2000 ppm	24	5.9±	0.7	2.9±	0.3	1.0±	0.2	0.56±	0.19	148±	47	132±	49	70±	18
8000 ppm	26	5.3±	1.1	2.7±	0.6	1.0±	0.1	0.80±	0.86	91±	41**	111±	80	45±	15**

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

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE

BIOCHEMISTRY (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	PHOSPHOLIPID		GOT		GPT		LDH		ALP		LAP		CPK	
		mg/dl		I U/l		I U/l		I U/l	I U/l		I U/l		I U/l		I U/l
Control	30	206±	57	288±	877	110±	308	1055±	2906	190±	87	68±	30	62±	21
500 ppm	33	230±	74	180±	196	78±	86	590±	338	244±	135	79±	32	85±	97
2000 ppm	24	245±	81	333±	353**	136±	117**	1044±	844**	527±	557**	89±	44	148±	318
8000 ppm	26	184±	125	1994±	4130**	512±	996**	3810±	7624**	795±	541**	95±	31*	156±	110**

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

\*\* :  $P \leq 0.01$

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE

BIOCHEMISTRY (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	UREA NITROGEN mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	30	22.0±	2.9	151±	2	4.6±	0.3	120±	2	8.9±	0.5	6.9±	0.9
500 ppm	33	22.1±	3.2	151±	2	4.6±	0.4	120±	3	9.1±	0.6	7.3±	0.9
2000 ppm	24	21.0±	8.3*	151±	2	4.6±	0.3	120±	3	9.2±	0.7	6.8±	0.8
8000 ppm	26	24.3±	12.4	151±	4	4.8±	0.6	119±	3	8.9±	0.8	6.8±	0.8

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

Test of Dunnett

APPENDIX F4

BIOCHEMISTRY (SUMMARY)

MOUSE:FEMALE

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
 SURVIVAL ANIMALS (104)

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	25	5.1±	0.3	2.7±	0.2	1.2±	0.2	0.56±	0.14	124±	29	69±	19	79±	16
500 ppm	27	5.2±	0.3	2.7±	0.2	1.1±	0.1	0.52±	0.19	117±	20	68±	17	75±	16
2000 ppm	16	4.9±	0.9	2.5±	0.5	1.1±	0.3	0.69±	0.51	87±	39**	65±	15	64±	22*
8000 ppm	04	4.2±	0.9	2.2±	0.4**	1.1±	0.2	0.61±	0.20	61±	26**	45±	12	35±	16**

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

\*\* :  $P \leq 0.01$

Test of Dunnett

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT IU/l		GPT IU/l		LDH IU/l		ALP IU/l		LAP IU/l		CPK IU/l	
Control	25	127±	28	107±	68	29±	17	509±	303	249±	96	60±	11	86±	40
500 ppm	27	134±	32	150±	101	39±	27	503±	200	309±	186	59±	11	103±	65
2000 ppm	16	124±	36	1518±	2757**	441±	918**	6005±	15559**	480±	216**	71±	14**	208±	330
8000 ppm	04	74±	29**	714±	307**	175±	78**	1092±	351**	853±	128**	69±	11	152±	24*

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	UREA NITROGEN		SODIUM		POTASSIUM		CHLORIDE		CALCIUM		INORGANIC PHOSPHORUS	
		mg/dl		mEq/l		mEq/l		mEq/l		mg/dl		mg/dl	
Control	25	19.1±	7.6	150±	2	4.6±	0.4	121±	2	8.7±	0.4	7.1±	1.2
500 ppm	27	17.5±	4.6	150±	2	4.5±	0.4	121±	2	8.7±	0.5	7.0±	1.1
2000 ppm	16	19.0±	5.9	149±	2	5.1±	1.3	120±	3	8.6±	0.5	7.7±	0.8
8000 ppm	04	29.3±	15.7	151±	2	4.8±	0.2	121±	3	7.8±	0.4**	6.9±	0.5

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

Test of Dunnett



1,4-ジオキサンのラット及びマウスを用いた  
経口(混水)投与によるがん原性試験

# APPENDIX

(G1~G4)

がん原性試験 NO. 0063 ; 0064

APPENDIX G1

URINALYSIS (SUMMARY)

RAT:MALE

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 SAMPLING DATE : 104-7  
 SEX : MALE

URINALYSIS

REPORT TYPE : A1

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	40	0	0	2	6	22	8	2		0	0	0	0	7	33		40	0	0	0	0	0		34	0	6	0	0	0		40	0	0	0
200 ppm	45	0	2	4	9	16	10	4		0	0	0	0	7	38		45	0	0	0	0	0		42	0	3	0	0	0		45	0	0	0
1000 ppm	35	0	0	6	7	21	1	0		0	0	0	0	6	29		35	0	0	0	0	0		34	0	1	0	0	0		35	0	0	0
5000 ppm	23	0	2	17	2	1	1	0	**	0	0	0	3	5	15		23	0	0	0	0	0		18	0	5	0	0	0		22	0	0	1

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

Test of CHI SQUARE

STUDY NO. : 0063  
ANIMAL : RAT F344  
SAMPLING DATE : 104-7  
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

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Group Name	NO. of Animals	Occult blood					Urobilinogen						
		-	±	+	2+	3+	CHI	±	+	2+	3+	4+	CHI
Control	40	39	0	1	0	0	40	0	0	0	0	0	
200 ppm	45	43	2	0	0	0	45	0	0	0	0	0	
1000 ppm	35	34	0	1	0	0	35	0	0	0	0	0	
5000 ppm	23	20	3	0	0	0	22	1	0	0	0	0	

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

\*\* :  $P \leq 0.01$

Test of CHI SQUARE

(JCL103)

BAIS 2

APPENDIX G2

URINALYSIS (SUMMARY)

RAT:FEMALE

STUDY NO. : 0063

URINALYSIS

ANIMAL : RAT F344

SAMPLING DATE : 104-7

SEX : FEMALE

REPORT TYPE : A1

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	39	0	0	8	3	19	9	0		0	0	1	4	20	14		39	0	0	0	0	0		34	0	5	0	0	0		39	0	0	0
200 ppm	38	0	2	13	7	12	4	0		0	0	1	5	18	14		38	0	0	0	0	0		32	0	6	0	0	0		37	0	0	1
1000 ppm	38	0	1	3	10	11	13	0	*	0	0	1	12	18	7		38	0	0	0	0	0		35	0	3	0	0	0		38	0	0	0
5000 ppm	24	0	7	8	5	3	1	0	**	0	0	0	2	11	11		24	0	0	0	0	0		20	0	4	0	0	0		22	1	0	1

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

Test of CHI SQUARE

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 SAMPLING DATE : 104-7  
 SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	39	37	2	0	0	0		39	0	0	0	0	
200 ppm	38	34	3	0	0	1		37	1	0	0	0	
1000 ppm	38	27	11	0	0	0	**	38	0	0	0	0	
5000 ppm	24	17	6	0	1	0	*	23	0	0	1	0	

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

Test of CHI SQUARE

APPENDIX G3

URINALYSIS (SUMMARY)

MOUSE:MALE



STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 SAMPLING DATE : 104-7  
 SEX : MALE

URINALYSIS

REPORT TYPE : A1

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+		-	±	+	2+
Control	32	0	4	7	10	10	1	0		0	2	25	5	0	0		32	0	0	0	0	0		31	1	0	0		29	2	1	0	0
500 ppm	34	0	5	7	7	12	3	0		0	1	21	12	0	0		34	0	0	0	0	0		33	1	0	0		32	1	0	0	1
2000 ppm	26	0	4	8	7	6	1	0		1	5	17	2	1	0		25	1	0	0	0	0		23	3	0	0		25	0	1	0	0
8000 ppm	26	0	12	14	0	0	0	0	**	0	1	13	9	3	0		26	0	0	0	0	0		23	3	0	0		19	3	2	1	1

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

Test of CHI SQUARE

(JCL104X)

STUDY NO. : 0064

URINALYSIS

ANIMAL : MOUSE BDF1

SAMPLING DATE : 104-7

SEX : MALE

REPORT TYPE : A1

PAGE : 2

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Group Name	NO. of Animals	Urobilinogen				CHI
		±	+	2+	3+ 4+	
Control	32	32	0	0	0	0
500 ppm	34	34	0	0	0	0
2000 ppm	26	26	0	0	0	0
8000 ppm	26	26	0	0	0	0

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

Test of CHI SQUARE

(JCL104X)

BAIS 2

APPENDIX G4

URINALYSIS (SUMMARY)

MOUSE : FEMALE

STUDY NO. : 0064

URINALYSIS

ANIMAL : MOUSE BDF1

SAMPLING DATE : 104-7

SEX : FEMALE

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose				CHI	Ketone body			CHI	Occult blood				CHI					
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+		2+	3+	4+		-	+	2+	3+		-	±	+	2+	3+
Control	29	0	1	8	4	6	8	2		0	0	21	4	3	1		29	0	0	0	0	0		13	16	0	0		28	1	0	0	0	
500 ppm	29	0	0	7	6	9	7	0		0	1	18	9	1	0		29	0	0	0	0	0		13	16	0	0		25	0	2	1	1	
2000 ppm	18	0	3	8	2	4	1	0		0	0	9	9	0	0	*	15	3	0	0	0	0	*	9	9	0	0		12	0	2	1	3	*
8000 ppm	5	0	3	1	1	0	0	0	*	0	0	1	4	0	0	*	4	1	0	0	0	0	*	1	4	0	0		2	0	1	0	2	**

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

Test of CHI SQUARE

(JCL104X)

BAIS2

STUDY NO. : 0064

URINALYSIS

ANIMAL : MOUSE BDF1

SAMPLING DATE : 104-7

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

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Group Name	NO. of Animals	Urobilinogen				CHI
		±	+	2+	3+ 4+	
Control	29	29	0	0	0	0
500 ppm	29	29	0	0	0	0
2000 ppm	18	18	0	0	0	0
8000 ppm	5	3	2	0	0	0 **

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

Test of CHI SQUARE

(JCL104X)

BAIS 2

1,4-ジオキサンのラット及びマウスを用いた  
経口(混水)投与によるがん原性試験

# APPENDIX

(H1~H8)

がん原性試験 NO. 0063 ; 0064

APPENDIX H1

GROSS FINDINGS (SUMMARY)

RAT:MALE:DEAD AND MORIBUND ANIMALS

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 10 (%)	200 ppm 5 (%)	1000 ppm 15 (%)	5000 ppm 28 (%)
skin/app	nodule		0 ( 0)	0 ( 0)	1 ( 7)	1 ( 4)
subcutis	edema		0 ( 0)	1 ( 20)	0 ( 0)	0 ( 0)
	jaundice		0 ( 0)	1 ( 20)	1 ( 7)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	mass		2 ( 20)	1 ( 20)	2 ( 13)	4 ( 14)
nasal cavit	fluid		0 ( 0)	0 ( 0)	1 ( 7)	1 ( 4)
lung/branch	red		3 ( 30)	2 ( 40)	2 ( 13)	6 ( 21)
	white patch/zone		1 ( 10)	0 ( 0)	0 ( 0)	1 ( 4)
	red patch/zone		0 ( 0)	0 ( 0)	1 ( 7)	2 ( 7)
	congestion		0 ( 0)	1 ( 20)	2 ( 13)	2 ( 7)
	edema		0 ( 0)	0 ( 0)	1 ( 7)	1 ( 4)
	nodule		0 ( 0)	0 ( 0)	2 ( 13)	0 ( 0)
lymph node	enlarged		2 ( 20)	1 ( 20)	0 ( 0)	0 ( 0)
	red		0 ( 0)	0 ( 0)	1 ( 7)	3 ( 11)
	red patch/zone		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
thymus	hemorrhage		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
spleen	enlarged		2 ( 20)	1 ( 20)	4 ( 27)	4 ( 14)
	white patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	black patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	nodule		1 ( 10)	1 ( 20)	0 ( 0)	0 ( 0)
	granular		0 ( 0)	1 ( 20)	0 ( 0)	0 ( 0)
heart	white		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)



STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0-104W)

Organ	Findings	Group Name NO. of Animals	Control 10 (%)	200 ppm 5 (%)	1000 ppm 15 (%)	5000 ppm 28 (%)
tongue	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
forestomach	rupture		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
	ulcer		0 ( 0)	0 ( 0)	3 ( 20)	4 ( 14)
	thick		0 ( 0)	0 ( 0)	1 ( 7)	1 ( 4)
gl stomach	red patch/zone		0 ( 0)	0 ( 0)	1 ( 7)	1 ( 4)
	ulcer		1 ( 10)	1 ( 20)	4 ( 27)	4 ( 14)
	fluid		1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)
	thick		1 ( 10)	0 ( 0)	4 ( 27)	4 ( 14)
	abscess		1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)
stomach	hemorrhage		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
duodenum	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
jejunum	dilated		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
ileum	red		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
	dilated		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
small intes	gas		1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)
cecum	dilated		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 7)
colon	dilated		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
rectum	red		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
large intes	gas		1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)
liver	enlarged		1 ( 10)	0 ( 0)	1 ( 7)	2 ( 7)
	pale		0 ( 0)	0 ( 0)	2 ( 13)	1 ( 4)
	white		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0-104W)

Organ	Findings	Group Name NO. of Animals	Control 10 (%)	200 ppm 5 (%)	1000 ppm 15 (%)	5000 ppm 28 (%)
Liver	yellow		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 7)
	white patch/zone		0 ( 0)	0 ( 0)	1 ( 7)	10 ( 36)
	red patch/zone		0 ( 0)	0 ( 0)	2 ( 13)	0 ( 0)
	nodule		1 ( 10)	0 ( 0)	2 ( 13)	16 ( 57)
	cyst		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	granular		1 ( 10)	1 ( 20)	0 ( 0)	2 ( 7)
pancreas	nodule		0 ( 0)	0 ( 0)	1 ( 7)	1 ( 4)
kidney	black		0 ( 0)	1 ( 20)	0 ( 0)	0 ( 0)
	white patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	nodule		1 ( 10)	0 ( 0)	1 ( 7)	1 ( 4)
	granular		3 ( 30)	0 ( 0)	2 ( 13)	3 ( 11)
urin bladd	urino:marked retention		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
	urine:brown		0 ( 0)	0 ( 0)	1 ( 7)	1 ( 4)
pituitary	enlarged		3 ( 30)	1 ( 20)	4 ( 27)	1 ( 4)
	black patch/zone		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
thyroid	enlarged		1 ( 10)	0 ( 0)	1 ( 7)	1 ( 4)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
adrenal	enlarged		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
testis	atrophic		0 ( 0)	0 ( 0)	1 ( 7)	4 ( 14)
	nodule		5 ( 50)	3 ( 60)	11 ( 73)	19 ( 68)

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0-104W)

Organ	Findings	Group Name NO. of Animals	Control 10 (%)	200 ppm 5 (%)	1000 ppm 15 (%)	5000 ppm 28 (%)
epididymis	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
semin ves	atrophic		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
prep/cii gl	nodule		1 ( 10)	0 ( 0)	0 ( 0)	1 ( 4)
brain	red patch/zone		0 ( 0)	0 ( 0)	2 ( 13)	1 ( 4)
	hemorrhage		0 ( 0)	0 ( 0)	1 ( 7)	1 ( 4)
eye	red		1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)
Zymbal gl	mass		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
muscle	mass		0 ( 0)	0 ( 0)	1 ( 7)	0 ( 0)
bone	nodule		0 ( 0)	0 ( 0)	3 ( 20)	0 ( 0)
peritoneum	nodule		1 ( 10)	1 ( 20)	1 ( 7)	11 ( 39)
abdominal c	hemorrhage		1 ( 10)	0 ( 0)	0 ( 0)	3 ( 11)
	ascites		3 ( 30)	1 ( 20)	1 ( 7)	9 ( 32)
adipose	yellow		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	nodule		1 ( 10)	0 ( 0)	2 ( 13)	0 ( 0)
thoracic ca	pleural fluid		2 ( 20)	1 ( 20)	3 ( 20)	1 ( 4)
other	nodule		1 ( 10)	0 ( 0)	2 ( 13)	1 ( 4)
whole body	anemic		1 ( 10)	0 ( 0)	0 ( 0)	1 ( 4)
	jaundice		0 ( 0)	1 ( 20)	0 ( 0)	1 ( 4)

APPENDIX H2

GROSS FINDINGS (SUMMARY)

RAT:FEMALE:DEAD AND MORIBUND ANIMALS

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0-104W)

Organ	Findings	Group Name NO. of Animals	Control 12 (%)	200 ppm 13 (%)	1000 ppm 12 (%)	5000 ppm 26 (%)
skin/app	reduced		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	nodule		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
	scab		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
subcutis	jaundice		2 ( 17)	1 ( 8)	1 ( 8)	3 ( 12)
	nodule		0 ( 0)	1 ( 8)	0 ( 0)	1 ( 4)
	mass		4 ( 33)	5 ( 38)	3 ( 25)	12 ( 46)
	cyst		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
nasal cavit	solid		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
trachea	mass		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	red		2 ( 17)	3 ( 23)	2 ( 17)	9 ( 35)
lung/branch	white patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 8)
	red patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 8)
	congestion		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	nodule		0 ( 0)	0 ( 0)	1 ( 8)	1 ( 4)
lymph node	enlarged		2 ( 17)	1 ( 8)	2 ( 17)	3 ( 12)
spleen	enlarged		8 ( 67)	2 ( 15)	6 ( 50)	7 ( 27)
	white patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	nodule		1 ( 8)	0 ( 0)	1 ( 8)	1 ( 4)
	deformed		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)

STUDY NO. : 0063  
ANIMAL : RAT F344  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 6

Organ	Findings	Group Name NO. of Animals	Control 12 (%)	200 ppm 13 (%)	1000 ppm 12 (%)	5000 ppm 26 (%)
spleen	granular		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	rupture		1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)
esophagus	dilated		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
forestomach	ulcer		3 ( 25)	3 ( 23)	1 ( 8)	4 ( 15)
	thick		0 ( 0)	2 ( 15)	0 ( 0)	0 ( 0)
sl stomach	red patch/zone		1 ( 8)	0 ( 0)	0 ( 0)	1 ( 4)
	black patch/zone		0 ( 0)	0 ( 0)	1 ( 8)	3 ( 12)
	ulcer		4 ( 33)	3 ( 23)	3 ( 25)	2 ( 8)
	fluid		0 ( 0)	1 ( 8)	1 ( 8)	1 ( 4)
	thick		1 ( 8)	5 ( 38)	1 ( 8)	2 ( 8)
	fluid:black		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
stomach	dilated		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
small intes	dilated		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
cecum	dilated		0 ( 0)	1 ( 8)	0 ( 0)	3 ( 12)
colon	dilated		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
liver	enlarged		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
	yellow		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
	white patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	6 ( 23)
	red patch/zone		0 ( 0)	1 ( 8)	1 ( 8)	0 ( 0)
	anemic		1 ( 8)	0 ( 0)	1 ( 8)	0 ( 0)
	nodule		0 ( 0)	1 ( 8)	1 ( 8)	17 ( 65)
	cyst		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)

STUDY NO. : 0063  
ANIMAL : RAT F344  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 7

Organ	Findings	Group Name NO. of Animals	Control 12 (%)	200 ppm 13 (%)	1000 ppm 12 (%)	5000 ppm 26 (%)
liver	deformed		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
	granular		3 ( 25)	0 ( 0)	1 ( 8)	0 ( 0)
	nodular		1 ( 8)	1 ( 8)	1 ( 8)	4 ( 15)
	adhesion		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
	herniation		2 ( 17)	0 ( 0)	0 ( 0)	1 ( 4)
pancreas	nodule		1 ( 8)	0 ( 0)	0 ( 0)	1 ( 4)
	nodular		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
kidney	pale		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
	granular		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
urin bladd	dilated		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
pituitary	enlarged		2 ( 17)	5 ( 38)	2 ( 17)	4 ( 15)
	atrophic		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	red patch/zone		4 ( 33)	1 ( 8)	2 ( 17)	6 ( 23)
	black patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	nodule		4 ( 33)	1 ( 8)	1 ( 8)	6 ( 23)
thyroid	enlarged		0 ( 0)	2 ( 15)	0 ( 0)	1 ( 4)
adrenal	red		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
	nodule		1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)
ovary	enlarged		1 ( 8)	0 ( 0)	1 ( 8)	0 ( 0)
	cyst		1 ( 8)	0 ( 0)	1 ( 8)	0 ( 0)
	fluid		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
uterus	enlarged		0 ( 0)	0 ( 0)	2 ( 17)	0 ( 0)

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 8

Organ	Findings	Group Name NO. of Animals	Control 12 (%)	200 ppm 13 (%)	1000 ppm 12 (%)	5000 ppm 26 (%)
uterus	nodule		1 ( 8)	1 ( 8)	2 ( 17)	1 ( 4)
	dilated lumen		0 ( 0)	0 ( 0)	1 ( 8)	1 ( 4)
	fluid		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
	thick		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
vagina	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	dilated lumen		1 ( 8)	0 ( 0)	0 ( 0)	1 ( 4)
	fluid		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 8)
spinal cord	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
eye	white		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	red		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
muscle	nodule		1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)
mediastinum	mass		0 ( 0)	1 ( 8)	0 ( 0)	1 ( 4)
peritoneum	nodule		1 ( 8)	0 ( 0)	1 ( 8)	1 ( 4)
retroperit	mass		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
abdominal c	hemorrhage		3 ( 25)	0 ( 0)	2 ( 17)	1 ( 4)
	mass		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
	ascites		2 ( 17)	1 ( 8)	1 ( 8)	0 ( 0)
adipose	red patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	nodule		2 ( 17)	0 ( 0)	0 ( 0)	1 ( 4)
thoracic ca	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 8)
	pleural fluid		1 ( 8)	1 ( 8)	0 ( 0)	7 ( 27)
other	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)



STUDY NO. : 0063  
ANIMAL : RAT F344  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 9

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Organ	Findings	Group Name NO. of Animals	Control 12 (%)	200 ppm 13 (%)	1000 ppm 12 (%)	5000 ppm 26 (%)
other	nodule		0 ( 0)	0 ( 0)	0 ( 0)	3 ( 12)
whole body	anemic		1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)
	jaundice		1 ( 8)	1 ( 8)	0 ( 0)	2 ( 8)
	wasting		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)

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(HPT080)

BAIS 2

APPENDIX H3

GROSS FINDINGS (SUMMARY)

RAT:MALE:SACRIFICED ANIMALS

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (104W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 40 (%)	200 ppm 45 (%)	1000 ppm 35 (%)	5000 ppm 22 (%)
skin/app	nodule		1 ( 3)	1 ( 2)	3 ( 9)	0 ( 0)
subcutis	mass		9 ( 23)	8 ( 18)	7 ( 20)	9 ( 41)
lung/branch	white patch/zone		1 ( 3)	1 ( 2)	0 ( 0)	0 ( 0)
	gray patch/zone		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	red patch/zone		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	yellow patch/zone		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	brown patch/zone		0 ( 0)	1 ( 2)	0 ( 0)	1 ( 5)
	nodule		4 ( 10)	3 ( 7)	1 ( 3)	3 ( 14)
	mass		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	atelectasis		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
lymph node	enlarged		0 ( 0)	1 ( 2)	1 ( 3)	1 ( 5)
spleen	enlarged		2 ( 5)	2 ( 4)	3 ( 9)	3 ( 14)
	white patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
	hemorrhage		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	infarct		1 ( 3)	1 ( 2)	1 ( 3)	4 ( 18)
	nodule		0 ( 0)	0 ( 0)	2 ( 6)	0 ( 0)
	adhesion		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
heart	white		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
oral cavity	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
tongue	white patch/zone		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
salivary gl	mass		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)

STUDY NO. : 0063  
ANIMAL : RAT F344  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS (104W)

Organ	Findings	Group Name NO. of Animals	Control 40 (%)	200 ppm 45 (%)	1000 ppm 35 (%)	5000 ppm 22 (%)
st stomach	ulcer		0 ( 0)	1 ( 2)	0 ( 0)	1 ( 5)
	thick		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
jejunum	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
anus	polyp		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
liver	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	3 ( 14)
	white		1 ( 3)	1 ( 2)	0 ( 0)	0 ( 0)
	brown		0 ( 0)	1 ( 2)	1 ( 3)	0 ( 0)
	white patch/zone		0 ( 0)	0 ( 0)	7 ( 20)	2 ( 9)
	red patch/zone		0 ( 0)	1 ( 2)	1 ( 3)	0 ( 0)
	yellow patch/zone		0 ( 0)	0 ( 0)	2 ( 6)	2 ( 9)
	brown patch/zone		2 ( 5)	0 ( 0)	6 ( 17)	1 ( 5)
	nodule		2 ( 5)	2 ( 4)	4 ( 11)	20 ( 91)
	cyst		1 ( 3)	3 ( 7)	2 ( 6)	5 ( 23)
	rough		1 ( 3)	1 ( 2)	1 ( 3)	5 ( 23)
	adhesion		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	herniation		1 ( 3)	4 ( 9)	1 ( 3)	0 ( 0)
	pancreas	nodule		0 ( 0)	1 ( 2)	1 ( 3)
kidney	nodule		0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)
	cyst		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
	granular		25 ( 63)	27 ( 60)	31 ( 89)	15 ( 68)
pituitary	enlarged		2 ( 5)	2 ( 4)	1 ( 3)	1 ( 5)
	red patch/zone		4 ( 10)	3 ( 7)	1 ( 3)	0 ( 0)

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (104W)

Organ	Findings	Group Name NO. of Animals	Control 40 (%)	200 ppm 45 (%)	1000 ppm 35 (%)	5000 ppm 22 (%)
pituitary	nodule		3 ( 8)	5 ( 11)	1 ( 3)	3 ( 14)
	cyst		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
thyroid	enlarged		0 ( 0)	3 ( 7)	2 ( 6)	1 ( 5)
	nodule		3 ( 8)	0 ( 0)	5 ( 14)	0 ( 0)
	mass		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
adrenal	enlarged		1 ( 3)	4 ( 9)	4 ( 11)	1 ( 5)
testis	left		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	enlarged		21 ( 53)	23 ( 51)	16 ( 46)	12 ( 55)
	atrophic		2 ( 5)	5 ( 11)	6 ( 17)	5 ( 23)
	nodule		39 ( 98)	43 ( 96)	35 (100)	20 ( 91)
semin ves	atrophic		10 ( 25)	9 ( 20)	7 ( 20)	4 ( 18)
prep/cli gl	nodule		3 ( 8)	3 ( 7)	5 ( 14)	1 ( 5)
eye	white		5 ( 13)	1 ( 2)	1 ( 3)	0 ( 0)
	yellow		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
muscle	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	mass		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
vertebra	deformed		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
mediastinum	mass		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
peritoneum	nodule		1 ( 3)	0 ( 0)	3 ( 9)	5 ( 23)
abdominal c	ascites		0 ( 0)	0 ( 0)	3 ( 9)	6 ( 27)
adipose	nodule		5 ( 13)	8 ( 18)	5 ( 14)	1 ( 5)
thoracic ca	hemorrhage		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)

STUDY NO. : 0063  
ANIMAL : RAT F344  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS (104W)

PAGE : 4

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Organ	Findings	Group Name NO. of Animals	Control 40 (%)	200 ppm 45 (%)	1000 ppm 35 (%)	5000 ppm 22 (%)
thoracic ca	pleural fluid		1 ( 3)	0 ( 0)	0 ( 0)	1 ( 5)
other	fluid		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
whole body	anemic		1 ( 3)	0 ( 0)	1 ( 3)	0 ( 0)

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(HPT080)

BAIS2

APPENDIX H4

GROSS FINDINGS (SUMMARY)

RAT:FEMALE:SACRIFICED ANIMALS

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (104W)

Organ	Findings	Group Name NO. of Animals	Control 38 (%)	200 ppm 37 (%)	1000 ppm 38 (%)	5000 ppm 24 (%)
skin/app	reduced		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
subcutis	jaundice		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	mass		6 ( 16)	9 ( 24)	11 ( 29)	8 ( 33)
lung/branch	brown		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	white patch/zone		0 ( 0)	0 ( 0)	1 ( 3)	2 ( 8)
	red patch/zone		0 ( 0)	1 ( 3)	1 ( 3)	1 ( 4)
	congestion		0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)
	edema		1 ( 3)	1 ( 3)	0 ( 0)	2 ( 8)
	nodule		3 ( 8)	2 ( 5)	1 ( 3)	3 ( 13)
lymph node	enlarged		0 ( 0)	1 ( 3)	0 ( 0)	1 ( 4)
spleen	enlarged		4 ( 11)	4 ( 11)	5 ( 13)	2 ( 8)
	infarct		1 ( 3)	0 ( 0)	0 ( 0)	1 ( 4)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 8)
heart	white		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
forestomach	red patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	ulcer		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 8)
st stomach	red patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
liver	red		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	brown		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	red patch/zone		1 ( 3)	1 ( 3)	2 ( 5)	0 ( 0)
	yellow patch/zone		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	brown patch/zone		2 ( 5)	1 ( 3)	5 ( 13)	1 ( 4)



STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (104W)

Organ	Findings	Group Name NO. of Animals	Control 38 (%)	200 ppm 37 (%)	1000 ppm 38 (%)	5000 ppm 24 (%)
liver	nodule		1 ( 3)	2 ( 5)	5 ( 13)	24 (100)
	cyst		0 ( 0)	0 ( 0)	1 ( 3)	3 ( 13)
	rough		3 ( 8)	5 ( 14)	4 ( 11)	0 ( 0)
	herniation		4 ( 11)	1 ( 3)	2 ( 5)	0 ( 0)
kidney	yellow patch/zone		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	granular		9 ( 24)	12 ( 32)	7 ( 18)	14 ( 58)
pituitary	enlarged		3 ( 8)	5 ( 14)	4 ( 11)	4 ( 17)
	red		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	white patch/zone		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	red patch/zone		7 ( 18)	6 ( 16)	5 ( 13)	3 ( 13)
	black patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	nodule		8 ( 21)	4 ( 11)	6 ( 16)	3 ( 13)
	cyst		0 ( 0)	0 ( 0)	1 ( 3)	1 ( 4)
thyroid	enlarged		0 ( 0)	1 ( 3)	0 ( 0)	1 ( 4)
	red patch/zone		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	nodule		4 ( 11)	2 ( 5)	4 ( 11)	2 ( 8)
adrenal	enlarged		1 ( 3)	0 ( 0)	0 ( 0)	1 ( 4)
ovary	cyst		3 ( 8)	2 ( 5)	2 ( 5)	1 ( 4)
uterus	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	nodule		1 ( 3)	6 ( 16)	3 ( 8)	0 ( 0)
	dilated lumen		0 ( 0)	1 ( 3)	0 ( 0)	2 ( 8)
vagina	fluid		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (104W)

Organ	Findings	Group Name NO. of Animals	Control 38 (%)	200 ppm 37 (%)	1000 ppm 38 (%)	5000 ppm 24 (%)
prep/cli gl	nodule		3 ( 8)	1 ( 3)	3 ( 8)	2 ( 8)
	mass		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
eye	small		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	white		1 ( 3)	2 ( 5)	0 ( 0)	1 ( 4)
	red		1 ( 3)	0 ( 0)	0 ( 0)	1 ( 4)
	red patch/zone		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
muscle	nodule		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
abdominal c	ascites		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
adipose	nodule		3 ( 8)	3 ( 8)	1 ( 3)	2 ( 8)
thoracic ca	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	pleural fluid		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 8)
whole body	anemic		0 ( 0)	1 ( 3)	0 ( 0)	1 ( 4)
	wasting		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)

APPENDIX H5

GROSS FINDINGS (SUMMARY)

MOUSE:MALE:DEAD AND MORIBUND ANIMALS

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0-104W)

Organ	Findings	Group Name NO. of Animals	Control 19 (%)	500 ppm 17 (%)	2000 ppm 25 (%)	8000 ppm 24 (%)
skin/app	wound		0 ( 0)	0 ( 0)	1 ( 4)	1 ( 4)
subcutis	black patch/zone		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	edema		1 ( 5)	2 ( 12)	1 ( 4)	0 ( 0)
	jaundice		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	2 ( 8)	0 ( 0)
	mass		0 ( 0)	1 ( 6)	0 ( 0)	2 ( 8)
nasal cavit	hemorrhage		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
lung/branch	red		2 ( 11)	3 ( 18)	3 ( 12)	4 ( 17)
	white patch/zone		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	red patch/zone		1 ( 5)	0 ( 0)	1 ( 4)	1 ( 4)
	congestion		1 ( 5)	0 ( 0)	1 ( 4)	2 ( 8)
	edema		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	nodule		6 ( 32)	3 ( 18)	4 ( 16)	5 ( 21)
	cyst		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
lymph node	enlarged		4 ( 21)	5 ( 29)	8 ( 32)	7 ( 29)
thymus	enlarged		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	involution		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
spleen	enlarged		2 ( 11)	4 ( 24)	4 ( 16)	4 ( 17)
	black patch/zone		1 ( 5)	0 ( 0)	2 ( 8)	0 ( 0)
	anemic		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	nodule		3 ( 16)	1 ( 6)	4 ( 16)	1 ( 4)
	deformed		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)

STUDY NO. : 0064  
ANIMAL : MOUSE BDF1  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0-104W)

Organ	Findings	Group Name NO. of Animals	Control 19 (%)	500 ppm 17 (%)	2000 ppm 25 (%)	8000 ppm 24 (%)
heart	red		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	dilated		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
forestomach	red patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	ulcer		0 ( 0)	0 ( 0)	1 ( 4)	2 ( 8)
sl stomach	red patch/zone		2 ( 11)	0 ( 0)	1 ( 4)	0 ( 0)
	black patch/zone		0 ( 0)	0 ( 0)	1 ( 4)	1 ( 4)
	ulcer		0 ( 0)	1 ( 6)	1 ( 4)	0 ( 0)
	fluid		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	thick		3 ( 16)	4 ( 24)	4 ( 16)	3 ( 13)
stomach	fluid		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
duodenum	white patch/zone		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
jejunum	red		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
ileum	nodule		1 ( 5)	0 ( 0)	1 ( 4)	1 ( 4)
	dilated		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
small intes	dilated lumen		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	fluid:brown		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
cecum	nodule		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	fluid		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
rectum	dilated lumen		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
large intes	dilated lumen		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
Liver	enlarged		3 ( 16)	1 ( 6)	0 ( 0)	2 ( 8)
	swollen		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0-104W)

Organ	Findings	Group Name NO. of Animals	Control 19 (%)	500 ppm 17 (%)	2000 ppm 25 (%)	8000 ppm 24 (%)
liver	pale		0 ( 0)	2 ( 12)	1 ( 4)	0 ( 0)
	yellow		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	white patch/zone		1 ( 5)	2 ( 12)	3 ( 12)	4 ( 17)
	red patch/zone		1 ( 5)	0 ( 0)	2 ( 8)	3 ( 13)
	black patch/zone		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	anemic		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		11 ( 58)	9 ( 53)	22 ( 88)	15 ( 63)
	adhesion		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	herniation		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
gall bladd	dilated		4 ( 21)	1 ( 6)	1 ( 4)	1 ( 4)
pancreas	nodule		0 ( 0)	0 ( 0)	3 ( 12)	0 ( 0)
kidney	pale		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	hemorrhage		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	anemic		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	hydronephrosis		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
ureter	dilated		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
urin bladd	hemorrhage		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	cyst		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	dilated		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	urine:marked retention		3 ( 16)	1 ( 6)	2 ( 8)	0 ( 0)

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0-104W)

Organ	Findings	Group Name NO. of Animals	Control 19 (%)	500 ppm 17 (%)	2000 ppm 25 (%)	8000 ppm 24 (%)
pituitary	enlarged		0 ( 0)	0 ( 0)	2 ( 8)	0 ( 0)
	nodule		1 ( 5)	0 ( 0)	1 ( 4)	0 ( 0)
testis	atrophic		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	red patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	adhesion		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	hard		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
epididymis	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
semin ves	enlarged		3 ( 16)	1 ( 6)	3 ( 12)	1 ( 4)
	atrophic		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	red		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	brown		2 ( 11)	2 ( 12)	3 ( 12)	0 ( 0)
	black		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	red patch/zone		0 ( 0)	1 ( 6)	1 ( 4)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
prostate	red		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
prep/cli gl	enlarged		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	4 ( 16)	1 ( 4)
brain	red patch/zone		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	mass		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
harder gl	nodule		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0-104W)

Organ	Findings	Group Name NO. of Animals	Control 19 (%)	500 ppm 17 (%)	2000 ppm 25 (%)	8000 ppm 24 (%)
vertebra	nodule		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
mediastinum	mass		2 ( 11)	0 ( 0)	0 ( 0)	0 ( 0)
retroperit	mass		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
abdominal c	hemorrhage		3 ( 16)	2 ( 12)	6 ( 24)	4 ( 17)
	mass		1 ( 5)	1 ( 6)	0 ( 0)	0 ( 0)
	ascites		3 ( 16)	3 ( 18)	2 ( 8)	2 ( 8)
adipose	nodule		1 ( 5)	2 ( 12)	4 ( 16)	2 ( 8)
thoracic ca	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	3 ( 13)
	mass		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	pleural fluid		3 ( 16)	3 ( 18)	3 ( 12)	2 ( 8)
other	nodule		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
	coagulation gland		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)
whole body	anemic		0 ( 0)	1 ( 6)	0 ( 0)	1 ( 4)
	fatty		0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)



APPENDIX H6

GROSS FINDINGS (SUMMARY)

MOUSE:FEMALE:DEAD AND MORIBUND ANIMALS

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0-104W)

Organ	Findings	Group Name NO. of Animals	Control 21 (%)	500 ppm 21 (%)	2000 ppm 33 (%)	8000 ppm 45 (%)
skin/app	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
subcutis	edema		9 ( 43)	4 ( 19)	6 ( 18)	2 ( 4)
	jaundice		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	nodule		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	mass		1 ( 5)	0 ( 0)	3 ( 9)	4 ( 9)
	thick		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
nasal cavit	fluid		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
lung/branch	dark		0 ( 0)	1 ( 5)	0 ( 0)	0 ( 0)
	red		3 ( 14)	6 ( 29)	8 ( 24)	2 ( 4)
	white patch/zone		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	red patch/zone		0 ( 0)	0 ( 0)	5 ( 15)	12 ( 27)
	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	congestion		0 ( 0)	0 ( 0)	2 ( 6)	2 ( 4)
	edema		3 ( 14)	0 ( 0)	3 ( 9)	1 ( 2)
	nodule		0 ( 0)	0 ( 0)	4 ( 12)	3 ( 7)
	atelectasis		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
Lymph node	enlarged		5 ( 24)	8 ( 38)	12 ( 36)	10 ( 22)
	red		1 ( 5)	1 ( 5)	0 ( 0)	0 ( 0)
spleen	enlarged		8 ( 38)	7 ( 33)	13 ( 39)	4 ( 9)
	white patch/zone		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	black patch/zone		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		1 ( 5)	1 ( 5)	0 ( 0)	1 ( 2)

STUDY NO. : 0064  
ANIMAL : MOUSE BDF1  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0-104W)

Organ	Findings	Group Name NO. of Animals	Control 21 (%)	500 ppm 21 (%)	2000 ppm 33 (%)	8000 ppm 45 (%)
spleen	deformed		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
heart	white patch/zone		0 ( 0)	1 ( 5)	0 ( 0)	0 ( 0)
forestomach	red patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)
	ulcer		0 ( 0)	1 ( 5)	2 ( 6)	0 ( 0)
stomach	red patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)
	hemorrhage		1 ( 5)	0 ( 0)	0 ( 0)	1 ( 2)
	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	ulcer		2 ( 10)	1 ( 5)	1 ( 3)	0 ( 0)
	erosion		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	fluid		0 ( 0)	0 ( 0)	0 ( 0)	6 ( 13)
	thick		3 ( 14)	2 ( 10)	3 ( 9)	2 ( 4)
	fluid:black		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	fluid		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)
duodenum	dilated		0 ( 0)	1 ( 5)	0 ( 0)	0 ( 0)
	fluid		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
jejunum	red		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
ileum	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	fluid		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
small intes	fluid		0 ( 0)	1 ( 5)	1 ( 3)	2 ( 4)
	fluid:black		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0-104W)

Organ	Findings	Group Name NO. of Animals	Control 21 (%)	500 ppm 21 (%)	2000 ppm 33 (%)	8000 ppm 45 (%)
cecum	fluid		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
large intes	fluid		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
liver	enlarged		6 ( 29)	6 ( 29)	0 ( 0)	2 ( 4)
	swollen		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	pale		0 ( 0)	0 ( 0)	2 ( 6)	1 ( 2)
	white		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	white patch/zone		8 ( 38)	7 ( 33)	1 ( 3)	5 ( 11)
	red patch/zone		0 ( 0)	1 ( 5)	3 ( 9)	16 ( 36)
	nodule		5 ( 24)	12 ( 57)	25 ( 76)	28 ( 62)
	cyst		0 ( 0)	1 ( 5)	0 ( 0)	0 ( 0)
	deformed		0 ( 0)	1 ( 5)	0 ( 0)	0 ( 0)
	granular		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	adhesion		1 ( 5)	0 ( 0)	1 ( 3)	1 ( 2)
gall bladd	dilated		1 ( 5)	2 ( 10)	0 ( 0)	3 ( 7)
pancreas	nodule		1 ( 5)	3 ( 14)	2 ( 6)	2 ( 4)
kidney	enlarged		2 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)
	pale		1 ( 5)	1 ( 5)	0 ( 0)	0 ( 0)
	black patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	hemorrhase		0 ( 0)	1 ( 5)	0 ( 0)	0 ( 0)
	anemic		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	nodule		0 ( 0)	1 ( 5)	1 ( 3)	0 ( 0)
	dilated		0 ( 0)	1 ( 5)	0 ( 0)	0 ( 0)

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 9

Organ	Findings	Group Name NO. of Animals	Control 21 (%)	500 ppm 21 (%)	2000 ppm 33 (%)	8000 ppm 45 (%)
kidney	hydronephrosis		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
urin bladd	red patch/zone		0 ( 0)	1 ( 5)	0 ( 0)	0 ( 0)
	dilated		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	urine:marked retention		1 ( 5)	1 ( 5)	0 ( 0)	0 ( 0)
	urine:red		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	urine:black		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
pituitary	enlarged		1 ( 5)	1 ( 5)	1 ( 3)	1 ( 2)
	white patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	red patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	nodule		1 ( 5)	1 ( 5)	0 ( 0)	0 ( 0)
ovary	enlarged		9 ( 43)	5 ( 24)	7 ( 21)	3 ( 7)
	red		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	black		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	mass		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	cyst		0 ( 0)	1 ( 5)	5 ( 15)	0 ( 0)
	fluid		1 ( 5)	5 ( 24)	1 ( 3)	2 ( 4)
	fluid:transparent		0 ( 0)	2 ( 10)	0 ( 0)	0 ( 0)
uterus	enlarged		0 ( 0)	0 ( 0)	1 ( 3)	2 ( 4)
	red patch/zone		0 ( 0)	1 ( 5)	0 ( 0)	0 ( 0)
	nodule		10 ( 48)	5 ( 24)	7 ( 21)	5 ( 11)
	nodular		0 ( 0)	2 ( 10)	0 ( 0)	0 ( 0)
	adhesion		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0-104W)

PAGE : 10

Organ	Findings	Group Name NO. of Animals	Control 21 (%)	500 ppm 21 (%)	2000 ppm 33 (%)	8000 ppm 45 (%)
uterus	dilated lumen		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
brain	white		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	black patch/zone		0 ( 0)	1 ( 5)	0 ( 0)	0 ( 0)
Harder gl	nodule		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
muscle	nodule		0 ( 0)	1 ( 5)	0 ( 0)	0 ( 0)
mediastinum	mass		0 ( 0)	5 ( 24)	2 ( 6)	0 ( 0)
peritoneum	nodular		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
abdominal c	hemorrhage		5 ( 24)	4 ( 19)	7 ( 21)	7 ( 16)
	ascites		8 ( 38)	7 ( 33)	7 ( 21)	2 ( 4)
mesenterium	nodular		1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
adipose	brown		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	nodule		3 ( 14)	0 ( 0)	1 ( 3)	0 ( 0)
thoracic ca	hemorrhage		0 ( 0)	1 ( 5)	1 ( 3)	1 ( 2)
	pleural fluid		8 ( 38)	9 ( 43)	9 ( 27)	3 ( 7)
other	swollen		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	hemorrhage		0 ( 0)	1 ( 5)	0 ( 0)	1 ( 2)
	mass		0 ( 0)	0 ( 0)	1 ( 3)	1 ( 2)
	absence		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
whole body	anemic		2 ( 10)	0 ( 0)	1 ( 3)	0 ( 0)
	wasting		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	fatty		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)

APPENDIX H7

GROSS FINDINGS (SUMMARY)

MOUSE:MALE:SACRIFICED ANIMALS

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (104W)

Organ	Findings	Group Name NO. of Animals	Control 31 (%)	500 ppm 33 (%)	2000 ppm 25 (%)	8000 ppm 26 (%)
skin/app	nodule		0 ( 0)	1 ( 3)	0 ( 0)	1 ( 4)
subcutis	mass		0 ( 0)	1 ( 3)	3 ( 12)	1 ( 4)
lung/branch	red		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	red patch/zone		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	nodule		9 ( 29)	11 ( 33)	13 ( 52)	6 ( 23)
	adhesion		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
lymph node	enlarged		1 ( 3)	5 ( 15)	0 ( 0)	6 ( 23)
spleen	enlarged		3 ( 10)	1 ( 3)	0 ( 0)	0 ( 0)
	black patch/zone		1 ( 3)	2 ( 6)	1 ( 4)	1 ( 4)
	nodule		2 ( 6)	4 ( 12)	4 ( 16)	1 ( 4)
salivary gl	enlarged		1 ( 3)	0 ( 0)	0 ( 0)	1 ( 4)
forestomach	nodule		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
gl stomach	nodule		1 ( 3)	0 ( 0)	1 ( 4)	0 ( 0)
	fluid		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	thick		1 ( 3)	2 ( 6)	0 ( 0)	1 ( 4)
	fluid:black		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
duodenum	nodule		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
small intes	black		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
liver	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	atrophic		0 ( 0)	1 ( 3)	0 ( 0)	2 ( 8)
	white patch/zone		3 ( 10)	0 ( 0)	2 ( 8)	0 ( 0)
	red patch/zone		7 ( 23)	1 ( 3)	11 ( 44)	24 ( 92)



STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (104W)

Organ	Findings	Group Name NO. of Animals	Control 31 (%)	500 ppm 33 (%)	2000 ppm 25 (%)	8000 ppm 26 (%)
liver	yellow patch/zone		0 ( 0)	1 ( 3)	1 ( 4)	0 ( 0)
	green patch/zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	brown patch/zone		1 ( 3)	1 ( 3)	0 ( 0)	1 ( 4)
	nodule		17 ( 55)	23 ( 70)	21 ( 84)	24 ( 92)
gall bladd	dilated		0 ( 0)	0 ( 0)	1 ( 4)	4 ( 15)
pancreas	red patch/zone		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	1 ( 3)	1 ( 4)	1 ( 4)
kidney	granular		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	hydronephrosis		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
urin bladd	red patch/zone		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	dilated		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	fluid		1 ( 3)	0 ( 0)	1 ( 4)	0 ( 0)
	urine:marked retention		0 ( 0)	2 ( 6)	0 ( 0)	0 ( 0)
thyroid	enlarged		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
adrenal	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
testis	atrophic		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	hard		9 ( 29)	9 ( 27)	2 ( 8)	1 ( 4)
semin ves	enlarged		29 ( 94)	28 ( 85)	16 ( 64)	4 ( 15)
	atrophic		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)
	brown		0 ( 0)	4 ( 12)	1 ( 4)	0 ( 0)
prep/cli gl	nodule		0 ( 0)	4 ( 12)	9 ( 36)	4 ( 15)
periph nerv	nodule		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)

STUDY NO. : 0064  
ANIMAL : MOUSE BDF1  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS (104#)

PAGE : 3

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Organ	Findings	Group Name NO. of Animals	Control 31 (%)	500 ppm 33 (%)	2000 ppm 25 (%)	8000 ppm 26 (%)
Harder gl	nodule		0 ( 0)	0 ( 0)	2 ( 8)	0 ( 0)
bone	nodule		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
adipose	red patch/zone		0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	nodule		6 ( 19)	6 ( 18)	6 ( 24)	6 ( 23)
other	nodule		1 ( 3)	1 ( 3)	1 ( 4)	1 ( 4)

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(HPT080)

BAIS 2

APPENDIX H8

GROSS FINDINGS (SUMMARY)

MOUSE:FEMALE:SACRIFICED ANIMALS

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (104#)

Organ	Findings	Group Name NO. of Animals	Control 29 (%)	500 ppm 29 (%)	2000 ppm 17 (%)	8000 ppm 5 (%)
subcutis	edema		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	mass		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
lungs/branch	red		1 ( 3)	0 ( 0)	0 ( 0)	1 ( 20)
	white patch/zone		0 ( 0)	1 ( 3)	0 ( 0)	1 ( 20)
	red patch/zone		0 ( 0)	2 ( 7)	1 ( 6)	0 ( 0)
	edema		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		1 ( 3)	1 ( 3)	1 ( 6)	1 ( 20)
lymph node	enlarged		4 ( 14)	4 ( 14)	6 ( 35)	1 ( 20)
	yellow patch/zone		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
thymus	atrophic		1 ( 3)	0 ( 0)	0 ( 0)	1 ( 20)
spleen	enlarged		2 ( 7)	3 ( 10)	6 ( 35)	0 ( 0)
	black patch/zone		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		1 ( 3)	3 ( 10)	0 ( 0)	0 ( 0)
salivary gl	atrophic		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 20)
forestomach	thick		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
gl stomach	ulcer		0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)
stomach	nodule		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
small intes	blue		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 20)
large intes	blue		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 20)
liver	enlarged		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	pale		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	red		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 20)

STUDY NO. : 0064  
ANIMAL : MOUSE BDF1  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS (104W)

Organ	Findings	Group Name NO. of Animals	Control 29 (%)	500 ppm 29 (%)	2000 ppm 17 (%)	8000 ppm 5 (%)
liver	white patch/zone		2 ( 7)	1 ( 3)	0 ( 0)	0 ( 0)
	red patch/zone		3 ( 10)	7 ( 24)	14 ( 82)	3 ( 60)
	yellow patch/zone		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	brown patch/zone		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		4 ( 14)	22 ( 76)	16 ( 94)	5 (100)
	deformed		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	adhesion		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 20)
gall bladd	enlarged		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	dilated		1 ( 3)	0 ( 0)	4 ( 24)	2 ( 40)
pancreas	red patch/zone		2 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		1 ( 3)	0 ( 0)	1 ( 6)	0 ( 0)
kidney	enlarged		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	brown		0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)
	nodule		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	hydronephrosis		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
ureter	dilated		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
pituitary	enlarged		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	nodule		3 ( 10)	2 ( 7)	2 ( 12)	0 ( 0)
adrenal	enlarged		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
ovary	enlarged		0 ( 0)	1 ( 3)	2 ( 12)	0 ( 0)
	cyst		8 ( 28)	7 ( 24)	4 ( 24)	0 ( 0)
	fluid:transparent		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (104W)

Organ	Findings	Group Name NO. of Animals	Control 29 (%)	500 ppm 29 (%)	2000 ppm 17 (%)	8000 ppm 5 (%)
uterus	enlarged		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	atrophic		0 ( 0)	0 ( 0)	0 ( 0)	3 ( 60)
	nodule		5 ( 17)	1 ( 3)	2 ( 12)	1 ( 20)
	nodular		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	dilated lumen		2 ( 7)	1 ( 3)	1 ( 6)	0 ( 0)
mediastinum	mass		0 ( 0)	2 ( 7)	0 ( 0)	0 ( 0)
peritoneum	adhesion		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
abdominal c	hemorrhage		0 ( 0)	2 ( 7)	1 ( 6)	0 ( 0)
	ascites		2 ( 7)	0 ( 0)	2 ( 12)	1 ( 20)
adipose	nodule		2 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)
thoracic ca	hemorrhage		1 ( 3)	0 ( 0)	0 ( 0)	1 ( 20)
	pleural fluid		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
other	nodule		1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
whole body	anemic		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)

1,4-ジオキサンのラット及びマウスを用いた  
経口(混水)投与によるがん原性試験

# APPENDIX

(I1~I4)

がん原性試験 NO. 0063 ; 0064

APPENDIX I 1

ORGAN WEIGHT (SUMMARY) , ABSOLUTE

RAT : MALE



STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE  
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	Body weight	ADRENL R	ADRENL L	TESTIS R	TESTIS L	HEART
Control	40	428± 36	0.037± 0.008	0.042± 0.017	2.669± 1.479	2.710± 0.933	1.260± 0.149
200 ppm	45	433± 32	0.056± 0.124	0.097± 0.357	2.606± 1.249	2.586± 1.071	1.233± 0.105
1000 ppm	35	410± 53	0.040± 0.034	0.049± 0.029	2.314± 1.032	2.630± 1.258	1.250± 0.168
5000 ppm	22	391± 71**	0.033± 0.006*	0.142± 0.478	2.603± 1.401	2.543± 1.225	1.141± 0.123**

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

Test of Dunnett

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : MALE  
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	LUNG R		LUNG L		KIDNEY R		KIDNEY L		SPLEEN		LIVER	
Control	40	1.072±	0.918	0.627±	0.869	1.405±	0.118	1.410±	0.111	1.225±	0.506	12.505±	1.724
200 ppm	45	0.909±	0.090	0.486±	0.044	1.415±	0.168	1.406±	0.156	1.344±	0.817	13.030±	2.128
1000 ppm	35	0.916±	0.098	0.492±	0.054	1.460±	0.153	1.464±	0.142	1.493±	1.164	13.498±	1.744
5000 ppm	22	1.036±	0.277	0.554±	0.158	1.400±	0.124	1.403±	0.124	1.765±	2.308	19.308±	4.053**

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

Test of Dunnett

STUDY NO. : 0063  
ANIMAL : RAT F344  
REPORT TYPE : A1  
SEX : MALE  
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
SURVIVAL ANIMALS (104)

PAGE : 3

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Group Name	NO. of Animals	BRAIN	
Control	40	2.063±	0.044
200 ppm	45	2.067±	0.040
1000 ppm	35	2.050±	0.063
5000 ppm	22	1.992±	0.065**

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX 12

ORGAN WEIGHT (SUMMARY), ABSOLUTE

RAT:FEMALE

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE  
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	Body weight	ADRENL R	ADRENL L	OVARY R	OVARY L	HEART
Control	38	303± 41	0.047± 0.056	0.051± 0.057	0.053± 0.015	0.057± 0.018	0.977± 0.107
200 ppm	37	301± 38	0.036± 0.007	0.042± 0.009	0.053± 0.014	0.065± 0.073	1.000± 0.156
1000 ppm	38	296± 29	0.036± 0.004	0.040± 0.006	0.193± 0.837	0.061± 0.039	0.937± 0.073
5000 ppm	24	242± 42**	0.035± 0.009	0.101± 0.315*	0.047± 0.019	0.055± 0.013	0.967± 0.116

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

STUDY NO. : 0063  
 ANIMAL : RAT F344  
 REPORT TYPE : A1  
 SEX : FEMALE  
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	LUNG R		LUNG L		KIDNEY R		KIDNEY L		SPLEEN		LIVER	
Control	38	0.700±	0.250	0.378±	0.143	1.030±	0.189	1.037±	0.194	1.465±	2.948	8.060±	1.115
200 ppm	37	0.714±	0.199	0.381±	0.108	1.028±	0.139	1.033±	0.135	1.176±	1.726	7.794±	1.182
1000 ppm	38	0.666±	0.086	0.360±	0.051	0.976±	0.072	0.979±	0.071	0.948±	0.879	8.039±	1.283
5000 ppm	24	0.935±	0.730	0.505±	0.365**	1.062±	0.117	1.058±	0.131	1.526±	2.232	17.192±	4.031**

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

Test of Dunnett

STUDY NO. : 0063  
ANIMAL : RAT F344  
REPORT TYPE : A1  
SEX : FEMALE  
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
SURVIVAL ANIMALS (104)

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Group Name	NO. of Animals	BRAIN	
Control	38	1.885±	0.034
200 ppm	37	1.883±	0.044
1000 ppm	38	1.859±	0.073
5000 ppm	24	1.836±	0.051**

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

Test of Dunnett

APPENDIX 13

ORGAN WEIGHT (SUMMARY) , ABSOLUTE

MOUSE : MALE



STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE  
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	Body weight	ADRENL R	ADRENL L	TESTIS R	TESTIS L	HEART
Control	31	48.7± 6.1	0.005± 0.001	0.005± 0.001	0.122± 0.021	0.127± 0.028	0.228± 0.019
500 ppm	33	47.3± 6.8	0.005± 0.001	0.005± 0.001	0.119± 0.021	0.124± 0.025	0.225± 0.022
2000 ppm	25	44.1± 7.6	0.004± 0.001	0.004± 0.001	0.126± 0.026	0.118± 0.023	0.214± 0.022*
8000 ppm	26	27.0± 3.0**	0.005± 0.002	0.005± 0.002	0.108± 0.021	0.108± 0.016**	0.201± 0.018**

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : MALE  
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	LUNG R		LUNG L		KIDNEY R		KIDNEY L		SPLEEN		LIVER	
Control	31	0.142±	0.029	0.070±	0.015	0.355±	0.071	0.341±	0.031	0.228±	0.365	2.043±	0.747
500 ppm	33	0.140±	0.026	0.082±	0.053	0.335±	0.029	0.335±	0.031	0.144±	0.186	2.244±	0.869
2000 ppm	25	0.162±	0.086	0.072±	0.020	0.321±	0.026*	0.322±	0.027*	0.129±	0.066	2.505±	1.166
8000 ppm	26	0.190±	0.017**	0.095±	0.010**	0.282±	0.024**	0.276±	0.025**	0.101±	0.040	1.731±	0.657

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

STUDY NO. : 0064  
ANIMAL : MOUSE BDF1  
REPORT TYPE : A1  
SEX : MALE  
UNIT: g

ORGAN WEIGHT: ABSOLUTE (SUMMARY)  
SURVIVAL ANIMALS (104)

PAGE : 3

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Group Name	NO. of Animals	BRAIN	
Control	31	0.450±	0.013
500 ppm	33	0.449±	0.016
2000 ppm	25	0.446±	0.010
8000 ppm	26	0.428±	0.012**

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX 14

ORGAN WEIGHT (SUMMARY), ABSOLUTE

MOUSE:FEMALE

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE  
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	Body weight	ADRENL R	ADRENL L	OVARY R	OVARY L	HEART
Control	29	35.3± 5.1	0.008± 0.012	0.006± 0.001	0.018± 0.018	0.020± 0.021	0.165± 0.022
500 ppm	29	33.8± 6.4	0.006± 0.001	0.006± 0.002	0.015± 0.020	0.096± 0.318	0.172± 0.032
2000 ppm	17	29.7± 4.7**	0.005± 0.001	0.006± 0.001	0.011± 0.010**	0.156± 0.515	0.194± 0.035**
8000 ppm	05	19.3± 2.8**	0.004± 0.001**	0.004± 0.001**	0.007± 0.004**	0.005± 0.001**	0.184± 0.049

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

STUDY NO. : 0064  
 ANIMAL : MOUSE BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE  
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
 SURVIVAL ANIMALS (104)

Group Name	NO. of Animals	LUNG R		LUNG L		KIDNEY R		KIDNEY L		SPLEEN		LIVER	
Control	29	0.129±	0.022	0.063±	0.010	0.247±	0.156	0.241±	0.137	0.191±	0.250	1.565±	0.446
500 ppm	29	0.125±	0.016	0.061±	0.008	0.221±	0.024	0.231±	0.064	0.232±	0.363	1.446±	0.364
2000 ppm	17	0.172±	0.063**	0.083±	0.022**	0.249±	0.034**	0.249±	0.040**	0.253±	0.217	1.520±	0.404
8000 ppm	05	0.208±	0.083**	0.099±	0.038**	0.233±	0.056	0.226±	0.066	0.161±	0.100	1.296±	0.541

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

Test of Dunnett

STUDY NO. : 0064  
ANIMAL : MOUSE BDF1  
REPORT TYPE : A1  
SEX : FEMALE  
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
SURVIVAL ANIMALS (104)

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Group Name	NO. of Animals	BRAIN	
Control	29	0.467±	0.016
500 ppm	29	0.467±	0.015
2000 ppm	17	0.473±	0.019
8000 ppm	05	0.436±	0.025**

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

Test of Dunnett

(HCL040)

BAIS 2