

p-ニトロアニソールのマウスを用いた
経口投与によるがん原性試験(混餌試験)報告書

試験番号：0402

APPENDICES

APPENDICES

APPENDIX A 1	CLINICAL OBSERVATION: SUMMARY, MOUSE: MALE (2-YEAR STUDY)
APPENDIX A 2	CLINICAL OBSERVATION: SUMMARY, MOUSE: FEMALE (2-YEAR STUDY)
APPENDIX B 1	BODY WEIGHT CHANGES: SUMMARY, MOUSE: MALE (2-YEAR STUDY)
APPENDIX B 2	BODY WEIGHT CHANGES: SUMMARY, MOUSE: FEMALE (2-YEAR STUDY)
APPENDIX C 1	FOOD CONSUMPTION CHANGES: SUMMARY, MOUSE: MALE (2-YEAR STUDY)
APPENDIX C 2	FOOD CONSUMPTION CHANGES: SUMMARY, MOUSE: FEMALE (2-YEAR STUDY)
APPENDIX D 1	CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: MALE (2-YEAR STUDY)
APPENDIX D 2	CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: FEMALE (2-YEAR STUDY)
APPENDIX E 1	HEMATOLOGY: SUMMARY, MOUSE: MALE (2-YEAR STUDY)
APPENDIX E 2	HEMATOLOGY: SUMMARY, MOUSE: FEMALE (2-YEAR STUDY)
APPENDIX F 1	BIOCHEMISTRY: SUMMARY, MOUSE: MALE (2-YEAR STUDY)
APPENDIX F 2	BIOCHEMISTRY: SUMMARY, MOUSE: FEMALE (2-YEAR STUDY)
APPENDIX G 1	URINALYSIS: SUMMARY, MOUSE: MALE (2-YEAR STUDY)
APPENDIX G 2	URINALYSIS: SUMMARY, MOUSE: FEMALE (2-YEAR STUDY)
APPENDIX H 1	GROSS FINDINGS: SUMMARY, MOUSE: MALE: ALL ANIMALS (2-YEAR STUDY)
APPENDIX H 2	GROSS FINDINGS: SUMMARY, MOUSE: FEMALE: ALL ANIMALS (2-YEAR STUDY)
APPENDIX H 3	GROSS FINDINGS: SUMMARY, MOUSE: MALE: SACRIFICED ANIMALS (2-YEAR STUDY)
APPENDIX H 4	GROSS FINDINGS: SUMMARY, MOUSE: FEMALE: SACRIFICED ANIMALS (2-YEAR STUDY)
APPENDIX H 5	GROSS FINDINGS: SUMMARY, MOUSE: MALE : DEAD AND MORIBUND ANIMALS (2-YEAR STUDY)
APPENDIX H 6	GROSS FINDINGS: SUMMARY, MOUSE: FEMALE: DEAD AND MORIBUND ANIMALS (2-YEAR STUDY)
APPENDIX I 1	ORGAN WEIGHT, ABSOLUTE: SUMMARY, MOUSE: MALE (2-YEAR STUDY)
APPENDIX I 2	ORGAN WEIGHT, ABSOLUTE: SUMMARY, MOUSE: FEMALE (2-YEAR STUDY)

APPENDICES (CONTINUED)

APPENDIX J 1	ORGAN WEIGHT, RELATIVE: SUMMARY, MOUSE: MALE (2-YEAR STUDY)
APPENDIX J 2	ORGAN WEIGHT, RELATIVE: SUMMARY, MOUSE: FEMALE (2-YEAR STUDY)
APPENDIX K 1	HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, MOUSE: MALE: ALL ANIMALS (2-YEAR STUDY)
APPENDIX K 2	HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, MOUSE: FEMALE: ALL ANIMALS (2-YEAR STUDY)
APPENDIX K 3	HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, MOUSE: MALE: SACRIFICED ANIMALS (2-YEAR STUDY)
APPENDIX K 4	HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, MOUSE: FEMALE: SACRIFICED ANIMALS (2-YEAR STUDY)
APPENDIX K 5	HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, MOUSE: MALE: DEAD AND MORIBUND ANIMALS (2-YEAR STUDY)
APPENDIX K 6	HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, MOUSE: FEMALE: DEAD AND MORIBUND ANIMALS (2-YEAR STUDY)
APPENDIX L 1	NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS-TIME RELATED, MOUSE: MALE (2-YEAR STUDY)
APPENDIX L 2	NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS-TIME RELATED, MOUSE: FEMALE (2-YEAR STUDY)
APPENDIX M 1	HISTOPATHOLOGICAL FINDINGS: NEOPLASTIC LESIONS: SUMMARY, MOUSE: MALE (2-YEAR STUDY)
APPENDIX M 2	HISTOPATHOLOGICAL FINDINGS: NEOPLASTIC LESIONS: SUMMARY, MOUSE: FEMALE (2-YEAR STUDY)
APPENDIX N 1	NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS, MOUSE: MALE (2-YEAR STUDY)
APPENDIX N 2	NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS, MOUSE: FEMALE (2-YEAR STUDY)
APPENDIX O 1	HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY, MOUSE: MALE: ALL ANIMALS (2-YEAR STUDY)
APPENDIX O 2	HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY, MOUSE: FEMALE: ALL ANIMALS (2-YEAR STUDY)
APPENDIX O 3	HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY, MOUSE: MALE: SACRIFICED ANIMALS (2-YEAR STUDY)
APPENDIX O 4	HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY, MOUSE: FEMALE: SACRIFICED ANIMALS (2-YEAR STUDY)

APPENDICES (CONTINUED)

APPENDIX O 5	HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY, MOUSE: MALE: DEAD AND MORIBUND ANIMALS (2-YEAR STUDY)
APPENDIX O 6	HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY, MOUSE: FEMALE: DEAD AND MORIBUND ANIMALS (2-YEAR STUDY)
APPENDIX P 1	IDENTITY AND IMPURITY OF <i>p</i> -NITROANISOLE IN THE 2-YEAR FEED STUDY
APPENDIX P 2	STABILITY OF <i>p</i> -NITROANISOLE IN THE 2-YEAR FEED STUDY
APPENDIX P 3	CONCENTRATION OF <i>p</i> -NITROANISOLE IN FORMULATED DIETS IN THE 2-YEAR FEED STUDY
APPENDIX P 4	STABILITY OF <i>p</i> -NITROANISOLE IN FORMULATED DIETS IN THE 2-YEAR FEED STUDY
APPENDIX P 5	HOMOGENEITY OF <i>p</i> -NITROANISOLE IN FORMULATED DIETS IN THE 2-YEAR FEED STUDY
APPENDIX Q	METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-YEAR FEED STUDY OF <i>p</i> -NITROANISOLE

APPENDIX A 1

CLINICAL OBSERVATION : SUMMARY, MOUSE : MALE

(2-YEAR STUDY)

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTON	Control	0	0	0	0	1	1	1	1	0	0	0	0	0	0
	5000 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	10000 ppm	0	0	0	0	0	1	1	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 2

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	20000 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	1	1	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 3

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	1	1	2	2	2	2	2	3	3	3	3	3	4	4
	20000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 4

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	10000 ppm	5	5	5	5	5	5	5	5	5	5	5	6	6	6
	20000 ppm	1	1	1	2	3	3	3	3	3	3	3	3	3	3
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	1	2	1	1	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 5

Clinical sign	Group Name	Administration Week-day			60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		57-7	58-7	59-7											
DEATH	Control	1	1	2	2	2	3	3	3	4	4	4	4	4	4
	5000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	2
	10000 ppm	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	20000 ppm	3	3	3	3	3	3	3	5	5	6	6	7	7	9
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	1	1	1	1	1	1	1	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	0
	10000 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	20000 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0	0
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 6

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	81-7	82-7	83-7
DEATH	Control	4	4	4	4	4	4	4	4	4	4	4	4	6	6
	5000 ppm	2	2	2	2	2	3	3	3	3	3	3	3	4	4
	10000 ppm	6	6	6	6	6	7	8	8	8	9	9	9	10	11
	20000 ppm	9	9	9	9	9	9	9	10	10	10	10	10	11	12
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	1	1	2	2	2	2	2	2
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	1	0	1	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	1	0	0	0	0	0	1	1	1	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	1	1	1	1	1	1	1	1	1	1	0	1	1	1

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 7

Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
DEATH	Control	6	6	7	7	7	8	8	9	9	9	9	10	10	10
	5000 ppm	4	4	4	4	5	5	5	6	8	8	8	9	9	9
	10000 ppm	11	11	11	12	12	12	12	13	13	13	13	14	16	17
	20000 ppm	13	13	13	14	15	15	15	16	17	17	17	17	17	18
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	1	1	1	1	1	1	1	1	1
	20000 ppm	2	3	4	4	4	4	4	4	4	4	5	5	6	6
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	5000 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	10000 ppm	0	0	1	1	2	2	1	1	2	2	1	0	0	0
	20000 ppm	0	0	1	0	1	0	0	1	5	5	5	7	5	3
FROG BELLY	Control	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	1	1	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	20000 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	1	1	1	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 8

Clinical sign	Group Name	Administration Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
DEATH	Control	10	10	11	11	13	14	14
	5000 ppm	10	11	11	13	13	15	15
	10000 ppm	17	17	18	18	18	20	21
	20000 ppm	20	22	24	27	27	27	27
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	1	1	2	2	2	2	2
	20000 ppm	6	6	7	7	7	7	7
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	1	1	1	1	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
PILOERECTION	Control	1	1	1	2	1	1	1
	5000 ppm	1	1	1	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	2	3	1	0	0	0	1
FROG BELLY	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0
	5000 ppm	0	1	1	1	1	1	1
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 9

Clinical sign	Group Name	Administration Week-day				4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1-7	2-7	3-7												
GUM	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	1		1	1	1	1	1	0	0	0	0	0	0
	5000 ppm	0	0	1		1	2	2	2	1	1	1	1	1	1	1
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	1	1
	20000 ppm	0	0	0		0	0	0	0	0	0	1	1	1	1	2
M. NOSE	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
M. NECK	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 10

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
GUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	5000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	10000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	2	2
	20000 ppm	1	1	1	1	1	1	1	1	1	1	1	0	0	0
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 11

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
GUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	1	2	1	1	1	1	1	1	1	1	1	1	1	1
	5000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	2	2
	10000 ppm	2	2	1	1	1	1	1	1	1	1	1	1	1	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 12

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
GUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	1	1	1	1	1	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1
INTERNAL MASS	Control	1	1	1	1	1	1	1	1	1	1	2	2	2	2
	5000 ppm	2	2	2	3	3	3	3	3	3	3	3	3	3	3
	10000 ppm	1	1	1	1	1	1	1	1	2	2	2	2	2	2
	20000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	1	1	1	1	1	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 13

Clinical sign	Group Name	Administration Week-day			60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		57-7	58-7	59-7											
GUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
INTERNAL MASS	Control	2	2	1	1	2	1	1	1	1	1	1	1	1	1
	5000 ppm	3	3	3	3	3	3	3	3	3	3	3	3	3	2
	10000 ppm	2	2	2	2	2	2	2	2	2	2	2	3	3	3
	20000 ppm	1	1	1	1	1	1	2	2	2	2	5	4	4	4
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 14

Clinical sign	Group Name	Administration Week-day			74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	81-7	82-7	83-7
		71-7	72-7	73-7											
GUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	1	1	1	1	1	1	1	1	1	1	0	1	1	1
INTERNAL MASS	Control	2	2	3	3	3	1	1	2	3	3	0	3	2	2
	5000 ppm	2	2	2	2	2	2	2	2	2	1	0	2	3	3
	10000 ppm	3	3	3	3	3	3	3	4	4	4	0	4	2	1
	20000 ppm	5	5	8	9	9	12	12	15	15	14	0	16	16	15
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	1	1	1	1	1	1	1	1	1	1	0	1	1	1
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 15

Clinical sign	Group Name	Administration Week-day			87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		84-7	85-7	86-7											
GUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	1	1	1	1	1	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	20000 ppm	0	1	1	1	1	1	1	1	1	1	1	1	1	1
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	1	1	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	20000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
INTERNAL MASS	Control	2	2	2	1	3	2	2	2	3	3	3	6	6	6
	5000 ppm	4	4	6	5	5	6	6	7	5	6	6	6	6	6
	10000 ppm	1	3	4	4	5	5	4	4	4	5	5	5	5	4
	20000 ppm	15	18	18	18	17	20	20	21	23	25	24	24	24	23
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	1	1	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 16

Clinical sign	Group Name	Administration Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
GUM	Control	0	0	0	0	0	0	1
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	1
DEFECT OF TEETH	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	1	1	1	1	1	1	1
	20000 ppm	1	1	1	1	1	1	1
EXTERNAL MASS	Control	0	0	0	0	0	0	2
	5000 ppm	0	0	1	0	1	0	0
	10000 ppm	1	2	2	2	2	1	1
	20000 ppm	1	0	0	0	0	0	0
INTERNAL MASS	Control	6	7	7	8	8	9	11
	5000 ppm	8	9	9	7	10	9	10
	10000 ppm	7	7	6	6	8	7	6
	20000 ppm	21	19	16	13	15	15	15
M. NOSE	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	1	1	1	1	1	1
	20000 ppm	0	0	0	0	0	0	0
M. PERI MOUTH	Control	0	0	0	0	0	0	1
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
M. PERI EAR	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	1	0	0	0	0	0	0
M. NECK	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	1	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 17

Clinical sign	Group Name	Administration Week-day				4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1-7	2-7	3-7												
M. ABDOMEN	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
CRUSTA	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 18

Clinical sign	Group Name	Administration Week-day				18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		15-7	16-7	17-7												
M. ABDOMEN	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
CRUSTA	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 19

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 20

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	1	1	1	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	1	1	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 21

Clinical sign	Group Name	Administration Week-day				60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		57-7	58-7	59-7												
M. ABDOMEN	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	1	0	0	0	0	0	0	0
CRUSTA	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	Control	0	0	0		0	0	0	0	0	0	0	1	1	1	1
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	1	1	1		1	1	1	1	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	1	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 22

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	81-7	82-7	83-7
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0	0
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	Control	1	1	1	1	1	1	2	2	2	2	0	2	2	2
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	1	1	1	1	1	0	1	1	0
	20000 ppm	0	0	0	0	0	0	1	0	1	0	0	1	1	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 23

Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	1	0	0	0	1	1	1	1
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	Control	2	2	2	2	2	2	2	2	2	2	2	1	1	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	5000 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	10000 ppm	0	0	1	1	1	1	0	0	0	0	1	0	1	0
	20000 ppm	0	1	1	0	0	0	0	1	1	1	1	3	3	3
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 24

Clinical sign	Group Name	Administration Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
M. ABDOMEN	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	1	1	1	1	1	0	0
	20000 ppm	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	Control	0	0	0	0	0	0	1
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
M. GENITALIA	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	1	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
CRUSTA	Control	0	0	0	0	0	0	0
	5000 ppm	1	1	1	1	1	1	1
	10000 ppm	1	1	1	1	1	1	1
	20000 ppm	0	0	0	0	0	0	0
TORTICOLLIS	Control	1	1	1	1	1	1	2
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	1	2	2	3	2	2	2
	5000 ppm	2	2	2	1	0	0	0
	10000 ppm	0	1	1	1	1	1	1
	20000 ppm	2	2	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	1	1	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 25

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HEMATURIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	47	49	50	50	50	50	50	50	50	50	50	50	50
	10000 ppm	50	50	50	50	50	50	50	50	50	50	50	50	49	49
	20000 ppm	50	50	50	50	50	50	50	50	50	50	50	50	50	50
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 26

Clinical sign	Group Name	Administration Week-day				18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		15-7	16-7	17-7												
ABNORMAL RESPIRATION	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
TACHYPNEA	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
HEMATURIA	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
YELLOW URINE	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	50	50	50		50	50	50	50	50	50	50	50	50	50	50
	10000 ppm	50	50	50		50	50	50	50	50	50	49	49	49	49	49
	20000 ppm	50	50	50		50	50	50	49	49	49	49	49	49	49	49
SMALL STOOL	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	1	0	0	0	0	0
	20000 ppm	0	0	0		0	0	1	0	0	0	0	0	0	0	0
OLIGO STOOL	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	1	0	0	0	0	0
	20000 ppm	0	0	0		0	0	1	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 27

Clinical sign	Group Name	Administration Week-day			32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		29-7	30-7	31-7											
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HEMATURIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	50	50	50	50	50	50	50	50	50	50	50	50	50	50
	10000 ppm	49	49	48	48	48	48	48	47	47	47	47	47	46	46
	20000 ppm	49	49	49	49	49	49	49	49	49	49	49	49	49	49
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 28

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	1	1	1	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	1	1	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HEMATURIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	50	50	50	50	50	50	50	50	50	50	50	49	49	49
	10000 ppm	45	45	45	45	45	45	45	45	45	45	45	44	44	44
	20000 ppm	49	49	49	48	47	47	47	47	47	47	47	47	47	47
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	1	1	1	0	0	1
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO STOOL	Control	0	0	0	1	0	0	0	0	0	0	0	0	1	1
	5000 ppm	0	0	0	0	0	0	0	0	1	1	2	1	1	2
	10000 ppm	0	0	0	0	0	0	0	0	0	0	2	1	2	2
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 29

Clinical sign	Group Name	Administration Week-day			60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		57-7	58-7	59-7											
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	1	1	1	1	1	1	1	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HEMATURIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	49	49	49	49	49	49	49	49	49	49	49	49	49	48
	10000 ppm	44	44	44	44	44	44	44	44	44	44	44	44	44	44
	20000 ppm	47	47	47	47	47	47	47	45	45	44	44	43	43	41
SMALL STOOL	Control	0	1	0	0	0	0	0	0	0	0	1	1	1	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	20000 ppm	0	0	0	0	0	0	1	0	0	1	1	0	1	0
OLIGO STOOL	Control	1	1	0	0	0	0	0	0	0	0	1	0	0	0
	5000 ppm	1	2	2	1	1	0	1	0	0	0	0	0	0	0
	10000 ppm	1	2	1	1	1	1	1	1	1	1	1	1	1	1
	20000 ppm	0	0	0	0	0	0	1	0	0	1	1	0	1	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 30

Clinical sign	Group Name	Administration Week-day			74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	81-7	82-7	83-7
		71-7	72-7	73-7											
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	1	1	2	2	2	2	2	2	1	0	1	1	0
	20000 ppm	0	0	0	0	0	0	1	0	1	0	0	1	1	0
TACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	1	1	2	2	1	1	1	1	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HEMATURIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	48	48	48	48	48	47	47	47	47	47	0	47	46	46
	10000 ppm	44	44	44	44	44	43	42	42	42	41	0	41	40	39
	20000 ppm	41	41	41	41	41	41	41	39	39	38	0	38	37	36
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	5000 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	10000 ppm	0	1	0	0	0	0	0	0	1	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	1
OLIGO STOOL	Control	0	0	0	0	0	0	2	1	0	1	0	1	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	2	0	1	2	2	2	2	2	2	1	0	1	1	0
	20000 ppm	0	0	0	0	1	0	1	0	1	0	0	1	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 31

Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	5000 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	10000 ppm	0	0	1	1	1	1	0	0	0	0	1	0	1	0
	20000 ppm	0	1	1	0	0	0	0	1	1	1	1	3	3	3
TACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HEMATURIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	46	46	45	46	45	45	45	44	42	42	42	41	40	41
	10000 ppm	39	39	39	38	38	38	37	36	36	36	36	35	33	32
	20000 ppm	35	35	34	32	31	31	31	30	29	29	28	28	27	26
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	1
OLIGO STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	2	2
	5000 ppm	0	0	0	0	0	0	0	0	0	0	2	0	0	1
	10000 ppm	1	2	1	1	1	2	0	0	0	0	0	0	0	0
	20000 ppm	0	3	2	0	0	0	0	2	2	0	0	0	0	1
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	20000 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 32

Clinical sign	Group Name	Administration Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
ABNORMAL RESPIRATION	Control	1	2	2	3	2	2	2
	5000 ppm	2	2	2	1	0	0	0
	10000 ppm	0	1	1	1	1	1	1
	20000 ppm	2	2	0	0	0	0	0
TACHYPNEA	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	Control	0	0	1	1	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
HEMATURIA	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
YELLOW URINE	Control	0	0	0	0	0	0	0
	5000 ppm	40	39	39	37	37	35	35
	10000 ppm	32	32	30	30	30	28	27
	20000 ppm	24	22	19	16	16	16	16
SMALL STOOL	Control	1	3	1	2	0	1	1
	5000 ppm	1	1	0	1	1	1	1
	10000 ppm	0	2	1	1	1	1	1
	20000 ppm	0	1	2	0	0	0	1
OLIGO STOOL	Control	1	3	1	2	0	0	1
	5000 ppm	1	1	0	0	0	1	1
	10000 ppm	0	1	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 33

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
NON REMARKABLE	Control	50	50	49	49	49	49	49	49	50	50	50	50	50	50
	5000 ppm	50	3	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 34

Clinical sign	Group Name	Administration		Week-day												
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7	
NON REMARKABLE	Control	50	50	50	50	50	50	50	50	50	50	49	49	49	49	49
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 35

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
NON REMARKABLE	Control	49	48	49	49	49	49	49	49	49	49	49	49	49	48
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 36

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
NON REMARKABLE	Control	49	49	49	48	49	49	49	49	49	49	48	47	47	47
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 37

Clinical sign	Group Name	Administration Week-day													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
NON REMARKABLE	Control	47	46	47	47	46	46	46	46	45	45	43	44	44	44
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(JIAN190)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 38

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	81-7	82-7	83-7
NON REMARKABLE	Control	43	43	42	42	42	44	43	42	41	41	46	41	40	40
	5000 ppm	0	0	0	0	0	0	0	0	0	0	47	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	41	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	38	0	0	0

(HAN190)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 39

Clinical sign	Group Name	Administration Week-day			87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		84-7	85-7	86-7											
NON REMARKABLE	Control	40	40	39	40	39	39	39	38	37	37	36	31	32	32
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crl:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 40

Clinical sign	Group Name	Administration Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
NON REMARKABLE	Control	32	30	30	29	28	26	22
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0

(HAN190)

BAIS 4

APPENDIX A 2

CLINICAL OBSERVATION : SUMMARY, MOUSE : FEMALE
(2-YEAR STUDY)

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 41

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROTATING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 42

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROTATING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTIO	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 43

Clinical sign	Group Name	Administration Week-day				32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		29-7	30-7	31-7												
DEATH	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
MORIBUND SACRIFICE	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
ROTATING	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	1
FROG BELLY	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	1
EXOPHTHALMOS	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 44

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
DEATH	Control	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	5000 ppm	0	0	0	0	0	0	0	0	0	1	1	1	2	2
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROTATING	Control	0	0	0	0	0	0	1	1	1	1	2	2	2	2
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	1	0	1	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 45

Clinical sign	Group Name	Administration Week-day													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
DEATH	Control	1	1	1	1	1	1	1	2	3	4	5	6	6	6
	5000 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	1	1	1	1	1	1	2	2	2	2	2	2	3	3
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROTATING	Control	0	0	0	1	1	1	1	1	1	1	1	2	1	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILORECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	Control	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	5000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	10000 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	20000 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 46

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	81-7	82-7	83-7
DEATH	Control	6	6	6	6	7	9	9	9	9	9	10	10	10	14
	5000 ppm	2	4	4	4	4	4	4	4	4	4	6	6	6	6
	10000 ppm	1	1	1	1	1	1	1	1	2	4	4	5	5	5
	20000 ppm	3	4	6	7	8	9	10	11	12	12	12	12	12	12
MORIBUND SACRIFICE	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
ROTATING	Control	1	1	1	1	1	1	1	1	1	1	0	1	1	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	1	1	1	1	1	1	1	1	1	0	1	3	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	1	1	1	1	1	2	1	2	1	0	0	0	2	0
	20000 ppm	2	1	1	0	0	0	0	0	0	0	0	0	1	1
FROG BELLY	Control	0	0	0	0	1	0	0	0	0	0	0	0	1	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	1	2	2	2	2	2	2	2	2	2	0	2	2	2
	5000 ppm	1	1	1	1	1	1	1	1	1	1	0	1	1	1
	10000 ppm	1	1	1	1	1	1	1	1	1	1	0	1	1	1
	20000 ppm	1	1	1	1	1	1	1	1	1	1	0	1	1	1

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 47

Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
DEATH	Control	15	15	15	16	17	19	19	20	20	20	21	22	22	23
	5000 ppm	6	8	8	8	8	8	8	10	10	11	11	12	12	12
	10000 ppm	5	6	7	8	9	10	13	14	14	15	15	15	15	15
	20000 ppm	12	12	12	15	16	19	19	20	21	22	22	25	26	27
MORIBUND SACRIFICE	Control	1	1	1	2	2	2	2	2	2	2	2	2	2	2
	5000 ppm	0	0	0	0	0	0	0	1	1	1	1	2	2	2
	10000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROTATING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	1	1	1	0
	5000 ppm	0	0	0	0	0	0	0	1	1	1	1	1	3	3
	10000 ppm	0	0	0	1	0	0	0	0	0	0	0	0	1	1
	20000 ppm	0	0	0	2	1	0	0	0	3	3	4	3	3	2
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	1
	5000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	10000 ppm	1	1	1	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	2

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 48

Clinical sign	Group Name	Administration Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
DEATH	Control	23	23	23	23	23	24	24
	5000 ppm	12	14	15	17	18	19	21
	10000 ppm	16	17	17	17	19	19	19
	20000 ppm	29	31	32	33	35	36	36
MORIBUND SACRIFICE	Control	2	2	3	3	3	3	3
	5000 ppm	2	2	2	2	2	2	2
	10000 ppm	1	1	1	1	1	1	1
	20000 ppm	1	1	1	1	1	1	1
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
ROTATING	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0
	5000 ppm	3	2	3	1	2	2	2
	10000 ppm	0	0	0	2	1	1	1
	20000 ppm	2	2	2	2	1	1	1
FROG BELLY	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	1	1	1	1	1	1	1
	5000 ppm	1	1	1	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	1	1	1	1	1	1	1

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 49

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 50

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
M. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 51

Clinical sign	Group Name	Administration Week-day			32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		29-7	30-7	31-7											
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 52

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	1	2	2	2	2	2	1	1	2	0	0
	10000 ppm	0	0	0	0	1	1	1	1	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 53

Clinical sign	Group Name	Administration Week-day				60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		57-7	58-7	59-7												
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	1	1	1	1	1	1	1	2	2	1	1	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	1	1	1	2	1	2	3	3	2	1	1	0	0	1	1
	5000 ppm	0	0	1	2	2	2	1	1	1	1	1	1	3	4	4
	10000 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	5	5
	20000 ppm	0	1	1	1	2	2	1	2	2	2	2	2	5	10	10
M. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	Control	0	0	0	1	1	1	1	1	1	1	1	1	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 54

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	81-7	82-7	83-7
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	1	1	1	1	1	1	1	1	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	1	1	1	1	0	1	1	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	1	1	1	1	1	1	1	1	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	1	1	1	1	0	1	1	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	1	1	1	1	1	1	1	1	0	1	1	0
	5000 ppm	0	1	1	1	1	1	1	2	2	2	0	2	2	2
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	1	1	1	0	1	1	1
EXTERNAL MASS	Control	1	2	2	2	2	2	2	2	2	3	0	3	3	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	1	1	1	1	2	1	1	1	2	2	0	2	3	2
	5000 ppm	4	2	2	2	2	2	2	3	6	6	0	5	5	5
	10000 ppm	3	5	4	5	5	7	9	10	11	10	0	9	9	9
	20000 ppm	9	9	10	9	10	10	9	9	11	15	0	16	16	18
M. EYE	Control	0	1	1	1	1	1	1	1	1	1	0	1	1	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 55

Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	1	1	1	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	1	1	1	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	0
EXTERNAL MASS	Control	1	1	1	2	2	2	2	2	2	3	3	3	4	3
	5000 ppm	0	0	0	1	1	1	1	2	2	2	2	2	1	1
	10000 ppm	0	2	2	2	2	2	2	2	2	1	1	1	3	3
	20000 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
INTERNAL MASS	Control	4	4	4	2	1	2	2	4	4	5	4	3	3	2
	5000 ppm	6	4	4	4	8	8	9	7	9	11	11	10	10	11
	10000 ppm	8	7	6	6	5	5	2	1	3	4	4	4	8	11
	20000 ppm	19	20	21	19	22	19	21	20	24	27	27	25	24	22
M. EYE	Control	1	1	1	1	1	1	1	1	1	1	1	1	2	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	1	1	1	1	1	1	1	1	1	0	0
	10000 ppm	0	1	1	1	0	0	0	0	0	0	0	0	1	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 56

Clinical sign	Group Name	Administration Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
EYE OPACITY	Control	0	1	1	1	1	1	1
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
CORNEAL OPACITY	Control	0	1	1	1	1	1	1
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
DEFECT OF TEETH	Control	0	0	0	0	0	0	0
	5000 ppm	2	2	2	2	2	2	2
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
EXTERNAL MASS	Control	3	3	3	3	3	3	3
	5000 ppm	1	2	2	3	4	3	2
	10000 ppm	2	1	1	1	1	1	1
	20000 ppm	0	0	0	0	0	0	0
INTERNAL MASS	Control	2	2	2	2	3	2	2
	5000 ppm	11	10	11	9	8	5	6
	10000 ppm	11	15	15	16	14	16	18
	20000 ppm	20	18	17	16	14	13	13
M. EYE	Control	1	1	1	1	1	1	1
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
M. PERI MOUTH	Control	1	1	1	1	1	1	1
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
M. NECK	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	2	2	3	2	2
	10000 ppm	1	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 57

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
M. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. INTERSCAPULUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 58

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
M. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. INTERSCAPULUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 59

Clinical sign	Group Name	Administration Week-day			32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		29-7	30-7	31-7											
M. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. INTERSCAPULUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 60

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
M. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. INTERSCAPULUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 61

Clinical sign	Group Name	Administration Week-day													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
M. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. INTERSCAPULUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. TAIL	Control	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 62

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	81-7	82-7	83-7
M. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. INTERSCAPULUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	1	0	1	1	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. TAIL	Control	1	1	1	1	1	1	1	1	1	1	0	1	1	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	1	1	1	2	0	0	0	0	0	0	0	0	0	1

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 63

Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
M. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ANTERIOR. DORSUM	Control	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	5000 ppm	0	0	0	0	1	1	1	2	2	2	2	2	1	1
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. INTERSCAPULUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	1	1	1	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 64

Clinical sign	Group Name	Administration Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
M. FORLIMB	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	1	1	1	1
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	1	1	1	0
	10000 ppm	1	1	1	1	1	1	1
	20000 ppm	0	0	0	0	0	0	0
M. ABDOMEN	Control	0	0	0	0	0	0	0
	5000 ppm	0	1	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
M. ANTERIOR. DORSUM	Control	1	1	1	1	1	1	1
	5000 ppm	1	1	1	1	1	1	1
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
M. INTERSCAPULUM	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	1	1	1	1	1
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
M. TAIL	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 65

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	10	2	1	1	1	1	1	1	2	50	50	50
	10000 ppm	41	49	50	50	50	50	50	50	50	50	50	50	50	50
	20000 ppm	50	50	50	50	50	50	50	50	50	50	50	50	50	50
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 66

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	50	50	50	50	50	50	50	50	50	50	50	50	50	50
	10000 ppm	50	50	50	50	50	50	50	50	50	50	50	50	50	50
	20000 ppm	50	50	50	50	50	50	50	50	50	50	50	50	50	50
SMALL STOOL	Control	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 67

Clinical sign	Group Name	Administration Week-day			32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		29-7	30-7	31-7											
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	50	50	50	50	50	50	50	50	50	50	50	50	50	50
	10000 ppm	50	50	50	50	50	50	50	50	50	50	50	50	50	50
	20000 ppm	50	50	50	50	50	50	50	50	50	50	50	50	50	50
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 68

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	Control	0	0	0	0	0	0	1	1	2	2	2	2	2	2
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	50	50	50	50	50	50	50	50	50	49	49	49	48	48
	10000 ppm	50	50	50	50	50	50	50	50	50	50	50	50	50	50
	20000 ppm	49	49	49	49	49	49	49	49	49	49	49	49	49	49
SMALL STOOL	Control	0	0	1	1	0	0	1	1	0	0	0	0	0	0
	5000 ppm	1	0	0	0	0	0	0	0	0	0	0	2	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO STOOL	Control	0	0	0	0	1	3	1	2	1	1	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 69

Clinical sign	Group Name	Administration Week-day													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	Control	2	2	2	2	2	2	3	2	2	2	3	3	3	3
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	48	48	48	48	48	48	48	48	48	48	48	48	48	48
	10000 ppm	50	50	50	50	50	50	50	50	50	50	50	50	50	50
	20000 ppm	49	49	49	49	49	49	48	48	48	48	48	48	47	47
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO STOOL	Control	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	2	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDP1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 70

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	81-7	82-7	83-7
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	Control	3	3	3	3	3	3	3	3	3	3	0	3	3	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	1	0	0	0	0	0	0	0	2	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	1	1	1	1	1	2	1	1	1	0	0	0	2	1
	20000 ppm	0	2	1	1	0	0	0	0	0	0	0	0	1	3
ABNORMAL RESPIRATION	Control	0	0	0	0	1	0	0	0	0	0	0	0	2	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	1	1	1	1	1	2	1	1	1	0	0	0	2	1
	20000 ppm	0	2	1	1	0	0	0	0	0	0	0	0	1	3
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	48	46	46	46	46	46	46	46	46	46	0	44	44	44
	10000 ppm	49	49	49	49	49	49	49	49	48	46	0	45	45	44
	20000 ppm	47	46	44	43	42	41	40	39	38	38	0	38	38	38
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	1	2	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	1	0	1	0	0	0	0	0	0	0	1	2	2
OLIGO STOOL	Control	0	0	0	0	0	1	2	1	1	1	0	1	2	0
	5000 ppm	0	0	0	0	0	0	0	0	0	2	0	1	1	0
	10000 ppm	0	0	0	0	0	0	2	2	1	0	0	0	0	0
	20000 ppm	0	1	2	4	0	0	0	0	0	0	0	2	2	3
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 71

Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	1	2	3	1	1	0	0	0	0	0	1	1	1	0
	5000 ppm	1	0	0	0	0	0	0	2	1	1	2	2	2	3
	10000 ppm	1	1	1	2	1	0	0	0	0	0	0	1	1	1
	20000 ppm	4	4	4	3	2	1	0	1	2	4	4	3	4	4
ABNORMAL RESPIRATION	Control	1	2	3	1	1	0	0	0	0	0	1	1	1	0
	5000 ppm	1	0	0	0	0	0	0	2	1	1	2	2	2	3
	10000 ppm	1	1	1	2	1	0	0	0	0	0	0	1	1	1
	20000 ppm	4	4	4	3	2	1	0	1	2	4	4	3	4	4
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	44	42	42	42	42	42	42	39	39	38	38	37	36	36
	10000 ppm	44	43	42	41	40	39	36	35	35	34	34	34	34	34
	20000 ppm	38	38	38	35	34	31	31	30	29	28	28	25	24	22
SMALL STOOL	Control	1	1	2	1	1	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	2	0	1	1	1	1	2	2
	10000 ppm	0	0	0	1	0	0	0	0	1	0	0	0	0	0
	20000 ppm	0	0	0	2	2	0	0	0	1	0	1	2	1	1
OLIGO STOOL	Control	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	5000 ppm	0	0	0	0	0	0	2	0	1	1	2	0	1	1
	10000 ppm	0	0	0	1	1	2	0	0	1	0	0	0	1	0
	20000 ppm	0	1	1	1	2	1	0	1	1	0	1	2	1	1
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 72

Clinical sign	Group Name	Administration Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
CRUSTA	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	1	1	1
	10000 ppm	0	0	1	1	1	1	1
	20000 ppm	0	0	0	0	0	0	0
TORTICOLLIS	Control	1	1	1	1	1	1	1
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	1	1	1	1	1	1	1
	20000 ppm	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0
	5000 ppm	3	2	4	2	3	4	3
	10000 ppm	0	0	0	0	1	1	1
	20000 ppm	3	2	3	2	1	1	1
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0
	5000 ppm	3	2	4	2	3	4	3
	10000 ppm	0	0	0	0	1	1	1
	20000 ppm	3	2	3	2	1	1	1
YELLOW URINE	Control	0	0	0	0	0	0	0
	5000 ppm	36	34	33	31	30	29	27
	10000 ppm	33	32	32	32	30	30	30
	20000 ppm	20	18	17	16	14	13	13
SMALL STOOL	Control	0	0	0	0	0	0	0
	5000 ppm	3	1	1	0	0	0	0
	10000 ppm	2	0	0	2	2	1	1
	20000 ppm	1	2	0	1	0	0	0
OLIGO STOOL	Control	1	1	0	0	0	0	0
	5000 ppm	4	1	2	1	0	0	0
	10000 ppm	2	0	0	1	0	0	0
	20000 ppm	2	1	0	0	0	1	1
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 73

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
NON REMARKABLE	Control	50	50	50	50	50	50	50	50	50	50	50	50	50	50
	5000 ppm	50	50	40	48	49	49	49	49	49	49	48	0	0	0
	10000 ppm	9	1	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 74

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
NON REMARKABLE	Control	49	50	50	50	50	50	50	50	50	50	50	50	50	50
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 75

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
NON REMARKABLE	Control	50	50	50	50	50	50	50	50	50	50	50	50	50	50
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 76

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
NON REMARKABLE	Control	50	50	49	49	49	47	48	48	47	47	47	47	47	47
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 77

Clinical sign	Group Name	Administration Week-day													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
NON REMARKABLE	Control	46	46	46	44	45	44	43	42	42	41	38	38	39	38
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(IAN190)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 78

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	81-7	82-7	83-7
NON REMARKABLE	Control	38	37	37	37	35	33	33	34	34	33	39	31	30	29
	5000 ppm	0	0	0	0	0	0	0	0	0	0	44	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	46	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	38	0	0	0

(HAN190)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 79

Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
NON REMARKABLE	Control	28	27	27	26	26	24	24	21	21	19	19	19	19	19
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 80

Clinical sign	Group Name	Administration Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
NON REMARKABLE	Control	19	19	18	18	17	17	17
	5000 ppm	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0

(IAN190)

BAIS 4

APPENDIX B 1

BODY WEIGHT CHANGES : SUMMARY, MOUSE : MALE (2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration week-day						
	0-0	1-7	2-7	3-7	4-7	5-7	6-7
Control	23.3± 0.9	23.8± 0.9	24.7± 1.1	25.5± 1.3	26.6± 1.4	27.1± 1.5	27.7± 1.8
5000 ppm	23.2± 0.9	23.5± 0.9	24.5± 1.1	25.5± 1.3	26.3± 1.3	26.8± 1.4	27.4± 1.5
10000 ppm	23.3± 0.9	22.9± 1.3**	24.2± 1.1	25.1± 1.0	25.9± 1.2*	26.2± 1.1**	27.0± 1.2
20000 ppm	23.3± 0.9	21.2± 1.1**	23.2± 1.2**	24.6± 1.4**	25.7± 1.2**	26.0± 1.2**	26.6± 1.2**

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day						
	7-7	8-7	9-7	10-7	11-7	12-7	13-7
Control	28.8± 1.9	29.1± 2.1	29.8± 2.2	30.9± 2.3	31.7± 2.3	32.0± 2.5	32.7± 2.5
5000 ppm	28.3± 1.6	28.8± 1.8	29.0± 2.2	29.9± 2.2	30.5± 2.3	30.8± 2.3	31.4± 2.4
10000 ppm	27.0± 1.2**	27.7± 1.4**	28.0± 1.6**	28.7± 1.7**	28.7± 1.7**	28.8± 1.7**	29.4± 1.9**
20000 ppm	26.7± 1.2**	27.3± 1.3**	27.6± 1.2**	27.7± 1.3**	27.8± 1.2**	27.8± 1.3**	28.5± 1.3**

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week-day						
	14-7	18-7	22-7	26-7	30-7	34-7	38-7
Control	33.6± 2.8	36.2± 3.1	38.7± 3.9	41.1± 4.2	43.5± 4.4	44.7± 4.6	47.0± 4.7
5000 ppm	32.1± 2.3	34.4± 2.7	36.4± 3.1	37.8± 3.4*	40.2± 3.9	41.2± 4.1	43.4± 4.4
10000 ppm	29.9± 1.9**	31.3± 2.1**	32.6± 2.5**	33.4± 2.6**	34.9± 3.0**	35.0± 3.6**	36.5± 3.8**
20000 ppm	28.8± 1.4**	29.7± 1.3**	30.2± 1.4**	30.7± 1.6**	31.1± 1.7**	31.2± 1.6**	31.2± 2.0**

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week-day						
	42-7	46-7	50-7	54-7	58-7	62-7	66-7
Control	48.2± 4.5	49.9± 4.4	50.6± 4.2	51.4± 4.8	51.6± 4.8	53.0± 4.0	53.9± 4.5
5000 ppm	44.9± 4.5	46.0± 4.4*	47.4± 4.8	48.2± 5.1	48.7± 5.9	49.8± 5.5	50.6± 5.9
10000 ppm	37.4± 4.0**	38.2± 4.4**	38.7± 4.6**	39.2± 5.2**	39.5± 5.4**	40.0± 5.9**	41.0± 5.9**
20000 ppm	31.9± 1.9**	32.1± 2.0**	32.1± 1.9**	32.4± 2.0**	32.3± 2.1**	32.3± 1.8**	32.3± 2.3**

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

Group Name	Administration week-day						
	70-7	74-7	78-7	82-7	86-7	90-7	94-7
Control	53.7± 5.4	54.4± 5.6	54.9± 6.1	55.4± 6.3	55.2± 6.4	55.4± 6.8	54.1± 7.7
5000 ppm	51.4± 4.9	51.6± 5.7	52.6± 5.4	52.7± 5.7	52.1± 6.0	52.2± 6.1	51.3± 6.5
10000 ppm	40.4± 6.1**	40.2± 6.1**	40.2± 5.7**	40.7± 5.0**	40.3± 4.8**	40.0± 4.7**	40.0± 6.0**
20000 ppm	32.0± 1.8**	31.3± 2.0**	31.4± 2.0**	30.7± 1.9**	30.5± 1.9**	30.0± 2.3**	30.0± 2.7**

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 104
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 6

Group Name	Administration week-day		
	98-7	102-7	104-7
Control	52.2± 9.0	50.8± 8.3	49.6± 7.8
5000 ppm	49.2± 7.7	48.7± 7.1	47.9± 7.4
10000 ppm	37.7± 5.1**	37.1± 5.6**	37.4± 4.9**
20000 ppm	30.4± 3.0**	29.8± 3.0**	29.6± 3.0**

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

Test of Dunnett

(HAN260)

BAIS 4

APPENDIX B 2

BODY WEIGHT CHANGES : SUMMARY, MOUSE : FEMALE
(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 7

Group Name	Administration week-day						
	0-0	1-7	2-7	3-7	4-7	5-7	6-7
Control	19.1± 0.8	19.5± 0.9	19.8± 0.9	20.2± 0.9	20.7± 0.9	21.3± 1.2	21.7± 1.2
5000 ppm	19.1± 0.8	18.8± 1.1*	19.6± 1.0	19.8± 1.0	20.6± 1.0	21.2± 1.0	21.5± 1.1
10000 ppm	19.1± 0.8	19.0± 0.8	19.5± 0.8	20.2± 0.9	20.6± 0.9	21.3± 1.0	21.4± 1.2
20000 ppm	19.1± 0.8	17.4± 0.8**	19.6± 1.1	20.4± 1.0	20.9± 1.0	21.3± 0.9	21.5± 1.0

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 8

Group Name	Administration week-day						
	7-7	8-7	9-7	10-7	11-7	12-7	13-7
Control	22.3± 1.2	22.6± 1.5	22.9± 1.4	23.4± 1.6	23.7± 1.6	23.7± 1.8	24.3± 2.0
5000 ppm	22.0± 1.2	22.5± 1.4	22.7± 1.4	23.1± 1.4	23.3± 1.6	23.3± 1.8	24.3± 1.8
10000 ppm	22.0± 1.2	22.3± 1.2	22.8± 1.2	23.1± 1.3	23.3± 1.3	23.3± 1.3	23.6± 1.4
20000 ppm	22.0± 0.9	22.1± 1.1	22.4± 1.1	22.8± 1.0	23.2± 1.1	23.1± 1.1	23.3± 1.2*

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 9

Group Name	Administration week-day						
	14-7	18-7	22-7	26-7	30-7	34-7	38-7
Control	24.7± 2.1	26.2± 2.3	27.7± 3.1	29.7± 3.8	31.3± 3.8	32.6± 4.0	33.9± 4.2
5000 ppm	24.2± 2.1	24.9± 2.3**	26.8± 2.7	27.9± 3.0	29.2± 3.2*	30.1± 3.8*	31.9± 4.1
10000 ppm	23.6± 1.4*	24.6± 1.4**	25.9± 1.7*	26.7± 1.7**	27.2± 1.8**	27.8± 2.0**	28.7± 2.5**
20000 ppm	23.5± 1.2*	24.3± 1.2**	25.1± 1.0**	25.5± 1.2**	26.1± 1.5**	26.8± 1.4**	26.8± 1.7**

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 10

Group Name	Administration		week-day									
	42-7		46-7		50-7		54-7		58-7		62-7	
Control	34.5±	4.9	35.7±	5.3	35.8±	5.8	36.3±	5.5	37.1±	6.0	38.0±	6.6
5000 ppm	32.4±	4.4	33.3±	4.1	33.6±	4.5	34.2±	4.7	34.8±	5.1	35.2±	4.9
10000 ppm	29.8±	2.6**	30.2±	2.7**	30.4±	3.1**	30.9±	3.2**	31.2±	3.4**	31.1±	3.4**
20000 ppm	27.9±	1.9**	28.3±	2.3**	28.0±	1.9**	28.4±	2.1**	28.6±	2.3**	28.2±	2.3**

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 11

Group Name	Administration week-day		78-7	82-7	86-7	90-7	94-7
	70-7	74-7					
Control	38.2± 7.2	38.7± 7.7	38.8± 8.0	37.8± 7.9	39.7± 7.5	40.4± 6.3	40.8± 6.5
5000 ppm	36.1± 4.9	36.3± 4.7	36.2± 4.6	36.6± 4.9	36.2± 4.7	35.6± 4.9	35.5± 5.6
10000 ppm	31.6± 3.6**	31.5± 3.5**	31.1± 3.6**	31.2± 3.3**	31.0± 3.2**	30.6± 3.5**	30.6± 3.3**
20000 ppm	28.0± 1.8**	27.4± 1.9**	27.3± 1.8**	26.9± 2.1**	27.2± 2.1**	26.7± 1.9**	27.0± 2.3**

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 12

Group Name	Administration week-day		
	98-7	102-7	104-7
Control	40.4 ± 6.6	39.5 ± 5.8	38.8 ± 5.7
5000 ppm	35.3 ± 5.7	34.7 ± 5.3**	34.9 ± 5.3*
10000 ppm	29.7 ± 3.1**	29.6 ± 3.7**	29.7 ± 5.2**
20000 ppm	27.1 ± 3.1**	27.4 ± 3.6**	27.1 ± 4.1**

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

Test of Dunnett

(HAN260)

BAIS 4

APPENDIX C 1

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : MALE
(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : AI 104
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration week-day(effective)						
	1-7(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	4.0± 0.2	3.9± 0.4	4.0± 0.5	4.1± 0.4	4.0± 0.3	3.9± 0.3	4.1± 0.3
5000 ppm	3.8± 0.4**	4.0± 0.5	4.2± 0.6	4.2± 0.5	4.1± 0.5	4.1± 0.4	4.1± 0.5
10000 ppm	3.7± 0.5**	4.1± 0.6	4.1± 0.5	4.0± 0.5	4.1± 0.5	4.1± 0.5	4.0± 0.4
20000 ppm	3.5± 0.9**	4.3± 0.9	4.2± 0.8	4.1± 0.8	4.2± 0.8	4.1± 0.7	4.1± 0.6

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day(effective)						
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	4.0± 0.3	4.0± 0.3	4.1± 0.3	4.0± 0.3	4.0± 0.3	3.9± 0.3	4.1± 0.3
5000 ppm	4.2± 0.5	4.0± 0.4	4.2± 0.3	4.0± 0.4	4.0± 0.3	3.9± 0.3	4.1± 0.4
10000 ppm	4.1± 0.4	3.9± 0.4	4.0± 0.4	3.9± 0.4	3.9± 0.4	3.9± 0.4	4.0± 0.4
20000 ppm	4.3± 0.7	4.0± 0.6	4.0± 0.7	4.1± 0.6	4.2± 0.6	4.0± 0.7	4.1± 0.6

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

(HAN260)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week-day(effective) 18-7(7)	22-7(7)	26-7(7)	30-7(7)	34-7(7)	38-7(7)	42-7(7)
Control	4.2± 0.3	4.2± 0.3	4.5± 0.4	4.3± 0.3	4.4± 0.4	4.6± 0.4	4.5± 0.5
5000 ppm	4.2± 0.4	4.2± 0.4	4.3± 0.4	4.5± 0.4*	4.6± 0.7	4.6± 0.5	4.7± 0.5
10000 ppm	4.1± 0.4	4.2± 0.4	4.3± 0.5	4.3± 0.4	4.5± 0.7	4.5± 0.5	4.5± 0.6
20000 ppm	4.3± 0.6	4.5± 0.8	4.6± 0.6	4.5± 0.6	5.0± 0.8**	5.0± 0.8*	4.6± 0.7

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week-day(effective)						
	46-7(7)	50-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)	70-7(7)
Control	4.6± 0.4	4.5± 0.3	4.6± 0.4	4.8± 0.5	4.7± 0.4	4.9± 0.5	4.9± 0.7
5000 ppm	4.6± 0.5	4.7± 0.4	4.8± 0.5	4.9± 0.5	4.9± 0.6	5.0± 0.6	5.0± 0.6
10000 ppm	4.6± 0.7	4.4± 0.7	4.4± 0.7	4.9± 0.7	4.8± 0.8	4.9± 0.7	4.8± 0.6
20000 ppm	4.8± 0.9	4.6± 0.9	4.9± 0.8	5.0± 1.0	5.0± 1.0	5.0± 1.0	5.4± 0.7**

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

Group Name	Administration week-day(effective)						
	74-7(7)	78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)	98-7(7)
Control	4.9± 0.5	5.0± 0.6	4.8± 0.6	4.9± 0.6	4.9± 0.8	4.8± 0.8	4.7± 1.0
5000 ppm	5.0± 0.6	5.4± 0.5	5.0± 0.7	5.2± 0.7	5.2± 0.7	5.1± 0.9	5.2± 0.9*
10000 ppm	4.8± 0.7	5.0± 0.8	4.8± 0.8	4.9± 0.8	4.8± 0.8	4.9± 0.8	4.9± 0.9
20000 ppm	5.2± 0.6	5.5± 0.8*	5.7± 0.8**	6.0± 0.9**	5.3± 1.0	6.1± 0.8**	6.5± 0.3**

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 104
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 6

Group Name	Administration week-day(effective)	
	102-7(7)	104-7(7)
Control	4.8± 0.9	4.6± 1.0
5000 ppm	5.0± 1.0	4.8± 0.8
10000 ppm	4.6± 0.8	4.8± 1.0
20000 ppm	6.5± 0.8**	6.5± 0.1 ?

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

? : Significant test is not applied, because No. of data in this group is less than 3.

APPENDIX C 2

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : FEMALE
(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : AI 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 7

Group Name	Administration week-day(effective)						
	1-7(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	3.6± 0.4	3.5± 0.4	3.5± 0.4	3.8± 0.3	3.8± 0.4	3.6± 0.3	3.8± 0.4
5000 ppm	3.3± 0.4**	3.4± 0.3	3.4± 0.2	3.6± 0.2	3.7± 0.3	3.6± 0.3	3.7± 0.3
10000 ppm	3.5± 0.5	3.5± 0.4	3.4± 0.4	3.6± 0.4**	3.7± 0.4	3.5± 0.4	3.6± 0.4*
20000 ppm	2.8± 0.5**	3.6± 0.6	3.4± 0.5	3.4± 0.5**	3.3± 0.4**	3.2± 0.4**	3.6± 0.5**

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

Group Name	Administration 8-7(7)	week-day(effective) 9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	3.7± 0.4	3.8± 0.5	3.8± 0.4	3.8± 0.4	3.8± 0.4	3.9± 0.5	4.0± 0.5
5000 ppm	3.8± 0.3	3.6± 0.3	3.6± 0.3	3.7± 0.3	3.7± 0.4	3.7± 0.4	3.7± 0.4*
10000 ppm	3.7± 0.3	3.7± 0.3	3.6± 0.3	3.7± 0.4	3.6± 0.3	3.7± 0.5	3.7± 0.4*
20000 ppm	3.5± 0.4*	3.5± 0.5**	3.5± 0.5**	3.8± 0.5	3.6± 0.4	3.8± 0.5	3.8± 0.5

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 9

Group Name	Administration week-day(effective)						
	18-7(7)	22-7(7)	26-7(7)	30-7(7)	34-7(7)	38-7(7)	42-7(7)
Control	3.8± 0.6	4.0± 0.5	4.3± 0.7	4.2± 0.7	4.5± 0.7	4.4± 0.6	4.6± 0.8
5000 ppm	3.7± 0.4	3.9± 0.4	4.1± 0.5	4.0± 0.5	4.3± 0.6	4.4± 0.7	4.7± 0.8
10000 ppm	4.0± 0.5	4.2± 0.7	4.4± 0.7	4.1± 0.6	4.4± 0.7	4.5± 0.7	4.8± 0.7
20000 ppm	3.8± 0.5	4.0± 0.5	4.1± 0.7	4.1± 0.7	4.3± 0.7	4.3± 0.8	4.7± 1.0

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 10

Group Name	Administration week-day(effective)						
	46-7(7)	50-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)	70-7(7)
Control	4.7± 0.8	4.5± 1.0	4.6± 0.9	4.8± 0.8	4.9± 0.8	4.7± 0.8	4.7± 0.8
5000 ppm	4.6± 0.7	4.3± 0.7	4.3± 0.7	4.8± 0.8	4.8± 0.6	4.6± 0.7	4.9± 0.8
10000 ppm	4.9± 0.7	4.6± 0.7	4.6± 0.7	5.2± 0.8*	5.0± 0.8	5.0± 0.9	5.0± 0.8
20000 ppm	4.9± 0.9	4.5± 0.9	4.8± 1.0	5.2± 1.0	4.9± 0.9	5.2± 1.1*	5.1± 0.9

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 11

Group Name	Administration week-day(effective)						
	74-7(7)	78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)	98-7(7)
Control	4.4± 0.7	4.7± 0.8	4.6± 1.1	4.9± 0.9	5.1± 1.1	5.1± 1.1	4.9± 0.8
5000 ppm	4.6± 0.8	4.9± 0.9	4.9± 0.8	5.0± 1.0	4.7± 1.2	4.9± 0.9	5.0± 1.4
10000 ppm	5.0± 0.7**	5.0± 0.7	5.2± 0.9*	5.5± 0.8*	5.4± 0.9	5.6± 0.8	5.6± 1.0*
20000 ppm	4.7± 1.0	5.1± 0.9	5.2± 1.2*	5.6± 1.0	5.4± 0.9	5.9± 1.2*	6.5± 0.8**

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

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 12

Group Name	Administration week-day(effective)	
	102-7(7)	104-7(7)
Control	4.9± 1.0	4.9± 1.1
5000 ppm	4.8± 1.1	5.2± 1.2
10000 ppm	5.7± 1.2*	5.7± 1.2
20000 ppm	5.7± 1.0	6.2± 0.8

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

Test of Dunnett

(HAN260)

BAIS 4

APPENDIX D 1

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

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDP1
UNIT : g/kg/day
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration (weeks)		2	3	4	5	6	7
	1							
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
5000 ppm	0.810± 0.085		0.816± 0.089	0.836± 0.136	0.792± 0.079	0.769± 0.087	0.745± 0.063	0.730± 0.073
10000 ppm	1.615± 0.201		1.680± 0.241	1.647± 0.212	1.561± 0.226	1.546± 0.180	1.502± 0.145	1.477± 0.150
20000 ppm	3.295± 0.789		3.711± 0.726	3.432± 0.607	3.206± 0.579	3.197± 0.552	3.086± 0.476	3.078± 0.402

(HAN300)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
UNIT : g/kg/d a y
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

Group Name	Administration (weeks)									
	8	9	10	11	12	13	14			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
5000 ppm	0.728± 0.064	0.681± 0.055	0.697± 0.057	0.664± 0.057	0.648± 0.052	0.622± 0.053	0.641± 0.059			
10000 ppm	1.481± 0.131	1.382± 0.134	1.378± 0.124	1.361± 0.141	1.368± 0.137	1.327± 0.117	1.346± 0.130			
20000 ppm	3.145± 0.433	2.917± 0.382	2.906± 0.400	2.964± 0.373	2.984± 0.412	2.827± 0.425	2.876± 0.380			

(HAN300)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDf1
 UNIT : g/kg/day
 REPORT TYPE : A1 104
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration (weeks)									
	18	22	26	30	34	38	42			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
5000 ppm	0.613± 0.055	0.584± 0.057	0.577± 0.055	0.562± 0.056	0.560± 0.084	0.528± 0.071	0.527± 0.067			
10000 ppm	1.316± 0.118	1.304± 0.129	1.285± 0.160	1.229± 0.129	1.299± 0.194	1.239± 0.175	1.205± 0.213			
20000 ppm	2.872± 0.352	2.961± 0.479	3.031± 0.415	2.893± 0.394	3.226± 0.479	3.201± 0.529	2.917± 0.460			

(HAN300)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g/kg/day
 REPORT TYPE : A1 104
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration (weeks)									
	46	50	54	58	62	66	70			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
5000 ppm	0.510± 0.064	0.501± 0.072	0.495± 0.065	0.497± 0.050	0.500± 0.087	0.498± 0.068	0.490± 0.063			
10000 ppm	1.200± 0.188	1.151± 0.185	1.143± 0.189	1.254± 0.255	1.223± 0.261	1.223± 0.273	1.206± 0.166			
20000 ppm	3.040± 0.569	2.888± 0.540	3.016± 0.546	3.098± 0.660	3.105± 0.600	3.098± 0.562	3.370± 0.477			

(HAN300)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g/kg/day
 REPORT TYPE : A1 104
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

Group Name	Administration (weeks)									
	74	78	82	86	90	94	98			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
5000 ppm	0.485± 0.053	0.517± 0.077	0.484± 0.079	0.503± 0.094	0.500± 0.088	0.500± 0.116	0.540± 0.135			
10000 ppm	1.214± 0.178	1.256± 0.222	1.203± 0.253	1.228± 0.232	1.201± 0.254	1.242± 0.227	1.308± 0.275			
20000 ppm	3.269± 0.354	3.485± 0.506	3.708± 0.570	3.961± 0.701	3.563± 0.691	4.178± 0.554	4.652± 0.354			

(HAN300)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
UNIT : g/kg/day
REPORT TYPE : A1 104
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 6

Group Name	Administration (weeks)	
	102	104
Control	0.000 ± 0.000	0.000 ± 0.000
5000 ppm	0.522 ± 0.125	0.507 ± 0.099
10000 ppm	1.233 ± 0.224	1.296 ± 0.347
20000 ppm	4.830 ± 0.799	4.693 ± 0.030

(HAN300)

BAIS 4

APPENDIX D 2

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

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g/kg/day
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 7

Group Name	Administration (weeks)		2	3	4	5	6	7
	1							
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
5000 ppm	0.873± 0.105		0.866± 0.086	0.857± 0.054	0.877± 0.047	0.868± 0.058	0.842± 0.066	0.845± 0.063
10000 ppm	1.860± 0.249		1.821± 0.227	1.702± 0.176	1.732± 0.163	1.722± 0.150	1.640± 0.140	1.648± 0.121
20000 ppm	3.170± 0.562		3.711± 0.596	3.321± 0.456	3.248± 0.501	3.103± 0.367	2.979± 0.386	3.243± 0.479

(HAN300)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDf1
 UNIT : g/kg/day
 REPORT TYPE : AI 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 8

Group Name	Administration (weeks)									
	8	9	10	11	12	13	14			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
5000 ppm	0.839± 0.066	0.791± 0.066	0.779± 0.053	0.792± 0.057	0.787± 0.057	0.761± 0.068	0.772± 0.059			
10000 ppm	1.663± 0.128	1.610± 0.155	1.565± 0.145	1.574± 0.146	1.567± 0.137	1.572± 0.190	1.579± 0.157			
20000 ppm	3.215± 0.395	3.148± 0.526	3.086± 0.419	3.255± 0.488	3.106± 0.400	3.232± 0.397	3.234± 0.433			

(HAN300)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g/kg/day
 REPORT TYPE : AI 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 9

Group Name	Administration (weeks)									
	18	22	26	30	34	38	42			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
5000 ppm	0.752± 0.071	0.732± 0.062	0.739± 0.075	0.690± 0.089	0.713± 0.090	0.696± 0.104	0.733± 0.127			
10000 ppm	1.616± 0.180	1.637± 0.223	1.645± 0.208	1.500± 0.196	1.575± 0.211	1.584± 0.191	1.607± 0.209			
20000 ppm	3.131± 0.441	3.229± 0.364	3.243± 0.518	3.114± 0.514	3.235± 0.480	3.190± 0.504	3.411± 0.630			

(HAN300)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDf1
 UNIT : g/kg/day
 REPORT TYPE : A1 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 10

Group Name	Administration (weeks)									
	46	50	54	58	62	66	70			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000		
5000 ppm	0.704± 0.129	0.654± 0.115	0.638± 0.105	0.701± 0.128	0.688± 0.110	0.645± 0.109	0.685± 0.117			
10000 ppm	1.611± 0.205	1.502± 0.190	1.492± 0.225	1.684± 0.256	1.618± 0.247	1.584± 0.266	1.599± 0.255			
20000 ppm	3.432± 0.592	3.186± 0.569	3.377± 0.663	3.609± 0.630	3.516± 0.615	3.699± 0.842	3.670± 0.569			

(HAN300)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g/kg/day
 REPORT TYPE : AI 104
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 11

Group Name	Administration (weeks)									
	74		78		82		86		90	
Control	0.000± 0.000		0.000± 0.000		0.000± 0.000		0.000± 0.000		0.000± 0.000	
5000 ppm	0.645± 0.125		0.678± 0.128		0.680± 0.112		0.701± 0.145		0.656± 0.155	
10000 ppm	1.588± 0.207		1.604± 0.236		1.684± 0.268		1.777± 0.276		1.769± 0.248	
20000 ppm	3.516± 0.739		3.741± 0.571		3.902± 0.756		4.161± 0.745		4.046± 0.695	

(HAN300)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
UNIT : g/kg/day
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 12

Group Name	Administration (weeks)	
	102	104
Control	0.000± 0.000	0.000± 0.000
5000 ppm	0.705± 0.164	0.766± 0.182
10000 ppm	1.912± 0.342	1.940± 0.422
20000 ppm	4.195± 0.823	4.557± 1.170

(HAN300)

BAIS 4

APPENDIX E 1

HEMATOLOGY : SUMMARY, MOUSE : MALE

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ³ /μl	
Control	32	9.06±	2.12	12.4±	2.7	40.4±	8.1	45.2±	4.2	13.8±	1.0	30.6±	1.8	1868±	470
5000 ppm	33	9.27±	1.28	13.0±	1.7	42.2±	4.9	45.7±	1.9	14.0±	0.6	30.7±	1.0	1926±	426
10000 ppm	26	8.77±	1.80	12.6±	2.4	40.8±	6.3	47.6±	6.3**	14.4±	0.6**	30.6±	2.5	2025±	477
20000 ppm	16	7.94±	2.48*	10.4±	3.2*	36.0±	9.1*	47.2±	7.6	13.3±	0.9	28.5±	2.5**	2054±	738

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	32	3.49±	4.86	2±	3	30±	12	1±	1	0±	0	4±	2	62±	13	0±	1
5000 ppm	33	2.44±	1.18	2±	2	28±	12	2±	1	0±	0	4±	2	64±	14	0±	1
10000 ppm	26	2.48±	1.72	2±	3	32±	16	2±	1	0±	0	4±	2	61±	17	0±	0
20000 ppm	16	2.37±	1.06	3±	2	37±	14	0±	0**	0±	0	3±	2	55±	15	1±	2

Significant difference ; * : P ≤ 0.05

** : P ≤ 0.01

Test of Dunnett

(HCL070)

BAIS 4

APPENDIX E 2

HEMATOLOGY : SUMMARY, MOUSE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ³ /μl	
Control	23	9.08±	1.01	13.1±	1.5	41.8±	3.8	46.1±	1.5	14.4±	0.3	31.3±	1.0	1073±	375
5000 ppm	24	9.46±	0.69	13.6±	0.8	43.4±	2.4	46.0±	2.2	14.4±	0.6	31.3±	0.8	1275±	344
10000 ppm	29	9.50±	1.47	13.2±	1.8	43.0±	5.5	45.6±	2.9	14.0±	0.7	30.7±	1.3	1321±	349
20000 ppm	13	8.27±	3.49	11.1±	4.4	37.7±	12.1	49.6±	12.2	13.8±	1.4**	28.5±	3.5**	1517±	695*

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (105W)

PAGE : 4

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	23	4.83±	11.61	1±	1	23±	13	2±	1	0±	0	4±	2	64±	18	6±	19
5000 ppm	24	2.58±	1.73	1±	2	22±	12	2±	1	0±	0	4±	2	70±	12	0±	1
10000 ppm	29	7.96±	25.99	1±	2	26±	15	2±	3	0±	0	3±	2	66±	16	1±	2
20000 ppm	13	3.93±	6.44	4±	5**	37±	19*	1±	0	0±	0	3±	2	54±	21	2±	3

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 4

APPENDIX F 1

BIOCHEMISTRY : SUMMARY, MOUSE : MALE

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (105#)

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	34	5.4±	0.9	2.9±	0.5	1.2±	0.2	0.17±	0.10	169±	56	120±	64	37±	33
5000 ppm	34	5.3±	0.8	3.0±	0.4	1.3±	0.2	0.17±	0.08	199±	50	128±	47	46±	24
10000 ppm	27	5.1±	0.5	2.9±	0.3	1.3±	0.1	0.18±	0.16	212±	62**	124±	32	33±	15
20000 ppm	16	6.0±	0.7**	3.2±	0.3**	1.2±	0.2	0.38±	0.37**	177±	32	250±	59**	28±	21

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (105#)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT I U/l		GPT I U/l		LDH I U/l		ALP I U/l		G-GTP I U/l		CPK I U/l	
Control	34	215±	99	208±	302	110±	134	1056±	2228	163±	111	3±	4	64±	66
5000 ppm	34	235±	73	114±	145	95±	143	754±	1044	160±	99	4±	5	51±	24
10000 ppm	27	225±	63	162±	263	134±	181	2087±	5779	296±	312*	2±	1	76±	85
20000 ppm	16	450±	119**	1250±	1590**	1157±	1198**	9029±	7690**	923±	691**	14±	15**	133±	46**

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0402

ANIMAL : MOUSE Crj:BDF1

MEASURE TIME : 1

SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (105W)

PAGE : 3

Group Name	NO. of Animals	UREA NITROGEN mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	34	24.0±	13.9	153±	2	4.1±	0.5	122±	4	9.3±	0.7	6.4±	0.8
5000 ppm	34	25.6±	5.6*	152±	2	4.0±	0.4	123±	4	9.3±	0.6	6.7±	0.9
10000 ppm	27	28.0±	8.6**	153±	2	4.1±	0.4	125±	4*	9.1±	0.5	6.8±	1.0
20000 ppm	16	27.6±	3.6**	152±	2	4.3±	0.4	121±	3	9.9±	0.5**	6.0±	0.9

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

Test of Dunnett

(HCL074)

BAIS 4

APPENDIX F 2

BIOCHEMISTRY : SUMMARY, MOUSE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	23	5.0±	0.4	2.9±	0.2	1.4±	0.2	0.15±	0.03	168±	32	69±	22	28±	14
5000 ppm	25	5.0±	0.8	2.8±	0.2	1.3±	0.2	0.15±	0.05	163±	44	86±	19	27±	12
10000 ppm	29	5.2±	0.8	2.9±	0.3	1.4±	0.2	0.16±	0.03	160±	40	127±	38**	23±	12
20000 ppm	13	5.9±	0.5**	3.4±	0.3**	1.4±	0.1	0.48±	0.59**	154±	62	225±	43**	24±	17

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BATS 4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDP1
 MEASURE TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 5

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT I U/l		GPT I U/l		LDH I U/l		ALP I U/l		G-GTP I U/l		CPK I U/l	
Control	23	138±	35	112±	84	37±	23	685±	950	176±	70	2±	1	95±	85
5000 ppm	25	165±	38	85±	37	47±	31	442±	573	227±	114	3±	4	110±	144
10000 ppm	29	245±	68**	294±	366**	324±	386**	1387±	1359*	495±	313**	5±	5**	108±	87
20000 ppm	13	398±	77**	1213±	1411**	1007±	1037**	9917±	11178**	943±	469**	14±	8**	222±	200**

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0402

ANIMAL : MOUSE Crj:BDF1

MEASURE TIME : 1

SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (105W)

PAGE : 6

Group Name	NO. of Animals	UREA NITROGEN mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	23	19.0±	5.1	151±	1	4.0±	0.5	123±	3	9.1±	0.5	6.2±	0.9
5000 ppm	25	21.8±	14.2	152±	3	4.1±	1.0	124±	2	9.0±	0.4	6.7±	1.7
10000 ppm	29	31.8±	30.1**	152±	4	4.1±	0.9	123±	4	9.6±	0.5**	7.0±	3.1
20000 ppm	13	33.5±	18.0**	153±	5	4.6±	0.9	120±	4*	10.1±	0.3**	6.8±	1.5

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

Test of Dunnett

(HCL074)

BAIS 4

APPENDIX G 1

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

STUDY NO. : 0402

ANIMAL : MOUSE Crj:BDF1

MEASURE TIME : 1

SEX : MALE

REPORT TYPE : A1

URINALYSIS

PAGE : 1

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body					CHI	Occult blood				CHI			
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	±	+		2+	3+	4+	-		±	+	2+
Control	36	0	6	15	7	6	2	0		0	4	23	8	1	0		36	0	0	0	0	0		20	12	4	0	0	0		28	3	0	1	4
5000 ppm	35	0	3	10	11	9	2	0		0	6	24	5	0	0		35	0	0	0	0	0		17	15	3	0	0	0		34	1	0	0	0
10000 ppm	29	0	3	11	4	9	2	0		0	9	19	1	0	0	*	29	0	0	0	0	0		19	10	0	0	0	0		29	0	0	0	0
20000 ppm	16	0	10	4	1	1	0	0	*	0	10	6	0	0	0	**	16	0	0	0	0	0		14	2	0	0	0	0		16	0	0	0	0

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

Test of CHI SQUARE

(HCL101)

BATS 4

STUDY NO. : 0402

URINALYSIS

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Urobilinogen					CHI
		±	+	2+	3+	4+	
Control	36	36	0	0	0	0	0
5000 ppm	35	35	0	0	0	0	0
10000 ppm	29	29	0	0	0	0	0
20000 ppm	16	16	0	0	0	0	0

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of CHI SQUARE

(HCL101)

BATS 4

APPENDIX G 2

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

STUDY NO. : 0402

ANIMAL : MOUSE Crj:BDf1

MEASURE TIME : 1

SEX : FEMALE

REPORT TYPE : A1

URINALYSIS

PAGE : 3

Group Name	NO. of Animals	pH_____							CHI	Protein_____					CHI	Glucose_____					CHI	Ketone body_____					CHI	Occult blood_____				CHI			
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	±	+		2+	3+	4+	-		±	+	2+
Control	24	0	1	4	8	8	2	1		0	4	16	3	1	0		24	0	0	0	0	0		2	11	5	6	0	0		20	3	0	1	0
5000 ppm	30	0	1	6	7	10	6	0		0	5	18	7	0	0		30	0	0	0	0	0		4	18	6	2	0	0		27	1	0	0	2
10000 ppm	30	0	2	8	12	5	3	0		0	15	12	3	0	0		30	0	0	0	0	0		2	22	4	2	0	0		29	0	0	1	0
20000 ppm	13	0	7	6	0	0	0	0	**	0	5	8	0	0	0		13	0	0	0	0	0		2	7	3	1	0	0		11	1	0	0	1

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

Test of CHI SQUARE

(HCL101)

BATS 4

STUDY NO. : 0402

URINALYSIS

ANIMAL : MOUSE Crj:BDF1

MEASURE TIME : 1

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Urobilinogen					CHI
		±	+	2+	3+	4+	
Control	24	24	0	0	0	0	0
5000 ppm	30	30	0	0	0	0	0
10000 ppm	30	30	0	0	0	0	0
20000 ppm	13	13	0	0	0	0	0

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

Test of CHI SQUARE

(HCL101)

BATS 4

APPENDIX H 1

GROSS FINDINGS : SUMMARY, MOUSE : MALE ALL ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control 50 (%)	5000 ppm 50 (%)	10000 ppm 50 (%)	20000 ppm 50 (%)
skin/app	nodule		1 (2)	0 (0)	0 (0)	0 (0)
	scab		0 (0)	1 (2)	1 (2)	0 (0)
subcutis	edema		3 (6)	5 (10)	5 (10)	1 (2)
	mass		2 (4)	2 (4)	4 (8)	0 (0)
lung	red		1 (2)	0 (0)	1 (2)	0 (0)
	white zone		0 (0)	0 (0)	1 (2)	0 (0)
	nodule		1 (2)	2 (4)	3 (6)	4 (8)
lymph node	enlarged		7 (14)	7 (14)	6 (12)	1 (2)
thymus	enlarged		1 (2)	0 (0)	0 (0)	0 (0)
spleen	enlarged		6 (12)	9 (18)	7 (14)	6 (12)
	white zone		1 (2)	1 (2)	0 (0)	0 (0)
	nodule		3 (6)	1 (2)	2 (4)	2 (4)
	accentuation of white pulp		0 (0)	0 (0)	0 (0)	1 (2)
tooth	absence		1 (2)	0 (0)	0 (0)	0 (0)
forestomach	nodule		1 (2)	2 (4)	0 (0)	0 (0)
	thick		1 (2)	0 (0)	0 (0)	0 (0)
small intes	dilated		0 (0)	0 (0)	1 (2)	0 (0)
large intes	dilated		1 (2)	0 (0)	0 (0)	0 (0)
liver	enlarged		6 (12)	4 (8)	6 (12)	4 (8)
	atrophic		0 (0)	0 (0)	0 (0)	1 (2)
	white zone		5 (10)	7 (14)	2 (4)	3 (6)
	red zone		1 (2)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 5

Organ	Findings	Group Name NO. of Animals	Control 50 (%)	5000 ppm 50 (%)	10000 ppm 50 (%)	20000 ppm 50 (%)
liver	brown zone		0 (0)	1 (2)	2 (4)	0 (0)
	nodule		12 (24)	26 (52)	42 (84)	48 (96)
	deformed		0 (0)	1 (2)	0 (0)	0 (0)
	rough		1 (2)	0 (0)	0 (0)	0 (0)
	nodular		0 (0)	0 (0)	0 (0)	2 (4)
	adhesion		0 (0)	0 (0)	0 (0)	1 (2)
pancreas	nodule		1 (2)	0 (0)	0 (0)	3 (6)
kidney	enlarged		2 (4)	0 (0)	2 (4)	0 (0)
	white zone		0 (0)	0 (0)	1 (2)	1 (2)
	nodule		1 (2)	1 (2)	0 (0)	1 (2)
	hydronephrosis		1 (2)	5 (10)	5 (10)	0 (0)
urin bladd	urine:marked retention		0 (0)	0 (0)	1 (2)	0 (0)
pituitary	enlarged		2 (4)	2 (4)	1 (2)	0 (0)
	red zone		1 (2)	1 (2)	1 (2)	0 (0)
	black zone		0 (0)	0 (0)	1 (2)	0 (0)
	nodule		0 (0)	1 (2)	1 (2)	0 (0)
	cyst		1 (2)	0 (0)	0 (0)	0 (0)
ovary	enlarged		3 (6)	8 (16)	5 (10)	5 (10)
	cyst		9 (18)	9 (18)	2 (4)	0 (0)
	absence		0 (0)	0 (0)	0 (0)	1 (2)
uterus	enlarged		0 (0)	0 (0)	1 (2)	0 (0)
	nodule		14 (28)	14 (28)	13 (26)	10 (20)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 ALL ANIMALS (0-105#)

PAGE : 6

Organ	Findings	Group Name NO. of Animals	Control 50 (%)	5000 ppm 50 (%)	10000 ppm 50 (%)	20000 ppm 50 (%)
uterus	dilated lumen		0 (0)	0 (0)	1 (2)	0 (0)
brain	red zone		0 (0)	1 (2)	1 (2)	0 (0)
Harder gl	enlarged		1 (2)	1 (2)	0 (0)	1 (2)
	nodule		0 (0)	0 (0)	1 (2)	1 (2)
mediastinum	nodule		0 (0)	0 (0)	0 (0)	2 (4)
	mass		2 (4)	4 (8)	0 (0)	0 (0)
peritoneum	nodule		0 (0)	0 (0)	0 (0)	1 (2)
	mass		1 (2)	0 (0)	0 (0)	0 (0)
	thick		0 (0)	1 (2)	0 (0)	0 (0)
retroperit	nodule		1 (2)	0 (0)	0 (0)	0 (0)
abdominal c	hemorrhage		0 (0)	0 (0)	2 (4)	9 (18)
	ascites		6 (12)	6 (12)	4 (8)	5 (10)
thoracic ca	pleural fluid		4 (8)	10 (20)	5 (10)	3 (6)
other	hindlimb:nodule		1 (2)	0 (0)	0 (0)	1 (2)
	lower jaw:nodule		0 (0)	0 (0)	1 (2)	0 (0)

(HPT080)

BAIS 4

APPENDIX H 2

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE ALL ANIMALS
(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 50 (%)	5000 ppm 50 (%)	10000 ppm 50 (%)	20000 ppm 50 (%)
skin/app	nodule		0 (0)	0 (0)	0 (0)	1 (2)
	scab		0 (0)	1 (2)	1 (2)	0 (0)
subcutis	edema		0 (0)	0 (0)	1 (2)	0 (0)
	mass		1 (2)	4 (8)	1 (2)	1 (2)
lung	white zone		0 (0)	1 (2)	0 (0)	0 (0)
	red zone		0 (0)	0 (0)	1 (2)	0 (0)
	nodule		7 (14)	5 (10)	3 (6)	2 (4)
lymph node	enlarged		4 (8)	11 (22)	3 (6)	0 (0)
thymus	enlarged		0 (0)	0 (0)	1 (2)	0 (0)
spleen	enlarged		2 (4)	0 (0)	0 (0)	1 (2)
	white zone		1 (2)	0 (0)	0 (0)	0 (0)
	black zone		1 (2)	0 (0)	0 (0)	0 (0)
	nodule		2 (4)	4 (8)	1 (2)	1 (2)
tooth	deformed		0 (0)	0 (0)	1 (2)	0 (0)
	absence		0 (0)	0 (0)	0 (0)	1 (2)
salivary gl	nodule		2 (4)	0 (0)	1 (2)	0 (0)
forestomach	nodule		0 (0)	0 (0)	2 (4)	1 (2)
gl stomach	nodule		0 (0)	0 (0)	0 (0)	1 (2)
	thick		2 (4)	4 (8)	1 (2)	0 (0)
stomach	nodule		0 (0)	0 (0)	1 (2)	0 (0)
small intes	nodule		0 (0)	2 (4)	0 (0)	0 (0)
liver	enlarged		1 (2)	0 (0)	0 (0)	2 (4)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDf1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 50 (%)	5000 ppm 50 (%)	10000 ppm 50 (%)	20000 ppm 50 (%)
liver	white zone		3 (6)	2 (4)	1 (2)	3 (6)
	red zone		3 (6)	4 (8)	1 (2)	0 (0)
	brown zone		0 (0)	1 (2)	1 (2)	1 (2)
	nodule		34 (68)	33 (66)	35 (70)	43 (86)
	deformed		1 (2)	0 (0)	1 (2)	0 (0)
pancreas	nodule		1 (2)	0 (0)	1 (2)	2 (4)
kidney	enlarged		0 (0)	1 (2)	0 (0)	0 (0)
	atrophic		1 (2)	0 (0)	0 (0)	0 (0)
	white		1 (2)	0 (0)	0 (0)	0 (0)
	nodule		1 (2)	0 (0)	1 (2)	0 (0)
	deformed		2 (4)	1 (2)	1 (2)	0 (0)
	hydronephrosis		2 (4)	3 (6)	3 (6)	2 (4)
urin bladd	nodule		0 (0)	1 (2)	0 (0)	0 (0)
	urine:marked retention		4 (8)	1 (2)	1 (2)	2 (4)
urethra	dilated		0 (0)	0 (0)	1 (2)	0 (0)
pituitary	black zone		0 (0)	0 (0)	1 (2)	0 (0)
testis	nodule		0 (0)	0 (0)	1 (2)	0 (0)
epididymis	nodule		2 (4)	0 (0)	1 (2)	1 (2)
	adhesion		0 (0)	1 (2)	0 (0)	0 (0)
semin ves	adhesion		2 (4)	0 (0)	0 (0)	0 (0)
prep/cli gl	nodule		6 (12)	0 (0)	0 (0)	0 (0)
brain	nodule		0 (0)	0 (0)	2 (4)	0 (0)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 3

Organ	Findings	Group Name	Control	5000 ppm	10000 ppm	20000 ppm
		NO. of Animals	50 (%)	50 (%)	50 (%)	50 (%)
brain	hypertrophy		0 (0)	0 (0)	0 (0)	1 (2)
Harder gl	enlarged		1 (2)	0 (0)	1 (2)	0 (0)
	nodule		1 (2)	1 (2)	1 (2)	1 (2)
peritoneum	nodule		0 (0)	0 (0)	0 (0)	1 (2)
retroperit	mass		1 (2)	0 (0)	0 (0)	0 (0)
abdominal c	hemorrhage		1 (2)	1 (2)	4 (8)	7 (14)
	mass		1 (2)	0 (0)	0 (0)	0 (0)
	ascites		2 (4)	2 (4)	4 (8)	2 (4)
mesenterium	nodule		1 (2)	1 (2)	0 (0)	0 (0)
adipose	nodule		1 (2)	0 (0)	0 (0)	0 (0)
thoracic ca	hemorrhage		0 (0)	1 (2)	1 (2)	0 (0)
	pleural fluid		1 (2)	4 (8)	2 (4)	0 (0)
other	nose:nodule		0 (0)	0 (0)	1 (2)	0 (0)
whole body	anemic		0 (0)	1 (2)	0 (0)	0 (0)

APPENDIX H 3

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

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 36 (%)	5000 ppm 35 (%)	10000 ppm 27 (%)	20000 ppm 16 (%)
skin/app	scab		0 (0)	1 (3)	1 (4)	0 (0)
subcutis	mass		1 (3)	0 (0)	0 (0)	0 (0)
lung	white zone		0 (0)	1 (3)	0 (0)	0 (0)
	red zone		0 (0)	0 (0)	1 (4)	0 (0)
	nodule		6 (17)	5 (14)	1 (4)	1 (6)
lymph node	enlarged		2 (6)	8 (23)	2 (7)	0 (0)
spleen	enlarged		1 (3)	0 (0)	0 (0)	0 (0)
	white zone		1 (3)	0 (0)	0 (0)	0 (0)
	black zone		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		1 (3)	4 (11)	1 (4)	0 (0)
tooth	absence		0 (0)	0 (0)	0 (0)	1 (6)
salivary gl	nodule		2 (6)	0 (0)	1 (4)	0 (0)
forestomach	nodule		0 (0)	0 (0)	2 (7)	0 (0)
gl stomach	nodule		0 (0)	0 (0)	0 (0)	1 (6)
	thick		2 (6)	4 (11)	1 (4)	0 (0)
liver	white zone		1 (3)	2 (6)	0 (0)	1 (6)
	red zone		2 (6)	3 (9)	1 (4)	0 (0)
	nodule		27 (75)	24 (69)	21 (78)	16 (100)
	deformed		1 (3)	0 (0)	0 (0)	0 (0)
pancreas	nodule		1 (3)	0 (0)	0 (0)	1 (6)
kidney	enlarged		0 (0)	1 (3)	0 (0)	0 (0)
	atrophic		1 (3)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 36 (%)	5000 ppm 35 (%)	10000 ppm 27 (%)	20000 ppm 16 (%)
kidney	nodule		1 (3)	0 (0)	1 (4)	0 (0)
	deformed		2 (6)	1 (3)	1 (4)	0 (0)
	hydronephrosis		1 (3)	0 (0)	0 (0)	1 (6)
urin bladd	urine:marked retention		1 (3)	0 (0)	0 (0)	0 (0)
epididymis	nodule		2 (6)	0 (0)	0 (0)	0 (0)
semin ves	adhesion		2 (6)	0 (0)	0 (0)	0 (0)
prep/cli gl	nodule		6 (17)	0 (0)	0 (0)	0 (0)
Harder gl	enlarged		1 (3)	0 (0)	0 (0)	0 (0)
	nodule		1 (3)	1 (3)	1 (4)	0 (0)
abdominal c	ascites		1 (3)	1 (3)	0 (0)	0 (0)
adipose	nodule		1 (3)	0 (0)	0 (0)	0 (0)
thoracic ca	pleural fluid		0 (0)	1 (3)	0 (0)	0 (0)
other	nose:nodule		0 (0)	0 (0)	1 (4)	0 (0)

(HPT080)

BAIS 4

APPENDIX H 4

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

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 23 (%)	5000 ppm 27 (%)	10000 ppm 30 (%)	20000 ppm 13 (%)
skin/app	nodule		1 (4)	0 (0)	0 (0)	0 (0)
	scab		0 (0)	1 (4)	1 (3)	0 (0)
subcutis	mass		1 (4)	1 (4)	1 (3)	0 (0)
lung	nodule		1 (4)	2 (7)	3 (10)	1 (8)
lymph node	enlarged		3 (13)	3 (11)	3 (10)	0 (0)
spleen	enlarged		3 (13)	0 (0)	3 (10)	2 (15)
	white zone		1 (4)	0 (0)	0 (0)	0 (0)
	nodule		2 (9)	1 (4)	2 (7)	0 (0)
	accentuation of white pulp		0 (0)	0 (0)	0 (0)	1 (8)
forestomach	nodule		1 (4)	0 (0)	0 (0)	0 (0)
liver	atrophic		0 (0)	0 (0)	0 (0)	1 (8)
	white zone		0 (0)	1 (4)	0 (0)	1 (8)
	red zone		1 (4)	0 (0)	0 (0)	0 (0)
	brown zone		0 (0)	1 (4)	1 (3)	0 (0)
	nodule		8 (35)	18 (67)	30 (100)	13 (100)
	deformed		0 (0)	1 (4)	0 (0)	0 (0)
	rough		1 (4)	0 (0)	0 (0)	0 (0)
pancreas	nodule		1 (4)	0 (0)	0 (0)	1 (8)
kidney	enlarged		0 (0)	0 (0)	1 (3)	0 (0)
	white zone		0 (0)	0 (0)	0 (0)	1 (8)
	nodule		1 (4)	1 (4)	0 (0)	0 (0)
	hydronephrosis		1 (4)	3 (11)	2 (7)	0 (0)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control 23 (%)	5000 ppm 27 (%)	10000 ppm 30 (%)	20000 ppm 13 (%)
pituitary	enlarged		2 (9)	1 (4)	1 (3)	0 (0)
	red zone		1 (4)	1 (4)	1 (3)	0 (0)
	black zone		0 (0)	0 (0)	1 (3)	0 (0)
	nodule		0 (0)	1 (4)	1 (3)	0 (0)
ovary	enlarged		0 (0)	1 (4)	0 (0)	1 (8)
	cyst		6 (26)	7 (26)	2 (7)	0 (0)
	absence		0 (0)	0 (0)	0 (0)	1 (8)
uterus	nodule		4 (17)	3 (11)	6 (20)	3 (23)
	dilated lumen		0 (0)	0 (0)	1 (3)	0 (0)
Harder gl	enlarged		0 (0)	0 (0)	0 (0)	1 (8)
mediastinum	nodule		0 (0)	0 (0)	0 (0)	2 (15)
abdominal c	hemorrhage		0 (0)	0 (0)	0 (0)	1 (8)
	ascites		1 (4)	1 (4)	0 (0)	1 (8)
thoracic ca	pleural fluid		0 (0)	1 (4)	0 (0)	0 (0)
other	lower jaw:nodule		0 (0)	0 (0)	1 (3)	0 (0)

(HPT080)

BATS 4

APPENDIX H 5

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

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 14 (%)	5000 ppm 15 (%)	10000 ppm 23 (%)	20000 ppm 34 (%)
skin/app	nodule		0 (0)	0 (0)	0 (0)	1 (3)
subcutis	edema		0 (0)	0 (0)	1 (4)	0 (0)
	mass		0 (0)	4 (27)	1 (4)	1 (3)
lung	nodule		1 (7)	0 (0)	2 (9)	1 (3)
lymph node	enlarged		2 (14)	3 (20)	1 (4)	0 (0)
thymus	enlarged		0 (0)	0 (0)	1 (4)	0 (0)
spleen	enlarged		1 (7)	0 (0)	0 (0)	1 (3)
	nodule		1 (7)	0 (0)	0 (0)	1 (3)
tooth	deformed		0 (0)	0 (0)	1 (4)	0 (0)
forestomach	nodule		0 (0)	0 (0)	0 (0)	1 (3)
stomach	nodule		0 (0)	0 (0)	1 (4)	0 (0)
small intes	nodule		0 (0)	2 (13)	0 (0)	0 (0)
liver	enlarged		1 (7)	0 (0)	0 (0)	2 (6)
	white zone		2 (14)	0 (0)	1 (4)	2 (6)
	red zone		1 (7)	1 (7)	0 (0)	0 (0)
	brown zone		0 (0)	1 (7)	1 (4)	1 (3)
	nodule		7 (50)	9 (60)	14 (61)	27 (79)
	deformed		0 (0)	0 (0)	1 (4)	0 (0)
pancreas	nodule		0 (0)	0 (0)	1 (4)	1 (3)
kidney	white		1 (7)	0 (0)	0 (0)	0 (0)
	hydronephrosis		1 (7)	3 (20)	3 (13)	1 (3)
urin bladd	nodule		0 (0)	1 (7)	0 (0)	0 (0)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 14 (%)	5000 ppm 15 (%)	10000 ppm 23 (%)	20000 ppm 34 (%)
urin bladd	urine:marked retention		3 (21)	1 (7)	1 (4)	2 (6)
urethra	dilated		0 (0)	0 (0)	1 (4)	0 (0)
pituitary	black zone		0 (0)	0 (0)	1 (4)	0 (0)
testis	nodule		0 (0)	0 (0)	1 (4)	0 (0)
epididymis	nodule		0 (0)	0 (0)	1 (4)	1 (3)
	adhesion		0 (0)	1 (7)	0 (0)	0 (0)
brain	nodule		0 (0)	0 (0)	2 (9)	0 (0)
	hypertrophy		0 (0)	0 (0)	0 (0)	1 (3)
Harder gl	enlarged		0 (0)	0 (0)	1 (4)	0 (0)
	nodule		0 (0)	0 (0)	0 (0)	1 (3)
peritoneum	nodule		0 (0)	0 (0)	0 (0)	1 (3)
retroperit	mass		1 (7)	0 (0)	0 (0)	0 (0)
abdominal c	hemorrhage		1 (7)	1 (7)	4 (17)	7 (21)
	mass		1 (7)	0 (0)	0 (0)	0 (0)
	ascites		1 (7)	1 (7)	4 (17)	2 (6)
mesenterium	nodule		1 (7)	1 (7)	0 (0)	0 (0)
thoracic ca	hemorrhage		0 (0)	1 (7)	1 (4)	0 (0)
	pleural fluid		1 (7)	3 (20)	2 (9)	0 (0)
whole body	anemic		0 (0)	1 (7)	0 (0)	0 (0)

APPENDIX H 6

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

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 27 (%)	5000 ppm 23 (%)	10000 ppm 20 (%)	20000 ppm 37 (%)
subcutis	edema		3 (11)	5 (22)	5 (25)	1 (3)
	mass		1 (4)	1 (4)	3 (15)	0 (0)
lung	red		1 (4)	0 (0)	1 (5)	0 (0)
	white zone		0 (0)	0 (0)	1 (5)	0 (0)
	nodule		0 (0)	0 (0)	0 (0)	3 (8)
lymph node	enlarged		4 (15)	4 (17)	3 (15)	1 (3)
thymus	enlarged		1 (4)	0 (0)	0 (0)	0 (0)
spleen	enlarged		3 (11)	9 (39)	4 (20)	4 (11)
	white zone		0 (0)	1 (4)	0 (0)	0 (0)
	nodule		1 (4)	0 (0)	0 (0)	2 (5)
tooth	absence		1 (4)	0 (0)	0 (0)	0 (0)
forestomach	nodule		0 (0)	2 (9)	0 (0)	0 (0)
	thick		1 (4)	0 (0)	0 (0)	0 (0)
small intes	dilated		0 (0)	0 (0)	1 (5)	0 (0)
large intes	dilated		1 (4)	0 (0)	0 (0)	0 (0)
liver	enlarged		6 (22)	4 (17)	6 (30)	4 (11)
	white zone		5 (19)	6 (26)	2 (10)	2 (5)
	brown zone		0 (0)	0 (0)	1 (5)	0 (0)
	nodule		4 (15)	8 (35)	12 (60)	35 (95)
	nodular		0 (0)	0 (0)	0 (0)	2 (5)
	adhesion		0 (0)	0 (0)	0 (0)	1 (3)
pancreas	nodule		0 (0)	0 (0)	0 (0)	2 (5)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control 27 (%)	5000 ppm 23 (%)	10000 ppm 20 (%)	20000 ppm 37 (%)
kidney	enlarged		2 (7)	0 (0)	1 (5)	0 (0)
	white zone		0 (0)	0 (0)	1 (5)	0 (0)
	nodule		0 (0)	0 (0)	0 (0)	1 (3)
	hydronephrosis		0 (0)	2 (9)	3 (15)	0 (0)
urin bladd	urine:marked retention		0 (0)	0 (0)	1 (5)	0 (0)
pituitary	enlarged		0 (0)	1 (4)	0 (0)	0 (0)
	cyst		1 (4)	0 (0)	0 (0)	0 (0)
ovary	enlarged		3 (11)	7 (30)	5 (25)	4 (11)
	cyst		3 (11)	2 (9)	0 (0)	0 (0)
uterus	enlarged		0 (0)	0 (0)	1 (5)	0 (0)
	nodule		10 (37)	11 (48)	7 (35)	7 (19)
brain	red zone		0 (0)	1 (4)	1 (5)	0 (0)
Harder gl	enlarged		1 (4)	1 (4)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	1 (5)	1 (3)
mediastinum	mass		2 (7)	4 (17)	0 (0)	0 (0)
peritoneum	nodule		0 (0)	0 (0)	0 (0)	1 (3)
	mass		1 (4)	0 (0)	0 (0)	0 (0)
	thick		0 (0)	1 (4)	0 (0)	0 (0)
retroperit	nodule		1 (4)	0 (0)	0 (0)	0 (0)
abdominal c	hemorrhage		0 (0)	0 (0)	2 (10)	8 (22)
	ascites		5 (19)	5 (22)	4 (20)	4 (11)
thoracic ca	pleural fluid		4 (15)	9 (39)	5 (25)	3 (8)

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 5

Organ	Findings	Group Name	Control	5000 ppm	10000 ppm	20000 ppm
		NO. of Animals	27 (%)	23 (%)	20 (%)	37 (%)
other	hindlimb:nodule		1 (4)	0 (0)	0 (0)	1 (3)

(HPT080)

BAIS 4

APPENDIX I 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : MALE

(2-YEAR STUDY)

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

PAGE : 1

Group Name	NO. of Animals	Body Weight	ADRENALS		TESTES		HEART		LUNGS		KIDNEYS	
Control	36	45.8± 8.0	0.012±	0.003	0.218±	0.026	0.232±	0.042	0.257±	0.104	0.649±	0.360
5000 ppm	35	45.2± 7.5	0.010±	0.002*	0.219±	0.028	0.225±	0.025	0.265±	0.087	0.605±	0.163
10000 ppm	27	34.7± 4.7**	0.010±	0.002**	0.203±	0.041	0.196±	0.020**	0.252±	0.047	0.542±	0.044**
20000 ppm	16	27.3± 2.8**	0.009±	0.002*	0.202±	0.027	0.167±	0.013**	0.227±	0.025	0.457±	0.066**

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

Test of Dunnett

(ICL040)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

PAGE : 2

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	36	0.161±	0.399	2.001±	0.931	0.446±	0.016
5000 ppm	35	0.243±	0.489	2.248±	0.653*	0.450±	0.016
10000 ppm	27	0.103±	0.127	2.607±	2.501	0.451±	0.020
20000 ppm	16	0.142±	0.118	5.750±	2.701**	0.435±	0.015

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

Test of Dunnett

(HCL040)

BAIS 4

APPENDIX I 2

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

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

PAGE : 3

Group Name	NO. of Animals	Body Weight	ADRENALS		OVARIES		HEART		LUNGS		KIDNEYS	
Control	23	35.8± 6.2	0.013±	0.002	0.060±	0.069	0.173±	0.031	0.218±	0.070	0.410±	0.043
5000 ppm	27	32.6± 5.1	0.012±	0.002	0.266±	1.027	0.174±	0.033	0.230±	0.028*	0.617±	1.011
10000 ppm	30	27.3± 5.3**	0.011±	0.002**	0.043±	0.040	0.152±	0.016*	0.253±	0.151	0.490±	0.524
20000 ppm	13	25.2± 4.1**	0.010±	0.002**	0.088±	0.216	0.145±	0.025**	0.210±	0.043	0.373±	0.082**

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

Test of Dunnett

(ICL040)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

PAGE : 4

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	23	0.202±	0.196	1.499±	0.341	0.463±	0.014
5000 ppm	27	0.197±	0.244	1.567±	0.413	0.466±	0.018
10000 ppm	30	0.283±	0.631	2.645±	0.954**	0.458±	0.020
20000 ppm	13	0.214±	0.221	6.056±	4.245**	0.436±	0.021**

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

Test of Dunnett

(HCL040)

BAIS 4

APPENDIX J 1

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : MALE

(2-YEAR STUDY)

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	36	45.8± 8.0	0.026± 0.009	0.492± 0.111	0.532± 0.207	0.590± 0.299	1.463± 0.874
5000 ppm	35	45.2± 7.5	0.023± 0.006	0.498± 0.099	0.513± 0.112	0.597± 0.177	1.385± 0.524
10000 ppm	27	34.7± 4.7**	0.029± 0.008	0.590± 0.126**	0.573± 0.081*	0.742± 0.188**	1.580± 0.168**
20000 ppm	16	27.3± 2.8**	0.035± 0.007**	0.743± 0.101**	0.617± 0.063**	0.839± 0.120**	1.676± 0.187**

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

Test of Dunnett

(HCL042)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE : 2

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	36	0.375± 0.933	4.529± 2.425	1.010± 0.224
5000 ppm	35	0.575± 1.141	5.251± 2.298	1.024± 0.178
10000 ppm	27	0.301± 0.357	7.575± 7.066**	1.324± 0.176**
20000 ppm	16	0.525± 0.454**	20.673± 7.440**	1.607± 0.126**

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

Test of Dunnett

(IICL042)

BAIS 4

APPENDIX J 2

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: %

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

PAGE : 3

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	23	35.8± 6.2	0.036± 0.007	0.167± 0.188	0.493± 0.102	0.642± 0.314	1.170± 0.190
5000 ppm	27	32.6± 5.1	0.039± 0.010	0.956± 3.824	0.541± 0.094	0.718± 0.103*	1.875± 2.845*
10000 ppm	30	27.3± 5.3**	0.041± 0.007	0.160± 0.146	0.570± 0.086**	0.963± 0.702**	1.885± 2.336**
20000 ppm	13	25.2± 4.1**	0.039± 0.009	0.373± 0.925	0.580± 0.061*	0.850± 0.206**	1.478± 0.160**

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

Test of Dunnett

(HCL042)

BAIS 4

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE : 4

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	23	0.600± 0.683	4.268± 1.135	1.330± 0.237
5000 ppm	27	0.607± 0.732	4.867± 1.219	1.467± 0.245
10000 ppm	30	1.017± 2.225	9.909± 3.902**	1.713± 0.204**
20000 ppm	13	0.792± 0.720	22.727±10.532**	1.775± 0.283**

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL042)

BAIS 4

APPENDIX K 1

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : MALE : ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

		Group Name	Control				5000 ppm				10000 ppm				20000 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ	Findings		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appandage}																		
skin/app			<50>				<50>				<50>				<50>			
	inflammation		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia:epidermis		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
subcutis			<50>				<50>				<50>				<50>			
	inflammation		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	xanthogranuloma		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
{Respiratory system}																		
nasal cavit			<50>				<50>				<50>				<50>			
	mineralization		3	0	0	0	6	0	0	0	5	0	0	0	1	0	0	0
			(6)	(0)	(0)	(0)	(12)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	eosinophilic change:olfactory epithelium		10	1	0	0	15	1	1	0	14	2	0	0	17	0	0	0
			(20)	(2)	(0)	(0)	(30)	(2)	(2)	(0)	(28)	(4)	(0)	(0)	(34)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				5000 ppm 50				10000 ppm 50				20000 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Respiratory system)																		
nasal cavit	eosinophilic change:respiratory epithelium		12 (24)	1 (2)	0 (0)	0 (0)	20 (40)	4 (8)	0 (0)	0 (0)	19 (38)	7 (14)	0 (0)	0 * (0)	29 (58)	10 (20)	0 (0)	0 ** (0)
	inflammation:foreign body		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 metaplasia:olfactory epithelium		6 (12)	0 (0)	0 (0)	0 (0)	10 (20)	0 (0)	0 (0)	0 (0)	4 (8)	0 (0)	0 (0)	0 (0)	4 (8)	0 (0)	0 (0)	0 (0)
	respiratory metaplasia:gland		9 (18)	0 (0)	0 (0)	0 (0)	6 (12)	1 (2)	0 (0)	0 (0)	8 (16)	0 (0)	0 (0)	0 (0)	3 (6)	0 (0)	0 (0)	0 (0)
	atrophy:olfactory epithelium		0 (0)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)	3 (6)	3 (6)	0 (0)	0 * (0)	1 (2)	0 (0)	0 (0)	0 (0)
	necrosis:olfactory epithelium		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)
lung	hemorrhage		0 (0)	2 (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)
	interstitial pneumonia		1 (2)	1 (2)	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)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				5000 ppm 50				10000 ppm 50				20000 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
lung			<50>				<50>				<50>				<50>			
	bronchopneumonia		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	bronchiolar-alveolar cell hyperplasia		3	0	0	0	44	3	0	0 **	40	2	0	0 **	36	5	0	0 **
			(6)	(0)	(0)	(0)	(88)	(6)	(0)	(0)	(80)	(4)	(0)	(0)	(72)	(10)	(0)	(0)
{Hematopoietic system}																		
bone marrow			<50>				<50>				<50>				<50>			
	erythropoiesis:increased		0	0	0	0	3	0	0	0	6	0	0	0 *	14	0	0	0 **
			(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(12)	(0)	(0)	(0)	(28)	(0)	(0)	(0)
	granulopoiesis:increased		3	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
			(6)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
lymph node			<50>				<50>				<50>				<50>			
	follicular hyperplasia		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
spleen			<50>				<50>				<50>				<50>			
	atrophy		2	0	0	0	1	0	0	0	5	0	0	0	3	0	0	0
			(4)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(6)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				5000 ppm 50				10000 ppm 50				20000 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																		
spleen			<50>				<50>				<50>				<50>			
	deposit of hemosiderin		0	0	0	0	0	0	0	0	8	0	0	0 **	13	1	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(16)	(0)	(0)	(0)	(26)	(2)	(0)	(0)
	deposit of melanin		1	0	0	0	1	0	0	0	1	1	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	granulation		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	extramedullary hematopoiesis		9	4	3	0	4	6	6	0	4	4	5	0	5	6	19	2 **
			(18)	(8)	(6)	(0)	(8)	(12)	(12)	(0)	(8)	(8)	(10)	(0)	(10)	(12)	(38)	(4)
	follicular hyperplasia		3	0	0	0	4	1	0	0	1	0	0	0	0	0	0	0
			(6)	(0)	(0)	(0)	(8)	(2)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Circulatory system}																		
heart			<50>				<50>				<50>				<50>			
	thrombus		0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	necrosis:focal		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 5

		Group Name	Control				5000 ppm				10000 ppm				20000 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ	Findings		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Circulatory system}																		
heart			<50>				<50>				<50>				<50>			
	mineralization		4	0	0	0	5	0	0	0	5	0	0	0	7	1	0	0
			(8)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(14)	(2)	(0)	(0)
	inflammatory cell nest		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	myocardial fibrosis		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	arteritis		2	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Digestive system}																		
tooth			<50>				<50>				<50>				<50>			
	dysplasia		8	10	8	0	26	11	2	0 **	18	13	6	0	23	5	1	0 **
			(16)	(20)	(16)	(0)	(52)	(22)	(4)	(0)	(36)	(26)	(12)	(0)	(46)	(10)	(2)	(0)
	odontogenic cyst		0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)
tongue			<50>				<50>				<50>				<50>			
	arteritis		2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 6

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				5000 ppm 50				10000 ppm 50				20000 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
stomach			<50>				<50>				<50>				<50>			
	hyperplasia:forestomach		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	erosion:glandular stomach		0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia:glandular stomach		35	4	0	0	39	5	0	0	33	4	0	0	32	7	0	0
			(70)	(8)	(0)	(0)	(78)	(10)	(0)	(0)	(66)	(8)	(0)	(0)	(64)	(14)	(0)	(0)
liver			<50>				<50>				<50>				<50>			
	angiectasis		2	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	thrombus		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(2)	(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	0	4	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(8)	(0)	(0)
	necrosis:focal		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	necrosis:single cell		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 7

Organ	Findings	Group Name No. of Animals on Study				Control 50				5000 ppm 50				10000 ppm 50				20000 ppm 50			
		Grade																			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Digestive system)																					
liver		<50>				<50>				<50>				<50>				<50>			
	fatty change	1 (2)	2 (4)	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)	0 (0)	0 (0)	0 (0)	0 (0)
	fatty change:central	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)	1 (2)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)
	granulation	13 (26)	0 (0)	0 (0)	0 (0)	15 (30)	0 (0)	0 (0)	0 (0)	6 (12)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 ** (0)
	extramedullary hematopoiesis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	5 (10)	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)	2 (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)
	acidophilic cell focus	5 (10)	2 (4)	0 (0)	0 (0)	5 (10)	2 (4)	1 (2)	0 (0)	3 (6)	3 (6)	0 (0)	0 (0)	9 (18)	4 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	basophilic cell focus	1 (2)	1 (2)	0 (0)	0 (0)	4 (8)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	vacuolated cell focus	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 8

Organ	Findings	Group Name	Control				5000 ppm				10000 ppm				20000 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver	hepatocellular hypertrophy:central		<50>				<50>				<50>				<50>			
		0	0	0	0	0	15	0	0 **	0	34	1	0 **	0	35	0	0 **	
		(0)	(0)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(68)	(2)	(0)	(0)	(70)	(0)	(0)	
	nuclear atypia:central		0	0	0	0	0	0	0	11	2	0	0 **	17	21	0	0 **	
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(22)	(4)	(0)	(0)	(34)	(42)	(0)	(0)	
gall bladd	hyperplasia		<49>				<50>				<50>				<50>			
		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
pancreas	islet cell hyperplasia		<50>				<50>				<50>				<50>			
		2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
{Urinary system}																		
kidney	cyst		<50>				<50>				<50>				<50>			
		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	
		(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
	hyaline droplet		1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	
		(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	
Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe																		
< a >		a : Number of animals examined at the site																
b		b : Number of animals with lesion																
(c)		c : b / a * 100																
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : AI
SEX : MALE

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

PAGE : 9

Organ	Findings	Group Name No. of Animals on Study Grade	Control				5000 ppm				10000 ppm				20000 ppm			
			50				50				50				50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Urinary system)																		
kidney			<50>				<50>				<50>				<50>			
	basophilic change		16 (32)	1 (2)	0 (0)	0 (0)	20 (40)	0 (0)	0 (0)	0 (0)	14 (28)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 ** (0)
	deposit of hemosiderin		0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	2 (4)	1 (2)	0 (0)	0 (0)	2 (4)	7 (14)	0 ** (0)	2 (4)	4 (8)	17 (34)	2 ** (4)
	lymphocytic infiltration		5 (10)	0 (0)	1 (2)	0 (0)	7 (14)	0 (0)	0 (0)	0 (0)	3 (6)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)
	inflammatory polyp		0 (0)	1 (2)	1 (2)	0 (0)	1 (2)	0 (0)	1 (2)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	hydronephrosis		0 (0)	0 (0)	3 (6)	1 (2)	1 (2)	0 (0)	3 (6)	0 (0)	0 (0)	1 (2)	0 (0)	2 (4)	0 (0)	0 (0)	2 (4)	0 (0)
urin bladd	mineralization: papilla		0 (0)	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)
	inflammation		<49>				<50>				<50>				<50>			
			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)	0 (0)	0 (0)	0 (0)
	lymphocytic infiltration		1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 10

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				5000 ppm 50				10000 ppm 50				20000 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
urethra	inflammation		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)
{Endocrine system}																		
pituitary	angiectasis		<50>				<50>				<50>				<49>			
			0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	cyst		6	0	0	0	3	0	0	0	3	0	0	0	4	0	0	0
			(12)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(8)	(0)	(0)	(0)
	hyperplasia		3	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0
			(6)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	Rathke pouch		2	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
thyroid	focal follicular cell hyperplasia		<50>				<49>				<50>				<50>			
			1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 11

Organ_____	Findings_____	Group Name	Control				5000 ppm				10000 ppm				20000 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
adrenal			<50>				<49>				<50>				<50>			
	spindle-cell hyperplasia		24	7	0	0	29	8	0	0	25	8	0	0	27	1	0	0
			(48)	(14)	(0)	(0)	(59)	(16)	(0)	(0)	(50)	(16)	(0)	(0)	(54)	(2)	(0)	(0)
	hyperplasia:cortical cell		2	0	0	0	3	0	0	0	2	0	0	0	1	0	0	0
			(4)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	focal hypertrophy:cortex		0	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Reproductive system}																		
testis			<50>				<50>				<50>				<50>			
	mineralization		27	18	2	0	32	9	4	0	23	3	0	0 **	5	0	0	0 **
			(54)	(36)	(4)	(0)	(64)	(18)	(8)	(0)	(46)	(6)	(0)	(0)	(10)	(0)	(0)	(0)
epididymis			<50>				<50>				<49>				<50>			
	spermatogenic granuloma		0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	xanthogranuloma		1	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 12

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				5000 ppm 50				10000 ppm 50				20000 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
semin ves	hemorrhage		<50>				<50>				<50>				<50>			
			0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammation		0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(2)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
prostate	inflammation		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
prep/cli gl	duct ectasia		<49>				<50>				<50>				<50>			
			0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(8)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Nervous system}																		
brain	mineralization		<50>				<50>				<50>				<50>			
			24	0	0	0	20	0	0	0	21	0	0	0	25	0	0	0
			(48)	(0)	(0)	(0)	(40)	(0)	(0)	(0)	(42)	(0)	(0)	(0)	(50)	(0)	(0)	(0)
{Special sense organs/appendage}																		
Harder gl	lymphocytic infiltration		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 13

Organ	Findings	Group Name No. of Animals on Study Grade	Control				5000 ppm				10000 ppm				20000 ppm			
			50				50				50				50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Special sense organs/appendage)																		
Harder gl	hyperplasia		<50>				<50>				<50>				<50>			
			1	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
(Musculoskeletal system)																		
muscle	mineralization		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

BAIS4

(HPT150)

APPENDIX K 2

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : FEMALE : ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 14

Organ	Findings	Group Name	Control				5000 ppm				10000 ppm				20000 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appandage}																		
skin/app			<50>				<50>				<50>				<50>			
	inflammation		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	scab		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
subcutis			<50>				<50>				<50>				<50>			
	inflammation		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Respiratory system}																		
nasal cavit			<50>				<50>				<50>				<50>			
	mineralization		0	0	0	0	2	0	0	0	3	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	eosinophilic change:olfactory epithelium		4	0	0	0	7	3	0	0	15	2	0	0 **	26	2	0	0 **
			(8)	(0)	(0)	(0)	(14)	(6)	(0)	(0)	(30)	(4)	(0)	(0)	(52)	(4)	(0)	(0)
	eosinophilic change:respiratory epithelium		26	6	0	0	30	13	1	1 *	29	13	0	0 *	20	24	1	0 **
			(52)	(12)	(0)	(0)	(60)	(26)	(2)	(2)	(58)	(26)	(0)	(0)	(40)	(48)	(2)	(0)
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																	
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
(c)	c : b / a * 100																	
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 15

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				5000 ppm 50				10000 ppm 50				20000 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavity	respiratory metaplasia:olfactory epithelium		<50>				<50>				<50>				<50>			
			3	0	0	0	3	0	0	0	4	0	0	0	1	0	0	0
			(6)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(8)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	respiratory metaplasia:gland		6	0	0	0	4	0	0	0	6	0	0	0	15	0	0	0 *
			(12)	(0)	(0)	(0)	(8)	(0)	(0)	(0)	(12)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
	atrophy:olfactory epithelium		0	0	0	0	1	1	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
nasopharynx	eosinophilic change:respiratory epithelium		<50>				<50>				<50>				<50>			
			3	0	0	0	5	0	3	1	7	3	1	0	11	0	0	0 *
			(6)	(0)	(0)	(0)	(10)	(0)	(6)	(2)	(14)	(6)	(2)	(0)	(22)	(0)	(0)	(0)
lung	hemorrhage		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory infiltration		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	interstitial pneumonia		0	0	0	0	3	0	0	0	3	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(2)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 16

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				5000 ppm 50				10000 ppm 50				20000 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
lung			<50>				<50>				<50>				<50>			
	bronchiolar-alveolar cell hyperplasia		0	0	0	0	40	2	0	0 **	40	0	0	0 **	41	2	0	0 **
			(0)	(0)	(0)	(0)	(80)	(4)	(0)	(0)	(80)	(0)	(0)	(0)	(82)	(4)	(0)	(0)
{Hematopoietic system}																		
bone marrow			<50>				<50>				<50>				<50>			
	myelofibrosis		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	erythropoiesis:increased		2	0	0	0	0	0	0	0	2	0	0	0	17	0	0	0 **
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(34)	(0)	(0)	(0)
	granulopoiesis:increased		1	0	0	0	3	0	0	0	2	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
spleen			<50>				<50>				<50>				<50>			
	deposit of hemosiderin		3	0	0	0	13	0	0	0 *	22	0	0	0 **	13	0	0	0 *
			(6)	(0)	(0)	(0)	(26)	(0)	(0)	(0)	(44)	(0)	(0)	(0)	(26)	(0)	(0)	(0)
	extramedullary hematopoiesis		5	6	9	0	8	1	4	0	11	5	3	1	9	3	29	0 **
			(10)	(12)	(18)	(0)	(16)	(2)	(8)	(0)	(22)	(10)	(6)	(2)	(18)	(6)	(58)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 17

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				5000 ppm 50				10000 ppm 50				20000 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Hematopoietic system}

spleen			<50>				<50>				<50>				<50>			
	follicular hyperplasia		0	1	0	0	2	0	0	0	0	0	0	0	0	0	0	0
			(0)	(2)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

{Circulatory system}

heart			<50>				<50>				<50>				<50>			
	thrombus		0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(2)	(0)	(0)	(0)	(0)	(0)
	mineralization		4	0	0	0	3	0	0	0	6	1	0	0	13	1	0	0 *
			(8)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(12)	(2)	(0)	(0)	(26)	(2)	(0)	(0)
	arteritis		1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

{Digestive system}

tooth			<50>				<50>				<50>				<50>			
	inflammation		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 18

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				5000 ppm 50				10000 ppm 50				20000 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
tooth	dysplasia		<50>				<50>				<50>				<50>			
			20	2	1	1	27	3	1	1	22	6	2	0	21	6	2	0
			(40)	(4)	(2)	(2)	(54)	(6)	(2)	(2)	(44)	(12)	(4)	(0)	(42)	(12)	(4)	(0)
	odontogenic cyst		0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)
tongue	arteritis		<50>				<50>				<50>				<50>			
			1	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(2)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
stomach	erosion:glandular stomach		<50>				<50>				<50>				<50>			
			1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia:glandular stomach		44	1	0	0	37	2	0	0	39	1	0	0	40	0	0	0
			(88)	(2)	(0)	(0)	(74)	(4)	(0)	(0)	(78)	(2)	(0)	(0)	(80)	(0)	(0)	(0)
liver	angiectasis		<50>				<50>				<50>				<50>			
			1	2	0	0	1	1	0	0	0	1	0	0	0	0	0	0
			(2)	(4)	(0)	(0)	(2)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	necrosis:focal		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																	
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
(c)	c : b / a * 100																	
Significant difference ;	* : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																	

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 19

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				5000 ppm 50				10000 ppm 50				20000 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver																		
	fatty change:central		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	inflammatory infiltration		1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	granulation		10	2	1	0	15	0	0	0	10	0	0	0	4	0	0	0
			(20)	(4)	(2)	(0)	(30)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(8)	(0)	(0)	(0)
	extramedullary hematopoiesis		0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	clear cell focus		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	acidophilic cell focus		2	0	0	0	4	0	0	0	9	0	0	0	7	0	0	0
			(4)	(0)	(0)	(0)	(8)	(0)	(0)	(0)	(18)	(0)	(0)	(0)	(14)	(0)	(0)	(0)
	basophilic cell focus		1	0	0	0	1	1	0	0	2	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(2)	(2)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	vacuolated cell focus		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 20

Organ_____	Findings_____	Group Name	Control				5000 ppm				10000 ppm				20000 ppm				
		No. of Animals on Study	50				50				50				50				
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
<hr/>																			
{Digestive system}																			
liver			<50>				<50>				<50>				<50>				
	hepatocellular hypertrophy:central		0	0	0	0	0	0	0	0	0	1	0	0	0	0	9	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(18)	(0)	(0)
	nuclear atypia:central		0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	
gall bladd			<50>				<50>				<50>				<50>				
	hyperplasia		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Urinary system}																			
kidney			<50>				<50>				<50>				<50>				
	cyst		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyaline droplet		1	0	6	3	1	1	6	3	1	1	5	2	0	0	5	1	1
			(2)	(0)	(12)	(6)	(2)	(2)	(12)	(6)	(2)	(2)	(10)	(4)	(0)	(0)	(10)	(2)	(2)
	basophilic change		0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 21

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				5000 ppm 50				10000 ppm 50				20000 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney			<50>				<50>				<50>				<50>			
	deposit of hemosiderin		0	0	0	0	1	0	0	0	1	1	2	0	0	5	24	5 **
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(2)	(4)	(0)	(0)	(10)	(48)	(10)
	lymphocytic infiltration		3	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
			(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory polyp		0	0	0	0	0	3	0	0	1	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(6)	(0)	(0)	(2)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	extramedullary hematopoiesis		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	hydronephrosis		0	0	1	1	0	2	3	1	0	2	2	0	0	0	0	0
			(0)	(0)	(2)	(2)	(0)	(4)	(6)	(2)	(0)	(4)	(4)	(0)	(0)	(0)	(0)	(0)
	mineralization:papilla		0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
urin bladd			<49>				<50>				<50>				<50>			
	lymphocytic infiltration		1	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
			(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
{Endocrine system}																		
pituitary			<49>				<50>				<50>				<50>			
	angiectasis		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0-105#)

PAGE : 22

Organ_____	Findings_____	Group Name	Control				5000 ppm				10000 ppm				20000 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
pituitary			<49>				<50>				<50>				<50>			
	hemorrhage		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	cyst		3	0	0	0	5	0	0	0	4	0	0	0	2	0	0	0
			(6)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(8)	(0)	(0)	(0)	(4)	(0)	(0)	(0)
	hyperplasia		4	2	0	0	3	1	0	0	4	0	0	0	2	1	0	0
			(8)	(4)	(0)	(0)	(6)	(2)	(0)	(0)	(8)	(0)	(0)	(0)	(4)	(2)	(0)	(0)
	Rathke pouch		0	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
thyroid			<50>				<50>				<50>				<50>			
	focal follicular cell hyperplasia		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
adrenal			<50>				<50>				<50>				<50>			
	spindle-cell hyperplasia		5	43	2	0	4	40	6	0	1	41	4	0	21	28	0	0 **
			(10)	(86)	(4)	(0)	(8)	(80)	(12)	(0)	(2)	(82)	(8)	(0)	(42)	(56)	(0)	(0)
	hyperplasia:cortical cell		2	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 23

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				5000 ppm 50				10000 ppm 50				20000 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
adrenal			<50>				<50>				<50>				<50>			
	focal fatty change:cortex		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Reproductive system}																		
ovary			<50>				<50>				<50>				<50>			
	thrombus		0	0	0	0	0	1	0	0	0	0	0	0	0	0	3	0
			(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(6)	(0)
	cyst		2	0	3	2	2	2	7	0	0	1	2	1	0	0	0	0
			(4)	(0)	(6)	(4)	(4)	(4)	(14)	(0)	(0)	(2)	(4)	(2)	(0)	(0)	(0)	(0)
uterus			<50>				<50>				<50>				<50>			
	cystic endometrial hyperplasia		10	10	1	0	8	12	4	0	11	10	7	0	8	5	2	0
			(20)	(20)	(2)	(0)	(16)	(24)	(8)	(0)	(22)	(20)	(14)	(0)	(16)	(10)	(4)	(0)
{Nervous system}																		
brain			<50>				<50>				<50>				<50>			
	mineralization		18	0	0	0	18	0	0	0	18	0	0	0	15	0	0	0
			(36)	(0)	(0)	(0)	(36)	(0)	(0)	(0)	(36)	(0)	(0)	(0)	(30)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 24

		Group Name	Control				5000 ppm				10000 ppm				20000 ppm			
		No. of Animals on Study	50				50				50				50			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Nervous system}																		
brain			<50>				<50>				<50>				<50>			
	epidermal cyst		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
{Special sense organs/appendage}																		
Harder gl			<50>				<50>				<50>				<50>			
	hyperplasia		0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Musculoskeletal system}																		
muscle			<50>				<50>				<50>				<50>			
	mineralization		0	0	0	0	0	0	0	0	1	1	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(2)	(0)	(0)	(2)	(0)	(0)	(0)
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																	
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
(c)	c : b / a * 100																	
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

(HPT150)

BAIS4

APPENDIX K 3

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : MALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name No. of Animals on Study Grade	Control 36				5000 ppm 35				10000 ppm 27				20000 ppm 16			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appandage}																		
skin/app			<36>				<35>				<27>				<16>			
	inflammation		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia:epidermis		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Respiratory system}																		
nasal cavit			<36>				<35>				<27>				<16>			
	mineralization		3	0	0	0	4	0	0	0	3	0	0	0	1	0	0	0
			(8)	(0)	(0)	(0)	(11)	(0)	(0)	(0)	(11)	(0)	(0)	(0)	(6)	(0)	(0)	(0)
	eosinophilic change:olfactory epithelium		8	1	0	0	15	0	0	0	7	2	0	0	5	0	0	0
			(22)	(3)	(0)	(0)	(43)	(0)	(0)	(0)	(26)	(7)	(0)	(0)	(31)	(0)	(0)	(0)
	eosinophilic change:respiratory epithelium		8	1	0	0	15	2	0	0	10	4	0	0	11	5	0	0 **
			(22)	(3)	(0)	(0)	(43)	(6)	(0)	(0)	(37)	(15)	(0)	(0)	(69)	(31)	(0)	(0)
	inflammation:foreign body		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)
	respiratory metaplasia:olfactory epithelium		4	0	0	0	8	0	0	0	2	0	0	0	2	0	0	0
			(11)	(0)	(0)	(0)	(23)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(13)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

		Group Name	Control				5000 ppm				10000 ppm				20000 ppm			
		No. of Animals on Study	36				35				27				16			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ	Findings		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit			<36>				<35>				<27>				<16>			
	respiratory metaplasia:gland		6	0	0	0	3	1	0	0	3	0	0	0	2	0	0	0
			(17)	(0)	(0)	(0)	(9)	(3)	(0)	(0)	(11)	(0)	(0)	(0)	(13)	(0)	(0)	(0)
	atrophy:olfactory epithelium		0	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(7)	(0)	(0)	(0)	(0)	(0)	(0)
	necrosis:olfactory epithelium		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
lung			<36>				<35>				<27>				<16>			
	hemorrhage		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	interstitial pneumonia		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	bronchiolar-alveolar cell hyperplasia		3	0	0	0	32	3	0	0 **	26	1	0	0 **	13	2	0	0 **
			(8)	(0)	(0)	(0)	(91)	(9)	(0)	(0)	(96)	(4)	(0)	(0)	(81)	(13)	(0)	(0)
{Hematopoietic system}																		
bone marrow			<36>				<35>				<27>				<16>			
	erythropoiesis:increased		0	0	0	0	1	0	0	0	3	0	0	0	4	0	0	0 *
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(11)	(0)	(0)	(0)	(25)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study Grade	Control 36				5000 ppm 35				10000 ppm 27				20000 ppm 16			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																		
bone marrow	granulopoiesis:increased		<36>				<35>				<27>				<16>			
			2	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(6)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
lymph node	follicular hyperplasia		<36>				<35>				<27>				<16>			
			1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
spleen	atrophy		<36>				<35>				<27>				<16>			
			0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	deposit of hemosiderin		<36>				<35>				<27>				<16>			
			0	0	0	0	0	0	0	0	7	0	0	0	5	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(26)	(0)	(0)	(0)	(31)	(0)	(0)	(0)
	deposit of melanin		<36>				<35>				<27>				<16>			
			1	0	0	0	1	0	0	0	1	1	0	0	0	0	0	0
			(3)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(4)	(4)	(0)	(0)	(0)	(0)	(0)	(0)
	granulation		<36>				<35>				<27>				<16>			
			0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)
	extramedullary hematopoiesis		<36>				<35>				<27>				<16>			
			7	1	1	0	2	3	0	0	1	1	1	0	5	1	3	0
			(19)	(3)	(3)	(0)	(6)	(9)	(0)	(0)	(4)	(4)	(4)	(0)	(31)	(6)	(19)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study Grade	Control 36				5000 ppm 35				10000 ppm 27				20000 ppm 16			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																		
spleen			<36>				<35>				<27>				<16>			
	follicular hyperplasia		3	0	0	0	4	1	0	0	1	0	0	0	0	0	0	0
			(8)	(0)	(0)	(0)	(11)	(3)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Circulatory system}																		
heart			<36>				<35>				<27>				<16>			
	thrombus		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	necrosis:focal		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	mineralization		1	0	0	0	2	0	0	0	1	0	0	0	1	0	0	0
			(3)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(6)	(0)	(0)	(0)
	arteritis		2	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Digestive system}																		
tooth			<36>				<35>				<27>				<16>			
	dysplasia		6	8	6	0	20	10	1	0 **	11	11	2	0 **	11	0	1	0 **
			(17)	(22)	(17)	(0)	(57)	(29)	(3)	(0)	(41)	(41)	(7)	(0)	(69)	(0)	(6)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 5

Organ	Findings	Group Name	Control				5000 ppm				10000 ppm				20000 ppm				
		No. of Animals on Study	36				35				27				16				
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
{Digestive system}																			
tooth	odontogenic cyst		<36>				<35>				<27>				<16>				
		0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	
tongue	arteritis		<36>				<35>				<27>				<16>				
		2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
stomach	hyperplasia:forestomach		<36>				<35>				<27>				<16>				
		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	
		(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
	erosion:glandular stomach		0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia:glandular stomach		29	4	0	0	27	5	0	0	20	3	0	0	11	3	0	0	
		(81)	(11)	(0)	(0)	(77)	(14)	(0)	(0)	(74)	(11)	(0)	(0)	(69)	(19)	(0)	(0)	(0)	
liver	angiectasis		<36>				<35>				<27>				<16>				
		2	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	
		(6)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
	thrombus		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 6

		Control				5000 ppm				10000 ppm				20000 ppm			
		36				35				27				16			
Group Name	No. of Animals on Study																
Grade		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ	Findings	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>																	
(Digestive system)																	
liver		<36>				<35>				<27>				<16>			
	necrosis:central	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(6)	(0)	(0)
	fatty change	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	fatty change:central	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)
	granulation	13	0	0	0	15	0	0	0	6	1	0	0	0	0	0	0 *
		(36)	(0)	(0)	(0)	(43)	(0)	(0)	(0)	(22)	(4)	(0)	(0)	(0)	(0)	(0)	(0)
	extramedullary hematopoiesis	0	0	0	0	0	0	0	0	1	0	0	0	2	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(13)	(0)	(0)	(0)
	clear cell focus	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	acidophilic cell focus	5	2	0	0	5	1	0	0	2	2	0	0	5	2	0	0
		(14)	(6)	(0)	(0)	(14)	(3)	(0)	(0)	(7)	(7)	(0)	(0)	(31)	(13)	(0)	(0)
	basophilic cell focus	1	1	0	0	3	0	0	0	0	0	0	0	0	0	0	0
		(3)	(3)	(0)	(0)	(9)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 7

Organ	Findings	Group Name No. of Animals on Study Grade	Control 36				5000 ppm 35				10000 ppm 27				20000 ppm 16			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver			<36>				<35>				<27>				<16>			
	vacuolated cell focus		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hepatocellular hypertrophy:central		0	0	0	0	0	14	0	0 **	0	22	0	0 **	0	13	0	0 **
			(0)	(0)	(0)	(0)	(0)	(40)	(0)	(0)	(0)	(81)	(0)	(0)	(0)	(81)	(0)	(0)
	nuclear atypia:central		0	0	0	0	0	0	0	0	8	0	0	0 **	8	6	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(50)	(38)	(0)	(0)
gall bladd			<36>				<35>				<27>				<16>			
	hyperplasia		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
pancreas			<36>				<35>				<27>				<16>			
	islet cell hyperplasia		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Urinary system}																		
kidney			<36>				<35>				<27>				<16>			
	basophilic change		16	1	0	0	20	0	0	0	12	0	0	0	1	0	0	0 *
			(44)	(3)	(0)	(0)	(57)	(0)	(0)	(0)	(44)	(0)	(0)	(0)	(6)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 8

Organ	Findings	Group Name No. of Animals on Study Grade	Control 36				5000 ppm 35				10000 ppm 27				20000 ppm 16			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Urinary system)																		
kidney			<36>				<35>				<27>				<16>			
	deposit of hemosiderin		0	0	0	0	1	0	1	0	0	0	2	0	0	1	4	1 **
			(0)	(0)	(0)	(0)	(3)	(0)	(3)	(0)	(0)	(0)	(7)	(0)	(0)	(6)	(25)	(6)
	lymphocytic infiltration		5	0	1	0	6	0	0	0	3	0	0	0	2	0	0	0
			(14)	(0)	(3)	(0)	(17)	(0)	(0)	(0)	(11)	(0)	(0)	(0)	(13)	(0)	(0)	(0)
	inflammatory polyp		0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hydronephrosis		0	0	2	0	0	0	1	0	0	0	0	0	0	0	1	0
			(0)	(0)	(6)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(6)	(0)
	mineralization:papilla		0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)
urin bladd			<36>				<35>				<27>				<16>			
	inflammation		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	lymphocytic infiltration		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
(Endocrine system)																		
pituitary			<36>				<35>				<27>				<16>			
	cyst		5	0	0	0	3	0	0	0	1	0	0	0	1	0	0	0
			(14)	(0)	(0)	(0)	(9)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(6)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 9

		Group Name No. of Animals on Study Grade	Control 36				5000 ppm 35				10000 ppm 27				20000 ppm 16			
Organ	Findings		1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
{Endocrine system}																		
pituitary			<36>				<35>				<27>				<16>			
	hyperplasia		2 (6)	0 (0)	0 (0)	0 (0)	2 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Rathke pouch		2 (6)	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)
thyroid			<36>				<35>				<27>				<16>			
	focal follicular cell 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)
adrenal			<36>				<34>				<27>				<16>			
	spindle-cell hyperplasia		18 (50)	7 (19)	0 (0)	0 (0)	19 (56)	8 (24)	0 (0)	0 (0)	14 (52)	7 (26)	0 (0)	0 (0)	11 (69)	1 (6)	0 (0)	0 (0)
	hyperplasia:cortical cell		2 (6)	0 (0)	0 (0)	0 (0)	2 (6)	0 (0)	0 (0)	0 (0)	2 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	focal hypertrophy:cortex		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)
{Reproductive system}																		
testis			<36>				<35>				<27>				<16>			
	mineralization		18 (50)	16 (44)	1 (3)	0 (0)	22 (63)	6 (17)	4 (11)	0 (0)	15 (56)	2 (7)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 10

Organ_____	Findings_____	Group Name	Control				5000 ppm				10000 ppm				20000 ppm			
		No. of Animals on Study	36				35				27				16			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
epididymis			<36>				<35>				<27>				<16>			
	spermatogenic granuloma		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	xanthogranuloma		1	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
			(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
semin ves			<36>				<35>				<27>				<16>			
	hemorrhage		0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammation		0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(3)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
prep/cli gl			<35>				<35>				<27>				<16>			
	duct ectasia		0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(11)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Nervous system}																		
brain			<36>				<35>				<27>				<16>			
	mineralization		17	0	0	0	14	0	0	0	13	0	0	0	7	0	0	0
			(47)	(0)	(0)	(0)	(40)	(0)	(0)	(0)	(48)	(0)	(0)	(0)	(44)	(0)	(0)	(0)
Grade	1 : Slight	2 : Moderate	3 : Marked	4 : Severe														
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
(c)	c : b / a * 100																	
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

STUDY NO. : 0402
 ANIMAL : MOUSE Grj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 11

Organ	Findings	Group Name No. of Animals on Study Grade	Control 36				5000 ppm 35				10000 ppm 27				20000 ppm 16			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Special sense organs/appendage}

Harder gl	lymphocytic infiltration	<36>				<35>				<27>				<16>			
		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)
	hyperplasia	1	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
		(3)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

(HPT150)

BAIS4

APPENDIX K 4

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : FEMALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 12

Organ	Findings	Group Name No. of Animals on Study Grade	Control 23				5000 ppm 27				10000 ppm 30				20000 ppm 13			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appandage}																		
skin/app			<23>				<27>				<30>				<13>			
	inflammation		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	scab		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Respiratory system}																		
nasal cavit			<23>				<27>				<30>				<13>			
	mineralization		0	0	0	0	2	0	0	0	2	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	eosinophilic change:olfactory epithelium		2	0	0	0	6	0	0	0	10	1	0	0	7	1	0	0 **
			(9)	(0)	(0)	(0)	(22)	(0)	(0)	(0)	(33)	(3)	(0)	(0)	(54)	(8)	(0)	(0)
	eosinophilic change:respiratory epithelium		12	2	0	0	17	7	1	0 *	18	11	0	0 **	4	9	0	0 **
			(52)	(9)	(0)	(0)	(63)	(26)	(4)	(0)	(60)	(37)	(0)	(0)	(31)	(69)	(0)	(0)
	respiratory metaplasia:olfactory epithelium		1	0	0	0	2	0	0	0	4	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(13)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	respiratory metaplasia:gland		4	0	0	0	2	0	0	0	3	0	0	0	5	0	0	0
			(17)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(38)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 13

Organ	Findings	Group Name No. of Animals on Study Grade	Control 23				5000 ppm 27				10000 ppm 30				20000 ppm 13			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit	atrophy:olfactory epithelium		<23>				<27>				<30>				<13>			
			0	0	0	0	1	1	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(4)	(4)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)
nasopharynx	eosinophilic change:respiratory epithelium		<23>				<27>				<30>				<13>			
			1	0	0	0	2	0	2	0	3	1	1	0	4	0	0	0
			(4)	(0)	(0)	(0)	(7)	(0)	(7)	(0)	(10)	(3)	(3)	(0)	(31)	(0)	(0)	(0)
lung	inflammatory infiltration		<23>				<27>				<30>				<13>			
			0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)
	interstitial pneumonia		<23>				<27>				<30>				<13>			
			0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	bronchiolar-alveolar cell hyperplasia		<23>				<27>				<30>				<13>			
			0	0	0	0	25	2	0	0 **	28	0	0	0 **	12	0	0	0 **
			(0)	(0)	(0)	(0)	(93)	(7)	(0)	(0)	(93)	(0)	(0)	(0)	(92)	(0)	(0)	(0)
{Hematopoietic system}																		
bone marrow	myelofibrosis		<23>				<27>				<30>				<13>			
			0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 14

		Group Name	Control				5000 ppm				10000 ppm				20000 ppm			
		No. of Animals on Study	23				27				30				13			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ	Findings		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>																		
{Hematopoietic system}																		
bone marrow			<23>				<27>				<30>				<13>			
	erythropoiesis:increased		1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (23)	0 (0)	0 (0)	0 (0)
	granulopoiesis:increased		0 (0)	0 (0)	0 (0)	0 (0)	2 (7)	0 (0)	0 (0)	0 (0)	2 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
spleen			<23>				<27>				<30>				<13>			
	deposit of hemosiderin		3 (13)	0 (0)	0 (0)	0 (0)	12 (44)	0 (0)	0 (0)	0 * (0)	20 (67)	0 (0)	0 (0)	0 ** (0)	9 (69)	0 (0)	0 (0)	0 ** (0)
	extramedullary hematopoiesis		5 (22)	1 (4)	0 (0)	0 (0)	5 (19)	1 (4)	1 (4)	0 (0)	9 (30)	2 (7)	0 (0)	0 (0)	6 (46)	1 (8)	3 (23)	0 * (0)
	follicular hyperplasia		0 (0)	1 (4)	0 (0)	0 (0)	2 (7)	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			<23>				<27>				<30>				<13>			
	mineralization		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 (23)	0 (0)	0 (0)	0 (0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : AI
 SEX : FEMALE

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

PAGE : 15

Organ	Findings	Group Name No. of Animals on Study Grade	Control 23				5000 ppm 27				10000 ppm 30				20000 ppm 13			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Circulatory system}																		
heart	arteritis		<23>				<27>				<30>				<13>			
			0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Digestive system}																		
tooth	inflammation		<23>				<27>				<30>				<13>			
			0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	dysplasia		12	1	0	0	16	3	0	1	14	6	2	0	6	2	0	0
			(52)	(4)	(0)	(0)	(59)	(11)	(0)	(4)	(47)	(20)	(7)	(0)	(46)	(15)	(0)	(0)
	odontogenic cyst		0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)
tongue	arteritis		<23>				<27>				<30>				<13>			
			1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
stomach	erosion:glandular stomach		<23>				<27>				<30>				<13>			
			0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (105%)

PAGE : 16

Organ	Findings	Group Name No. of Animals on Study Grade	Control 23				5000 ppm 27				10000 ppm 30				20000 ppm 13			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
stomach	hyperplasia:glandular stomach		<23>				<27>				<30>				<13>			
			22	1	0	0	23	2	0	0	27	1	0	0	13	0	0	0
			(96)	(4)	(0)	(0)	(85)	(7)	(0)	(0)	(90)	(3)	(0)	(0)	(100)	(0)	(0)	(0)
liver	angiectasis		<23>				<27>				<30>				<13>			
			1	2	0	0	1	0	0	0	0	1	0	0	0	0	0	0
			(4)	(9)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory infiltration		0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(3)	(0)	(0)	(0)	(0)	(0)	(0)
	granulation		10	2	1	0	15	0	0	0	10	0	0	0	4	0	0	0
			(43)	(9)	(4)	(0)	(56)	(0)	(0)	(0)	(33)	(0)	(0)	(0)	(31)	(0)	(0)	(0)
	acidophilic cell focus		1	0	0	0	4	0	0	0	8	0	0	0	3	0	0	0
			(4)	(0)	(0)	(0)	(15)	(0)	(0)	(0)	(27)	(0)	(0)	(0)	(23)	(0)	(0)	(0)
	basophilic cell focus		1	0	0	0	1	1	0	0	2	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(4)	(4)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hepatocellular hypertrophy:central		0	0	0	0	0	0	0	0	0	1	0	0	0	5	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(38)	(0)	(0)
gall bladd	hyperplasia		<23>				<27>				<30>				<13>			
			1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 17

Organ	Findings	Group Name No. of Animals on Study Grade	Control 23				5000 ppm 27				10000 ppm 30				20000 ppm 13			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Urinary system)																		
kidney			<23>				<27>				<30>				<13>			
	cyst		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyaline droplet		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)
	deposit of hemosiderin		0	0	0	0	0	0	0	0	0	1	1	0	0	2	2	1 *
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(3)	(0)	(0)	(15)	(15)	(8)
	lymphocytic infiltration		3	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
			(13)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory polyp		0	0	0	0	0	2	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)
	hydronephrosis		0	0	1	0	0	0	2	1	0	1	0	0	0	0	0	0
			(0)	(0)	(4)	(0)	(0)	(0)	(7)	(4)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)
	mineralization:papilla		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
urin bladd			<23>				<27>				<30>				<13>			
	lymphocytic infiltration		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 18

Organ	Findings	Group Name No. of Animals on Study Grade	Control 23				5000 ppm 27				10000 ppm 30				20000 ppm 13			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Endocrine system)																		
pituitary			<23>				<27>				<30>				<13>			
	angiectasis		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)
	cyst		3	0	0	0	4	0	0	0	3	0	0	0	0	0	0	0
			(13)	(0)	(0)	(0)	(15)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia		3	1	0	0	1	1	0	0	3	0	0	0	1	1	0	0
			(13)	(4)	(0)	(0)	(4)	(4)	(0)	(0)	(10)	(0)	(0)	(0)	(8)	(8)	(0)	(0)
	Rathke pouch		0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
thyroid			<23>				<27>				<30>				<13>			
	focal follicular cell hyperplasia		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
adrenal			<23>				<27>				<30>				<13>			
	spindle-cell hyperplasia		0	21	2	0	1	21	5	0	1	23	4	0	4	9	0	0 *
			(0)	(91)	(9)	(0)	(4)	(78)	(19)	(0)	(3)	(77)	(13)	(0)	(31)	(69)	(0)	(0)
	hyperplasia:cortical cell		2	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(9)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 19

Organ	Findings	Group Name No. of Animals on Study Grade	Control 23				5000 ppm 27				10000 ppm 30				20000 ppm 13			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
adrenal	focal fatty change:cortex		<23>				<27>				<30>				<13>			
			0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Reproductive system}																		
ovary	cyst		<23>				<27>				<30>				<13>			
			1	0	1	2	2	2	5	0	0	1	2	1	0	0	0	0
			(4)	(0)	(4)	(9)	(7)	(7)	(19)	(0)	(0)	(3)	(7)	(3)	(0)	(0)	(0)	(0)
uterus	cystic endometrial hyperplasia		<23>				<27>				<30>				<13>			
			5	9	1	0	7	9	4	0	9	9	5	0	6	1	1	0
			(22)	(39)	(4)	(0)	(26)	(33)	(15)	(0)	(30)	(30)	(17)	(0)	(46)	(8)	(8)	(0)
{Nervous system}																		
brain	mineralization		<23>				<27>				<30>				<13>			
			10	0	0	0	11	0	0	0	14	0	0	0	4	0	0	0
			(43)	(0)	(0)	(0)	(41)	(0)	(0)	(0)	(47)	(0)	(0)	(0)	(31)	(0)	(0)	(0)
	epidermal cyst		<23>				<27>				<30>				<13>			
			0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)
Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe																		
< a > a : Number of animals examined at the site																		
b b : Number of animals with lesion																		
(c) c : b / a * 100																		
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 20

Organ	Findings	Group Name No. of Animals on Study Grade				Control 23				5000 ppm 27				10000 ppm 30				20000 ppm 13			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Special sense organs/appendage}

Harder gl		<23>				<27>				<30>				<13>			
	hyperplasia	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

(HPT150)

BATS4

APPENDIX K 5

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : MALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 1

		Group Name	Control				5000 ppm				10000 ppm				20000 ppm			
		No. of Animals on Study	14				15				23				34			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ_____	Findings_____		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>																		
{Integumentary system/appandage}																		
subcutis			<14>				<15>				<23>				<34>			
	inflammation		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	xanthogranuloma		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)
{Respiratory system}																		
nasal cavit			<14>				<15>				<23>				<34>			
	mineralization		0	0	0	0	2	0	0	0	2	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(13)	(0)	(0)	(0)	(9)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	eosinophilic change:olfactory epithelium		2	0	0	0	0	1	1	0	7	0	0	0	12	0	0	0
			(14)	(0)	(0)	(0)	(0)	(7)	(7)	(0)	(30)	(0)	(0)	(0)	(35)	(0)	(0)	(0)
	eosinophilic change:respiratory epithelium		4	0	0	0	5	2	0	0	9	3	0	0	18	5	0	0 *
			(29)	(0)	(0)	(0)	(33)	(13)	(0)	(0)	(39)	(13)	(0)	(0)	(53)	(15)	(0)	(0)
	respiratory metaplasia:olfactory epithelium		2	0	0	0	2	0	0	0	2	0	0	0	2	0	0	0
			(14)	(0)	(0)	(0)	(13)	(0)	(0)	(0)	(9)	(0)	(0)	(0)	(6)	(0)	(0)	(0)
	respiratory metaplasia:gland		3	0	0	0	3	0	0	0	5	0	0	0	1	0	0	0
			(21)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(22)	(0)	(0)	(0)	(3)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

		Group Name	Control				5000 ppm				10000 ppm				20000 ppm			
		No. of Animals on Study	14				15				23				34			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ_____	Findings_____		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>																		
{Respiratory system}																		
nasal cavit			<14>				<15>				<23>				<34>			
	atrophy:olfactory epithelium		0	0	0	0	2	0	0	0	2	1	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(13)	(0)	(0)	(0)	(9)	(4)	(0)	(0)	(3)	(0)	(0)	(0)
lung			<14>				<15>				<23>				<34>			
	hemorrhage		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	interstitial pneumonia		0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(7)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	bronchopneumonia		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	bronchiolar-alveolar cell hyperplasia		0	0	0	0	12	0	0	0	14	1	0	0	23	3	0	0
			(0)	(0)	(0)	(0)	(80)	(0)	(0)	(0)	(61)	(4)	(0)	(0)	(68)	(9)	(0)	(0)
<hr/>																		
{Hematopoietic system}																		
bone marrow			<14>				<15>				<23>				<34>			
	erythropoiesis:increased		0	0	0	0	2	0	0	0	3	0	0	0	10	0	0	0
			(0)	(0)	(0)	(0)	(13)	(0)	(0)	(0)	(13)	(0)	(0)	(0)	(29)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 3

		Group Name	Control				5000 ppm				10000 ppm				20000 ppm			
		No. of Animals on Study	14				15				23				34			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Hematopoietic system)																		
bone marrow			<14>				<15>				<23>				<34>			
	granulopoiesis:increased		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(7)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
spleen			<14>				<15>				<23>				<34>			
	atrophy		2	0	0	0	1	0	0	0	4	0	0	0	3	0	0	0
			(14)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(17)	(0)	(0)	(0)	(9)	(0)	(0)	(0)
	deposit of hemosiderin		0	0	0	0	0	0	0	0	1	0	0	0	8	1	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(24)	(3)	(0)	(0)
	extramedullary hematopoiesis		2	3	2	0	2	3	6	0	3	3	4	0	0	5	16	2 *
			(14)	(21)	(14)	(0)	(13)	(20)	(40)	(0)	(13)	(13)	(17)	(0)	(0)	(15)	(47)	(6)
(Circulatory system)																		
heart			<14>				<15>				<23>				<34>			
	thrombus		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	mineralization		3	0	0	0	3	0	0	0	4	0	0	0	6	1	0	0
			(21)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(17)	(0)	(0)	(0)	(18)	(3)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE CrJ-BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study Grade	Control 14				5000 ppm 15				10000 ppm 23				20000 ppm 34			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Circulatory system}																		
heart	inflammatory cell nest		<14>				<15>				<23>				<34>			
			0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	myocardial fibrosis		<14>				<15>				<23>				<34>			
			0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Digestive system}																		
tooth	dysplasia		<14>				<15>				<23>				<34>			
			2	2	2	0	6	1	1	0	7	2	4	0	12	5	0	0
			(14)	(14)	(14)	(0)	(40)	(7)	(7)	(0)	(30)	(9)	(17)	(0)	(35)	(15)	(0)	(0)
stomach	hyperplasia:glandular stomach		<14>				<15>				<23>				<34>			
			6	0	0	0	12	0	0	0	13	1	0	0	21	4	0	0
			(43)	(0)	(0)	(0)	(80)	(0)	(0)	(0)	(57)	(4)	(0)	(0)	(62)	(12)	(0)	(0)
liver	necrosis:central		<14>				<15>				<23>				<34>			
			0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(9)	(0)	(0)
	necrosis:focal		<14>				<15>				<23>				<34>			
			1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(7)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 5

Organ	Findings	Group Name No. of Animals on Study Grade	Control 14				5000 ppm 15				10000 ppm 23				20000 ppm 34			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver			<14>				<15>				<23>				<34>			
	necrosis:single cell		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)
	fatty change		1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0 *
			(7)	(14)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	fatty change:central		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)
	extramedullary hematopoiesis		0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(9)	(0)	(0)	(0)
	acidophilic cell focus		0	0	0	0	0	1	1	0	1	1	0	0	4	2	0	0
			(0)	(0)	(0)	(0)	(0)	(7)	(7)	(0)	(4)	(4)	(0)	(0)	(12)	(6)	(0)	(0)
	basophilic cell focus		0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(7)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hepatocellular hypertrophy:central		0	0	0	0	0	1	0	0	0	12	1	0 **	0	22	0	0 **
			(0)	(0)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(52)	(4)	(0)	(0)	(65)	(0)	(0)
	nuclear atypia:central		0	0	0	0	0	0	0	0	3	2	0	0	9	15	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(13)	(9)	(0)	(0)	(26)	(44)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 6

Organ	Findings	Group Name No. of Animals on Study Grade	Control 14				5000 ppm 15				10000 ppm 23				20000 ppm 34			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Digestive system)																		
pancreas	islet cell hyperplasia		<14>				<15>				<23>				<34>			
			1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
(Urinary system)																		
kidney	cyst		<14>				<15>				<23>				<34>			
			0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyaline droplet		1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
			(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)
	basophilic change		0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(9)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	deposit of hemosiderin		0	0	0	0	0	2	0	0	0	2	5	0	2	3	13	1 *
			(0)	(0)	(0)	(0)	(0)	(13)	(0)	(0)	(0)	(9)	(22)	(0)	(6)	(9)	(38)	(3)
	lymphocytic infiltration		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory polyp		0	1	0	0	1	0	1	0	0	1	0	0	0	0	0	0
			(0)	(7)	(0)	(0)	(7)	(0)	(7)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 7

		Group Name	Control				5000 ppm				10000 ppm				20000 ppm			
		No. of Animals on Study	14				15				23				34			
Organ_____	Findings_____	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney			<14>				<15>				<23>				<34>			
	hydronephrosis		0	0	1	1	1	0	2	0	0	1	0	2	0	0	1	0
		(0)	(0)	(7)	(7)	(7)	(0)	(13)	(0)	(0)	(4)	(0)	(9)	(0)	(0)	(3)	(0)	
urethra			<14>				<15>				<23>				<34>			
	inflammation		0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)
{Endocrine system}																		
pituitary			<14>				<15>				<23>				<33>			
	angiectasis		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
			<14>				<15>				<23>				<34>			
	cyst		1	0	0	0	0	0	0	0	2	0	0	0	3	0	0	0
		(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(9)	(0)	(0)	(0)	(9)	(0)	(0)	(0)	
			<14>				<15>				<23>				<34>			
	hyperplasia		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		(7)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
adrenal			<14>				<15>				<23>				<34>			
	spindle-cell hyperplasia		6	0	0	0	10	0	0	0	11	1	0	0	16	0	0	0
		(43)	(0)	(0)	(0)	(67)	(0)	(0)	(0)	(48)	(4)	(0)	(0)	(47)	(0)	(0)	(0)	

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : AI
 SEX : MALE

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

PAGE : 8

Organ	Findings	Group Name No. of Animals on Study Grade	Control 14				5000 ppm 15				10000 ppm 23				20000 ppm 34			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
adrenal	hyperplasia:cortical cell		<14>				<15>				<23>				<34>			
			0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)
	focal hypertrophy:cortex		<14>				<15>				<23>				<34>			
			0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Reproductive system}																		
testis	mineralization		<14>				<15>				<23>				<34>			
			9	2	1	0	10	3	0	0	8	1	0	0 *	4	0	0	0 **
			(64)	(14)	(7)	(0)	(67)	(20)	(0)	(0)	(35)	(4)	(0)	(0)	(12)	(0)	(0)	(0)
epididymis	spermatogenic granuloma		<14>				<15>				<22>				<34>			
			0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
prostate	inflammation		<14>				<15>				<23>				<34>			
			0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)
{Nervous system}																		
brain	mineralization		<14>				<15>				<23>				<34>			
			7	0	0	0	6	0	0	0	8	0	0	0	18	0	0	0
			(50)	(0)	(0)	(0)	(40)	(0)	(0)	(0)	(35)	(0)	(0)	(0)	(53)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 9

Organ_____	Findings_____	Group Name				Control				5000 ppm				10000 ppm				20000 ppm			
		No. of Animals on Study				14				15				23				34			
		Grade																			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4				
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)			

{Special sense organs/appendage}

Harder gl	hyperplasia	<14>				<15>				<23>				<34>			
		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

{Musculoskeletal system}

muscle	mineralization	<14>				<15>				<23>				<34>			
		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

(HPT150)

BAIS4

APPENDIX K 6

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : FEMALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 10

Organ	Findings	Group Name No. of Animals on Study Grade	Control 27				5000 ppm 23				10000 ppm 20				20000 ppm 37			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appandage}																		
subcutis			<27>				<23>				<20>				<37>			
	inflammation		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Respiratory system}																		
nasal cavit			<27>				<23>				<20>				<37>			
	mineralization		0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(3)	(0)	(0)	(0)
	eosinophilic change:olfactory epithelium		2	0	0	0	1	3	0	0	5	1	0	0	19	1	0	0 **
			(7)	(0)	(0)	(0)	(4)	(13)	(0)	(0)	(25)	(5)	(0)	(0)	(51)	(3)	(0)	(0)
	eosinophilic change:respiratory epithelium		14	4	0	0	13	6	0	1	11	2	0	0	16	15	1	0
			(52)	(15)	(0)	(0)	(57)	(26)	(0)	(4)	(55)	(10)	(0)	(0)	(43)	(41)	(3)	(0)
	respiratory metaplasia:olfactory epithelium		2	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
			(7)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)
	respiratory metaplasia:gland		2	0	0	0	2	0	0	0	3	0	0	0	10	0	0	0
			(7)	(0)	(0)	(0)	(9)	(0)	(0)	(0)	(15)	(0)	(0)	(0)	(27)	(0)	(0)	(0)
nasopharynx			<27>				<23>				<20>				<37>			
	eosinophilic change:respiratory epithelium		2	0	0	0	3	0	1	1	4	2	0	0	7	0	0	0
			(7)	(0)	(0)	(0)	(13)	(0)	(4)	(4)	(20)	(10)	(0)	(0)	(19)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : AI
SEX : FEMALE

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

PAGE : 11

Organ	Findings	Group Name No. of Animals on Study Grade	Control 27				5000 ppm 23				10000 ppm 20				20000 ppm 37			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
lung	hemorrhage		<27>				<23>				<20>				<37>			
			0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(0)	(0)	(0)
	interstitial pneumonia		0	0	0	0	2	0	0	0	2	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(9)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(3)	(0)	(0)	(0)
	bronchiolar-alveolar cell hyperplasia		0	0	0	0	15	0	0	0 **	12	0	0	0 **	29	2	0	0 **
			(0)	(0)	(0)	(0)	(65)	(0)	(0)	(0)	(60)	(0)	(0)	(0)	(78)	(5)	(0)	(0)
{Hematopoietic system}																		
bone marrow	erythropoiesis:increased		<27>				<23>				<20>				<37>			
			1	0	0	0	0	0	0	0	2	0	0	0	14	0	0	0 **
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(38)	(0)	(0)	(0)
	granulopoiesis:increased		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
spleen	deposit of hemosiderin		<27>				<23>				<20>				<37>			
			0	0	0	0	1	0	0	0	2	0	0	0	4	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(11)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 12

Organ	Findings	Group Name No. of Animals on Study Grade	Control 27				5000 ppm 23				10000 ppm 20				20000 ppm 37			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																		
spleen			<27>				<23>				<20>				<37>			
	extramedullary hematopoiesis		0	5	9	0	3	0	3	0 *	2	3	3	1	3	2	26	0 **
			(0)	(19)	(33)	(0)	(13)	(0)	(13)	(0)	(10)	(15)	(15)	(5)	(8)	(5)	(70)	(0)
{Circulatory system}																		
heart			<27>				<23>				<20>				<37>			
	thrombus		0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(5)	(0)	(5)	(0)	(0)	(0)	(0)	(0)
	mineralization		4	0	0	0	3	0	0	0	5	1	0	0	10	1	0	0
			(15)	(0)	(0)	(0)	(13)	(0)	(0)	(0)	(25)	(5)	(0)	(0)	(27)	(3)	(0)	(0)
	arteritis		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Digestive system}																		
tooth			<27>				<23>				<20>				<37>			
	dysplasia		8	1	1	1	11	0	1	0	8	0	0	0	15	4	2	0
			(30)	(4)	(4)	(4)	(48)	(0)	(4)	(0)	(40)	(0)	(0)	(0)	(41)	(11)	(5)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 13

Organ	Findings	Group Name No. of Animals on Study Grade	Control 27				5000 ppm 23				10000 ppm 20				20000 ppm 37			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
tongue	arteritis		<27>				<23>				<20>				<37>			
			0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
stomach	erosion:glandular stomach		<27>				<23>				<20>				<37>			
			1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia:glandular stomach		<27>				<23>				<20>				<37>			
			22	0	0	0	14	0	0	0	12	0	0	0	27	0	0	0
			(81)	(0)	(0)	(0)	(61)	(0)	(0)	(0)	(60)	(0)	(0)	(0)	(73)	(0)	(0)	(0)
liver	angiectasis		<27>				<23>				<20>				<37>			
			0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	necrosis:focal		<27>				<23>				<20>				<37>			
			1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	fatty change:central		<27>				<23>				<20>				<37>			
			0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)
	inflammatory infiltration		<27>				<23>				<20>				<37>			
			1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 14

Organ	Findings	Group Name No. of Animals on Study Grade	Control 27				5000 ppm 23				10000 ppm 20				20000 ppm 37			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Digestive system}

liver			<27>				<23>				<20>				<37>			
	extramedullary hematopoiesis		0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(3)	(0)	(0)	(0)
	clear cell focus		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	acidophilic cell focus		1	0	0	0	0	0	0	0	1	0	0	0	4	0	0	0
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(11)	(0)	(0)	(0)
	vacuolated cell focus		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)
	hepatocellular hypertrophy:central		0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(11)	(0)	(0)
	nuclear atypia:central		0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(3)	(0)	(0)	(0)

{Urinary system}

kidney			<27>				<23>				<20>				<37>			
	hyaline droplet		1	0	6	3	1	1	6	3	1	0	5	2	0	0	5	1
			(4)	(0)	(22)	(11)	(4)	(4)	(26)	(13)	(5)	(0)	(25)	(10)	(0)	(0)	(14)	(3)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 15

Organ	Findings	Group Name No. of Animals on Study Grade	Control 27				5000 ppm 23				10000 ppm 20				20000 ppm 37			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney			<27>				<23>				<20>				<37>			
	basophilic change		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)
	deposit of hemosiderin		0	0	0	0	1	0	0	0	1	0	1	0	0	3	22	4 **
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(5)	(0)	(5)	(0)	(0)	(8)	(59)	(11)
	inflammatory polyp		0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(5)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
urin bladd	extramedullary hematopoiesis		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(0)	(0)	(0)
	hydronephrosis		0	0	0	1	0	2	1	0	0	1	2	0	0	0	0	0
			(0)	(0)	(0)	(4)	(0)	(9)	(4)	(0)	(0)	(5)	(10)	(0)	(0)	(0)	(0)	(0)
	mineralization:papilla		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)
pituitary	lymphocytic infiltration		<26>				<23>				<20>				<37>			
			0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)
hemorrhage			<26>				<23>				<20>				<37>			
			0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 16

Organ	Findings	Group Name No. of Animals on Study Grade	Control 27				5000 ppm 23				10000 ppm 20				20000 ppm 37			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
pituitary			<26>				<23>				<20>				<37>			
	cyst		0	0	0	0	1	0	0	0	1	0	0	0	2	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(5)	(0)	(0)	(0)
	hyperplasia		1	1	0	0	2	0	0	0	1	0	0	0	1	0	0	0
			(4)	(4)	(0)	(0)	(9)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(3)	(0)	(0)	(0)
	Rathke pouch		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
adrenal			<27>				<23>				<20>				<37>			
	spindle-cell hyperplasia		5	22	0	0	3	19	1	0	0	18	0	0 *	17	19	0	0 *
			(19)	(81)	(0)	(0)	(13)	(83)	(4)	(0)	(0)	(90)	(0)	(0)	(46)	(51)	(0)	(0)
	hyperplasia:cortical cell		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Reproductive system}																		
ovary			<27>				<23>				<20>				<37>			
	thrombus		0	0	0	0	0	1	0	0	0	0	0	0	0	0	3	0
			(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(8)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0-105#)

PAGE : 17

Organ	Findings	Group Name No. of Animals on Study Grade	Control 27				5000 ppm 23				10000 ppm 20				20000 ppm 37			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
ovary	cyst		<27>				<23>				<20>				<37>			
			1	0	2	0	0	0	2	0	0	0	0	0	0	0	0	0
			(4)	(0)	(7)	(0)	(0)	(0)	(9)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
uterus	cystic endometrial hyperplasia		<27>				<23>				<20>				<37>			
			5	1	0	0	1	3	0	0	2	1	2	0	2	4	1	0
			(19)	(4)	(0)	(0)	(4)	(13)	(0)	(0)	(10)	(5)	(10)	(0)	(5)	(11)	(3)	(0)
{Nervous system}																		
brain	mineralization		<27>				<23>				<20>				<37>			
			8	0	0	0	7	0	0	0	4	0	0	0	11	0	0	0
			(30)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
{Musculoskeletal system}																		
muscle	mineralization		<27>				<23>				<20>				<37>			
			0	0	0	0	0	0	0	0	1	1	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(5)	(5)	(0)	(0)	(3)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

APPENDIX L 1

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

MOUSE : MALE

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

Time related Weeks	Items	Group Name	Control	5000 ppm	10000 ppm	20000 ppm
0 - 52	NO. OF EXAMINED ANIMALS		0	0	5	3
	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	3	3	8
	NO. OF ANIMALS WITH TUMORS		1	2	3	7
	NO. OF ANIMALS WITH SINGLE TUMORS		0	2	1	2
	NO. OF ANIMALS WITH MULTIPLE TUMORS		1	0	2	5
	NO. OF BENIGN TUMORS		1	0	1	1
	NO. OF MALIGNANT TUMORS		1	2	4	12
	NO. OF TOTAL TUMORS		2	2	5	13
79 - 104	NO. OF EXAMINED ANIMALS		10	12	15	23
	NO. OF ANIMALS WITH TUMORS		9	11	13	23
	NO. OF ANIMALS WITH SINGLE TUMORS		6	4	4	3
	NO. OF ANIMALS WITH MULTIPLE TUMORS		3	7	9	20
	NO. OF BENIGN TUMORS		4	6	7	3
	NO. OF MALIGNANT TUMORS		9	16	18	44
	NO. OF TOTAL TUMORS		13	22	25	47
105 - 105	NO. OF EXAMINED ANIMALS		36	35	27	16
	NO. OF ANIMALS WITH TUMORS		30	27	25	16
	NO. OF ANIMALS WITH SINGLE TUMORS		11	11	9	2
	NO. OF ANIMALS WITH MULTIPLE TUMORS		19	16	16	14
	NO. OF BENIGN TUMORS		30	19	17	5
	NO. OF MALIGNANT TUMORS		29	27	31	32
	NO. OF TOTAL TUMORS		59	46	48	37

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

Time-related Weeks	Items	Group Name	Control	5000 ppm	10000 ppm	20000 ppm
0 - 105	NO. OF EXAMINED ANIMALS		50	50	50	50
	NO. OF ANIMALS WITH TUMORS		40	40	42	46
	NO. OF ANIMALS WITH SINGLE TUMORS		17	17	15	7
	NO. OF ANIMALS WITH MULTIPLE TUMORS		23	23	27	39
	NO. OF BENIGN TUMORS		35	25	25	9
	NO. OF MALIGNANT TUMORS		39	45	54	88
	NO. OF TOTAL TUMORS		74	70	79	97

(HPT070)

BATS4

APPENDIX L 2

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

MOUSE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 3

Time-related Weeks	Items	Group Name	Control	5000 ppm	10000 ppm	20000 ppm
0 - 52	NO. OF EXAMINED ANIMALS		1	1	0	1
	NO. OF ANIMALS WITH TUMORS		1	1	0	1
	NO. OF ANIMALS WITH SINGLE TUMORS		1	1	0	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0
	NO. OF BENIGN TUMORS		0	0	0	0
	NO. OF MALIGNANT TUMORS		1	1	0	1
	NO. OF TOTAL TUMORS		1	1	0	1
53 - 78	NO. OF EXAMINED ANIMALS		9	3	1	10
	NO. OF ANIMALS WITH TUMORS		9	3	1	10
	NO. OF ANIMALS WITH SINGLE TUMORS		7	3	1	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		2	0	0	10
	NO. OF BENIGN TUMORS		2	0	0	3
	NO. OF MALIGNANT TUMORS		9	3	1	19
	NO. OF TOTAL TUMORS		11	3	1	22
79 - 104	NO. OF EXAMINED ANIMALS		17	19	19	26
	NO. OF ANIMALS WITH TUMORS		15	19	18	26
	NO. OF ANIMALS WITH SINGLE TUMORS		11	11	3	2
	NO. OF ANIMALS WITH MULTIPLE TUMORS		4	8	15	24
	NO. OF BENIGN TUMORS		3	8	8	2
	NO. OF MALIGNANT TUMORS		16	23	30	57
	NO. OF TOTAL TUMORS		19	31	38	59
105 - 105	NO. OF EXAMINED ANIMALS		23	27	30	13
	NO. OF ANIMALS WITH TUMORS		22	24	30	13
	NO. OF ANIMALS WITH SINGLE TUMORS		9	7	6	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		13	17	24	13
	NO. OF BENIGN TUMORS		23	26	17	5
	NO. OF MALIGNANT TUMORS		20	27	56	27
	NO. OF TOTAL TUMORS		43	53	73	32

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 4

Time-related Weeks	Items	Group Name	Control	5000 ppm	10000 ppm	20000 ppm
0 - 105	NO. OF EXAMINED ANIMALS		50	50	50	50
	NO. OF ANIMALS WITH TUMORS		47	47	49	50
	NO. OF ANIMALS WITH SINGLE TUMORS		28	22	10	3
	NO. OF ANIMALS WITH MULTIPLE TUMORS		19	25	39	47
	NO. OF BENIGN TUMORS		28	34	25	10
	NO. OF MALIGNANT TUMORS		46	54	87	104
	NO. OF TOTAL TUMORS		74	88	112	114
(HPT070)						BAIS4

APPENDIX M 1

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS : SUMMARY

MOUSE : MALE

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name No. of animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
(Integumentary system/appandage)						
subcutis			<50>	<50>	<50>	<50>
	lipoma		1 (2%)	0 (0%)	0 (0%)	0 (0%)
	leiomyosarcoma		0 (0%)	1 (2%)	0 (0%)	0 (0%)
	histiocytic sarcoma		0 (0%)	0 (0%)	1 (2%)	1 (2%)
	hemangiosarcoma		1 (2%)	0 (0%)	0 (0%)	0 (0%)
(Respiratory system)						
lung			<50>	<50>	<50>	<50>
	bronchiolar-alveolar adenoma		6 (12%)	2 (4%)	1 (2%)	1 (2%)
	bronchiolar-alveolar carcinoma		3 (6%)	1 (2%)	2 (4%)	1 (2%)
(Hematopoietic system)						
bone marrow			<50>	<50>	<50>	<50>
	hemangioma		0 (0%)	0 (0%)	0 (0%)	1 (2%)
lymph node			<50>	<50>	<50>	<50>
	malignant lymphoma		8 (16%)	13 (26%)	6 (12%)	3 (6%)
spleen			<50>	<50>	<50>	<50>
	hemangioma		4 (8%)	1 (2%)	0 (0%)	0 (0%)
	malignant lymphoma		0 (0%)	2 (4%)	0 (0%)	2 (4%)
	mastcytoma:malignant		0 (0%)	0 (0%)	6 (12%)	0 (0%)

< a > a : Number of animals examined at the site
 b (c) b : Number of animals with neoplasm c : b / a * 100

(HPT085)

BAIS4

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDf1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name No. of animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
(Hematopoietic system)						
spleen	hemangiosarcoma		<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)
(Digestive system)						
salivary gl	histiocytic sarcoma		<50> 2 (4%)	<50> 0 (0%)	<50> 2 (4%)	<50> 0 (0%)
stomach	squamous cell papilloma		<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)	<50> 1 (2%)
liver	hemangioma		<50> 7 (14%)	<50> 2 (4%)	<50> 1 (2%)	<50> 0 (0%)
	hepatocellular adenoma		12 (24%)	17 (34%)	18 (36%)	3 (6%)
	histiocytic sarcoma		2 (4%)	0 (0%)	0 (0%)	1 (2%)
	mastcytoma:malignant		0 (0%)	1 (2%)	0 (0%)	0 (0%)
	hemangiosarcoma		1 (2%)	1 (2%)	0 (0%)	0 (0%)
	hepatocellular carcinoma		16 (32%)	11 (22%)	14 (28%)	39 (78%)
	hepatoblastoma		1 (2%)	12 (24%)	18 (36%)	38 (76%)
pancreas	islet cell adenoma		<50> 1 (2%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)
(Urinary system)						
kidney	renal cell carcinoma		<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)

< a > a : Number of animals examined at the site
 b (c) b : Number of animals with neoplasm c : b / a * 100

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDf1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 3

Organ_____	Findings_____	Group Name No. of animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
{Urinary system}						
urin bladd	histiocytic sarcoma		<49> 0 (0%)	<50> 1 (2%)	<50> 1 (2%)	<50> 0 (0%)
{Endocrine system}						
adrenal	cortical adenoma		<50> 0 (0%)	<49> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)
{Reproductive system}						
epididymis	histiocytic sarcoma		<50> 3 (6%)	<50> 1 (2%)	<49> 1 (2%)	<50> 1 (2%)
prep/cli gl	histiocytic sarcoma		<49> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
{Nervous system}						
brain	meningioma:malignant		<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
periph nerv	histiocytic sarcoma		<50> 0 (0%)	<50> 0 (0%)	<50> 2 (4%)	<50> 0 (0%)
{Special sense organs/appendage}						
Harder gl	adenoma		<50> 3 (6%)	<50> 2 (4%)	<50> 3 (6%)	<50> 2 (4%)
{Musculoskeletal system}						
muscle	histiocytic sarcoma		<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
< a > a : Number of animals examined at the site b (c) b : Number of animals with neoplasm c : b / a * 100						

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 4

Organ	Findings	Group Name No. of animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
{Musculoskeletal system}						
bone	hemangioma		<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
{Body cavities}						
peritoneum	hemangiosarcoma		<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
adipose	hemangioma		<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)

< a > a : Number of animals examined at the site
b (c) b : Number of animals with neoplasm c : b / a * 100

(HPT085)

BAIS4

APPENDIX M 2

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS : SUMMARY

MOUSE : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 5

Organ_____	Findings_____	Group Name No. of animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
{Integumentary system/appandage}						
skin/app	squamous cell papilloma		<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
	squamous cell carcinoma		0 (0%)	0 (0%)	1 (2%)	0 (0%)
subcutis	lipoma		<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
	hemangioma		0 (0%)	1 (2%)	0 (0%)	0 (0%)
	fibrosarcoma		1 (2%)	0 (0%)	0 (0%)	0 (0%)
	schwannoma:malignant		0 (0%)	0 (0%)	0 (0%)	1 (2%)
	hemangiosarcoma		0 (0%)	0 (0%)	1 (2%)	0 (0%)
{Respiratory system}						
lung	bronchiolar-alveolar adenoma		<50> 2 (4%)	<50> 2 (4%)	<50> 3 (6%)	<50> 1 (2%)
	bronchiolar-alveolar carcinoma		0 (0%)	0 (0%)	2 (4%)	0 (0%)
{Hematopoietic system}						
bone marrow	hemangioma		<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
lymph node	malignant lymphoma		<50> 16 (32%)	<50> 16 (32%)	<50> 14 (28%)	<50> 3 (6%)

< a > a : Number of animals examined at the site
 b (c) b : Number of animals with neoplasm c : b / a * 100

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 6

Organ	Findings	Group Name No. of animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
{Hematopoietic system}						
spleen	hemangioma		<50> 1 (2%)	<50> 1 (2%)	<50> 1 (2%)	<50> 0 (0%)
	malignant lymphoma		7 (14%)	7 (14%)	4 (8%)	1 (2%)
	hemangiosarcoma		1 (2%)	0 (0%)	0 (0%)	0 (0%)
{Digestive system}						
stomach	squamous cell papilloma		<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)
liver	hemangioma		<50> 3 (6%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)
	hepatocellular adenoma		5 (10%)	18 (36%)	13 (26%)	4 (8%)
	histiocytic sarcoma		1 (2%)	0 (0%)	0 (0%)	3 (6%)
	hepatocellular carcinoma		2 (4%)	12 (24%)	41 (82%)	46 (92%)
	hepatoblastoma		0 (0%)	0 (0%)	8 (16%)	38 (76%)
{Endocrine system}						
pituitary	adenoma		<49> 3 (6%)	<50> 7 (14%)	<50> 5 (10%)	<50> 0 (0%)
{Reproductive system}						
ovary	cystadenoma		<50> 2 (4%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)

< a > a : Number of animals examined at the site
 b (c) b : Number of animals with neoplasm c : b / a * 100

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDP1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 7

Organ	Findings	Group Name No. of animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
{Reproductive system}						
ovary	hemangioma		<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 2 (4%)
	granulosa-theca cell tumor		1 (2%)	0 (0%)	0 (0%)	0 (0%)
	histiocytic sarcoma		1 (2%)	1 (2%)	0 (0%)	0 (0%)
uterus	endometrial stromal polyp		<50> 5 (10%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)
	histiocytic sarcoma		15 (30%)	16 (32%)	15 (30%)	12 (24%)
mammary gl	adenocarcinoma		<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)
{Special sense organs/appendage}						
Harder gl	adenoma		<50> 3 (6%)	<50> 1 (2%)	<50> 2 (4%)	<50> 3 (6%)
{Musculoskeletal system}						
muscle	hemangioma		<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)
	leiomyosarcoma		0 (0%)	0 (0%)	1 (2%)	0 (0%)
	hemangiosarcoma		1 (2%)	0 (0%)	0 (0%)	0 (0%)
bone	osteosarcoma		<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)

< a > a : Number of animals examined at the site
 b (c) b : Number of animals with neoplasm c : b / a * 100

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 8

Organ	Findings	Group Name No. of animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
{Body cavities}						
peritoneum	histiocytic sarcoma		<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)

< a > a : Number of animals examined at the site
b (c) b : Number of animals with neoplasm c : b / a * 100

(IPT085)

BAIS4

APPENDIX N 1

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS,

MOUSE : MALE

(2-YEAR STUDY)

STUDY No. : 0402
 ANIMAL : MOUSE Crj:BDF1
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 1

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : ALL SITE TUMOR : hemangioma				
Tumor rate				
Overall rates(a)	9/50(18.0)	2/50(4.0)	1/50(2.0)	1/50(2.0)
Adjusted rates(b)	19.44	2.86	0.0	6.25
Terminal rates(c)	7/36(19.4)	1/35(2.9)	0/27(0.0)	1/16(6.3)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.8595			
Prevalence method(d)	P = 0.9795			
Combined analysis(d)	P = 0.9905			
Cochran-Armitage test(e)	P = 0.0042**			
Fisher Exact test(e)		P = 0.0256*	P = 0.0078**	P = 0.0078**
SITE : ALL SITE TUMOR : histiocytic sarcoma				
Tumor rate				
Overall rates(a)	9/50(18.0)	2/50(4.0)	7/50(14.0)	3/50(6.0)
Adjusted rates(b)	16.67	4.35	14.29	5.26
Terminal rates(c)	5/36(13.9)	0/35(0.0)	3/27(11.1)	0/16(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.2352			
Prevalence method(d)	P = 0.9285			
Combined analysis(d)	P = 0.8117			
Cochran-Armitage test(e)	P = 0.1724			
Fisher Exact test(e)		P = 0.0256*	P = 0.3929	P = 0.0606
SITE : ALL SITE TUMOR : malignant lymphoma				
Tumor rate				
Overall rates(a)	8/50(16.0)	15/50(30.0)	6/50(12.0)	5/50(10.0)
Adjusted rates(b)	11.11	25.71	14.81	12.50
Terminal rates(c)	4/36(11.1)	9/35(25.7)	4/27(14.8)	2/16(12.5)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.8806			
Prevalence method(d)	P = 0.4234			
Combined analysis(d)	P = 0.7276			
Cochran-Armitage test(e)	P = 0.1116			
Fisher Exact test(e)		P = 0.0765	P = 0.3871	P = 0.2768

STUDY No. : 0402
 ANIMAL : MOUSE Crj:BDF1
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 2

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : ALL SITE				
TUMOR : mastcytoma:malignant				
Tumor rate				
Overall rates(a)	0/50(0.0)	1/50(2.0)	6/50(12.0)	0/50(0.0)
Adjusted rates(b)	0.0	0.0	11.11	0.0
Terminal rates(c)	0/36(0.0)	0/35(0.0)	3/27(11.1)	0/16(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.4336			
Prevalence method(d)	P = 0.2543			
Combined analysis(d)	P = 0.2844			
Cochran-Armitage test(e)	P = 0.8453			
Fisher Exact test(e)		P = 0.5000	P = 0.0133*	P = N.C.

(HPT360A)

BAIS4

(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 P-values associated with the trend test.

Standard method : Death analysis

Prevalence method : Incidental tumor test

Combined analysis : Death analysis + Incidental tumor test

(e): The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.

? : The conditional probabilities of the largest and smallest possible outcomes can not be estimated or this P-value is beyond the estimated P-value.

----- : There is no data which should be statistical analysis.

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

N.C.:Statistical value cannot be calculated and was not significant.

STUDY No. : 0402
 ANIMAL : MOUSE Crj:BDf1
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 1

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : lung TUMOR : bronchiolar-alveolar adenoma				
Tumor rate				
Overall rates(a)	6/50(12.0)	2/50(4.0)	1/50(2.0)	1/50(2.0)
Adjusted rates(b)	13.89	5.71	3.70	6.25
Terminal rates(c)	5/36(13.9)	2/35(5.7)	1/27(3.7)	1/16(6.3)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.9483			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0372*			
Fisher Exact test(e)		P = 0.1343	P = 0.0559	P = 0.0559
SITE : lung TUMOR : bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	3/50(6.0)	1/50(2.0)	2/50(4.0)	1/50(2.0)
Adjusted rates(b)	8.33	2.86	0.0	6.25
Terminal rates(c)	3/36(8.3)	1/35(2.9)	0/27(0.0)	1/16(6.3)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.2900			
Prevalence method(d)	P = 0.7036			
Combined analysis(d)	P = 0.5578			
Cochran-Armitage test(e)	P = 0.3979			
Fisher Exact test(e)		P = 0.3087	P = 0.5000	P = 0.3087
SITE : lung TUMOR : bronchiolar-alveolar adenoma, bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	9/50(18.0)	3/50(6.0)	3/50(6.0)	2/50(4.0)
Adjusted rates(b)	22.22	8.57	3.70	12.50
Terminal rates(c)	8/36(22.2)	3/35(8.6)	1/27(3.7)	2/16(12.5)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.2900			
Prevalence method(d)	P = 0.9583			
Combined analysis(d)	P = 0.9164			
Cochran-Armitage test(e)	P = 0.0288*			
Fisher Exact test(e)		P = 0.0606	P = 0.0606	P = 0.0256*

STUDY No. : 0402
 ANIMAL : MOUSE Crj:BDf1
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 2

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : lymph node TUMOR : malignant lymphoma				
Tumor rate				
Overall rates(a)	8/50(16.0)	13/50(26.0)	6/50(12.0)	3/50(6.0)
Adjusted rates(b)	11.11	20.51	14.81	6.25
Terminal rates(c)	4/36(11.1)	7/35(20.0)	4/27(14.8)	1/16(6.3)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.8806			
Prevalence method(d)	P = 0.6689			
Combined analysis(d)	P = 0.8716			
Cochran-Armitage test(e)	P = 0.0380*			
Fisher Exact test(e)		P = 0.1631	P = 0.3871	P = 0.0999
SITE : spleen TUMOR : hemangioma				
Tumor rate				
Overall rates(a)	4/50(8.0)	1/50(2.0)	0/50(0.0)	0/50(0.0)
Adjusted rates(b)	8.11	2.13	0.0	0.0
Terminal rates(c)	2/36(5.6)	0/35(0.0)	0/27(0.0)	0/16(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.9081 ?			
Prevalence method(d)	P = 0.9884			
Combined analysis(d)	P = 0.9961			
Cochran-Armitage test(e)	P = 0.0176*			
Fisher Exact test(e)		P = 0.1811	P = 0.0587	P = 0.0587
SITE : spleen TUMOR : mastcytoma:malignant				
Tumor rate				
Overall rates(a)	0/50(0.0)	0/50(0.0)	6/50(12.0)	0/50(0.0)
Adjusted rates(b)	0.0	0.0	11.11	0.0
Terminal rates(c)	0/36(0.0)	0/35(0.0)	3/27(11.1)	0/16(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.3699			
Prevalence method(d)	P = 0.2507			
Combined analysis(d)	P = 0.2390			
Cochran-Armitage test(e)	P = 0.6742			
Fisher Exact test(e)		P = N. C.	P = 0.0133*	P = N. C.

STUDY No. : 0402
 ANIMAL : MOUSE Crj:BDF1
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 3

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : spleen TUMOR : hemangioma, hemangiosarcoma				
Tumor rate				
Overall rates(a)	4/50(8.0)	2/50(4.0)	0/50(0.0)	0/50(0.0)
Adjusted rates(b)	8.11	4.26	0.0	0.0
Terminal rates(c)	2/36(5.6)	1/35(2.9)	0/27(0.0)	0/16(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.9081 ?			
Prevalence method(d)	P = 0.9839			
Combined analysis(d)	P = 0.9942			
Cochran-Armitage test(e)	P = 0.0172*			
Fisher Exact test(e)		P = 0.3389	P = 0.0587	P = 0.0587
SITE : liver TUMOR : hemangioma				
Tumor rate				
Overall rates(a)	7/50(14.0)	2/50(4.0)	1/50(2.0)	0/50(0.0)
Adjusted rates(b)	16.67	2.86	0.0	0.0
Terminal rates(c)	6/36(16.7)	1/35(2.9)	0/27(0.0)	0/16(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.6963			
Prevalence method(d)	P = 0.9990			
Combined analysis(d)	P = 0.9968			
Cochran-Armitage test(e)	P = 0.0031**			
Fisher Exact test(e)		P = 0.0798	P = 0.0297*	P = 0.0062**
SITE : liver TUMOR : hepatocellular adenoma				
Tumor rate				
Overall rates(a)	12/50(24.0)	17/50(34.0)	18/50(36.0)	3/50(6.0)
Adjusted rates(b)	30.56	40.00	48.39	12.50
Terminal rates(c)	11/36(30.6)	14/35(40.0)	13/27(48.1)	2/16(12.5)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.9104 ?			
Prevalence method(d)	P = 0.8716			
Combined analysis(d)	P = 0.9072			
Cochran-Armitage test(e)	P = 0.0130*			
Fisher Exact test(e)		P = 0.1891	P = 0.1376	P = 0.0113*

STUDY No. : 0402
 ANIMAL : MOUSE Crj:BDf1
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 4

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : liver TUMOR : hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	16/50(32.0)	11/50(22.0)	14/50(28.0)	39/50(78.0)
Adjusted rates(b)	40.54	22.86	40.63	100.00
Terminal rates(c)	14/36(38.9)	8/35(22.9)	10/27(37.0)	16/16(100.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.2489			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.1839	P = 0.4138	P < 0.0001**
SITE : liver TUMOR : hepatoblastoma				
Tumor rate				
Overall rates(a)	1/50(2.0)	12/50(24.0)	18/50(36.0)	38/50(76.0)
Adjusted rates(b)	2.78	21.43	37.04	81.25
Terminal rates(c)	1/36(2.8)	7/35(20.0)	10/27(37.0)	13/16(81.3)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**?			
Prevalence method(d)	P < 0.0001**			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.0009**	P < 0.0001**	P < 0.0001**
SITE : liver TUMOR : hemangioma, hemangiosarcoma				
Tumor rate				
Overall rates(a)	8/50(16.0)	3/50(6.0)	1/50(2.0)	0/50(0.0)
Adjusted rates(b)	19.44	5.71	0.0	0.0
Terminal rates(c)	7/36(19.4)	2/35(5.7)	0/27(0.0)	0/16(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.6963			
Prevalence method(d)	P = 0.9994			
Combined analysis(d)	P = 0.9984			
Cochran-Armitage test(e)	P = 0.0013**			
Fisher Exact test(e)		P = 0.0999	P = 0.0154*	P = 0.0029**

STUDY No. : 0402
 ANIMAL : MOUSE Crj:BDF1
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 5

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : liver TUMOR : hepatocellular adenoma, hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	22/50(44.0)	26/50(52.0)	25/50(50.0)	40/50(80.0)
Adjusted rates(b)	54.05	57.14	68.75	100.00
Terminal rates(c)	19/36(52.8)	20/35(57.1)	18/27(66.7)	16/16(100.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.4509			
Prevalence method(d)	P < 0.0001**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P = 0.0002**			
Fisher Exact test(e)		P = 0.2742	P = 0.3444	P = 0.0002**
SITE : liver TUMOR : hepatocellular carcinoma, hepatoblastoma				
Tumor rate				
Overall rates(a)	16/50(32.0)	19/50(38.0)	28/50(56.0)	43/50(86.0)
Adjusted rates(b)	40.54	37.14	63.33	100.00
Terminal rates(c)	14/36(38.9)	13/35(37.1)	16/27(59.3)	16/16(100.0)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**?			
Prevalence method(d)	P < 0.0001**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.3377	P = 0.0131*	P < 0.0001**
SITE : liver TUMOR : hepatocellular adenoma, hepatocellular carcinoma, hepatoblastoma				
Tumor rate				
Overall rates(a)	22/50(44.0)	27/50(54.0)	33/50(66.0)	43/50(86.0)
Adjusted rates(b)	54.05	57.14	80.00	100.00
Terminal rates(c)	19/36(52.8)	20/35(57.1)	21/27(77.8)	16/16(100.0)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**?			
Prevalence method(d)	P < 0.0001**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.2119	P = 0.0219*	P < 0.0001**

STUDY No. : 0402
ANIMAL : MOUSE Crj:BDF1
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 6

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : epididymis TUMOR : histiocytic sarcoma				
Tumor rate				
Overall rates(a)	3/50(6.0)	1/50(2.0)	1/49(2.0)	1/50(2.0)
Adjusted rates(b)	7.32	2.78	2.63	0.0
Terminal rates(c)	2/36(5.6)	0/35(0.0)	0/27(0.0)	0/16(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0909			
Prevalence method(d)	P = 0.9514			
Combined analysis(d)	P = 0.7538			
Cochran-Armitage test(e)	P = 0.3288			
Fisher Exact test(e)		P = 0.3087	P = 0.3163	P = 0.3087
SITE : Harderian gland TUMOR : adenoma				
Tumor rate				
Overall rates(a)	3/50(6.0)	2/50(4.0)	3/50(6.0)	2/50(4.0)
Adjusted rates(b)	8.33	5.71	9.09	6.06
Terminal rates(c)	3/36(8.3)	2/35(5.7)	2/27(7.4)	0/16(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.4762			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.7421			
Fisher Exact test(e)		P = 0.5000	P = 0.6611	P = 0.5000

(HPT360A)

BAIS4

- (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 P-values associated with the trend test.
Standard method : Death analysis
Prevalence method : Incidental tumor test
Combined analysis : Death analysis + Incidental tumor test
(e): The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.
? : The conditional probabilities of the largest and smallest possible outcomes can not be estimated or this P-value is beyond the estimated P-value.
----- : There is no data which should be statistical analysis.
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$
N.C.: Statistical value cannot be calculated and was not significant.

APPENDIX N 2

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS,

MOUSE : FEMALE

(2-YEAR STUDY)

STUDY No. : 0402
 ANIMAL : MOUSE Crj:BDF1
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 3

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : ALL SITE TUMOR : hemangioma				
Tumor rate				
Overall rates(a)	4/50(8.0)	1/50(2.0)	2/50(4.0)	2/50(4.0)
Adjusted rates(b)	8.70	3.70	6.67	4.88
Terminal rates(c)	2/23(8.7)	1/27(3.7)	2/30(6.7)	0/13(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.9818 ?			
Prevalence method(d)	P = 0.3386			
Combined analysis(d)	P = 0.6881			
Cochran-Armitage test(e)	P = 0.5259			
Fisher Exact test(e)		P = 0.1811	P = 0.3389	P = 0.3389
SITE : ALL SITE TUMOR : histiocytic sarcoma				
Tumor rate				
Overall rates(a)	18/50(36.0)	17/50(34.0)	15/50(30.0)	15/50(30.0)
Adjusted rates(b)	18.52	18.52	23.33	30.77
Terminal rates(c)	4/23(17.4)	5/27(18.5)	7/30(23.3)	4/13(30.8)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.9388			
Prevalence method(d)	P = 0.1057			
Combined analysis(d)	P = 0.6867			
Cochran-Armitage test(e)	P = 0.4908			
Fisher Exact test(e)		P = 0.5000	P = 0.3355	P = 0.3355

(HPT360A)

BATS4

STUDY No. : 0402
 ANIMAL : MOUSE Crj:BDf1
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 4

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : ALL SITE				
TUMOR : malignant lymphoma				
Tumor rate				
Overall rates(a)	23/50(46.0)	23/50(46.0)	18/50(36.0)	4/50(8.0)
Adjusted rates(b)	60.87	44.44	33.33	23.08
Terminal rates(c)	14/23(60.9)	12/27(44.4)	10/30(33.3)	3/13(23.1)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.9969			
Prevalence method(d)	P = 0.9915			
Combined analysis(d)	P = 0.9999			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.5794	P = 0.2081	P < 0.0001**

(HPT360A)

BAIS4

(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 P-values associated with the trend test.

Standard method : Death analysis

Prevalence method : Incidental tumor test

Combined analysis : Death analysis + Incidental tumor test

(e): The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.

? : The conditional probabilities of the largest and smallest possible outcomes cannot be estimated or this P-value is beyond the estimated P-value.

— : There is no data which should be statistical analysis.

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

N.C.:Statistical value cannot be calculated and was not significant.

STUDY No. : 0402
 ANIMAL : MOUSE Crj:BDF1
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 7

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : lung TUMOR : bronchiolar-alveolar adenoma				
Tumor rate				
Overall rates(a)	2/50(4.0)	2/50(4.0)	3/50(6.0)	1/50(2.0)
Adjusted rates(b)	8.70	4.76	9.38	7.69
Terminal rates(c)	2/23(8.7)	1/27(3.7)	2/30(6.7)	1/13(7.7)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.6014			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.6256			
Fisher Exact test(e)		P = 0.6913	P = 0.5000	P = 0.5000
SITE : lung TUMOR : bronchiolar-alveolar adenoma, bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	2/50(4.0)	2/50(4.0)	5/50(10.0)	1/50(2.0)
Adjusted rates(b)	8.70	4.76	12.50	7.69
Terminal rates(c)	2/23(8.7)	1/27(3.7)	3/30(10.0)	1/13(7.7)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.3849			
Prevalence method(d)	P = 0.5505			
Combined analysis(d)	P = 0.5212			
Cochran-Armitage test(e)	P = 0.7421			
Fisher Exact test(e)		P = 0.6913	P = 0.2180	P = 0.5000
SITE : lymph node TUMOR : malignant lymphoma				
Tumor rate				
Overall rates(a)	16/50(32.0)	16/50(32.0)	14/50(28.0)	3/50(6.0)
Adjusted rates(b)	34.78	18.52	23.53	15.38
Terminal rates(c)	8/23(34.8)	5/27(18.5)	7/30(23.3)	2/13(15.4)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.9959			
Prevalence method(d)	P = 0.8902			
Combined analysis(d)	P = 0.9973			
Cochran-Armitage test(e)	P = 0.0009**			
Fisher Exact test(e)		P = 0.5848	P = 0.4138	P = 0.0008**

STUDY No. : 0402
 ANIMAL : MOUSE Crj:BDF1
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 8

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : spleen TUMOR : malignant lymphoma				
Tumor rate				
Overall rates(a)	7/50(14.0)	7/50(14.0)	4/50(8.0)	1/50(2.0)
Adjusted rates(b)	26.09	25.93	10.00	7.69
Terminal rates(c)	6/23(26.1)	7/27(25.9)	3/30(10.0)	1/13(7.7)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.7188			
Prevalence method(d)	P = 0.9668			
Combined analysis(d)	P = 0.9757			
Cochran-Armitage test(e)	P = 0.0202*			
Fisher Exact test(e)		P = 0.6129	P = 0.2623	P = 0.0297*
SITE : liver TUMOR : hemangioma				
Tumor rate				
Overall rates(a)	3/50(6.0)	1/50(2.0)	0/50(0.0)	0/50(0.0)
Adjusted rates(b)	8.70	3.70	0.0	0.0
Terminal rates(c)	2/23(8.7)	1/27(3.7)	0/30(0.0)	0/13(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.9439 ?			
Prevalence method(d)	P = 0.9646			
Combined analysis(d)	P = 0.9909			
Cochran-Armitage test(e)	P = 0.0405*			
Fisher Exact test(e)		P = 0.3087	P = 0.1212	P = 0.1212
SITE : liver TUMOR : hepatocellular adenoma				
Tumor rate				
Overall rates(a)	5/50(10.0)	18/50(36.0)	13/50(26.0)	4/50(8.0)
Adjusted rates(b)	21.74	55.56	31.43	15.38
Terminal rates(c)	5/23(21.7)	15/27(55.6)	8/30(26.7)	2/13(15.4)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.7657			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.2320			
Fisher Exact test(e)		P = 0.0019**	P = 0.0332*	P = 0.5000

STUDY No. : 0402
 ANIMAL : MOUSE Crj:BDFl
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 9

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : liver TUMOR : histiocytic sarcoma				
Tumor rate				
Overall rates(a)	1/50(2.0)	0/50(0.0)	0/50(0.0)	3/50(6.0)
Adjusted rates(b)	0.0	0.0	0.0	7.41
Terminal rates(c)	0/23(0.0)	0/27(0.0)	0/30(0.0)	0/13(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.3452			
Prevalence method(d)	P = 0.0125* ?			
Combined analysis(d)	P = 0.0340*			
Cochran-Armitage test(e)	P = 0.0877			
Fisher Exact test(e)		P = 0.5000	P = 0.5000	P = 0.3087
SITE : liver TUMOR : hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	2/50(4.0)	12/50(24.0)	41/50(82.0)	46/50(92.0)
Adjusted rates(b)	6.06	38.71	100.00	97.06
Terminal rates(c)	1/23(4.3)	9/27(33.3)	30/30(100.0)	12/13(92.3)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0467* ?			
Prevalence method(d)	P < 0.0001**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.0038**	P < 0.0001**	P < 0.0001**
SITE : liver TUMOR : hepatoblastoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	0/50(0.0)	8/50(16.0)	38/50(76.0)
Adjusted rates(b)	0.0	0.0	20.00	61.54
Terminal rates(c)	0/23(0.0)	0/27(0.0)	6/30(20.0)	8/13(61.5)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**?			
Prevalence method(d)	P < 0.0001**			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = N. C.	P = 0.0029**	P < 0.0001**

STUDY No. : 0402
 ANIMAL : MOUSE Crj:BDFl
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 10

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : liver TUMOR : hepatocellular adenoma, hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	7/50(14.0)	24/50(48.0)	44/50(88.0)	47/50(94.0)
Adjusted rates(b)	26.09	70.97	100.00	97.06
Terminal rates(c)	6/23(26.1)	19/27(70.4)	30/30(100.0)	12/13(92.3)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0467* ?			
Prevalence method(d)	P < 0.0001**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.0002**	P < 0.0001**	P < 0.0001**
SITE : liver TUMOR : hepatocellular carcinoma, hepatoblastoma				
Tumor rate				
Overall rates(a)	2/50(4.0)	12/50(24.0)	42/50(84.0)	48/50(96.0)
Adjusted rates(b)	6.06	38.71	100.00	100.00
Terminal rates(c)	1/23(4.3)	9/27(33.3)	30/30(100.0)	13/13(100.0)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**?			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.0038**	P < 0.0001**	P < 0.0001**
SITE : liver TUMOR : hepatocellular adenoma, hepatocellular carcinoma, hepatoblastoma				
Tumor rate				
Overall rates(a)	7/50(14.0)	24/50(48.0)	45/50(90.0)	48/50(96.0)
Adjusted rates(b)	26.09	70.97	100.00	100.00
Terminal rates(c)	6/23(26.1)	19/27(70.4)	30/30(100.0)	13/13(100.0)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**?			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.0002**	P < 0.0001**	P < 0.0001**

STUDY No. : 0402
 ANIMAL : MOUSE Crj:BDf1
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 11

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : pituitary gland TUMOR : adenoma				
Tumor rate				
Overall rates(a)	3/49(6.1)	7/50(14.0)	5/50(10.0)	0/50(0.0)
Adjusted rates(b)	13.04	18.52	15.63	0.0
Terminal rates(c)	3/23(13.0)	5/27(18.5)	4/30(13.3)	0/13(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.9394			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0882			
Fisher Exact test(e)		P = 0.1672	P = 0.3689	P = 0.1175
SITE : uterus TUMOR : endometrial stromal polyp				
Tumor rate				
Overall rates(a)	5/50(10.0)	1/50(2.0)	0/50(0.0)	0/50(0.0)
Adjusted rates(b)	21.74	3.70	0.0	0.0
Terminal rates(c)	5/23(21.7)	1/27(3.7)	0/30(0.0)	0/13(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.9994			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0078**			
Fisher Exact test(e)		P = 0.1022	P = 0.0281*	P = 0.0281*
SITE : uterus TUMOR : histiocytic sarcoma				
Tumor rate				
Overall rates(a)	15/50(30.0)	16/50(32.0)	15/50(30.0)	12/50(24.0)
Adjusted rates(b)	18.52	18.52	23.33	30.77
Terminal rates(c)	4/23(17.4)	5/27(18.5)	7/30(23.3)	4/13(30.8)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.9203			
Prevalence method(d)	P = 0.1119			
Combined analysis(d)	P = 0.6656			
Cochran-Armitage test(e)	P = 0.4294			
Fisher Exact test(e)		P = 0.5000	P = 0.5862	P = 0.3264

STUDY No. : 0402
 ANIMAL : MOUSE Crj:BDF₁
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 12

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
SITE : Harderian gland				
TUMOR : adenoma				
Tumor rate				
Overall rates(a)	3/50(6.0)	1/50(2.0)	2/50(4.0)	3/50(6.0)
Adjusted rates(b)	11.54	3.13	4.76	15.38
Terminal rates(c)	2/23(8.7)	0/27(0.0)	1/30(3.3)	2/13(15.4)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.3745			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.7731			
Fisher Exact test(e)		P = 0.3087	P = 0.5000	P = 0.6611

(HPT360A)

BAIS4

- (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 P-values associated with the trend test.
 Standard method : Death analysis
 Prevalence method : Incidental tumor test
 Combined analysis : Death analysis + Incidental tumor test
 (e): The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.
 ? : The conditional probabilities of the largest and smallest possible outcomes can not be estimated or this P-value is beyond the estimated P-value.
 ----- : There is no data which should be statistical analysis.
 Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$
 N.C. : Statistical value cannot be calculated and was not significant.

PPENDIX O 1

HISTOPATHOLOGICAL FINDINGS : METATSASIS OF TUMOR : SUMMARY

MOUSE : MALE : ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 1

Organ	Findings	Group Name No. of Animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
{Respiratory system}						
nasal cavit	metastasis:subcutis tumor		<50> 0	<50> 0	<50> 0	<50> 1
	metastasis:peripheral nerve tumor		0	0	1	0
lung	leukemic cell infiltration		<50> 2	<50> 4	<50> 2	<50> 1
	metastasis:liver tumor		2	2	2	10
{Hematopoietic system}						
bone marrow	leukemic cell infiltration		<50> 3	<50> 3	<50> 3	<50> 2
spleen	leukemic cell infiltration		<50> 2	<50> 7	<50> 0	<50> 2
{Circulatory system}						
heart	leukemic cell infiltration		<50> 0	<50> 1	<50> 0	<50> 0
	metastasis:liver tumor		0	0	0	1
{Digestive system}						
salivary gl	leukemic cell infiltration		<50> 0	<50> 1	<50> 0	<50> 0
stomach	leukemic cell infiltration		<50> 0	<50> 1	<50> 0	<50> 0
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 2

Group Name No. of Animals on Study		Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
Organ	Findings				
{Digestive system}					
stomach		<50>	<50>	<50>	<50>
	metastasis:spleen tumor	0	0	2	0
	metastasis:epididymis tumor	1	0	0	0
small intes		<50>	<50>	<50>	<50>
	leukemic cell infiltration	1	3	1	0
liver		<50>	<50>	<50>	<50>
	leukemic cell infiltration	2	4	1	1
	metastasis:subcutis tumor	0	0	1	1
	metastasis:peripheral nerve tumor	0	0	1	0
	metastasis:spleen tumor	0	0	6	0
	metastasis:epididymis tumor	2	0	0	1
	metastasis:salivary gland tumor	1	0	0	0
pancreas		<50>	<50>	<50>	<50>
	leukemic cell infiltration	0	2	1	0
{Urinary system}					
kidney		<50>	<50>	<50>	<50>
	leukemic cell infiltration	1	2	2	2
	metastasis:liver tumor	0	1	0	0
	metastasis:spleen tumor	0	0	1	0
urin bladd		<50>	<50>	<50>	<50>
	leukemic cell infiltration	1	1	2	0
< a > a : Number of animals examined at the site b b : Number of animals with lesion					

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 3

Group Name No. of Animals on Study		Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
Organ	Findings				
{Endocrine system}					
pituitary		<50>	<50>	<50>	<50>
	leukemic cell infiltration	0	1	0	0
	metastasis:spleen tumor	0	0	1	0
adrenal		<50>	<50>	<50>	<50>
	leukemic cell infiltration	1	1	0	0
	metastasis:spleen tumor	0	0	1	0
{Reproductive system}					
testis		<50>	<50>	<50>	<50>
	metastasis:epididymis tumor	0	0	1	0
epididymis		<50>	<50>	<50>	<50>
	leukemic cell infiltration	0	2	1	0
	metastasis:subcutis tumor	0	0	1	0
{Musculoskeletal system}					
muscle		<50>	<50>	<50>	<50>
	leukemic cell infiltration	0	0	1	0
{Body cavities}					
peritoneum		<50>	<50>	<50>	<50>
	metastasis:liver tumor	0	0	0	1
< a >	a : Number of animals examined at the site				
b	b : Number of animals with lesion				

APPENDIX O 2

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

MOUSE : FEMALE : ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
(Integumentary system/appandage)						
subcutis	leukemic cell infiltration		<50> 1	<50> 1	<50> 1	<50> 0
(Respiratory system)						
nasal cavit	metastasis:uterus tumor		<50> 0	<50> 1	<50> 2	<50> 0
larynx	leukemic cell infiltration		<50> 0	<50> 2	<50> 0	<50> 0
trachea	leukemic cell infiltration		<50> 0	<50> 1	<50> 0	<50> 0
lung	leukemic cell infiltration		<50> 11	<50> 14	<50> 8	<50> 1
	metastasis:liver tumor		1	0	0	4
	metastasis:uterus tumor		2	5	3	3
	metastasis:peritoneum tumor		1	0	0	0
(Hematopoietic system)						
bone marrow	leukemic cell infiltration		<50> 7	<50> 8	<50> 3	<50> 2
	metastasis:liver tumor		0	0	0	1
	metastasis:uterus tumor		2	5	3	0
	metastasis:ovary tumor		0	1	0	0

< a > a : Number of animals examined at the site
 b b : Number of animals with lesion

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 5

Organ	Findings	Group Name No. of Animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
(Hematopoietic system)						
lymph node			<50>	<50>	<50>	<50>
	leukemic cell infiltration		1	3	1	0
	metastasis:uterus tumor		1	7	1	0
	metastasis:subcutis tumor		1	0	0	0
spleen			<50>	<50>	<50>	<50>
	leukemic cell infiltration		11	13	9	1
	metastasis:liver tumor		0	0	1	0
	metastasis:uterus tumor		2	8	4	1
	metastasis:peritoneum tumor		1	0	0	0
(Circulatory system)						
heart			<50>	<50>	<50>	<50>
	leukemic cell infiltration		2	5	3	0
(Digestive system)						
tongue			<50>	<50>	<50>	<50>
	leukemic cell infiltration		1	1	1	0
salivary gl			<50>	<50>	<50>	<50>
	leukemic cell infiltration		13	6	6	2
stomach			<50>	<50>	<50>	<50>
	leukemic cell infiltration		0	1	0	0
	metastasis:uterus tumor		1	0	0	0

< a > a : Number of animals examined at the site
 b b : Number of animals with lesion

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 6

Organ	Findings	Group Name No. of Animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
(Digestive system)						
stomach			<50>	<50>	<50>	<50>
	metastasis:peritoneum tumor		1	0	0	0
	metastasis:subcutis tumor		1	0	0	0
small intes			<50>	<50>	<50>	<50>
	leukemic cell infiltration		0	0	1	0
	metastasis:subcutis tumor		1	0	0	0
liver			<50>	<50>	<50>	<50>
	leukemic cell infiltration		13	14	9	1
	metastasis:uterus tumor		10	11	7	5
	metastasis:ovary tumor		0	1	0	0
gall bladd			<50>	<50>	<50>	<50>
	leukemic cell infiltration		1	1	0	0
pancreas			<50>	<50>	<50>	<50>
	leukemic cell infiltration		5	7	6	1
	metastasis:liver tumor		0	0	0	1
	metastasis:uterus tumor		1	4	1	1
	metastasis:subcutis tumor		1	0	0	0
(Urinary system)						
kidney			<50>	<50>	<50>	<50>
	leukemic cell infiltration		4	11	9	1
	metastasis:uterus tumor		3	5	2	2
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 7

Organ	Findings	Group Name No. of Animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
{Urinary system}						
urin bladd			<50>	<50>	<50>	<50>
	leukemic cell infiltration		5	9	5	1
	metastasis:uterus tumor		1	1	2	0
{Endocrine system}						
thyroid			<50>	<50>	<50>	<50>
	leukemic cell infiltration		1	1	2	0
parathyroid			<50>	<50>	<50>	<50>
	leukemic cell infiltration		0	1	0	0
adrenal			<50>	<50>	<50>	<50>
	leukemic cell infiltration		1	1	1	0
	metastasis:uterus tumor		1	1	2	0
{Reproductive system}						
ovary			<50>	<50>	<50>	<50>
	leukemic cell infiltration		7	7	5	1
	metastasis:liver tumor		0	0	0	2
	metastasis:uterus tumor		6	11	5	3
uterus			<50>	<50>	<50>	<50>
	leukemic cell infiltration		4	5	4	0
	metastasis:peritoneum tumor		1	0	0	0
vagina			<50>	<50>	<50>	<50>
	leukemic cell infiltration		3	3	3	0
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0-105W)

PAGE : 8

		Group Name No. of Animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
Organ	Findings					
{Reproductive system}						
vagina	metastasis:uterus tumor		<50> 3	<50> 1	<50> 3	<50> 1
{Nervous system}						
brain	leukemic cell infiltration		<50> 0	<50> 1	<50> 1	<50> 0
{Special sense organs/appendage}						
Harder gl	leukemic cell infiltration		<50> 1	<50> 2	<50> 3	<50> 0
	metastasis:liver tumor		0	0	0	1
{Musculoskeletal system}						
muscle	leukemic cell infiltration		<50> 0	<50> 1	<50> 2	<50> 0
{Body cavities}						
peritoneum	leukemic cell infiltration		<50> 1	<50> 0	<50> 0	<50> 1
	metastasis:liver tumor		0	0	0	2

< a > a : Number of animals examined at the site
 b b : Number of animals with lesion

AAPPENDIX O 3

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

MOUSE : MALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name No. of Animals on Study	Control 36	5000 ppm 35	10000 ppm 27	20000 ppm 16
{Respiratory system}						
lung			<36>	<35>	<27>	<16>
	leukemic cell infiltration		0	2	1	1
	metastasis:liver tumor		2	2	1	4
{Hematopoietic system}						
bone marrow			<36>	<35>	<27>	<16>
	leukemic cell infiltration		0	0	2	0
spleen			<36>	<35>	<27>	<16>
	leukemic cell infiltration		2	5	0	1
{Digestive system}						
small intes			<36>	<35>	<27>	<16>
	leukemic cell infiltration		0	2	1	0
liver			<36>	<35>	<27>	<16>
	leukemic cell infiltration		0	2	0	1
	metastasis:spleen tumor		0	0	3	0
	metastasis:epididymis tumor		1	0	0	0
	metastasis:salivary gland tumor		1	0	0	0
pancreas			<36>	<35>	<27>	<16>
	leukemic cell infiltration		0	1	0	0
{Urinary system}						
kidney			<36>	<35>	<27>	<16>
	leukemic cell infiltration		0	1	0	1
< a > a : Number of animals examined at the site b b : Number of animals with lesion						

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

Group Name		Control	5000 ppm	10000 ppm	20000 ppm
No. of Animals on Study		36	35	27	16
Organ	Findings				
{Urinary system}					
urin bladd	leukemic cell infiltration	<36> 0	<35> 0	<27> 2	<16> 0
{Reproductive system}					
epididymis	leukemic cell infiltration	<36> 0	<35> 0	<27> 1	<16> 0
{Musculoskeletal system}					
muscle	leukemic cell infiltration	<36> 0	<35> 0	<27> 1	<16> 0
< a >	a : Number of animals examined at the site				
b	b : Number of animals with lesion				

(JPT150)

BAIS4

APPENDIX O 4

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

MOUSE : FEMALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 3

Group Name No. of Animals on Study		Control 23	5000 ppm 27	10000 ppm 30	20000 ppm 13
Organ	Findings				
{Integumentary system/appendage}					
subcutis	leukemic cell infiltration	<23> 1	<27> 0	<30> 0	<13> 0
{Respiratory system}					
lung	leukemic cell infiltration	<23> 4	<27> 3	<30> 2	<13> 1
{Hematopoietic system}					
bone marrow	leukemic cell infiltration	<23> 3	<27> 3	<30> 2	<13> 2
lymph node	leukemic cell infiltration	<23> 1	<27> 3	<30> 0	<13> 0
spleen	leukemic cell infiltration	<23> 5	<27> 4	<30> 5	<13> 1
	metastasis:liver tumor	0	0	1	0
{Circulatory system}					
heart	leukemic cell infiltration	<23> 1	<27> 0	<30> 1	<13> 0
{Digestive system}					
salivary gl	leukemic cell infiltration	<23> 9	<27> 1	<30> 3	<13> 2
liver	leukemic cell infiltration	<23> 7	<27> 3	<30> 3	<13> 1
< a >	a : Number of animals examined at the site				
b	b : Number of animals with lesion				

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDP1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 4

Group Name No. of Animals on Study		Control 23	5000 ppm 27	10000 ppm 30	20000 ppm 13
Organ	Findings				
(Digestive system)					
pancreas		<23>	<27>	<30>	<13>
	leukemic cell infiltration	3	3	3	1
	metastasis:uterus tumor	0	0	1	0
(Urinary system)					
kidney		<23>	<27>	<30>	<13>
	leukemic cell infiltration	1	7	3	1
urin bladd		<23>	<27>	<30>	<13>
	leukemic cell infiltration	2	4	1	1
(Reproductive system)					
ovary		<23>	<27>	<30>	<13>
	leukemic cell infiltration	2	1	1	1
	metastasis:liver tumor	0	0	0	1
	metastasis:uterus tumor	0	1	0	0
uterus		<23>	<27>	<30>	<13>
	leukemic cell infiltration	1	0	1	0
vagina		<23>	<27>	<30>	<13>
	leukemic cell infiltration	0	1	1	0
(Nervous system)					
brain		<23>	<27>	<30>	<13>
	leukemic cell infiltration	0	1	0	0

< a > a : Number of animals examined at the site
 b b : Number of animals with lesion

STUDY NO. : 0402
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 5

		Group Name	Control	5000 ppm	10000 ppm	20000 ppm
		No. of Animals on Study	23	27	30	13
Organ	Findings					
(Body cavities)						
peritoneum	metastasis:liver tumor		<23> 0	<27> 0	<30> 0	<13> 2
< a > a : Number of animals examined at the site						
b b : Number of animals with lesion						

(JPT150)

BAIS4

PPENDIX O 5

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

MOUSE : MALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDf1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 1

Group Name No. of Animals on Study		Control 14	5000 ppm 15	10000 ppm 23	20000 ppm 34
Organ	Findings				
{Respiratory system}					
nasal cavit	metastasis:subcutis tumor	<14> 0	<15> 0	<23> 0	<34> 1
	metastasis:peripheral nerve tumor	0	0	1	0
lung	leukemic cell infiltration	<14> 2	<15> 2	<23> 1	<34> 0
	metastasis:liver tumor	0	0	1	6
{Hematopoietic system}					
bone marrow	leukemic cell infiltration	<14> 3	<15> 3	<23> 1	<34> 2
spleen	leukemic cell infiltration	<14> 0	<15> 2	<23> 0	<34> 1
{Circulatory system}					
heart	leukemic cell infiltration	<14> 0	<15> 1	<23> 0	<34> 0
	metastasis:liver tumor	0	0	0	1
{Digestive system}					
salivary gl	leukemic cell infiltration	<14> 0	<15> 1	<23> 0	<34> 0
stomach	leukemic cell infiltration	<14> 0	<15> 1	<23> 0	<34> 0

< a > a : Number of animals examined at the site
 b b : Number of animals with lesion

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDf1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

		Group Name No. of Animals on Study	Control 14	5000 ppm 15	10000 ppm 23	20000 ppm 34
Organ	Findings					
(Digestive system)						
stomach			<14>	<15>	<23>	<34>
	metastasis:spleen tumor		0	0	2	0
	metastasis:epididymis tumor		1	0	0	0
small intes			<14>	<15>	<23>	<34>
	leukemic cell infiltration		1	1	0	0
liver			<14>	<15>	<23>	<34>
	leukemic cell infiltration		2	2	1	0
	metastasis:subcutis tumor		0	0	1	1
	metastasis:peripleral nerve tumor		0	0	1	0
	metastasis:spleen tumor		0	0	3	0
	metastasis:epididymis tumor		1	0	0	1
pancreas			<14>	<15>	<23>	<34>
	leukemic cell infiltration		0	1	1	0
(Urinary system)						
kidney			<14>	<15>	<23>	<34>
	leukemic cell infiltration		1	1	2	1
	metastasis:liver tumor		0	1	0	0
	metastasis:spleen tumor		0	0	1	0
urin bladd			<14>	<15>	<23>	<34>
	leukemic cell infiltration		1	1	0	0
(Endocrine system)						
pituitary			<14>	<15>	<23>	<34>
	leukemic cell infiltration		0	1	0	0

< a > a : Number of animals examined at the site
 b b : Number of animals with lesion

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 3

		Group Name No. of Animals on Study	Control 14	5000 ppm 15	10000 ppm 23	20000 ppm 34
Organ	Findings					
{Endocrine system}						
pituitary			<14>	<15>	<23>	<34>
	metastasis:spleen tumor		0	0	1	0
adrenal			<14>	<15>	<23>	<34>
	leukemic cell infiltration		1	1	0	0
	metastasis:spleen tumor		0	0	1	0
{Reproductive system}						
testis			<14>	<15>	<23>	<34>
	metastasis:epididymis tumor		0	0	1	0
epididymis			<14>	<15>	<23>	<34>
	leukemic cell infiltration		0	2	0	0
	metastasis:subcutis tumor		0	0	1	0
{Body cavities}						
peritoneum			<14>	<15>	<23>	<34>
	metastasis:liver tumor		0	0	0	1
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

(JPT150)

BAIS4

APPENDIX O 6

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

MOUSE : FEMALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study	Control 27	5000 ppm 23	10000 ppm 20	20000 ppm 37
{Integumentary system/appandage}						
subcutis	leukemic cell infiltration		<27> 0	<23> 1	<20> 1	<37> 0
{Respiratory system}						
nasal cavit	metastasis:uterus tumor		<27> 0	<23> 1	<20> 2	<37> 0
larynx	leukemic cell infiltration		<27> 0	<23> 2	<20> 0	<37> 0
trachea	leukemic cell infiltration		<27> 0	<23> 1	<20> 0	<37> 0
lung	leukemic cell infiltration		<27> 7	<23> 11	<20> 6	<37> 0
	metastasis:liver tumor		1	0	0	4
	metastasis:uterus tumor		2	5	3	3
	metastasis:peritoneum tumor		1	0	0	0
{Hematopoietic system}						
bone marrow	leukemic cell infiltration		<27> 4	<23> 5	<20> 1	<37> 0
	metastasis:liver tumor		0	0	0	1
	metastasis:uterus tumor		2	5	3	0
	metastasis:ovary tumor		0	1	0	0
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 5

		Group Name	Control	5000 ppm	10000 ppm	20000 ppm
		No. of Animals on Study	27	23	20	37
Organ	Findings					
{Hematopoietic system}						
lymph node			<27>	<23>	<20>	<37>
	leukemic cell infiltration		0	0	1	0
	metastasis:uterus tumor		1	7	1	0
	metastasis:subcutis tumor		1	0	0	0
spleen			<27>	<23>	<20>	<37>
	leukemic cell infiltration		6	9	4	0
	metastasis:uterus tumor		2	8	4	1
	metastasis:peritoneum tumor		1	0	0	0
{Circulatory system}						
heart			<27>	<23>	<20>	<37>
	leukemic cell infiltration		1	5	2	0
{Digestive system}						
tongue			<27>	<23>	<20>	<37>
	leukemic cell infiltration		1	1	1	0
salivary gl			<27>	<23>	<20>	<37>
	leukemic cell infiltration		4	5	3	0
stomach			<27>	<23>	<20>	<37>
	leukemic cell infiltration		0	1	0	0
	metastasis:uterus tumor		1	0	0	0
	metastasis:peritoneum tumor		1	0	0	0
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 6

		Group Name	Control	5000 ppm	10000 ppm	20000 ppm
		No. of Animals on Study	27	23	20	37
Organ	Findings					
{Digestive system}						
stomach			<27>	<23>	<20>	<37>
	metastasis:subcutis tumor		1	0	0	0
small intes			<27>	<23>	<20>	<37>
	leukemic cell infiltration		0	0	1	0
	metastasis:subcutis tumor		1	0	0	0
liver			<27>	<23>	<20>	<37>
	leukemic cell infiltration		6	11	6	0
	metastasis:uterus tumor		10	11	7	5
	metastasis:ovary tumor		0	1	0	0
gall bladd			<27>	<23>	<20>	<37>
	leukemic cell infiltration		1	1	0	0
pancreas			<27>	<23>	<20>	<37>
	leukemic cell infiltration		2	4	3	0
	metastasis:liver tumor		0	0	0	1
	metastasis:uterus tumor		1	4	0	1
	metastasis:subcutis tumor		1	0	0	0
{Urinary system}						
kidney			<27>	<23>	<20>	<37>
	leukemic cell infiltration		3	4	6	0
	metastasis:uterus tumor		3	5	2	2
urin bladd			<27>	<23>	<20>	<37>
	leukemic cell infiltration		3	5	4	0
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 7

Group Name		Control	5000 ppm	10000 ppm	20000 ppm
No. of Animals on Study		27	23	20	37
Organ	Findings				
(Urinary system)					
urin bladd		<27>	<23>	<20>	<37>
	metastasis:uterus tumor	1	1	2	0
(Endocrine system)					
thyroid		<27>	<23>	<20>	<37>
	leukemic cell infiltration	1	1	2	0
parathyroid		<27>	<23>	<20>	<37>
	leukemic cell infiltration	0	1	0	0
adrenal		<27>	<23>	<20>	<37>
	leukemic cell infiltration	1	1	1	0
	metastasis:uterus tumor	1	1	2	0
(Reproductive system)					
ovary		<27>	<23>	<20>	<37>
	leukemic cell infiltration	5	6	4	0
	metastasis:liver tumor	0	0	0	1
	metastasis:uterus tumor	6	10	5	3
uterus		<27>	<23>	<20>	<37>
	leukemic cell infiltration	3	5	3	0
	metastasis:peritoneum tumor	1	0	0	0
vagina		<27>	<23>	<20>	<37>
	leukemic cell infiltration	3	2	2	0
	metastasis:uterus tumor	3	1	3	1

< a > a : Number of animals examined at the site
 b b : Number of animals with lesion

STUDY NO. : 0402
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 8

		Group Name No. of Animals on Study	Control 27	5000 ppm 23	10000 ppm 20	20000 ppm 37
Organ	Findings					
{Nervous system}						
brain			<27>	<23>	<20>	<37>
	leukemic cell infiltration		0	0	1	0
{Special sense organs/appendage}						
Harder gl			<27>	<23>	<20>	<37>
	leukemic cell infiltration		1	2	3	0
	metastasis:liver tumor		0	0	0	1
{Musculoskeletal system}						
muscle			<27>	<23>	<20>	<37>
	leukemic cell infiltration		0	1	2	0
{Body cavities}						
peritoneum			<27>	<23>	<20>	<37>
	leukemic cell infiltration		1	0	0	1
< a > a : Number of animals examined at the site b b : Number of animals with lesion						

(JPT150)

BAIS4

APPENDIX P 1

IDENTITY AND IMPURITY OF *p*-NITROANISOLE
IN THE 2-YEAR FEED STUDY

IDENTITY AND IMPURITY OF *p*-NITROANISOLE IN THE 2-YEAR FEED STUDYTest Substance : *p*-Nitroanisole (Wako Pure Chemical Industries, Ltd.)

Lot No. : KSJ0005

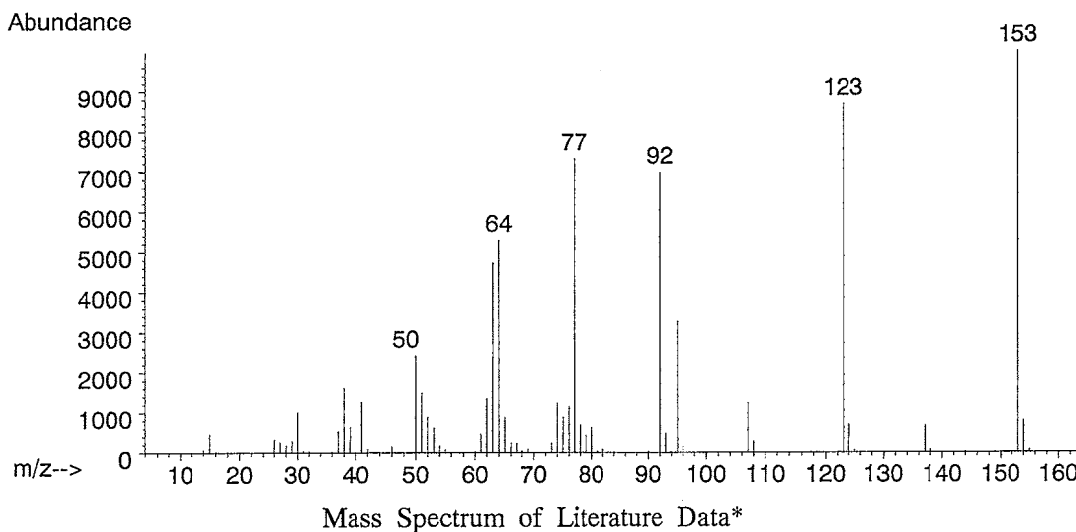
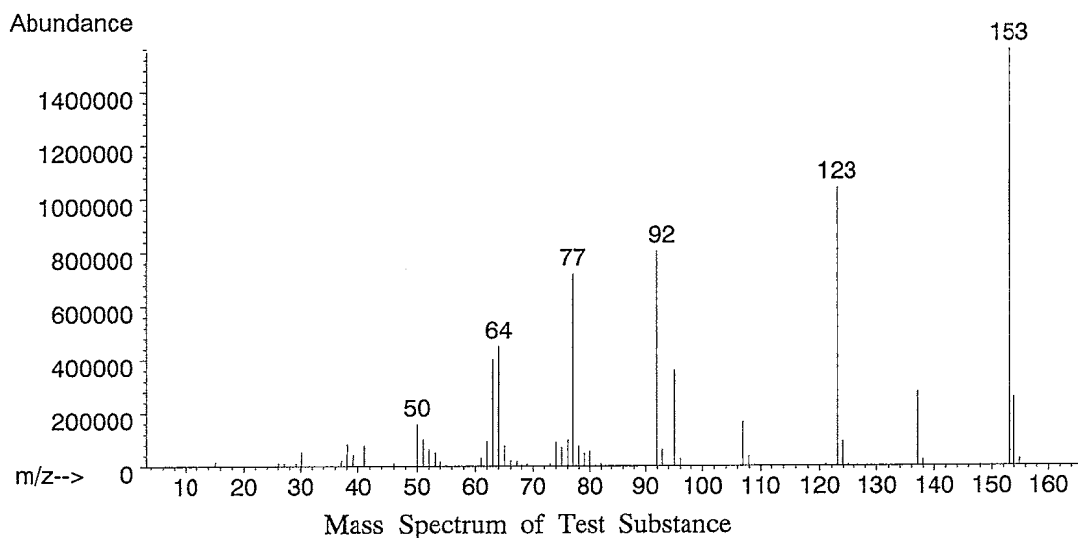
1. Spectral data

Mass Spectrometry

Instrument : Hewlett Packard 5989B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Result: The mass spectrum was consistent with literature spectrum.

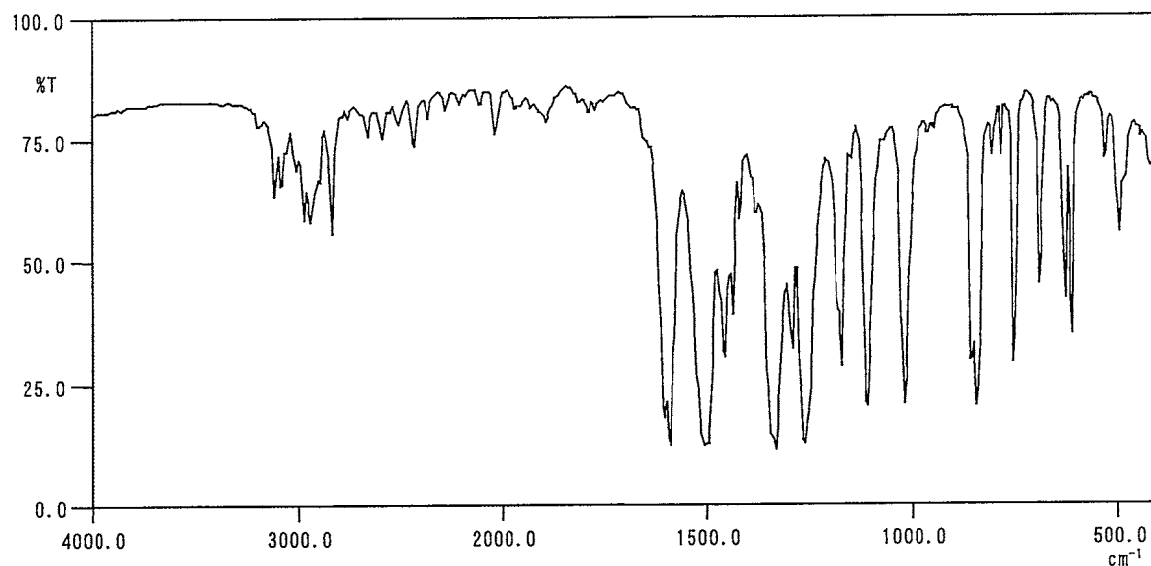
(*McLafferty FW, ed. 1994. Wiley Registry of Mass Spectral Data. 6th ed.
New York, NY : John Wiley and Sons.)

Infrared Spectrometry

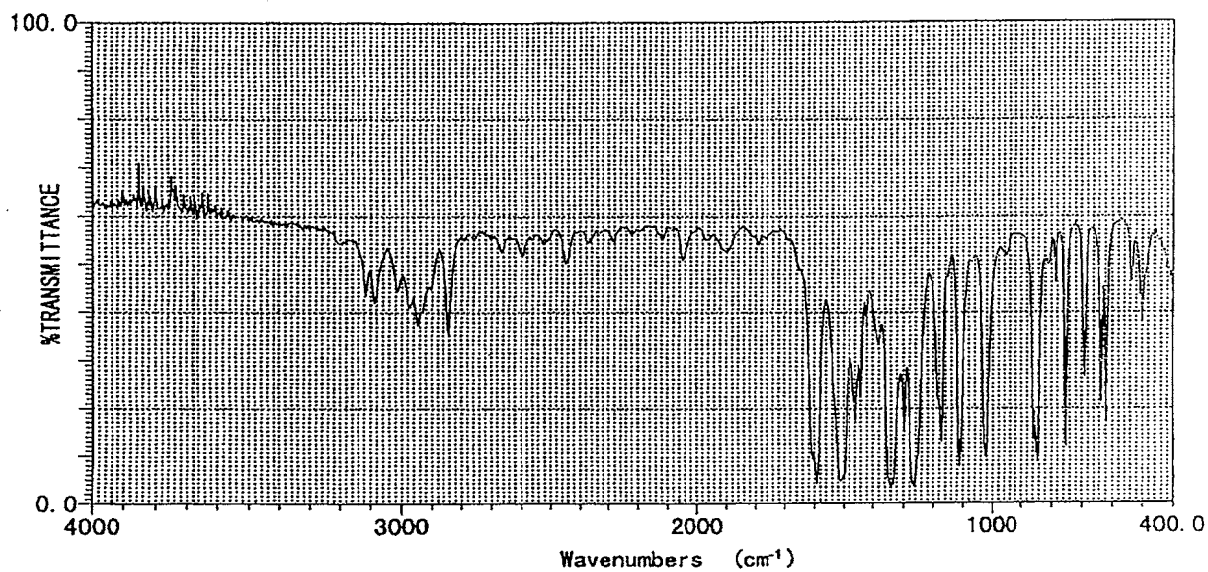
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 2.0 cm^{-1}



Infrared Spectrum of Test Substance



Infrared Spectrum of Literature Data*

Result: The infrared spectrum was consistent with literature spectrum.

(*Performed by Wako Pure Chemical Industries, Ltd.)

2. Impurity

Instrument : Hewlett Packard 5890A Gas Chromatograph
Column : INNOWAX (0.2 mm ϕ \times 50 m)
Column Temperature : 80 °C \rightarrow (15 °C/min) \rightarrow 280 °C (5 min)
Flow Rate : 1 mL/min
Detector : FID (Flame Ionization Detector)
Injection Volume : 1 μ L

Sample Name	Peak No.	Area (%)	Peak Name
Test Substance	1	0.25	<i>m</i> -Chloronitrobenzene
	2	99.75	<i>p</i> -Nitroanisole

Result: Gas chromatography indicated one major peak (peak No.2) and one impurity. It was identified by comparing GC-MS with that of *m*-chloronitrobenzene (peak No.1) in the *p*-nitroanisole. The amount in the test substance were 0.25% (The quantity value by the standard sample was 0.28%.) with a gas chromatograph.

3. Conclusion: The test substance was identified as *p*-nitroanisole by mass spectrum and infrared spectrum. Gas chromatography indicated one major peak (*p*-nitroanisole) and one impurity. The impurity was *m*-chloronitrobenzene in the test substance.

APPENDIX P 2

STABILITY OF *p*-NITROANISOLE IN FEEDING OF MICE IN THE 2-YEAR FEED STUDY

STABILITY OF *p*-NITROANISOLE IN THE 2-YEAR FEED STUDY

Test Substance : *p*-Nitroanisole (Wako Pure Chemical Industries, Ltd.)

Lot No. : KSJ0005

1. Sample : This lot was used from 1999.12.2 to 2001.12.5. Test substance was stored in a dark place at room temperature.

2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : INNOWAX (0.2 mm ϕ \times 50 m)

Column Temperature : 80 °C \rightarrow (15 °C/min) \rightarrow 280 °C (5 min)

Flow Rate : 1 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
1999.11.04	1	10.259	0.25
	2	13.134	99.75
2001.12.26	1	10.244	0.25
	2	13.073	99.75

Result: Gas chromatography indicated one major peak (peak No.2) and one impurity (peak No.1 < 0.3% of total area) analyzed on 1999.11.04 and one major peak (peak No.2) and one impurity (peak No.1 < 0.3% of total area) analyzed on 2001.12.26. No new trace impurity peak in the test substance analyzed on 2001.12.26 was detected.

3. Conclusion: The test substance was stable for about 26 months in a dark place at room temperature.

APPENDIX P 3

CONCENTRATION OF *p*-NITROANISOLE IN FORMULATED
DIETS IN THE 2-YEAR FEED STUDY

CONCENTRATION OF *p*-NITROANISOLE IN FORMULATED DIETS IN THE 2-YEAR FEED STUDY

Date Analyzed	Target Concentration		
	5000 ^a	10000	20000
1999.12.01	5170 (103) ^b	10200 (102)	20700 (104)
2000.01.26	5200 (104)	10000 (100)	20000 (100)
2000.04.19	4810 (96.2)	9470 (94.7)	19100 (95.5)
2000.07.12	4790 (95.8)	10000 (100)	19100 (95.5)
2000.10.04	4910 (98.2)	9740 (97.4)	19600 (98.0)
2000.12.27	5230 (105)	10200 (102)	20000 (100)
2001.03.21	4890 (97.8)	9880 (98.8)	19900 (99.5)
2001.06.06	5110 (102)	9850 (98.5)	20500 (103)
2001.08.29	5100 (102)	10500 (105)	20700 (104)
2001.11.21	4910 (98.2)	10500 (105)	20000 (100)

^a ppm

^b %

Analytical method : The samples were analyzed by high performance liquid chromatography.

Instrument : Hewlett Packard 1090 High Performance Liquid Chromatograph

Column : TSK GEL ODS-80TM (4.6 mm ϕ \times 15 cm)

Column Temperature : Room Temperature

Flow Rate : 1 mL/min

Mobile Phase : Distilled Water : Acetonitrile = 1 : 1

Detector : UV (295 nm)

Injection Volume : 20 μ L

APPENDIX P 4

STABILITY OF *p*-NITROANISOLE IN FORMULATED DIETS
IN THE 2-YEAR FEED STUDY

STABILITY OF *p*-NITROANISOLE IN FORMULATED DIETS IN THE 2-YEAR FEED STUDY

Date Prepared	Date Analyzed	Target Concentration	
		300 ^a	40000
1998.09.24	1998.09.24	314 (100) ^b	40500 (100)
	1998.10.02 ^c	264 (84.1)	37700 (93.1)
	1998.10.29 ^d	304 (96.8)	39400 (97.3)

^a ppm

^b % (Percentage was based on the concentration on date of preparation.)

^c Animal room samples

^d Cold storage samples

Analytical method : The samples were analyzed by high performance liquid chromatography.

Instrument : Hewlett Packard 1090 High Performance Liquid Chromatograph

Column : TSK GEL ODS-80TM (4.6 mm ϕ \times 15 cm)

Column Temperature : Room Temperature

Flow Rate : 1 mL/min

Mobile Phase : Distilled Water : Acetonitrile = 1 : 1

Detector : UV (295 nm)

Injection Volume : 20 μ L

APPENDIX P 5

HOMOGENEITY OF *p*-NITROANISOLE IN FORMULATED DIETS IN THE 2-YEAR FEED STUDY

HOMOGENEITY OF *p*-NITROANISOLE IN FORMULATED DIETS IN THE 2-YEAR FEED STUDY

	Target Concentration		
	5000 ^a	10000	20000
Coefficient Variation	3.33 ^b	3.05	1.26

^a ppm

^b % (n=7)

Analytical method : The samples were analyzed by high performance liquid chromatography.

Instrument : Hewlett Packard 1090 High Performance Liquid Chromatograph

Column : TSK GEL ODS-80TM (4.6 mm ϕ \times 15 cm)

Column Temperature : Room Temperature

Flow Rate : 1 mL/min

Mobile Phase : Distilled Water : Acetonitrile = 1 : 1

Detector : UV (295 nm)

Injection Volume : 20 μ L

APPENDIX Q

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY
IN THE 2-YEAR FEED STUDY OF *p*-NITROANISOLE

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY
IN THE 2-YEAR FEED STUDY OF *p*-NITROANISOLE

Item	Method	Unit	Decimal place
Hematology			
Red blood cell (RBC)	Light scattering method ¹⁾	$\times 10^6/\mu\text{L}$	2
Hemoglobin(Hgb)	Cyanmethemoglobin method ¹⁾	g/dL	1
Hematocrit(Hct)	Calculated as $\text{RBC} \times \text{MCV}/10$ ¹⁾	%	1
Mean corpuscular volume(MCV)	Light scattering method ¹⁾	fL	1
Mean corpuscular hemoglobin(MCH)	Calculated as $\text{Hgb}/\text{RBC} \times 10$ ¹⁾	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as $\text{Hgb}/\text{Hct} \times 100$ ¹⁾	g/dL	1
Platelet	Light scattering method ¹⁾	$\times 10^3/\mu\text{L}$	0
White blood cell(WBC)	Light scattering method ¹⁾	$\times 10^3/\mu\text{L}$	2
Differential WBC	Pattern recognition method ²⁾ (Wright staining)	%	0
Biochemistry			
Total protein(TP)	Biuret method ³⁾	g/dL	1
Albumin (Alb)	BCG method ³⁾	g/dL	1
A/G ratio	Calculated as $\text{Alb}/(\text{TP} - \text{Alb})$ ³⁾	—	1
T-bilirubin	Alkaline azobilirubin method ³⁾	mg/dL	2
Glucose	GlcK·G-6-PDH method ³⁾	mg/dL	0
T-cholesterol	CE·COD·POD method ³⁾	mg/dL	0
Triglyceride	LPL·GK·GPO·POD method ³⁾	mg/dL	0
Phospholipid	PLD·ChOD·POD method ³⁾	mg/dL	0
Glutamic oxaloacetic transaminase (GOT)	JSCC method ³⁾	IU/L	0
Glutamic pyruvic transaminase (GPT)	JSCC method ³⁾	IU/L	0
Lactate dehydrogenase (LDH)	SFBC method ³⁾	IU/L	0
Alkaline phosphatase (ALP)	GSCC method ³⁾	IU/L	0
γ -Glutamyl transpeptidase (γ -GTP)	L· γ -Glutamyl-p-nitroanilide method ³⁾	IU/L	0
Creatine phosphokinase (CPK)	JSCC method ³⁾	IU/L	0
Urea nitrogen	Urease·GLDH method ³⁾	mg/dL	1
Sodium	Ion selective electrode method ³⁾	mEq/L	0
Potassium	Ion selective electrode method ³⁾	mEq/L	1
Chloride	Ion selective electrode method ³⁾	mEq/L	0
Calcium	OCPC method ³⁾	mg/dL	1
Inorganic phosphorus	PNP·XOD·POD method ³⁾	mg/dL	1

1) Automatic blood cell analyzer (ADVIA120 : Bayer Corporation)

2) Automatic blood cell differential analyzer (MICROX HEG-120NA : OMRON Corporation)

3) Automatic analyzer (Hitachi 7070 : Hitachi, Ltd.)