β－クロロプロピオン酸のラット及びマウスを用いた
経口投与によるがん原性試験(混水試験)報告書

試験番号

ラット/0141；マウス/0140

APPENDIX

(E-1～R2)

APPENDIXES (CONTINUED)

APPENDIXES (CONTINUED)

APPENDIXES (CONTINUED)

APPENDIXES (CONTINUED)

APPENDIX E 1

CHEMICAL INTAKE CHANGES : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
800 ppm	87.110± 8.543	79.792± 9.754	77.343± 8.785	69.988± 6.381	67.048± 12.137	66.271± 14.931	59.019± 7.667
2400 ppm	236.059± 31.779	208.537± 21.148	195.691± 13.056	189.532± 34.535	165.619± 9.176	162.350± 9.705	152.004± 10.017
7200 ppm	673.389± 42.947	586.713± 89.108	550.126± 29.085	488.453± 29.819	474.474± 38.509	456.203± 25.409	427.923± 21.350

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
800 ppm	56.322± 4.657	55.983± 7.953	52.253± 7.406	51.152± 8.368	48.449± 5.055	48.657± 5.598	47.796± 8.216
2400 ppm	149.148± 9.965	146.332± 11.694	138.942± 9.924	135.495± 11.929	134.463± 12.184	134.380± 10.871	128.198± 8.994
7200 ppm	419.932± 23.771	438.091±126.544	400.623± 70.768	377.636± 22.311	380.478± 23.146	391.535± 59.715	374.231± 62.692

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg/kg/d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
800 ppm	42.864± 4.558	42.259± 4.556	40.107± 5.014	37.787± 4.018	38.441± 3.462	37.973± 3.298	37.015± 2.933
2400 ppm	117.471± 7.372	113.683± 7.450	110.689± 6.796	106.219± 6.838	108.189± 5.401	105.797± 4.832	108.198± 9.524
7200 ppm	336.168± 24.025	345.791± 41.991	324.654± 20.331	311.957± 20.387	320.438± 19.894	316.145± 21.150	311.378± 21.755

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
800 ppm	36.124± 2.372	35.839± 2.451	36.512± 2.661	35.430± 2.499	35.191± 2.160	33.987± 2.462	33.710± 2.026
2400 ppm	106.178± 18.349	102.773± 4.744	108.595± 20.540	101.237± 5.330	101.159± 4.988	101.901± 12.631	98.512± 4.780
7200 ppm	308.181± 26.065	304.831± 26.252	308.757± 26.673	306.708± 20.369	303.590± 16.068	296.232± 17.767	294.722± 18.475

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
800 ppm	33.121± 2.300	32.942± 2.053	32.719± 1.863	33.190± 2.102	33.225± 2.311	32.662± 1.675	33.039± 2.395
2400 ppm	98.697± 5.646	99.273± 10.701	95.800± 6.132	96.585± 4.721	96.722± 5.190	96.323± 9.558	97.066± 7.108
7200 ppm	292.588± 15.966	289.682± 16.818	294.836± 21.968	292.480± 18.485	291.839± 18.590	289.381± 22.409	292.243± 17.238

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
800 ppm	32.041± 2.218	32.875± 2.263	33.397± 2.243	33.033± 2.357	32.899± 2.567	32.121± 3.102	32.783± 3.200
2400 ppm	97.207± 4.289	99.526± 7.011	98.337± 4.913	96.686± 5.111	95.545± 4.405	94.039± 5.452	94.612± 5.835
7200 ppm	290.196± 14.993	293.566± 28.858	299.443± 27.629	291.172± 19.877	288.514± 15.929	284.714± 16.936	286.769± 18.911

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
800 ppm	33.407± 4.340	33.770± 4.862	35.889± 5.887	35.426± 5.449	35.520± 5.430	36.389± 5.446	36.940± 5.965
2400 ppm	97.320± 10.633	95.840± 8.951	99.599± 7.392	98.979± 8.504	98.611± 9.979	101.620± 12.545	102.870± 17.513
7200 ppm	288.308± 20.584	273.338± 23.023	289.601± 18.376	294.255± 32.246	281.809± 20.899	289.965± 45.713	278.969± 29.839

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
800 ppm	35.766± 6.599	38.196± 7.340	36.471± 7.340	35.598± 5.775	37.584± 8.383	41.412± 9.351	40.254± 10.994
2400 ppm	96.191± 10.962	102.744± 14.306	99.960± 19.261	102.913± 25.108	104.031± 25.407	103.757± 19.087	106.842± 29.246
7200 ppm	282.092± 29.193	288.923± 20.970	281.890± 25.277	278.526± 17.927	284.891± 23.982	304.292± 66.359	285.913± 43.834

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (SUMMARY)
ALL ANIMALS

Group Name	Administration (weeks) 100	102	104
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000
800 ppm	40.775± 9.872	45.498± 10.715	50.313± 17.597
2400 ppm	109.011± 38.105	116.721± 26.922	123.115± 34.429
7200 ppm	312.892± 82.115	320.768± 56.658	320.429± 46.850

APPENDIX D 2

CHEMICAL INTAKE CHANGES : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
800 ppm	107.584± 13.868	107.082± 28.469	99.046± 16.791	97.884± 27.874	98.751± 32.722	94.701± 27.184	86.325± 22.877
2400 ppm	271.034± 14.150	241.870± 14.328	240.310± 27.737	227.756± 25.825	208.577± 16.788	204.418± 15.798	212.203± 57.471
7200 ppm	739.083± 35.867	652.026± 24.895	620.981± 39.444	579.410± 70.948	539.390± 34.567	536.763± 35.883	513.889± 40.966

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
800 ppm	82.829± 20.999	86.879± 27.429	81.573± 27.430	85.781± 28.863	-	85.370± 29.867	81.274± 26.376
2400 ppm	197.527± 33.715	193.454± 23.813	188.125± 54.255	181.238± 20.706	-	175.775± 24.041	177.647± 24.308
7200 ppm	493.543± 38.503	497.757± 38.957	468.205± 31.923	468.958± 33.082	-	464.569± 29.038	452.592± 34.363

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
800 ppm	80.035± 33.427	79.447± 29.241	68.396± 14.351	71.994± 25.486	68.825± 22.303	74.541± 29.397	69.960± 29.676
2400 ppm	176.740± 35.057	175.083± 25.688	165.986± 19.551	159.702± 25.790	160.980± 27.244	162.940± 29.247	155.115± 20.133
7200 ppm	435.093± 34.165	436.122± 36.515	432.544± 38.689	422.257± 78.879	441.679±137.805	442.924±118.317	436.472±123.145

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
800 ppm	67.304± 23.956	65.274± 17.764	66.692± 19.903	63.425± 22.326	60.809± 15.227	60.105± 17.620	58.921± 16.343
2400 ppm	151.843± 24.288	156.459± 31.127	152.398± 20.514	145.343± 18.479	144.549± 19.089	141.544± 15.948	140.636± 18.482
7200 ppm	440.869±152.457	402.750± 35.746	415.163± 29.932	395.932± 28.745	404.703± 32.373	397.081± 40.549	399.266± 33.737

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
800 ppm	57.424± 18.137	59.148± 18.311	56.428± 16.908	56.827± 21.828	54.475± 21.499	52.501± 19.292	50.463± 15.209
2400 ppm	142.145± 21.359	139.021± 19.356	137.084± 18.135	132.345± 21.269	130.997± 17.267	127.764± 15.614	134.517± 21.675
7200 ppm	397.951± 30.416	410.912± 66.077	394.647± 45.256	388.650± 50.617	382.889± 35.336	375.941± 33.848	386.895± 34.415

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
800 ppm	49.296± 13.768	45.767± 8.194	48.426± 12.546	47.553± 12.267	44.583± 7.581	45.052± 9.287	47.327± 12.753
2400 ppm	123.752± 16.804	122.872± 15.111	124.895± 17.084	123.882± 16.278	120.642± 14.389	116.480± 19.578	119.304± 14.201
7200 ppm	377.431± 34.380	364.916± 35.128	382.598± 38.889	380.326± 41.633	369.996± 44.807	356.207± 42.315	376.665± 52.277

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
800 ppm	48.373± 11.431	48.618± 12.496	49.316± 10.857	47.482± 9.969	51.572± 12.202	48.533± 9.714	47.736± 10.759
2400 ppm	122.133± 13.440	121.796± 13.514	122.758± 16.169	124.959± 14.208	124.378± 14.795	126.059± 14.935	127.259± 16.089
7200 ppm	383.090± 52.706	378.305± 80.096	382.994± 56.353	399.886± 65.429	379.088± 53.722	383.679± 52.832	376.492± 48.130

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
800 ppm	48.042± 14.002	53.260± 11.754	51.646± 14.719	52.601± 19.553	48.846± 11.501	52.597± 16.423	53.671± 17.940
2400 ppm	121.033± 16.932	133.464± 23.469	126.809± 25.751	125.474± 20.231	124.477± 23.802	124.363± 26.872	124.762± 22.185
7200 ppm	374.116± 52.030	393.363± 80.028	388.311± 55.268	386.175± 56.863	385.701± 65.685	408.779± 75.873	398.711± 84.286

STUDY NO. : 0141
ANIMAL : RAT F344
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (SUMMARY)
ALL ANIMALS

Group Name	Administration (weeks) 100	102	104
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000
800 ppm	55.234± 20.042	58.182± 18.026	61.034± 23.600
2400 ppm	130.454± 25.226	140.580± 36.001	137.031± 27.385
7200 ppm	397.810± 87.656	425.546±112.700	417.420±103.136

APPENDIX E 3

CHEMICAL INTAKE CHANGES : SUMMARY, MOSUE : MALE

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
250 ppm	39.462± 4.835	39.618± 7.514	37.996± 8.578	37.171± 8.299	38.323± 10.581	37.118± 9.534	35.225± 7.577
1000 ppm	162.708± 23.845	163.347± 27.695	150.431± 28.184	147.702± 24.484	140.390± 22.605	134.210± 18.441	132.459± 18.837
4000 ppm	479.043± 62.362	511.108± 75.673	488.740±101.908	499.528±149.191	489.873±122.474	510.408±164.962	480.683±142.602

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
250 ppm	34.769± 9.855	32.046± 8.492	30.835± 9.300	29.537± 9.169	28.151± 5.531	25.712± 4.332	26.503± 6.923
1000 ppm	126.123± 18.802	117.247± 16.246	112.745± 15.459	109.199± 19.266	107.886± 22.659	97.708± 12.655	98.417± 12.889
4000 ppm	467.798±116.711	481.641±169.756	459.422±160.386	451.001±160.045	416.241±126.027	226.982± 67.436	374.704± 50.352

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
250 ppm	25.101± 6.873	24.051± 7.375	22.756± 6.223	22.233± 6.514	20.954± 2.056	20.309± 2.052	22.148± 6.876
1000 ppm	93.553± 11.826	87.918± 13.173	83.163± 9.325	85.757± 18.791	80.691± 11.431	79.746± 8.522	82.442± 10.335
4000 ppm	339.763± 45.219	317.512± 46.368	308.612± 47.380	302.449± 35.647	285.218± 34.169	286.531± 34.130	303.780± 36.933

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
250 ppm	21.943± 5.230	19.825± 1.852	20.154± 5.922	21.504± 6.072	20.110± 1.683	20.268± 2.000	20.891± 5.471
1000 ppm	82.272± 8.900	79.364± 9.059	77.546± 9.425	83.497± 9.522	80.815± 9.229	79.451± 8.563	77.136± 8.792
4000 ppm	287.848± 36.498	284.430± 35.086	285.191± 41.342	296.808± 41.432	286.951± 33.929	285.430± 49.999	289.195± 56.361

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg/kg/d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
250 ppm	19.760± 2.095	19.463± 2.022	19.783± 2.841	20.560± 2.310	20.549± 3.049	20.103± 3.032	21.639± 5.328
1000 ppm	77.691± 9.320	77.040± 7.768	74.459± 7.286	78.163± 7.496	77.756± 8.257	75.764± 8.065	78.253± 7.678
4000 ppm	281.629± 32.172	274.882± 33.236	271.754± 33.309	293.540± 35.237	282.105± 37.575	302.614± 51.124	292.097± 34.710

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
250 ppm	21.227± 5.768	19.765± 2.579	20.082± 6.144	23.352± 5.419	21.473± 2.858	22.152± 4.049	23.004± 6.987
1000 ppm	75.827± 6.625	74.136± 7.149	74.335± 6.695	82.050± 9.064	80.275± 8.487	78.647± 8.695	79.030± 9.334
4000 ppm	280.673± 31.669	285.531± 35.617	289.826± 34.467	304.536± 37.816	304.284± 40.780	307.887± 40.139	305.365± 38.123

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
250 ppm	21.762± 5.802	22.417± 7.950	22.056± 4.789	23.099± 5.852	23.840± 7.237	24.296± 8.113	23.725± 7.612
1000 ppm	75.513± 8.874	76.650± 9.927	76.334± 12.392	83.281± 13.912	84.538± 14.836	80.355± 14.401	84.915± 17.427
4000 ppm	288.422± 40.247	290.202± 39.453	291.214± 42.217	320.898± 47.947	318.918± 44.884	312.637± 46.909	308.464± 42.148

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (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
250 ppm	23.617± 7.710	24.885± 7.356	24.284± 8.118	24.829± 8.207	23.636± 7.280	24.374± 7.071	26.695± 10.488
1000 ppm	88.075± 22.568	87.761± 24.802	82.691± 22.937	87.040± 31.645	84.964± 28.839	87.473± 13.601	86.597± 15.073
4000 ppm	315.611± 43.586	305.790± 45.535	302.509± 52.717	315.014± 59.887	314.997± 49.730	328.186± 55.597	311.426± 52.900

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHENGES (SUMMARY)
ALL ANIMALS

Group Name	Administration (weeks) 100	102	104
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000
250 ppm	26.357± 10.765	26.350± 11.023	27.707± 8.986
1000 ppm	88.418± 15.989	90.304± 17.087	91.794± 17.854
4000 ppm	322.705± 48.134	343.334± 59.100	355.623± 49.782

APPENDIX E 4

CHEMICAL INTAKE CHANGES : SUMMARY, MOSUE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
1000 ppm	198.595± 19.958	178.606± 18.918	189.684± 58.109	190.783± 47.861	194.936± 45.334	193.530± 53.222	188.563± 46.942
4000 ppm	585.713± 77.353	580.083± 79.006	601.319±105.875	631.894±148.844	596.275±126.700	605.337±142.382	593.590±123.273
16000 ppm	1695.383±178.056	1711.768±356.686	1680.837±383.288	1714.146±438.902	1858.022±412.174	1964.562±464.942	1702.917±339.832

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
1000 ppm	180.870± 37.201	182.645± 44.152	176.648± 48.684	166.907± 38.782	167.318± 41.377	167.966± 56.717	161.172± 38.220
4000 ppm	612.098±179.788	628.229±190.898	607.218±163.509	602.493±160.389	595.428±142.693	583.995±141.669	560.406±121.691
16000 ppm	1741.370±386.481	1787.736±389.862	1766.781±418.085	1707.563±335.053	1680.107±382.624	2672.966±664.411	1793.317±389.313

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
1000 ppm	157.663± 37.389	150.635± 47.453	143.264± 49.650	132.807± 27.796	130.731± 39.599	120.446± 26.102	130.360± 37.228
4000 ppm	543.500±126.718	525.821±135.482	499.349±156.209	485.140± 94.909	458.165±100.032	445.533± 96.057	471.658±119.801
16000 ppm	1762.993±416.082	1768.972±344.369	1677.977±317.880	1637.059±417.743	1477.866±308.675	1451.315±328.942	1697.819±345.302

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
1000 ppm	144.677± 22.495	116.795± 28.030	117.753± 23.097	130.931± 52.156	117.909± 29.615	118.695± 25.200	118.040± 26.070
4000 ppm	562.501±122.496	445.455± 95.245	451.613±105.577	450.192± 94.411	440.289± 76.938	442.997± 84.005	445.037± 90.970
16000 ppm	1974.312±271.102	1528.854±391.227	1499.192±312.367	1534.158±296.015	1520.125±397.268	1596.512±332.459	1540.056±265.784

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg/kg/d a y
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
1000 ppm	110.885± 27.053	111.714± 23.929	108.686± 18.632	111.527± 22.624	107.739± 19.656	104.516± 18.610	115.632± 29.833
4000 ppm	435.121± 95.125	430.496± 58.018	419.539± 97.015	430.955± 75.127	429.622± 79.467	409.643± 87.370	429.542± 85.783
16000 ppm	1544.022±293.028	1415.786±267.782	1440.453±312.545	1567.865±272.014	1539.894±319.348	1485.978±231.823	1481.733±238.428

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
1000 ppm	111.634± 26.361	109.408± 35.819	112.252± 35.543	104.016± 29.963	114.488± 23.257	108.380± 25.036	116.801± 46.775
4000 ppm	420.776± 65.140	401.812± 55.065	400.203± 65.587	421.858± 94.697	409.001± 73.313	406.110± 78.453	414.759± 78.112
16000 ppm	1461.006±233.436	1444.943±194.611	1467.235±235.936	1477.317±261.347	1498.697±192.552	1478.781±273.084	1501.269±235.673

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
1000 ppm	112.431± 43.357	107.380± 19.344	112.482± 50.548	112.420± 17.057	119.296± 38.782	110.231± 18.374	116.141± 22.751
4000 ppm	404.630± 73.113	412.965± 73.710	391.789± 76.617	432.802±103.344	419.531± 74.414	407.374± 57.899	423.433± 97.699
16000 ppm	1436.118±274.974	1420.442±193.980	1414.827±201.425	1520.514±149.842	1516.157±213.296	1444.410±205.757	1435.075±211.503

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (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
1000 ppm	110.340± 18.730	110.610± 19.630	107.072± 18.374	112.352± 20.648	108.909± 21.127	108.882± 27.284	107.028± 33.975
4000 ppm	437.877±113.727	428.616±110.540	415.733±154.087	419.035± 64.895	419.343± 70.035	397.471± 63.474	404.182± 82.754
16000 ppm	1501.622±230.490	1483.154±247.750	1434.596±208.289	1470.357±190.607	1441.078±251.676	1401.607±190.795	1421.123±297.351

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
UNIT : mg／kg／d a y
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHENGES (SUMMARY)
ALL ANIMALS

Group Name	Administration (weeks) 100	102	104
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000
1000 ppm	113.702± 40.443	113.890± 41.141	112.981± 26.556
4000 ppm	418.070± 79.089	436.745± 85.833	438.750±113.074
16000 ppm	1488.026±253.249	1499.296±234.368	1478.110±240.256

APPENDIX F 1

HEMATOLOGY : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV f ℓ	MCH p g	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	35	8.23± 1.70	14.3± 2.7	42.4± 6.6	52.4± 5.7	17.4± 1.0	33.4± 2.2	904± 233
800 ppm	41	8.43± 1.77	14.3± 3.2	42.3± 8.1	50.6± 3.5	16.8± 1.1	33.4± 2.1	956± 235
2400 ppm	43	9.26± 1.33*	15.7± 2.1*	45.8± 5.5	50.0± 4.8*	17.1± 1.2	34.2± 1.6	778± 185*
7200 ppm	42	10.65± 1.60**	17.3± 2.7**	50.9± 7.8**	47.8± 1.6**	16.2± 0.8**	34.0± 1.0	659± 167**

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

Group Name	NO. of Animals	WBC $10^3/\mu\ell$		Differential WBC (%) N-BAND		N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	35	13.89±	39.92	2±	2	49±	15	1±	1	0±	0	5±	2	35±	11	7±	18
800 ppm	41	4.80±	2.05	2±	2	55±	9	2±	1	0±	0	5±	2	35±	8	3±	2
2400 ppm	43	3.91±	1.08*	2±	2	54±	8	2±	1	0±	0	5±	2	36±	7	2±	2
7200 ppm	42	3.89±	1.61**	1±	1	50±	9	2±	1	0±	0	5±	1	41±	8*	2±	2

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX F 2

HEMATOLOGY : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV f ℓ	MCH p g	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	34	8.23± 0.65	15.0± 1.0	43.2± 2.6	52.7± 2.0	18.2± 0.4	34.6± 1.0	700± 88
800 ppm	37	8.01± 0.68	14.4± 1.3	41.9± 3.4	52.4± 2.4	18.0± 0.7	34.4± 0.9	662± 115
2400 ppm	41	7.95± 1.01	14.4± 1.5*	41.7± 3.8	53.0± 5.5	18.2± 1.3	34.5± 1.6	665± 126
7200 ppm	42	7.96± 0.98	14.3± 1.9*	41.8± 4.8	52.6± 1.9	17.9± 0.8	34.1± 1.3	682± 121

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

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

Group Name	NO. of Animals	WBC $10^3/\mu\ell$		Differential WBC (%) N-BAND		N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	34	2.95±	2.14	1±	1	50±	9	2±	1	0±	0	6±	2	39±	9	2±	2
800 ppm	37	3.45±	5.22	2±	1	48±	13	2±	1	0±	0	6±	1	40±	12	3±	6
2400 ppm	41	4.05±	6.36	2±	2	47±	13	1±	1	0±	0	5±	2	41±	11	4±	7
7200 ppm	42	2.65±	1.89	1±	2	49±	12	1±	1	0±	0	5±	2	41±	12	2±	2

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

(JCL71A)

APPENDIX F 3

HEMATOLOGY : SUMMARY, MOSUE : MALE

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV f ℓ	MCH p g	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	38	9.87± 0.81	13.8± 1.1	42.8± 2.9	43.5± 1.9	14.0± 0.5	32.2± 0.7	1851± 503
250 ppm	32	9.56± 1.05	13.1± 1.6	40.7± 4.8	42.7± 3.1	13.7± 1.0	32.0± 1.0	1991± 749
1000 ppm	38	9.72± 0.94	13.6± 1.2	42.0± 3.6	43.3± 1.7	14.0± 0.6	32.3± 0.5	1744± 427
4000 ppm	40	9.82± 0.46	13.8± 0.7	42.4± 2.3	43.2± 1.6	14.1± 0.6	32.5± 1.0	1898± 315

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

(HCL070)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

Group Name	NO. of Animals	WBC $10^3/\mu\ell$		Differential WBC (%) N-BAND		N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	38	2.94±	1.18	0±	1	36±	10	1±	1	0±	0	5±	2	55±	10	2±	3
250 ppm	32	3.29±	2.02	1±	1*	39±	15	1±	1	0±	0	5±	2	52±	15	2±	2
1000 ppm	38	2.76±	1.37	1±	1	37±	10	1±	1	0±	0	6±	2	53±	10	2±	2
4000 ppm	40	2.54±	1.08	1±	2	37±	12	1±	1	0±	0	5±	2	53±	12	3±	3

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX F 4

HEMATOLOGY : SUMMARY, MOSUE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

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

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV f ℓ	MCH p g	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	27	9.73± 0.81	14.0± 1.1	42.6± 3.2	43.8± 1.9	14.4± 0.6	32.8± 0.9	1108± 303
1000 ppm	33	9.49± 1.28	13.6± 1.8	41.9± 5.7	44.2± 2.4	14.4± 0.6	32.5± 1.1	1096± 375
4000 ppm	29	9.13± 1.52	13.0± 2.0	40.5± 5.1	44.9± 5.1	14.4± 0.8	32.1± 1.8	1184± 365
16000 ppm	39	9.38± 1.04	13.3± 1.4*	41.2± 4.0	44.1± 1.8	14.2± 0.4	32.2± 0.9**	1296± 319

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

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

Group Name	NO. of Animals	WBC $10^3/\mu\ell$		Differential WBC (%) N-BAND		N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	27	1.98±	1.35	1±	1	36±	15	1±	1	0±	0	6±	3	52±	15	4±	5
1000 ppm	33	2.98±	2.92	1±	1	32±	12	2±	2	0±	0	6±	2	53±	15	6±	9
4000 ppm	29	3.75±	8.16	1±	1	39±	13	1±	1	0±	0	5±	3	49±	14	4±	4
16000 ppm	39	1.70±	2.17	1±	1	38±	12	1±	1	0±	0	4±	2*	54±	13	3±	4

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX G 1

BIOCHEMISTRY : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	TOTAL PROTEIN g/dl	ALBUMIN g/dl	A/G RATIO	T-BILIRUBIN mg/dl	GLUCOSE mg/dl	T-CHOLESTEROL mg/dl	TRIGLYCERIDE mg/dl
Control	35	6.9± 0.5	3.1± 0.3	0.8± 0.1	0.33± 0.22	167± 33	205± 56	235± 146
800 ppm	41	6.8± 0.5	3.1± 0.2	0.8± 0.1	0.28± 0.06	163± 30	181± 46	203± 122
2400 ppm	43	6.8± 0.3	3.1± 0.2	0.9± 0.1	0.31± 0.21	166± 20	152± 44**	157± 128*
7200 ppm	42	6.7± 0.2**	3.2± 0.1**	0.9± 0.1**	0.32± 0.08	158± 16	111± 41**	105± 171**

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	PHOSPHOLIPID mg/dℓ	GOT IU/ℓ	GPT IU/ℓ	LDH IU/ℓ	ALP IU/ℓ	G-GTP IU/ℓ	CPK IU/ℓ
Control	35	323± 101	107± 157	23± 22	308± 244	187± 95	7± 6	135± 244
800 ppm	41	283± 84	59± 22	16± 6	208± 84	241± 379	7± 4	82± 21
2400 ppm	43	235± 72**	70± 58	18± 9	190± 58*	191± 56	7± 3	76± 14
7200 ppm	42	174± 72**	71± 20	17± 4	218± 103	240± 97**	9± 4*	80± 25

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	UREA NITROGEN mg/dℓ		CREATININE mg/dℓ		SODIUM mEq/ℓ		POTASSIUM mEq/ℓ		CHLORIDE mEq/ℓ		CALCIUM mg/dℓ		INORGANIC PHOSPHORUS mg/dℓ	
Control	35	24.1±	5.3	0.7±	0.1	143±	2	3.6±	0.4	107±	2	11.0±	0.5	4.4±	0.8
800 ppm	41	23.1±	3.8	0.7±	0.1	143±	2	3.6±	0.3	106±	1	10.8±	0.4	4.3±	0.7
2400 ppm	43	21.7±	5.4*	0.6±	0.1**	143±	2	3.6±	0.3	106±	1	10.7±	0.4**	4.0±	0.7*
7200 ppm	42	18.4±	2.3**	0.5±	0.1**	142±	1*	3.8±	0.3	107±	1	10.4±	0.3**	3.9±	0.6**

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX G 2

BIOCHEMISTRY : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	TOTAL PROTEIN g/dℓ	ALBUMIN g/dℓ	A/G RATIO	T-BILIRUBIN mg/dℓ	GLUCOSE mg/dℓ	T-CHOLESTEROL mg/dℓ	TRIGLYCERIDE mg/dℓ
Control	34	7.2± 0.5	3.6± 0.2	1.0± 0.1	0.24± 0.05	162± 26	159± 40	139± 94
800 ppm	37	7.2± 0.4	3.6± 0.3	1.0± 0.1	0.27± 0.08	161± 22	157± 50	156± 127
2400 ppm	41	7.1± 0.5	3.5± 0.3	1.0± 0.1	0.26± 0.13	161± 23	140± 41	106± 100
7200 ppm	42	7.0± 0.5	3.6± 0.3	1.1± 0.1*	0.24± 0.04	155± 21	122± 29**	73± 33**

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	PHOSPHOLIPID mg/dℓ	GOT IU/ℓ	GPT IU/ℓ	LDH IU/ℓ	ALP IU/ℓ	G-GTP IU/ℓ	CPK IU/ℓ
Control	34	286± 79	116± 62	34± 17	346± 487	151± 148	3± 1	79± 19
800 ppm	37	286± 96	144± 166	36± 23	331± 462	141± 76	3± 2	85± 33
2400 ppm	41	248± 76*	131± 103	34± 20	317± 377	157± 100	4± 4	85± 32
7200 ppm	42	223± 51**	93± 40	24± 7**	243± 181	149± 80	2± 1**	83± 24

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	UREA NITROGEN mg/dℓ	CREATININE mg/dℓ	SODIUM mEq/ℓ	POTASSIUM mEq/ℓ	CHLORIDE mEq/ℓ	CALCIUM mg/dℓ	INORGANIC PHOSPHORUS mg/dℓ
Control	34	17.0± 1.9	0.5± 0.1	142± 2	3.5± 0.3	106± 2	10.7± 0.4	3.7± 1.0
800 ppm	37	17.4± 4.1	0.5± 0.1	142± 2	3.5± 0.4	106± 2	10.7± 0.3	3.6± 0.8
2400 ppm	41	15.8± 2.3*	0.5± 0.1	142± 2	3.7± 0.3	107± 2	10.5± 0.4	3.8± 0.9
7200 ppm	42	16.9± 3.8	0.5± 0.1	141± 2	3.8± 0.5**	107± 2**	10.5± 0.3*	3.8± 0.8

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX G 3

BIOCHEMISTRY : SUMMARY, MOSUE : MALE

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	TOTAL PROTEIN g/dℓ	ALBUMIN g/dℓ	A/G RATIO	T-BILIRUBIN mg/dℓ	GLUCOSE mg/dℓ	T-CHOLESTEROL mg/dℓ	TRIGLYCERIDE mg/dℓ
Control	38	5.6± 0.7	2.8± 0.3	1.0± 0.1	0.38± 0.14	180± 40	114± 38	76± 31
250 ppm	32	5.9± 0.9	2.9± 0.5	1.0± 0.1	0.41± 0.12	172± 43	129± 61	76± 26
1000 ppm	38	5.7± 0.7	2.8± 0.3	1.0± 0.1	0.42± 0.18	178± 46	109± 40	70± 19
4000 ppm	40	5.6± 0.5	2.8± 0.3	1.0± 0.1	0.40± 0.11	179± 33	95± 24**	66± 16

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	GOT IU/ℓ		GPT IU/ℓ		LDH IU/ℓ		ALP IU/ℓ		CPK IU/ℓ		UREA NITROGEN mg/dℓ		SODIUM mEq/ℓ	
Control	38	173±	278	62±	73	516±	506	186±	68	49±	80	22.8±	6.3	155±	2
250 ppm	32	275±	413	142±	317	872±	1618	204±	105	44±	58	22.2±	6.4	155±	2
1000 ppm	38	168±	298	52±	78	736±	1242	224±	121	40±	21	22.2±	7.7	155±	2
4000 ppm	40	98±	151**	23±	32**	387±	339	186±	55	49±	31	20.4±	2.9	155±	2

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	POTASSIUM mEq／ℓ	CHLORIDE mEq／ℓ	CALCIUM mg／dℓ	INORGANIC PHOSPHORUS mg／dℓ
Control	38	4.2± 0.4	123± 3	9.2± 0.5	6.2± 0.7
250 ppm	32	4.2± 0.4	123± 3	9.4± 0.9	6.1± 0.7
1000 ppm	38	4.2± 0.4	124± 2	9.1± 0.5	6.3± 0.8
4000 ppm	40	4.2± 0.3	124± 3	9.0± 0.4	6.4± 0.8

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX G 4

BIOCHEMISTRY : SUMMARY, MOSUE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	TOTAL PROTEIN g/dℓ	ALBUMIN g/dℓ	A/G RATIO	T-BILIRUBIN mg/dℓ	GLUCOSE mg/dℓ	T-CHOLESTEROL mg/dℓ	TRIGLYCERIDE mg/dℓ
Control	27	5.4± 0.7	2.7± 0.4	1.1± 0.1	0.34± 0.10	135± 35	84± 50	73± 20
1000 ppm	33	5.4± 0.6	2.8± 0.2	1.1± 0.2	0.44± 0.18	138± 32	80± 27	64± 17
4000 ppm	29	5.7± 0.7	2.9± 0.3**	1.1± 0.2	0.40± 0.14	143± 34	88± 65	70± 30
16000 ppm	39	5.3± 0.6	2.9± 0.3**	1.2± 0.1**	0.37± 0.09	138± 36	75± 14	50± 12**

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

(HCL074)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	GOT IU/ℓ	GPT IU/ℓ	LDH IU/ℓ	ALP IU/ℓ	CPK IU/ℓ	UREA NITROGEN mg/dℓ	SODIUM mEq/ℓ
Control	27	235± 636	66± 207	707± 1748	283± 103	108± 192	16.1± 4.1	153± 2
1000 ppm	33	140± 191	59± 118	679± 974	390± 159*	81± 94	26.6± 48.6	154± 2
4000 ppm	29	94± 43	21± 12*	662± 1140	310± 147	71± 71	19.8± 8.2	153± 3
16000 ppm	39	87± 39	17± 12**	427± 319	354± 108*	318± 694**	20.9± 13.4*	154± 3

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (105)

Group Name	NO. of Animals	POTASSIUM mEq／ℓ		CHLORIDE mEq／ℓ		CALCIUM mg／dℓ		INORGANIC PHOSPHORUS mg／dℓ	
Control	27	4.1±	0.4	123±	4	9.2±	0.6	6.4±	0.9
1000 ppm	33	4.6±	1.1*	123±	3	9.3±	0.6	7.0±	4.1
4000 ppm	29	4.2±	0.4	124±	4	9.4±	0.7	6.0±	1.0
16000 ppm	39	4.2±	0.5	126±	4**	8.9±	0.4	5.8±	1.0

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX H 1

URINALYSIS : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
SAMPLING DATE : 104-2
SEX : MALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	pH 5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	Protein −	±	+	2+	3+	4+	CHI	Glucose −	±	+	2+	3+	4+	CHI	Ketone body −	±	+	2+	3+	4+	CHI	Bilirubin −	+	2+	3+	CHI
Control	36	0	0	11	17	7	1	0		0	0	0	0	19	17		36	0	0	0	0	0		36	0	0	0	0	0		36	0	0	0	
800 ppm	43	0	1	11	21	9	1	0		0	0	0	0	15	28		43	0	0	0	0	0		42	1	0	0	0	0		43	0	0	0	
2400 ppm	43	0	2	23	13	4	1	0		0	0	0	1	24	18		43	0	0	0	0	0		43	0	0	0	0	0		42	1	0	0	
7200 ppm	42	0	6	32	4	0	0	0	**	0	0	0	9	23	10	**	42	0	0	0	0	0		41	1	0	0	0	0		42	0	0	0	

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

STUDY NO. : 0141
ANIMAL : RAT F344
SAMPLING DATE : 104-2
SEX : MALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	Occult blood −	±	+	2+	3+	CHI	Urobilinogen ±	+	2+	3+	4+	CHI
Control	36	36	0	0	0	0		36	0	0	0	0	
800 ppm	43	43	0	0	0	0		43	0	0	0	0	
2400 ppm	43	39	4	0	0	0		42	1	0	0	0	
7200 ppm	42	38	4	0	0	0		42	0	0	0	0	

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

APPENDIX H 2

URINALYSIS : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
SAMPLING DATE : 104-2
SEX : FEMALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	pH 5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	Protein −	±	+	2+	3+	4+	CHI	Glucose −	±	+	2+	3+	4+	CHI	Ketone body −	±	+	2+	3+	4+	CHI	Bilirubin −	+	2+	3+	CHI
Control	36	0	0	3	20	10	2	1		0	0	0	5	20	11		36	0	0	0	0	0		34	2	0	0	0	0		36	0	0	0	
800 ppm	39	0	1	8	11	11	7	1		0	0	1	8	26	4		39	0	0	0	0	0		35	4	0	0	0	0		39	0	0	0	
2400 ppm	43	0	2	18	14	8	1	0	*	0	0	1	8	31	3	*	43	0	0	0	0	0		40	3	0	0	0	0		43	0	0	0	
7200 ppm	45	0	6	28	9	2	0	0	**	0	0	2	19	24	0	**	45	0	0	0	0	0		44	1	0	0	0	0		45	0	0	0	

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

STUDY NO. : 0141
ANIMAL : RAT F344
SAMPLING DATE : 104-2
SEX : FEMALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	Occult blood −	±	+	2+	3+	CHI	Urobilinogen ±	+	2+	3+	4+	CHI
Control	36	34	1	0	0	1		36	0	0	0	0	
800 ppm	39	34	4	0	1	0		39	0	0	0	0	
2400 ppm	43	37	2	2	0	2		43	0	0	0	0	
7200 ppm	45	28	6	2	4	5	*	45	0	0	0	0	

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

APPENDIX H 3

URINALYSIS : SUMMARY, MOSUE : MALE

(2-YEAR STUDY)

STUDY NO. : 0140 URINALYSIS
ANIMAL : MOUSE BDF1
SAMPLING DATE : 104-2
SEX : MALE REPORT TYPE : A1

Group Name	NO. of Animals	pH 5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	Protein −	±	+	2+	3+	4+	CHI	Glucose −	±	+	2+	3+	4+	CHI	Ketone body −	±	+	2+	3+	4+	CHI	Occult blood −	±	+	2+	3+	CHI
Control	38	0	2	16	14	6	0	0		0	2	22	14	0	0		38	0	0	0	0	0		26	12	0	0	0	0		33	1	4	0	0	
250 ppm	33	0	7	8	17	1	0	0	*	0	1	25	6	1	0		33	0	0	0	0	0		23	10	0	0	0	0		31	1	1	0	0	
1000 ppm	39	0	7	16	13	3	0	0		0	0	29	9	1	0		39	0	0	0	0	0		20	18	1	0	0	0		35	2	1	1	0	
4000 ppm	41	0	10	26	5	0	0	0	**	0	0	26	14	1	0		41	0	0	0	0	0		24	16	1	0	0	0		40	1	0	0	0	

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

(JCL101)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
SAMPLING DATE : 104-2
SEX : MALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	Urobilinogen ±	+	2+	3+	4+	CHI
Control	38	38	0	0	0	0	
250 ppm	33	33	0	0	0	0	
1000 ppm	39	39	0	0	0	0	
4000 ppm	41	41	0	0	0	0	

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

APPENDIX H 4

URINALYSIS : SUMMARY, MOSUE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
SAMPLING DATE : 104-2
SEX : FEMALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	pH 5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	Protein −	±	+	2+	3+	4+	CHI	Glucose −	±	+	2+	3+	4+	CHI	Ketone body −	±	+	2+	3+	4+	CHI	Occult blood −	±	+	2+	3+	CHI
Control	27	0	0	4	10	12	1	0		0	1	19	7	0	0		27	0	0	0	0	0		12	15	0	0	0	0		22	4	0	1	0	
1000 ppm	33	0	4	6	16	4	3	0	*	0	3	21	9	0	0		33	0	0	0	0	0		14	18	1	0	0	0		27	1	1	3	1	
4000 ppm	30	0	4	16	8	2	0	0	**	0	1	17	12	0	0		30	0	0	0	0	0		8	19	3	0	0	0		28	1	0	1	0	
16000 ppm	39	1	30	8	0	0	0	0	**	0	1	32	6	0	0		39	0	0	0	0	0		2	33	4	0	0	0	**	37	0	0	1	1	

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
SAMPLING DATE : 104-2
SEX : FEMALE REPORT TYPE : A1

URINALYSIS

Group Name	NO. of Animals	Urobilinogen ±	+	2+	3+	4+	CHI
Control	27	27	0	0	0	0	
1000 ppm	33	33	0	0	0	0	
4000 ppm	30	30	0	0	0	0	
16000 ppm	39	39	0	0	0	0	

Significent difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

APPENDIX I 1

GROSS FINDINGS : SUMMARY, RAT : MALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name / NO. of Animals	Control 14 (%)	800 ppm 7 (%)	2400 ppm 7 (%)	7200 ppm 8 (%)
skin/app	ulcer		1 (7)	0 (0)	0 (0)	0 (0)
subcutis	jaundice		0 (0)	0 (0)	0 (0)	1 (13)
	mass		0 (0)	2 (29)	2 (29)	1 (13)
lung	white zone		1 (7)	0 (0)	0 (0)	0 (0)
	voluminus		1 (7)	1 (14)	0 (0)	0 (0)
thymus	nodule		0 (0)	0 (0)	0 (0)	1 (13)
spleen	enlarged		1 (7)	2 (29)	1 (14)	2 (25)
heart	white		0 (0)	1 (14)	0 (0)	0 (0)
artery/aort	induration		1 (7)	0 (0)	0 (0)	0 (0)
forestomach	nodule		0 (0)	0 (0)	1 (14)	0 (0)
	ulcer		2 (14)	1 (14)	1 (14)	0 (0)
small intes	nodule		1 (7)	0 (0)	0 (0)	0 (0)
cecum	nodule		1 (7)	0 (0)	0 (0)	0 (0)
large intes	stenosed		1 (7)	0 (0)	0 (0)	0 (0)
liver	enlarged		2 (14)	1 (14)	0 (0)	1 (13)
	nodule		1 (7)	0 (0)	0 (0)	1 (13)
	nodular		0 (0)	0 (0)	0 (0)	1 (13)
	herniation		1 (7)	1 (14)	0 (0)	0 (0)
pancreas	nodule		0 (0)	0 (0)	0 (0)	1 (13)
kidney	granular		3 (21)	0 (0)	1 (14)	0 (0)
urin bladd	urine:marked retention		0 (0)	0 (0)	1 (14)	0 (0)
	fluid:red		0 (0)	0 (0)	0 (0)	1 (13)

Organ	Findings	Group Name / NO. of Animals	Control 14 (%)	800 ppm 7 (%)	2400 ppm 7 (%)	7200 ppm 8 (%)
pituitary	enlarged		5 (36)	2 (29)	3 (43)	2 (25)
	red zone		0 (0)	1 (14)	0 (0)	0 (0)
	nodule		1 (7)	0 (0)	0 (0)	0 (0)
thyroid	enlarged		1 (7)	0 (0)	0 (0)	0 (0)
adrenal	enlarged		0 (0)	0 (0)	0 (0)	1 (13)
testis	enlarged		0 (0)	0 (0)	0 (0)	1 (13)
	atrophic		3 (21)	1 (14)	1 (14)	1 (13)
	nodule		4 (29)	3 (43)	2 (29)	5 (63)
	fluid		0 (0)	0 (0)	1 (14)	0 (0)
	fluid:transparent		0 (0)	0 (0)	1 (14)	0 (0)
prep/cli gl	nodule		1 (7)	0 (0)	0 (0)	0 (0)
brain	hemorrhage		1 (7)	1 (14)	0 (0)	0 (0)
Zymbal gl	nodule		1 (7)	1 (14)	0 (0)	0 (0)
muscle	nodule		0 (0)	0 (0)	0 (0)	1 (13)
abdominal c	mass		0 (0)	0 (0)	0 (0)	1 (13)
	ascites		0 (0)	0 (0)	0 (0)	1 (13)
thoracic ca	pleural fluid		1 (7)	0 (0)	0 (0)	1 (13)
whole body	anemic		0 (0)	1 (14)	1 (14)	1 (13)
	jaundice		0 (0)	0 (0)	1 (14)	0 (0)

APPENDIX I 2

GROSS FINDINGS : SUMMARY, RAT : FEMALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

Organ	Findings	Group Name / NO. of Animals	Control 13	(%)	800 ppm 12	(%)	2400 ppm 7	(%)	7200 ppm 5	(%)
skin/app	nodule		1	(8)	0	(0)	0	(0)	0	(0)
subcutis	jaundice		0	(0)	1	(8)	0	(0)	0	(0)
	mass		2	(15)	4	(33)	1	(14)	1	(20)
lung	red patch/zone		0	(0)	0	(0)	1	(14)	0	(0)
lymph node	enlarged		2	(15)	0	(0)	0	(0)	1	(20)
thymus	enlarged		1	(8)	0	(0)	0	(0)	0	(0)
spleen	enlarged		5	(38)	3	(25)	3	(43)	2	(40)
	hemorrhage		0	(0)	1	(8)	0	(0)	0	(0)
	nodule		0	(0)	0	(0)	1	(14)	0	(0)
	deformed		1	(8)	1	(8)	0	(0)	0	(0)
liver	enlarged		0	(0)	0	(0)	1	(14)	0	(0)
	pale		0	(0)	1	(8)	0	(0)	0	(0)
	yellow		0	(0)	1	(8)	0	(0)	0	(0)
	granular		1	(8)	0	(0)	1	(14)	0	(0)
	accentuation of lobular structure		1	(8)	0	(0)	0	(0)	0	(0)
kidney	cyst		0	(0)	1	(8)	0	(0)	0	(0)
	hydronephrosis		0	(0)	1	(8)	0	(0)	1	(20)
urin bladd	urine:marked retention		0	(0)	1	(8)	0	(0)	0	(0)
pituitary	enlarged		5	(38)	4	(33)	2	(29)	1	(20)
	red zone		1	(8)	1	(8)	1	(14)	0	(0)
	nodule		0	(0)	2	(17)	1	(14)	0	(0)
thyroid	black		1	(8)	0	(0)	0	(0)	0	(0)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

Organ	Findings	Group Name NO. of Animals	Control 13 (%)	800 ppm 12 (%)	2400 ppm 7 (%)	7200 ppm 5 (%)
uterus	nodule		1 (8)	3 (25)	1 (14)	4 (80)
prep/cli gl	nodule		1 (8)	0 (0)	0 (0)	0 (0)
spinal cord	hemorrhage		0 (0)	0 (0)	1 (14)	0 (0)
retroperit	mass		0 (0)	1 (8)	0 (0)	0 (0)
abdominal c	hemorrhage		0 (0)	0 (0)	0 (0)	1 (20)
thoracic ca	hemorrhage		1 (8)	0 (0)	0 (0)	1 (20)
	mass		1 (8)	0 (0)	0 (0)	0 (0)
	pleural fluid		0 (0)	1 (8)	0 (0)	0 (0)
whole body	anemic		2 (15)	3 (25)	0 (0)	0 (0)

APPENDIX I 3

GROSS FINDINGS : SUMMARY, RAT : MALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / NO. of Animals	Control 36 (%)	800 ppm 43 (%)	2400 ppm 43 (%)	7200 ppm 42 (%)
skin/app	nodule		5 (14)	5 (12)	2 (5)	5 (12)
subcutis	mass		6 (17)	8 (19)	8 (19)	2 (5)
lung	red		1 (3)	0 (0)	0 (0)	0 (0)
	white zone		0 (0)	0 (0)	1 (2)	0 (0)
	red zone		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		2 (6)	3 (7)	2 (5)	4 (10)
	voluminus		1 (3)	0 (0)	0 (0)	0 (0)
lymph node	enlarged		1 (3)	0 (0)	0 (0)	0 (0)
thymus	red		1 (3)	0 (0)	0 (0)	0 (0)
spleen	enlarged		4 (11)	1 (2)	1 (2)	1 (2)
	nodule		0 (0)	1 (2)	1 (2)	0 (0)
	deformed		1 (3)	1 (2)	0 (0)	0 (0)
heart	white zone		0 (0)	2 (5)	0 (0)	0 (0)
forestomach	nodule		0 (0)	0 (0)	1 (2)	0 (0)
gl stomach	nodule		1 (3)	0 (0)	0 (0)	0 (0)
	ulcer		0 (0)	1 (2)	0 (0)	1 (2)
	thick		0 (0)	1 (2)	0 (0)	0 (0)
small intes	nodule		0 (0)	1 (2)	0 (0)	0 (0)
liver	enlarged		1 (3)	0 (0)	0 (0)	0 (0)
	white zone		1 (3)	1 (2)	1 (2)	0 (0)
	red zone		0 (0)	0 (0)	1 (2)	1 (2)
	brown zone		0 (0)	2 (5)	0 (0)	0 (0)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / NO. of Animals	Control 36 (%)	800 ppm 43 (%)	2400 ppm 43 (%)	7200 ppm 42 (%)
liver	nodule		6 (17)	3 (7)	3 (7)	2 (5)
	herniation		2 (6)	1 (2)	0 (0)	1 (2)
pancreas	white zone		0 (0)	0 (0)	0 (0)	1 (2)
	nodule		1 (3)	1 (2)	0 (0)	1 (2)
kidney	deformed		0 (0)	1 (2)	0 (0)	0 (0)
	granular		3 (8)	3 (7)	0 (0)	0 (0)
pituitary	enlarged		2 (6)	2 (5)	1 (2)	0 (0)
	white zone		0 (0)	0 (0)	1 (2)	0 (0)
	red zone		0 (0)	1 (2)	0 (0)	0 (0)
	nodule		5 (14)	4 (9)	2 (5)	2 (5)
thyroid	enlarged		5 (14)	1 (2)	4 (9)	5 (12)
	nodule		0 (0)	2 (5)	0 (0)	0 (0)
adrenal	enlarged		1 (3)	1 (2)	1 (2)	1 (2)
	nodule		0 (0)	1 (2)	0 (0)	0 (0)
testis	enlarged		0 (0)	0 (0)	1 (2)	1 (2)
	nodule		33 (92)	43 (100)	43 (100)	41 (98)
prostate	enlarged		0 (0)	1 (2)	0 (0)	0 (0)
	brown zone		0 (0)	2 (5)	0 (0)	0 (0)
prep/cli gl	enlarged		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		1 (3)	1 (2)	0 (0)	0 (0)
spinal cord	brown zone		0 (0)	0 (0)	0 (0)	1 (2)
eye	white		0 (0)	5 (12)	2 (5)	0 (0)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / NO. of Animals	Control 36 (%)	800 ppm 43 (%)	2400 ppm 43 (%)	7200 ppm 42 (%)
eye	nodule		0 (0)	1 (2)	0 (0)	0 (0)
Zymbal gl	nodule		0 (0)	1 (2)	0 (0)	0 (0)
	mass		0 (0)	1 (2)	0 (0)	0 (0)
peritoneum	nodule		0 (0)	2 (5)	0 (0)	0 (0)
abdominal c	ascites		0 (0)	2 (5)	0 (0)	0 (0)
thoracic ca	pleural fluid		1 (3)	0 (0)	0 (0)	0 (0)
other	tail:nodule		0 (0)	0 (0)	1 (2)	0 (0)
	ear:nodule		0 (0)	1 (2)	0 (0)	0 (0)

APPENDIX I 4

GROSS FINDINGS : SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / NO. of Animals	Control 37 (%)	800 ppm 38 (%)	2400 ppm 43 (%)	7200 ppm 45 (%)
skin/app	nodule		0 (0)	2 (5)	2 (5)	0 (0)
	scab		1 (3)	0 (0)	0 (0)	1 (2)
subcutis	yellow		1 (3)	0 (0)	0 (0)	0 (0)
	mass		6 (16)	8 (21)	2 (5)	3 (7)
lung	red		0 (0)	0 (0)	0 (0)	1 (2)
	black zone		0 (0)	0 (0)	1 (2)	0 (0)
	nodule		2 (5)	2 (5)	0 (0)	1 (2)
lymph node	enlarged		1 (3)	2 (5)	1 (2)	0 (0)
spleen	enlarged		0 (0)	2 (5)	3 (7)	1 (2)
	nodule		0 (0)	0 (0)	2 (5)	0 (0)
	deformed		0 (0)	1 (3)	0 (0)	0 (0)
	adhesion		0 (0)	1 (3)	0 (0)	0 (0)
forestomach	ulcer		1 (3)	0 (0)	0 (0)	0 (0)
gl stomach	nodule		0 (0)	1 (3)	0 (0)	1 (2)
	ulcer		1 (3)	1 (3)	1 (2)	0 (0)
liver	yellow		1 (3)	0 (0)	0 (0)	0 (0)
	white zone		1 (3)	0 (0)	1 (2)	0 (0)
	red zone		3 (8)	0 (0)	2 (5)	0 (0)
	nodule		3 (8)	4 (11)	1 (2)	2 (4)
	deformed		0 (0)	1 (3)	0 (0)	0 (0)
	granular		0 (0)	1 (3)	1 (2)	0 (0)
	herniation		1 (3)	1 (3)	5 (12)	7 (16)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / NO. of Animals	Control 37 (%)	800 ppm 38 (%)	2400 ppm 43 (%)	7200 ppm 45 (%)
pancreas	white zone		0 (0)	1 (3)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	1 (2)	0 (0)
kidney	cyst		0 (0)	0 (0)	1 (2)	0 (0)
	granular		0 (0)	1 (3)	0 (0)	1 (2)
pituitary	enlarged		4 (11)	3 (8)	3 (7)	2 (4)
	white zone		0 (0)	0 (0)	0 (0)	1 (2)
	red zone		1 (3)	4 (11)	8 (19)	4 (9)
	nodule		3 (8)	5 (13)	2 (5)	6 (13)
thyroid	enlarged		1 (3)	2 (5)	2 (5)	0 (0)
	red zone		0 (0)	0 (0)	0 (0)	1 (2)
	nodule		0 (0)	1 (3)	0 (0)	0 (0)
adrenal	enlarged		0 (0)	0 (0)	0 (0)	2 (4)
ovary	cyst		1 (3)	0 (0)	2 (5)	3 (7)
uterus	nodule		0 (0)	0 (0)	1 (2)	4 (9)
	cyst		0 (0)	0 (0)	1 (2)	0 (0)
	dilated lumen		2 (5)	2 (5)	4 (9)	4 (9)
vagina	nodule		1 (3)	0 (0)	0 (0)	0 (0)
spinal cord	hemorrhage		0 (0)	0 (0)	0 (0)	1 (2)
eye	white		4 (11)	6 (16)	1 (2)	0 (0)
bone	deformed		0 (0)	1 (3)	0 (0)	0 (0)
peritoneum	nodule		1 (3)	0 (0)	0 (0)	0 (0)
abdominal c	hemorrhage		1 (3)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name NO. of Animals	Control 37 (%)	800 ppm 38 (%)	2400 ppm 43 (%)	7200 ppm 45 (%)
adipose	nodule		1 (3)	0 (0)	0 (0)	0 (0)
thoracic ca	pleural fluid		0 (0)	1 (3)	0 (0)	0 (0)

APPENDIX I 5

GROSS FINDINGS : SUMMARY, MOSUE : MALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name / NO. of Animals	Control 12 (%)	250 ppm 17 (%)	1000 ppm 12 (%)	4000 ppm 10 (%)
skin/app	hard		1 (8)	0 (0)	0 (0)	0 (0)
subcutis	edema		0 (0)	2 (12)	0 (0)	0 (0)
	mass		0 (0)	1 (6)	0 (0)	1 (10)
lung	red		0 (0)	0 (0)	0 (0)	2 (20)
	nodule		4 (33)	4 (24)	4 (33)	1 (10)
	voluminus		0 (0)	1 (6)	0 (0)	0 (0)
lymph node	enlarged		0 (0)	3 (18)	4 (33)	1 (10)
	black		0 (0)	1 (6)	0 (0)	0 (0)
spleen	enlarged		0 (0)	0 (0)	4 (33)	1 (10)
	nodule		0 (0)	2 (12)	0 (0)	0 (0)
gl stomach	thick		0 (0)	0 (0)	1 (8)	1 (10)
small intes	nodule		1 (8)	0 (0)	0 (0)	1 (10)
cecum	red		0 (0)	0 (0)	1 (8)	0 (0)
large intes	nodule		1 (8)	0 (0)	0 (0)	0 (0)
liver	enlarged		0 (0)	2 (12)	0 (0)	0 (0)
	white zone		0 (0)	3 (18)	0 (0)	2 (20)
	black zone		0 (0)	0 (0)	0 (0)	1 (10)
	nodule		7 (58)	5 (29)	4 (33)	4 (40)
	cyst		0 (0)	1 (6)	1 (8)	0 (0)
	deformed		0 (0)	0 (0)	0 (0)	1 (10)
pancreas	nodule		1 (8)	0 (0)	1 (8)	0 (0)
kidney	enlarged		0 (0)	2 (12)	0 (0)	0 (0)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name / NO. of Animals	Control 12 (%)	250 ppm 17 (%)	1000 ppm 12 (%)	4000 ppm 10 (%)
kidney	pale		0 (0)	0 (0)	0 (0)	1 (10)
	white zone		1 (8)	0 (0)	0 (0)	0 (0)
	nodule		0 (0)	1 (6)	0 (0)	0 (0)
	deformed		1 (8)	1 (6)	0 (0)	0 (0)
	hydronephrosis		0 (0)	2 (12)	1 (8)	1 (10)
urin bladd	nodule		0 (0)	2 (12)	0 (0)	1 (10)
	urine:marked retention		2 (17)	1 (6)	0 (0)	0 (0)
	fluid:red		0 (0)	0 (0)	0 (0)	1 (10)
testis	atrophic		0 (0)	1 (6)	0 (0)	0 (0)
	hard		0 (0)	0 (0)	1 (8)	0 (0)
epididymis	white		0 (0)	1 (6)	0 (0)	0 (0)
	nodule		0 (0)	1 (6)	0 (0)	0 (0)
semin ves	enlarged		0 (0)	1 (6)	0 (0)	0 (0)
prep/cli gl	enlarged		0 (0)	1 (6)	0 (0)	0 (0)
	nodule		0 (0)	1 (6)	0 (0)	1 (10)
	hard		0 (0)	0 (0)	1 (8)	0 (0)
brain	yellow		0 (0)	1 (6)	0 (0)	0 (0)
periph nerv	nodule		0 (0)	0 (0)	0 (0)	1 (10)
Harder gl	nodule		0 (0)	1 (6)	0 (0)	0 (0)
mediastinum	nodule		1 (8)	0 (0)	0 (0)	0 (0)
	mass		0 (0)	0 (0)	1 (8)	0 (0)
peritoneum	nodule		0 (0)	0 (0)	0 (0)	1 (10)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name / NO. of Animals	Control 12	(%)	250 ppm 17	(%)	1000 ppm 12	(%)	4000 ppm 10	(%)
peritoneum	mass		0	(0)	0	(0)	1	(8)	0	(0)
retroperit	mass		0	(0)	1	(6)	2	(17)	0	(0)
abdominal c	nodule		0	(0)	1	(6)	0	(0)	0	(0)
	ascites		0	(0)	2	(12)	4	(33)	0	(0)
mesenterium	nodule		0	(0)	1	(6)	0	(0)	0	(0)
thoracic ca	hemorrhage		1	(8)	1	(6)	0	(0)	1	(10)
	mass		0	(0)	0	(0)	1	(8)	0	(0)
	pleural fluid		1	(8)	4	(24)	4	(33)	1	(10)
whole body	anemic		0	(0)	1	(6)	0	(0)	0	(0)

APPENDIX I 6

GROSS FINDINGS : SUMMARY, MOSUE : FEMALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

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

Organ	Findings	Group Name / NO. of Animals	Control 23 (%)	1000 ppm 16 (%)	4000 ppm 20 (%)	16000 ppm 11 (%)
subcutis	edema		1 (4)	1 (6)	1 (5)	1 (9)
lung	red		0 (0)	0 (0)	0 (0)	1 (9)
	white zone		0 (0)	0 (0)	1 (5)	0 (0)
	red zone		0 (0)	1 (6)	0 (0)	0 (0)
	nodule		1 (4)	2 (13)	2 (10)	1 (9)
	voluminus		1 (4)	1 (6)	0 (0)	0 (0)
lymph node	enlarged		7 (30)	1 (6)	6 (30)	0 (0)
thymus	enlarged		0 (0)	0 (0)	1 (5)	0 (0)
spleen	enlarged		7 (30)	1 (6)	3 (15)	1 (9)
	nodule		0 (0)	1 (6)	1 (5)	1 (9)
heart	enlarged		1 (4)	0 (0)	0 (0)	0 (0)
	white		1 (4)	0 (0)	0 (0)	0 (0)
	white zone		1 (4)	0 (0)	0 (0)	0 (0)
	nodule		1 (4)	0 (0)	0 (0)	0 (0)
salivary gl	enlarged		0 (0)	1 (6)	0 (0)	0 (0)
gl stomach	erosion		1 (4)	0 (0)	0 (0)	0 (0)
large intes	nodule		0 (0)	0 (0)	1 (5)	0 (0)
liver	enlarged		0 (0)	0 (0)	4 (20)	3 (27)
	white zone		5 (22)	1 (6)	1 (5)	0 (0)
	red zone		1 (4)	1 (6)	0 (0)	1 (9)
	nodule		2 (9)	2 (13)	0 (0)	0 (0)
	adhesion		0 (0)	1 (6)	0 (0)	1 (9)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

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

Organ	Findings	Group Name / NO. of Animals	Control 23	(%)	1000 ppm 16	(%)	4000 ppm 20	(%)	16000 ppm 11	(%)
pancreas	nodule		1	(4)	1	(6)	0	(0)	0	(0)
kidney	pale		1	(4)	0	(0)	0	(0)	0	(0)
	red zone		1	(4)	0	(0)	0	(0)	0	(0)
	nodule		1	(4)	0	(0)	0	(0)	0	(0)
	nodular		0	(0)	0	(0)	1	(5)	0	(0)
	hydronephrosis		0	(0)	1	(6)	1	(5)	1	(9)
pituitary	enlarged		1	(4)	2	(13)	1	(5)	0	(0)
ovary	enlarged		0	(0)	0	(0)	1	(5)	2	(18)
	cyst		0	(0)	2	(13)	3	(15)	0	(0)
uterus	enlarged		0	(0)	0	(0)	0	(0)	1	(9)
	nodule		6	(26)	3	(19)	3	(15)	3	(27)
	dilated		1	(4)	0	(0)	0	(0)	0	(0)
	dilated lumen		0	(0)	1	(6)	0	(0)	0	(0)
vagina	nodule		0	(0)	1	(6)	0	(0)	0	(0)
prep/cli gl	nodule		0	(0)	0	(0)	1	(5)	0	(0)
brain	yellow		0	(0)	0	(0)	0	(0)	1	(9)
	red patch/zone		0	(0)	1	(6)	0	(0)	1	(9)
	red zone		1	(4)	0	(0)	0	(0)	0	(0)
periph nerv	nodule		0	(0)	1	(6)	0	(0)	0	(0)
muscle	mass		1	(4)	1	(6)	0	(0)	0	(0)
mediastinum	nodule		0	(0)	0	(0)	1	(5)	0	(0)
	mass		1	(4)	1	(6)	1	(5)	1	(9)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

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

Organ	Findings	Group Name / NO. of Animals	Control 23 (%)	1000 ppm 16 (%)	4000 ppm 20 (%)	16000 ppm 11 (%)
peritoneum	nodule		2 (9)	0 (0)	0 (0)	0 (0)
	mass		0 (0)	1 (6)	0 (0)	0 (0)
retroperit	mass		0 (0)	1 (6)	1 (5)	0 (0)
abdominal c	hemorrhage		0 (0)	1 (6)	0 (0)	1 (9)
	ascites		10 (43)	4 (25)	10 (50)	2 (18)
thoracic ca	nodule		0 (0)	0 (0)	1 (5)	0 (0)
	mass		1 (4)	0 (0)	0 (0)	0 (0)
	pleural fluid		13 (57)	4 (25)	12 (60)	4 (36)
other	hindlimb:nodule		2 (9)	0 (0)	0 (0)	0 (0)
whole body	anemic		2 (9)	0 (0)	1 (5)	0 (0)

APPENDIX I 7

GROSS FINDINGS : SUMMARY, MOSUE : MALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / NO. of Animals	Control 38 (%)	250 ppm 33 (%)	1000 ppm 38 (%)	4000 ppm 40 (%)
skin/app	nodule		1 (3)	0 (0)	0 (0)	1 (3)
lung	nodule		9 (24)	13 (39)	6 (16)	8 (20)
	cyst		0 (0)	0 (0)	1 (3)	0 (0)
	adhesion		0 (0)	0 (0)	1 (3)	0 (0)
lymph node	enlarged		1 (3)	2 (6)	2 (5)	3 (8)
spleen	enlarged		1 (3)	1 (3)	1 (3)	1 (3)
	black zone		0 (0)	1 (3)	3 (8)	2 (5)
	nodule		0 (0)	1 (3)	1 (3)	1 (3)
salivary gl	enlarged		1 (3)	0 (0)	0 (0)	0 (0)
gl stomach	ulcer		0 (0)	0 (0)	1 (3)	0 (0)
	thick		9 (24)	8 (24)	2 (5)	4 (10)
duodenum	invagination		0 (0)	1 (3)	0 (0)	0 (0)
jejunum	diverticula		0 (0)	0 (0)	1 (3)	0 (0)
small intes	nodule		2 (5)	0 (0)	0 (0)	0 (0)
colon	nodule		1 (3)	0 (0)	0 (0)	0 (0)
liver	white zone		2 (5)	0 (0)	0 (0)	0 (0)
	red zone		2 (5)	1 (3)	3 (8)	1 (3)
	nodule		25 (66)	23 (70)	19 (50)	11 (28)
	cyst		5 (13)	1 (3)	1 (3)	0 (0)
pancreas	nodule		0 (0)	2 (6)	2 (5)	0 (0)
kidney	atrophic		0 (0)	0 (0)	0 (0)	2 (5)
	white zone		0 (0)	0 (0)	1 (3)	0 (0)

Organ	Findings	Group Name / NO. of Animals	Control 38	(%)	250 ppm 33	(%)	1000 ppm 38	(%)	4000 ppm 40	(%)
kidney	nodule		0	(0)	0	(0)	1	(3)	0	(0)
	hydronephrosis		1	(3)	0	(0)	0	(0)	2	(5)
urin bladd	urine:marked retention		2	(5)	0	(0)	0	(0)	0	(0)
pituitary	nodule		1	(3)	0	(0)	0	(0)	0	(0)
thyroid	enlarged		0	(0)	1	(3)	0	(0)	0	(0)
epididymis	nodule		2	(5)	0	(0)	0	(0)	0	(0)
semin ves	adhesion		1	(3)	0	(0)	1	(3)	0	(0)
prep/cli gl	enlarged		0	(0)	1	(3)	0	(0)	0	(0)
	nodule		2	(5)	0	(0)	1	(3)	1	(3)
	cyst		4	(11)	9	(27)	10	(26)	4	(10)
eye	white		1	(3)	0	(0)	0	(0)	0	(0)
Harder gl	enlarged		1	(3)	1	(3)	0	(0)	2	(5)
	nodule		0	(0)	0	(0)	0	(0)	1	(3)
bone	nodule		0	(0)	0	(0)	1	(3)	0	(0)
mediastinum	mass		0	(0)	0	(0)	0	(0)	1	(3)
peritoneum	nodule		0	(0)	0	(0)	1	(3)	0	(0)
abdominal c	ascites		0	(0)	1	(3)	1	(3)	0	(0)
thoracic ca	pleural fluid		0	(0)	0	(0)	2	(5)	1	(3)
other	tail:nodule		1	(3)	0	(0)	1	(3)	0	(0)
	ear:nodule		0	(0)	0	(0)	0	(0)	1	(3)

APPENDIX I 8

GROSS FINDINGS : SUMMARY, MOSUE : FEMALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / NO. of Animals	Control 27	(%)	1000 ppm 33	(%)	4000 ppm 30	(%)	16000 ppm 39	(%)
subcutis	mass		0	(0)	2	(6)	1	(3)	1	(3)
lung	nodule		4	(15)	2	(6)	3	(10)	3	(8)
lymph node	enlarged		1	(4)	6	(18)	3	(10)	1	(3)
spleen	enlarged		2	(7)	2	(6)	3	(10)	1	(3)
	nodule		0	(0)	2	(6)	0	(0)	0	(0)
forestomach	nodule		0	(0)	2	(6)	0	(0)	0	(0)
	thick		0	(0)	1	(3)	0	(0)	0	(0)
gl stomach	ulcer		1	(4)	0	(0)	2	(7)	0	(0)
	thick		3	(11)	2	(6)	1	(3)	0	(0)
liver	enlarged		0	(0)	1	(3)	1	(3)	0	(0)
	red zone		3	(11)	3	(9)	1	(3)	3	(8)
	nodule		9	(33)	6	(18)	6	(20)	3	(8)
	cyst		2	(7)	2	(6)	0	(0)	0	(0)
pancreas	nodule		0	(0)	4	(12)	1	(3)	0	(0)
	cyst		0	(0)	0	(0)	0	(0)	1	(3)
kidney	atrophic		0	(0)	1	(3)	0	(0)	0	(0)
	nodule		0	(0)	0	(0)	0	(0)	1	(3)
	hydronephrosis		0	(0)	3	(9)	6	(20)	3	(8)
ureter	dilated		0	(0)	1	(3)	0	(0)	0	(0)
pituitary	enlarged		4	(15)	1	(3)	2	(7)	0	(0)
	black zone		1	(4)	0	(0)	0	(0)	0	(0)
	nodule		2	(7)	1	(3)	2	(7)	1	(3)

Organ	Findings	Group Name / NO. of Animals	Control 27 (%)	1000 ppm 33 (%)	4000 ppm 30 (%)	16000 ppm 39 (%)
thyroid	enlarged		0 (0)	0 (0)	1 (3)	0 (0)
ovary	enlarged		1 (4)	0 (0)	0 (0)	1 (3)
	cyst		6 (22)	4 (12)	5 (17)	11 (28)
uterus	nodule		1 (4)	1 (3)	4 (13)	5 (13)
	dilated		0 (0)	0 (0)	0 (0)	1 (3)
	dilated lumen		0 (0)	0 (0)	1 (3)	4 (10)
prep/cli gl	nodule		0 (0)	0 (0)	0 (0)	1 (3)
eye	absence		0 (0)	1 (3)	0 (0)	0 (0)
Harder gl	enlarged		1 (4)	2 (6)	0 (0)	0 (0)
mediastinum	mass		0 (0)	1 (3)	0 (0)	0 (0)
retroperit	mass		0 (0)	0 (0)	0 (0)	1 (3)
abdominal c	ascites		1 (4)	3 (9)	1 (3)	2 (5)
thoracic ca	hemorrhage		0 (0)	0 (0)	0 (0)	1 (3)
	nodule		0 (0)	1 (3)	0 (0)	0 (0)
	pleural fluid		3 (11)	2 (6)	2 (7)	3 (8)
other	forelimb:nodule		0 (0)	0 (0)	1 (3)	0 (0)

APPENDIX J 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

Group Name	NO. of Animals	Body Weight	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	36	419± 45	0.089± 0.054	4.811± 1.570	1.234± 0.159	1.649± 0.726	3.002± 0.265
800 ppm	43	410± 37	0.152± 0.420	5.224± 1.445	1.245± 0.155	1.487± 0.393	2.942± 0.311
2400 ppm	43	392± 34*	0.111± 0.262*	6.642± 2.730**	1.154± 0.085**	1.410± 0.109*	2.786± 0.282**
7200 ppm	42	357± 21**	0.118± 0.321**	6.835± 1.345**	1.097± 0.073**	1.375± 0.103**	2.613± 0.176**

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	36	1.685±	2.170	13.892±	2.083	2.068±	0.046
800 ppm	43	1.199±	0.318	12.918±	1.376	2.055±	0.050
2400 ppm	43	1.309±	1.405	11.930±	1.873**	2.043±	0.091*
7200 ppm	42	0.971±	0.358**	10.161±	1.220**	2.013±	0.043**

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX J 2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

Group Name	NO. of Animals	Body Weight	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	37	308± 25	0.082± 0.033	0.126± 0.035	0.943± 0.064	1.030± 0.060	2.077± 0.216
800 ppm	38	296± 35	0.076± 0.010	0.124± 0.020	0.933± 0.069	1.075± 0.135	2.120± 0.369
2400 ppm	43	294± 33	0.070± 0.011*	0.136± 0.052	0.923± 0.071	1.075± 0.137	2.032± 0.181
7200 ppm	45	253± 30**	0.077± 0.054**	0.167± 0.189	0.887± 0.078**	1.030± 0.204	1.990± 0.303

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	37	0.619±	0.224	8.127±	1.500	1.884±	0.047
800 ppm	38	0.915±	1.029	8.526±	2.383	1.883±	0.060
2400 ppm	43	0.895±	1.001	7.763±	1.322	1.868±	0.059
7200 ppm	45	0.562±	0.266	6.701±	1.237**	1.834±	0.053**

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX J 3

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : MALE

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

Group Name	NO. of Animals	Body Weight	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	38	44.3± 7.3	0.011± 0.003	0.208± 0.034	0.210± 0.024	0.233± 0.156	0.649± 0.053
250 ppm	33	43.2± 6.5	0.011± 0.004	0.199± 0.042	0.211± 0.021	0.227± 0.126	0.650± 0.045
1000 ppm	38	41.9± 5.8	0.010± 0.003	0.210± 0.030	0.196± 0.021*	0.219± 0.085	0.637± 0.055
4000 ppm	40	37.2± 4.2**	0.010± 0.003	0.204± 0.027	0.188± 0.022**	0.201± 0.047*	0.655± 0.105

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	38	0.105±	0.169	1.773±	0.438	0.456±	0.013
250 ppm	33	0.141±	0.311	1.980±	0.681	0.456±	0.012
1000 ppm	38	0.099±	0.108	1.677±	0.594	0.450±	0.012
4000 ppm	40	0.084±	0.074	1.376±	0.212**	0.460±	0.032

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX J 4

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

Group Name	NO. of Animals	Body Weight	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	27	32.2± 4.3	0.013± 0.003	0.195± 0.735	0.162± 0.024	0.187± 0.015	0.435± 0.061
1000 ppm	33	29.0± 4.2	0.011± 0.002*	0.049± 0.055	0.144± 0.011*	0.189± 0.041	0.487± 0.430
4000 ppm	30	28.1± 3.2**	0.011± 0.003	0.084± 0.156	0.156± 0.026	0.201± 0.057	0.719± 0.700
16000 ppm	39	24.0± 1.8**	0.010± 0.002**	0.067± 0.117	0.128± 0.012**	0.182± 0.071**	0.486± 0.323

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	27	0.133±	0.168	1.351±	0.208	0.468±	0.014
1000 ppm	33	0.152±	0.093	1.569±	1.069	0.466±	0.016
4000 ppm	30	0.213±	0.357	1.484±	0.839	0.464±	0.013
16000 ppm	39	0.071±	0.056**	1.133±	0.423**	0.447±	0.010**

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX K 1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	36	419± 45	0.022± 0.016	1.151± 0.374	0.297± 0.052	0.406± 0.224	0.725± 0.104
800 ppm	43	410± 37	0.039± 0.111	1.277± 0.351	0.308± 0.074	0.373± 0.170	0.726± 0.136
2400 ppm	43	392± 34*	0.032± 0.090	1.688± 0.660**	0.297± 0.038	0.363± 0.044	0.717± 0.101
7200 ppm	42	357± 21**	0.032± 0.084	1.918± 0.374**	0.308± 0.018**	0.386± 0.027**	0.733± 0.048

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	36	0.425± 0.629	3.351± 0.644	0.498± 0.048
800 ppm	43	0.294± 0.091	3.175± 0.466	0.505± 0.053
2400 ppm	43	0.335± 0.370	3.060± 0.517	0.526± 0.051
7200 ppm	42	0.270± 0.090	2.844± 0.293**	0.566± 0.034**

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX K 2

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	37	308± 25	0.027± 0.013	0.042± 0.014	0.308± 0.030	0.336± 0.030	0.679± 0.091
800 ppm	38	296± 35	0.026± 0.006	0.042± 0.009	0.321± 0.058	0.371± 0.086	0.736± 0.230
2400 ppm	43	294± 33	0.024± 0.004	0.047± 0.021	0.317± 0.037	0.368± 0.049**	0.698± 0.099
7200 ppm	45	253± 30**	0.032± 0.031	0.065± 0.068**	0.354± 0.045**	0.411± 0.076**	0.796± 0.156**

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	37	0.204± 0.086	2.659± 0.592	0.616± 0.056
800 ppm	38	0.334± 0.421	2.960± 1.134	0.645± 0.084
2400 ppm	43	0.296± 0.273	2.654± 0.448	0.642± 0.071
7200 ppm	45	0.223± 0.103	2.660± 0.440	0.736± 0.099**

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX K 3

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : MALE

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	38	44.3± 7.3	0.026± 0.008	0.482± 0.110	0.481± 0.071	0.576± 0.615	1.497± 0.229
250 ppm	33	43.2± 6.5	0.027± 0.010	0.472± 0.125	0.501± 0.109	0.560± 0.452	1.537± 0.245
1000 ppm	38	41.9± 5.8	0.024± 0.007	0.509± 0.092	0.477± 0.084	0.536± 0.228	1.545± 0.225
4000 ppm	40	37.2± 4.2**	0.027± 0.008	0.555± 0.095**	0.511± 0.070	0.547± 0.140*	1.785± 0.367**

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	38	0.281± 0.629	4.110± 1.294	1.059± 0.193
250 ppm	33	0.336± 0.693	4.872± 2.577	1.083± 0.196
1000 ppm	38	0.258± 0.349	4.155± 2.031	1.098± 0.187
4000 ppm	40	0.227± 0.201	3.734± 0.677	1.256± 0.198**

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX K 4

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	27	32.2± 4.3	0.040± 0.011	0.668± 2.609	0.509± 0.093	0.593± 0.105	1.374± 0.287
1000 ppm	33	29.0± 4.2	0.039± 0.008	0.165± 0.179	0.505± 0.070	0.661± 0.147	1.803± 2.171
4000 ppm	30	28.1± 3.2**	0.041± 0.008	0.285± 0.517	0.557± 0.088*	0.715± 0.167**	2.616± 2.616**
16000 ppm	39	24.0± 1.8**	0.043± 0.008	0.275± 0.486	0.535± 0.048*	0.761± 0.294**	2.014± 1.276**

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	27	0.414± 0.470	4.238± 0.706	1.479± 0.202
1000 ppm	33	0.541± 0.381*	5.431± 3.601*	1.639± 0.247
4000 ppm	30	0.717± 1.002	5.183± 2.146**	1.671± 0.175*
16000 ppm	39	0.295± 0.214	4.669± 1.279**	1.873± 0.126**

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX L 1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name	Control				800 ppm				2400 ppm				7200 ppm			
		No. of Animals	14				7				7				8			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]																		
nasal cavit	hemorrhage		1 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	thrombus		0 (0)	0 (0)	1 (7)	0 (0)	0 (0)	3 (43)	0 (0)	0 * (0)	0 (0)	0 (0)	1 (14)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
	mineralization		6 (43)	0 (0)	0 (0)	0 (0)	4 (57)	0 (0)	0 (0)	0 (0)	2 (29)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
	eosinophilic change:olfactory epithelium		8 (57)	0 (0)	0 (0)	0 (0)	7 (100)	0 (0)	0 (0)	0 (0)	3 (43)	2 (29)	0 (0)	0 (0)	2 (25)	1 (13)	0 (0)	0 (0)
	eosinophilic change:respiratory epithelium		5 (36)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
	inflammation:foreign body		5 (36)	0 (0)	0 (0)	0 (0)	2 (29)	1 (14)	0 (0)	0 (0)	1 (14)	1 (14)	0 (0)	0 (0)	2 (25)	1 (13)	0 (0)	0 (0)
	inflammation:respiratory epithelium		1 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	respiratory metaplasia:olfactory epithelium		0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (25)	0 (0)	0 (0)	0 (0)
	respiratory metaplasia:gland		11 (79)	0 (0)	0 (0)	0 (0)	3 (43)	0 (0)	0 (0)	0 (0)	5 (71)	0 (0)	0 (0)	0 (0)	3 (38)	0 (0)	0 (0)	0 (0)
larynx	inflammation		1 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
lung	congestion		0 (0)	2 (14)	0 (0)	0 (0)	0 (0)	0 (0)	2 (29)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	2 (25)	0 (0)
	thrombus		0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				800 ppm				2400 ppm				7200 ppm			
		No. of Animals	14				7				7				8			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]																		
lung	accumulation of foamy cells		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
	interstitial penumonia		0 (0)	0 (0)	1 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	bronchiolar-alveolar cell hyperplasia		1 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Hematopoietic system]																		
bone marrow	granulation		1 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	increased hematopoiesis		0 (0)	5 (36)	0 (0)	0 (0)	0 (0)	2 (29)	1 (14)	0 (0)	1 (14)	3 (43)	0 (0)	0 (0)	0 (0)	2 (25)	0 (0)	0 (0)
	reticulosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)
lymph node	lymphadenitis		0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)
spleen	deposit of hemosiderin		7 (50)	3 (21)	0 (0)	0 (0)	2 (29)	1 (14)	0 (0)	0 (0)	4 (57)	1 (14)	0 (0)	0 (0)	2 (25)	0 (0)	0 (0)	0 (0)
	extramedullary hematopoiesis		3 (21)	2 (14)	1 (7)	0 (0)	2 (29)	1 (14)	1 (14)	0 (0)	2 (29)	1 (14)	0 (0)	0 (0)	1 (13)	1 (13)	0 (0)	0 (0)
[Circulatory system]																		
heart	thrombus		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				800 ppm				2400 ppm				7200 ppm			
		No. of Animals	14				7				7				8			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Circulatory system]																		
heart	myocardial fibrosis		5 (36)	6 (43)	0 (0)	0 (0)	5 (71)	1 (14)	0 (0)	0 (0)	3 (43)	2 (29)	0 (0)	0 (0)	5 (63)	2 (25)	0 (0)	0 (0)
[Digestive system]																		
tongue	mineralization		0 (0)	1 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	arteritis		2 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
stomach	mineralization		0 (0)	0 (0)	1 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	erosion:forestomach		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
	ulcer:forestomach		0 (0)	1 (7)	1 (7)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
	hyperplasia:forestomach		1 (7)	1 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	2 (25)	1 (13)	0 (0)	0 (0)
	erosion:glandular stomach		1 (7)	1 (7)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	1 (14)	1 (14)	0 (0)	0 (0)	3 (38)	0 (0)	0 (0)	0 (0)
liver	herniation		1 (7)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	necrosis:central		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	necrosis:focal		0 (0)	3 (21)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 14				800 ppm 7				2400 ppm 7				7200 ppm 8			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Digestive system]																		
liver	vacuolic change		1 (7)	0 (0)	1 (7)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	degeneration:central		0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)
	granulation		5 (36)	1 (7)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)
	basophilic cell focus		1 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	mixed cell focus		1 (7)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	spongiosis hepatis		5 (36)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (43)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	bile duct hyperplasia		7 (50)	6 (43)	0 (0)	0 (0)	3 (43)	3 (43)	0 (0)	0 (0)	5 (71)	2 (29)	0 (0)	0 (0)	1 (13)	4 (50)	0 (0)	0 (0)
	biliary cyst		1 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
pancreas	atrophy		0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	2 (29)	1 (14)	0 (0)	0 * (0)	1 (13)	0 (0)	0 (0)	0 (0)
[Urinary system]																		
kidney	infarct		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
	mineralization		2 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				800 ppm				2400 ppm				7200 ppm			
		No. of Animals	14				7				7				8			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Urinary system]																		
kidney	chronic nephropathy		1 (7)	5 (36)	3 (21)	3 (21)	1 (14)	4 (57)	0 (0)	0 (0)	1 (14)	2 (29)	2 (29)	1 (14)	1 (13)	3 (38)	1 (13)	0 (0)
[Endocrine system]																		
pituitary	necrosis:focal		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
	cyst		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
	hyperplasia		6 (43)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
adrenal	extramedullary hematopoiesis		0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hyperplasia:cortical cell		1 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hyperplasia:medulla		4 (29)	1 (7)	0 (0)	0 (0)	2 (29)	1 (14)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	3 (38)	0 (0)	0 (0)	0 (0)
	focal fatty change:cortex		2 (14)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	1 (14)	1 (14)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
	cortical vacuolation:diffuse		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Reproductive system]																		
testis	atrophy		0 (0)	1 (7)	7 (50)	0 (0)	3 (43)	1 (14)	1 (14)	0 * (0)	1 (14)	2 (29)	3 (43)	0 (0)	0 (0)	1 (13)	3 (38)	0 (0)

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				800 ppm				2400 ppm				7200 ppm			
		No. of Animals	14				7				7				8			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Reproductive system]																		
testis	mineralization		5 (36)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	2 (25)	0 (0)	0 (0)	0 (0)
	arteritis		0 (0)	1 (7)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	interstitial cell hyperplasia		4 (29)	0 (0)	0 (0)	0 (0)	2 (29)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	3 (38)	0 (0)	0 (0)	0 (0)
prostate	mineralization		0 (0)	0 (0)	1 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	inflammation		1 (7)	4 (29)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	1 (14)	2 (29)	1 (14)	0 (0)	1 (13)	2 (25)	0 (0)	0 (0)
	hyperplasia		4 (29)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
mammary gl	galactocele		6 (43)	0 (0)	0 (0)	0 (0)	4 (57)	0 (0)	0 (0)	0 (0)	4 (57)	0 (0)	0 (0)	0 (0)	2 (25)	0 (0)	0 (0)	0 (0)
[Nervous system]																		
brain	hemorrhage		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
spinal cord	hemorrhage		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Special sense organs/appandage]																		
eye	inflammation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				800 ppm				2400 ppm				7200 ppm			
		No. of Animals	14				7				7				8			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Special sense organs/appandage]																		
eye	cataract		1 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	retinal atrophy		5 (36)	3 (21)	3 (21)	0 (0)	4 (57)	1 (14)	0 (0)	0 (0)	4 (57)	2 (29)	0 (0)	0 (0)	4 (50)	2 (25)	0 (0)	0 (0)
	keratitis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
Harder gl	lymphocytic infiltration		3 (21)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	granulation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
[Body cavities]																		
mesenterium	infarct		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

APPENDIX L 2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

Organ	Findings	Group Name	Control				800 ppm				2400 ppm				7200 ppm			
		No. of Animals	13				12				7				5			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]																		
nasal cavit	thrombus		1 (8)	2 (15)	0 (0)	0 (0)	1 (8)	3 (25)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	1 (20)	0 (0)
	mineralization		1 (8)	0 (0)	0 (0)	0 (0)	4 (33)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)
	eosinophilic change:olfactory epithelium		11 (85)	0 (0)	0 (0)	0 (0)	6 (50)	1 (8)	0 (0)	0 (0)	2 (29)	2 (29)	1 (14)	0 * (0)	2 (40)	0 (0)	1 (20)	0 (0)
	eosinophilic change:respiratory epithelium		2 (15)	0 (0)	0 (0)	0 (0)	5 (42)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)
	inflammation:foreign body		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	inflammation:respiratory epithelium		2 (15)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	respiratory metaplasia:olfactory epithelium		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	respiratory metaplasia:gland		11 (85)	0 (0)	0 (0)	0 (0)	9 (75)	0 (0)	0 (0)	0 (0)	6 (86)	0 (0)	0 (0)	0 (0)	3 (60)	0 (0)	0 (0)	0 (0)
larynx	inflammation		0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
lung	congestion		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	inflammatory infiltration		0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)
	bronchiolar-alveolar cell hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				800 ppm				2400 ppm				7200 ppm			
		No. of Animals	13				12				7				5			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Hematopoietic system]																		
bone marrow	granulation		2 (15)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (14)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	increased hematopoiesis		1 (8)	2 (15)	0 (0)	0 (0)	1 (8)	4 (33)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	2 (40)	0 (0)	0 (0)
	reticulosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
lymph node	lymphadenitis		1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
spleen	hemorrhage		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	deposit of hemosiderin		2 (15)	4 (31)	0 (0)	0 (0)	1 (8)	4 (33)	0 (0)	0 (0)	2 (29)	2 (29)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)
	extramedullary hematopoiesis		1 (8)	3 (23)	2 (15)	1 (8)	0 (0)	3 (25)	1 (8)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)
	lymphoid hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	capsule hyperplasia		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Circulatory system]																		
heart	thrombus		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	myocardial fibrosis		4 (31)	0 (0)	0 (0)	0 (0)	8 (67)	1 (8)	0 (0)	0 (0)	3 (43)	0 (0)	0 (0)	0 (0)	2 (40)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				800 ppm				2400 ppm				7200 ppm			
		No. of Animals	13				12				7				5			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Circulatory system]																		
heart	pericarditis		0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Digestive system]																		
tongue	arteritis		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
stomach	ulcer:forestomach		0 (0)	2 (15)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hyperplasia:forestomach		0 (0)	2 (15)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	erosion:glandular stomach		0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	0 (0)	0 (0)	2 (29)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
liver	necrosis:central		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	vacuolic change		1 (8)	1 (8)	2 (15)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	degeneration:central		2 (15)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	granulation		4 (31)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	3 (43)	1 (14)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)
	extramedullary hematopoiesis		1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	basophilic cell focus		1 (8)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				800 ppm				2400 ppm				7200 ppm			
		No. of Animals	13				12				7				5			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Digestive system]																		
liver	mixed cell focus		0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	spongiosis hepatis		3 (23)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)
	bile duct hyperplasia		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (29)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	mobilization of Kuppfer cell		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)
	vacuolic change:peripheral		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
pancreas	atrophy		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Urinary system]																		
kidney	basophilic change		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	mineralization		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	chronic nephropathy		3 (23)	3 (23)	0 (0)	0 (0)	3 (25)	3 (25)	2 (17)	0 (0)	1 (14)	3 (43)	0 (0)	0 (0)	0 (0)	2 (40)	0 (0)	0 (0)
	hydronephrosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)
	tubular necrosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 13				800 ppm 12				2400 ppm 7				7200 ppm 5			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Endocrine system]																		
pituitary	angiectasis		3 (23)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	cyst		2 (15)	2 (15)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	0 (0)	2 (29)	0 (0)	0 (0)	0 (0)	3 (60)	0 (0)	0 (0)	0 (0)
	hyperplasia		1 (8)	0 (0)	0 (0)	0 (0)	4 (33)	0 (0)	0 (0)	0 (0)	1 (14)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
thyroid	C-cell hyperplasia		2 (15)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
adrenal	hemorrhage		1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	peliosis-like lesion		2 (15)	1 (8)	0 (0)	0 (0)	4 (33)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	necrosis:focal		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)
	hyperplasia:medulla		2 (15)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	focal fatty change:cortex		2 (15)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	0 (0)	0 (0)	2 (29)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)
	cortical vacuolation:diffuse		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)
[Reproductive system]																		
uterus	hyperplasia:gland		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 13				800 ppm 12				2400 ppm 7				7200 ppm 5			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Reproductive system]																		
uterus	cystic endometrial hyperplasia		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)
mammary gl	galactocele		8 (62)	0 (0)	0 (0)	0 (0)	10 (83)	0 (0)	0 (0)	0 (0)	4 (57)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)
[Nervous system]																		
brain	hemorrhage		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Special sense organs/appandage]																		
eye	retinal atrophy		5 (38)	5 (38)	0 (0)	0 (0)	7 (58)	5 (42)	0 (0)	0 (0)	4 (57)	2 (29)	1 (14)	0 (0)	1 (20)	2 (40)	0 (0)	0 (0)
Harder gl	degeneration		0 (0)	0 (0)	0 (0)	0 (0)	6 (50)	0 (0)	0 (0)	0 * (0)	1 (14)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)
	lymphocytic infiltration		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)
	granulation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Musculoskeletal system]																		
bone	osteosclerosis		0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Body cavities]																		
peritoneum	hematoma		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

APPENDIX L 3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name	Control				800 ppm				2400 ppm				7200 ppm			
		No. of Animals	36				43				43				42			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Integumentary system/appandage]																		
skin/app	hyperplasia:epidermis		0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	scab		0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Respiratory system]																		
nasal cavit	adhesion		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	thrombus		0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	mineralization		17 (47)	0 (0)	0 (0)	0 (0)	19 (44)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 ** (0)	6 (14)	0 (0)	0 (0)	0 ** (0)
	eosinophilic change:olfactory epithelium		19 (53)	5 (14)	0 (0)	0 (0)	30 (70)	4 (9)	0 (0)	0 (0)	28 (65)	8 (19)	1 (2)	0 (0)	20 (48)	13 (31)	3 (7)	0 * (0)
	eosinophilic change:respiratory epithelium		11 (31)	0 (0)	0 (0)	0 (0)	10 (23)	0 (0)	0 (0)	0 (0)	13 (30)	0 (0)	0 (0)	0 (0)	8 (19)	0 (0)	0 (0)	0 (0)
	inflammation:foreign body		7 (19)	6 (17)	0 (0)	0 (0)	16 (37)	7 (16)	1 (2)	0 (0)	14 (33)	4 (9)	0 (0)	0 (0)	9 (21)	9 (21)	2 (5)	0 (0)
	inflammation:respiratory epithelium		5 (14)	0 (0)	0 (0)	0 (0)	4 (9)	1 (2)	0 (0)	0 (0)	4 (9)	0 (0)	0 (0)	0 (0)	4 (10)	0 (0)	0 (0)	0 (0)
	respiratory metaplasia:olfactory epithelium		6 (17)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 * (0)	9 (21)	0 (0)	0 (0)	0 (0)	7 (17)	0 (0)	0 (0)	0 (0)
	respiratory metaplasia:gland		29 (81)	0 (0)	0 (0)	0 (0)	31 (72)	0 (0)	0 (0)	0 (0)	37 (86)	0 (0)	0 (0)	0 (0)	34 (81)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				800 ppm				2400 ppm				7200 ppm			
		No. of Animals	36				43				43				42			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]																		
larynx	inflammation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
lung	congestion		0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	osseous metaplasia		1 (3)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)
	accumulation of foamy cells		2 (6)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	interstitial penumonia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	bronchiolar-alveolar cell hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)	4 (9)	2 (5)	0 (0)	0 (0)	3 (7)	1 (2)	0 (0)	0 (0)
[Hematopoietic system]																		
bone marrow	thrombus		0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	granulation		3 (8)	2 (6)	0 (0)	0 (0)	1 (2)	2 (5)	0 (0)	0 (0)	5 (12)	1 (2)	0 (0)	0 (0)	11 (26)	1 (2)	0 (0)	0 (0)
	increased hematopoiesis		3 (8)	0 (0)	0 (0)	0 (0)	4 (9)	3 (7)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	3 (7)	2 (5)	0 (0)	0 (0)
	reticulosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
lymph node	lymphadenitis		0 (0)	2 (6)	0 (0)	0 (0)	4 (9)	0 (0)	0 (0)	0 (0)	1 (2)	1 (2)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 36				800 ppm 43				2400 ppm 43				7200 ppm 42			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Hematopoietic system]																		
spleen	deposit of hemosiderin		27 (75)	1 (3)	0 (0)	0 (0)	39 (91)	1 (2)	0 (0)	0 (0)	41 (95)	0 (0)	0 (0)	0 * (0)	36 (86)	1 (2)	0 (0)	0 (0)
	fibrosis		0 (0)	1 (3)	0 (0)	0 (0)	3 (7)	1 (2)	0 (0)	0 (0)	6 (14)	0 (0)	0 (0)	0 * (0)	0 (0)	0 (0)	0 (0)	0 (0)
	extramedullary hematopoiesis		19 (53)	0 (0)	0 (0)	0 (0)	23 (53)	5 (12)	0 (0)	0 (0)	36 (84)	0 (0)	0 (0)	0 ** (0)	14 (33)	0 (0)	0 (0)	0 (0)
	stromal hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Circulatory system]																		
heart	myocardial fibrosis		18 (50)	16 (44)	1 (3)	0 (0)	17 (40)	24 (56)	1 (2)	0 (0)	21 (49)	18 (42)	2 (5)	0 (0)	26 (62)	9 (21)	0 (0)	0 * (0)
	endocardial hyperplasia		0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
artery/aort	mineralization		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	arteritis		0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Digestive system]																		
tooth	dysplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
tongue	arteritis		4 (11)	1 (3)	0 (0)	0 (0)	5 (12)	1 (2)	0 (0)	0 (0)	5 (12)	2 (5)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				800 ppm				2400 ppm				7200 ppm			
		No. of Animals	36				43				43				42			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Digestive system]																		
stomach	mineralization		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	ulcer:forestomach		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hyperplasia:forestomach		0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	erosion:glandular stomach		3 (8)	0 (0)	0 (0)	0 (0)	4 (9)	1 (2)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	4 (10)	0 (0)	0 (0)	0 (0)
small intes	diverticula		0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
liver	herniation		2 (6)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	peliosis		1 (3)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	vacuolic change		1 (3)	0 (0)	0 (0)	0 (0)	3 (7)	1 (2)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)
	cyst		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	granulation		26 (72)	1 (3)	0 (0)	0 (0)	19 (44)	0 (0)	0 (0)	0 * (0)	22 (51)	1 (2)	0 (0)	0 (0)	19 (45)	0 (0)	0 (0)	0 * (0)
	extramedullary hematopoiesis		0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	clear cell focus		5 (14)	0 (0)	0 (0)	0 (0)	4 (9)	0 (0)	1 (2)	0 (0)	7 (16)	3 (7)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 36				800 ppm 43				2400 ppm 43				7200 ppm 42			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Digestive system]																		
liver	acidophilic cell focus		2 (6)	1 (3)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	6 (14)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	basophilic cell focus		2 (6)	1 (3)	0 (0)	0 (0)	4 (9)	2 (5)	0 (0)	0 (0)	3 (7)	1 (2)	0 (0)	0 (0)	6 (14)	1 (2)	0 (0)	0 (0)
	vacuolated cell focus		4 (11)	0 (0)	0 (0)	0 (0)	4 (9)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)
	mixed cell focus		1 (3)	0 (0)	0 (0)	0 (0)	6 (14)	1 (2)	1 (2)	0 (0)	9 (21)	2 (5)	1 (2)	0 * (0)	2 (5)	0 (0)	0 (0)	0 (0)
	spongiosis hepatis		16 (44)	0 (0)	0 (0)	0 (0)	20 (47)	0 (0)	0 (0)	0 (0)	16 (37)	1 (2)	0 (0)	0 (0)	7 (17)	0 (0)	0 (0)	0 * (0)
	bile duct hyperplasia		10 (28)	26 (72)	0 (0)	0 (0)	24 (56)	19 (44)	0 (0)	0 * (0)	16 (37)	27 (63)	0 (0)	0 (0)	3 (7)	39 (93)	0 (0)	0 * (0)
	mobilization of Kupffer cell		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	biliary cyst		5 (14)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
pancreas	atrophy		9 (25)	0 (0)	0 (0)	0 (0)	10 (23)	0 (0)	0 (0)	0 (0)	15 (35)	5 (12)	0 (0)	0 * (0)	9 (21)	1 (2)	1 (2)	0 (0)
	hyperplasia:acinar cell		3 (8)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
[Urinary system]																		
kidney	infarct		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 36				800 ppm 43				2400 ppm 43				7200 ppm 42			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Urinary system]																		
kidney	cyst		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	fibrosis		0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	chronic nephropathy		0 (0)	6 (17)	27 (75)	3 (8)	0 (0)	9 (21)	29 (67)	5 (12)	1 (2)	19 (44)	23 (53)	0 * (0)	6 (14)	22 (52)	13 (31)	0 ** (0)
[Endocrine system]																		
pituitary	angiectasis		2 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	cyst		1 (3)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)
	hyperplasia		14 (39)	0 (0)	0 (0)	0 (0)	17 (40)	1 (2)	0 (0)	0 (0)	13 (30)	3 (7)	0 (0)	0 (0)	16 (38)	2 (5)	0 (0)	0 (0)
	osseous metaplasia		0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Rathke pouch		1 (3)	0 (0)	0 (0)	0 (0)	4 (9)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)
thyroid	ultimibranchial body remanet		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)
	C-cell hyperplasia		6 (17)	0 (0)	0 (0)	0 (0)	6 (14)	0 (0)	0 (0)	0 (0)	11 (26)	1 (2)	0 (0)	0 (0)	4 (10)	0 (0)	0 (0)	0 (0)
	focal follicular cell hyperplasia		3 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 36				800 ppm 43				2400 ppm 43				7200 ppm 42			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Endocrine system]																		
parathyroid	cyst		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
panc islet	hyperplasia		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
adrenal	peliosis-like lesion		0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	hyperplasia:cortical cell		7 (19)	0 (0)	0 (0)	0 (0)	4 (9)	0 (0)	0 (0)	0 (0)	4 (9)	3 (7)	0 (0)	0 (0)	7 (17)	0 (0)	1 (2)	0 (0)
	hyperplasia:medulla		15 (42)	2 (6)	0 (0)	0 (0)	17 (40)	4 (9)	0 (0)	0 (0)	11 (26)	1 (2)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 ** (0)
	focal fatty change:cortex		3 (8)	1 (3)	0 (0)	0 (0)	10 (23)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)
[Reproductive system]																		
testis	atrophy		3 (8)	2 (6)	31 (86)	0 (0)	0 (0)	1 (2)	41 (95)	0 (0)	0 (0)	0 (0)	43 (100)	0 * (0)	0 (0)	0 (0)	42 (100)	0 * (0)
	mineralization		11 (31)	0 (0)	0 (0)	0 (0)	16 (37)	0 (0)	0 (0)	0 (0)	17 (40)	0 (0)	0 (0)	0 (0)	18 (43)	0 (0)	0 (0)	0 (0)
	arteritis		1 (3)	3 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	interstitial cell hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
epididymis	inflammation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 36 <1> (%)	<2> (%)	<3> (%)	<4> (%)	800 ppm 43 <1> (%)	<2> (%)	<3> (%)	<4> (%)	2400 ppm 43 <1> (%)	<2> (%)	<3> (%)	<4> (%)	7200 ppm 42 <1> (%)	<2> (%)	<3> (%)	<4> (%)
[Reproductive system]																		
prostate	inflammation		4 (11)	7 (19)	0 (0)	0 (0)	10 (23)	8 (19)	1 (2)	0 (0)	2 (5)	9 (21)	1 (2)	0 (0)	3 (7)	3 (7)	0 (0)	0 (0)
	hyperplasia		5 (14)	1 (3)	0 (0)	0 (0)	5 (12)	1 (2)	0 (0)	0 (0)	12 (28)	0 (0)	0 (0)	0 (0)	5 (12)	0 (0)	0 (0)	0 (0)
	arteritis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
mammary gl	galactocele		7 (19)	0 (0)	0 (0)	0 (0)	9 (21)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 * (0)
prep/cli gl	duct ectasia		0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Nervous system]																		
brain	hemorrhage		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	thrombus		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Special sense organs/appandage]																		
eye	cataract		1 (3)	0 (0)	0 (0)	0 (0)	1 (2)	4 (9)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	retinal atrophy		18 (50)	10 (28)	7 (19)	0 (0)	17 (40)	13 (30)	12 (28)	0 (0)	15 (35)	21 (49)	6 (14)	1 (2)	5 (12)	29 (69)	8 (19)	0 ** (0)
	keratitis		0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name	Control				800 ppm				2400 ppm				7200 ppm			
		No. of Animals	36				43				43				42			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Special sense organs/appandage]																		
Harder gl	lymphocytic infiltration		3 (8)	0 (0)	0 (0)	0 (0)	6 (14)	0 (0)	0 (0)	0 (0)	5 (12)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

APPENDIX L 4

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

Organ	Findings	Group Name / No. of Animals	Control 37				800 ppm 38				2400 ppm 43				7200 ppm 45			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Integumentary system/appandage]																		
skin/app	inflammation		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	epidermal cyst		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
subcutis	inflammation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
[Respiratory system]																		
nasal cavit	thrombus		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	1 (3)	0 (0)	0 (0)	1 (2)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	mineralization		4 (11)	0 (0)	0 (0)	0 (0)	13 (34)	0 (0)	0 (0)	0 * (0)	1 (2)	0 (0)	0 (0)	0 (0)	7 (16)	0 (0)	0 (0)	0 (0)
	eosinophilic change:olfactory epithelium		20 (54)	8 (22)	2 (5)	0 (0)	17 (45)	10 (26)	3 (8)	0 (0)	15 (35)	15 (35)	6 (14)	0 (0)	13 (29)	23 (51)	3 (7)	0 * (0)
	eosinophilic change:respiratory epithelium		14 (38)	0 (0)	0 (0)	0 (0)	10 (26)	1 (3)	0 (0)	0 (0)	16 (37)	0 (0)	0 (0)	0 (0)	16 (36)	0 (0)	0 (0)	0 (0)
	inflammation:foreign body		5 (14)	1 (3)	0 (0)	0 (0)	3 (8)	2 (5)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)
	inflammation:respiratory epithelium		4 (11)	0 (0)	0 (0)	0 (0)	4 (11)	1 (3)	0 (0)	0 (0)	4 (9)	1 (2)	0 (0)	0 (0)	4 (9)	0 (0)	0 (0)	0 (0)
	respiratory metaplasia:olfactory epithelium		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	respiratory metaplasia:gland		32 (86)	0 (0)	0 (0)	0 (0)	31 (82)	0 (0)	0 (0)	0 (0)	38 (88)	0 (0)	0 (0)	0 (0)	39 (87)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 37				800 ppm 38				2400 ppm 43				7200 ppm 45			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]																		
larynx	inflammation		1 (3)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)
lung	congestion		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)
	accumulation of foamy cells		6 (16)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 * (0)	1 (2)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)
	bronchiolar-alveolar cell hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	2 (5)	1 (3)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
[Hematopoietic system]																		
bone marrow	granulation		11 (30)	1 (3)	0 (0)	0 (0)	9 (24)	4 (11)	0 (0)	0 (0)	9 (21)	3 (7)	1 (2)	0 (0)	14 (31)	7 (16)	0 (0)	0 (0)
	increased hematopoiesis		0 (0)	1 (3)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	3 (7)	1 (2)	0 (0)	0 (0)	1 (2)	1 (2)	0 (0)	0 (0)
	reticulosis		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)
lymph node	lymphadenitis		5 (14)	0 (0)	0 (0)	0 (0)	3 (8)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	3 (7)	1 (2)	0 (0)	0 (0)
spleen	deposit of hemosiderin		30 (81)	3 (8)	0 (0)	0 (0)	31 (82)	4 (11)	0 (0)	0 (0)	32 (74)	5 (12)	0 (0)	0 (0)	32 (71)	10 (22)	0 (0)	0 (0)
	fibrosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	extramedullary hematopoiesis		12 (32)	1 (3)	1 (3)	0 (0)	27 (71)	1 (3)	0 (0)	0 ** (0)	28 (65)	1 (2)	0 (0)	0 * (0)	17 (38)	2 (4)	1 (2)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 37				800 ppm 38				2400 ppm 43				7200 ppm 45			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Hematopoietic system]																		
spleen	lymphoid hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	stromal hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Circulatory system]																		
heart	myocardial fibrosis		28 (76)	4 (11)	0 (0)	0 (0)	27 (71)	7 (18)	0 (0)	0 (0)	30 (70)	2 (5)	0 (0)	0 (0)	27 (60)	4 (9)	0 (0)	0 (0)
	endocardial hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
artery/aort	arteriosclerosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Digestive system]																		
tooth	inflammation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	dysplasia		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
tongue	arteritis		3 (8)	1 (3)	0 (0)	0 (0)	4 (11)	0 (0)	0 (0)	0 (0)	7 (16)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)
stomach	inflammatory infiltration		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	ulcer:forestomach		0 (0)	1 (3)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 37				800 ppm 38				2400 ppm 43				7200 ppm 45			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Digestive system]																		
stomach	hyperplasia:forestomach		0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	erosion:glandular stomach		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
liver	herniation		1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	4 (9)	0 (0)	0 (0)	0 (0)	6 (13)	0 (0)	0 (0)	0 (0)
	hemorrhage		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	peliosis		2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	necrosis:central		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	necrosis:focal		0 (0)	0 (0)	1 (3)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	2 (5)	1 (2)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	vacuolic change		4 (11)	0 (0)	1 (3)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 * (0)
	degeneration:peripheral		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	granulation		27 (73)	1 (3)	0 (0)	0 (0)	16 (42)	6 (16)	1 (3)	0 * (0)	30 (70)	5 (12)	0 (0)	0 (0)	31 (69)	2 (4)	0 (0)	0 (0)
	lymphoid hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	clear cell focus		1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / No. of Animals	Control 37				800 ppm 38				2400 ppm 43				7200 ppm 45			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Digestive system]																		
liver	acidophilic cell focus		0 (0)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)
	basophilic cell focus		3 (8)	0 (0)	0 (0)	0 (0)	6 (16)	0 (0)	0 (0)	0 (0)	12 (28)	0 (0)	0 (0)	0 * (0)	12 (27)	0 (0)	0 (0)	0 (0)
	vacuolated cell focus		0 (0)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	mixed cell focus		4 (11)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)
	spongiosis hepatis		1 (3)	0 (0)	0 (0)	0 (0)	5 (13)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)
	bile duct hyperplasia		4 (11)	0 (0)	0 (0)	0 (0)	16 (42)	0 (0)	0 (0)	0 ** (0)	25 (58)	0 (0)	0 (0)	0 ** (0)	12 (27)	0 (0)	0 (0)	0 (0)
	bile ductular proliferation		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	cholangiofibrosis		1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	mobilization of Kuppfer cell		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
pancreas	atrophy		1 (3)	0 (0)	0 (0)	0 (0)	6 (16)	0 (0)	0 (0)	0 (0)	4 (9)	0 (0)	0 (0)	0 (0)	6 (13)	2 (4)	0 (0)	0 (0)
	hyperplasia:acinar cell		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Urinary system]																		
kidney	infarct		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 37				800 ppm 38				2400 ppm 43				7200 ppm 45			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Urinary system]																		
kidney	cyst		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	mineralization		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	chronic nephropathy		2 (5)	17 (46)	9 (24)	0 (0)	5 (13)	22 (58)	4 (11)	2 (5)	12 (28)	24 (56)	6 (14)	0 (0) **	18 (40)	19 (42)	3 (7)	0 (0) **
	tubular necrosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)
[Endocrine system]																		
pituitary	angiectasis		1 (3)	0 (0)	0 (0)	0 (0)	4 (11)	2 (5)	0 (0)	0 (0)	2 (5)	1 (2)	1 (2)	0 (0)	1 (2)	2 (4)	0 (0)	0 (0)
	cyst		14 (38)	2 (5)	0 (0)	0 (0)	12 (32)	1 (3)	0 (0)	0 (0)	16 (37)	1 (2)	0 (0)	0 (0)	13 (29)	0 (0)	0 (0)	0 (0)
	hyperplasia		9 (24)	5 (14)	0 (0)	0 (0)	8 (21)	5 (13)	0 (0)	0 (0)	11 (26)	4 (9)	0 (0)	0 (0)	13 (29)	1 (2)	0 (0)	0 (0)
	Rathke pouch		0 (0)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
thyroid	ultimibranchial body remanet		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	C-cell hyperplasia		14 (38)	0 (0)	0 (0)	0 (0)	7 (18)	0 (0)	0 (0)	0 (0)	12 (28)	1 (2)	0 (0)	0 (0)	4 (9)	1 (2)	0 (0)	0 (0) **
	focal follicular cell hyperplasia		2 (5)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / No. of Animals	Control 37				800 ppm 38				2400 ppm 43				7200 ppm 45			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Endocrine system]																		
panc islet	hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
adrenal	hemorrhage		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	peliosis-like lesion		12 (32)	5 (14)	0 (0)	0 (0)	14 (37)	4 (11)	0 (0)	0 (0)	20 (47)	2 (5)	0 (0)	0 (0)	19 (42)	0 (0)	0 (0)	0 * (0)
	cyst		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hyperplasia:cortical cell		9 (24)	0 (0)	0 (0)	0 (0)	8 (21)	1 (3)	0 (0)	0 (0)	1 (2)	1 (2)	0 (0)	0 ** (0)	5 (11)	0 (0)	0 (0)	0 (0)
	hyperplasia:medulla		6 (16)	0 (0)	0 (0)	0 (0)	5 (13)	0 (0)	0 (0)	0 (0)	5 (12)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 * (0)
	accesory cortical nodule		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	focal fatty change:cortex		3 (8)	3 (8)	0 (0)	0 (0)	5 (13)	0 (0)	0 (0)	0 (0)	13 (30)	0 (0)	0 (0)	0 * (0)	10 (22)	1 (2)	0 (0)	0 (0)
[Reproductive system]																		
ovary	cyst		2 (5)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)
uterus	hyperplasia:epithelium		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hyperplasia:gland		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	1 (2)	1 (2)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / No. of Animals	Control 37				800 ppm 38				2400 ppm 43				7200 ppm 45			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Reproductive system]																		
uterus	cystic endometrial hyperplasia		2 (5)	2 (5)	1 (3)	0 (0)	3 (8)	2 (5)	0 (0)	0 (0)	3 (7)	3 (7)	0 (0)	0 (0)	4 (9)	9 (20)	0 (0)	0 (0)
mammary gl	hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	galactocele		19 (51)	0 (0)	0 (0)	0 (0)	26 (68)	0 (0)	0 (0)	0 (0)	26 (60)	0 (0)	0 (0)	0 (0)	22 (49)	0 (0)	0 (0)	0 (0)
[Special sense organs/appandage]																		
eye	cataract		2 (5)	2 (5)	0 (0)	0 (0)	3 (8)	3 (8)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)
	retinal atrophy		9 (24)	20 (54)	8 (22)	0 (0)	3 (8)	26 (68)	9 (24)	0 (0)	9 (21)	28 (65)	6 (14)	0 (0)	1 (2)	33 (73)	11 (24)	0 ** (0)
Harder gl	degeneration		14 (38)	0 (0)	0 (0)	0 (0)	10 (26)	2 (5)	0 (0)	0 (0)	12 (28)	0 (0)	1 (2)	0 (0)	11 (24)	1 (2)	0 (0)	0 (0)
	lymphocytic infiltration		3 (8)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	granulation		3 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	4 (9)	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)
[Musculoskeletal system]																		
bone	fracture		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	osteosclerosis		1 (3)	1 (3)	1 (3)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	3 (7)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name	Control				800 ppm				2400 ppm				7200 ppm			
		No. of Animals	37				38				43				45			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Body cavities]																		
adipose	granulation		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

APPENDIX L 5

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : MALE : DEAD AND MORIBUND ANIMALS

MOSUE (2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / No. of Animals	Control 12				250 ppm 17				1000 ppm 12				4000 ppm 10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Integumentary system/appandage]																		
skin/app	ulcer		0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
subcutis	inflammation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Respiratory system]																		
nasal cavit	eosinophilic change:olfactory epithelium		3 (25)	1 (8)	0 (0)	0 (0)	3 (18)	0 (0)	0 (0)	0 (0)	5 (42)	1 (8)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)
	eosinophilic change:respiratory epithelium		6 (50)	1 (8)	0 (0)	0 (0)	2 (12)	1 (6)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 * (0)	2 (20)	6 (60)	0 (0)	0 * (0)
	respiratory metaplasia:olfactory epithelium		2 (17)	0 (0)	0 (0)	0 (0)	3 (18)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
	respiratory metaplasia:gland		3 (25)	1 (8)	0 (0)	0 (0)	2 (12)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
lung	congestion		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)
	thrombus		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	inflammatory infiltration		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
	accumulation of foamy cells		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	bronchiolar-alveolar cell hyperplasia		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / No. of Animals	Control 12				250 ppm 17				1000 ppm 12				4000 ppm 10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Hematopoietic system]																		
bone marrow	increased hematopoiesis		0 (0)	1 (8)	0 (0)	0 (0)	2 (12)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
lymph node	lymphadenitis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
spleen	extramedullary hematopoiesis		2 (17)	3 (25)	0 (0)	0 (0)	1 (6)	5 (29)	1 (6)	1 (6)	0 (0)	1 (8)	3 (25)	0 (0)	1 (10)	2 (20)	2 (20)	0 (0)
[Circulatory system]																		
heart	bacteria		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hemorrhage		0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	necrosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)
	inflammatory infiltration		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	myocardial fibrosis		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	endocardial hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
artery/aort	arteritis		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Digestive system]																		
tooth	dysplasia		4 (33)	0 (0)	1 (8)	0 (0)	5 (29)	2 (12)	0 (0)	0 (0)	8 (67)	1 (8)	0 (0)	0 (0)	6 (60)	0 (0)	0 (0)	0 (0)

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				250 ppm				1000 ppm				4000 ppm			
		No. of Animals	12				17				12				10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Digestive system]																		
tongue	inflammatory infiltration		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
salivary gl	atrophy		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)
	lymphocytic infiltration		2 (17)	0 (0)	0 (0)	0 (0)	2 (12)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
stomach	mineralization		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hyperplasia:forestomach		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
	hyperplasia:glandular stomach		5 (42)	0 (0)	0 (0)	0 (0)	3 (18)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)
	ectopia:glandular stomach		1 (8)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
liver	angiectasis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)
	necrosis:central		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)
	necrosis:focal		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	granulation		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	basophilic cell focus		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 12				250 ppm 17				1000 ppm 12				4000 ppm 10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Digestive system]																		
pancreas	atrophy		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	inflammation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Urinary system]																		
kidney	infarct		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	basophilic change		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	1 (10)	0 (0)	0 (0)
	inflammatory infiltration		0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	inflammatory polyp		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	arteritis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hydronephrosis		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	2 (12)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
	papillary necrosis		0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	mineralization:cortex		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	4 (33)	0 (0)	0 (0)	0 (0)	3 (30)	0 (0)	0 (0)	0 (0)
	dilatation:tubular lumen		0 (0)	1 (8)	0 (0)	0 (0)	1 (6)	1 (6)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name	Control				250 ppm				1000 ppm				4000 ppm			
		No. of Animals	12				17				12				10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Urinary system]																		
kidney	glomerulosclerosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	vacuolic change:proximal tubule		6 (50)	0 (0)	0 (0)	0 (0)	4 (24)	0 (0)	0 (0)	0 (0)	5 (42)	0 (0)	0 (0)	0 (0)	7 (70)	0 (0)	0 (0)	0 (0)
	eosinophilic droplet:proximal tubule		0 (0)	0 (0)	0 (0)	0 (0)	3 (18)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
urin bladd	inflammation		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hyperplasia		0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Endocrine system]																		
pituitary	Rathke pouch		1 (8)	0 (0)	0 (0)	0 (0)	2 (12)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
adrenal	hemorrhage		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
	spindle-cell hyperplasia		5 (42)	0 (0)	0 (0)	0 (0)	7 (41)	0 (0)	0 (0)	0 (0)	7 (58)	0 (0)	0 (0)	0 (0)	7 (70)	0 (0)	0 (0)	0 (0)
	hyperplasia:cortical cell		2 (17)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)
	accesory cortical nodule		1 (8)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
[Reproductive system]																		
testis	aplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 12				250 ppm 17				1000 ppm 12				4000 ppm 10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Reproductive system]																		
testis	atrophy		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	mineralization		11 (92)	0 (0)	0 (0)	0 (0)	8 (47)	0 (0)	0 (0)	0 * (0)	12 (100)	0 (0)	0 (0)	0 (0)	6 (60)	0 (0)	0 (0)	0 (0)
epididymis	spermatogenic granuloma		1 (8)	0 (0)	0 (0)	0 (0)	2 (12)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
	xanthogranuloma		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
prostate	inflammation		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
prep/cli gl	duct ectasia		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	1 (6)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)
[Nervous system]																		
brain	hemorrhage		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
	deposit of calcium		6 (50)	0 (0)	0 (0)	0 (0)	6 (35)	0 (0)	0 (0)	0 (0)	8 (67)	0 (0)	0 (0)	0 (0)	5 (50)	0 (0)	0 (0)	0 (0)
	hyaline body		6 (50)	0 (0)	0 (0)	0 (0)	7 (41)	0 (0)	0 (0)	0 (0)	10 (83)	0 (0)	0 (0)	0 (0)	3 (30)	0 (0)	0 (0)	0 (0)
[Special sense organs/appandage]																		
eye	keratitis		0 (0)	0 (0)	0 (0)	0 (0)	2 (12)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 12				250 ppm 17				1000 ppm 12				4000 ppm 10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Special sense organs/appandage]																		
Harder gl	lymphocytic infiltration		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Body cavities]																		
pleura	inflammation		1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
peritoneum	hemorrhage		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
adipose	granulation		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

APPENDIX L 6

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : FEMALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

Organ	Findings	Group Name / No. of Animals	Control 23				1000 ppm 16				4000 ppm 20				16000 ppm 11			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Integumentary system/appandage]																		
skin/app	epidermal cyst		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Respiratory system]																		
nasal cavit	thrombus		0 (0)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	eosinophilic change:olfactory epithelium		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	2 (13)	0 (0)	0 (0)	3 (15)	0 (0)	0 (0)	0 (0)	5 (45)	0 (0)	0 (0)	0 * (0)
	eosinophilic change:respiratory epithelium		9 (39)	2 (9)	0 (0)	0 (0)	2 (13)	2 (13)	0 (0)	0 (0)	5 (25)	12 (60)	1 (5)	0 ** (0)	3 (27)	4 (36)	1 (9)	0 (0)
	respiratory metaplasia:olfactory epithelium		1 (4)	0 (0)	0 (0)	0 (0)	2 (13)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)
	respiratory metaplasia:gland		3 (13)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
lung	congestion		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)
	hemorrhage		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	edema		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	thrombus		0 (0)	0 (0)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	inflammatory infiltration		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				1000 ppm				4000 ppm				16000 ppm			
		No. of Animals	23				16				20				11			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]																		
lung	accumulation of foamy cells		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Hematopoietic system]																		
bone marrow	increased hematopoiesis		0 (0)	3 (13)	0 (0)	0 (0)	0 (0)	3 (19)	0 (0)	0 (0)	3 (15)	0 (0)	0 (0)	0 * (0)	0 (0)	0 (0)	0 (0)	0 (0)
	myelofibrosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
lymph node	congestion		0 (0)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	lymphadenitis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	follicular hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
spleen	extramedullary hematopoiesis		0 (0)	3 (13)	5 (22)	0 (0)	1 (6)	4 (25)	1 (6)	0 (0)	1 (5)	3 (15)	3 (15)	0 (0)	0 (0)	1 (9)	2 (18)	0 (0)
	follicular hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Circulatory system]																		
heart	thrombus		0 (0)	0 (0)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	necrosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 23				1000 ppm 16				4000 ppm 20				16000 ppm 11			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Circulatory system]																		
heart	myocardial fibrosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	arteritis		0 (0)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
artery/aort	arteritis		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Digestive system]																		
tooth	dysplasia		3 (13)	0 (0)	0 (0)	0 (0)	2 (13)	0 (0)	0 (0)	0 (0)	3 (15)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)
tongue	arteritis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (13)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
salivary gl	lymphocytic infiltration		3 (13)	0 (0)	0 (0)	0 (0)	5 (31)	0 (0)	0 (0)	0 (0)	2 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
stomach	ulcer:forestomach		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)
	hyperplasia:forestomach		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	0 (0)
	erosion:glandular stomach		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	ulcer:glandular stomach		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hyperplasia:glandular stomach		4 (17)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 23				1000 ppm 16				4000 ppm 20				16000 ppm 11			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Digestive system]																		
liver	angiectasis		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	thrombus		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	clear cell focus		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	biliary cyst		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Urinary system]																		
kidney	basophilic change		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)
	hydronephrosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	1 (9)	0 (0)
	glomerulosclerosis		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	desquamation:pelvis		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	6 (30)	0 (0)	0 (0)	0 * (0)	2 (18)	0 (0)	0 (0)	0 (0)
	eosinophilic droplet:proximal tubule		3 (13)	3 (13)	0 (0)	0 (0)	5 (31)	0 (0)	0 (0)	0 (0)	4 (20)	0 (0)	0 (0)	0 (0)	4 (36)	0 (0)	0 (0)	0 (0)
[Endocrine system]																		
pituitary	angiectasis		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 23				1000 ppm 16				4000 ppm 20				16000 ppm 11			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Endocrine system]																		
pituitary	hyperplasia		8 (35)	0 (0)	0 (0)	0 (0)	2 (13)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 * (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Rathke pouch		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)
thyroid	arteritis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
adrenal	inflammatory infiltration		0 (0)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	spindle-cell hyperplasia		22 (96)	0 (0)	0 (0)	0 (0)	15 (94)	0 (0)	0 (0)	0 (0)	19 (95)	0 (0)	0 (0)	0 (0)	11 (100)	0 (0)	0 (0)	0 (0)
	accesory cortical nodule		2 (9)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Reproductive system]																		
ovary	angiectasis		2 (9)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	0 (0)
	necrosis		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	cyst		0 (0)	0 (0)	0 (0)	0 (0)	2 (13)	0 (0)	1 (6)	0 (0)	6 (30)	0 (0)	0 (0)	0 * (0)	0 (0)	0 (0)	0 (0)	0 (0)
uterus	dilatation		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	2 (13)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 23				1000 ppm 16				4000 ppm 20				16000 ppm 11			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Reproductive system]																		
uterus	cystic endometrial hyperplasia		13 (57)	0 (0)	0 (0)	0 (0)	10 (63)	0 (0)	0 (0)	0 (0)	12 (60)	0 (0)	0 (0)	0 (0)	5 (45)	0 (0)	0 (0)	0 (0)
	xanthogranuloma		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)
[Nervous system]																		
brain	hemorrhage		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	deposit of calcium		9 (39)	0 (0)	0 (0)	0 (0)	3 (19)	0 (0)	0 (0)	0 (0)	11 (55)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)
	hyaline body		16 (70)	0 (0)	0 (0)	0 (0)	6 (38)	0 (0)	0 (0)	0 (0)	12 (60)	0 (0)	0 (0)	0 (0)	3 (27)	0 (0)	0 (0)	0 (0)
[Special sense organs/appandage]																		
Harder gl	lymphocytic infiltration		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	2 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Musculoskeletal system]																		
muscle	necrosis		2 (9)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

APPENDIX L 7

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : MALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name	Control				250 ppm				1000 ppm				4000 ppm			
		No. of Animals	38				33				38				40			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Integumentary system/appandage]																		
skin/app	hyperplasia		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	epidermal cyst		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
subcutis	inflammation		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	granulation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	xanthogranuloma		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)
[Respiratory system]																		
nasal cavit	inflammation		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	eosinophilic change:olfactory epithelium		19 (50)	1 (3)	0 (0)	0 (0)	12 (36)	3 (9)	0 (0)	0 (0)	18 (47)	5 (13)	0 (0)	0 (0)	11 (28)	0 (0)	0 (0)	0 (0)
	eosinophilic change:respiratory epithelium		16 (42)	5 (13)	1 (3)	0 (0)	8 (24)	5 (15)	0 (0)	0 (0)	7 (18)	1 (3)	0 (0)	0 ** (0)	7 (18)	25 (63)	2 (5)	0 ** (0)
	respiratory metaplasia:olfactory epithelium		10 (26)	0 (0)	0 (0)	0 (0)	4 (12)	0 (0)	0 (0)	0 (0)	7 (18)	0 (0)	0 (0)	0 (0)	4 (10)	0 (0)	0 (0)	0 (0)
	respiratory metaplasia:gland		17 (45)	8 (21)	1 (3)	0 (0)	6 (18)	1 (3)	0 (0)	0 ** (0)	7 (18)	0 (0)	0 (0)	0 ** (0)	6 (15)	0 (0)	0 (0)	0 ** (0)
lung	lymphocytic infiltration		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 38				250 ppm 33				1000 ppm 38				4000 ppm 40			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]																		
lung	granulation		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
	ossification		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	bronchiolar-alveolar cell hyperplasia		1 (3)	0 (0)	0 (0)	0 (0)	2 (6)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Hematopoietic system]																		
bone marrow	myelofibrosis		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	megakaryocyte:increased		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
lymph node	lymphadenitis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (6)	0 (0)	0 (0)	1 (3)	2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
spleen	deposit of melanin		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	3 (8)	1 (3)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)
	extramedullary hematopoiesis		0 (0)	1 (3)	0 (0)	0 (0)	2 (6)	1 (3)	1 (3)	0 (0)	1 (3)	2 (5)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)
	follicular hyperplasia		2 (5)	1 (3)	0 (0)	0 (0)	2 (6)	2 (6)	0 (0)	0 (0)	7 (18)	1 (3)	0 (0)	0 (0)	3 (8)	1 (3)	0 (0)	0 (0)
[Circulatory system]																		
heart	granulation		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 38				250 ppm 33				1000 ppm 38				4000 ppm 40			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Circulatory system]																		
heart	myocardial fibrosis		2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	endocardial hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
[Digestive system]																		
tooth	dysplasia		24 (63)	4 (11)	1 (3)	0 (0)	24 (73)	2 (6)	0 (0)	0 (0)	29 (76)	0 (0)	0 (0)	0 (0)	32 (80)	1 (3)	0 (0)	0 (0)
tongue	arteritis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
salivary gl	atrophy		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	lymphocytic infiltration		16 (42)	0 (0)	0 (0)	0 (0)	16 (48)	0 (0)	0 (0)	0 (0)	15 (39)	0 (0)	0 (0)	0 (0)	19 (48)	0 (0)	0 (0)	0 (0)
	xanthogranuloma		0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
stomach	hyperplasia:forestomach		1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	erosion:glandular stomach		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hyperplasia:glandular stomach		24 (63)	0 (0)	0 (0)	0 (0)	18 (55)	0 (0)	0 (0)	0 (0)	16 (42)	0 (0)	0 (0)	0 (0)	16 (40)	0 (0)	0 (0)	0 (0)
	ectopia:glandular stomach		5 (13)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (8)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name	Control				250 ppm				1000 ppm				4000 ppm			
		No. of Animals	38				33				38				40			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Digestive system]																		
liver	angiectasis		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	necrosis:central		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	necrosis:focal		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
	granulation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	clear cell focus		5 (13)	1 (3)	0 (0)	0 (0)	3 (9)	0 (0)	0 (0)	0 (0)	2 (5)	1 (3)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
	acidophilic cell focus		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	basophilic cell focus		4 (11)	0 (0)	0 (0)	0 (0)	3 (9)	0 (0)	0 (0)	0 (0)	4 (11)	0 (0)	0 (0)	0 (0)	4 (10)	0 (0)	0 (0)	0 (0)
	vacuolated cell focus		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	biliary cyst		3 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
pancreas	inflammation		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Urinary system]																		
kidney	basophilic change		10 (26)	0 (0)	0 (0)	0 (0)	10 (30)	0 (0)	0 (0)	0 (0)	9 (24)	1 (3)	0 (0)	0 (0)	14 (35)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				250 ppm				1000 ppm				4000 ppm			
		No. of Animals	38				33				38				40			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Urinary system]																		
kidney	inflammatory polyp		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
	hydronephrosis		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	3 (8)	0 (0)	0 (0)	0 (0)
	mineralization:papilla		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
	mineralization:cortex		20 (53)	0 (0)	0 (0)	0 (0)	17 (52)	0 (0)	0 (0)	0 (0)	15 (39)	0 (0)	0 (0)	0 (0)	14 (35)	0 (0)	0 (0)	0 (0)
	glomerulosclerosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	desquamation:pelvis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
	vacuolic change:proximal tubule		38 (100)	0 (0)	0 (0)	0 (0)	31 (94)	0 (0)	0 (0)	0 (0)	35 (92)	0 (0)	0 (0)	0 (0)	38 (95)	0 (0)	0 (0)	0 (0)
	eosinophilic droplet:proximal tubule		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
[Endocrine system]																		
pituitary	cyst		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
	Rathke pouch		5 (13)	0 (0)	0 (0)	0 (0)	11 (33)	0 (0)	0 (0)	0 (0)	4 (11)	0 (0)	0 (0)	0 (0)	5 (13)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name / No. of Animals	Control 38				250 ppm 33				1000 ppm 38				4000 ppm 40			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Endocrine system]																		
adrenal	spindle-cell hyperplasia		28 (74)	0 (0)	0 (0)	0 (0)	25 (76)	0 (0)	0 (0)	0 (0)	28 (74)	0 (0)	0 (0)	0 (0)	28 (70)	0 (0)	0 (0)	0 (0)
	hyperplasia:cortical cell		17 (45)	1 (3)	0 (0)	0 (0)	12 (36)	2 (6)	0 (0)	0 (0)	18 (47)	3 (8)	0 (0)	0 (0)	24 (60)	0 (0)	0 (0)	0 (0)
	hyperplasia:medulla		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	accesory cortical nodule		0 (0)	0 (0)	0 (0)	0 (0)	3 (9)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Reproductive system]																		
testis	aplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
	atrophy		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	mineralization		33 (87)	0 (0)	0 (0)	0 (0)	29 (88)	0 (0)	0 (0)	0 (0)	33 (87)	0 (0)	0 (0)	0 (0)	35 (88)	0 (0)	0 (0)	0 (0)
epididymis	necrosis:focal		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	degeneration:focal		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	inflammation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
	spermatogenic granuloma		3 (8)	1 (3)	0 (0)	0 (0)	3 (9)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				250 ppm				1000 ppm				4000 ppm			
		No. of Animals	38				33				38				40			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Reproductive system]																		
semin ves	mineralization		2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
prostate	inflammation		1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
prep/cli gl	duct ectasia		1 (3)	5 (13)	0 (0)	0 (0)	1 (3)	9 (27)	0 (0)	0 (0)	1 (3)	10 (26)	0 (0)	0 (0)	0 (0)	5 (13)	0 (0)	0 (0)
	xanthogranuloma		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Nervous system]																		
brain	deposit of calcium		25 (66)	0 (0)	0 (0)	0 (0)	17 (52)	1 (3)	0 (0)	0 (0)	22 (58)	0 (0)	0 (0)	0 (0)	25 (63)	0 (0)	0 (0)	0 (0)
	hyaline body		26 (68)	0 (0)	0 (0)	0 (0)	28 (85)	0 (0)	0 (0)	0 (0)	27 (71)	0 (0)	0 (0)	0 (0)	33 (83)	0 (0)	0 (0)	0 (0)
	epidermal cyst		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Special sense organs/appandage]																		
eye	cataract		0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	keratitis		4 (11)	0 (0)	1 (3)	0 (0)	1 (3)	0 (0)	1 (3)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	5 (13)	0 (0)	0 (0)	0 (0)
Harder gl	lymphocytic infiltration		2 (5)	0 (0)	0 (0)	0 (0)	4 (12)	0 (0)	0 (0)	0 (0)	3 (8)	0 (0)	0 (0)	0 (0)	3 (8)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name	Control				250 ppm				1000 ppm				4000 ppm			
		No. of Animals	38				33				38				40			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Special sense organs/appandage]																		
Harder gl	hyperplasia		1 (3)	0 (0)	0 (0)	0 (0)	2 (6)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Body cavities]																		
retroperit	xanthogranuloma		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
adipose	granulation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

APPENDIX L 8

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : FEMALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

Organ	Findings	Group Name	Control				1000 ppm				4000 ppm				16000 ppm			
		No. of Animals	27				33				30				39			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Integumentary system/appandage]																		
skin/app	hyperplasia:epidermis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
[Respiratory system]																		
nasal cavit	eosinophilic change:olfactory epithelium		1 (4)	0 (0)	0 (0)	0 (0)	4 (12)	1 (3)	0 (0)	0 (0)	3 (10)	0 (0)	0 (0)	0 (0)	13 (33)	1 (3)	0 (0)	0 ** (0)
	eosinophilic change:respiratory epithelium		15 (56)	5 (19)	0 (0)	0 (0)	16 (48)	5 (15)	1 (3)	0 (0)	4 (13)	17 (57)	8 (27)	1 ** (3)	15 (38)	16 (41)	7 (18)	0 ** (0)
	inflammation:respiratory epithelium		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	respiratory metaplasia:olfactory epithelium		1 (4)	0 (0)	0 (0)	0 (0)	7 (21)	0 (0)	0 (0)	0 (0)	6 (20)	0 (0)	0 (0)	0 (0)	3 (8)	0 (0)	0 (0)	0 (0)
	respiratory metaplasia:gland		3 (11)	0 (0)	0 (0)	0 (0)	10 (30)	0 (0)	0 (0)	0 (0)	2 (7)	2 (7)	0 (0)	0 (0)	3 (8)	0 (0)	0 (0)	0 (0)
lung	hemorrhage		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	thrombus		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	inflammatory infiltration		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	lymphocytic infiltration		2 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	ossification		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				1000 ppm				4000 ppm				16000 ppm			
		No. of Animals	27				33				30				39			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]																		
lung	accumulation of foamy cells		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
	bronchiolar cell hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)
	bronchiolar-alveolar cell hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	pleuritis		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Hematopoietic system]																		
bone marrow	increased hematopoiesis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	myelofibrosis		1 (4)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
lymph node	lymphadenitis		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)
spleen	Russel body		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	deposit of melanin		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)
	extramedullary hematopoiesis		1 (4)	0 (0)	0 (0)	0 (0)	1 (3)	2 (6)	0 (0)	0 (0)	0 (0)	0 (0)	2 (7)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)
	follicular hyperplasia		1 (4)	0 (0)	0 (0)	0 (0)	4 (12)	4 (12)	0 (0)	0 (0)	3 (10)	2 (7)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				1000 ppm				4000 ppm				16000 ppm			
		No. of Animals	27				33				30				39			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Circulatory system]																		
heart	mineralization		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
	arteritis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
artery/aort	arteritis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Digestive system]																		
tooth	dysplasia		4 (15)	0 (0)	0 (0)	0 (0)	3 (9)	0 (0)	0 (0)	0 (0)	4 (13)	0 (0)	0 (0)	0 (0)	11 (28)	0 (0)	0 (0)	0 (0)
tongue	arteritis		1 (4)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	2 (7)	0 (0)	0 (0)	0 (0)	1 (3)	1 (3)	0 (0)	0 (0)
salivary gl	lymphocytic infiltration		13 (48)	0 (0)	0 (0)	0 (0)	16 (48)	0 (0)	0 (0)	0 (0)	20 (67)	0 (0)	0 (0)	0 (0)	19 (49)	0 (0)	0 (0)	0 (0)
stomach	hyperplasia:forestomach		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
	erosion:glandular stomach		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	ulcer:glandular stomach		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hyperplasia:glandular stomach		8 (30)	0 (0)	0 (0)	0 (0)	8 (24)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 ** (0)	0 (0)	0 (0)	0 (0)	0 ** (0)
liver	angiectasis		1 (4)	0 (0)	0 (0)	0 (0)	2 (6)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				1000 ppm				4000 ppm				16000 ppm			
		No. of Animals	27				33				30				39			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Digestive system]																		
liver	clear cell focus		2 (7)	0 (0)	0 (0)	0 (0)	3 (9)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (8)	0 (0)	0 (0)	0 (0)
	basophilic cell focus		3 (11)	0 (0)	0 (0)	0 (0)	3 (9)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	biliary cyst		1 (4)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Urinary system]																		
kidney	hyaline cast		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	lymphocytic infiltration		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	inflammatory polyp		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	3 (10)	1 (3)	0 (0)	0 (0)	3 (8)	0 (0)	0 (0)	0 (0)
	hydronephrosis		0 (0)	0 (0)	0 (0)	0 (0)	4 (12)	0 (0)	0 (0)	0 (0)	5 (17)	1 (3)	0 (0)	0 * (0)	3 (8)	0 (0)	0 (0)	0 (0)
	glomerulosclerosis		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	desquamation:pelvis		1 (4)	0 (0)	0 (0)	0 (0)	12 ** (36)	0 (0)	0 (0)	0 (0)	10 * (33)	0 (0)	0 (0)	0 (0)	17 ** (44)	0 (0)	0 (0)	0 (0)
	eosinophilic droplet:proximal tubule		0 (0)	1 (4)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
ureter	inflammatory polyp		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

Organ	Findings	Group Name	Control				1000 ppm				4000 ppm				16000 ppm			
		No. of Animals	27				33				30				39			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Endocrine system]																		
pituitary	angiectasis		2 (7)	1 (4)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
	cyst		2 (7)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hyperplasia		6 (22)	2 (7)	0 (0)	0 (0)	6 (18)	2 (6)	0 (0)	0 (0)	8 (27)	1 (3)	0 (0)	0 (0)	3 (8)	0 (0)	0 (0)	0 * (0)
	Rathke pouch		0 (0)	0 (0)	0 (0)	0 (0)	2 (6)	0 (0)	0 (0)	0 (0)	2 (7)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
thyroid	inflammatory infiltration		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
adrenal	hemorrhage		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	fatty change		4 (15)	1 (4)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
	spindle-cell hyperplasia		27 (100)	0 (0)	0 (0)	0 (0)	33 (100)	0 (0)	0 (0)	0 (0)	30 (100)	0 (0)	0 (0)	0 (0)	39 (100)	0 (0)	0 (0)	0 (0)
	hyperplasia:cortical cell		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)
	hyperplasia:medulla		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	accesory cortical nodule		1 (4)	0 (0)	0 (0)	0 (0)	2 (6)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	3 (8)	0 (0)	0 (0)	0 (0)
[Reproductive system]																		
ovary	angiectasis		2 (7)	0 (0)	0 (0)	0 (0)	2 (6)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	4 (10)	0 (0)	0 (0)	0 (0)

Organ	Findings	Group Name	Control				1000 ppm				4000 ppm				16000 ppm			
		No. of Animals	27				33				30				39			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Reproductive system]																		
ovary	thrombus		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)
	cyst		9 (33)	0 (0)	0 (0)	0 (0)	6 (18)	0 (0)	0 (0)	0 (0)	6 (20)	0 (0)	0 (0)	0 (0)	14 (36)	0 (0)	0 (0)	0 (0)
uterus	dilatation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	3 (8)	0 (0)	0 (0)	0 (0)
	hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	cystic endometrial hyperplasia		22 (81)	2 (7)	0 (0)	0 (0)	31 (94)	0 (0)	0 (0)	0 (0)	24 (80)	0 (0)	0 (0)	0 (0)	36 (92)	0 (0)	0 (0)	0 (0)
[Nervous system]																		
brain	hemorrhage		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	deposit of calcium		13 (48)	0 (0)	0 (0)	0 (0)	13 (39)	0 (0)	0 (0)	0 (0)	15 (50)	0 (0)	0 (0)	0 (0)	15 (38)	0 (0)	0 (0)	0 (0)
	hyaline body		22 (81)	0 (0)	0 (0)	0 (0)	27 (82)	0 (0)	0 (0)	0 (0)	25 (83)	0 (0)	0 (0)	0 (0)	37 (95)	0 (0)	0 (0)	0 (0)
spinal cord	epidermal cyst		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
[Special sense organs/appandage]																		
eye	keratitis		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name	Control				1000 ppm				4000 ppm				16000 ppm			
		No. of Animals	27				33				30				39			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Special sense organs/appandage]																		
Harder gl	lymphocytic infiltration		3 (11)	0 (0)	0 (0)	0 (0)	3 (9)	0 (0)	0 (0)	0 (0)	5 (17)	0 (0)	0 (0)	0 (0)	3 (8)	0 (0)	0 (0)	0 (0)
[Body cavities]																		
adipose	granulation		0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

APPENDIX M 1

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS-TIME RELATED

RAT : MALE

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

Time-related Weeks	Items	Group Name	Control	800 ppm	2400 ppm	7200 ppm
0 - 52	NO. OF EXAMINED ANIMALS		0	0	1	1
	NO. OF ANIMALS WITH TUMORS		0	0	1	1
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	1	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	1
	NO. OF BENIGN TUMORS		0	0	1	0
	NO. OF MALIGNANT TUMORS		0	0	0	2
	NO. OF TOTAL TUMORS		0	0	1	2
53 - 78	NO. OF EXAMINED ANIMALS		2	1	0	1
	NO. OF ANIMALS WITH TUMORS		1	1	0	1
	NO. OF ANIMALS WITH SINGLE TUMORS		0	1	0	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		1	0	0	1
	NO. OF BENIGN TUMORS		2	0	0	3
	NO. OF MALIGNANT TUMORS		0	1	0	0
	NO. OF TOTAL TUMORS		2	1	0	3
79 - 104	NO. OF EXAMINED ANIMALS		12	6	6	6
	NO. OF ANIMALS WITH TUMORS		11	6	6	6
	NO. OF ANIMALS WITH SINGLE TUMORS		3	1	2	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		8	5	4	5
	NO. OF BENIGN TUMORS		19	10	9	8
	NO. OF MALIGNANT TUMORS		5	4	1	4
	NO. OF TOTAL TUMORS		24	14	10	12
105 - 106	NO. OF EXAMINED ANIMALS		36	43	43	42
	NO. OF ANIMALS WITH TUMORS		36	43	43	42
	NO. OF ANIMALS WITH SINGLE TUMORS		6	13	15	16
	NO. OF ANIMALS WITH MULTIPLE TUMORS		30	30	28	26
	NO. OF BENIGN TUMORS		79	89	77	71
	NO. OF MALIGNANT TUMORS		13	7	9	12
	NO. OF TOTAL TUMORS		92	96	86	83

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

Time-related Weeks	Items	Group Name	Control	800 ppm	2400 ppm	7200 ppm
0 - 106	NO. OF EXAMINED ANIMALS		50	50	50	50
	NO. OF ANIMALS WITH TUMORS		48	50	50	50
	NO. OF ANIMALS WITH SINGLE TUMORS		9	15	18	17
	NO. OF ANIMALS WITH MULTIPLE TUMORS		39	35	32	33
	NO. OF BENIGN TUMORS		100	99	87	82
	NO. OF MALIGNANT TUMORS		18	12	10	18
	NO. OF TOTAL TUMORS		118	111	97	100

APPENDIX M 2

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS-TIME RELATED

RAT : FEMALE

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

Time-related Weeks	Items	Group Name	Control	800 ppm	2400 ppm	7200 ppm
0 - 52	NO. OF EXAMINED ANIMALS		0	0	0	0
	NO. OF ANIMALS WITH TUMORS		0	0	0	0
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	0	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0
	NO. OF BENIGN TUMORS		0	0	0	0
	NO. OF MALIGNANT TUMORS		0	0	0	0
	NO. OF TOTAL TUMORS		0	0	0	0
53 - 78	NO. OF EXAMINED ANIMALS		6	1	0	2
	NO. OF ANIMALS WITH TUMORS		6	1	0	2
	NO. OF ANIMALS WITH SINGLE TUMORS		5	0	0	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		1	1	0	1
	NO. OF BENIGN TUMORS		4	1	0	0
	NO. OF MALIGNANT TUMORS		3	1	0	3
	NO. OF TOTAL TUMORS		7	2	0	3
79 - 104	NO. OF EXAMINED ANIMALS		7	11	7	3
	NO. OF ANIMALS WITH TUMORS		7	9	7	3
	NO. OF ANIMALS WITH SINGLE TUMORS		3	6	3	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		4	3	4	2
	NO. OF BENIGN TUMORS		11	9	8	3
	NO. OF MALIGNANT TUMORS		3	5	3	3
	NO. OF TOTAL TUMORS		14	14	11	6
105 - 106	NO. OF EXAMINED ANIMALS		37	38	43	45
	NO. OF ANIMALS WITH TUMORS		26	30	30	38
	NO. OF ANIMALS WITH SINGLE TUMORS		16	19	19	25
	NO. OF ANIMALS WITH MULTIPLE TUMORS		10	11	11	13
	NO. OF BENIGN TUMORS		33	37	36	50
	NO. OF MALIGNANT TUMORS		5	9	8	4
	NO. OF TOTAL TUMORS		38	46	44	54

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

Time-related Weeks	Items	Group Name	Control	800 ppm	2400 ppm	7200 ppm
0 - 106	NO. OF EXAMINED ANIMALS		50	50	50	50
	NO. OF ANIMALS WITH TUMORS		39	40	37	43
	NO. OF ANIMALS WITH SINGLE TUMORS		24	25	22	27
	NO. OF ANIMALS WITH MULTIPLE TUMORS		15	15	15	16
	NO. OF BENIGN TUMORS		48	47	44	53
	NO. OF MALIGNANT TUMORS		11	15	11	10
	NO. OF TOTAL TUMORS		59	62	55	63

APPENDIX M 3

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS-TIME RELATED

MOUSE : MALE

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

Time-related Weeks	Items	Group Name	Control	250 ppm	1000 ppm	4000 ppm
0 - 52	NO. OF EXAMINED ANIMALS		1	2	0	2
	NO. OF ANIMALS WITH TUMORS		0	0	0	1
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	0	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0
	NO. OF BENIGN TUMORS		0	0	0	0
	NO. OF MALIGNANT TUMORS		0	0	0	1
	NO. OF TOTAL TUMORS		0	0	0	1
53 - 78	NO. OF EXAMINED ANIMALS		0	3	1	2
	NO. OF ANIMALS WITH TUMORS		0	2	1	2
	NO. OF ANIMALS WITH SINGLE TUMORS		0	2	1	2
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0
	NO. OF BENIGN TUMORS		0	1	0	0
	NO. OF MALIGNANT TUMORS		0	1	1	2
	NO. OF TOTAL TUMORS		0	2	1	2
79 - 104	NO. OF EXAMINED ANIMALS		11	12	11	6
	NO. OF ANIMALS WITH TUMORS		10	10	10	6
	NO. OF ANIMALS WITH SINGLE TUMORS		8	4	7	4
	NO. OF ANIMALS WITH MULTIPLE TUMORS		2	6	3	2
	NO. OF BENIGN TUMORS		2	5	2	2
	NO. OF MALIGNANT TUMORS		10	17	13	6
	NO. OF TOTAL TUMORS		12	22	15	8
105 - 105	NO. OF EXAMINED ANIMALS		38	33	38	40
	NO. OF ANIMALS WITH TUMORS		31	28	23	20
	NO. OF ANIMALS WITH SINGLE TUMORS		20	12	18	12
	NO. OF ANIMALS WITH MULTIPLE TUMORS		11	16	5	8
	NO. OF BENIGN TUMORS		17	24	12	15
	NO. OF MALIGNANT TUMORS		25	23	20	14
	NO. OF TOTAL TUMORS		42	47	32	29

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

Time-related Weeks	Items	Group Name	Control	250 ppm	1000 ppm	4000 ppm
0 - 105	NO. OF EXAMINED ANIMALS		50	50	50	50
	NO. OF ANIMALS WITH TUMORS		41	40	34	29
	NO. OF ANIMALS WITH SINGLE TUMORS		28	18	26	19
	NO. OF ANIMALS WITH MULTIPLE TUMORS		13	22	8	10
	NO. OF BENIGN TUMORS		19	30	14	17
	NO. OF MALIGNANT TUMORS		35	41	34	23
	NO. OF TOTAL TUMORS		54	71	48	40

APPENDIX M 4

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS-TIME RELATED

MOUSE: FEMALE

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

Time-related Weeks	Items	Group Name	Control	1000 ppm	4000 ppm	16000 ppm
0 - 52	NO. OF EXAMINED ANIMALS		0	1	1	0
	NO. OF ANIMALS WITH TUMORS		0	0	1	0
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	1	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0
	NO. OF BENIGN TUMORS		0	0	0	0
	NO. OF MALIGNANT TUMORS		0	0	1	0
	NO. OF TOTAL TUMORS		0	0	1	0
53 - 78	NO. OF EXAMINED ANIMALS		4	2	3	2
	NO. OF ANIMALS WITH TUMORS		3	2	3	2
	NO. OF ANIMALS WITH SINGLE TUMORS		3	2	2	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	1	1
	NO. OF BENIGN TUMORS		0	0	1	0
	NO. OF MALIGNANT TUMORS		3	2	3	3
	NO. OF TOTAL TUMORS		3	2	4	3
79 - 104	NO. OF EXAMINED ANIMALS		19	13	16	9
	NO. OF ANIMALS WITH TUMORS		18	11	14	7
	NO. OF ANIMALS WITH SINGLE TUMORS		10	7	9	6
	NO. OF ANIMALS WITH MULTIPLE TUMORS		8	4	5	1
	NO. OF BENIGN TUMORS		2	7	3	0
	NO. OF MALIGNANT TUMORS		24	8	16	8
	NO. OF TOTAL TUMORS		26	15	19	8
105 - 105	NO. OF EXAMINED ANIMALS		27	33	30	39
	NO. OF ANIMALS WITH TUMORS		15	22	20	17
	NO. OF ANIMALS WITH SINGLE TUMORS		8	16	17	10
	NO. OF ANIMALS WITH MULTIPLE TUMORS		7	6	3	7
	NO. OF BENIGN TUMORS		15	12	12	9
	NO. OF MALIGNANT TUMORS		9	16	11	15
	NO. OF TOTAL TUMORS		24	28	23	24

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

Time-related Weeks	Items	Group Name	Control	1000 ppm	4000 ppm	16000 ppm
0 - 105	NO. OF EXAMINED ANIMALS		50	49	50	50
	NO. OF ANIMALS WITH TUMORS		36	35	38	26
	NO. OF ANIMALS WITH SINGLE TUMORS		21	25	29	17
	NO. OF ANIMALS WITH MULTIPLE TUMORS		15	10	9	9
	NO. OF BENIGN TUMORS		17	19	16	9
	NO. OF MALIGNANT TUMORS		36	26	31	26
	NO. OF TOTAL TUMORS		53	45	47	35

APPENDIX N 1

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS : SUMMARY

RAT : MALE :

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 50 (%)	800 ppm 50 (%)	2400 ppm 50 (%)	7200 ppm 50 (%)
[Integumentary system/appandage]						
skin/app	squamous cell papilloma		2 (4)	0 (0)	2 (4)	0 (0)
	trichoepithelioma		1 (2)	0 (0)	1 (2)	0 (0)
	keratoacanthoma		2 (4)	0 (0)	1 (2)	0 (0)
	calcifying epithelioma		0 (0)	0 (0)	0 (0)	1 (2)
	sebaceous adenoma		0 (0)	0 (0)	0 (0)	1 (2)
	squamous cell carcinoma		0 (0)	1 (2)	0 (0)	0 (0)
subcutis	fibroma		3 (6)	6 (12)	5 (10)	3 (6)
	lipoma		1 (2)	1 (2)	0 (0)	0 (0)
	schwannoma		1 (2)	1 (2)	0 (0)	0 (0)
	fibrosarcoma		0 (0)	2 (4)	0 (0)	0 (0)
	schwannoma:malignant		0 (0)	1 (2)	0 (0)	1 (2)
	malignant fibrous histiocytoma		0 (0)	0 (0)	1 (2)	0 (0)
[Respiratory system]						
nasal cavit	adenoma		0 (0)	0 (0)	1 (2)	0 (0)
lung	bronchiolar-alveolar adenoma		2 (4)	1 (2)	2 (4)	3 (6)
	bronchiolar-alveolar carcinoma		0 (0)	0 (0)	1 (2)	1 (2)
[Hematopoietic system]						
thymus	thymoma:benign		0 (0)	0 (0)	1 (2)	0 (0)
spleen	fibroma		0 (0)	1 (2)	0 (0)	0 (0)
	mononuclear cell leukemia		11 (22)	2 (4)	1 (2)	7 (14)

Organ	Findings	Group Name / NO. of Animals	Control 50 (%)	800 ppm 50 (%)	2400 ppm 50 (%)	7200 ppm 50 (%)
[Circulatory system]						
heart	hemangiosarcoma		0 (0)	0 (0)	1 (2)	0 (0)
[Digestive system]						
stomach	squamous cell papilloma		0 (0)	0 (0)	1 (2)	2 (4)
	leiomyoma		1 (2)	0 (0)	0 (0)	0 (0)
	squamous cell carcinoma		0 (0)	0 (0)	0 (0)	1 (2)
small intes	fibrosarcoma		0 (0)	0 (0)	0 (0)	1 (2)
liver	hepatocellular adenoma		1 (2)	0 (0)	0 (0)	1 (2)
	cholangiocellular adenoma		1 (2)	0 (0)	0 (0)	0 (0)
	hepatocellular carcinoma		1 (2)	0 (0)	0 (0)	1 (2)
	cholangiocellular carcinoma		0 (0)	0 (0)	0 (0)	1 (2)
[Urinary system]						
urin bladd	transitional cell papilloma		0 (0)	2 (4)	0 (0)	0 (0)
[Endocrine system]						
pituitary	adenoma		22 (44)	15 (30)	10 (20)	6 (12)
	adenocarcinoma		0 (0)	0 (0)	1 (2)	0 (0)
thyroid	C-cell adenoma		6 (12)	6 (12)	5 (10)	10 (20)
	follicular adenoma		1 (2)	0 (0)	0 (0)	1 (2)
	C-cell carcinoma		2 (4)	0 (0)	1 (2)	0 (0)
	follicular adenocarcinoma		0 (0)	0 (0)	2 (4)	1 (2)
panc islet	adenoma		1 (2)	2 (4)	2 (4)	2 (4)

Organ	Findings	Group Name / NO. of Animals	Control 50 (%)	800 ppm 50 (%)	2400 ppm 50 (%)	7200 ppm 50 (%)
[Endocrine system]						
panc islet	adenocarcinoma		0 (0)	1 (2)	0 (0)	0 (0)
adrenal	pheochromocytoma		8 (16)	7 (14)	4 (8)	3 (6)
	pheochromocytoma:malignant		1 (2)	2 (4)	1 (2)	2 (4)
[Reproductive system]						
testis	interstitial cell tumor		41 (82)	47 (94)	48 (96)	48 (96)
	rete testis adenoma		1 (2)	0 (0)	1 (2)	1 (2)
mammary gl	adenoma		0 (0)	2 (4)	0 (0)	0 (0)
	fibroadenoma		0 (0)	1 (2)	2 (4)	0 (0)
	adenocarcinoma		0 (0)	0 (0)	1 (2)	0 (0)
prep/cli gl	adenoma		4 (8)	5 (10)	1 (2)	0 (0)
	squamous cell carcinoma		0 (0)	0 (0)	0 (0)	1 (2)
[Nervous system]						
brain	glioma		1 (2)	0 (0)	0 (0)	0 (0)
spinal cord	glioma		1 (2)	0 (0)	0 (0)	1 (2)
[Special sense organs/appandage]						
Zymbal gl	adenoma		0 (0)	2 (4)	0 (0)	0 (0)
	squamous cell carcinoma		1 (2)	1 (2)	0 (0)	0 (0)
[Body cavities]						
peritoneum	fibroma		1 (2)	0 (0)	0 (0)	0 (0)
	mesothelioma		0 (0)	2 (4)	0 (0)	0 (0)

APPENDIX N 2

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE :

(2-YEAR STUDY)

Organ	Findings	Group Name / NO. of Animals	Control 50 (%)	800 ppm 50 (%)	2400 ppm 50 (%)	7200 ppm 50 (%)
[Integumentary system/appandage]						
skin/app	basal cell epithelioma		0 (0)	1 (2)	0 (0)	0 (0)
	sebaceous adenoma		0 (0)	0 (0)	1 (2)	0 (0)
	squamous cell carcinoma		0 (0)	1 (2)	0 (0)	0 (0)
subcutis	fibroma		2 (4)	0 (0)	0 (0)	1 (2)
	lipoma		0 (0)	0 (0)	0 (0)	1 (2)
	fibrosarcoma		1 (2)	0 (0)	0 (0)	0 (0)
	liposarcoma		0 (0)	1 (2)	0 (0)	0 (0)
[Respiratory system]						
lung	bronchiolar-alveolar adenoma		1 (2)	2 (4)	0 (0)	1 (2)
	bronchial carcinoma		1 (2)	0 (0)	0 (0)	0 (0)
[Hematopoietic system]						
thymus	thymoma:malignant		0 (0)	1 (2)	0 (0)	0 (0)
spleen	mononuclear cell leukemia		5 (10)	9 (18)	11 (22)	5 (10)
[Digestive system]						
stomach	squamous cell papilloma		1 (2)	0 (0)	0 (0)	1 (2)
large intes	leiomyosarcoma		0 (0)	1 (2)	0 (0)	0 (0)
liver	hepatocellular adenoma		1 (2)	0 (0)	1 (2)	0 (0)
[Urinary system]						
urin bladd	transitional cell papilloma		0 (0)	0 (0)	1 (2)	1 (2)
[Endocrine system]						
pituitary	adenoma		20 (40)	24 (48)	21 (42)	21 (42)

Organ	Findings	Group Name / NO. of Animals	Control 50 (%)	800 ppm 50 (%)	2400 ppm 50 (%)	7200 ppm 50 (%)
[Endocrine system]						
pituitary	adenocarcinoma		1 (2)	0 (0)	0 (0)	0 (0)
thyroid	C-cell adenoma		7 (14)	5 (10)	3 (6)	4 (8)
panc islet	adenoma		1 (2)	0 (0)	0 (0)	1 (2)
adrenal	pheochromocytoma		3 (6)	0 (0)	0 (0)	3 (6)
	cortical adenoma		0 (0)	0 (0)	1 (2)	1 (2)
[Reproductive system]						
ovary	sertoli cell tumor		0 (0)	0 (0)	2 (4)	0 (0)
uterus	adenoma		0 (0)	0 (0)	1 (2)	0 (0)
	endometrial stromal polyp		5 (10)	5 (10)	8 (16)	13 (26)
	adenocarcinoma		1 (2)	0 (0)	0 (0)	2 (4)
	endometrial stromal sarcoma		0 (0)	1 (2)	0 (0)	3 (6)
vagina	leiomyosarcoma		1 (2)	0 (0)	0 (0)	0 (0)
mammary gl	adenoma		0 (0)	1 (2)	1 (2)	0 (0)
	fibroadenoma		2 (4)	7 (14)	3 (6)	3 (6)
	adenocarcinoma		1 (2)	0 (0)	0 (0)	0 (0)
prep/cli gl	adenoma		4 (8)	2 (4)	1 (2)	0 (0)
[Nervous system]						
spinal cord	glioma		0 (0)	0 (0)	0 (0)	1 (2)
[Special sense organs/appandage]						
Zymbal gl	adenoma		1 (2)	0 (0)	0 (0)	0 (0)

Organ	Findings	Group Name / NO. of Animals	Control 50 (%)	800 ppm 50 (%)	2400 ppm 50 (%)	7200 ppm 50 (%)
[Body cavities]						
retroperit	leiomyosarcoma		0 (0)	1 (2)	0 (0)	0 (0)

APPENDIX N 3

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS : SUMMARY

MOUSE: MALE

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 50 (%)	250 ppm 50 (%)	1000 ppm 50 (%)	4000 ppm 50 (%)
[Integumentary system/appandage]						
subcutis	xanthoma		0 (0)	0 (0)	1 (2)	1 (2)
	histiocytic sarcoma		0 (0)	0 (0)	0 (0)	1 (2)
[Respiratory system]						
lung	bronchiolar-alveolar adenoma		6 (12)	11 (22)	2 (4)	6 (12)
	bronchiolar-alveolar carcinoma		4 (8)	5 (10)	7 (14)	5 (10)
[Hematopoiotic system]						
bone marrow	hemangioma		1 (2)	1 (2)	1 (2)	0 (0)
lymph node	malignant lymphoma		1 (2)	4 (8)	7 (14)	5 (10)
spleen	mastcytoma:benign		0 (0)	0 (0)	1 (2)	0 (0)
	hemangioma		0 (0)	3 (6)	1 (2)	2 (4)
	malignant lymphoma		1 (2)	1 (2)	2 (4)	0 (0)
	mastcytoma:malignant		1 (2)	0 (0)	0 (0)	0 (0)
	hemangiosarcoma		0 (0)	1 (2)	1 (2)	0 (0)
[Circulatory system]						
heart	hemangiosarcoma		0 (0)	1 (2)	0 (0)	0 (0)
[Digestive system]						
stomach	histiocytic sarcoma		1 (2)	0 (0)	0 (0)	0 (0)
small intes	adenoma		1 (2)	0 (0)	0 (0)	0 (0)
	histiocytic sarcoma		1 (2)	0 (0)	0 (0)	1 (2)
large intes	histiocytic sarcoma		1 (2)	1 (2)	0 (0)	0 (0)

Organ	Findings	Group Name / NO. of Animals	Control 50 (%)	250 ppm 50 (%)	1000 ppm 50 (%)	4000 ppm 50 (%)
[Digestive system]						
liver	hemangioma		0 (0)	2 (4)	0 (0)	0 (0)
	hepatocellular adenoma		7 (14)	7 (14)	5 (10)	3 (6)
	histiocytic sarcoma		0 (0)	2 (4)	0 (0)	2 (4)
	hemangiosarcoma		6 (12)	7 (14)	6 (12)	4 (8)
	hepatocellular carcinoma		18 (36)	18 (36)	8 (16)	4 (8)
[Urinary system]						
kidney	hemangiosarcoma		0 (0)	0 (0)	1 (2)	0 (0)
urin bladd	transitional cell papilloma		0 (0)	1 (2)	0 (0)	0 (0)
[Endocrine system]						
pituitary	adenoma		2 (4)	1 (2)	0 (0)	0 (0)
thyroid	C-cell adenoma		0 (0)	0 (0)	1 (2)	0 (0)
panc islet	adenoma		0 (0)	0 (0)	0 (0)	1 (2)
[Reproductive system]						
epididymis	hemangioma		0 (0)	1 (2)	0 (0)	0 (0)
	histiocytic sarcoma		1 (2)	0 (0)	0 (0)	0 (0)
[Nervous system]						
brain	schwannoma:malignant		0 (0)	1 (2)	0 (0)	0 (0)
periph nerv	histiocytic sarcoma		0 (0)	0 (0)	0 (0)	1 (2)
[Special sense organs/appandage]						
Harder gl	adenoma		2 (4)	3 (6)	1 (2)	4 (8)

Organ	Findings	Group Name / NO. of Animals	Control 50 (%)	250 ppm 50 (%)	1000 ppm 50 (%)	4000 ppm 50 (%)
[Musculoskeletal system]						
muscle	hemangioma		0 (0)	0 (0)	1 (2)	0 (0)
bone	chondrosarcoma		0 (0)	0 (0)	1 (2)	0 (0)
[Body cavities]						
peritoneum	histiocytic sarcoma		0 (0)	0 (0)	1 (2)	0 (0)

APPENDIX N 4

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS : SUMMARY

MOUSE: FEMALE

(2-YEAR STUDY)

Organ	Findings	Group Name / NO. of Animals	Control 50 (%)	1000 ppm 49 (%)	4000 ppm 50 (%)	16000 ppm 50 (%)
[Integumentary system/appandage]						
subcutis	xanthoma		0 (0)	0 (0)	1 (2)	1 (2)
	leiomyosarcoma		1 (2)	1 (2)	0 (0)	0 (0)
	sarcoma:NOS		0 (0)	1 (2)	0 (0)	0 (0)
[Respiratory system]						
lung	bronchiolar-alveolar adenoma		3 (6)	4 (8)	1 (2)	1 (2)
	bronchiolar-alveolar carcinoma		1 (2)	1 (2)	3 (6)	3 (6)
[Hematopoietic system]						
lymph node	malignant lymphoma		16 (32)	13 (27)	13 (26)	9 (18)
	mastcytoma:malignant		0 (0)	0 (0)	0 (0)	1 (2)
spleen	hemangioma		0 (0)	1 (2)	1 (2)	0 (0)
	malignant lymphoma		1 (2)	3 (6)	2 (4)	1 (2)
	mastcytoma:malignant		1 (2)	0 (0)	0 (0)	0 (0)
	hemangiosarcoma		0 (0)	1 (2)	0 (0)	0 (0)
[Digestive system]						
stomach	squamous cell papilloma		0 (0)	1 (2)	0 (0)	0 (0)
large intes	leiomyosarcoma		0 (0)	0 (0)	1 (2)	0 (0)
liver	hemangioma		1 (2)	1 (2)	1 (2)	1 (2)
	hepatocellular adenoma		1 (2)	0 (0)	1 (2)	0 (0)
	histiocytic sarcoma		2 (4)	1 (2)	2 (4)	2 (4)
	hemangiosarcoma		4 (8)	0 (0)	1 (2)	1 (2)

Organ	Findings	Group Name / NO. of Animals	Control 50 (%)	1000 ppm 49 (%)	4000 ppm 50 (%)	16000 ppm 50 (%)
[Digestive system]						
liver	hepatocellular carcinoma		0 (0)	1 (2)	0 (0)	0 (0)
[Urinary system]						
kidney	renal cell carcinoma		0 (0)	0 (0)	0 (0)	1 (2)
[Endocrine system]						
pituitary	adenoma		7 (14)	4 (8)	7 (14)	1 (2)
	adenocarcinoma		0 (0)	1 (2)	1 (2)	0 (0)
thyroid	follicular adenoma		1 (2)	1 (2)	0 (0)	0 (0)
adrenal	pheochromocytoma		0 (0)	0 (0)	1 (2)	0 (0)
[Reproductive system]						
ovary	cystadenoma		3 (6)	2 (4)	0 (0)	1 (2)
uterus	leiomyoma		0 (0)	1 (2)	0 (0)	1 (2)
	hemangioma		0 (0)	0 (0)	1 (2)	0 (0)
	endometrial stromal polyp		0 (0)	0 (0)	0 (0)	1 (2)
	histiocytic sarcoma		9 (18)	2 (4)	6 (12)	7 (14)
vagina	basal cell carcinoma		0 (0)	0 (0)	0 (0)	1 (2)
mammary gl	adenocarcinoma		0 (0)	1 (2)	1 (2)	0 (0)
[Special sense organs/appandage]						
Harder gl	adenoma		1 (2)	3 (6)	1 (2)	1 (2)
[Musculoskeletal system]						
bone	osteosarcoma		1 (2)	0 (0)	1 (2)	0 (0)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0-105W)

Organ	Findings	Group Name / NO. of Animals	Control 50 (%)	1000 ppm 49 (%)	4000 ppm 50 (%)	16000 ppm 50 (%)
[Body cavities]						
peritoneum	hemangioma		0 (0)	1 (2)	1 (2)	0 (0)
retroperit	hemangioma		0 (0)	0 (0)	0 (0)	1 (2)

APPENDIX O 1

NEOPLASTIC LESIONS - INCIDENCE AND STATISTICAL ANIMALS

RAT : MALE

(2-YEAR STUDY)

STUDY No. : 0141
ANIMAL : RAT F344
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

Group Name	Control	800 ppm	2400 ppm	7200 ppm
	SITE : subcutis TUMOR : fibroma			
Overall Rates(a)	3/50(6.0)	6/50(12.0)	5/50(10.0)	3/50(6.0)
Adjusted Rates(b)	8.33	17.65	9.30	5.88
Terminal Rates(c)	3/36(8.3)	5/43(11.6)	4/43(9.3)	1/42(2.4)
Standard Rates(d)	P = 0.0484*			
Prevalence Rates(d)	P = 0.9442			
Combind analysis(d)	P = 0.7127			
Cochran-Armitage Test(e)	P = 0.5985			
Fisher Exact Test(e)		P = 0.2728	P = 0.3790	P = 0.3392
	SITE : lung TUMOR : bronchiolar-alveolar adenoma			
Overall Rates(a)	2/50(4.0)	1/50(2.0)	2/50(4.0)	3/50(6.0)
Adjusted Rates(b)	7.14	2.78	7.69	7.14
Terminal Rates(c)	2/36(5.6)	1/43(2.3)	2/43(4.7)	3/42(7.1)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.2271			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.4083			
Fisher Exact Test(e)		P = 0.4926	P = 0.3088	P = 0.4909
	SITE : lung TUMOR : bronchiolar-alveolar adenoma,bronchiolar-alveolar carcinoma			
Overall Rates(a)	2/50(4.0)	1/50(2.0)	3/50(6.0)	4/50(8.0)
Adjusted Rates(b)	7.14	2.78	11.54	11.76
Terminal Rates(c)	2/36(5.6)	1/43(2.3)	3/43(7.0)	4/42(9.5)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.1285			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.2096			
Fisher Exact Test(e)		P = 0.4926	P = 0.4909	P = 0.3574

Group Name	Control	800 ppm	2400 ppm	7200 ppm
	SITE : spleen TUMOR : mononuclear cell leukemia			
Overall Rates(a)	11/50(22.0)	2/50(4.0)	1/50(2.0)	7/50(14.0)
Adjusted Rates(b)	22.50	0.0	0.0	10.42
Terminal Rates(c)	8/36(22.2)	0/43(0.0)	0/43(0.0)	4/42(9.5)
Standard Rates(d)	P = 0.4759			
Prevalence Rates(d)	P = 0.5141			
Combind analysis(d)	P = 0.5110			
Cochran-Armitage Test(e)	P = 0.9868			
Fisher Exact Test(e)		P = 0.0170*	P = 0.0052**	P = 0.2711
	SITE : stomach TUMOR : squamous cell papilloma,squamous cell carcinoma			
Overall Rates(a)	0/50(0.0)	0/50(0.0)	1/50(2.0)	3/50(6.0)
Adjusted Rates(b)	0.0	0.0	5.88	9.09
Terminal Rates(c)	0/36(0.0)	0/43(0.0)	1/43(2.3)	3/42(7.1)
Standard Rates(d)	P = -------			
Prevalence Rates(d)	P = 0.0114*			
Combind analysis(d)	P = -------			
Cochran-Armitage Test(e)	P = 0.0139*			
Fisher Exact Test(e)		P = 0.5000	P = 0.4950	P = 0.1325
	SITE : pituitary gland TUMOR : adenoma			
Overall Rates(a)	22/50(44.0)	15/50(30.0)	10/50(20.0)	6/50(12.0)
Adjusted Rates(b)	43.33	29.55	17.65	16.00
Terminal Rates(c)	14/36(38.9)	12/43(27.9)	7/43(16.3)	4/42(9.5)
Standard Rates(d)	P = 0.8041			
Prevalence Rates(d)	P = 0.9998			
Combind analysis(d)	P = 0.9998			
Cochran-Armitage Test(e)	P = 0.0008**			
Fisher Exact Test(e)		P = 0.2145	P = 0.0484*	P = 0.0056**

Group Name	Control	800 ppm	2400 ppm	7200 ppm
	SITE : pituitary gland TUMOR : adenoma,adenocarcinoma			
Overall Rates(a)	22/50(44.0)	15/50(30.0)	11/50(22.0)	6/50(12.0)
Adjusted Rates(b)	43.33	29.55	23.53	16.00
Terminal Rates(c)	14/36(38.9)	12/43(27.9)	8/43(18.6)	4/42(9.5)
Standard Rates(d)	P = 0.8041			
Prevalence Rates(d)	P = 0.9998			
Combind analysis(d)	P = 0.9998			
Cochran-Armitage Test(e)	P = 0.0008**			
Fisher Exact Test(e)		P = 0.2145	P = 0.0707	P = 0.0056**
	SITE : thyroid TUMOR : C-cell adenoma			
Overall Rates(a)	6/50(12.0)	6/48(12.5)	5/50(10.0)	10/50(20.0)
Adjusted Rates(b)	21.43	13.33	11.63	35.29
Terminal Rates(c)	4/36(11.1)	5/42(11.9)	5/43(11.6)	10/42(23.8)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.0971			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.1806			
Fisher Exact Test(e)		P = 0.4066	P = 0.4872	P = 0.2557
	SITE : thyroid TUMOR : C-cell adenoma,C-cell carcinoma			
Overall Rates(a)	8/50(16.0)	6/48(12.5)	6/50(12.0)	10/50(20.0)
Adjusted Rates(b)	28.57	13.33	13.95	35.29
Terminal Rates(c)	6/36(16.7)	5/42(11.9)	6/43(14.0)	10/42(23.8)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.1953			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.3705			
Fisher Exact Test(e)		P = 0.4445	P = 0.4157	P = 0.4300

Group Name	Control	800 ppm	2400 ppm	7200 ppm
	SITE : pancreas islet TUMOR : adenoma,adenocarcinoma			
Overall Rates(a)	1/50(2.0)	3/50(6.0)	2/50(4.0)	2/50(4.0)
Adjusted Rates(b)	4.55	7.41	4.65	4.76
Terminal Rates(c)	1/36(2.8)	3/43(7.0)	2/43(4.7)	2/42(4.8)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.4736			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.9177			
Fisher Exact Test(e)		P = 0.3235	P = 0.4926	P = 0.4926
	SITE : adrenal gland TUMOR : pheochromocytoma			
Overall Rates(a)	8/50(16.0)	7/50(14.0)	4/50(8.0)	3/50(6.0)
Adjusted Rates(b)	26.67	15.56	17.65	9.09
Terminal Rates(c)	8/36(22.2)	6/43(14.0)	4/43(9.3)	3/42(7.1)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.9637			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.0988			
Fisher Exact Test(e)		P = 0.4854	P = 0.2169	P = 0.1322
	SITE : adrenal gland TUMOR : pheochromocytoma,pheochromocytoma:malignant			
Overall Rates(a)	9/50(18.0)	8/50(16.0)	5/50(10.0)	5/50(10.0)
Adjusted Rates(b)	26.67	17.78	17.65	11.11
Terminal Rates(c)	9/36(25.0)	7/43(16.3)	5/43(11.6)	4/42(9.5)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.8961			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.2417			
Fisher Exact Test(e)		P = 0.4846	P = 0.2379	P = 0.2379

Group Name	Control	800 ppm	2400 ppm	7200 ppm
	SITE : testis TUMOR : interstitial cell tumor			
Overall Rates(a)	41/50(82.0)	47/50(94.0)	48/50(96.0)	48/50(96.0)
Adjusted Rates(b)	100.00	100.00	100.00	100.00
Terminal Rates(c)	35/36(97.2)	43/43(100.0)	43/43(100.0)	42/42(100.0)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.0181*			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.0620			
Fisher Exact Test(e)		P = 0.3744	P = 0.3468	P = 0.3468
	SITE : preputial/clitoral gland TUMOR : adenoma			
Overall Rates(a)	4/50(8.0)	5/50(10.0)	1/50(2.0)	0/50(0.0)
Adjusted Rates(b)	8.33	14.81	2.13	0.0
Terminal Rates(c)	3/36(8.3)	5/43(11.6)	0/43(0.0)	0/42(0.0)
Standard Rates(d)	P = 1.0000 ?			
Prevalence Rates(d)	P = 0.9926			
Combind analysis(d)	P = 0.9964			
Cochran-Armitage Test(e)	P = 0.0228*			
Fisher Exact Test(e)		P = 0.4883	P = 0.1998	P = 0.0688

(a): Number of tumor-bearing animals/number of animals examined at the site.
(b): Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.
(c): Observed tumor incidence at terminal kill.
(d): Beneath the control incidence are the Pvalues associated with the trend test.
Standard method : Death analysis
Prevalence method : Incidental tumor test
Combind analysis : Death analysis + Incidenta ltumor test
(e): The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates.
? : The conditional probabities of the largest and smallest possible out comes can not estimated or this P-value is beyond the estimated P-value
------ : There is no date which should be statistic analysis
Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01

APPENDIX O 2

NEOPLASTIC LESIONS - INCIDENCE AND STATISTICAL ANIMALS

RAT : FEMALE

(2-YEAR STUDY)

Group Name	Control	800 ppm	2400 ppm	7200 ppm
	SITE : spleen TUMOR : mononuclear cell leukemia			
Overall Rates(a)	5/50(10.0)	9/50(18.0)	11/50(22.0)	5/50(10.0)
Adjusted Rates(b)	6.67	25.00	29.63	6.38
Terminal Rates(c)	2/37(5.4)	7/38(18.4)	8/43(18.6)	2/45(4.4)
Standard Rates(d)	P = 0.6698			
Prevalence Rates(d)	P = 0.7696			
Combind analysis(d)	P = 0.8120			
Cochran-Armitage Test(e)	P = 0.5514			
Fisher Exact Test(e)		P = 0.2379	P = 0.1300	P = 0.3710
	SITE : pituitary gland TUMOR : adenoma			
Overall Rates(a)	20/50(40.0)	24/50(48.0)	21/50(42.0)	21/50(42.0)
Adjusted Rates(b)	41.03	47.37	39.58	44.44
Terminal Rates(c)	15/37(40.5)	18/38(47.4)	16/43(37.2)	20/45(44.4)
Standard Rates(d)	P = 0.9778			
Prevalence Rates(d)	P = 0.4251			
Combind analysis(d)	P = 0.7033			
Cochran-Armitage Test(e)	P = 0.8861			
Fisher Exact Test(e)		P = 0.3742	P = 0.4784	P = 0.4784
	SITE : pituitary gland TUMOR : adenoma,adenocarcinoma			
Overall Rates(a)	21/50(42.0)	24/50(48.0)	21/50(42.0)	21/50(42.0)
Adjusted Rates(b)	41.03	47.37	39.58	44.44
Terminal Rates(c)	15/37(40.5)	18/38(47.4)	16/43(37.2)	20/45(44.4)
Standard Rates(d)	P = 0.9888			
Prevalence Rates(d)	P = 0.4251			
Combind analysis(d)	P = 0.7441			
Cochran-Armitage Test(e)	P = 0.7827			
Fisher Exact Test(e)		P = 0.4242	P = 0.4271	P = 0.4271

Group Name	Control	800 ppm	2400 ppm	7200 ppm
	SITE : thyroid TUMOR : C-cell adenoma			
Overall Rates(a)	7/50(14.0)	5/50(10.0)	3/50(6.0)	4/49(8.2)
Adjusted Rates(b)	18.18	18.75	6.82	8.89
Terminal Rates(c)	4/37(10.8)	5/38(13.2)	2/43(4.7)	4/45(8.9)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.8367			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.4370			
Fisher Exact Test(e)		P = 0.4062	P = 0.1917	P = 0.3073
	SITE : thyroid TUMOR : C-cell adenoma,C-cell carcinoma			
Overall Rates(a)	7/50(14.0)	5/50(10.0)	3/50(6.0)	4/49(8.2)
Adjusted Rates(b)	18.18	18.75	6.82	8.89
Terminal Rates(c)	4/37(10.8)	5/38(13.2)	2/43(4.7)	4/45(8.9)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.8367			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.4370			
Fisher Exact Test(e)		P = 0.4062	P = 0.1917	P = 0.3073
	SITE : adrenal gland TUMOR : pheochromocytoma			
Overall Rates(a)	3/50(6.0)	0/50(0.0)	0/50(0.0)	3/50(6.0)
Adjusted Rates(b)	8.11	0.0	0.0	7.89
Terminal Rates(c)	3/37(8.1)	0/38(0.0)	0/43(0.0)	3/45(6.7)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.2430			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.3732			
Fisher Exact Test(e)		P = 0.1325	P = 0.1325	P = 0.3392

Group Name	Control	800 ppm	2400 ppm	7200 ppm
	SITE : adrenal gland TUMOR : pheochromocytoma,pheochromocytoma:malignant			
Overall Rates(a)	3/50(6.0)	0/50(0.0)	0/50(0.0)	3/50(6.0)
Adjusted Rates(b)	8.11	0.0	0.0	7.89
Terminal Rates(c)	3/37(8.1)	0/38(0.0)	0/43(0.0)	3/45(6.7)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.2430			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.3732			
Fisher Exact Test(e)		P = 0.1325	P = 0.1325	P = 0.3392
	SITE : uterus TUMOR : endometrial stromal polyp			
Overall Rates(a)	5/50(10.0)	5/50(10.0)	8/50(16.0)	13/50(26.0)
Adjusted Rates(b)	11.11	11.63	22.22	31.58
Terminal Rates(c)	3/37(8.1)	4/38(10.5)	8/43(18.6)	12/45(26.7)
Standard Rates(d)	P = 1.0000 ?			
Prevalence Rates(d)	P = 0.0083**			
Combind analysis(d)	P = 0.0148*			
Cochran-Armitage Test(e)	P = 0.0113*			
Fisher Exact Test(e)		P = 0.3710	P = 0.3141	P = 0.0676
	SITE : uterus TUMOR : endometrial stromal sarcoma			
Overall Rates(a)	0/50(0.0)	1/50(2.0)	0/50(0.0)	3/50(6.0)
Adjusted Rates(b)	0.0	0.0	0.0	2.63
Terminal Rates(c)	0/37(0.0)	0/38(0.0)	0/43(0.0)	1/45(2.2)
Standard Rates(d)	P = 0.0859			
Prevalence Rates(d)	P = 0.1587			
Combind analysis(d)	P = 0.0286*			
Cochran-Armitage Test(e)	P = 0.0300*			
Fisher Exact Test(e)		P = 0.4950	P = 0.5000	P = 0.1325

Group Name	Control	800 ppm	2400 ppm	7200 ppm
	SITE : uterus TUMOR : endometrial stromal polyp,endometrial stromal sarcoma			
Overall Rates(a)	5/50(10.0)	6/50(12.0)	8/50(16.0)	16/50(32.0)
Adjusted Rates(b)	11.11	11.63	22.22	31.58
Terminal Rates(c)	3/37(8.1)	4/38(10.5)	8/43(18.6)	13/45(28.9)
Standard Rates(d)	P = 0.2063			
Prevalence Rates(d)	P = 0.0038**			
Combind analysis(d)	P = 0.0027**			
Cochran-Armitage Test(e)	P = 0.0013**			
Fisher Exact Test(e)		P = 0.4872	P = 0.3141	P = 0.0238*
	SITE : mammary gland TUMOR : fibroadenoma			
Overall Rates(a)	2/50(4.0)	7/50(14.0)	3/50(6.0)	3/50(6.0)
Adjusted Rates(b)	5.56	16.28	7.41	6.25
Terminal Rates(c)	2/37(5.4)	5/38(13.2)	2/43(4.7)	2/45(4.4)
Standard Rates(d)	P = 0.3997			
Prevalence Rates(d)	P = 0.7227			
Combind analysis(d)	P = 0.7281			
Cochran-Armitage Test(e)	P = 0.6584			
Fisher Exact Test(e)		P = 0.1045	P = 0.4909	P = 0.4909
	SITE : mammary gland TUMOR : squamous cell papilloma,fibroadenoma,squamous cell carcinoma			
Overall Rates(a)	2/50(4.0)	7/50(14.0)	3/50(6.0)	3/50(6.0)
Adjusted Rates(b)	5.56	16.28	7.41	6.25
Terminal Rates(c)	2/37(5.4)	5/38(13.2)	2/43(4.7)	2/45(4.4)
Standard Rates(d)	P = 0.3997			
Prevalence Rates(d)	P = 0.7227			
Combind analysis(d)	P = 0.7281			
Cochran-Armitage Test(e)	P = 0.6584			
Fisher Exact Test(e)		P = 0.1045	P = 0.4909	P = 0.4909

Group Name	Control	800 ppm	2400 ppm	7200 ppm
	SITE : preputial/clitoral gland TUMOR : adenoma			
Overall Rates(a)	4/50(8.0)	2/50(4.0)	1/50(2.0)	0/50(0.0)
Adjusted Rates(b)	5.56	2.63	5.56	0.0
Terminal Rates(c)	1/37(2.7)	1/38(2.6)	1/43(2.3)	0/45(0.0)
Standard Rates(d)	P = 0.9620			
Prevalence Rates(d)	P = 0.9278			
Combind analysis(d)	P = 0.9904			
Cochran-Armitage Test(e)	P = 0.0504			
Fisher Exact Test(e)		P = 0.3574	P = 0.1998	P = 0.0688

(a): Number of tumor-bearing animals/number of animals examined at the site.
(b): Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.
(c): Observed tumor incidence at terminal kill.
(d): Beneath the control incidence are the Pvalues associated with the trend test.
Standard method : Death analysis
Prevalence method : Incidental tumor test
Combind analysis : Death analysis + Incidenta ltumor test
(e): The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates.
? : The conditional probabities of the largest and smallest possible out comes can not estimated or this P-value is beyond the estimated P-value
------ : There is no date which should be statistic analysis
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01

APPENDIX O 3

NEOPLASTIC LESIONS - INCIDENCE AND STATISTICAL ANIMALS

MOSUE : MALE

(2-YEAR STUDY)

Group Name	Control	250 ppm	1000 ppm	4000 ppm
	SITE : lung TUMOR : bronchiolar-alveolar adenoma			
Overall Rates(a)	6/50(12.0)	11/50(22.0)	2/50(4.0)	6/50(12.0)
Adjusted Rates(b)	13.16	31.43	4.35	15.00
Terminal Rates(c)	5/38(13.2)	9/33(27.3)	0/38(0.0)	6/40(15.0)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.7210			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.5860			
Fisher Exact Test(e)		P = 0.1955	P = 0.1606	P = 0.3807
	SITE : lung TUMOR : bronchiolar-alveolar carcinoma			
Overall Rates(a)	4/50(8.0)	5/50(10.0)	7/50(14.0)	5/50(10.0)
Adjusted Rates(b)	5.26	9.76	10.53	10.00
Terminal Rates(c)	2/38(5.3)	2/33(6.1)	4/38(10.5)	4/40(10.0)
Standard Rates(d)	P = 0.6892			
Prevalence Rates(d)	P = 0.3219			
Combind analysis(d)	P = 0.4810			
Cochran-Armitage Test(e)	P = 0.9208			
Fisher Exact Test(e)		P = 0.4883	P = 0.2958	P = 0.4883
	SITE : lung TUMOR : bronchiolar-alveolar adenoma,bronchiolar-alveolar carcinoma			
Overall Rates(a)	10/50(20.0)	16/50(32.0)	9/50(18.0)	11/50(22.0)
Adjusted Rates(b)	18.42	38.89	13.95	25.00
Terminal Rates(c)	7/38(18.4)	11/33(33.3)	4/38(10.5)	10/40(25.0)
Standard Rates(d)	P = 0.6892			
Prevalence Rates(d)	P = 0.5895			
Combind analysis(d)	P = 0.6730			
Cochran-Armitage Test(e)	P = 0.7221			
Fisher Exact Test(e)		P = 0.2039	P = 0.4839	P = 0.4833

Group Name	Control	250 ppm	1000 ppm	4000 ppm
	SITE : lymph node TUMOR : malignant lymphoma			
Overall Rates(a)	1/50(2.0)	4/50(8.0)	7/50(14.0)	5/50(10.0)
Adjusted Rates(b)	2.63	3.03	5.26	10.00
Terminal Rates(c)	1/38(2.6)	1/33(3.0)	2/38(5.3)	4/40(10.0)
Standard Rates(d)	P = 0.6624			
Prevalence Rates(d)	P = 0.0645			
Combind analysis(d)	P = 0.2255			
Cochran-Armitage Test(e)	P = 0.3658			
Fisher Exact Test(e)		P = 0.1998	P = 0.0430*	P = 0.1210
	SITE : spleen TUMOR : hemangioma			
Overall Rates(a)	0/50(0.0)	3/50(6.0)	1/50(2.0)	2/50(4.0)
Adjusted Rates(b)	0.0	6.98	2.63	5.00
Terminal Rates(c)	0/38(0.0)	2/33(6.1)	1/38(2.6)	2/40(5.0)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.2963			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.6260			
Fisher Exact Test(e)		P = 0.1325	P = 0.4950	P = 0.2574
	SITE : spleen TUMOR : hemangioma,hemangiosarcoma			
Overall Rates(a)	0/50(0.0)	4/50(8.0)	2/50(4.0)	2/50(4.0)
Adjusted Rates(b)	0.0	9.30	5.26	5.00
Terminal Rates(c)	0/38(0.0)	2/33(6.1)	2/38(5.3)	2/40(5.0)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.4264			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.9099			
Fisher Exact Test(e)		P = 0.0688	P = 0.2574	P = 0.2574

Group Name	Control	250 ppm	1000 ppm	4000 ppm
	SITE : liver TUMOR : hepatocellular adenoma			
Overall Rates(a)	7/50(14.0)	7/50(14.0)	5/50(10.0)	3/50(6.0)
Adjusted Rates(b)	18.42	21.21	13.16	5.00
Terminal Rates(c)	7/38(18.4)	7/33(21.2)	5/38(13.2)	2/40(5.0)
Standard Rates(d)	P = 0.1753			
Prevalence Rates(d)	P = 0.9852			
Combind analysis(d)	P = 0.9548			
Cochran-Armitage Test(e)	P = 0.1513			
Fisher Exact Test(e)		P = 0.3882	P = 0.4062	P = 0.1917
	SITE : liver TUMOR : hemangiosarcoma			
Overall Rates(a)	6/50(12.0)	7/50(14.0)	6/50(12.0)	4/50(8.0)
Adjusted Rates(b)	15.79	12.20	10.53	6.67
Terminal Rates(c)	6/38(15.8)	4/33(12.1)	4/38(10.5)	2/40(5.0)
Standard Rates(d)	P = 0.4832			
Prevalence Rates(d)	P = 0.8590			
Combind analysis(d)	P = 0.8306			
Cochran-Armitage Test(e)	P = 0.3709			
Fisher Exact Test(e)		P = 0.4863	P = 0.3807	P = 0.3944
	SITE : liver TUMOR : hepatocellular carcinoma			
Overall Rates(a)	18/50(36.0)	18/50(36.0)	8/50(16.0)	4/50(8.0)
Adjusted Rates(b)	31.71	44.44	20.00	10.00
Terminal Rates(c)	12/38(31.6)	14/33(42.4)	6/38(15.8)	4/40(10.0)
Standard Rates(d)	P = 0.9952			
Prevalence Rates(d)	P = 0.9996			
Combind analysis(d)	P = 1.0000			
Cochran-Armitage Test(e)	P = 0.0003**			
Fisher Exact Test(e)		P = 0.4230	P = 0.0617	P = 0.0053**

Group Name	Control	250 ppm	1000 ppm	4000 ppm
	SITE : liver TUMOR : hemangioma,hemangiosarcoma			
Overall Rates(a)	6/50(12.0)	9/50(18.0)	6/50(12.0)	4/50(8.0)
Adjusted Rates(b)	15.79	18.18	10.53	6.67
Terminal Rates(c)	6/38(15.8)	6/33(18.2)	4/38(10.5)	2/40(5.0)
Standard Rates(d)	P = 0.4832			
Prevalence Rates(d)	P = 0.9172			
Combind analysis(d)	P = 0.8920			
Cochran-Armitage Test(e)	P = 0.2510			
Fisher Exact Test(e)		P = 0.3291	P = 0.3807	P = 0.3944
	SITE : liver TUMOR : hepatocellular adenoma,hepatocellular carcinoma			
Overall Rates(a)	23/50(46.0)	24/50(48.0)	13/50(26.0)	7/50(14.0)
Adjusted Rates(b)	44.74	61.11	32.50	15.00
Terminal Rates(c)	17/38(44.7)	20/33(60.6)	11/38(28.9)	6/40(15.0)
Standard Rates(d)	P = 0.9293			
Prevalence Rates(d)	P = 1.0000			
Combind analysis(d)	P = 1.0000			
Cochran-Armitage Test(e)	P = 0.0001**			
Fisher Exact Test(e)		P = 0.4774	P = 0.1075	P = 0.0078**
	SITE : Harderian gland TUMOR : adenoma			
Overall Rates(a)	2/50(4.0)	3/50(6.0)	1/50(2.0)	4/50(8.0)
Adjusted Rates(b)	5.26	8.82	2.63	9.52
Terminal Rates(c)	2/38(5.3)	2/33(6.1)	1/38(2.6)	3/40(7.5)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.2256			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.3467			
Fisher Exact Test(e)		P = 0.4909	P = 0.4926	P = 0.3574

(a): Number of tumor-bearing animals/number of animals examined at the site.
(b): Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.
(c): Observed tumor incidence at terminal kill.
(d): Beneath the control incidence are the Pvalues associated with the trend test.
Standard method : Death analysis
Prevalence method : Incidental tumor test
Combind analysis : Death analysis + Incidenta ltumor test
(e): The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates.
? : The conditional probabities of the largest and smallest possible out comes can not estimated or this P-value is beyond the estimated P-value

Group Name	Control	250 ppm	1000 ppm	4000 ppm
	SITE : ALL SITE TUMOR : hemangioma			
Overall Rates(a)	1/50(2.0)	7/50(14.0)	2/50(4.0)	2/50(4.0)
Adjusted Rates(b)	2.63	14.58	5.26	5.00
Terminal Rates(c)	1/38(2.6)	4/33(12.1)	2/38(5.3)	2/40(5.0)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.7461			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.4552			
Fisher Exact Test(e)		P = 0.0430*	P = 0.4926	P = 0.4926
	SITE : ALL SITE TUMOR : histiocytic sarcoma			
Overall Rates(a)	4/50(8.0)	3/50(6.0)	1/50(2.0)	5/50(10.0)
Adjusted Rates(b)	7.89	3.03	0.0	0.0
Terminal Rates(c)	3/38(7.9)	1/33(3.0)	0/38(0.0)	0/40(0.0)
Standard Rates(d)	P = 0.0322*			
Prevalence Rates(d)	P = 0.9738			
Combind analysis(d)	P = 0.2311			
Cochran-Armitage Test(e)	P = 0.3992			
Fisher Exact Test(e)		P = 0.4895	P = 0.1998	P = 0.4883
	SITE : ALL SITE TUMOR : malignant lymphoma			
Overall Rates(a)	2/50(4.0)	5/50(10.0)	9/50(18.0)	5/50(10.0)
Adjusted Rates(b)	2.63	6.06	10.26	10.00
Terminal Rates(c)	1/38(2.6)	2/33(6.1)	3/38(7.9)	4/40(10.0)
Standard Rates(d)	P = 0.7497			
Prevalence Rates(d)	P = 0.1624			
Combind analysis(d)	P = 0.4015			
Cochran-Armitage Test(e)	P = 0.6975			
Fisher Exact Test(e)		P = 0.2425	P = 0.0427*	P = 0.2425

Group Name	Control	250 ppm	1000 ppm	4000 ppm
	SITE : ALL SITE TUMOR : hemangiosarcoma			
Overall Rates(a)	6/50(12.0)	7/50(14.0)	7/50(14.0)	4/50(8.0)
Adjusted Rates(b)	15.79	12.12	13.16	6.67
Terminal Rates(c)	6/38(15.8)	4/33(12.1)	5/38(13.2)	2/40(5.0)
Standard Rates(d)	P = 0.5904			
Prevalence Rates(d)	P = 0.8436			
Combind analysis(d)	P = 0.8479			
Cochran-Armitage Test(e)	P = 0.3570			
Fisher Exact Test(e)		P = 0.4863	P = 0.4863	P = 0.3944

(HPT360A)

BAIS2

(a): Number of tumor-bearing animals/number of animals examined at the site.
(b): Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.
(c): Observed tumor incidence at terminal kill.
(d): Beneath the control incidence are the Pvalues associated with the trend test.
Standard method : Death analysis
Prevalence method : Incidental tumor test
Combind analysis : Death analysis + Incidenta ltumor test
(e): The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates.
? : The conditional probabities of the largest and smallest possible out comes can not estimated or this P-value is beyond the estimated P-value
------ : There is no date which should be statistic analysis
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01

APPENDIX O 4

NEOPLASTIC LESIONS - INCIDENCE AND STATISTICAL ANIMALS

MOSUE :FEMALE

(2-YEAR STUDY)

Group Name	Control	1000 ppm	4000 ppm	16000 ppm
	SITE : lung TUMOR : bronchiolar-alveolar adenoma			
Overall Rates(a)	3/50(6.0)	4/49(8.2)	1/50(2.0)	1/50(2.0)
Adjusted Rates(b)	11.11	9.52	2.27	2.56
Terminal Rates(c)	3/27(11.1)	1/33(3.0)	0/30(0.0)	1/39(2.6)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.9106			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.2106			
Fisher Exact Test(e)		P = 0.5000	P = 0.3235	P = 0.3235
	SITE : lung TUMOR : bronchiolar-alveolar carcinoma			
Overall Rates(a)	1/50(2.0)	1/49(2.0)	3/50(6.0)	3/50(6.0)
Adjusted Rates(b)	0.0	3.03	7.50	5.13
Terminal Rates(c)	0/27(0.0)	1/33(3.0)	1/30(3.3)	2/39(5.1)
Standard Rates(d)	P = 0.2922			
Prevalence Rates(d)	P = 0.2308			
Combind analysis(d)	P = 0.1883			
Cochran-Armitage Test(e)	P = 0.2874			
Fisher Exact Test(e)		P = 0.2525	P = 0.3235	P = 0.3235
	SITE : lung TUMOR : bronchiolar-alveolar adenoma,bronchiolar-alveolar carcinoma			
Overall Rates(a)	4/50(8.0)	5/49(10.2)	4/50(8.0)	4/50(8.0)
Adjusted Rates(b)	11.11	11.90	9.09	7.69
Terminal Rates(c)	3/27(11.1)	2/33(6.1)	1/30(3.3)	3/39(7.7)
Standard Rates(d)	P = 0.2922			
Prevalence Rates(d)	P = 0.6922			
Combind analysis(d)	P = 0.6102			
Cochran-Armitage Test(e)	P = 0.8547			
Fisher Exact Test(e)		P = 0.5000	P = 0.3579	P = 0.3579

Group Name	Control	1000 ppm	4000 ppm	16000 ppm
	SITE : lymph node TUMOR : malignant lymphoma			
Overall Rates(a)	16/50(32.0)	13/49(26.5)	13/50(26.0)	9/50(18.0)
Adjusted Rates(b)	16.67	22.50	13.51	12.77
Terminal Rates(c)	4/27(14.8)	7/33(21.2)	4/30(13.3)	4/39(10.3)
Standard Rates(d)	P = 0.9748			
Prevalence Rates(d)	P = 0.7168			
Combind analysis(d)	P = 0.9658			
Cochran-Armitage Test(e)	P = 0.1282			
Fisher Exact Test(e)		P = 0.4092	P = 0.3904	P = 0.1514
	SITE : spleen TUMOR : malignant lymphoma			
Overall Rates(a)	1/50(2.0)	3/49(6.1)	2/50(4.0)	1/50(2.0)
Adjusted Rates(b)	0.0	9.09	5.88	2.56
Terminal Rates(c)	0/27(0.0)	3/33(9.1)	1/30(3.3)	1/39(2.6)
Standard Rates(d)	P = 1.0000 ?			
Prevalence Rates(d)	P = 0.6703			
Combind analysis(d)	P = 0.7698			
Cochran-Armitage Test(e)	P = 0.5509			
Fisher Exact Test(e)		P = 0.3162	P = 0.4926	P = 0.2475
	SITE : liver TUMOR : hemangiosarcoma			
Overall Rates(a)	4/50(8.0)	0/49(0.0)	1/50(2.0)	1/50(2.0)
Adjusted Rates(b)	12.50	0.0	3.33	2.56
Terminal Rates(c)	3/27(11.1)	0/33(0.0)	1/30(3.3)	1/39(2.6)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.8084			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.4505			
Fisher Exact Test(e)		P = 0.0715	P = 0.1998	P = 0.1998

Group Name	Control	1000 ppm	4000 ppm	16000 ppm
	SITE : liver TUMOR : hemangioma,hemangiosarcoma			
Overall Rates(a)	5/50(10.0)	1/49(2.0)	2/50(4.0)	2/50(4.0)
Adjusted Rates(b)	15.63	3.03	6.67	5.13
Terminal Rates(c)	4/27(14.8)	1/33(3.0)	2/30(6.7)	2/39(5.1)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.7896			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.5518			
Fisher Exact Test(e)		P = 0.1261	P = 0.2425	P = 0.2425
	SITE : pituitary gland TUMOR : adenoma			
Overall Rates(a)	7/50(14.0)	4/48(8.3)	7/50(14.0)	1/48(2.1)
Adjusted Rates(b)	22.22	6.06	21.88	2.70
Terminal Rates(c)	6/27(22.2)	2/33(6.1)	6/30(20.0)	1/37(2.7)
Standard Rates(d)	P = 0.9243			
Prevalence Rates(d)	P = 0.9746			
Combind analysis(d)	P = 0.9917			
Cochran-Armitage Test(e)	P = 0.0544			
Fisher Exact Test(e)		P = 0.3191	P = 0.3882	P = 0.0484*
	SITE : pituitary gland TUMOR : adenoma,adenocarcinoma			
Overall Rates(a)	7/50(14.0)	5/48(10.4)	8/50(16.0)	1/48(2.1)
Adjusted Rates(b)	22.22	9.09	21.88	2.70
Terminal Rates(c)	6/27(22.2)	3/33(9.1)	6/30(20.0)	1/37(2.7)
Standard Rates(d)	P = 0.9053			
Prevalence Rates(d)	P = 0.9826			
Combind analysis(d)	P = 0.9943			
Cochran-Armitage Test(e)	P = 0.0418*			
Fisher Exact Test(e)		P = 0.4331	P = 0.4854	P = 0.0484*

Group Name	Control	1000 ppm	4000 ppm	16000 ppm
	SITE : ovary TUMOR : cystadenoma			
Overall Rates(a)	3/50(6.0)	2/49(4.1)	0/50(0.0)	1/50(2.0)
Adjusted Rates(b)	8.82	5.56	0.0	2.56
Terminal Rates(c)	2/27(7.4)	1/33(3.0)	0/30(0.0)	1/39(2.6)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.8346			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.3765			
Fisher Exact Test(e)		P = 0.4816	P = 0.1325	P = 0.3235
	SITE : uterus TUMOR : histiocytic sarcoma			
Overall Rates(a)	9/50(18.0)	2/49(4.1)	6/50(12.0)	7/50(14.0)
Adjusted Rates(b)	12.90	0.0	6.67	7.69
Terminal Rates(c)	1/27(3.7)	0/33(0.0)	2/30(6.7)	3/39(7.7)
Standard Rates(d)	P = 0.4926			
Prevalence Rates(d)	P = 0.4000			
Combind analysis(d)	P = 0.4437			
Cochran-Armitage Test(e)	P = 0.6955			
Fisher Exact Test(e)		P = 0.0458*	P = 0.3291	P = 0.4234
	SITE : Harderian gland TUMOR : adenoma			
Overall Rates(a)	1/50(2.0)	3/49(6.1)	1/50(2.0)	1/50(2.0)
Adjusted Rates(b)	3.70	9.09	3.33	2.56
Terminal Rates(c)	1/27(3.7)	3/33(9.1)	1/30(3.3)	1/39(2.6)
Standard Rates(d)	P = ------			
Prevalence Rates(d)	P = 0.7791			
Combind analysis(d)	P = ------			
Cochran-Armitage Test(e)	P = 0.5755			
Fisher Exact Test(e)		P = 0.3162	P = 0.2475	P = 0.2475

(a): Number of tumor-bearing animals/number of animals examined at the site.
(b): Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.
(c): Observed tumor incidence at terminal kill.
(d): Beneath the control incidence are the Pvalues associated with the trend test.
Standard method : Death analysis
Prevalence method : Incidental tumor test
Combind analysis : Death analysis + Incidenta ltumor test
(e): The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates.
? : The conditional probabities of the largest and smallest possible out comes can not estimated or this P-value is beyond the estimated P-value

Group Name	Control	1000 ppm	4000 ppm	16000 ppm
	SITE : ALL SITE TUMOR : hemangioma			
Overall Rates(a)	1/50(2.0)	3/49(6.1)	4/50(8.0)	2/50(4.0)
Adjusted Rates(b)	3.70	6.06	13.33	5.13
Terminal Rates(c)	1/27(3.7)	2/33(6.1)	4/30(13.3)	2/39(5.1)
Standard Rates(d)	P = 0.5355			
Prevalence Rates(d)	P = 0.5682			
Combind analysis(d)	P = 0.6551			
Cochran-Armitage Test(e)	P = 0.9306			
Fisher Exact Test(e)		P = 0.3162	P = 0.1998	P = 0.4926
	SITE : ALL SITE TUMOR : histiocytic sarcoma			
Overall Rates(a)	9/50(18.0)	3/49(6.1)	8/50(16.0)	9/50(18.0)
Adjusted Rates(b)	12.90	3.03	6.67	10.26
Terminal Rates(c)	1/27(3.7)	1/33(3.0)	2/30(6.7)	4/39(10.3)
Standard Rates(d)	P = 0.3867			
Prevalence Rates(d)	P = 0.3162			
Combind analysis(d)	P = 0.3089			
Cochran-Armitage Test(e)	P = 0.4111			
Fisher Exact Test(e)		P = 0.0955	P = 0.4846	P = 0.3993
	SITE : ALL SITE TUMOR : malignant lymphoma			
Overall Rates(a)	17/50(34.0)	16/49(32.7)	15/50(30.0)	10/50(20.0)
Adjusted Rates(b)	16.67	30.30	18.92	14.89
Terminal Rates(c)	4/27(14.8)	10/33(30.3)	5/30(16.7)	5/39(12.8)
Standard Rates(d)	P = 0.9821			
Prevalence Rates(d)	P = 0.7724			
Combind analysis(d)	P = 0.9777			
Cochran-Armitage Test(e)	P = 0.0885			
Fisher Exact Test(e)		P = 0.4598	P = 0.4586	P = 0.1636

Group Name	Control	1000 ppm	4000 ppm	16000 ppm
	SITE : ALL SITE TUMOR : hemangiosarcoma			
Overall Rates(a)	4/50(8.0)	1/49(2.0)	1/50(2.0)	1/50(2.0)
Adjusted Rates(b)	12.50	0.0	3.33	2.56
Terminal Rates(c)	3/27(11.1)	0/33(0.0)	1/30(3.3)	1/39(2.6)
Standard Rates(d)	P = 0.5020			
Prevalence Rates(d)	P = 0.8084			
Combind analysis(d)	P = 0.8639			
Cochran-Armitage Test(e)	P = 0.3382			
Fisher Exact Test(e)		P = 0.2063	P = 0.1998	P = 0.1998

(HPT360A)

BAIS2

(a): Number of tumor-bearing animals/number of animals examined at the site.
(b): Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.
(c): Observed tumor incidence at terminal kill.
(d): Beneath the control incidence are the Pvalues associated with the trend test.
Standard method : Death analysis
Prevalence method : Incidental tumor test
Combind analysis : Death analysis + Incidenta ltumor test
(e): The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates.
? : The conditional probabities of the largest and smallest possible out comes can not estimated or this P-value is beyond the estimated P-value
------ : There is no date which should be statistic analysis
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01

APPENDIX P 1

HISTOLOGICAL FINDINGS :METASTASIS OF TUMOR : SUMMARY

RAT: MALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / No. of Animals	Control 14	800 ppm 7	2400 ppm 7	7200 ppm 8
[Respiratory system]						
lung	leukemic cell infiltration		1	2	1	2
[Hematopoietic system]						
bone marrow	leukemic cell infiltration		1	0	1	2
lymph node	leukemic cell infiltration		1	1	0	1
[Digestive system]						
liver	leukemic cell infiltration		1	1	0	2
pancreas	leukemic cell infiltration		0	1	0	1
[Urinary system]						
kidney	leukemic cell infiltration		1	0	0	1
[Endocrine system]						
pituitary	leukemic cell infiltration		0	0	0	1
[Nervous system]						
brain	leukemic cell infiltration		1	1	0	0
	metastasis:pituitary tumor		1	0	1	0
spinal cord	leukemic cell infiltration		1	0	0	0

APPENDIX P 2

HISTOLOGICAL FINDINGS :METASTASIS OF TUMOR : SUMMARY

RAT: FEMALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

Organ	Findings	Group Name / No. of Animals	Control 13	800 ppm 12	2400 ppm 7	7200 ppm 5
[Respiratory system]						
nasal cavit	leukemic cell infiltration		1	0	0	0
lung	leukemic cell infiltration		3	2	3	2
	metastasis:uterus tumor		0	0	0	2
[Hematopoietic system]						
bone marrow	leukemic cell infiltration		2	1	2	1
lymph node	leukemic cell infiltration		1	0	2	2
thymus	leukemic cell infiltration		1	0	0	0
[Digestive system]						
large intes	metastasis:retroperitoneum tumor		0	1	0	0
liver	leukemic cell infiltration		2	2	3	2
pancreas	leukemic cell infiltration		0	1	0	0
[Urinary system]						
kidney	leukemic cell infiltration		2	0	2	2
	metastasis:lung tumor		1	0	0	0
urin bladd	leukemic cell infiltration		0	0	0	1
[Endocrine system]						
thyroid	leukemic cell infiltration		0	0	0	1
adrenal	leukemic cell infiltration		0	0	1	1

Organ	Findings	Group Name / No. of Animals	Control 13	800 ppm 12	2400 ppm 7	7200 ppm 5
[Reproductive system]						
ovary	leukemic cell infiltration		0	0	2	0
uterus	leukemic cell infiltration		0	0	0	1
[Nervous system]						
brain	leukemic cell infiltration		0	0	1	0
	metastasis:pituitary tumor		3	0	0	0
spinal cord	leukemic cell infiltration		0	0	2	0

APPENDIX P 3

HISTOLOGICAL FINDINGS :METASTASIS OF TUMOR : SUMMARY

RAT: MALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0141
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / No. of Animals	Control 36	800 ppm 43	2400 ppm 43	7200 ppm 42
[Respiratory system]						
lung	leukemic cell infiltration		3	0	0	0
	metastasis:adrenal tumor		0	1	1	0
	metastasis:thyroid tumor		1	0	0	0
[Hematopoietic system]						
bone marrow	leukemic cell infiltration		1	0	0	0
lymph node	leukemic cell infiltration		2	0	0	1
[Digestive system]						
liver	leukemic cell infiltration		4	0	0	0

APPENDIX P 4

HISTOLOGICAL FINDINGS :METASTASIS OF TUMOR : SUMMARY

RAT: FEMALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

Organ	Findings	Group Name / No. of Animals	Control 37	800 ppm 38	2400 ppm 43	7200 ppm 45
[Respiratory system]						
lung	leukemic cell infiltration		0	2	1	0
	metastasis:uterus tumor		0	0	0	1
[Hematopoietic system]						
bone marrow	leukemic cell infiltration		0	2	0	0
lymph node	leukemic cell infiltration		0	3	1	0
[Digestive system]						
small intes	metastasis:uterus tumor		0	0	0	1
liver	leukemic cell infiltration		0	3	5	0
pancreas	leukemic cell infiltration		0	1	0	0
	metastasis:uterus tumor		1	0	0	0
[Endocrine system]						
adrenal	leukemic cell infiltration		0	2	0	0
[Nervous system]						
brain	metastasis:pituitary tumor		0	0	2	0

APPENDIX P 5

HISTOLOGICAL FINDINGS :METASTASIS OF TUMOR : SUMMARY

MOUSE: MALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / No. of Animals	Control 12	250 ppm 17	1000 ppm 12	4000 ppm 10
[Integumentary system/appandage]						
skin/app	leukemic cell infiltration		0	1	1	0
[Respiratory system]						
nasal cavit	leukemic cell infiltration		0	1	0	0
	metastasis:subcutis tumor		0	0	0	1
	metastasis:periferal nerve tumor		0	0	0	1
lung	leukemic cell infiltration		1	1	1	1
	metastasis:liver tumor		2	3	1	1
	metastasis:subcutis tumor		0	0	0	1
	metastasis:periferal nerve tumor		0	0	0	1
	metastasis:large intestine tumor		1	0	0	0
	metastasis:heart tumor		0	1	0	0
[Hematopoietic system]						
bone marrow	leukemic cell infiltration		1	0	3	0
	metastasis:liver tumor		0	1	0	1
lymph node	leukemic cell infiltration		1	0	0	0
	metastasis:subcutis tumor		0	0	0	1
thymus	leukemic cell infiltration		0	0	2	0
spleen	leukemic cell infiltration		0	1	5	1
	metastasis:liver tumor		0	1	0	0

Organ	Findings	Group Name / No. of Animals	Control 12	250 ppm 17	1000 ppm 12	4000 ppm 10
[Circulatory system]						
heart	leukemic cell infiltration		1	0	1	0
[Digestive system]						
tongue	leukemic cell infiltration		0	0	1	0
salivary gl	leukemic cell infiltration		1	0	1	0
stomach	leukemic cell infiltration		0	1	0	0
liver	leukemic cell infiltration		1	0	1	1
	metastasis:subcutis tumor		0	0	0	1
pancreas	leukemic cell infiltration		0	0	1	0
[Urinary system]						
kidney	leukemic cell infiltration		1	0	0	0
	metastasis:liver tumor		0	1	0	0
urin bladd	leukemic cell infiltration		1	0	0	0
	metastasis:liver tumor		0	1	0	2
[Endocrine system]						
adrenal	leukemic cell infiltration		1	1	2	0
[Reproductive system]						
epididymis	leukemic cell infiltration		1	0	0	0
semin ves	leukemic cell infiltration		0	1	0	0

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name / No. of Animals	Control 12	250 ppm 17	1000 ppm 12	4000 ppm 10
[Nervous system]						
brain	leukemic cell infiltration		1	0	0	0
spinal cord	leukemic cell infiltration		1	0	0	0
[Special sense organs/appandage]						
eye	leukemic cell infiltration		1	0	1	0
Harder gl	leukemic cell infiltration		1	1	0	0
[Body cavities]						
pleura	metastasis:lung tumor		0	0	0	1

APPENDIX P 6

HISTOLOGICAL FINDINGS :METASTASIS OF TUMOR : SUMMARY

MOUSE: FEMALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

Organ	Findings	Group Name / No. of Animals	Control 23	1000 ppm 16	4000 ppm 20	16000 ppm 11
[Integumentary system/appandage]						
skin/app	leukemic cell infiltration		5	0	3	0
[Respiratory system]						
nasal cavit	leukemic cell infiltration		3	2	1	1
lung	leukemic cell infiltration		12	5	9	2
	metastasis:liver tumor		0	0	0	1
	metastasis:uterus tumor		3	0	2	2
	metastasis:subcutis tumor		1	0	0	0
[Hematopoietic system]						
bone marrow	leukemic cell infiltration		8	2	6	2
	metastasis:uterus tumor		1	1	0	1
lymph node	metastasis:uterus tumor		0	0	2	1
spleen	leukemic cell infiltration		9	4	6	2
[Circulatory system]						
heart	leukemic cell infiltration		7	1	6	0
	metastasis:uterus tumor		1	0	1	0
	metastasis:subcutis tumor		1	0	0	0
[Digestive system]						
tongue	leukemic cell infiltration		1	1	1	0

Organ	Findings	Group Name / No. of Animals	Control 23	1000 ppm 16	4000 ppm 20	16000 ppm 11
[Digestive system]						
salivary gl	leukemic cell infiltration		6	1	5	1
stomach	leukemic cell infiltration		6	1	4	0
liver	leukemic cell infiltration		10	2	6	2
	metastasis:uterus tumor		4	1	4	4
	metastasis:spleen tumor		0	1	0	0
pancreas	leukemic cell infiltration		7	1	7	1
	metastasis:uterus tumor		3	0	0	1
[Urinary system]						
kidney	leukemic cell infiltration		3	1	6	1
	metastasis:liver tumor		1	0	1	0
	metastasis:uterus tumor		0	0	1	0
urin bladd	leukemic cell infiltration		6	1	5	0
[Endocrine system]						
pituitary	leukemic cell infiltration		1	0	1	0
	metastasis:liver tumor		0	0	0	1
thyroid	leukemic cell infiltration		0	0	2	0
adrenal	leukemic cell infiltration		3	0	2	1
[Reproductive system]						
ovary	leukemic cell infiltration		10	2	6	1

Organ	Findings	Group Name / No. of Animals	Control 23	1000 ppm 16	4000 ppm 20	16000 ppm 11
[Reproductive system]						
ovary	metastasis:uterus tumor		4	0	1	3
uterus	leukemic cell infiltration		7	3	4	2
	metastasis:subcutis tumor		1	0	0	0
vagina	leukemic cell infiltration		0	1	0	0
[Nervous system]						
brain	leukemic cell infiltration		3	2	0	1
	metastasis:liver tumor		0	0	0	1
spinal cord	leukemic cell infiltration		2	1	0	0
	metastasis:liver tumor		1	0	0	1
[Special sense organs/appandage]						
eye	leukemic cell infiltration		4	3	7	1
Harder gl	leukemic cell infiltration		5	2	4	0
[Musculoskeletal system]						
muscle	leukemic cell infiltration		4	2	5	0
[Body cavities]						
peritoneum	leukemic cell infiltration		2	0	1	0

APPENDIX P 7

HISTOLOGICAL FINDINGS :METASTASIS OF TUMOR : SUMMARY

MOUSE: MALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / No. of Animals	Control 38	250 ppm 33	1000 ppm 38	4000 ppm 40
[Respiratory system]						
nasal cavit	leukemic cell infiltration		0	0	1	1
lung	leukemic cell infiltration		0	1	1	1
	metastasis:liver tumor		2	2	1	0
[Hematopoietic system]						
bone marrow	leukemic cell infiltration		1	0	0	1
lymph node	leukemic cell infiltration		0	1	0	0
spleen	leukemic cell infiltration		1	0	0	2
[Circulatory system]						
heart	leukemic cell infiltration		0	0	0	1
[Digestive system]						
salivary gl	leukemic cell infiltration		0	1	2	1
stomach	leukemic cell infiltration		0	0	0	1
small intes	leukemic cell infiltration		0	1	0	0
large intes	metastasis:small intestine tumor		1	0	0	0
liver	leukemic cell infiltration		2	1	1	1
pancreas	leukemic cell infiltration		0	1	1	0
[Urinary system]						
kidney	leukemic cell infiltration		0	1	0	1

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / No. of Animals	Control 38	250 ppm 33	1000 ppm 38	4000 ppm 40
[Endocrine system]						
thyroid	leukemic cell infiltration		0	0	0	1
[Reproductive system]						
testis	leukemic cell infiltration		0	0	1	0
[Nervous system]						
brain	leukemic cell infiltration		0	0	1	0
[Special sense organs/appandage]						
Harder gl	leukemic cell infiltration		0	0	0	1

APPENDIX P 8

HISTOLOGICAL FINDINGS :METASTASIS OF TUMOR : SUMMARY

MOUSE: FEMALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

Organ	Findings	Group Name / No. of Animals	Control 27	1000 ppm 33	4000 ppm 30	16000 ppm 39
[Integumentary system/appandage]						
skin/app	leukemic cell infiltration		0	1	0	0
subcutis	leukemic cell infiltration		1	0	0	1
[Respiratory system]						
nasal cavit	leukemic cell infiltration		0	0	1	0
lung	leukemic cell infiltration		1	2	3	3
[Hematopoietic system]						
bone marrow	leukemic cell infiltration		0	3	3	1
	metastasis:uterus tumor		0	0	1	0
lymph node	leukemic cell infiltration		0	1	0	0
thymus	leukemic cell infiltration		1	0	1	0
spleen	leukemic cell infiltration		1	2	2	0
[Circulatory system]						
heart	leukemic cell infiltration		0	1	0	1
[Digestive system]						
tongue	leukemic cell infiltration		0	2	1	0
salivary gl	leukemic cell infiltration		1	3	2	1
stomach	leukemic cell infiltration		0	0	2	0
liver	leukemic cell infiltration		2	4	3	2

STUDY NO. : 0140
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name / No. of Animals	Control 27	1000 ppm 33	4000 ppm 30	16000 ppm 39
[Digestive system]						
liver	metastasis:uterus tumor		1	0	2	1
pancreas	leukemic cell infiltration		1	4	1	0
	metastasis:uterus tumor		0	0	1	0
[Urinary system]						
kidney	leukemic cell infiltration		0	3	3	1
urin bladd	leukemic cell infiltration		1	1	1	2
[Endocrine system]						
adrenal	leukemic cell infiltration		0	0	1	0
[Reproductive system]						
ovary	leukemic cell infiltration		1	1	1	0
	metastasis:uterus tumor		1	0	0	0
uterus	leukemic cell infiltration		1	0	1	1
[Special sense organs/appandage]						
Harder gl	leukemic cell infiltration		0	1	0	1
[Musculoskeletal system]						
muscle	leukemic cell infiltration		0	1	1	0

APPENDIX Q 1

IDENTITY OF β-CHLOROPROPIONIC ACID

(2-YEAR STUDY)

IDENTITY OF β-CHLOROPROPIONIC ACID(TWO-YEAR STUDIES)

A. Lot no. FBO 02

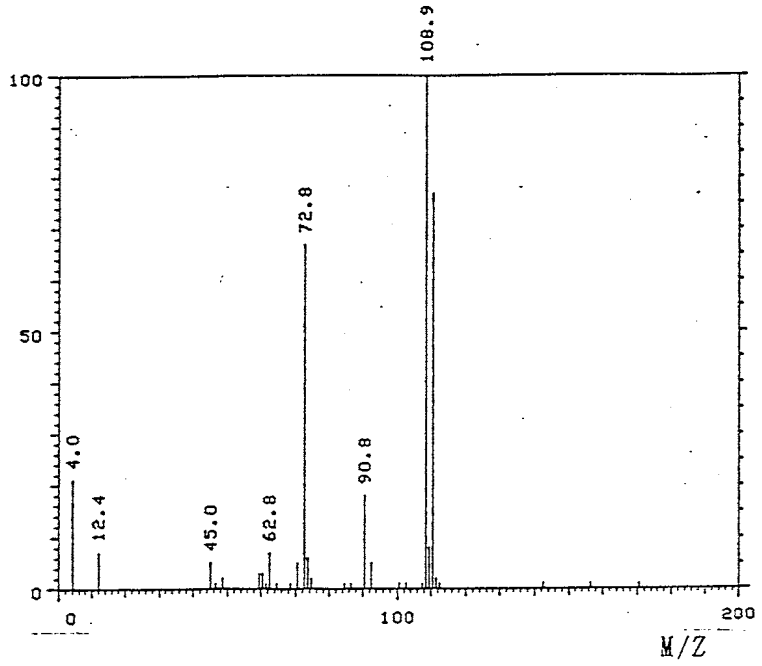
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B

Ionization : CI(Chemical Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

Result:

Molecular Weight

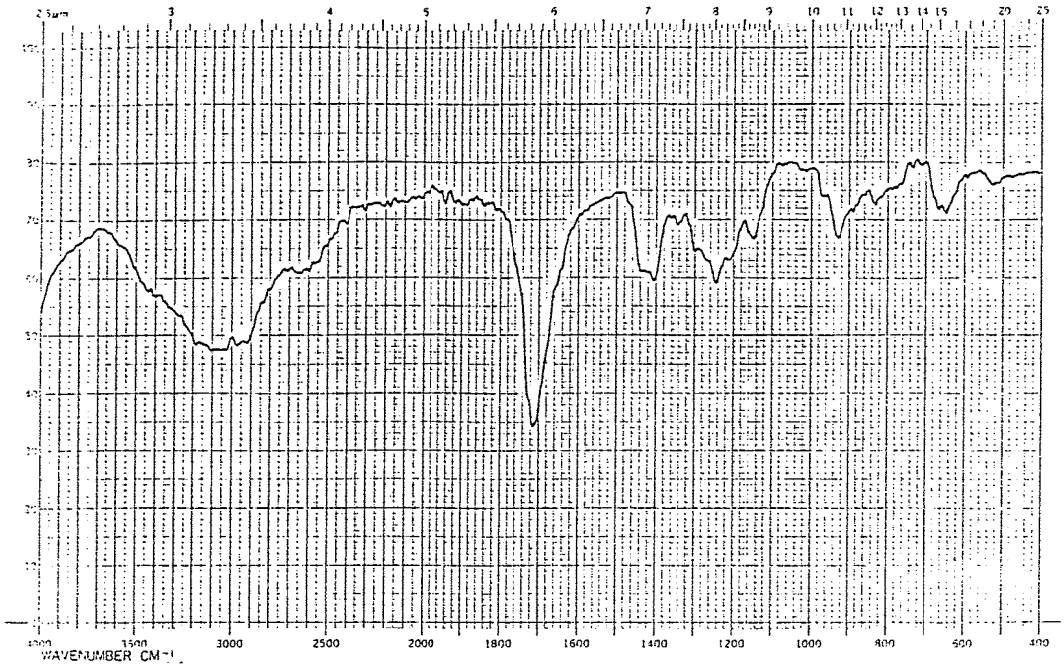
Calculated Value (+H^+)	109.0
Determined Value	108.9

Infrared Spectrometry

Instrument : Hitachi 270-30

Cell : KBr

Slit : Medium



Infrared Spectrum of Test Substance

Results:

Determined Value Wave Number(cm^{-1})	Literature Values* Wave Number(cm^{-1})
620～ 700	620～ 700
850～1000	850～1000
1100～1170	1100～1170
1180～1320	1180～1320
1380～1460	1380～1460
1600～1800	1600～1800
2800～3400	2800～3400

(*Performed by the WAKO PURE CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The result of the mass spectrum agreed with the calculated value and the infrared spectrum agreed with the literature values. Consequently, the test substance was identified as β-chloropropionic acid.

B. Lot no. FCV 02

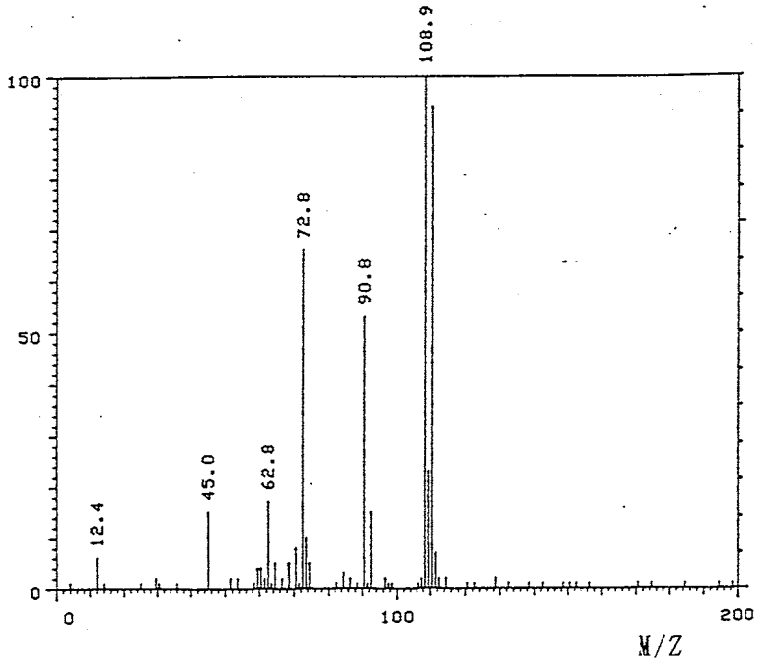
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B

Ionization : CI(Chemical Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

Result:

Molecular Weight

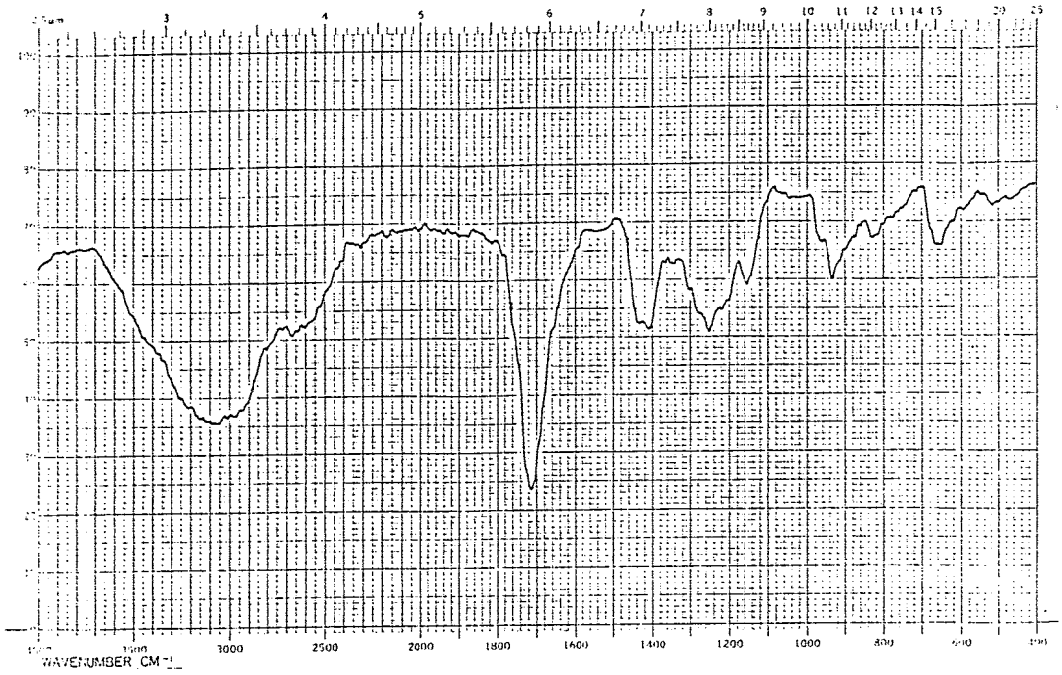
Calculated Value ($+H^+$)	109.0
Determined Value	108.9

Infrared Spectrometry

Instrument : Hitachi 270-30

Cell : KBr

Slit : Medium



Infrared Spectrum of Test Substance

Results:

Determined Value Wave Number(cm^{-1})	Literature Values* Wave Number(cm^{-1})
620～ 700	620～ 700
850～1000	850～1000
1100～1170	1100～1170
1180～1320	1180～1320
1380～1460	1380～1460
1600～1800	1600～1800
2800～3400	2800～3400

(*Performed by the WAKO PURE CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The result of the mass spectrum agreed with the calculated value and the infrared spectrum agreed with the literature values. Consequently, the test substance was identified as β-chloropropionic acid.

C. Lot no. FCX 01

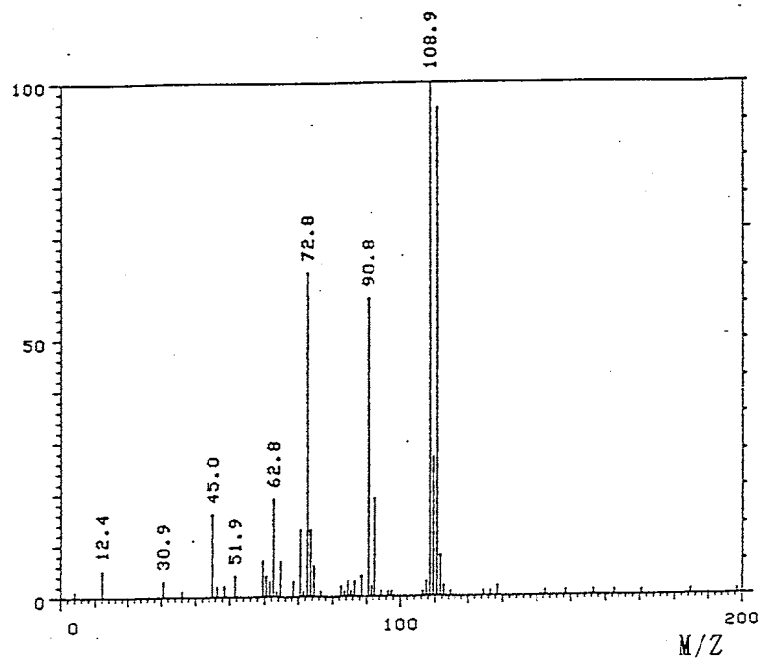
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B

Ionization : CI(Chemical Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

Result:

Molecular Weight

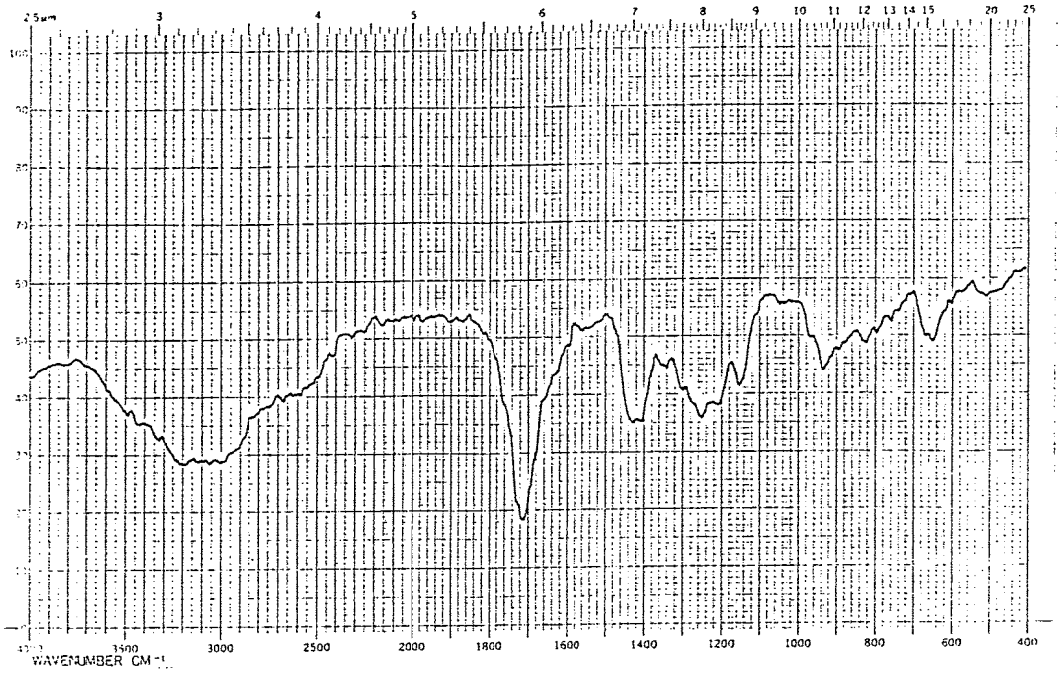
Calculated Value (+H^+)	109.0
Determined Value	108.9

Infrared Spectrometry

Instrument : Hitachi 270-30

Cell : KBr

Slit : Medium



Infrared Spectrum of Test Substance

Results:

Determined Value Wave Number(cm^{-1})	Literature Values* Wave Number(cm^{-1})
620～ 700	620～ 700
850～1000	850～1000
1100～1170	1100～1170
1180～1320	1180～1320
1380～1460	1380～1460
1600～1800	1600～1800
2800～3400	2800～3400

(*Performed by the WAKO PURE CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The result of the mass spectrum agreed with the calculated value and the infrared spectrum agreed with the literature values. Consequently, the test substance was identified as β-chloropropionic acid.

APPENDIX Q 2

STABILITY OF β-CHLOROPROPIONIC ACID

(2-YEAR STUDY)

STABILITY OF β-CHLOROPROPIONIC ACID(TWO-YEAR STUDIES)

A. Lot no. FBO 02

1. Sample: This lot was used from 1989.11.20 to 1989.12.21. Test substance was stored at 5°C.

2. Infrared Spectrometry

Instrument : Hitachi 270-30

Cell : KBr

Slit : Medium

Results: Infrared spectrum of the test substance agreed with before use and after use.

1989.11.10(date analyzed) Wave Number(cm^{-1})	1989.12.22(date analyzed) Wave Number(cm^{-1})
620～ 700	620～ 700
850～1000	850～1000
1100～1170	1100～1170
1180～1320	1180～1320
1380～1460	1380～1460
1600～1800	1600～1800
2800～3400	2800～3400

3. Gas Chromatography

Instrument: Hewlett Packard 5890A

Column: FALM(2mmφ × 2m)

Column Temperature: 160°C

Flow Rate: 28 ml/min

Detector: FID(Flame Ionization Detector)

Injection Volume: 1 μl

Results: Gas chromatography indicated one major peak(peak No.4) and three impurities(peak No.1, 2, 3 < 7% of total area) analyzed at 1989.11.10 and one major peak(peak No.4) and four impurities(peak No.1, 2, 3, 4 < 8% of total area) analyzed at 1989.12.22. The new trace impurity peak in the test substance analyzed at 1989.12.22 was less than 0.7% of total peak.

Date	Peak No.	Retention Time(min)	AREA COUNT	(percent of total peak)
1989.11.10	1	0.047	420	0.4897
(date analyzed)	2	0.293	2512	2.9319
	3	0.933	2040	2.3803
	4	4.33	80720	94.1981
1989.12.22	1	0.033	390	0.4417
(date analyzed)	2	0.287	3431	3.8905
	3	0.798	600	0.6806
	4	0.942	2507	2.843
	5	4.325	81263	92.1441

4. Conclusions: The results indicated that the test substance did not change when stored in the dark at 5°C during this period(for about 6 weeks).

B. Lot no. FCV 02

1. Sample: This lot was used from 1989.12.21 to 1991.01.07. Test substance was stored at 5°C.

2. Infrared Spectrometry

Instrument : Hitachi 270-30

Cell : KBr

Slit : Medium

Results: Infrared spectrum of the test substance agreed with before use and after use.

1989.12.21(date analyzed) Wave Number(cm^{-1})	1991.01.07(date analyzed) Wave Number(cm^{-1})
620～ 700	620～ 700
850～1000	850～1000
1100～1170	1100～1170
1180～1320	1180～1320
1380～1460	1380～1460
1600～1800	1600～1800
2800～3400	2800～3400

3. Gas Chromatography

Instrument: Hewlett Packard 5890A

Column: FALM(2mm ϕ × 2m)

Column Temperature: 160°C

Flow Rate: 28 ml/min

Detector: FID(Flame Ionization Detector)

Injection Volume: 1 μl

Results: Gas chromatography indicated one major peak(peak No. 3) and two impurities(peak No. 1, 2 < 3% of total area) analyzed at 1989. 12. 21 and one major peak(peak No. 3) and three impurities(peak No. 1, 2, 3, 4 < 8% of total area) analyzed at 1991. 01. 08. The new trace impurity peaks in the test substance analyzed at 1989. 12. 22 were less than 5% of total peak.

Date	Peak No.	Retention Time(min)	AREA COUNT	(percent of total peak)
1989. 12. 21	1	0. 775	155	0. 1866
(date analyzed)	2	0. 923	2257	2. 7181
	3	4. 302	80612	97. 0953
1991. 01. 07	1	0. 033	326	0. 3653
(date analyzed)	2	0. 285	3637	4. 0811
	3	0. 795	644	0. 7224
	4	0. 942	2479	2. 7817
	5	4. 328	82041	92. 0496

4. Conclusions: The results indicated that the test substance did not change when stored in the dark at 5°C during this period(for about 13 months).

C. Lot no. FCX 01

1. Sample: This lot was used from 1991.01.10 to 1991.12.25. Test substance was stored at 5°C.

2. Infrared Spectrometry

Instrument : Hitachi 270-30

Cell : KBr

Slit : Medium

Results: Infrared spectrum of the test substance agreed with before use and after use.

1991.01.04(date analyzed) Wave Number(cm^{-1})	1991.12.25(date analyzed) Wave Number(cm^{-1})
620～ 700	620～ 700
850～1000	850～1000
1100～1170	1100～1170
1180～1320	1180～1320
1380～1460	1380～1460
1600～1800	1600～1800
2800～3400	2800～3400

3. Gas Chromatography

Instrument: Hewlett Packard 5890A

Column: FALM(2mmϕ × 2m)

Column Temperature: 160°C

Flow Rate: 28 ml/min

Detector: FID(Flame Ionization Detector)

Injection Volume: 1 μl

Results: Gas chromatography indicated one major peak(peak No.5) and four impurities(peak No.1,2,3,4 < 7% of total area) analyzed at 1991.01.04 and one major peak(peak No.5) and four impurities(peak No.1,2,3,4 < 8% of total area) analyzed at 1991.12.17. The new trace impurity peak in the test substance analyzed at 1991.12.17 was not detected.

Date	Peak No.	Retention Time(min)	AREA COUNT	(percent of total peak)
1991.01.04	1	0.042	329	0.375
(date analyzed)	2	0.29	3340	3.8024
	3	0.812	508	0.5781
	4	0.928	2071	2.3578
	5	4.333	81594	92.8867
1991.12.25	1	0.042	318	0.3592
(date analyzed)	2	0.287	4504	5.0813
	3	0.808	581	0.6558
	4	0.94	1535	1.7314
	5	4.33	81695	92.1723

4. Conclusions: The results indicated that the test substance did not change when stored in the dark at 5°C during this period(for about 12 months).

APPENDIX Q 3

CONDETRATION OF β-CHLOROPROPIONIC ACID IN DRINKING WATER

(2-YEAR STUDY)

CONCENTRATION OF β-CHLOROPROPIONIC ACID IN DRINKING WATER(TWO-YEAR STUDIES)

(Rat)

	Target Concentration(ppm)		
Date analyzed	800	2400	7200
1989.12.11	807.6(101.0)*	2408.7(100.4)	7315.8(101.6)
1990.03.22	786.5(98.3)	2913.3(121.4)	7884.0(109.5)
1990.06.25	920.6(115.1)	2488.8(103.7)	6821.6(94.7)
1990.10.01	806.1(100.8)	3073.0(128.0)	7249.1(100.7)
1991.01.07	814.3(101.8)	2912.7(121.4)	7469.5(103.7)
1991.04.19	777.8(97.2)	2313.6(96.4)	6863.3(95.3)
1991.07.21	787.6(98.4)	2425.9(101.1)	7201.4(100.0)
1991.10.28	713.9(89.2)	2133.6(88.9)	6210.8(86.3)

(*) % of target concentration

Analytical method : The sample were analyzed by the gas chromatography.

Instrument : Hewlett Packard 5890A
Column : FALM(2mmφ × 2m)
Column Temperature: 130℃
Flow Rate : 30ml/min
Detector : FID(Flame Ionization Detector)
Injection Volume : 1μl

CONCENTRATION OF β-CHLOROPROPIONIC ACID IN DRINKING WATER(TWO-YEAR STUDIES)

(Mouse・Male)

	Target Concentration(ppm)		
Date analyzed	250	1000	4000
1989.11.20	266.5(106.6)	1005.4(100.5)	4084.8(102.1)
1990.03.22	291.1(116.5)	1010.7(101.1)	4060.7(101.5)
1990.06.25	255.7(102.3)	1125.0(112.5)	3889.7(97.2)
1990.10.01	319.6(127.8)	1015.8(101.6)	4233.2(105.8)
1991.01.07	296.7(118.7)	1066.9(106.7)	4453.9(111.3)
1991.04.19	231.1(92.4)	1008.5(100.9)	3562.1(89.1)
1991.07.21	243.9(97.5)	1001.6(100.2)	3815.6(95.4)
1991.10.28	234.9(93.9)	887.6(88.8)	3391.1(84.8)

(*) % of target concentration

Analytical method : The sample were analyzed by the gas chromatography.

Instrument : Hewlett Packard 5890A
Column : FALM(2mmφ × 2m)
Column Temperature: 130℃
Flow Rate : 30ml/min
Detector : FID(Flame Ionization Detector)
Injection Volume : 1μl

CONCENTRATION OF β-CHLOROPROPIONIC ACID IN DRINKING WATER(TWO-YEAR STUDIES)

(Mouse・Female)

	Target Concentration(ppm)		
Date analyzed	1000	4000	16000
1989.11.20	1005.4(100.5)*	4084.8(102.1)	16300.9(101.9)
1990.03.22	1010.7(101.1)	4060.7(101.5)	16876.7(104.9)
1990.06.25	1125.0(112.5)	3889.7(97.2)	15842.3(99.0)
1990.10.01	1015.8(101.6)	4233.2(105.8)	15720.5(98.3)
1991.01.07	1066.9(106.7)	4453.9(111.3)	17077.3(106.7)
1991.04.19	1008.5(100.9)	3562.1(89.1)	17479.0(109.2)
1991.07.21	1001.6(100.2)	3815.6(95.4)	17585.1(109.9)
1991.10.28	887.6(88.8)	3391.1(84.8)	15051.8(94.1)

(*) % of target concentration

Analytical method : The sample were analyzed by the gas chromatography.

Instrument : Hewlett Packard 5890A
Column : FALM(2mmφ × 2m)
Column Temperature: 130℃
Flow Rate : 30ml/min
Detector : FID(Flame Ionization Detector)
Injection Volume : 1μl

APPENDIX Q 4

STABILITY OF β-CHLOROPROPIONIC ACID IN DRINKING WATER

(2-YEAR STUDY)

STABILITY OF β-CHLOROPROPIONIC ACID IN DRINKING WATER(TWO-YEAR STUDIES)

(Rat)

	Target Concentration(ppm)		
Date analyzed	800	2400	7200
1989.12.11(a)	807.6	2408.7	7315.8
1989.12.15(b)	824.1	2448.3	7367.1

(a) Date of preparation
(b) The stability of β-chloropropionic acid in drinking water was established for 4 days when stored at 25℃

Analytical method : The sample were analyzed by the gas chromatography.

Instrument : Hewlett Packard 5890A
Column : FALM(2mmφ × 2m)
Column Temperature: 130℃
Flow Rate : 30ml/min
Detector : FID(Flame Ionization Detector)
Injection Volume : 1μl

STABILITY OF β-CHLOROPROPIONIC ACID IN DRINKING WATER(TWO-YEAR STUDIES)

(Mouse・Male)

	Target Concentration(ppm)		
Date	250	1000	4000
1989.11.20(a)	266.5	1005.4	4084.8
1989.11.24(b)	233.2	943.3	3634.6

(Mouse・Female)

	Target Concentration(ppm)		
Date	1000	4000	16000
1989.11.20(a)	1005.4	4084.8	16300.9
1989.11.24(b)	943.3	3634.6	16137.8

(a) Date of preparation
(b) The stability of β-chloropropionic acid in drinking water was established for 4 days when stored at 25℃

Analytical method : The sample were analyzed by the Gas Chromatography.

Instrument	: Hewlett Packard 5890A	Flow Rate	: 30ml/min
Column	: FALM(2mmφ × 2m)	Detector	: FID(Flame Ionization)
Column Temperature	: 130℃	Injection Volume	: 1μl

APPENDIX R 1

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS

METHODS FOR HEMATOLOGY,BIOCHEMISTRY AND URINARYSIS

Item	Method	Unit
Hematology		
Red blood cell (RBC)	Light scattering method [1]	$\times 10^6/\mu l$
Hemoglobin (Hgb)	Cyanmethmoglobin method [1]	g/dl
Hematocrit (Hct)	Caluculated as RBC×MCV/10 [1]	%
Mean corpuscular volume (MCV)	Light scattering method [1]	fl
Mean corpuscular hemoglobin (MCH)	Caluculated as Hgb/RBC×10 [1]	pg
Mean corpuscular hemoglobin concentration (MCHC)	Caluculated as Hgb/Hct×10 [1]	g/dl
Platelet	Light scattering method [1]	$\times 10^3/\mu l$
White blood cell (WBC)	Light scattering method [1]	$\times 10^3/\mu l$
Differntial WBC	Pattern recognition method [2] (May Grunwald Giemsa staining)	%
Biochemistry		
Total protein (TP)	Biuret method [3]	g/dl
Albumin (Alb)	BCG method [3]	g/dl
A/G ratio	Caluculated as Alb/(TP-Alb) [3]	
T-bilirubin	Michaelson method [3]	mg/dl
Glucose	Enzymatic method (HK・G-6-PDH) [3]	mg/dl
T-cholesterol	Enzymatic method (CEH・COD・POD) [3]	mg/dl
Triglyceride	Enzymatic method (GK・GPO・POD) [3]	mg/dl
Phospholipid	Enzymatic method (PLD・COD・POD) [3]	mg/dl
Glutamic oxaloacetic transaminase (GOT)	Karmen method [3]	IU/l
Glutamic pyruvic transaminase (GPT)	Karmen method [3]	IU/l
Lactate dehydrogenase (LDH)	Wroblewski-LaDue method [3]	IU/l
Alkaline phosphatase (ALP)	GSCC method [3]	IU/l
γ-Glutamyl transpeptidase (G-GTP)	L-γ-Glutamyl p-nitroanilide substrate method [3]	IU/l
Creatine phosphokinase (CPK)	GSCC method [3]	IU/l
Urea nitrogen	Enzymatic method (Ureadse・GLDH) [3]	mg/dl
Creatinine	Jaffe metod [3]	mg/dl
Sodium	Flame photometry [4]	mEq/l
Potassium	Flame photometry [4]	mEq/l
Chloride	Coulometric titration [4]	mEq/l
Calcium	OCPC method [3]	mg/dl
Inorganic phosphrus	Enzymatic method (SPL・PGM・G-6-PDH) [3]	mg/dl
Urinalysis		
pH,Protein,Glucose,Ketone body,Bilirubin, Occult Blood,Urobilinogen	Urinalysis reagent paper metod [5]	

1) Automatic blood cell analyzer (Technicon H・1 : Technicon Instruments Corporation,USA)

2) Automatic blood cell differntial analyzer (Hitachi 8200 : Hitachi ,Ltd.,Japan)

3) Automatic analyzer (Hitachi 705 : Hitachi ,Ltd.,Japan)

4) Flame photometer (Hitachi 750 : Hitachi ,Ltd.,Japan)

5) Ames regent strips for urinalysis (Multistix,Uro-Labstix : Miles Sankyo Co.,Ltd.,Japan)

APPENDIX R 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY

	TEST ITEM	DECIMAL PLACE	UNIT
HEMATOLOGY	Red blood cell	2	$10^6/\mu l$
	Hemoglobin	1	g/dl
	Hematocrit	1	%
	MCV	1	fl
	MCH	1	pg
	MCHC	1	g/dl
	Platelet	0	$\times 10^3/\mu l$
	White blood cell	2	$\times 10^3/\mu l$
	Differential WBC	0	%
BIOCHEMISTRY	Total protein	1	g/dl
	Albumin	1	g/dl
	A/G ratio	1	—
	T-bilirubin	2	mg/dl
	Glucose	0	mg/dl
	T-cholesterol	0	mg/dl
	Triglyceride	0	mg/dl
	Phospholipid	0	mg/dl
	GOT	0	IU/l
	GPT	0	IU/l
	LDH	0	IU/l
	ALP	0	IU/l
	γ -GTP	0	IU/l
	CPK	0	IU/l
	Urea nitrogen	1	mg/dl
	Creatinine	1	mg/dl
	Sodium	0	mEq/l
	Potassium	1	mEq/l
	Chloride	0	mEq/l
	Calcium	1	mg/dl
	Inorganic phosphorus	1	mg/dl