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 ( $2\mbox{-YEAR}$ 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 ( $2\text{-YEAR}$ 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 p-NITROANISOLE IN THE 2-YEAR FEED STUDY
APPENDIX P 2	STABILITY OF $p$ -NITROANISOLE IN THE 2-YEAR FEED STUDY
APPENDIX P 3	CONCENTRATION OF $p$ -NITROANISOLE IN FORMULATED DIETS IN THE 2-YEAR FEED STUDY
APPENDIX P 4	STABILITY OF $p$ -NITROANISOLE IN FORMULATED DIETS IN THE 2-YEAR FEED STUDY
APPENDIX P 5	HOMOGENEITY OF $p$ -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 $p$ -NITROANISOLE

# APPENDIX A 1

CLINICAL OBSERVATION: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

ANIMAL : MOUSE Crj:BDF1 ALL

REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : MALE

ODA · REIDE															TAGE .
Clinical sign	Group Name	Admini	stration W	eek-day											
	···	1-7	2-7	3-7	4-7	5 <b>-</b> 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 ррш	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 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TUNCHBACK 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	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	Õ	1	1	ō	0	ō	Õ	ō	Õ	ō
	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	Õ	Ö	Ö	Õ	Ö	ŏ	0
	10000 ppm	0	0	0	o o	0	0	0	Ö	0	ő	Ŏ	0	Ö	ŏ
	20000 ppm	0	0	0	ō	0	Ō	ō	0	ō	0	0	ő	ő	Ö
EXOPITHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	Ö	0	0	Ö	Ö
	10000 ррш	0	0	Ö	0	ő	0	0	0	0	0	0	0	0	0
	20000 ppm	Ö	ő	Ö	0	Õ	ő	0	0	0	0	Ö	0	0	ő

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

SEX : MALE

Clinical sign	Group Name	Admin	istration W	eek-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
EATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	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
ORIBUND 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
OCOMOTOR 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
ATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TUNCHBACK 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 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ILOERECTION	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

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-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
EATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	i	1	2	2	2	2	2	3	3	3	3	3	4	4
	20000 ррш	1	1	1	1	1	1	1	1	1	1	1	1	1	1
DRIBUND 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
OCOMOTOR 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
ATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UNCHBACK 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 բբա	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROG 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
XOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	٥	0

STUDY NO. : 0402 CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

Clinical sign	Group Name	Admini	stration W	eek-day											
	Ozoup Namo	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
	0			0	•	•					•				
EATH	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
ORIBUND 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
OCOMOTOR 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	ō	0	0	0	ō	0	0	0	0	0	Ö
	20000 ppm	0	0	0	0	0	0	Ö	0	Ö	0	0	0	0	Ö
ATERAL	Control	0	0	0	•	0	0	0		•	0	0	•	•	•
AICKAL		0		0	0				0	0	-		0	0	0
	5000 ppm		0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JUNCHBACK 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
ILOERECTION	Control	0	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	Ō	0	0	0	0	0	Ö	ō	0	ō	Ô	ő
	20000 ppm	0	0	0	0	0	0	0	0	0	ō	0	0	0	Ö
ROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	Ö	0	0	ŏ	0	0	0	0	0	0	ŏ
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	U	v	U	U	U	U	v	U	U	U	U	U	U	U
EXOPIITIIALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	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

linical sign	Group Name	Admini	stration W	eek-dav											
		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
EATII	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
ORIBUND 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 0
	20000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	U	U
OCOMOTOR 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
ATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TUNCHBACK 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	I	1	I	1	1	1	1	0	0	. 0
	20000 թվու	0	0	0	0	0	0	0	0	0	0	0	0	0	U
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
	mqq 00001	0	0	0	0	1	1	1	1	1	1	1	l o	1 0	I o
	20000 ppm	0	0	0	0	0	0	1	0	0	0	0	0	U	0
ROG 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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-dav											
		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
									_		_	,			
eath	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
ORIBUND 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
OCOMOTOR 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
ATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	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
JUNCHBACK 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	Õ	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	i	0	0	0	0	0	i	1	1	0	0	0	0	0
	20000 ppm	0	0	0	Ō	Ō	0	ō	ō	0	0	0	1	1	1
ROG 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	Ō	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	ő	0	ő	0	Ō	0	0	0	0	0	0	0	0
XOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	Ô	Ô	Õ	Õ	Ö	Ō	0	0	0	0	0	0	0
	20000 ppm	1	1	1	1	i	1	1	1	1	1	0	1	1	1

STUDY NO. : 0402 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

												-			
linical sign	Group Name		istration W 85-7		87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		84-7	85-1	86-7	81-1		89-1	90-7	91-1	92-1	93-1	94-1		90-7	91-1
БАТЫ	Control	6	6	7	7	7	8	8	9	9	9	9	10	10	10
Ditti	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
DRIBUND 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
OCOMOTOR 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	Đ	0	0	0	0	0
ATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UNCHBACK 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
ILOERECTION	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 ррш	0	0	1	0	1	0	0	1	5	5	5	7	5	3
ROG BELLY	Control	0	0	0	0	i	0	0	0	0	0	0	0	0	0
	5000 ррш	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
XOPIITHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE									PAGE :
Clinical sign	Group Name	Admini	stration	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 ррш	10	11	11	13	13	15	15	
	10000 ppm	17	17	18	18	18	20	21	
	20000 ррш	20	22	24	27	27	27	27	
ORIBUND 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 ррт	6	6	7	7	7	7	7	
OCOMOTOR 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	
ATERAL	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	
JUNCHBACK 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 ррт	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	ō	ō	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	õ	ō	ō	Ô	0	
	20000 ppm	0	0	0	0	0	0	Õ	

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : MALE

Clinical sign	Group Name	Admini	stration We	ek-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
:UM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
, one	5000 ppm	Ö	0	0	0	0	0	0	0	0	0	0	0	0	ů
	10000 ppm	Ö	Ö	0	0	0	Ö	Õ	0	0	0	0	0	. 0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
efect 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
XTERNAL 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 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NTERNAL 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	i	1
	20000 ррш	0	0	0	0	0	0	0	0	0	1	1	1	1	2
I. 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
LPERI 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
. 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. 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

#### CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

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

SEX : MALE

Clinical sign	Group Name	Admini	istration W	eek-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
JM.	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
efect 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 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XTERNAL 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NTERNAL 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	i	2	2
	20000 ppm	1	1	1	1	1	1	1	1	1	1	1	0	0	0
. 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
. 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
. 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
. 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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

### CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	stration W	leek-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	ō	Ö	ŏ	Ö	0	0	ŏ	0	ő	0	0	0	0	0
	10000 ppm	0	0	0	Ō	0	0	Ö	Õ	0	Ö	Ŏ	0	Ô	0
	20000 ppm	0	0	0	0	0	0	0	0	ō	Ö	Ö	ō	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	D	0	0	0	0	0	0	0	0	0	0	0
XTERNAL 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
NTERNAL 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	i	1	l	1	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
. 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
I. 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.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
. 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY)

MOUSE Crj:BDF1 ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : MALE

Clinical sign	Group Name	Admini	istration W	leek-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
UM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
efect 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
XTERNAL 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 ррш	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
NTERNAL 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	i	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
. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. 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
I. 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	i	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
I. 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

SEX : MALE

linical sign	Group Name	Admini	stration W	leek-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
UM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	D	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
efect 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
	mqq 00001	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XTERNAL 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
NTERNAL 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
. 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	0	0 0	0
	20000 ppm	0	0	0	0 -	0	0	U	U	U	U	U	v	U	U
.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
.PERI EAR	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
	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
. 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		
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : MALE

PAGE: 14

Clinical sign	Group Name		stration R												
. <del>.</del>		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
UM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ррш	0	0	0	0	0	0	0	0	0	Ō	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EFECT 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XTERNAL 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	I	1	1	1	1	1	1	1	1	0	1	1	1
NTERNAL 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
I. 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
I. 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	I	1	1	1	1	1	1	1	1	0	1	1	1
I. 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

(HAN190)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : MALE

Clinical sign	Group Name	Admin: 84-7	istration W 85-7	Veek-day _ 86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		84-1	85-7	80-1	81-1	88-1		90-7	91-1	92-1	95-1		90-1		91-1
GUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	ō	0	0	0	0	0	0	•	. 0	0	0	0	0	0
	10000 ppm	0	0	0	0	1	1	1	1	i	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 ррш	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	i	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 5	6 5	6 5	6 5	6
	10000 ppm 20000 ppm	1 15	3 18	4 18	4 18	5 17	5 20	4 20	4 21	4 23	25	5 24	24	24	4 23
M MOCE		^	٥	0	0	٥	0	0	0	0	0	0	0	0	0
M. NOSE	Control	0	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	0
	10000 ppm 20000 ppm	0 0	0	0 0	0 0	0	0	0	0	0	0	0	0	0	0
	20000 рры	U	Ū	Ü	U	U	Ū	v	Ū	J	Ü	v	v	Ū	V
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 ррт	1	I	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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0402 CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

SEX : MALE PAGE: 16

Clinical sign			Stration	Veek-day _				
	Group Name	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 ррш	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 ррш	1	1	1	1	1	1	i
EXTERNAL MASS	Control	0	0	0	0	0	0	2
THE PARTY OF THE P	5000 ppm	0	ő	1	Ö	1	Ö	0
	10000 ррш	1	2	2	2	2	1	1
	20000 ppm	1	0	0	ő	0	Ô	Ô
	20000 ppm	•	•	Ü	ŭ	ŭ	•	•
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
III. HVOL	5000 ppm	0	0	0	0	0	0	0
								1
	10000 ppm	0 0	1 0	1 0	1 0	1 0	1 0	0
	20000 ррт	U	U	U	U	U	U	
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	ī	0	Ö	0	0	0	0
	21111 //	-	•	-	-	-		•
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
					0			

### CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

OPT TUDE : A1 104

SEX : MALE

Clinical sign	Group Name		stration We												
	· · · · · · · · · · · · · · · · · · ·	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
A A D D ANGELL				_	_						_	_	_	_	_
A. 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
. 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	O	0	0	0	0	0	0	0	0	0	0
	20000 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррш	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 ррві	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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RREGULAR 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 ррш	0	0	0	0	0	0	0	0	ō	0	o	0	ō	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	Õ
	10000 ppm	0	Ō	o O	0	0	0	0	0	0	Ö	ő	0	0	0
	20000 ppm	Ô	0	0	ŏ	Ö	Ŏ	ŏ	Ö	0	ő	ő	Ö	0	0

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : MALE

Clinical sign	Group Name	Admin	istration W	eek-dav						_					
		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
. 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
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
	mqq 00001	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	. 0	0	0	0	0	0	0
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORT1COLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RREGULAR 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
ESPIRATORY 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	Ō	0	0	0	0	0	Ō	0	0	ō	0

### CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admin	stration W	eek-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
	-														
I. 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
I. 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 ррш	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 ррш	0	0	0	0	0	0	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 ррш	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 ррш	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 ррш	0	0	0	0	0	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	O

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

SBDF1 ALL

SEX : MALE

Clinical sign	Group Name	Admin	istration W	eek-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	•	•		•		•		
m. ADDOMEN	5000 ppm	0	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
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	U	U	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	o o	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	Ö
	20000 ppm	0	0	0	0	0	Ö	Ö	0	0	0	0	0	0	0
	División pp.	•	· ·	·	·	ŭ	v	•	·	•	Ū	U	٠	v	U
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	ō	ō	Ō	Ö	Õ	Õ	Ŏ	Ô	Ŏ	ŏ	ő
	10000 ppm	0	0	0	Ö	Ö	0	0	0	Õ	0	0	0	0	Ö
	20000 ppm	0	0	0	Ö	ő	0	ō	ő	ő	ő	ő	0	0	0
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	Ö	Ö	0	0	Ô	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 թբա	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	•	•	
TORTICOBETS	5000 ppm	0	0		0	0	0	0	0	0	0	0	0	0	0
	10000 ppm 10000 ppm	0	0	0 0	0	0 0	0	0	0	0	0	0	0	0	0
	20000 ppm 20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	U	U	U	U	Ū	0	U	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	Ö
	10000 ppm	0	Ö	Ö	0	0	ŏ	0	0	Ô	Ô	Î	0	0	Ö
	20000 ppm	0	Ö	ő	Ö	Ö	Ö	0	ő	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ALLO THE COLL DOOR MINOR	5000 ppm	0	0	0	0	0	-	=	-	-	1		-	0	0
	10000 ppm maga 00001	0		0			0	0	0	0	Ţ	1	0	0	0
		0	0 0	0	0	0	0	0	0 0	0	0	1	0	0	0
	20000 ррш	U	U	U	U	U	U	U	U	υ	0	0	0	0	0

#### CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

OPT TVDE : A1 104

SEX : MALE

Clinical sign	Group Name	Admin	istration W	eek-day			<u> </u>								
		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. 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
. 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 ррт	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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	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	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	Ö	0	Ō	0	Ō	0	0	Ö	Ō
	20000 ppm	0	0	0	0	0	0	Ô	0	0	0	0	0	ō	ō
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 ррш	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	Ō	0

STUDY NO. : 0402 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-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
. 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
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
. 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
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	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
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORT1COLL1S	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
RREGULAR 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	i	1	1	1	0	1	1	0
	20000 ppm	0	0	0	0	0	0	1	0	1	0	0	1	1	0
ESPIRATORY 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	Ō	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : MALE

Clinical sign	Group Name	Admin	istration W	eek-day _											
	<del></del>	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	97-1
. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I. ADDORIGN	5000 ppm	0	0	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	i
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррш	·	v	Ū	v	Ū	v	v	v	Ū	v	v	v	v	V
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	Ö	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	Ö	0	0	0	Ö	Ö	Ŏ	0	ő
	20000 ppm	ō	Ŏ	0	ō	Ô	0	ō	0	0	Õ	Ô	0	Ô	0
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
A CAMELLE	5000 ppm	0	0	0	ő	0	0	ŏ	0	0	0	0	0	0	0
	10000 ppm	0	0	0	Ō	0	0	Ö	0	0	o o	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	Ô	Ŏ	0	0	ĺ	0	Ö	Ô	i	1	1	1
	10000 ppm	0	0	0	Ö	0	0	0	0	0	0	0	1	1	1
	20000 ppm	ō	ő	0	Ö	0	ō	0	ō	o	ō	o o	ō	o	Ô
TORTICOLLIS	Control	2	2	2	2	2	2	2	2	2	2	2	1	1	1
***************************************	5000 ppm	0	0	ő	Õ	0	0	0	0	0	0	0	Ô	0	0
	10000 ppm	0	0	0	Ö	Ö	0	0	0	0	0	0	0	0	Ö
	20000 ppm	0	0	0	ō	0	ō	0	0	Ö	Ô	ō	0	Ô	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	5000 ppm	0	0	1	1	i	1	1	1	1	1	1	î	1	1
	10000 ppm	0	0	1	1	î	1	Ô	0	Ô	Ô	1	Ô	1	0
	20000 ppm	0	1	1	0	Ô	Ô	ő	ì	1	1	1	3	3	3
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ALL THE OWN BOOK HONOR	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Č

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	stration '	Week-dav					
		98-7	99-7	100-7	101-7	102-7	103-7	104-7	
M. ABDOMEN	Control	0	0	0	0	0	0	0	
A. ADDORIGIN	5000 ppm	0	0	0	0	0	0	0	
	10000 ppm	1	ı	1	1	1	0	0	
	20000 ppm	0	0	0	0	0	0	0	
	20000 ppm	U	U	υ	U	U	V	U	
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	Õ	0	0	Ō	Õ	0	ō	
	nooo ppm	•	·	v	•	Ü	v	٧	
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	
	20111 pp	•	•	•	•	•	•	•	
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	l	1	I	I	1	1	
	20000 ppm	0	0	0	0	0	0	0	
monm. oo. 1. 70				_		_			
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 ррш	0	0	0	0	0	0	0	
IRREGULAR BREATHING	Control	1	2	2	3	2	2	2	
THEOCEAN DIGHTHING	5000 ppm	2	2	2	3 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	
The state of the s	5000 ppm	0	0	0	Ô	0	0	0	
	10000 ррш	0	0	0	0	0	0	0	
	20000 ppm	0	0	0	0	0	0	0	
	որդի օօօօ	v	U	U	U	U	U	U	

#### CLINICAL OBSERVATION (SUMMARY)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

ALL ANIMALS

SEX : MALE

										<del></del> .					
Clinical sign	Group Name		stration W												
		1-7	2-7	3-7	4-7	5 <del>-</del> 7	6-7	7-7 	8-7	9-7	10-7	11-7	12-7	13-7	14-7
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ADNORMAL RESPIRATION	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	Ö	Ô	0	0	0	0	Ö	Ö	0	Ö	0	0	Ô	0
	20000 ррш	v	•	v	·	v	v	•	·	v	v	•	•	·	Ů
ACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	mqq 00001	0	0	0	0	0	0	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
IEMATURIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	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
MALL 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
DLICO 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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : MALE

Clinical sign	Group Name	Admini	stration W												
		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	28-1
MODIAL RECRUMENTON	Otu-1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRATION	Control	0	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
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	U	U	U	U	U	Ū	U	U	U	U	U	U	U	U
ACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL 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
EMATURIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ELLOW 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	49	49	49	49
	20000 ppm	50	50	50	50	50	50	49	49	49	49	49	49	49	49
MALL 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	1	0	0	0	0
	20000 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0	0
LIGO STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	5000 ppm	0	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	C
	20000 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0	C
UBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	(
warrand lid 1 Idill	5000 ppm	0	0	0	Ö	0	Ö	0	Ö	Ŏ	ō	0	Ö	0	(
	10000 ppm	0	0	0	0	0	ō	ő	Ö	0	o	0	0	0	ď
	20000 ppm	Õ	0	Ö	ő	Õ	ő	ő	0	0	0	0	0	0	(

STUDY NO. : 0402 CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

PAGE: 27 SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-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
	a					2	•	0	0	0		^			0
BNORMAL 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
CHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NORMAL 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 ррш	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
MATURIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ELLOW 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
ALL 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
IGO 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
IBNORMAL 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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : MALE

linical sign	Group Name	Admini	stration W	eek-dav											
		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
											•	•	•	•	•
BNORMAL 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
CHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MATURIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ELLOW 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 ррт	45	45	45	45	45	45	45	45	45	45	45	44	44	44
	20000 ррт	19	19	49	48	47	47	47	47	47	47	47	47	47	47
MLL 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
	mqq 00001	o	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
IGO 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
	mqq 00001	0	0	0	0	0	0	0	0	0	0	2	1	2	2
	20000 ppm	0	0	0	ō	0	ō	0	Ō	0	0	0	ō	0	0
JBNORMAL 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	Ö	0	ō	ō	Ö	0	0	0
	20000 ppm	Ö	0	0	0	0	0	ő	0	ŏ	Ö	Ö	Ŏ	0	ō

STUDY NO. : 0402 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

SEA · MALE															TROD . Z
Clinical sign	Group Name		istration W												
		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
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
individual radii 1011	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 ррш	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
	mqq 0005	0	0	0	0	0	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	ı	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

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

#### CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-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
BNORMAL 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
ACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	l	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
BNORMAL 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
EMATURIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	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
ELLOW 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
	mqq 00001	14	44	44	44	44	43	42	42	42	41	0	41	40	39
	20000 ррт	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	i	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
LIGO STOOL	Control	0	0	0	0	0	0	2	1	0	1	0	i	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	2	0	ī	2	2	2	2	2	2	1	0	1	i	0
	20000 ppm	0	0	0	ō	1	Ö	1	0	1	Ô	ő	ī	ō	Ö
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	ō	0	Ō	0	ō	Ö	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	ő	0	0	ő	Ö	ő	ő	i	Õ	0	0	0	0

#### CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day _											<del></del> .
	· · · · · · · · · · · · · · · · · · ·	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
MINORIME RESITION	5000 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	î
	10000 ppm	0	0	1	1	1	1	0	0	0	Ô	1	0	î	0
	20000 ppm	0	1	1	0	0	0	0	1	1	1	1	3	3	3
	20000 ppm	U	1	1	U	U	U	U		1			•	J	J
ACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
THE COURT	5000 ppm	Ö	0	0	0	0	0	0	0	Ō	0	0	0	0	0
	10000 ррш	0	0	0	0	0	0	0	Ö	0	Ö	0	0	ō	0
	20000 ppm	Ő	0	0	0	0	0	0	0	Õ	Ö	0	0	Ö	0
	20000 ppm	· ·	·	Ü	v	v	v	ŭ	·	Ū	ŭ	v	•	•	
EMATURIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ELLOW 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
MALL STOOL	Control	0	0	0	0	0	. 0	0	0	0	0	0	0	1	1
SILIDD STOOD	5000 ppm	0	0	0	ő	0	. 0	0	0	0	Ö	0	0	ō	Ô
	10000 ppm	0	i	0	0	0	0	Ö	0	0	ő	Ö	Ŏ	ŏ	ŏ
	20000 ppm	0	1	0	0	0	0	0	0	0	0	ő	0	0	i
	20000 ինա	U	1		U	U	Ū	Ū	v	Ū	v	٧	J	v	1
LIGO 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
UBNORMAL 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	Ď	ō	0	1	0	ō	0	0	0	0	0	0
	20000 ppm	Ö	1	0	Ō	0	ō	0	0	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY)

ANIMAL : MOUSE Cr.j:BDF1
REPORT TYPE : A1 104

: MOUSE Crj:BDF1 ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	stration '	Week-day _					
vage	see als 1 mms	98-7	99-7	100-7	101-7	102-7	103-7	104-7	
					<del></del>	<del></del>			
ABNORMAL RESPIRATION	Control	1	2	2	3	2	2	2	
	5000 ppm	2	2	2	1	0	0	0	
	10000 ppm	0	1	1	i	1	1	1	
	20000 ррш	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 ррш	0	0	0	0	0	0	0	
ABNORMAL RESPIRA. SOUND	Control	0	0	1	1	0	0	0	
	5000 ррш	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 ррт	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 ррш	32	32	30	30	30	28	27	
	20000 ppm	24	22	19	16	16	16	16	
SMALL STOOL	Control	ı	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 ррш	0	0	0	0	0	0	0	

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

### CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

PAGE: 33

Clinical sign	Group Name	Admini	stration W	eek-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

CLINICAL OBSERVATION (SUMMARY)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-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
VON REMARKABLE	Control	50	50	50	50	50	50	50	50	50	49	49	49	49	49
OU UDWINIDED	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

### CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-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
ION 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	Ō
	20000 ppm	0	0	0	0	0	0	0	0	. 0	0	0	0	0	0

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-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	O	Ω	0	0	0

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

#### CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	stration W	leek-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

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

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day _		<del> </del>	<del> </del>								
		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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

## CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

linical sign	Group Name	Admini	stration W	eek-day											
		84-7	85-7	86-7	87-7	88-7	897	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
ION 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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

Clinical sign	Group Name	Admin	istration	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 ррш	0	0	0	0	0	0	0		
	10000 ppm	0	0	0	0	0	0	0		
	20000 ррш	0	0	0	0	0	0	0		

BAIS 4 (HAN190)

# APPENDIX A 2

CLINICAL OBSERVATION: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

STUDY NO. : 0402

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : FEMALE

SEA . PENALE															TAGE .
Clinical sign	Group Name	Admini	stration W	eek-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
nonombion robition	5000 ppm	Ö	ŏ	ŏ	0	ŏ	0	0	Ö	ō	0	0	0	0	0
	10000 ppm	ů	ő	Õ	Ŏ	Ō	0	0	0	0	0	0	0	0	0
	20000 ppm	Ö	0	0	0	ō	Ď	0	0	0	0	0	0	0	Ō
ROTATING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	ő	ŏ	Ö	0	Ö	Ö	Ö	Ö	ő	Ö	Ö	ŏ	Ö
	10000 ррш	0	Ŏ	Ö	Ö	0	Ö	ŏ	Ď	Ö	Ö	ů.	Ö	Ö	Ö
	20000 ppm	0	0	0	0	0	0	0	0	o	0	0	ō	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1 IBOLKBOTTON	5000 ppm	0	0	0	0	0	0	ő	0	ő	0	0	Ö	Ő	ŏ
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ő
	20000 ppm	o	Õ	ő	ő	Ö	0	ő	0	Ö	ő	ő	Ö	ō	Ö
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I NOO BABBII	5000 ppm	0	0	0	0	0	Ö	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	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	U	U	υ	U	U	U	U	U	U	V	U	U	U	U
EXOPIITHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0

# CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-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
EATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DRIBUND 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
OCOMOTOR 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
INCHBACK 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
OTATING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROG 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	Ō	0
XOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	ō	0	0	ō	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	0

STUDY NO. : 0402 CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

PAGE: 43 SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-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-
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
ORIBUND 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	(
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
ROTATING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	10000 ppm	0	0	0	0	0	0	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	(
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	10000 ppm	0	0	0	0	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	(
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	20000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	1
EXOPIITHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	5000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	6
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(

## ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

# CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-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	I	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
ORIBUND 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
OCOMOTOR 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UNCHBACK 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OTATING	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	C	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ILOERECTION	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 ррш	0	0	٥	0	0	0	0	0	0	0	0	0	0	0
ROG 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
XOPIITIIALMOS	Control	0	0	0	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	ō	ō	o o
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

STUDY NO. : 0402 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : FEMALE

linical sign	Group Name		stration W												
		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
CATTLE	Control	1	1	1	1	1	1	1	2	3	4	5	6	6	6
EATH	5000 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	10000 ppm	ő	0	Ő	0	ő	0	0	0	0	0	0	0	0	0
		1	1	1	1	1	1	2	2	2	2	2	. 2	3	3
	20000 ppm	1	1	1	1	1	1	4	۷	2	2	L	. 2	J	v
ORIBUND 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
OCOMOTOR 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
INCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SHOULDHOM TODITION	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	Ō	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	ő	0	0	0	0	0	0	0	0	0	0	0	0	0
OTATING	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 ррш	ō	0	ō	0	0	0	0	0	0	0	0	0	0	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1242,0011011	5000 ppm	0	0	0	Ö	Õ	0	0	0	0	0	0	0	0	0
	10000 ppm	0 .	0	0	Ö	Ö	0	ō	ō	0	0	0	0	0	ł
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROG BELLY	Control	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	5000 ppm	ő	0	0	0	0	0	ō	ō	0	0	0	0	0	0
	10000 ppm	ŏ	0	ō	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	Ö	Ö	0	0	0	0	0	0	0	0	0	0
VODIITUAI VOS	Control	0	0	0	0	0	0	0	0	0	0	1	1	1	1
XOPIITHALMOS	Control 5000 ppm	1		1	1	1	1	1	1	1	1	1	1	1	1
	mqq 0000 mqq 00001	0	1 0	0	0	0	0	0	1	1	1	i	i	l	1
		0	0	0	0	0	0	0	1	1	1	1	1	1	1
	20000 ppm	U	U	U	U	U	v	•	r				-		

STUDY NO. : 0402

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admin	istration W	eek-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
EATH	Control	6	6	6	6	7	9	9	9	9	9	10	10	10	14
DA III	5000 ppm	2	4	4	4	4	4	4	4	4	4	6	6	6	6
	10000 ppm	1	1	1	1	1	1	i	1	2	4	4	5	5	5
	20000 ppm	3	4	6	7	8	9	10	11	12	12	12	12	12	12
	20000 ррш	v	4	O	ı	٥	9	10	11	12	12	14	12	12	12
ORIBUND 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
DOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DOGIOTOR MOTORITATE DISOR	5000 ppm	0	0	0	0	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 20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 քիրո	U	U	U	U	U	v	U	U	U		U	U	U	U
INCIBACK 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	1	1
OTATING	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	Ö	0	0	0	0	0	Ō	0	0	0	0	0
	20000 ppm	ō	Ö	0	ő	0	ō	ő	0	Ő	ő	0	ő	o	0
ILOERECTION	Control	0	1	1	1	1	1	1	1	1	1	0	1	3	0
TPOPWPOI TOM	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	1	1	1	1		2	1	2	1	0	0	0	2	0
	20000 ppm 20000 ppm	2	1	1	0	1 0	0	0	0	0	0	0	0	1	1
	ZOOOO ppm	4	1	1	U	U	U	U	U	U	U	U	U	1	1
ROG 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	Q	0	0	0	0	0
XOPIITHALMOS	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	i	1	1	1	1	0	1	i	1
	20000 ppm	1	1	1	1	1	1	1	1	1	1	0	1	1	1

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

SEX : FEMALE

STUDY NO. : 0402

Clinical sign	Group Name	Admin	stration W	leek-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
EATH	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
ORIBUND 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	i	1	1	1	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
OCOMOTOR 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TUNCHBACK 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 բթա	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
ROG 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
XOPIITHALMOS	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	i	1	1	0	0	0	0	0	0	0	0	0	0	C
	20000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	2

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

## CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admin	istration	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	i	1	1	1	1	1	1
	20000 ppm	i	i	1	ĩ	i	1	1
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	Ö	Ö	0	0	0
	10000 ppm	Ö	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
	20000 pput	v	U	U	U	U	U	υ
JUNCHBACK POSITION	Control	0	0	0	0	0	0	0
	5000 ррш	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	0	0	ő	o	ő	ő
ROTATING	Control	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	ō	0	Ö
	10000 ppm	0	0	Ö	0	0	0	0
	20000 ppm	ō	0	ő	o	0	0	0
PILOERECTION	Control	•	•					
TLUERECTION	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	ō	0	0
	20000 ppm	0	0	0	ő	0	ő	Ö
SXOPIITIIALMOS	Control	1	I	1	1	1	1	1
	5000 ppm	ì	i	1	0	Ó	0	0
	10000 ppm	0	0	0	0	0	0	
	20000 ppm	1	1	1	1	1	1	0 1
	20000 ppm	r	ı	1	1	1	1	Ł

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

SEX : FEMALE

Clinical sign	Group Name	Admini	stration We	ek-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 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	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 ррт	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 ррш	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

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-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
ORNEAL 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 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррт	0	0	0	0	0	0	0	0	0	0	1	1	1	1
1. 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

## CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name		istration W												
		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
WE ARMAYING		•			•	•	•	0	0	•		^	0	0	0
YE 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
	10000 ppm	0	0	0	0	0	0	0 0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	U	U	U	U	U	U	U	U	υ
ORNEAL 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
EFECT 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
XTERNAL 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
NTERNAL 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 բբա	1	1	1	1	1	1	1	1	1	1	1	1	1	1
. 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
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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. 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	Ō	0	0	0	0	0	0	0	0	0	0	0	0	0

### CLINICAL OBSERVATION (SUMMARY)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	stration We	eek-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	Ò	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 ррт	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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	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 ррт	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

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : FEMALE

Clinical sign	Group Name		istration W												70.7
		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
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SIL OF NOTE !	5000 ppm	0	Ö	0	0	Ů	Ö	Ö	i	1	1	1	1	1	ĭ
	10000 ppm	0	0	0	0	ŏ	ő	Ö	Ô	Ô	Ô	ō	0	ō	ō
	20000 ppm	Ő	0	Ö	Ö	Ö	ō	Ö	0	0	0	ō	0	0	0
	20000 2000														
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	1	1	1	1	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
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	1	1	1	1	1	1	1	2	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	9	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	1	1	2	1	2	3	3	2	1	1	0	0	1
	5000 ррт	0	0	1	2	2	2	1	1	1	1	1	1	3	4
	10000 ppm	0	0	0	1	i	1	1	1	1	1	1	1	1	5
	20000 ppm	0	1	1	1	2	2	1	2	2	2	2	2	5	10
i. 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	1	1	1	1	1	1	1	1	1	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	mqq 00001	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I. 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

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W												
		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
YE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10 01110111	5000 ppm	1	1	1	1	1	1	1	1	0	0	0	0	0	0
	10000 ppm	Ō	0	0	0	0	0	i	1	1	1	0	1	1	1
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORNEAL 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	i	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 2	1 2	0 2
	5000 ppm	0	1	1	1	1	1	1	2	2	2	0			
	mqq 00001	0	0	0	0	0	0	0	0	0	0	0	0	0	0 1
	20000 ppm	0	0	0	0	0	0	0	1	1	1	0	1	1	1
XTERNAL MASS	Control	1	2	2	2	2	2	2	2	2	3 0	0	3	3 0	1
	5000 ppm	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	U	U	v	U	v
INTERNAL MASS	Control	1	1	1	1	2	1	1	1 3	2 6	2 6	0	2 5	3 5	2 5
	5000 ppm	4	2	2	2	2	2	2			10	0	9	9	9
	10000 ppm	3	5	4	5	5	7 10	9 9	10 9	11 11	10 15	0	16	16	18
	20000 ppm	9	9	10	9	10	10	y	Э	11	19	-	10		
n. eye	Control	0	1	1	1 0	1 0	1 0	1 0	1 0	1 0	1 0	0 0	1 0	1 0	1 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	Ŏ	0
	20000 ppm	0	0	U	U	U	U	U	U	J		-	-		
M. PERI MOUTH	Control	0	0	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
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	U	U	U	U	U	
A. 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				
	10000 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0 0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	υ	U	U	U

#### CLINICAL OBSERVATION (SUMMARY)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

MOUSE Crj:BDF1 ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	leek-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	i	0	0	0	0 .	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORNEAL 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
EFECT 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	I	1	1	1	1	1	1	1	I	1	1	1	1	0
XTERNAL MASS	Control	1	1	1	2	2	2	2	2	2	3	3	3	4	3
	5000 ppm	0	0	0	1	I	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
NTERNAL 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 ррт	8	7	6	6	5	5	2	1	3	4	4	4	8	11
	20000 ррт	19	20	21	19	22	19	21	20	24	27	27	25	24	22
. 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
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
. 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

### CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admin	stration '	Week-dav				
ar ·-		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	ō	0	ō	0	0	0
	10000 ppm	0	0	0	0	0	0	0
	20000 ppm	0	ō	0	0	0	0	ō
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
	Sooo Min	v	U	U	U	U	U	U
EXTERNAL MASS	Control	3	3	3	3	3	3	3
	5000 ррш	i	2	2	3	4	3	2
	10000 ppm	2	1	1	1	i	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	i	1	1	1
	5000 ppm	0	Ô	0	0	0	0	0
	10000 ppm	0	Ö	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0
	20000 ppui	U	v	U	U	v	U	U
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 ррш	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	i	Ö	0	0	ő	0	0
	20000 ppm	0	ŏ	0	0	0	0	0

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

SEX : FEMALE

Clinical sign	Group Name	Admini	stration We	eek-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
A. 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I. 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	Ô	0	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	Ô	0	Ö	ő	ő	Ö	Ö	Õ	0	Ö	0	0	0	0
	10000 ppm	0	ő	Ö	ő	ő	0	ō	Ö	ō	ō	Ö	Ö	Ö	ů
	20000 ppm	0	0	0	0	0	0	0	0	ō	0	Ō	0	0	ō
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	Ö	Ō	0	ō	0	ō	Ŏ	0	0	Õ	Ö
	20000 ppm	ō	0	Ö	ō	ō	0	0	0	ō	0	ő	0	Ö	ō
ANEMIA	Control	0	0	0	0	0	0	0	0	Q	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	Õ	0	0	0	0	0
	10000 ppm	0	ō	0	0	0	0	ő	0	0	Ö	0	0	ő	0
	20000 ppm	0	0	0	0	0	0	Õ	0	ŏ	Õ	0	0	0	Õ

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : FEMALE

linical sign	Group Name		stration W	Yeek-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
. 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
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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	U	U
. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ррт	0	0	0	0	0	0	0	0	0	0	0	_	-	_
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	, 0	U	U	U
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	_
	mqq 00001	0	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	U	U	U	U
. 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 0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	Ū	0	U	U	U
. 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	υ	U	U	U	U
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	-	
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ррш	0	0	0	0	0	0	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	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	υ	U	U	U

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

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-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
FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PORLIMB	5000 ppm	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	20000 ppm	U	U	U	U	v	U	U	U	U	U	v	v	U	v
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
. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	Ö	0	ō	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	Ö	ő	0	0	0	ō	0	0	0	0	0	0
	20000 ppm	0	0	0	ő	Ö	0	0	Õ	0	0	0	0	0	0
	Door ppm	•	•	-	_	-	-								
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
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
HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	Ō	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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	Ö	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	Õ	Ď	0	ő	ō	0	0	0	0	0	0	0	0
	20000 ppm	•	•	•	-	•	•	-	-	•	-	*	•	•	-
NEMTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	. 0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

## CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	istration W	eek-day _		<del></del>									
		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
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
BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	9	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. 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	Ō	0	0	0	0
	10000 ppm	0	0	0	ō	ō	Ŏ	Ō	0	0	Ö	0	0	0	0
	20000 ppm	Ō	0	0	0	0	0	0	0	Ō	0	Ō	ō	0	0
ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	Ö	Õ	Õ	ŏ	0	0	Ô	ŏ	Õ	0	Ö	ŏ
	10000 ppm	0	0	0	0	0	0	0	Õ	0	Ö	0	0	0	ő
	20000 ppm	0	0	ō	0	0	0	Ö	0	0	0	Ö	0	ő	Ö
. 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	Ô	0	Ō	0	0	ō	0
	10000 ppm	0	0	0	0	0	0	0	0	0	Õ	ō	Ō	Ö	Ő
	20000 ррт	0	0	0	0	0	0	0	0	0	ō	0	ő	0	0
. 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	Ō	0
	10000 ppm	0	0	0	0	0	0	0	0	Ō	0	Ö	Ŏ	Ŏ	Õ
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. 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	Ŏ
	10000 ppm	Ö	0	0	ő	0	0	0	0	0	0	0	0	0	0
	20000 ppm	Ö	0	0	0	0	0	0	0	0	0	0	0	0	0
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
•	5000 ppm	Ö	0	0	0	0	0	Ö	0	0	0	0	ı	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	Ö	0	0	0	0	0	Ö	0	0	0	0	0	0	0

STUDY NO. : 0402 ANIMAL : MOUSE Cr.j:BDF1

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	leek-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
			•	•		0	•	•	٥	0	0	0	0	0	0
M. FORLIMB	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
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	U	U	U	U	U	U	U
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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. 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
. 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
. 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
.IIINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. 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
NEMTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	٥	0	0	0	0	0	0	0	1

#### CLINICAL OBSERVATION (SUMMARY)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104 ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-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
L 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 ррт	0	0	0	0	0	0	0	0	0	0	0	. 0	0	0
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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L 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 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. 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
I. 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 բբա	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. 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
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	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

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

#### CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

M. FORLIMB M. BREAST M. ABDOMEN	Control 5000 ppm 10000 ppm 20000 ppm Control 5000 ppm 10000 ppm 20000 ppm	84-7 0 0 0 0 0	85-7 0 0 0 0 0	86-7 0 0 0 0	87-7 0 0 0 0	0 0 0 0	89-7 0 0 0	90-7	91-7 0 0	92-7 0 0	93-7 0 0	94-7 0 0	95-7 0 0	96-7 0 0	97-7 0 0
1. BREAST	5000 ppm 10000 ppm 20000 ppm Control 5000 ppm 10000 ppm 20000 ppm	0 0 0 0	0 0 0 0	0 0 0	0 0 0	0 0	0	0	0	0					
. BREAST	5000 ppm 10000 ppm 20000 ppm Control 5000 ppm 10000 ppm 20000 ppm	0 0 0 0	0 0 0 0	0 0 0	0 0 0	0 0	0	0	0	0					
	10000 ppm 20000 ppm Control 5000 ppm 10000 ppm 20000 ppm	0 0 0 0	0 0 0 0	0 0 0	0	0	0				0	0	0	0	n
	20000 ppm  Control 5000 ppm 10000 ppm 20000 ppm	0 0 0	0 0 0	0 0	0										
	Control 5000 ppm 10000 ppm 20000 ppm	0	0 0	0		0		0	0	0	0	0	0	0	0
	5000 ppm 10000 ppm 20000 ppm Control	0 0	0	0	0		0	0	1	1	1	1	1	1	1
. ABDOMEN	10000 ppm 20000 ppm Control	0	0			0	0	0	0	0	0	0	0	0	0
I. ABDOMEN	20000 ppm Control				0	0	0	0	0	0	0	0	0	0	0
1. ABDOMEN	Control	0	Λ	0	0	0	0	0	0	0	0	0	0	1	1
I. ABDOMEN			v	0	0	0	0	0	0	0	0	0	0	0	0
	E000 ppr	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	avvu ppm	0	0	0	0	0	0	0	0	ŏ	Õ	0	Ö	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	o
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ō	0
I. 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	î	î
	10000 ppm	0	0	0	0	.0	0	0	0	0	0	0	0	0	Ô
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	Ö
L INTERSCAPULUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	ō	0	õ	Ö	0	Ö	0	Õ	0	0	0
	10000 ppm	0	0	0	0	1	1	1	1	1	i	1	1	1	1
	20000 ppm	0	. 0	0	0	ō	ō	Ö	0	Ô	Ô	0	Ô	0	0
. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	ŏ	Ö	0	0	0	0	0	0	0	0	0
	10000 ppm	0	ī	1	1	ĺ	1	i	1	1	1	1	1	1	1
	20000 ррш	0	0	0	ō	ō	0	ō	Ô	0	0	0	0	0	0
I. TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	٥	٥
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	ů	0	0	0	0	0	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
NEMTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	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

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104 CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

AL . MOUSE CEJ. EDI'I

SEX : FEMALÊ

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 0 0 0 0 0 0 0 0 0 0 0
M. ABDOMEN   Control   O   O   O   O   O   O   O   O   O
M. ABDOMEN   Control   O   O   O   O   O   O   O   O   O
M. BREAST   Control   O   O   O   O   O   O   O   O   O
M. BREAST  Control 0 0 0 0 0 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 0 0 0 0 0
M. ABDOMEN   Control   0   0   0   0   0   0   0   0   0
M. ABDOMEN
M. ABDOMEN  Control  0  0  0  0  0  0  0  0  0  0  0  0  0
M. ABDOMEN  Control 1000 ppm 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
Todo   Ppm   O   I   O   O   O   O   O   O   O   O
10000 ppm   0   0   0   0   0   0   0   0   0
10000 ppm
M. ANTERIOR. DORSUM   Control   1   1   1   1   1   1   1   1   1
M. ANTERIOR. DORSUM  Control  1
5000 ppm 1 1 1 1 1 1 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 1 1 1 1 1 1
20000 ppm 0 0 0 0 0 0 0
20000 ppm 0 0 0 0 0 0 0
M INTERCOADILIE
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
5000 ppm 0 0 1 1 1 1 1
10000 ppm 0 0 0 0 0 0
20000 ppm 0 0 0 0 0 0 0
M. TAIL Control 0 0 0 0 0 0
5000 ppm 0 0 0 0 0 0 0
10000 ppm 0 0 0 0 0 0
20000 ppm 0 0 0 0 0 0
ANEMIA Control 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
··

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

#### CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-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
										-					
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	Ō	0
RTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RREGULAR 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
NORMAL 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ELLOW URINE	Control	0	0	0	0	0	0	0	. 0	0	0	0	0	0	0
	5000 ppm	0	0	10	2	1	1	i	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
ALL 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	Ō	0	0	Ō	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	Ō	0
IGO 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	Ō	0	0	0	0	0	Ô	Ö
	20000 ррш	0	0	0	0	ō	Ō	Ö	0	ŏ	ő	o	0	o	0
BNORMAL 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	Ö	Ö	0	0	Ö	ő
	10000 ppm	0	0	0	0	0	0	ō	0	Ö	ő	0	0	Ö	Ö
	20000 ppm	0	0	0	0	0	0	Ö	Ō	Ö	ŏ	0	0	Ö	0

CLINICAL OBSERVATION (SUMMARY)

ANIMAL : MOUSE Crj:BDF1 ALL ANIMALS

REPORT TYPE : AI 104

STUDY NO. : 0402

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-dav											
		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
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RREGULAR 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
BNORMAL 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
ELLOW 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 ррт	50	50	50	50	50	50	50	50	50	50	50	50	50	50
MALL 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LIGO 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
UBNORMAL 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	9
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

#### CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

DEA - PERIOLE															
Clinical sign	Group Name	Admini	istration W												
		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
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
CORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	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 ррт	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 ррт	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

### CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : FEMALE

Clinical sign	Group Name	Admin	istration W	eek-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
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	. 0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORTICOLLIS	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
RREGULAR 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
BNORMAL 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
ELLOW 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 ррт	49	49	49	49	49	49	49	49	49	49	49	49	49	49
MALL 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
LIGO 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UBNORMAL 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

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

#### CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admin	istration W	leek-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
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORTICOLLIS	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	О	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 ррш	0	0	0	0	0	0	0	0	0	0	0	i	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

### CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : FEMALE

Clinical sign	Group Name		stration W												
		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
CRUSIA	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	Ô	0	0	0	0	0	0	0
	20000 ррш	U	V	U	·	U	•	v	0	0	v	v	· ·	Ü	U
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 ррт	49	49	49	49	49	49	49	49	48	46	0	45	45	44
	20000 ррт	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	ō	0	ō	0	0	0	0	0	0	0	0	0	Ō
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	O	0	0
	20000 ppm	0	1	0	1	0	0	0	0	0	0	0	i	2	2
OLIGO STOOL	Control	0	0	0	0	0	1	2	1	1	1	0	1	2	0
	5000 ppm	Ŏ	Ŏ	Ö	Q	ŏ	Ō	0	ō	õ	2	ŏ	î	1	Ö
	10000 ppm	0	Ö	0	ů 0	ů	Ö	2	2	i	0	0	Ô	ō	Ö
	20000 ppm	ő	1	2	4	Ö	Ö	0	0	Ô	ŏ	0	2	2	3
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
warring that I will	5000 ppm	0	0	0	0	0	0	0	0	Ö	0	0	Ö	Ö	Ö
	10000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	i	0
	20000 ppm	0	0	0	0	Ö	Ő	0	0	0	0	ő	0	Ô	Ö

## CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1 ALL A

REPORT TYPE : A1 104

STUDY NO. : 0402

SEX : FEMALE

Clinical sign	Group Name		istration W												
- · · · · · · · · · · · · · · · · · · ·		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
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20011	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	Õ	0	Ö	0	Ö	Ö	Ŏ	0	0	ő
	20000 ppm	0	0	0	ō	ō	ō	ō	Õ	0	ō	ō	Ŏ	0	ō
ORTICOLLIS	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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RREGULAR 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
BNORMAL 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	i	1	2	i	0	0	0	0	0	0	1	I	1
	20000 ррш	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 ррш	0	0	0	2	2	0	0	0	1	0	1	2	1	1
DLIGO 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	ı	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

CLINICAL OBSERVATION (SUMMARY)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	stration '	Week-day _			-	
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
				<del></del>				
CRUSTA	Control	0	0	0	0	0	0	0
choom	5000 ppm	0	0	0	ŏ	i	1	i
	10000 ppm	0	0	1	1	1	1	Ĺ
	20000 ppm	0	0	0	0	0	0	0
TORTICOLLIS	Control	1	1	1	1	1	1	1
TORTTOOLDID	5000 ppm	Ô	Ô	0	Ô	Ô	Ô	Ô
	10000 ppm	1	1	1	1	1	1	1
	20000 ppm	0	Ô	0	0	0	0	0
	Sooo bhm	v	v	U	v	U	v	v
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
IBNOIGHD ADOI INTITON	5000 ppm	3	2	4	2	3	4	3
	10000 ppm	0	0	Õ	0	1	1	1
	20000 ppm	3	2	3	2	1	1	1
YELLOW URINE	Control	0	0	0	0	0	0	0
IBEBON OKINE	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
WILL DOWN	0 . 1	•	•	^	•	•	0	0
SMALL STOOL	Control	0	0	0	0	0	0	0
	5000 ppm 10000 ppm	3	1 0	1 0	0 2	0 2	0 1	0 1
		2 1	2	0	1	0	0	0
	20000 ppm	1	4	υ	1	U	U	U
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	Ö	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	0
		Ö	0	Ö	Ō	Ö	Õ	Ō
	20000 ppm	0	0	0	0	0	0	0

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

### CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-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
VON 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 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

ALL ANIMALS

SEX : FEMALE

PAGE: 74

Clinical sign	Group Name	Admini	stration W	eek-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	n	0	0	0	0	n	0	Ω	Ω	0	Α	٥	0	0

CLINICAL OBSERVATION (SUMMARY)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

ALL ANIMALS

ADI VIII TITO TITO

SEX : FEMALE

PAGE: 75

Clinical sign	Group Name	Admini	stration W	leek-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
ior, Reminianes	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	0	0	0	0	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)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

### CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day							·				
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54 <b>-</b> 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

CLINICAL OBSERVATION (SUMMARY)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

ALL ANIMALS

SEX : FEMALE

PAGE: 77

Clinical sign	Group Name	Admini	stration W	eek-day _											
<del></del>		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

(HAN190)

CLINICAL OBSERVATION (SUMMARY)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-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
IONI DISMASHIZATNI S	0 . 1	00	97	0.7	97	95	99	00			90	00	0.	0.0	50
NON REMARKABLE	Control 5000 ppm	38 0	37 0	37 0	37 0	35 0	33 0	33 0	34 0	34 n	33 0	39 44	31 0	30 0	29 0
	10000 ppm	0	ő	Ö	Ö	Ő	Ö	0	Ö	0	ő	46	ő	Ŏ	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	38	0	0	0

CLINICAL OBSERVATION (SUMMARY)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-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
VON REMARKABLE	Control	28	27	27	26	26	24	24	21	21	19	19	19	19	19
NON REMINIMADES	5000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	0	Ō	0	0	0	0	0	0	0	0	0	0	0
	20000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

98-7 99-7 100-7 101-7 102-7 103-7 104-7	
	<del> </del>
NON REMARKABLE Control 19 19 18 18 17 17 17	
5000 ppm 0 0 0 0 0 0	
10000 ppm 0 0 0 0 0 0 0	
20000 ppm 0 0 0 0 0 0	

# APPENDIX B 1

BODY WEIGHT CHANGES: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

ANIMAL : MOUSE Crj:BDF1

UNIT : g REPORT TYPE : A1 104

SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 1

roup 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 ррш	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 ррт	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 differ	rence; *: P ≤ 0.05	**: P ≤ 0.01		Test of Dunnett			

(HAN260)

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

ANIMAL : MOUSE Crj:BDF1

UNIT : g
REPORT TYPE : AI 104

SEX : MALE

roup 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 differe	ence; *: P ≦ 0.05	o*: P ≤ 0.01		Test of Dunnett				
HAN260)		· · · · · · · · · · · · · · · · · · ·						B

ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : A1 104

SEX : MALE

BODY WEIGHT CHANGES

(SUMMARY)

ALL ANIMALS

roup 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± i.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 ≤ 0.05	** : P ≤ 0.01		Test of Dunnett			

(HAN260)

BAIS 4

ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : AI 104

SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 4 Group Name Administration week-day\_ 50-7 42-7 46-7 54-7 58-7 62-7 66-7 Control 48.2± 4.5 49.9± 4.4  $50.6 \pm 4.2$ 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 39.5± 5.4\*\* 10000 ppm 37.4± 4.0\*\* 38.2± 4.4\*\* 38.7± 4.6\*\* 39.2± 5.2\*\* 40.0± 5.9\*\* 41.0± 5.9\*\* 20000 ррт 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)

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : A1 104

BODY WEIGHT CHANGES

ALL ANIMALS

(SUMMARY)

roup 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 <b>*</b> *	40.7± 5.0**	40.3± 4.8★	40.0± 4.7**	40.0± 6.0**
20000 ррт	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 ≤ 0.05	** : P ≤ 0.01		Test of Dunnett		· · · · · · · · · · · · · · · · · · ·	

ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : AI 104

BODY WEIGHT CHANGES

ALL ANIMALS

(SUMMARY)

SEX : MALE				PAGE : 6
Group Name	Administration	n 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 <b>**</b>	37.4± 4.9 <b>**</b>	
20000 ppm	30.4± 3.0≉	29.8± 3.0★★	29.6± 3.0≠	
0. 10 100				
Significant difference;	*: P ≤ 0.05	**: P ≤ 0.01	Test of Dunnett	
(HAN260)				BAIS

# APPENDIX B 2

BODY WEIGHT CHANGES: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

ANIMAL : MOUSE Crj:BDF1

UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

roup Name	Administration	n 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± i.0	21.3± 0.9	21.5± 1.0	
Significant difference;	*: P ≤ 0.05	** : P ≤ 0.01		Test of Dunnett				
IAN260)				<del></del>				

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES

(SUMMARY)

ALL ANIMALS

Group Name	Administrati	on 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 ррш	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 թրա	22.0± 0.9	22. l± 1. i	22.4± 1.1	22.8± 1.0	23.2± 1.1	23.1± 1.1	23.3± 1.2*	
Significant difference;	*: P ≤ 0.05	**: P ≤ 0.01		Test of Dunnett				
(HAN260)		<del> </del>						BAIS

ANIMAL : MOUSE Cri:BDF1
UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES

(SUMMARY)

ALL ANIMALS

		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
0000 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**
ingq 0000	23.5± 1.2*	24.3± 1.2★*	25. [± 1. 0**	25.5± 1.2**	26.1± 1.5**	26.8± 1.4**	26.8± 1.7**
			· · · · · · · · · · · · · · · · · · ·				
Significant difference;	* : P ≤ 0.05	**: P ≤ 0.01		Test of Dunnett			

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)

PAGE: 10

ALL ANIMALS

roup Name	Administration	n week-day						
	42-7	46-7	50-7	54-7	58-7	62-7	66-7	
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	38.6± 7.0	
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	35.7± 4.8	
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**	31.8± 3.7**	
20000 ррш	27.9± 1.9**	28.3± 2.3**	28.0± 1.9**	28.4± 2.1**	28.6± 2.3★★	28. 2± 2. 3 <b>*</b> *	28.1± 1.7**	
Significant difference;	*: P ≤ 0.05	**: P ≤ 0.01		Test of Dunnett				
AN260)								BA

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES

ALL ANIMALS

(SUMMARY)

Group Name	Administration	week-day						
	70-7	74-7	78-7	82-7	86-7	90-7	94-7	
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 ррш	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 ррт	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 differ	ence; *: P ≤ 0.05 *	* : P ≤ 0.01		Test of Dunnett				

(HAN260)

BAIS 4

ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY) ALL ANIMALS

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 ррш	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**	
· · · · · · · · · · · · · · · · · · ·	<del> </del>	<u> </u>	<del> </del>	
Significant differe	ence; *: P ≦ 0.05	** : P ≦ 0.01	Test of Dunnett	
(HAN260)	-			BAIS 4

(HAN260)

BAIS 4

## APPENDIX C 1

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

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 differe	ence; *: P ≤ 0.05	*: P ≤ 0.01		Test of Dunnett			

(HAN260)

ANIMAL : MOUSE Crj:BDF1

UNIT : g
REPORT TYPE : AI 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 2

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	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 ррт	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 differ	rence; *: P ≤ 0.05	**: P ≤ 0.01		Test of Dunnett			

(HAN260)

ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 104

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

SEX : MALE								AGE : 3
Group Name	Administration 18-7(7)	on week-day(effective) 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 ррш	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 ррт	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 ≤ 0.05	**: P ≤ 0.01		Test of Dunnett				
(HAN260)		· · · · · · · · · · · · · · · · · · ·				· · · · · · -		BAIS 4

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : A1 104

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

oup Name	Administratio	on 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生 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 ррш	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 ррт	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 ≤ 0.05	** : P ≤ 0.01		Test of Dunnett			<del></del>

ANIMAL : MOUSE Crj:BDF1

UNIT : g
REPORT TYPE : A1 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

roup Name	Administratio	on 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生 1.0
5000 ррш	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**
							<del>-</del>
Significant difference;	* : P ≤ 0.05	** : P ≤ 0.01		Test of Dunnett			
(HAN260)		· · · · · · · · · · · · · · · · · · ·			· · · · · · · · · · · · · · · · · · ·		

ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 104

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

SEX : MALE				PAGE: 6
Group Name	Administration 102-7(7)	week-day(effective) 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 ррш	6.5± 0.8≠*	6.5± 0.1 ?		
Significant differ	rence; *: P ≤ 0.05	** : P ≤ 0.01	Test of Dunnett	
? : Significant te	est is not applied, because No.	of data in this group is less th	an 3.	
(IIAN260)				BAIS 4

## APPENDIX C 2

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

ANIMAL : MOUSE Crj:BDF1

UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

roup Name	Administration 1-7(7)	week-day(effective) 2-7(7)	3-7(7)	4-7 (7)	5-7 (7)	6-7 (7)	7-7 (7)
Control	3.6生 0.4	3.5生 0.4	3.5± 0.4	3.8± 0.3	3.8± 0.4	3.6± 0.3	3.8生 0.4
5000 ррш	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 ррш	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 ррт	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 differen	rce; *: P ≦ 0.05 *	*: P ≤ 0.01		Test of Dunnett			

(HAN260)

BAIS 4

PAGE: 7

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

Group Name	Administration	week-day(effective)					
	8-7 (7)	9-7(7)	10-7 (7)	11-7(7)	12-7 (7)	13-7(7)	14-7(7)
Control	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 ррш	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 ррт	3.5± 0.4*	3.5± 0.5**	3.5± 0.5 <b>*</b> *	3.8± 0.5	3.6± 0.4	3.8± 0.5	3.8± 0.5
						<del> </del>	
Significant difference	$*: P \leq 0.05$	*o* : P ≤ 0.01		Test of Dunnett			
HAN260)					· · · · · · · · · · · · · · · · · · ·		

PAGE: 8

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : A1 104

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

oup 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生 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
mqq 0000	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
0000 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

(HAN260)

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1
UNIT : g REPORT TYPE : A1 104

SEX : FEMALE

PAGE: 10

Group Name	Administration 46-7(7)	on week-day(effective) 50-7(7)	54-7(7)	58-7 (7)	62-7(7)	66-7(7)	70-7(7)	
				<del></del>				
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 ррт	4.9± 0.9	4.5± 0.9	4.8± 1.0	5.2± 1.0	4.9± 0.9	5.2± i.1*	5.1± 0.9	
Significant difference;	*: P ≤ 0.05	** : P ≤ 0.01		Test of Dunnett				
(HAN260)	· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·		·				BAIS

ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

Froup 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 ррт	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 ррш	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**
	<del></del>						
Significant differe	ence; *: P ≤ 0.05 *	*: P ≤ 0.01		Test of Dunnett			

(HAN260)

BAIS 4

PAGE: 11

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : A1 104

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

SEX : FEMALE				PAGE: 12
Group Name	Administration 102-7(7)	week-day(effective) 104-7(7)		
Control	4.9± 1.0	4.9± 1.1		
5000 ррш	4.8± 1.1	5. 2± 1. 2		
10000 ppm	5.7± 1.2*	5.7± 1.2		
20000 ррт	5.7± 1.0	6.2± 0.8		
	nce; *: P ≦ 0.05	**: P ≦ 0.01	Test of Dunnett	
(HAN260)				BAIS 4

# APPENDIX D 1

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

ANIMAL : MOUSE Crj:BDF1
UNIT : g/kg/day

REPORT TYPE : A1 104

SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

roup Name	Administration	(weeks)					
-	1	2	3	4	5	6	7
Control	0.000生 0.000	0.000± 0.000	0.000生 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
5000 ррш	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

PAGE: 1

ANIMAL : MOUSE Crj:BDF1 UNIT : g/kg/day
REPORT TYPE : A1 104

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

Group Name	Administration	(weeks)					
	8	9	10	11	12	13	14
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000主 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 ррт	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

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1
UNIT : g/kg/day

REPORT TYPE: Al 104

SEX : MALE

PAGE: 3

Group Name	Administration	(weeks)					<u></u>
	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
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)

ANIMAL : MOUSE Crj:BDF1 UNIT : g/kg/day

REPORT TYPE : A1 104

SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

roup 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生 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)

CHEMICAL INTAKE CHANGES (SUMMARY)

ANIMAL : MOUSE Crj:BDF1
UNIT : g/kg/day

ALL ANIMALS

REPORT TYPE : A1 104 SEX : MALE

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生 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 ррш	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 թթա	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)

ANIMAL : MOUSE Crj:BDF1
UNIT : g/kg/day

REPORT TYPE : A1 104 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

SEX : MALE				PAGE: 6
Group Name	Administration 102	(weeks)		
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)

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1
UNIT : g/kg/day

J. DDF 1 ALL F

REPORT TYPE : AI 104 SEX : FEMALE

PAGE: 7

Administration	(weeks)					
1	2	3	4	5	6	7
$0.000 \pm 0.000$	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
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
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
1.000= 0.010		11102= 01110	11.102 01.100	1.7252 0.100		1.010= 0.101
3.170± 0.562	3.711± 0.596	3.321± 0.456	3.248± 0.501	3.103± 0.367	2.979± 0.386	$3.243 \pm 0.479$
	1 0.000 ± 0.000 0.873 ± 0.105 1.860 ± 0.249	1 2  0.000 ± 0.000 0.000 ± 0.000  0.873 ± 0.105 0.866 ± 0.086  1.860 ± 0.249 1.821 ± 0.227	1 2 3 $0.000 \pm 0.000$ $0.000 \pm 0.000$ $0.000 \pm 0.000$ $0.873 \pm 0.105$ $0.866 \pm 0.086$ $0.857 \pm 0.054$ $1.860 \pm 0.249$ $1.821 \pm 0.227$ $1.702 \pm 0.176$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

(HAN300)

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

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

Group Name	Administrat	ion (weeks)						
	8	9	10	11		13	14	
Control	0.000± 0.00	0.000± 0.0	0.000±	0.000 0.000±	0.000 0.000	± 0.000 0.000±	2 0.000 0.000±	0. 000
5000 ррш	0.839± 0.06	6 0.791± 0.0	0.779±	0.053 0.792±	0.057 0.787	± 0.057 0.761=	± 0.068 0.772±	0. 059
10000 ppm	1.663± 0.12	8 1.610± 0.1	55 1.565±	0.145 1.574±	0.146 1.567	± 0.137 1.572=	± 0.190 1.579±	0. 157
20000 ррш	3.215± 0.39	5 3.148± 0.5	3.086±	0.419 3.255±	0.488 3.106	± 0.400 3.232=	± 0.397 3.234±	0. 433

(HAN300) BAIS 4

CHEMICAL INTAKE CHANGES (SUMMARY) ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1
UNIT : g/kg/day

REPORT TYPE : A1 104

SEX : FEMALE

PAGE: 9

Group Name	Administration	(weeks)				·	· <del> </del>
	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土 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 թրա	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)

ANIMAL : MOUSE Crj:BDF1
UNIT : g/kg/day
REPORT TYPE : A1 104

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

SEX : FEMALE

PAGE: 10

Administration	(weeks)					
46	50	54	58	62	66	70
$0.000 \pm 0.000$	0.000± 0.000	0.000± 0.000	0.000± 0.000	$0.000\pm0.000$	0.000± 0.000	$0.000 \pm 0.000$
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
1 611 + 0 005	1 500-1 0 100	1 400 + 0 00"	1 004 + 0 000	t C10+ 0 047	1 5044 0 000	1 500 + 0 055
1.611± 0.205	1.502± 0.190	1.492± 0.225	1.684± 0.256	1.618± 0.247	1.584生 0.266	1.599± 0.255
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
	$0.000 \pm 0.000$ $0.704 \pm 0.129$ $1.611 \pm 0.205$	46     50       0.000 ± 0.000     0.000 ± 0.000       0.704 ± 0.129     0.654 ± 0.115       1.611 ± 0.205     1.502 ± 0.190	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

(HAN300)

ANIMAL : MOUSE Crj:BDF1 UNIT : g/kg/day REPORT TYPE : A1 104

CHEMICAL INTAKE CHANGES (SUMMARY) ALL ANIMALS

SEX : FEMALE

PAGE: 11

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生 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	0.696± 0.117	0.710± 0.181
10000 ррш	1.588± 0.207	1.604± 0.236	1.684± 0.268	1.777± 0.276	1.769± 0.248	1.846± 0.268	1.908± 0.322
20000 ррш	3.516± 0.739	3.741± 0.571	3.902± 0.756	4.161± 0.745	4.046± 0.695	4.402± 0.858	4.746± 0.532

(HAN300)

CHEMICAL INTAKE CHANGES (SUMMARY)

ANIMAL : MOUSE Cri:BDF1
UNIT : g/kg/day

ALL ANIMALS

REPORT TYPE : A1 104 SEX : FEMALE

PAGE: 12

Group Name	Administration 102	(weeks) 104		
Control	0.000± 0.000	0.000± 0.000		
5000 ррш	0.705± 0.164	0.766± 0.182		
10000 ррш	1.912± 0.342	1.940± 0.422		
20000 ррт	4.195± 0.823	4.557± 1.170		
(HAN300)			 	

### APPENDIX E 1

HEMATOLOGY: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: 1

SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

Group Name	NO. of Animals	RED BLOOD CELL 1 O⁵∕µl	HEMOGLOBIN g/dl	HEMATOCRIT %	MCV f <b>£</b>	MCH pg	MCHC g∕dl	PLATELET 1 0³/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土 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 ; \*:  $P \le 0.05$  \*\*:  $P \le 0.01$  Test of Dunnett

(HCL070)

BAIS 4

PAGE: 1

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

ANIMAL : MOUSE Crj:BDF1 MEASURE. TIME: 1

SEX : MALE

REPORT TYPE : A1

PAGE: 2

Group Name	NO. of Animals	₩BC 1 0³/1		Dif N-BAND	ferentia	N-SEG	6) 	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±	i	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 ррш	16	2.37±	1.06	3±	2	37±	14	0±	0 <del>**</del>	0±	0	3±	2	55±	15	1±	2
Significan	t difference	; *:P:	≤ 0.05	**: P ≦	0.01	<u> </u>		Test	of Dunne	lt							
(HCL070)									•					· · · · · · · · · · · · · · · · · · ·			BAIS 4

(HCL070)

### APPENDIX E 2

HEMATOLOGY: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: 1 SEX : FEMALE

REPORT TYPE : A1 PAGE: 3

Group Name	NO. of Animals	RED BLOOD CELL 1 05/µl	HEMOGLOBIN g/dl	HEMATOCRIT %	MCV f l	MCH pg	MCHC g/dl	PLATELET 1 0³/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 ррш	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*

(HCL070) BAIS 4

ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1

SEX : FEMALE

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

Group Name	NO. of	WBC	· · · · · · · · · · · · · · · · · · ·	Dif	ferential	WBC (%	6)							<i></i>			
Toup name	Animals	1 0 <sup>3</sup> /		N-BAND		N-SEG		EOSINO		BASO		MONO		LYMPHO	·- ··	OTHER	
Control	23	4. 83±	11.61	1土	ī	23土	13	2±	1	0±	0	4±	2	64 <u>-1-</u>	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	t difference	*:P	<b>≤</b> 0.05	**: P ≦	0.01			Test	of Dunr	ıett							

### APPENDIX F 1

BIOCHEMISTRY: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

SEX : MALE PAGE: 1

Group Name	NO. of Animals	TOTAL P	ROTEIN	albumin g/dl	I	A/G RAT	10	T-BILI mg/dl		GLUCOSE mg/dl		T-CHOLE:	STEROL	TRIGLYCI mg/dl	ERIDE
Control	34	5.4±	0.9	2.9±	0.5	1. 2±	0.2	0.17±	0.10	169±	56	120生	64	37±	33
5000 ррш	34	5.3±	0.8	3.0±	0.4	1.3±	0.2	0.17±	0. 08	199±	50	128±	47	46±	24
10000 ррш	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

(HCL074) BAIS 4

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : MALE REPORT

REPORT TYPE : A1

PAGE: 2

roup Name	NO. of Animals	PHOSPHO mg/dl	LIPID	GOT I U/	<b>l</b>	GPT I U/	e 	LDH I U/	l	ALP IU/:	2	G-GTP I U/L	!	CPK IU/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生	1198**	9029±	7690**	923±	691**	14±	15**	133±	46**

(HCL074)

ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1

SEX : MALE

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

SEX : MALE	REPORT	TYPE : A1												PAGE: 3
Group Name	NO. of Animals	UREA NITROGEN mg/dl		SODIUM m Eq / £		POTASSI m Eq/		CHLORIDE mEq/2		CALCIUM mg/dl		INORGAN 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 ≤ (	). 05 +	* : P ≤ 0.01		·		Test of Dunne	ett					
(HCL074)							<del></del>							BAIS

# APPENDIX F 2

BIOCHEMISTRY: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

PAGE: 4

roup Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RAT	10	T-BILI mg/dl		GLUCOSE mg/dl		T-CHOLES mg/dl	STEROL	TRIGLYCERI 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土	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士	12
mqq 0000.	29	5.2±	0.8	2.9±	0.3	1.4±	0.2	0.16±	0.03	160±	40	127±	38**	23生	12
20000 ррш	13	5.9±	0. 5**	3.4±	0.3**	1.4±	0. 1	0.48±	0.59**	154±	62	225±	43**	24±	17

(HCL074)

BIOCHEMISTRY (SUMMARY) ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1 ALL ANIMALS (105W)

SEX : FEMALE

REPORT TYPE : AI

PAGE: 5

roup Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT IU/L		GPT I U/	l	LDH IU/	<i>e</i>	ALP IU/I	<u> </u>	G-GTP IU/L		CPK IU/A	2
Control	23	138±	35	112±	84	37±	23	685±	<b>9</b> 50	176±	70	2±	1	95±	85
5000 ррш	25	165±	38	85±	37	47±	31	442±	573	227±	114	3±	4	110±	144
10000 ррш	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**

(HCL074)

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: 1 SEX: FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

Group Name	NO. of Animals	urea nitrogen mg/d&		SODIUM m Eq / L		POTASSIUM mEq/l		CHLORIDE m Eq / 2		CALCIUM mg/dl		INORGAN mg/dl	TC PHOSPHORUS
Control	23	19.0土	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

PAGE: 6

(HCL074)

.

### APPENDIX G 1

URINALYSIS: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

URINALYSIS

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: 1

SEX : MALE

REPORT TYPE : A1

PAGE: 1

Group Name	NO. of	pH_	pll									Protein					Glucose					Ketone body					Occult blood				
	Animals	5. 0	6.0	6. 5	7. 0	7.5	8. 0	8.5	CHI	- ±	+	2+ 3	+ 4+	CHI		±	+ 2	+ 3+	4+ CHI	<del> ±</del>	: +	2+ 3	3+ 41	CHI		±	+	2+ 3+	CH)		
Control	36	0	6	15	7	6	2	0		0 4	23	8	1 0		36	0	0	0 0	0	20 1	2 4	0	0 (	)	28	3	0	1 4			
5000 ррш	35	0	3	10	11	9	2	0		0 6	24	5	0 0		35	0	0	0 0	0	17 1	5 3	0	0 (	<b>)</b>	34	. 1	0	0 0	ı		
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 (	)	29	0	0	0 0	ı		
20000 ррш	16	0	10	4	1	1	0	0	*	0 10	6	0	0 0	**	16	0	0	0 0	0	14	0 8	0	0 (	)	16	0	0	0 0	1		

(HCL101)

URINALYSIS

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: 1

SEX : MALE

REPORT TYPE : A1

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

Significant difference ;  $*: P \leq 0.05$ 

**\*\*** : P ≤ 0.01

Test of CHI SQUARE

(HCL101)

BAIS 4

# APPENDIX G 2

URINALYSIS: SUMMARY, MOUSE: FEMALE

URINALYSIS

ANIMAL : MOUSE Crj:BDF1 MEASURE. TIME: 1

SEX : FEMALE

REPORT TYPE : A1

PAGE: 3

Group Name	NO. of	.Hq								Prot	ein_					Gluc	ose				Keto	ne b	odv				00	cult	b1o	bo	
	Animals	5.0	6.0	6.5	7. 0	7. 5	8.0	8, 5	CHI	- :	± +	2+	3+	4+ C	HI	- :	± +	- 2+	3+	4+ CHI	- :		-		4+ C	HI ———				+ 3+	CH
Control	24	0	i	1	8	8	2	1		0	4 16	3	1	0		24	0	0 0	0	0	2 1	1 8	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 1	8 6	5 2	0	0		27	1	0	0 2	
10000 ррш	30	0	2	8	12	5	3	0		0 1	5 12	3	0	0		30	0	0 0	0	0	2 2	2 4	1 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	3 1	0	0		11	1	0	0 1	

(HCL101)

BAIS 4

URINALYSIS

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: 1

SEX : FEMALE

PAGE: 4 REPORT TYPE : A1 NO. of Urobilinogen Group Name ± + 2+ 3+ 4+ CHI Animals Control 24 24 0 0 0 0 5000 ppm 30 0 0 0 0 30 10000 ppm 30 30 0 0 0 0 20000 ppm 13 0 0 0 0 13 Significant difference ;  $*: P \le 0.05$   $**: P \le 0.01$ Test of CHI SQUARE (HCL101) BAIS 4

### APPENDIX H 1

GROSS FINDINGS: SUMMARY, MOUSE: MALE ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1

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

REPORT TYPE : A1 : FEMALE

an	Findings	Group Name NO. of Animals	Control 50 (%)	5000 ppm 50 (%)	10000 ppm 50 (%)	20000 ppm 50 (%)
n/app	nodule		1 (2)	0 ( 0)	0 ( 0)	0 ( 0)
	scab		0 ( 0)	I (2)	1 (2)	0 ( 0)
cutis	edema		3 (6)	5 (10)	5 (10)	1 ( 2)
	mass		2 ( 4)	2 ( 4)	4 ( 8)	0 ( 0)
	red		1 (2)	0 (0)	1 ( 2)	0 ( 0)
	white zone		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
	nodule		i (2)	2 ( 4)	3 (6)	4 ( 8)
h node	enlarged		7 (14)	7 (14)	6 (12)	1 ( 2)
ıs	enlarged		1 (2)	0 ( 0)	0 ( 0)	0 ( 0)
en.	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)
ħ	absence		1 (2)	0 ( 0)	0 ( 0)	0 ( 0)
stomach	nodule		1 (2)	2 ( 4)	0 ( 0)	0 ( 0)
	thick		1 (2)	0 ( 0)	0 ( 0)	0 ( 0)
l intes	dilated		0 ( 0)	0 ( 0)	i (2)	0 ( 0)
e intes	dilated		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
Γ	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)

ANIMAL : MOUSE Crj:BDF1

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

REPORT TYPE : A1 : FEMALE

rgan	Findings	Group Name Control NO. of Animals 50 (%)	5000 ppm 50 (%)	10000 ppm 50 (%)	20000 ppm 50 (%)
iver	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)
ancreas	nodule	1 ( 2)	0 ( 0)	0 ( 0)	3 (6)
dney	enlarged	2 ( 4)	o ( ö)	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)
in bladd	urine:marked retention	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
ituitary	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)
ary/	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)
erus	enlarged	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
	nodule	14 (28)	14 ( 28)	13 ( 26)	10 (20)

ANIMAL : MOUSE Crj:BDF1

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

REPORT TYPE : A1

SEX

: FEMALE

PAGE: 6

hrgan	Findings	Group Name Control NO. of Animals 50 (%)	5000 ppm 50 (%)	10000 ppm 50 (%)	20000 ppm 50 (%)
terus	dilated lumen	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
rain	red zone	0 ( 0)	1 ( 2)	1 ( 2)	0 ( 0)
larder gl	enlarged	1 ( 2)	1 (2)	0 ( 0)	1 ( 2)
	nodule	0 ( 0)	0 ( 0)	1 ( 2)	1 ( 2)
nediastinum	nodule	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)
	mass	2 ( 4)	4 ( 8)	0 ( 0)	0 ( 0)
eritoneum	nodule	0 ( 0)	0 ( 0)	0 ( 0)	i ( 2)
	mass	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	thick	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
etroperit	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)
choracic ca	pleural fluid	4 ( 8)	10 (20)	5 (10)	3 (6)
ther	hindlimb:nodule	1 ( 2)	0 ( 0)	0 ( 0)	1 ( 2)
	lower jaw:nodule	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)

(HPT080)

# APPENDIX H 2

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

ANIMAL : MOUSE Crj:BDF1

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

REPORT TYPE : A1 SEX : MALE

gan	Findings	Group Name Control NO. of Animals 50 (%)	5000 ppm 50 (%)	10000 ppm 50 (%)	20000 ppm 50 (%)
in/app	nodule	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	scab	0 ( 0)	1 (2)	1 (2)	0 ( 0)
bcutis	edetira	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
	mass	1 ( 2)	4 ( 8)	1 ( 2)	1 ( 2)
ing	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)
mph node	enlarged	4 ( 8)	11 (22)	3 ( 6)	0 ( 0)
ıymus	enlarged	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
leen	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)
ooth	deformed	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
	absence	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
alivary gl	nodule	2 ( 4)	0 ( 0)	1 ( 2)	0 ( 0)
orestomach	nodule	0 ( 0)	0 ( 0)	2 ( 4)	1 (2)
l stomach	nodule	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	thick	2 ( 4)	4 ( 8)	1 ( 2)	0 ( 0)
tomach	пodule	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
mall intes	nodule	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)
ver.	enlarged	1 ( 2)	0 ( 0)	0 ( 0)	2 ( 4)

ANIMAL : MOUSE Crj:BDF1

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

REPORT TYPE : A1 SEX : MALE

Organ	Findings	Group Name Control NO. of Animals 50 (%)	5000 ppm 50 (%)	10000 ppm 50 (%)	20000 ppm 50 (%)
liver	White zone	3 ( 6)	2 ( 4)	1 ( 2)	3 ( 6)
11461	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)

ANIMAL : MOUSE Crj:BDF1

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

REPORT TYPE : A1

SEX : MALE PAGE : 3

rgan	Findings	Group Name Control NO. of Animals 50 (%)	5000 ppm 50 (%)	10000 ppm 50 (%)	20000 ppm 50 (%)
		2 ( 2)	2 ( 2)	0 ( 0)	1 ( 0)
rain	hypertrophy	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
arder gl	enlarged	1 ( 2)	0 (0)	1 (2)	0 ( 0)
	nodule	1 ( 2)	1 ( 2)	1 (2)	1 ( 2)
eritoneum	nodule	0 ( 0)	0 ( 0)	0 ( 0)	1 (2)
troperit	mass	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
dominal 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)
senterium	nodule	1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)
ipose	nodule	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
oracic ca	hemorrhage	0 ( 0)	1 ( 2)	1 (2)	0 ( 0)
	pleural fluid	1 ( 2)	4 ( 8)	2 ( 4)	0 ( 0)
her	nose:nodule	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
ole body	anemic	0 ( 0)	1 (2)	0 ( 0)	0 ( 0)

(HPT080)

BAIS 4

# APPENDIX H 3

GROSS FINDINGS: SUMMARY, MOUSE: MALE: SACRIFICED ANIMALS

STUDY NO. : 0402 ANIMAL : MOUSE Crj:BDF1

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (105W)

REPORT TYPE : A1 : MALE SEX

Organ	Findings	Group Name Control NO. of Animals 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)

ANIMAL : MOUSE Crj:BDF1

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (105W)

REPORT TYPE : A1

SEX : MALE PAGE : 2

rgan	Findings	Group Name Control NO. of Animals 36 (%)	5000 ppm 35 (%)	10000 ppm 27 (%)	20000 ppm 16 (%)
idney	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)
rin bladd	urine:marked retention	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
ididymis	nodu1e	2 (6)	0 ( 0)	0 (0)	0 ( 0)
nin ves	adhesion	2 (6)	0 ( 0)	0 ( 0)	0 ( 0)
ep/cli gl	nodule	6 (17)	0 ( 0)	0 ( 0)	0 ( 0)
der gl	enlarged	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule	1 ( 3)	1 ( 3)	1 (4)	0 ( 0)
dominal c	ascites	1 ( 3)	1 (3)	0 ( 0)	0 ( 0)
pose	nodule	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
racic ca	pleural fluid	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
ier	nose:nodule	0 (0)	0 ( 0)	1 (4)	0 ( 0)

(HPT080)

BAIS 4

### APPENDIX H 4

GROSS FINDINGS: SUMMARY, MOUSE: FEMALE: SACRIFICED ANIMALS

ANIMAL : MOUSE Crj:BDF1

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (105W)

REPORT TYPE: A1

: FEMALE SEX

gan	Findings	Group Name Control NO. of Animals 23 (%)	5000 ppm 27 (%)	10000 ppm 30 (%)	20000 ppm 13 (%)
kin/app	nodule	1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
	scab	0 ( 0)	1 (4)	1 ( 3)	0 ( 0)
ubcutis	mass	1 (4)	1 (4)	1 ( 3)	0 ( 0)
ing	nodule	1 (4)	2 ( 7)	3 (10)	1 ( 8)
ymph node	enlarged	3 (13)	3 (11)	3 (10)	0 ( 0)
oleen	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)
orestomach	nodule	1 (4)	0 ( 0)	0 ( 0)	0 ( 0)
iver	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	[ ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
ancreas	nodule	1 ( 4)	0 ( 0)	0 ( 0)	1 (8)
idney	enlarged	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	white zone	0 ( 0)	0 ( 0)	0 ( 0)	I (8)
	nodule	1 ( 4)	1 (4)	0 ( 0)	0 ( 0)
	hydronephrosis	1 ( 4)	3 (11)	2 ( 7)	0 ( 0)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (105W)

SEX : FEMALE

rgan	Findings	Group Name Control NO. of Animals 23 (%)	5000 ppm 27 (%)	10000 ppm 30 (%)	20000 ppm 13 (%)
ituitary	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)
vary	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)
terus	nodule	4 (17)	3 (11)	6 (20)	3 (23)
	dilated lumen	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
arder gl	enlarged	0 ( 0)	0 ( 0)	0 ( 0)	1 (8)
ediastinum	nodule	0 ( 0)	0 ( 0)	0 ( 0)	2 (15)
bdominal c	hemorrhage	0 ( 0)	0 ( 0)	0 ( 0)	1 (8)
	ascites	1 ( 4)	1 ( 4)	0 ( 0)	1 ( 8)
noracic ca	pleural fluid	0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)
ther	lower jaw:nodule	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)

### APPENDIX H 5

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

#### GROSS FINDINGS (SUMMARY)

ANTMAL : MOUSE Cri:BDF1

DEAD AND MORIBUND ANIMALS (0-105W)

REPORT TYPE : A1 SEX : MALE

organ	Findings	Group Name ContNO. of Animals 14 (%		10000 ppm 23 (%)	20000 ppm 34 (%)
kin/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)
ung	nodule	1 (	7) 0 ( 0)	2 ( 9)	1 ( 3)
ymph node	enlarged	2 (	3 (20)	1 ( 4)	0 ( 0)
diymus	enlarged	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)	1 ( 3)
stomach	nodule	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 (	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)	1 (4)	0 ( 0)
pancreas	nodule	0 (	0 ( 0)	1 ( 4)	1 ( 3)
tidney	white	1 (	7) 0 ( 0)	0 ( 0)	0 ( 0)
	hydronephrosis	1 (	7) 3 (20)	3 (13)	1 ( 3)
rin bladd	nodule	0 (	0) 1 ( 7)	0 ( 0)	0 ( 0)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

### GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name Control NO. of Animals 14 (%)	5000 ppm 15 (%)	10000 ppm 23 (%)	20000 ppm 34 (%)
urin bladd	urine:marked retention	3 (21)	1 ( 7)	1 (4)	2 ( 6)
ırethra	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)
orain	nodule	0 ( 0)	0 ( 0)	2 ( 9)	0 ( 0)
	hypertrophy	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
larder gl	enlarged	0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)
	nodule	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
eritoneum	nodu1e	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)
nesenterium	nodule	1 ( 7)	1 ( 7)	0 ( 0)	0 ( 0)
horacic ca	hemorrhage	0 ( 0)	1 ( 7)	i ( 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

GROSS FINDINGS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

DEAD AND MORIBUND ANIMALS (0-105W)

REPORT TYPE : A1 SEX : FEMALE

rgan	Findings	Group Name Control NO. of Animals 27 (%)	5000 ppm 23 (%)	10000 ppm 20 (%)	20000 ppm 37 (%)
ubcutis	edema	3 (11)	5 ( 22)	5 (25)	1 ( 3)
	mass	1 (4)	1 ( 4)	3 (15)	0 ( 0)
ung	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)
ymph node	enlarged	4 ( 15)	4 (17)	3 (15)	1 ( 3)
hymus	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)
ooth	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)

GROSS FINDINGS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

DEAD AND MORIBUND ANIMALS (0-105W)

REPORT TYPE : A1 SEX : FEMALE

gan	Findings	Group Name Control NO. of Animals 27 (%)	5000 ppm 23 (%)	10000 ppm 20 (%)	20000 ppm 37 (%)
dney	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)
in bladd	urine:marked retention	0 ( 0)	0 ( 0)	1 ( 5)	0 ( 0)
tuitary	enlarged	0 ( 0)	1 (4)	0 ( 0)	0 ( 0)
	cyst	1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
ary	enlarged	3 (11)	7 (30)	5 (25)	4 (11)
	cyst	3 (11)	2 ( 9)	0 ( 0)	0 ( 0)
erus	enlarged	0 ( 0)	0 ( 0)	1 ( 5)	0 ( 0)
	nodu]e	10 ( 37)	11 (48)	7 (35)	7 (19)
rain	red zone	0 ( 0)	1 ( 4)	1 ( 5)	0 ( 0)
rder gl	enlarged	1 ( 4)	1 ( 4)	0 ( 0)	0 ( 0)
	nodule	0 ( 0)	0 ( 0)	1 ( 5)	1 ( 3)
ediastinum	mass	2 ( 7)	4 (17)	0 ( 0)	0 ( 0)
eritoneum	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)
etroperit	nodule	1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
dominal c	hemorrhage	0 ( 0)	0 ( 0)	2 (10)	8 (22)
	ascites	5 (19)	5 (22)	4 (20)	4 (11)
oracic ca	pleural fluid	4 ( 15)	9 (39)	5 (25)	3 ( 8)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name NO. of Animals	Control 27 (%)	5000 ppm 23 (%)	10000 ppm 20 (%)	20000 ppm 37 (%)
other	hindlimb:nodule		1 (4)	0 ( 0)	0 ( 0)	1 ( 3)
HPT080)						

### APPENDIX I 1

ORGAN WEIGHT, ABSOLUTE: SUMMARY, MOUSE: MALE

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE UNIT: g ORGAN WEIGHT: ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (105W)

PAGE: 1

coup Name	NO. of Animals	Body Weight	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS	
Control	36	45.8± 8.0	0.012± 0.003	0.218生 0.02	6 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± 0.02	8 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± 0.04	.1 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± 0.02	.7 0.167± 0.013**	0.227± 0.025	0.457± 0.068**	

(IICL040)

BAIS 4

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1

REPORT TYPE 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 ррш	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	
Significan	t difference;	* : P ≤ 0.05 **	: P ≤ 0.01	Test of Dunnett	
(HCI 040)					BAIS

(HCL040)

BAIS 4

# APPENDIX I 2

ORGAN WEIGHT, ABSOLUTE: SUMMARY, MOUSE: FEMALE

ANIMAL : MOUSE Cr.j:BDF1
REPORT TYPE : A1

REPORT TYPE : SEX : FEMALE UNIT: g ORGAN WEIGHT: ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (105W)

PAGE: 3

roup Name	NO. of Animals	Body W	eight	ADREI	VALS	OVAR	IES	HEAR	ſ	LUNG	5	KIDN	EYS
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. [**	0.010±	0.002**	0.088±	0.216	0.145±	0.025**	0.210±	0.043	0.373±	0. 082**

(IICL040)

BAIS 4

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1
SEX : FEMALE
INIT: P

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

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 ррт	13	0.214± 0.221	6.056± 4.245**	0.436± 0.021**	

BAIS 4

(HCL040)

# APPENDIX J 1

ORGAN WEIGHT, RELATIVE: SUMMARY, MOUSE: MALE

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 <b>**</b>	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≉≉

(HCL042)

BAIS 4

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE UNIT: % ORGAN WEIGHT: RELATIVE (SUMMARY) SURVIVAL ANIMALS (105W)

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN	
Control	36	0.375生 0.933	4.529± 2.425	$1.010\pm0.224$	
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**	

(IICL042)

BAIS 4

# APPENDIX J 2

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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE UNIT: %

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

PAGE: 3

roup 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生 4.1**	0.039± 0.009	0.373± 0.925	0.580± 0.061*	0.850± 0.206**	1.478± 0.160**

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE UNIT: % ORGAN WEIGHT: RELATIVE (SUMMARY)
SURVIVAL ANIMALS (105W)

UNIT: %					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 ррт	13	0.792± 0.720	22.727±10.532**	1.775± 0.283 <b>*</b> *	
Significan	t difference ;	*: P ≤ 0.05 **	: P ≤ 0.01	Test of Dunnett	
(IICL042)	· · · · · · · · · · · · · · · · · · ·	<del> </del>			RAISA

(IICL042)

BAIS 4

## APPENDIX K 1

HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: MALE: ALL ANIMALS

(2-YEAR STUDY)

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE ALL ANIMALS (0-105W)

PAGE: 1

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

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

SEX : MALE

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

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

)rgan	Group Name No. of Animal Grade	Control s on Study 50  1 2 3 4  (%) (%) (%) (%)	5000 ppm 50 1 2 3 4 (%) (%) (%)	10000 ppm 50 1 2 3 4 (%) (%) (%) (%)	20000 ppm 50 1 2 3 4 (%) (%) (%) (%)
(Respiratory	system}				
nasal cavit	eosinophilic change respiratory epithelium	(50) 12 1 0 0 (24) (2) (0) (0)	20 4 0 0 ( 40) ( 8) ( 0) ( 0)	(50) 19 7 0 0 * (38) (14) (0) (0)	<pre></pre>
	inflammation:foreign body	0 0 0 0 0 (0) (0)	0 0 0 0 0 ( 0) ( 0)	0 0 0 0 0 ( 0) ( 0)	1 0 0 <b>0</b> (2) ( 0) ( 0) ( <b>0</b> )
	respiratory metaplasia:olfactory epithelium	6 0 0 0 (12) (0) (0) (0)	10 0 0 0 0 (20) ( 0) ( 0) ( 0)	4 0 0 0 0 ( 8) ( 0) ( 0) ( 0)	4 0 0 <b>0</b> (8) (0) (0) (0)
	respiratory metaplasia:gland	9 0 0 0 0 (18) (0) (0)	6 I 0 0 (12) (2) (0) (0)	8 0 0 0 (16) (0) (0) (0)	3 0 0 0 0 (6) (6) (0) (0)
	atrophy:olfactory epithelium	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	3 3 0 0 *	1 0 0 <b>0</b> (2) ( 0) ( 0) ( 0)
	necrosis:olfactory epithelium	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 0 (0)	( 0) ( 0) ( 0) ( 0)
lung	hemorrhage	<50> 0 2 0 0 ( 0) ( 4) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
	interstitial pneumonia	1 1 0 0 ( 2) ( 2) ( 0) ( 0)	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)

<sup>(</sup>a) b b: Number of animals with lesion

<sup>(</sup>c) c:b/a \* 100

Significant difference;  $*: P \le 0.05$  \*\*:  $P \le 0.01$  Test of Chi Square

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE ALL ANIMALS (0-105W)

		Group Name No. of Animals on Study				5000 ppm 50			10000 ppm 50					20000 ppm 50									
Organ	Findings	Grade	1 :	2	3 (%)	(%)	-	<u>(%)</u>	(%)	(%)	) (	<u>4</u> (%)	<u>1</u> %)	5)	2 (%)	(%)	(%)		(%)	(%)	(%)	<u>4</u> (%	
Respiratory :	system)																						
lung	bronchopneumonia		0 0) ( :	<50> 1 2) (	0	0		0	0	50> 0 ( 0)		0	( (		(5) 0 0)	0	0 ( 0)	(	0	<5 0 ( 0)	0	0 ( 0	
	bronchiolar—alveolar cell hyperplasia		3 6) (	0 0) (	0	0 ( 0)	( !	14 38) (	3 6)	0 ( 0)		0 <b>**</b>	40 ( 80		2 4)	0 ( 0)	0 *** ( 0)		36 72) (	5 ( 10)	0 ( 0)		) ** ))
{Hematopoieti	c system)																						
oone marrow	erythropoiesis:increased	(	0 0) (	<50> 0 0) (	0	0 ( 0)	(	3 6) (	0	50> 0 ( 0		0 0)		5 2) (	0	0 ( 0)	0 * ( 0)	(	14 28)	<5 0 ( 0)	0> 0 ( 0)		) ** ))
	granulopoiesis:increased	(	3 6) (	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)
lymph node	follicular hyperplasia	(	1 2) (	<50) 0 0) (	0	0 ( 0)	(	0	0	50> 0 ( 0		0 0)		) (0)	0	0 ( 0)	0 ( 0)	(	0 0)	<5 0 ( 0)	0 ( 0)		0 0)
spleen	atrophy	(	2 4) (	<50) 0 0) (	0	0 ( 0)	. (	1 2)	0	50> 0 ( 0	) )) (	0 0)		5 0) (	0		0 ( 0)	(	3 6)	<5 0 ( 0)	60> 0 ( 0)	( (	
Grade <a>&gt; b (c) Significant d</a>	1: Slight 2: Moderate 3 a: Number of animals examined at the s b: Number of animals with lesion c: b / a * 100 lifference: *: P≤ 0.05 **: P:		vere																				

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 SEX

: MALE

	•	Name Control f Animals on Study 50	5000 ppm 50	10000 ppm 50	20000 ppm 50				
Organ	No. C Grade Findings		1 2 3 4 (%) (%) (%)	1 2 3 4 (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)				
Hematopoie	tic system)		·						
pleen	deposit of hemosiderin	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<pre></pre>	(50) 13 1 0 0 ≠ (26) (20) (0) (0)				
	deposit of melanin	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (2) (0) (0)	1 1 0 0 ( 2) ( 2) ( 0) ( 0)	0 0 0 0				
	granulation	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 ( 0) ( 0)				
	extramedullary hematopoiesis	9 4 3 0 (18) (8) (6) (0)	4 6 6 0 ( 8) ( 12) ( 12) ( 0)	4 4 5 0 ( 8) ( 8) ( 10) ( 0)	5 6 19 2 * (10) (12) (38) (4)				
	follicular hyperplasia	3 0 0 0 0 (6) (6) (7)	4 1 0 0 (8) (2) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0				
(Circulator	ry system)								
eart	thrombus	(50) 0 1 0 0 (0) (2) (0) (0)	<50> 0 1 0 0 ( 0) ( 2) ( 0) ( 0)	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<pre></pre>				
	necrosis:focal	i 0 0 0 ( 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)				
Grade < a > b ( c )	1: Slight 2: Moderate 3: Ma a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 t difference; *: P ≤ 0.05 **: P ≤ 0.0								

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE ALL ANIMALS (0-105W)

	Group N	ame Control	5000 ppm	10000 ppm	20000 ppm 50				
gan	No. of Grade Findings	Animals on Study 50  1 2 3 4  (%) (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	50 1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)				
Circulator	y system)								
eart	mineralization	4 0 0 0 ( 8) ( 0) ( 0) ( 0)	<pre></pre>	\$50> 5 0 0 0 (10) (0) (0) (0)	7 1 0 0 ( 14) ( 2) ( 0) ( 0)				
	inflammatory cell nest	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 ( 0) ( 0)	0 0 0 0				
	myocardial fibrosis	0 0 0 0 0 ( 0) ( 0)	0 0 0 0 0 ( 0) ( 0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0				
	arteritis	2 0 0 0 0 (4) ( 0) ( 0) ( 0)	0 0 0 0 0 (0) (0)	1 0 0 0 (2) (0) (0)	0 0 0 0 0 (0)				
)igestive	system)								
ooth	dysplasia	<50> 8 10 8 0 ( 16) ( 20) ( 16) ( 0)	<pre></pre>	(50) 18 13 6 0 (36) (26) (12) (0)	<pre></pre>				
	odontogenic cyst	0 0 0 0 0 (0) (0)	0 0 0 0 0 ( 0) ( 0)	0 0 1 0 ( 0) ( 2) ( 0)	0 0 0 0 0				
ongue	arteritis	<50> 2 0 0 0 ( 4) ( 0) ( 0) ( 0)	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<pre></pre>	<pre></pre>				
rade (a > b	1: Slight 2: Moderate 3: Mark a: Number of animals examined at the site b: Number of animals with lesion c: b/a * 100	ed 4: Severe			-131-				

SEX

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

: MOUSE Crj:BDF1 ANIMAL

REPORT TYPE : A1 : MALE ALL ANIMALS (0-105W)

PAGE: 6 20000 ppm 10000 ppm 5000 ppm Group Name Control 50 50 50 No. of Animals on Study 50

Organ	Findings	Grade 1 2 3 4 (%) (%) (%)	1 2 3 4 (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)
{Digestive s	ystem)				
stomach	hyperplasia:forestomach	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( <b>0</b> )
	erosion:glandular stomach	0 0 0 0 0 ( 0) ( 0)	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0
	hyperplasia:glandular stomach	35 4 0 0 (70) (8) (0) (0)	39 5 0 0 (78) (10) (0) (0)	33 4 0 0 (66) (8) (0) (0)	32 7 0 0 (64) (14) (0) (0)
liver	angiectasis	<50> 2 0 0 0 ( 4) ( 0) ( 0) ( 0)	\$50> 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
	thrombus	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0	0 0 0 0 0
	necrosis:central	0 0 0 0 0 (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0)	0 4 0 0 ( 0) ( 8) ( 0) ( 0)
	necrosis:focal	1 0 0 0 0 (2) ( 0) ( 0) ( 0)	1 0 0 0 0 (2) (0) (0) (0)	0 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) ( 0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)

Grade

l : Slight

2 : Moderate

3 : Marked

4 : Severe

<a>>

a: Number of animals examined at the site

b

b: Number of animals with lesion

c:b/a\*100 (c)

Significant difference ;  $*: P \le 0.05$  \*\*:  $P \le 0.01$  Test of Chi Square

STUDY NO. : 0402 REPORT TYPE : AI

SEX

ANIMAL : MOUSE Crj:BDF1

: MALE

4 : Severe

ALL ANIMALS (0-105W)

PAGE: 7

									3 (%)	) (%		(%)		%) (	(%)	(%)	(%)		%)	(%)		<u>(</u>
f																						
f	atty change	1 ( 2	1 2 2) ( 4		0 0) (	0 0)	1 ( 2)	0		0 ) (		0 0)		<50> 0 0) (	0	0 ( 0)	0 ( 0)		<50: 0 0) (	0	Q ( Q	
	fatty change:central		0) ( (	0 0) (	0 0) (	0	0 ( 0)	0 ( 0)			0) (	0	( :	1 2) (	0	0 ( 0)	0 ( 0)	. (	1 2) (	0 (0)	( 0	
E	granulation	13 ( 26	3 ( 6) (	0 0) (	0 0) (	0	15 ( 30)	0 ( 0)	0 ( 0)	) ( (	0	6 12)	•	l 2) (	0 0) (	0	0 ( 0)		0 0) (	0 (0)		0 ** 0)
e	extramedullary hematopoiesis		0 (	0 0) (	0 (	0 0)	0 ( 0)	( 0)	0 ( 0)	) ( 1	0 0)	1 (2)		0 0) (	0	0 ( 0)	5 ( 10)		0 0) (	0 ( 0)	( )	) (i)
¢	clear cell focus	( (	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 Q)
3	acidophilic cell focus	( 10	5 0) (	2 4) (	0	0 ( 0)	5 ( 10)	2 ( 4)	1 ( 2)		0 0)	3 ( 6)		3 6) (	0	0 ( 0)	9 ( 18)		4 8) (	0 ( 0)		0 0)
}	basophilic cell focus		1 2) (	1 2) (	0	0 ( 0)	4 ( 8)	( 2)	0 ( 0)		0 0)	0 ( 0)	(	0 0) (	0	0 ( 0)	0 ( 0)		0	0 ( 0)		0 0)
	vacuolated cell focus		1																	0		0

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

3 : Marked Grade 1 : Slight 2 : Moderate a : Number of animals examined at the site < a >

b b: Number of animals with lesion

c:b/a\*100

Significant difference ;  $*: P \le 0.05$  \*\*:  $P \le 0.01$  Test of Chi Square

SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

ALL ANIMALS (0-105W)

Organ		Group Name Control  No. of Animals on Study 50  Grade 1 2 3 4  (%) (%) (%) (%)	5000 ppm 50 1 2 3 4 (%) (%) (%) (%)	10000 ppm 50 1 2 3 4 (%) (%) (%)	20000 ppm 50 1 2 3 4 (%) (%) (%) (%)
{Digestive sy	vstem}				
liver	hepatocellular hypertrophy:central	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(50> 0 15 0 0 ** ( 0) ( 30) ( 0) ( 0)	<pre></pre>	<50> 0 35 0 0 ** ( 0) ( 70) ( 0) ( 0)
	nuclear atypia:central	0 0 0 0 0 0 ( 0)	0 0 0 0 0 (0) (0)	11 2 0 0 *** (22) (4) (0) (0)	17 21 0 0 *** ( 34) ( 42) ( 0) ( 0)
gall bladd	hyperplasia	<49> 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<pre></pre>
pancreas	islet cell hyporplasia	<50> 2 0 0 0 ( 4) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<pre></pre>
{Urinary sys	tem)				
kidney	cyst	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(50) 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	<pre></pre>	(50) 0 0 0 0 (0) (0) (0) (0)
	hyaline droplet	1 0 0 0 0 (2) ( 0) ( 0) ( 0)	0 0 0 0 0 (0) (0)	0 0 1 0 (0) (2) (0)	0 0 0 0 0 (0) (0)
Grade <a>&gt; b (c) Significant</a>	1: Slight 2: Moderate 3 a: Number of animals examined at the s b: Number of animals with lesion c: b / a * 100 difference: *: P ≤ 0.05 **: P:				

(HPT150)

SEX

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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : AI

: MALE

PAGE: 9

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	5000 ppm 50 1 2 3 4 (%) (%) (%) (%)	10000 ppm 50 1 2 3 4 (%) (%) (%) (%)	20000 ppm 50 1 2 3 4 (%) (%) (%) (%)
{Urinary sy	stem)				
kidney	basophilic change	(50) 16 1 0 0 (32) (2) (0) (0)	(50) 20 0 0 0 (40) (0) (0) (0)	(50) 14 0 0 0 (28) (0) (0) (0)	(50) 1 0 0 0 *** (2) (0) (0) (0)
	deposit of hemosiderin	0 0 0 0 0 (0) (0)	1 2 1 0 ( 2) ( 4) ( 2) ( 0)	0 2 7 0 ***	2 4 17 2 ** ( 4) ( 8) ( 34) ( 4)
	lymphocytic infiltration	5 0 1 0 (10) (0) (2) (0)	7 0 0 0 (14) ( 0) ( 0) ( 0)	3 0 0 0 0 (6) (6) (70) (70)	2 0 0 0 0 (4) (0) (0) (0)
	inflammatory polyp	0 1 1 0 ( 0) ( 2) ( 2) ( 0)	1 0 1 0	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 ( 0) ( 0)
	hydronephrosis	0 0 3 1 ( 0) ( 6) ( 2)	1 0 3 0 ( 2) ( 0) ( 6) ( 0)	0 1 0 2 ( 0) ( 2) ( 0) ( 4)	0 0 2 0 ( 0) ( 4) ( 0)
	mineralization:papilla	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) ( 0) ( 0) ( 0)
urin bladd	inflammation	<49> 0 1 0 0 ( 0) ( 2) ( 0) ( 0)	<50> 0 0 0 0 0 0 0 0 0 0 0	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
	lymphocytic infiltration	1 0 0 0 0 (2) (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:b/a\*100 (c)

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

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : AI SEX : MALE ALL ANIMALS (0-105W)

		Group Name Control  No. of Animals on Study 50  Grade 1 2 3 4	5000 ppm 50 1 2 3 4	10000 ppm 50 1 2 3 4	20000 ppm 50 1 2 3 4
rgan	Findings	(%) (%) (%) (%)	(%) (%) (%)	(%) (%) (%)	(%) (%) (%) (%)
Urinary sys	tem)				
rethra	inflammation	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(50) 0 0 1 0 (0) (0) (2) (0)
Endocrine s	ystem)				
ituitary	angiectasis	<50> 0 0 0 0 ( o) ( o) ( o) ( o)	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(50) 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	<49> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
	cyst	6 0 0 0 (12) (0) (0) (0)	3 0 0 0 0 (6) (6) (0) (0)	3 0 0 0 0 (6) (6) (0) (0)	4 0 0 0 0 ( 8) ( 0) ( 0)
	hyperplasia	3 0 0 0 0	3 0 0 0 0	0 0 0 0 0	0 0 0 0 0
	Rathke pouch	2 0 0 0 0 (4) (0) (0) (0)	1 0 0 0 0 (2) ( 0) ( 0) ( 0)	0 0 0 0 0	0 0 0 0 0
liyroid	focal follicular cell hyperplasia	<50> 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	<49> 0 0 0 0 0 0 0 0 0 0 0	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0

b

(a) a: Number of animals examined at the site

b: Number of animals with lesion

c:b/a \* 100

(c) Significant difference ; \* :  $P \le 0.05$  \*\* :  $P \le 0.01$  Test of Chi Square

(HPT150)

BAIS4

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1
SEX : MALE

ALL ANIMALS (0-105W)

Organ	1	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	5000 ppm 50 1 2 3 4 (%) (%) (%) (%)	10000 ppm 50 1 2 3 4 (%) (%) (%) (%)	20000 ppm 50 1 2 3 4 (%) (%) (%) (%)
(Endocrine s	ystem}				
adrenal	spindle-cell hyperplasia	<50> 24 7 0 0 ( 48) ( 14) ( 0) ( 0)	29 8 0 0 ( 59) ( 16) ( 0) ( 0)	<50> 25 8 0 0 (50) (16) (0) (0)	<50> 27 1 0 0 (54) (2) (0) (0)
	hyperplasia:cortical cell	2 0 0 0 (4) (0) (0) (0)	3 0 0 0 0	2 0 0 0 0 (4) (0) (0) (0)	1 0 0 0 ( 2) ( 0) ( 0) ( 0)
•	focal hypertrophy:cortex	0 0 0 0 0 (0)	2 0 0 0 0 (4) (0) (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0
{Reproductiv	ve system)				
testis	mineralization	<50> 27 18 2 0 (54) (36) (4) (0)	(50) 32 9 4 0 (64) (18) (8) (0)	<pre></pre>	50> 5 0 0 0 *** (10) ( 0) ( 0) ( 0)
epididymis	spermatogenic granuloma	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<pre></pre>	<49> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
	xanthogranuloma	1 0 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0
Grade <a> b (c) Significant</a>	i: Slight 2: Moderate 3 a: Number of animals examined at the s b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤				

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

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

SEX : MALE

)rgan		p Name	5000 ppm 50 1 2 3 4 (%) (%) (%)	10000 ppm 50 1 2 3 4 (%) (%) (%) (%)	20000 ppm 50 1 2 3 4 (%) (%) (%) (%)
(Reproductive	system)				
semin ves	hemorrhage	(50) 0 0 1 0 (0) (0) (2) (0)	<pre></pre>	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
	inflammation	0 0 1 0 ( 0) ( 2) ( 0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 ( 0) ( 0)	0 0 0 0 0 (0)
prostate	inflammation	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(50) 1 0 0 0 ( 2) ( 0) ( 0) ( 0)
prep/cli gl	duct ectasia	<49> 0 4 0 0 ( 0) ( 8) ( 0) ( 0)	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	0 0 0 0 ( 0) ( 0) ( 0) ( 0)
{Nervous syst	.em}				
brain	mineralization	<50> 24 0 0 0 ( 48) ( 0) ( 0) ( 0)	<50> 20 0 0 0 (40) (0) (0) (0)	<50> 21 0 0 0 (42) (0) (0) (0)	<50> 25 0 0 0 (50) ( 0) ( 0) ( 0)
{Special sens	se organs/appendage)				
Harder gl	lymphocytic infiltration	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<pre></pre>	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	50> 1 0 0 0 ( 2) ( 0) ( 0) ( 0)
Grade <a>&gt; b (c) Significant</a>	<pre>1: Slight 2: Moderate 3: 1 a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤ 0</pre>	Marked 4: Severe			

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 SEX : MALE

ALL ANIMALS (0-105W)

Organ		Group Name         Control           No. of Animals on Study         50           Grade         1         2         3         4           (%)         (%)         (%)         (%)	5000 ppm 50 1 2 3 4 (%) (%) (%) (%)	10000 ppm 50 1 2 3 4 (%) (%) (%) (%)	20000 ppm 50 1 2 3 4 (%) (%) (%) (%)
Special sen	se organs/appendage)				
Harder gl	hyperplasia	(50) 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	<pre></pre>	(50) 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	(50) (0)(0)(0)(0)(0)
(Musculoskel	etal system)				
nuscle	mineralization	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
Grade <a> b (c)</a>	1: Slight 2: Moderate 3 a: Number of animals examined at the s b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤				

## APPENDIX K 2

HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: FEMALE: ALL ANIMALS

(2-YEAR STUDY)

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1

SEX

: FEMALE

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

(HPT150)

: FEMALE

SEX

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

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

	No	oup Name . of Animals on Study ade 1	Contr 50		4	1		00 ppr 50		4	Í	1	0000 ; 50		4	1	200	00 р 50	pm 3	4
Organ	Findings	(%)	(%)	(%)	(%)	(%)	(%			(%)	(%)		(%)	(%)	(%	(%)	(%		(%)	(%)
{Respiratory	system}																			
nasal cavit	respiratory metaplasia olfactory epithel	ium 3 ( 6)	<50: 0 ( 0) (	0	0 ( 0)	3 ( 6)	0		0 0) (	0 0)	4 ( 8)	(	<50 0 0) (	0 0)	0 ( 0	1 ( 2)		<50> ) )) (	0	0 ( 0)
	respiratory metaplasia:gland	6 ( 12)	0 ( 0) (	0 0)	0 ( 0)	4 ( 8)	0 ( 0		0 0) (	0	6 ( 12)		0	0 (0)	0 )	15 ( 30)	( (		0	( 0) 0 *
	atrophy:olfactory epithelium	0 ( 0)	0 ( 0) (	0 0)	0 ( 0)	1 ( 2)	l ( 2	) (	0 0) (	0	( 0)	) (	1 2) (	0	0 )	0 ( 0)	( (		0	0 ( 0)
nasopharynx	eosinophilic change:respiratory epithel		<50 0 ( 0) (	0	0 ( 0)	5 ( 10)	0		3 6) (	1 2)	7 ( 14)		<50 3 6) (	1	0 )	11 ( 22)		<50) ) )) (	0	0 : ( 0)
ung	hemorrhage	0 ( 0)	<50 0 ( 0) (	0	0 ( 0)	0 ( 0)	0		0 0) (	0 0)	0 ( 0)		<50 1 2) (	0	( (	0 ( 0)		<50) ) ) (	0	0 ( 0)
	inflammatory infiltration	0 ( 0)	0 ( 0) (	0 (0)	0 ( 0)	0 ( 0)			0 0) (	0 0)	0		1 2)	0 ( 0)	( (	0 ( 0)		0 0) (	0 0)	0 ( 0)
	interstitial pneumonia	( 0)	0 ( 0) (	0 ( 0)	0 ( 0)	3 ( 6)	( (	) )) (	0 (	0 0)	3 ( 6		0	0 ( 0)	(	1 ( 2)		0 0) (	0 0)	( 0)
Grade < a >     b ( c )	1: Slight 2: Moderate 3: a: Number of animals examined at the sit b: Number of animals with lesion c: b / a * 100	Marked 4: Sever	<u>.</u>																	

ANIMAL : MOUSE Crj:BDF1

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

REPORT TYPE : A1 SEX

: FEMALE

	N	roup Name lo. of Animals on Study	Cont 50				5000 50	)				000 р 50	pm				оррт 50	
Organ	Findings	rade <u>1</u> (%)	(%)	3 (%)	(%)	(%)	<u>2</u> (%)	(%)	<u>4</u> (%)	(%)	(%		3 (%)	(%)	(%)	(%)	(%)	(%)
{Respiratory	system}																	
lung	bronchiolar—alveolar cell hyperplasia	0 ( 0)	<50 0 ( 0) (	0	0	40 ( 80)	(50 2 ( 4)	0	0 ** ( 0)	40 ( 80)	0		0	0 ** ( 0)	41 ( 82)	2	50> 0 ( 0)	0 *¤ ( 0)
(Hematopoieti	c system)																	
oone marrow	myelofibrosis	0 ( 0)	(50 0 ( 0) (	. 0	0 ( 0)	0 ( 0) (	<5( 0 ( 0)	0	0 ( 0)	1 ( 2)	0	<50> ) )) (	0	0	0 ( 0)	0	50> 0 ( 0)	0 ( 0)
	erythropoiesis:increased	2 ( 4)	0 ( 0) (	0	0	0 ( 0)	0 ( 0)	0	0 ( 0)	2 ( 4)	0 )	) )) (	0	0	17 ( 34)	0 ( 0)	0 ( 0)	0 *= ( 0)
	granulopoiesis:increased	1 ( 2)	0 (0) (	0	0 ( 0)	3 (6)	0	0 ( 0)	0 ( 0)	2 ( 4)	0	) )) (	0	0	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
spleen	deposit of hemosiderin	3 ( 6)	<50 0 ( 0) (	0	0	13 ( 26) +	<50 0 ( 0)	0	0 * ( 0)	22 ( 44)	0	<50> ) )) (	0	0 ** ( 0)	13 ( 26)	0	50> 0 ( 0)	0 *
	extramedullary hematopoiesis	5 ( 10)	6 (12) (	9 18)	0 ( 0)	8 (16)	1 (2)	4 (8)	0 ( 0)	11 ( 22)	5 ( 10		3 6)	1 ( 2)	9 ( 18)	3 ( 6)	29 ( 58)	0 *** ( 0)
Grade (a) b (c)	1: Slight 2: Moderate 3: a: Number of animals examined at the sit b: Number of animals with lesion c: b / a * 100	Marked 4: Severe	<u>.</u>															

SEX

(HPT150)

ANIMAL : MOUSE Crj:BDF1

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

REPORT TYPE : A1 : FEMALE

PAGE: 17

BAIS4

Organ	No	roup Name Control b. of Animals on Study 50 rade 1 2 3 4 (%) (%) (%) (%)	5000 ppm 50 1 2 3 4 (%) (%) (%) (%)	10000 ppm 50 1 2 3 4 (%) (%) (%) (%)	20000 ppm 50 1 2 3 4 (%) (%) (%) (%)
fra					
· -	etic system)				
spleen	follicular hyperplasia	<50> 0 1 0 0 ( 0) ( 2) ( 0) ( 0)	<50> 2	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
{Circulato	ry system]				
heart	thrombus	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 1 0 ( 2) ( 0) ( 2) ( 0)	<pre></pre>
	mineralization	4 0 0 0 0 (8) (0) (0) (0)	3 0 0 0 0 (6) (6) (7)	6 1 0 0 (12) (2) (0) (0)	13 1 0 0 ** ( 26) ( 2) ( 0) ( 0)
	arteritis	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 ( 0) ( 0)
{Digestive	system)				
tooth	inflammation	( 0) ( 0) ( 0) ( 0)	(50) 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(50) (0)(0)(0)(0)
Grade <a> b (c)</a>	<pre>l: Slight 2: Moderate 3: a: Number of animals examined at the sit b: Number of animals with lesion c: b / a * 100 at difference; *: P ≤ 0.05 **: P ≤ 0.05</pre>				

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1

SEX : FEMALE

REPORT TYPE : A1

	i	Group Name Control No. of Animals on Study 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
rgan	Findings	Frade 1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	<u>i</u> <u>2</u> <u>3</u> <u>4</u> (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)
(Digestive :	system}				
tooth	dysplasia	<50> 20 2 1 1 ( 40) ( 4) ( 2) ( 2)	<pre></pre>	<50> 22 6 2 0 (44) (12) (4) (0)	21 6 2 0 ( 42) ( 12) ( 4) ( 0)
	odontogenic cyst	0 0 0 0 0 (0)	0 0 0 0 0	0 0 1 0 (0) (2) (0)	0 0 0 0 0 (0) (0)
tongue	arteritis	<50> 1 1 0 0 ( 2) ( 2) ( 0) ( 0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	(50) 0 0 0 0 (0) (0) (0) (0)
stomach	erosion:glandular stomach	<50> 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	<50> 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
	hyperplasia:glandular stomach	44 1 0 0 (88) (2) (0) (0)	37 2 0 0 (74) (4) (0) (0)	39 1 0 0 (78) ( 2) ( 0) ( 0)	40 0 0 0 (80) ( 0) ( 0) ( 0)
iver	angiectasis	<50> 1 2 0 0 ( 2) ( 4) ( 0) ( 0)	(50) i i 0 0 (2) (2) (0) (0)	<50> 0 1 0 0 ( 0) ( 2) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
	necrosis:focal	1 0 0 0 ( 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)
Grade <a> b (c)</a>	1: Slight 2: Moderate 3 a: Number of animals examined at the si b: Number of animals with lesion c: b/a*100	: Marked 4 : Severe te			

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

: MOUSE Crj:BDF1 ANIMAL

REPORT TYPE : A1

PAGE: 19 SEX : FEMALE 10000 ppm 5000 ppm 20000 ppm Control Group Name 50 No. of Animals on Study 50 50 50 3 Grade (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) Findings\_ Organ\_ {Digestive system} <50> <50> <50> liver 0 0 0 0 0 0 0 0 0 fatty change:central (0)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) 0 0 0 0 0 0 0 0 0 inflammatory infiltration (2)(2)(0)(0) (0)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) 0 0 0 0 granulation (20) (0) (0) (0) (8)(0)(0)(0) (20) (4) (2) (0) (30) (0) (0) (0) 0 0 0 1 0 0 1 0 0 extramedullary hematopoiesis 0 (2)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) clear cell focus 0 0 0 (0)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0)

> 0 0

0

0

(4)(0)(0)(0)

(2)(0)(0)(0)

0

(0)(0)(0)(0)

4

(8)(0)(0)(0)

(2)(2)(0)(0)

(0)(0)(0)(0)

1

0

0

0

(18) (0) (0) (0)

(4)(0)(0)(0)

(0)(0)(0)(0)

0 0

0

0 0 0

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

acidophilic cell focus

basophilic cell focus

vacuolated cell focus

0

(14) (0) (0) (0)

0

(0)(0)(0)(0)

(2)(0)(0)(0)

0

<sup>&</sup>lt; a > a: Number of animals examined at the site

b: Number of animals with lesion b

<sup>(</sup>c) c:b/a \* 100

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

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1

(HPT150)

SEX

: FEMALE

Group Name Control 5000 ppm 10000 ppm 20000 ppm No. of Animals on Study 50 50 50 50 Grade (%) (%) (%) Organ\_ Findings\_ (Digestive system) liver <50> hepatocellular hypertrophy:central 0 0 1 0 0 \*\* (0)(0)(0)(0) (0)(0)(0)(0) (0)(2)(0)(0) (0)(18)(0)(0) nuclear atypia:central 0 0 0 0 0 0 0 0 0 1 0 (0)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) (2)(0)(0)(0) <50> <50> gall bladd hyperplasia 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) {Urinary system} kidnev <50> 0 0 0 0 0 0 0 0 0 0 0 0 0 cyst (0)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) hyaline droplet 0 1 5 0 0 5 (2) (0) (12) (6) (2)(2)(12)(6) (2)(2)(10)(4) (0)(0)(10)(2) basophilic change (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;  $*: P \le 0.05$  \*\*:  $P \le 0.01$  Test of Chi Square

ANIMAL : MOUSE Crj:BDF1

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1 SEX : FEMALE

Organ		Group Name Control  No. of Animals on Study 50  Grade 1 2 3 4  (%) (%) (%) (%)	5000 ppm 50 1 2 3 4 (%) (%) (%) (%)	10000 ppm 50 1 2 3 4 (%) (%) (%) (%)	20000 ppm 50 1 2 3 4 (%) (%) (%) (%)
{Urinary sys	tem)				
kidney	deposit of hemosiderin	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 1 1 2 0 ( 2) ( 2) ( 4) ( 0)	<pre></pre>
	lymphocytic infiltration	3 0 0 0 0 (6) (6) (7)	0 0 0 0 0 0 ( 0) ( 0)	3 0 0 0 0 (6) (6) (0) (0)	0 0 0 0 0 (0) (0)
	inflammatory polyp	0 0 0 0 0 (0)	0 3 0 0	1 1 0 0 (2) (2) (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 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 ( 0) ( 0)
	hydronephrosis	0 0 1 1 (0) (0) (2) (2)	0 2 3 1 (0) (4) (6) (2)	0 2 2 0 ( 0) ( 4) ( 4) ( 0)	0 0 0 0 0 (0) (0)
	mineralization:papilla	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) ( 0) ( 0) ( 0)	1 0 0 0 0 (2) (0) (0) (0)
urin bladd	lymphocytic infiltration	(49) 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	<50> 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	<pre></pre>	(50) 1 0 0 0 ( 2) ( 0) ( 0) ( 0)
{Endocrine s	ystem)				
pituitary	angiectasis	<49> 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>	<50> 0 1 0 0 ( 0) ( 2) ( 0) ( 0)	( 0) ( 0) ( 0) ( 0) ( 0) ( 0) ( 0) ( 0)
Grade <a>&gt; b (c) Significant</a>	1: Slight 2: Moderate 3 a: Number of animals examined at the s b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤				

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : FEMALE

Organ	Findings	Group Name   Control	5000 ppm 50 1 2 3 4 (%) (%) (%) (%)	10000 ppm 50 1 2 3 4 (%) (%) (%) (%)	20000 ppm 50 1 2 3 4 (%) (%) (%) (%)
{Endocrine sy	rstem}				
pituitary	lemorrhage	<49> 0 1 0 0 ( 0) ( 2) ( 0) ( 0)	<pre></pre>	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
	cyst	3 0 0 0 0 (6) (6) (7)	5 0 0 0 (10) ( 0) ( 0) ( 0)	4 0 0 0 0 (8) (0) (0) (0)	2 0 0 0 0 (4) (0) (0) (0)
	hyporplasia	4 2 0 0 (8) (4) (0) (0)	3 1 0 0 (6) (2) (0) (0)	4 0 0 0 0 (8) ( 0) ( 0) ( 0)	2 1 0 0 (4) (2) (0) (0)
	Rathke pouch	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	1 0 0 0 0 (2) ( 0) ( 0) ( 0)	0 0 0 0 0 (0) (0)
thyroid	focal follicular cell hyperplasia	(50) 1 0 0 0 ( 2) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<pre></pre>	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
adrenal	spindle-cell hyperplasia	5 43 2 0 ( 10) ( 86) ( 4) ( 0)	<pre></pre>	(50) 1 41 4 0 ( 2) (82) ( 8) ( 0)	<pre></pre>
	hyperplasia:cortical cell	2 0 0 0 0 ( 4) ( 0) ( 0) ( 0)	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 ( 2) ( 0) ( 0) ( 0)	0 0 0 0 0 (0) (0)

(c) c:b/a\*100

Significant difference ; \* :  $P \le 0.05$  \*\* :  $P \le 0.01$  Test of Chi Square

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : FEMALE

PAGE: 23

Organ	Findings	Group Name   Control No. of Animals on Study   50   Grade   1   2   3   4   (%)   (%)   (%)   (%)	5000 ppm 50 1 2 3 4 (%) (%) (%) (%)	10000 ppm 50 1 2 3 4 (%) (%) (%) (%)	20000 ppm 50 1 2 3 4 (%) (%) (%) (%)
{Endocrine :	system)				
adrenal	focal fatty change:cortex	(50) 0 1 0 0 ( 0) ( 2) ( 0) ( 0)	(50) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
{Reproducti	ve system}				
ovary	thrombus	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(50) 0 1 0 0 (0)(2)(0)(0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<50> 0 0 3 0 ( 0) ( 0) ( 6) ( 0)
	cyst	2 0 3 2 ( 4) ( 0) ( 6) ( 4)	2 2 7 0 (4) (4) (14) (0)	0 1 2 1 ( 0) ( 2) ( 4) ( 2)	0 0 0 0 0 (0) (0)
uterus	cystic endometrial hyperplasia	(50) 10  10  1  0 ( 20) ( 20) ( 2) ( 0)	(50) 8 12 4 0 (16) (24) (8) (0)	<50> 11 10 7 0 (22) (20) (14) (0)	(50) 8 5 2 0 (16) (10) (4) (0)
{Nervous sy	rstem)				
brain	mineralization	<50> 18 0 0 0 ( 36) ( 0) ( 0) ( 0)	\( \langle 50 \rangle \) 18	\( \frac{50}{18} \) (36) (0) (0) (0)	(50) 15 0 0 0 (30) (0) (0) (0)
Grade <a>&gt; b (c) Significant</a>	1: Slight 2: Moderate a: Number of animals examined at th b: Number of animals with lesion c: b / a * 100 t difference; *: P ≤ 0.05 **:	3: Marked 4: Severe te site  P ≤ 0.01 Test of Chi Square			

(HPT150)

BAIS4

ANIMAL : MOUSE Crj:BDF1

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1

SEX : FEMALE

Organ	No	coup Name Control of Animals on Study 50 rade 1 2 (%) (%) (%)	34_	5000 ppm 50 1 2 3 4 (%) (%) (%) (%)	10000 ppm 50 1 2 3 4 (%) (%) (%) (%)	20000 ppm 50 1 2 3 4 (%) (%) (%) (%)
{Nervous system	)					
brain	epidermal cyst	(50) 0 0 ( 0) ( 0) (	0 0 0 (	<pre></pre>	<50> 0 1 0 0 ( 0) ( 2) ( 0) ( 0)	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
{Special sense	organs/appendage}					
Harder gl	hyperplasia	(50) 0 0 ( 0) ( 0) (	0 0 0	<pre></pre>	<50> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<pre></pre>
{Musculoskeleta	l system}					
muscle	mineralization	(50) (0)(0)(	0 0 0 0) (	<50> 0 0 0 0 0) ( 0) ( 0) ( 0)	<50> 1 1 0 0 ( 2) ( 2) ( 0) ( 0)	(50) 1 0 0 0 ( 2) ( 0) ( 0) ( 0)
<a> a &gt; a b b b c c &gt; c <a> c</a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a>	: Slight 2: Moderate 3: n: Number of animals examined at the sit n: Number of animals with lesion n: b / a * 100 Cference; *: P ≤ 0.05 **: P ≤					

## APPENDIX K 3

HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: MALE: SACRIFICED ANIMALS

(2-YEAR STUDY)

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

SACRIFICED ANIMALS (105W)

REPORT TYPE : A1 SEX

: MALE

Organ	No	oup Name . of Animals on Study ade 1 (%)	Cont 36 2 (%)		<u>4</u> (%)	1 (%)	5000 3 2 (%)		<u>4</u> (%)	<u>1</u> (%)		0000 27 2 (%)		<u>4</u> (%)		1 (%)		) ppm 16 3 (%)		<del>4</del> %)
(Integumentar	y system/appandage)																			
skin/app	inflammation	0 ( 0)	<36 0 ( 0) (	0	0 ( 0)	0 ( 0)	<3 1 ( 3)	0	0 ( 0)	0 ( 0)		<27 0 0)	0	0 ( 0)	(	0 0)	0	16> 0 ( 0)	( (	
	hyperplasia:epidermis	( 0)	0 ( 0) (	0 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)		0	0 ( 0)	( 0)	(	0	0 ( 0)	0 ( 0)	(	
{Respiratory	system)																			
nasal cavit	mineralization	3 ( 8)	<36 0 ( 0) (	0	0 ( 0)	4 ( 11)	0	5> 0 ( 0)		3 ( 11)		<2° 0 0)	7> 0 ( 0)	0 ( 0)		1 6)	0	16> 0 ( 0)		0 0)
	eosinophilic change:olfactory epithelium		1 ( 3)	0 (0)	0 ( 0)	15 ( 43)	0 ( 0)	0 ( 0)	0 ( 0)	7 ( 26)	) (	2 7)	0 ( 0)	0 ( 0)	) (	5 31)	0 ( 0)	( 0)		0 0)
	eosinophilic change respiratory epitheli		1 ( 3)	0 (0)	0 ( 0)	15 ( 43)	2 ( 6)	0 ( 0)	0 ( 0)	10 ( 37)		4 15)	0 ( 0)	0 ( 0)		11 69)	5 ( 31)	( 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)		1 6)	0 ( 0)	0 ( 0)		0 0)
	respiratory metaplasia:olfactory epithe		0 ( 0)	0	0 ( 0)	8 ( 23)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 7)		0	0 ( 0)	0 ( 0)		2 13)	0 ( 0)	0 ( 0)		0 0)

Grade

<sup>1 :</sup> Slight

<sup>2 :</sup> Moderate

<sup>3 :</sup> Marked

<sup>4 :</sup> Severe

<sup>&</sup>lt; a >

b

a: Number of animals examined at the site

b: Number of animals with lesion

<sup>(</sup>c) c:b/a \* 100

Significant difference ; \* :  $P \le 0.05$  \*\* :  $P \le 0.01$  Test of Chi Square

SEX

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

STUDY NO. : 0402 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

: MALE

Organ	Findings	Group Name No. of Animals on Study Grade	Contr 36 2 (%)	-o1 3 (%)	<u>4</u> (%)	1 (%)	5000 35 2 (%)		4 (%)	<u>1</u> (%)	100	000 pj 27	pm 3 (%)	<u>4</u> (%)	1 (%)		0000 16 <u>2</u> (%)		4 (%)
or gan	rmungs	(,0)		(10)					(/e/										
{Respiratory s	system)																		
nasal cavit	respiratory metaplasia:gland	6 ( 17)	(36) 0 ( 0) (	0	0 0)	3 ( 9)	(3) (3)	0	0 ( 0)	3 ( 11)		<27> ) )) (	0	0	2 ( 13)	) (	<16 0 0) (	5> 0 ( 0)	0 ( 0)
	atrophy:olfactory epithelium	0 ( 0)	0 ( 0) (	0	0 (0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)	( 7	2 7) (	0	0 ( 0)	0 ( 0)	) (	0	0 ( 0)	0 ( 0)
	necrosis:olfactory epithelium	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)
lung	hemorrhage	( 0)	<360 1 ( 3) (	0	0 (0)	0 ( 0)	<3: 0 ( 0)	0	0 ( 0)	0 ( 0)		<27> 0 0) (	0	0 ( 0)	0 ( 0)		<16 0 0)	6> 0 ( 0)	0 ( 0)
	interstitial pneumonia	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)
	bronchiolar-alveolar cell hyperplasi		0 ( 0) (	0	0 ( 0)	32 ( 91)	3 ( 9)	0 ( 0)	0 ** ( 0)	26 ( 96)		1 4) (	0	0 ** ( 0)	13 ( 81)		2 13)	0 ( 0)	0 *
(Hematopoietic	c system]																		
bone marrow	erythropoiesis:increased	( 0)	<36: 0 ( 0) (	0	0	1 ( 3)	(3 ( 0)	0	0 ( 0)	3 ( 11)		<27> 0 0) (	0	0 ( 0)	4 ( 25		0) 0 <10	6> 0 ( 0)	0 * ( 0)
Grade <a>&gt; b (c) Significant d</a>	<ul><li>a: Number of animals examined at the</li><li>b: Number of animals with lesion</li><li>c: b / a * 100</li></ul>		÷					_											

SEX

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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

: MALE

PAGE: 3

		Group Name Control No. of Animals on Study 36			5000 ppm 35				10000 ppm 27					20000 ppm 16							
Organ	Findings	Grade <u>1</u> (%)	(%)	(%)	(%)	(%)		2 %)	(%)	(%)	(5	<u>(</u> %)	(%)	(%)	(%)	<u>(</u>	<u>1</u> %)	(%)	(%)	(	<u>4</u> (%)
Hematopoietic	system)																				
one marrow	granulopoiesis:increased	2 ( 6)	<36 0 ( 0) (	0	0 ( 0)	1 ( 3)		<35) 0 0) (	0	0 ( 0)	(	0 0) (	<27 0 0)	7> 0 ( 0)	0 ( 0)		0 0) (	<16 0 0)	0		0 0)
ymph node	follicular kyperplasia	1 ( 3)	<36 0 ( 0) (	0	0 ( 0)	0 ( 0)	(	<35) 0 0) (	0	0 ( 0)		0 0) (	<27 0 0)	7> 0 ( 0)	0 ( 0)		0 0) (	<16 0 0)	0		0 0)
pleen	atrophy	0 ( 0)	<36 0 ( 0) (	0	0 ( 0)	0 ( 0)		<350 0 0) (	0	0 ( 0)		l 4) (	(2° 0 0)	7> 0 ( 0)	0 ( 0)		0 0) (	<18 0 0)	6> 0 ( 0)		0
	deposit of hemosiderin	0 ( 0)	0 ( 0)	0 (0)	0 ( 0)	0 ( 0)	(	0 0) (	0	0 ( 0)		7 6) (	0 0)	0 ( 0)	0 **		5 31) (	0 ()	0 ( 0)		0 * 0)
	deposit of melanin	1 ( 3)	0 ( 0)	0 (0)	0 ( 0)	1 ( 3)	(	0 0) (	0 0)	0 ( 0)		1 <b>4</b> ) (	1 4)	0 ( 0)	0 ( 0)		0 (0)	0 (0)	0 ( 0)		0 0)
	granulation	( 0)	0 ( 0)	0	0 ( 0)	0 ( 0)	) (	0 0) (	0 0)	0 ( 0)	(	0 0) (	1 4)	0 ( 0)	0 ( 0)	(	0	0 (0)	0 ( 0)		0 0)
	extramedullary hematopoiesis	7 ( 19)	1 ( 3)	1 (3)	0 ( 0)	2 ( 6)	) (	3 9) (	0 0)	0 ( 0)	(	1 4) (	1 4)	1 ( 4)	0 ( 0)		5 31) (	1 (6)	3 ( 19)		0

Grade 1 : Slight

2 : Moderate

3 : Marked

4 : Severe

a: Number of animals examined at the site

b: Number of animals with lesion b

c:b/a \* 100 (c)

Significant difference ; \* :  $P \le 0.05$  \*\* :  $P \le 0.01$  Test of Chi Square

(IIPT150)

< a >

BAIS4

STUDY NO. : 0402 ANIMAL : MOUSE Crj:BDF1

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

REPORT TYPE : A1 SEX : MALE

Organ	Findings	Group Name Control  No. of Animals on Study 36  Grade 1 2 3 4  (%) (%) (%) (%)	5000 ppm 35 1 2 3 4 (%) (%) (%) (%)	10000 ppm 27 1 2 3 4 (%) (%) (%) (%)	20000 ppm 16 1 2 3 4 (%) (%) (%) (%)
{Hematopoi	etic system)				
spleen	follicular hyperplasia	36> 3 0 0 0 ( 8) ( 0) ( 0) ( 0)	<pre></pre>	27> 1 0 0 0 ( 4) ( 0) ( 0) ( 0)	( 0) ( 0) ( 0) ( 0)
{Circulato	ry system)				
heart	thrombus	<36> 0 1 0 0 ( 0) ( 3) ( 0) ( 0)	<35> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<27> 0 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	( 0) ( 0) ( 0) ( 0)
	necrosis:focal	1 0 0 0 0 (3) (3) (6)	0 0 0 0 0 (0) (0)	0 0 0 0 0 ( 0) ( 0)	0 0 0 0 0 (0) (0) (0)
	mineralization	1 0 0 0 0 (3) (0) (0) (0)	2 0 0 0 0 (6) (6) (0) (0)	i 0 0 0 (4)(0)(0)(0)	1 0 0 0 0 (6) (6) (7)
	arteritis	2 0 0 0 0 ( 6) ( 6) ( 0) ( 0)	0 0 0 0 0 ( 0) ( 0)	1 0 0 0 0 (4) (0) (0)	0 0 0 0 0 (0) (0)
{Digestive	system)				
tooth	dysplasia	<36> 6 8 6 0 ( 17) ( 22) ( 17) ( 0)	35> 20 i0 i 0 *** (57) (29) (3) (0)	<pre></pre>	<16> 11 0 1 0 *** (69) (0) (6) (0)
Grade <a> b columnities</a>	1: Slight 2: Moderate a: Number of animals examined at b: Number of animals with lesion c: b / a * 100 at difference; *: P ≤ 0.05 ***	$3: Marked$ $4: Severe$ the site $: P \leq 0.01  \text{Test of Chi Square}$			

ANIMAL : MOUSE Crj:BDF1

HISTOPATHOLOGICAL FINDINGS : NON-NBOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

REPORT TYPE : AI : MALE SEX

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

<sup>&</sup>lt;a>>

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

b (c)

c:b/a \* 100

Significant difference ; \* :  $P \le 0.05$  \*\* :  $P \le 0.01$  Test of Chi Square

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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : MALE

PAGE: 6

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

< a >

b

(c)

a : Number of animals examined at the site

Significant difference;  $*: P \le 0.05$  \*\*:  $P \le 0.01$  Test of Chi Square

b: Number of animals with lesion

c:b/a \* 100

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

SEX

: MALE

	Ī	Group Name No. of Animals on Study Grade I			701 3 4		5000 ррт 35 I 2 3 4			10000 ppm 27 1 2 3 4			20000 ppm 16 1 2 3 4			4	
rgan	Findings	(%)	(%)	(%)	(%)	(%)	(%)	(%)	<u>4</u> (%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
Digestive sy:	stem)																
iver	vacuolated cell focus	1 ( 3)	(36) 0 ( 0) (	0	0 0)	0 ( 0)	(3 ( 0)	5> 0 ( 0)	0 ( 0)	0 ( 0)	<27: 0 ( 0) (	0	0 ( 0)	0 ( 0)	0	16> 0 ( 0)	0 ( 0)
	hepatocellular hypertrophy:central	0 ( 0)	0 ( 0) (	0 (0	0	0 ( 0)	14 ( 40)	0 ( 0)	0 ** ( 0)	0 ( 0)	22 (81) (	0 0)	0 *=* ( 0)	0 ( 0)	13 ( 81)	0 ( 0)	0 ** ( 0)
	nuclear atypia:central	0 ( 0)	0 ( 0) (	0	0 (0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	(30)	0 ( 0) (	0	0 **	8 ( 50)	6 ( 38)	0 ( 0)	0 ** ( 0)
all bladd	hyperplasia	1 ( 3)	<360 0 ( 0) (	0	0 (0)	0 ( 0)	(3 0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	<27 0 ( 0) (	0	0 ( 0)	0 ( 0)	0	16> 0 ( 0)	0 ( 0)
pancreas	islet cell hyperplasia	1 ( 3)	<36) 0 ( 0) (	0	0 ( 0)	0 ( 0)	<3 0 ( 0)	35> 0 (0)	0 ( 0)	0 ( 0)	<27 0 ( 0) (	0	0 ( 0)	0 ( 0)	0	16> 0 ( 0)	0 ( 0)
Urinary syst	em)																
idney	basophilic change	16 ( 44)	<367 1 ( 3) (	0	0 ( 0)	20 ( 57)	( 0)	0 ( 0)	0 ( 0)	12 ( 44)	<27 0 ( 0) (	0	0 ( 0)	1 (6)	0	0 ( 0)	0 *
Grade ( a >  b ( c ) Significant d	<ul> <li>a: Number of animals examined at the si</li> <li>b: Number of animals with lesion</li> <li>c: b / a * 100</li> </ul>																<u> </u>
(HPT150)															<del></del>		BA

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

SEX : MALE

PAGE: 8

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

< a > b 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

ANIMAL : MOUSE Crj:BDF1 HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS (105W)

REPORT TYPE : A1 : MALE SEX

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

Grade l : Slight

<sup>2 :</sup> Moderate

<sup>3 :</sup> Marked

<sup>4 :</sup> Severe

<sup>&</sup>lt; a >

a : Number of animals examined at the site

b b: Number of animals with lesion

c:b/a \* 100

<sup>(</sup>c)

Significant difference;  $*: P \le 0.05$  \*\*:  $P \le 0.01$  Test of Chi Square

SEX

(HPT150)

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : AI

: MALE

PAGE: 10

BAIS4

	N	roup Name Control b. of Animals on Study 36	5000 ppm 35	10000 ppm 27	20000 ppm 16
Organ	Findings	rade 1 2 3 4 (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)
{Reproductive	system}				
epididymis	spermatogenic granuloma	( 0) ( 0) ( 0) ( 0)	(35> 1 0 0 0 (3) (0) (0) (0)	0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<pre></pre>
	xanthogranuloma	1 0 0 0 0 (3) ( 3) ( 0) ( 0)	0 0 0 0 0 (0) (0)	2 0 0 0 0 (7) ( 0) ( 0) ( 0)	0 0 0 0 0
semin ves	hemorrhage	<pre></pre>	35> 0 0 0 0 0 0 0 0	<27> 0 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	( 0) ( 0) ( 0) ( 0)
	inflammation	0 0 1 0 (0) (3) (0)	1 0 0 0 0 (3) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
prep/cli gl	duct ectasia	<35> 0 4 0 0 ( 0) ( 11) ( 0) ( 0)	<35> 0 0 0 0 0 0 0 0 0	<27> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	( 0) ( 0) ( 0) ( 0)
{Nervous syst	tem)				
brain	mineralization	<pre></pre>	<pre></pre>	\( \langle 27 \rangle \) 13	7 0 0 0 (44) (0) (0) (0)
Grade <a>&gt; b (c) Significant of</a>	<ul><li>a: Number of animals examined at the sit</li><li>b: Number of animals with lesion</li><li>c: b / a * 100</li></ul>				

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

SEX : MALE PAGE : 11

Organ	Findings	Group Name No. of Animals on Stu Grade	udy _1 _(%)		ntro 36	3	<u>4</u> (%)		<u>1</u> (%)		35	3 (%)		<u>4</u> (%)		<u>1</u> (%)	 0000 27 2 (%)		 (%)		1 (%)	 2 (%)	16	3 (%)	(	<u>4</u> %)
{Special sens	se organs/appendage)																									
Harder gl	lymphocytic infiltration		0 ( 0)	0	36>	0 0) (	0	,	0		<35	0	١. (	0	(	0	<27 0	0	0	,	1	 0	16>	0		0
	hyperplasia	,	1 (3)	0		0	0 ( 0)	(	0) 1 3)	(	o) ( o) (	( 0) 0 ( 0)		0 0)		0) 1 4)	0) 0 0)	0 )	0) 0 0)	(	6) 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;  $*: P \le 0.05$   $**: P \le 0.01$  Test of Chi Square

(HPT150)

BAIS4

## APPENDIX K 4

HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: FEMALE: SACRIFICED ANIMALS

(2-YEAR STUDY)

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

: FEMALE

REPORT TYPE : A1

SEX

SACRIFICED ANIMALS (105W)

	Ī	Group Name No. of Animals on Study	Contr 23				0 ррm 27			10000 30	)			20000		
Organ	Findings	Grade <u>1</u> (%)	<u>2</u> (%)	(%)	<u>4</u> (%)	1 2 (%) (%)	(%)	(%)	(%)	2 (%)	(%)	(%)	<u>1</u> (%)	2 (%)	(%)	<u>4</u> (%)
(Integumentar	y system/appandage)															
skin/app	inflaumation	0 ( 0)	(23) 0 ( 0) (	0	0 0)	0 1 ( 0) ( 4)	27> 0 ( 0)	0 ( 0)	0 ( 0) (	<30 0 ( 0)	0	0 ( 0)	0 ( 0)	0	3> 0 ( 0)	0 ( 0)
	scab	0 ( 0)	0 ( 0) (	0 0) (	0 0)	0 0	0 ( 0)	0 ( 0)	1 ( 3)	0 (0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0
Respiratory	system)															
asal cavit	mineralization	( 0)	(23) 0 ( 0) (	0	0	2 0 ( 7) ( 0)		0 ( 0)	2 ( 7)	<30 0 ( 0)	0	0 ( 0)	0 ( 0)	0	3> 0 ( 0)	0 ( 0)
	eosinophilic change:olfactory epitheli		0 (0) (	0	0 0)	6 0 (22) ( 0)	0 ( 0)	0 ( 0)	10 ( 33)	1 (3)	0 ( 0)	0 ( 0)	7 ( 54)	1 ( 8)	0 ( 0)	0 ** ( 0)
	eosinophilic change:respiratory epithe		2 ( 9) (	0 (	0 0)	17 7 (63) (26)	1 ( 4)	0 *	18 ( 60)	11 ( 37)	0 ( 0)	0 ** ( 0)	4 (31)	9 ( 69)	0 ( 0)	0 ** ( 0)
	respiratory metaplasia:olfactory epith		0 ( 0) (	0 (	0 0)	2 0 (7) (0)	0 ( 0)	0 ( 0)	4 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	respiratory metaplasia:gland	4 ( 17)	0 ( 0) (	0 0) (	0 0)	2 0 ( 7) ( 0)	0 ( 0)	0 ( 0)	3 (10)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 38)	0 ( 0)	0 ( 0)	0 ( 0)
Grade ( a >	1: Slight 2: Moderate 3 a: Number of animals examined at the si b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤									<u> </u>						

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

SEX

: FEMALE

Organ	Ne	roup Name Control (o. of Λnimals on Study 23 (rade 1 2 3 4 (%) (%) (%) (%)	5000 ppm 27 1 2 3 4 (%) (%) (%) (%)	10000 ppm 30 1 2 3 4 (%) (%) (%) (%)	20000 ppm 13 1 2 3 4 (%) (%) (%) (%)
{Respiratory s	system)				
nasal cavit	atrophy:olfactory epithelium	( 0) ( 0) ( 0) ( 0)	27> 1 1 0 0 ( 4) ( 4) ( 0) ( 0)	<pre></pre>	(13) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
nasopharynx	eosinophilic change:respiratory epithel	ium	<27> 2 0 2 0 ( 7) ( 0) ( 7) ( 0)	3 1 1 0 (10) (3) (3) (0)	<13> 4 0 0 0 (31) (0) (0) (0)
lung	inflammatory infiltration	<23> 0 0 0 0 0 0 0 0 0 0 0	<27> 0 0 0 0 0 0 0 0 0 0 0	<30> 0 1 0 0 ( 0) ( 3) ( 0) ( 0)	0 0 0 0 ( 0) ( 0) ( 0) ( 0)
	interstitial pneumonia	0 0 0 0 0 (0) (0)	1 0 0 0 (4) (0) (0) (0)	1 0 0 0 ( 3) ( 0) ( 0) ( 0)	0 0 0 0 0 ( 0) ( 0) ( 0)
	bronchiolar—alveolar cell hyperplasia	0 0 0 0 0 (0) (0)	25 2 0 0 *** ( 93) ( 7) ( 0) ( 0)	28 0 0 0 *** ( 93) ( 0) ( 0) ( 0)	12 0 0 0 *** ( 92) ( 0) ( 0) ( 0)
{Ilematopoietic	c system)				
bone marrow	myelofibrosis	<23> 0 0 0 0 0 (0) (0) (0)	<27> 0 0 0 0 0 0 0 0 0 0 0	30> 1 0 0 0 ( 3) ( 0) ( 0) ( 0)	<13> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
< a > b	a : Number of animals examined at the sit b : Number of animals with lesion c : b / a * 100				

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : AI

SEX

: FEMALE

SWORTLIOED WATERING (

20000 ppm 10000 ppm Group Name Control 5000 ppm 13 27 30 23 No. of Animals on Study Grade (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) Findings\_ {Hematopoietic system} ⟨23⟩ <13> bone marrow 0 0 0 0 3 0 0 0 0 0 0 0 erythropoiesis:increased (23) (0) (0) (0) (0)(0)(0)(0) (4)(0)(0)(0) (0)(0)(0)(0) 2 0 0 0 0 0 0 granulopoiesis:increased (7)(0)(0)(0) (7)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) <23> (27) ⟨30⟩ spleen 0 \*\* 0 0 0 \*\* 3 0 0 0 12 0 0 \* deposit of hemosiderin (44) (0) (0) (0) (67) (0) (0) (0) (69) (0) (0) (0) (13) (0) (0) (0) 6 3 0 \* 0 extramedullary hematopoiesis (22) (4) (0) (0) (19) (4) (4) (0) (30) (7) (0) (0) (46) (8) (23) (0) 1 0 0 follicular hyperplasia (0)(0)(0)(0) (0)(0)(0)(0) (0)(4)(0)(0) (7)(0)(0)(0) {Circulatory system} <13> ⟨23⟩ <30> heart 0 0 0 0 0 0 0 mineralization (0)(0)(0)(0) ( 0) ( 0) ( 0) ( 0) (3)(0)(0)(0) (23) (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 b (c) c:b/a \* 100 Significant difference;  $*: P \leq 0.05$  \*\*:  $P \leq 0.01$  Test of Chi Square

(HPT150)

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : AI

SEX

: FEMALE

Organ	No	oup Name Control of Animals on Study 23 ade 1 2 3 4 (%) (%) (%) (%) (%)	5000 ppm 27 <u>i</u> 2 3 4 (%) (%) (%) (%)	10000 ppm 30 1 2 3 4 (%) (%) (%) (%)	20000 ppm 13 <u>i</u> 2 3 4 (%) (%) (%) (%)
			(10)	(10) (10)	(10) (10) (10)
Circulator	ry system)				
eart	arteritis	(23) 0 0 0 0 (0) (0) (0) (0)	0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(30) 1 0 0 0 ( 3) ( 0) ( 0) ( 0)	0 0 0 0 ( 0) ( 0) ( 0) ( 0)
Digestive	system)				
ooth	inflammation	<pre>&lt;23&gt; 0     0     0 ( 0) ( 0) ( 0) ( 0)</pre>	<27>     1	<30> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<13> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
	dysplasia	12 1 0 0 (52) (4) (0) (0)	16 3 0 1 (59) (11) (0) (4)	14 6 2 0 (47) (20) (7) (0)	6 2 0 0 (46) (15) (0) (0)
	odontogenic cyst	0 0 0 0	0 0 0 0 0 (0)	0 0 1 0 ( 0) ( 3) ( 0)	0 0 0 0 0 0 ( 0) ( 0)
ongue	arteritis	23> 1 0 0 0 ( 4) ( 0) ( 0) ( 0)	<27> 0 0 0 0 0 0 0 0 0	<30> 1 0 0 0 ( 3) ( 0) ( 0) ( 0)	<13> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
tomach	erosion:glandular stomach	<pre></pre>	(27) 1 0 0 0 (4) (0) (0) (0)	<30> 0 0 0 0 0 0 0 0	<13> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
rade (a > b (c) lignificant	1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 t difference; *: P ≤ 0.05 **: P ≤ 0				

ANIMAL

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

: MOUSE Crj:BDF1

REPORT TYPE : A1

: FEMALE

SACRIFICED ANIMALS (105W)

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

<sup>1 :</sup> Slight Grade

<sup>2 :</sup> Moderate

<sup>3 :</sup> Marked

<sup>4 :</sup> Severe

<sup>&</sup>lt; a >

a: Number of animals examined at the site

ь b: Number of animals with lesion

c:b/a \* 100

<sup>(</sup>c)

Significant difference; \*:  $P \le 0.05$  \*\*:  $P \le 0.01$  Test of Chi Square

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE SACRIFICED ANIMALS (105W)

	No.	op Name Control of Animals on Study 23	5000 ppm 27	10000 ppm 30	20000 ppm 13
rgan	Findings	de <u>1 2 3 4</u> (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)
Urinary sys	tem)				
idney	cyst	<23> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	27> 1 0 0 0 (4) (0) (0) (0)	(0)(0)(0)(0)	(13> 0 0 0 0 (0) (0) (0) (0)
	hyaline droplet	0 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)
	deposit of hemosiderin	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 1 0 (0) (0)	0 2 2 1 *
	lymphocytic infiltration	3 0 0 0 0 (13) (0) (0) (0)	0 0 0 0 0 0 ( 0) ( 0)	3 0 0 0 0 (10) (0) (0) (0)	0 0 0 0 0 ( 0) ( 0)
	inflammatory polyp	0 0 0 0 0 (0) (0)	0 2 0 0 ( 0) ( 7) ( 0) ( 0)	0 1 0 0 (0) (0)	0 0 0 0 0 ( 0) ( 0)
	lıydronephrosis	0 0 1 0 (0) (4) (0)	0 0 2 1 ( 0) ( 7) ( 4)	0 1 0 0 (0) (0)	0 0 0 0 0 ( 0) ( 0)
	mineralization:papilla	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	1 0 0 0 0 (3) (0) (0)	0 0 0 0 0 ( 0)
rin bladd	lymphocytic infiltration	223> 1 0 0 0 ( 4) ( 0) ( 0) ( 0)	27> 1 0 0 0 ( 4) ( 0) ( 0) ( 0)	( 0) ( 0) ( 0) ( 0) ( 0) ( 0) ( 0) ( 0)	<pre></pre>
Grade (a) b (c)	1: Slight 2: Moderate 3:: a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100	Marked 4 : Severe			

SEX

(IIPT150)

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

PAGE: 18

BAIS4

SACRIFICED ANIMALS (105W)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

: FEMALE

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

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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : AI

SEX : FEMALE

Y 1 - DDL 1 OUD ATTEMED

Organ	Findings	Group Name Control  No. of Animals on Study 23  Grade 1 2 3 4  (%) (%) (%) (%)	5000 ppm 27 1 2 3 4 (%) (%) (%) (%)	10000 ppm 30 1 2 3 4 (%) (%) (%) (%)	20000 ppm 13 1 2 3 4 (%) (%) (%) (%)
Endocrine sy	stem]				
drenal	focal fatty change:cortex	<pre></pre>	<pre></pre>	(30) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(13) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
Reproductive	system)				
ovary	cyst	(23) 1 0 1 2 ( 4) ( 0) ( 4) ( 9)	27> 2 2 5 0 ( 7) ( 7) ( 19) ( 0)	<pre></pre>	<13> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
terus	cystic endometrial hyperplasia	<23> 5 9 1 0 ( 22) ( 39) ( 4) ( 0)	7 9 4 0 ( 26) ( 33) ( 15) ( 0)	30> 9 9 5 0 (30) (30) (17) (0)	(13) 6 1 1 0 (46) (8) (8) (0)
Nervous syst	em}				
rain	mineralization	<23> 10 0 0 0 (43) (0) (0) (0)	27> 11 0 0 0 (41) (0) (0) (0)	(30) 14 0 0 0 (47) (0) (0) (0)	4 0 0 0 (31) (0) (0) (0)
	epidermal cyst	0 0 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)

(HPT150)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

PAGE: 20

BATS4

SACRIFICED ANIMALS (105W)

		Group Name No. of Animals	ame Control Animals on Study 23				5000 2	ppm 7			20000 ppm 13								
rgan	Findings	Grade		(%)	3 (%)	(%)	<u>(%)</u>	2 (%)	3 (%)	(%)	1 (%)	(%)	(%)	(%)	<u>(</u>	i %)	2 (%)	3 (%)	<u>4</u> (%
Special ser	nse organs/appendage}																		
arder gl	lyperplasia		0 (0) (	<23 0 ( 0) (	) 0 0) (	0 (0)	2 ( 7)	0		0 ( 0)	0 ( 0) (	0 0 0)	0	0		0 0) (	<13 0 0) (	3> 0 ( 0)	0
Grade (a) b (c)	1: Slight 2: Moderate a: Number of animals examined at b: Number of animals with lesion c: b / a * 100		4 : Severe	<u>.</u>		-													

## APPENDIX K 5

HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: MALE: DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : AI SEX : MALE

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

PAGE: 1

Urgan		oup Name Control of Animals on Study 14 dde 1 2 3 4 (%) (%) (%) (%)	5000 ppm 15 1 2 3 4 (%) (%) (%) (%)	10000 ppm 23  1 2 3 4 (%) (%) (%) (%)	20000 ppm 34 1 2 3 4 (%) (%) (%) (%)
{Integumenta	ry system/appandage)				
subcutis	inflaumation	(14) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	0 1 0 0 ( 0) ( 7) ( 0) ( 0)	<23> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	0 0 0 0 ( 0) ( 0) ( 0) ( 0)
	xanthogranuloma	0 0 0 0 0 (0) (0)	0 0 0 0 0	0 0 0 0 0 (0)	1 0 0 0 0 (3) (0) (0) (0)
{Respiratory					
nasal cavit	wineralization	(14) 0 0 0 0 (0) (0) (0) (0)	<15> 2 0 0 0 (13) (0) (0) (0)	23> 2 0 0 0 ( 9) ( 0) ( 0) ( 0)	34> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
	eosinophilic change:olfactory epithelium	2 0 0 0 (14) (0) (0) (0)	0 1 1 0 ( 0) ( 7) ( 7) ( 0)	7 0 0 0 (30) ( 0) ( 0) ( 0)	12 0 0 0 ( 35) ( 0) ( 0) ( 0)
	eosinophilic change:respiratory epitheli	1III 4 0 0 0 0 (29) (0) (0) (0)	5 2 0 0 (33) (13) (0) (0)	9 3 0 0 (39) (13) (0) (0)	18 5 0 0 1 (53) (15) (0) (0)
	respiratory metaplasia:olfactory epithel	2 0 0 0 0 (14) (0) (0) (0)	2 0 0 0 0 (13) (0) (0) (0)	2 0 0 0 0 ( 9) ( 0) ( 0)	2 0 0 0 0 (6) (6) (0) (0)
	respiratory metaplasia:gland	3 0 0 0 (21) (0) (0) (0)	3 0 0 0 (20) (0) (0) (0)	5 0 0 0 ( 22) ( 0) ( 0) ( 0)	1 0 0 0 0 (0) (3) (6)

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 ; \* :  $P \le 0.05$  \*\* :  $P \le 0.01$  Test of Chi Square

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

PAGE: 2

DEAD AND MORIBUND ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

SEX : MALE

	Grade	Animals on Study 14  1 2 3 4	5000 ppm 15 1 2 3 4 (%) (%) (%) (%)	10000 ppm 23 1 2 3 4 (%) (%) (%) (%)	20000 ppm 34 1 2 3 4
rgan	Findings	(%) (%) (%) (%)	(%) (%) (%)	(%) (%) (%) (%)	(%) (%) (%) (%)
Respiratory s	ystem)				
asal cavit	atrophy:olfactory epithelium	0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<15> 2 0 0 0 ( 13) ( 0) ( 0) ( 0)	<pre></pre>	(34> 1 0 0 0 ( 3) ( 0) ( 0) ( 0)
ing	hemorrhage	(14) 0 1 0 0 (0) (7) (0) (0)	0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<pre></pre>	(34) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
	interstitial pneumonia	0 1 0 0 (0) (7) (0) (0)	0 1 0 0 (0) (7) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 ( 0) ( 0)
	bronchopneumonia	0 1 0 0 (0) (7) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 ( 0) ( 0)
	bronchiolar-alveolar cell hyperplasia	0 0 0 0 0 0 (0) (0)	12 0 0 0 *** ( 80) ( 0) ( 0) ( 0)	14 1 0 0 *** (61) (4) (0) (0)	23 3 0 0 == (68) (9) (0) (0)
dematopoietic	: system)				
one marrow	erythropoiesis:increased	0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<15> 2 0 0 0 ( 13) ( 0) ( 0) ( 0)	<23> 3 0 0 0 ( 13) ( 0) ( 0) ( 0)	34> 10 0 0 0 (29) (0) (0) (0)
a > b c )	1: Slight 2: Moderate 3: Mar a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 .fference; *: P ≤ 0.05 **: P ≤ 0.01	xed 4: Severe  Test of Chi Square			

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1

SEX : MALE

1 D

\( \begin{array}{cccccccccccccccccccccccccccccccccccc	<pre></pre>	<pre></pre>	<34> 0 0 0 0 0 0 0 0 0 0 0 <34>
1 0 0 0 (7) (0) (0) (0)	1 0 0 0 (7) (0) (0) (0) <15> 1 0 0 0	0 0 0 0 ( 0) ( 0) ( 0) ( 0) <23> 4 0 0 0	0 0 0 0 0 ( 0) ( 0) ( 0)
2 0 0 0 0 (14) (0) (0) (0)	1 0 0 0	4 0 0 0	
		(11) ( 0) ( 0) ( 0)	3 0 0 0 0
0 0 0 0 0 (0)	0 0 0 0 0	1 0 0 0 ( 4) ( 0) ( 0) ( 0)	8 1 0 0 (24) (3) (0) (0)
2 3 2 0 (14) (21) (14) (0)	2 3 6 0 (13) (20) (40) (0)	3 3 4 0 (13) (13) (17) (0)	0 5 16 2 * ( 0) ( 15) ( 47) ( 6)
0 0 0 0 ( 0) ( 0) ( 0) ( 0)	0 1 0 0 ( 0) ( 7) ( 0) ( 0)	<23> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<pre></pre>
3 0 0 0 (21) (0) (0) (0)	3 0 0 0 0 (20) (0) (0)	4 0 0 0 (17) (0) (0) (0)	6 1 0 0 (18) (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 1 0 0 (0) (0) (0) (0) (0) (0) (0) (0) (0)  3 0 0 0 3 0 0 0 (21) (0) (0) (0) (20) (0) (0) (0)  : Marked 4: Severe	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : AI SEX : MALE

	Group No. of Grade	Name Control Animals on Study 14 1 2 3 4	5000 ppm 15 1 2 3 4	10000 ppm 23 1 2 3 4	20000 ppm 34 1 2 3 4
Organ	Findings	(%) (%) (%) (%)	(%) (%) (%)	(%) (%) (%) (%)	(%) (%) (%) (%)
{Circulator	y system)				
neart	inflammatory cell nest	0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(15> 1 0 0 0 (7) (0) (0) (0)	<23> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	34> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
	myocardial fibrosis	0 0 0 0 0 0 ( 0) ( 0)	0 0 0 0 0 (0) (0)	1 0 0 0 ( 4) ( 0) ( 0) ( 0)	0 0 0 0 0
{Digestive	system)				
tooth	dysplusia	<14> 2 2 2 0 (14) (14) (14) (0)	(15) 6 1 1 0 (40) (7) (7) (0)	<pre></pre>	(34) 12 5 0 0 (35) (15) (0) (0)
stomach	hyperplasia:glandular stomach	6 0 0 0 ( 43) ( 0) ( 0) ( 0)	\( \lambda 15 \rangle \) 12	<23> 13 1 0 0 (57) (4) (0) (0)	<pre></pre>
liver	necrosis:central	<14> 0 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<15> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<23> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<34> 0 3 0 0 ( 0) ( 9) ( 0) ( 0)
	necrosis:focal	1 0 0 0 0 (7) (0) (0) (0)	1 0 0 0 0 (7) (0) (0) (0)	0 0 0 0 0 ( 0) ( 0)	0 0 0 0 0
Grade < a > b	1: Slight 2: Moderate 3: Marla: Number of animals examined at the site b: Number of animals with lesion c: b/a * 100	sed 4 : Severe			

: MOUSE Crj:BDF1 ANIMAL

REPORT TYPE : A1 SEX : MALE HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0-105W)

PAGE: 5

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

4 : Severe 2 : Moderate 3 : Marked 1 : Slight Grade

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

ď c:b/a\*100 (c)

Significant difference;  $*: P \le 0.05$  \*\*:  $P \le 0.01$  Test of Chi Square

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

Jrgan	Findings	Group Name No. of Animals on Study Grade(%)	Contr 14 2 (%)	01 3 (%)	<u>4</u> (%)	<u>1</u> (%)		5 3 (%)	<u>4</u> (%)	<u> </u>	1	.0000 2: 2 (%)	ppm 3 (%)	<u>4</u> (%)	-	<u>1</u> (%)		0 ррт 34 <u>3</u> (%)		4 (%)
Digestive s	system)																			
ancreas	islet cell hyperplasia	1 ( 7)	(14) 0 ( 0) (	0	0 ()	0 ( 0)	0	.5> 0 ( 0)	0 ( 0)		0 0) (	<2: 0 0)	0	0 ( 0)	(	0 0) (	0	34> 0 ( 0		0
Urinary sys	stem)																			
idney	cyst	0 ( 0)	<142 0 ( 0) (	0	0 (0)	1 ( 7)	0	( 0)	0 ( 0)		0 0) (	<2 0 0)	0	0 ( 0)	(	0	0	(34> 0 ( 0		0 0)
	hyaline droplet	( 7)	0 ( 0) (	0	0	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)		0 0) (	0 0)	1 ( 4)	0 ( 0)	(	0	0 ( 0)	0 )		0
	basophilic change	0 ( 0)	0 ( 0) (	0	0	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	(	2 9) (	0 0)	0 ( 0)	0 ( 0)	(	0 0)	0 ( 0)	0 ( 0		0
	deposit of hemosiderin	0 ( 0)	0 ( 0) (	0	0 ( 0)	0 ( 0)	2 ( 13)	0 ( 0)	0 ( 0)	(	0 0) (	2 9)	5 ( 22)	0 ( 0)	(	2 6)	3 ( 9)	13 ) ( 38	; 3) (	1 3
	lymphocytic infiltration	0 ( 0)	0 ( 0) (	0 0)	0 ( 0)	1 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)		0 0) (	0	0 ( 0)	0 ( 0)	(	0	0 ( 0)	(	) ()	0
	inflammatory polyp	0 ( 0)	1 ) ( 7) (	0 0)	0	i ( 7)	0 ( 0)	1 (7)	0 ( 0)	(	0 0) (	i (4)	0 ( 0)	0 ( 0)	(	0 0)	0 ( 0)	(	0 0) (	0

Grade 1: Slight 2: Moderate 3: Marked 4: Severe

(HPT150)

BAIS4

 $<sup>\</sup>langle a \rangle$  a : Number of animals examined at the site

b b: Number of animals with lesion

<sup>(</sup> c ) c : b / a \* 100 Significant difference ; \* : P  $\leq$  0.05 \*\* : P  $\leq$  0.01 Test of Chi Square

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

BIODI NO.	•	0102
ANIMAL	:	MOUSE Crj:BDF1
REPORT TYPE	:	A1
SEX	:	MALE

0		Group Name No. of Animals on Study	Contr				5000	5			1	0000 23				000 34		
rgan	Findings	Grade <u>1</u> (%)	2 (%)	3 (%)	(%)	(%)	2 (%)	3 (%)	(%)	(%)	)	2 (%)	3 (%)	(%)	<u>1</u> (%	2 (%)	(%)	(%)
Urinary syste	om)																	
idney	lıydronephrosis	( 0) (	<142 0 0) (	1	1 7)	1 ( 7)	0	5> 2 ( 13)	0 ( 0)	0 ( 0)		<23 1 4) (	0	2 ( 9)	0 ( 0	<34 0 0) (	> 1 3)	0 ( 0)
rethra	inflammation	( 0) (	<142 0 0) (	0	0 0)	0 ( 0)	<1 0 ( 0)	0	0 ( 0)	0 ( 0)		<23 0 0) (	0 0)	0 ( 0)	0 ( 0	<34 0 0) (	> 1 3)	0 ( 0)
Endocrine sys	tem)																	
tuitary	angiectasis	0 ( 0) (	<142 0 0) (	0	0 0)	0 ( 0)	〈1 0 ( 0)	0	0 ( 0)	1 ( 4)		<23 0 0) (	> 0 0>	0 ( 0)	0 (	<33 0 0) (	0 (0)	0 ( 0)
	cyst	( 7) (	0 (	0	0 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	( 9)	) (	0 0) (	0	0 ( 0)	3 ( 9	0 0) (	0 0)	0 ( 0)
	hyperplasia	( 7) (	0 0) (	0	0 0)	1 (7)	0 ( 0)	0 ( 0)	0 ( 0)	( 0)		0	0	0 ( 0)	( 0	0 0) (	0 (0)	0 ( 0)
drenal	spindle-cell hyperplasia	6 ( 43) (	<142 0 0) (	0	0 0)	10 ( 67)	0	.5> 0 ( 0)	0 ( 0)	11 ( 48		<23 1 4) (	0	0 ( 0)	16 ( <b>4</b> 7	<34 0 0) (	0 (0)	0 ( 0)

(HPT150)

DEAD AND MORTRI

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

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1

SEX

: MALE

		oup Name Control . of Animals on Study 14	5000 ppm 15	10000 ppm 23	20000 ppm 34
)rgan		1 2 3 4   (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%)
{Endocrine sy	rstem)				
adrenal	hyperplasia:cortical cell	(14) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	(15) 1 0 0 0 (7) (0) (0) (0)	<23> 0 0 0 0 0 0 0 0 0 0 0 0 0 0	34> 1 0 0 0 ( 3) ( 0) ( 0) ( 0)
	focal hypertrophy:cortex	0 0 0 0 0 (0)	1 0 0 0 0 (7) (0) (0) (0)	1 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0
{Reproductive	e system)				
testis	mineralization	9 2 1 0 (64) (14) (7) (0)	(15) 10 3 0 0 (67) (20) (0) (0)	<pre></pre>	\( \frac{\dagger{34}}{4} \) \( \frac{4}{12} \) ( \( 0) \) ( \( 0) \) ( \( 0) \)
epididymis	spermatogenic granuloma	0 0 0 0 ( 0) ( 0) ( 0) ( 0)	1 0 0 0 ( 7) ( 0) ( 0) ( 0)	<22> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	34> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
prostate	inflammation	<14> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<15> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<23> 0 0 0 0 0 0 0 0 0 0 0	34> 1 0 0 0 ( 3) ( 0) ( 0) ( 0)
Nervous syst	tem)				
brain	mineralization	7 0 0 0 ( 50) ( 0) ( 0) ( 0)	6 0 0 0 (40) (0) (0) (0)	<23> 8 0 0 0 ( 35) ( 0) ( 0) ( 0)	(34) 18 0 0 0 (53) (0) (0) (0)
Grade <a>a&gt;</a> b (c) Significant	1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤ 0				

ANIMAL : MOUSE Crj:BDF1

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

REPORT TYPE : AI

SEX : MALE

		Group Name No. of Animals on	Study	1	ıtrol l4					5000 1					10	0000 23				2	20000 3.		
Organ	Findings	Grade	(%)	(%)	(%		(%)		(%)	(%)	(%)			(%)		2 (%)	(%)	(%)	(5	1 %)	2 (%)	(%)	(%)
Special sens	e organs/appendage}																						
Harder gl	hyperplasia		0 ( 0)	0	0 ( 0)		0 0)	(	1 7)	<1 0 ( 0)	5> 0 ( 0)	0 ( 0)	(	0 ( 0)	(	<23 0 0) (		0 ( 0)		0 0) (	<3- 0 0)	4> 0 ( 0) (	0
(Musculoskele	tal system)																						
muscle	mineralization		0 ( 0)		(4> 0 ( 0)	) (	0 0)	(	0 0)	<1 0 ( 0)		0 ( 0)	(	1 (4)	(	<23 0 0) (		0	( (	o) (	<3- 0 0)	4> 0 ( 0) (	0
Grade (a) b (c)	1: Slight 2: Moderate a: Number of animals examined at the b: Number of animals with lesion c: b / a * 100 ifference; *: P ≤ 0.05 **: P	site	: Severe								<del></del>												

BAIS4

## APPENDIX K 6

HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: FEMALE: DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : AI

SEX : FEMALE

		Group Name No. of Animals on Study	Cont 27	,	4	1	5000 23	}	4	1	100	00 p <u>i</u> 20		4		2	0000 37 2	7	4
Organ	Findings	Grade <u>1</u> (%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%		3 (%)	(%)	(%	5)	(%)	(%)	(%)
Integumentary	y system/appandage)																		
subcutis	inflaumation	1 ( 4)	<27 0 ( 0) (	0	0 ( 0)	0 ( 0)	<2: 0 ( 0)	0	0 ( 0)	0 ( 0)	0	<20>	0	0 ( 0)	0 ( 0		<37 0 0)	0	0 ( 0)
(Respiratory	system)																		
nasal cavit	mineralization	0 ( 0)	<27 0 ( 0)	0	0 ( 0)	0 ( 0)	〈2: 0 ( 0)	0	0 ( 0)	1 ( 5)	C		0	0 ( 0)	1 ( 3		<37 0 0)	0	0 ( 0)
	eosinophilic change:olfactory epithel		0 ( 0) (	0	0 ( 0)	1 ( 4)	3 ( 13)	0	0	5 ( 25)	( 5	; i) (	0	0	19 ( 51		1	0 ( 0)	0 *= ( 0)
	eosinophilic change:respiratory epith		4 ( 15)	0	0 ( 0)	13 ( 57)	6 ( 26)	0 ( 0)	1 ( 4)	11 ( 55)	2 ( 10		0	0	16 ( 43		15 41)	1 (3)	0 ( 0)
	respiratory metaplasia:olfactory epith		0 ( 0)	0	0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	( (		0	0 ( 0)	1 ( 3		0 0)	0	0 ( 0)
	respiratory metaplasia:gland	2 ( 7)	0 ( 0)	0	0 ( 0)	2 ( 9)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 15)	( (		0 0)	0	10 ( 27		0 0)	0 ( 0)	0 ( 0)
nasopharynx	eosinophilic change:respiratory epith		<27 0 ( 0)	0	0 ( 0)	3 ( 13)	(2: 0 ( 0)	1	1 ( 4)	4 ( 20)	2		0	0 ( 0)	7 ( 19		<3′ 0 0)	0	0 ( 0)
Grade (a) b (c)	1: Slight 2: Moderate 3 a: Number of animals examined at the s b: Number of animals with lesion c: b / a * 100 lifference; *: P ≤ 0.05 **: P ≤				<del></del>									···					

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : AI

SEX : FEMALE

DEAD AND MORIBUND ANIMALS (0-105W)

Organ	No.	oup Name of Animals on Study ade 1 (%)		01 3 (%)	<u>4</u> (%)	<u>l</u> (%)	5000 23 2 (%)		1 (%)		0 ppm 20 3 (%)	<u>4</u> (%)	<u>1</u> (%)		37 37 (%)	<u>4</u> (%)
{Respiratory	system)															
lung	hemorrhage	0 ( 0) (	<27> 0 0) (	0 0) (	0 0)	0 ( 0) (	<23 0 0) (			1		0 ( 0)	0 ( 0)	0		0 ( 0)
	interstitial pneumonia	0 ( 0) (	0 (	0 0) (	0 0)	2 ( 9) (	0 0) (	0 0	2 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	bronchiolar-alveolar cell hyperplasia	0 ( 0) (	0 (	0 0) (	0	15 ( 65) (	0 0) (	0 0 **	12 ( 60)	0 ( 0)	0 ( 0)	0 ** ( 0)	29 ( 78)	2 ( 5)	0 ( 0)	0 ** ( 0)
{Hematopoieti	c system)															
oole marrow	erythropoiesis:increased	1 ( 4) (	<27> 0 0) (	0 0) (	0 0)	0 ( 0) (	<23 0 0) (	> 0 0 0) ( 0)	2 ( 10)	0	20> 0 ( 0)	0 ( 0)	14 ( 38)	0	37> 0 ( 0)	0 *°
	granulopoiesis:increased	1 ( 4) (	0 (	0 0) (	0 0)	( 4) (	0 0) (	0 0 0	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
spleen	deposit of hemosiderin	( 0) (	<27> 0 0) (	0 0) (	0 0)	1 ( 4) (	<23 0 0) (	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2 ( 10)	0	20> 0 ( 0)	0 ( 0)	4 ( 11)	0	(37> 0 ( 0)	0 ( 0)
Grade (a) b (c)	1: Slight 2: Moderate 3:: a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 lifference; *: P ≤ 0.05 **: P ≤ 0	Marked 4: Severe  01 Test of Chi Square				<u> </u>					-					

(HPT150)

: MOUSE Crj:BDF1

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

ANIMAL REPORT TYPE : A1

SEX

: FEMALE

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

(48) (0) (4) (0)

(40) (0) (0) (0)

Grade

1 : Slight 2 : Moderate

3 : Marked

4 : Severe

(30) (4) (4) (4)

< a >

a : Number of animals examined at the site

b

(c)

b: Number of animals with lesion c:b/a \* 100

Significant difference; \* :  $P \le 0.05$  \*\* :  $P \le 0.01$  Test of Chi Square

(HPT150)

BAIS4

(41) (11) (5) (0)

SEX : FEMALE

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

PAGE: 13

Drgan	Findings	Group Name         Control           No. of Animals on Study         27           Grade         1         2         3         4           (%)         (%)         (%)         (%)	5000 ppm 23 1 2 3 4 (%) (%) (%) (%)	10000 ppm 20 1 2 3 4 (%) (%) (%) (%)	20000 ppm 37 1 2 3 4 (%) (%) (%) (%)
					(15) (15)
Digestive s	ystem}				
ongue	arteritis	<27> 0 1 0 0 ( 0) ( 4) ( 0) ( 0)	(23) 0 0 0 0 (0) (0) (0) (0)	0 0 0 0 ( 0) ( 0) ( 0) ( 0)	37> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)
tomach	erosion:glandular stomach	(27> 1 0 0 0 (4) (0) (0) (0)	<pre></pre>	<20> 0 0 0 0 0 0 0 0 0) ( 0) ( 0) ( 0)	<37> 0 0 0 0 0 0 0 0 0 0 0
	hyperplasia:glandular stomach	22 0 0 0 (81) (0) (0) (0)	14 0 0 0 (61) (0) (0) (0)	12 0 0 0 (60) (0) (0) (0)	27 0 0 0 (73) ( 0) ( 0) ( 0)
iver	angiectasis	<27> 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>	(20) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	0 0 0 0 ( 0) ( 0) ( 0) ( 0)
	necrosis:focal	1 0 0 0 ( 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)
	fatty change:central	0 0 0 0 0 (0) (0)	0 0 0 0 0 ( 0) ( 0)	0 0 0 0 0 ( 0) ( 0)	1 0 0 0 0 (3) (0) (0)
	inflammatory infiltration	1 0 0 0 0 (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)

b: Number of animals with lesion

(c) c:b/a \* 100

Significant difference ; \* :  $P \le 0.05$  \*\* :  $P \le 0.01$  Test of Chi Square

(HPT150)

BAIS4

ANIMAL : MOUSE Crj:BDF1

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

REPORT TYPE : A1 SEX : FEMALE

		Group Name   Control	5000 ppm 23 1 2 3 4	10000 ppm 20 1 2 3 4	20000 ppm 37 1 2 3 4
Organ	Findings	(%) (%) (%)	(%) (%) (%) (%)	(%) (%) (%) (%)	(%) (%) (%) (%)
{Digestive	system)				
liver	extramedullary hematopoiesis	(27) 0 0 0 0 (0) (0) (0) (0)	C23> 0 0 0 0 0 0 0 0 0 0 0	1 0 0 0 ( 5) ( 0) ( 0) ( 0)	37> 1 0 0 0 ( 3) ( 0) ( 0) ( 0)
	clear cell focus	0 0 0 0 0 ( 0) ( 0)	1 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	acidophilic cell focus	1 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (5) ( 0) ( 0) ( 0)	4 0 0 0 0 (11) (0) (0) (0)
	vacuolated cell focus	0 0 0 0 0 ( 0)	0 0 0 0 0 ( 0) ( 0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (3) ( 0) ( 0)
	hepatocellular hypertrophy:central	0 0 0 0 0 (0) (0)	0 0 0 0 0	0 0 0 0 0 (0)	0 4 0 0 (0) (11) (0) (0)
	nuclear atypia:central	0 0 0 0 0 (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (5) (0) (0)	1 0 0 0 0 (3) ( 0) ( 0)
{Urinary sy	vstem)				
kidney	hyaline droplet	(27) 1 0 6 3 (4) (0) (22) (11)	<pre></pre>	<20> 1 0 5 2 ( 5) ( 0) ( 25) ( 10)	37> 0 0 5 1 ( 0) ( 0) ( 14) ( 3)
Grade <a>&gt; b (c)</a>	1: Slight 2: Moderate 3 a: Number of animals examined at the s b: Number of animals with lesion c: b / a * 100	: Marked 4 : Severe ite			

(HPT150)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE

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

PAGE: 15

Grad	(%)	2 3 4 (%) (%) (%	1 (%)	2 3 (%) (%		(%)	2 3 4 (%) (%) (%)	(%) (%)	<u>3 4</u> (%) (%)
	( 0) (	0 0 0		<23> 0 ( ( 0) ( 0		0 ( 0) (	<20> 0 0 0 ( 0) ( 0) ( 0)	1 0 ( 3) ( 0)	0 0
emosiderin	0 ( 0) (	0 0 0		0 (		1 ( 5) (	0 1 0 (0) (5) (0)	0 3	22 4 ** ( 59) ( 11)
polyp	( 0) (	0 0 0		1 (	0 0) ( 0)	1 ( 5) (	0 0 0	0 0	0 0
ry hematopoiesis	( 0) (	0 0 0		0 (		0 ( 0) (	1 0 0 (5) (0) (0)	0 0	0 0 ( 0)
is	0 ( 0) (	0 0 1 0 ( 4	0 ( 0)	2 1	0 ( 0)	0 ( 0) (	1 2 0 5) (10) (0)	0 0 (0)	0 0 (0)
on∶papilla	0 ( 0) (	0 0 0 0		0 (		0 ( 0) (	0 0 0	1 0 (3) (0)	0 0 (0)
infiltration	( 0) (					0 ( 0) (	<20> 0 0 0 0 0 0 0 0 0 0	1 0	0 0
	0 ( 0) (					0 ( 0) (	<20> 0 0 0 0 0) ( 0) ( 0)	0 0	0 0
	nfiltration  2: Moderate 3: Ma	( 0) ( 0 ( 0) (	0 0 0 0 0 0 (0) (0) (0) (0) (0) (0) (0)	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0

( c )

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

c:b/a\*100

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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : FEMALE

Organ	Findings	Group Name   Control	5000 ppm 23 <u>1 2 3 4</u> (%) (%) (%) (%)	10000 ppm 20 1 2 3 4 (%) (%) (%) (%)	20000 ppm 37 1 2 3 4 (%) (%) (%) (%) (%)
n gan	r Ind Ings	(%) (%) (%)	(x) (x) (x)	(%) (%) (%)	(%) (%) (%)
{Endocrine s	system)				
pituitary	cyst	<26> 0 0 0 0 0 (0) (0) (0)	223> 1 0 0 0 ( 4) ( 0) ( 0) ( 0)	1 0 0 0 ( 5) ( 0) ( 0) ( 0)	37> 2 0 0 0 ( 5) ( 0) ( 0) ( 0)
	hyperplasia	1 1 0 0 ( 4) ( 4) ( 0) ( 0)	2 0 0 0 0 ( 9) ( 0) ( 0)	1 0 0 0 ( 5) ( 0) ( 0) ( 0)	1 0 0 0 0 (3) (0) (0)
	Rathke pouch	0 0 0 0 0 (0) (0)	1 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 ( 0) ( 0)	0 0 0 0 0 ( 0) ( 0)
adrenal	spindle-cell hyperplasia	\$\frac{\z27}{5}\$ \$5  22  0  (19)  (81)  (0)  (0)\$	<pre></pre>	<pre></pre>	. <37> 17 19 0 0 = (46) (51) (0) (0)
	hyperplasia:cortical cell	0 0 0 0 0 ( 0) ( 0)	0 0 0 0 0 ( 0) ( 0)	1 0 0 0 0 (5) ( 0) ( 0) ( 0)	0 0 0 0 0 ( 0) ( 0)
{Reproductiv	ve system)				
ovary	thrombus	0 0 0 0 0 ( 0) ( 0) ( 0)	<pre></pre>	<20> 0 0 0 0 0 0 0 0 0 0 0	37> 0 0 3 0 0 0) ( 0) ( 8) ( 0)
Grade <a>&gt; b (c) Significant</a>	1: Slight 2: Moderate a: Number of animals examined at the b: Number of animals with lesion c: b/a*100	3 : Marked 4 : Severe site			

(HPT150)

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : FEMALE

PAGE: 17

Organ	No	coup Name	5000 ppm 23 1 2 3 4 (%) (%) (%) (%)	10000 ppm 20 1 2 3 4 (%) (%) (%) (%)	20000 ppm 37 1 2 3 4 (%) (%) (%) (%)
{Reproducti	ve system}				
ovary	cyst	(27) 1 0 2 0 (4) (0) (7) (0)	0 0 2 0 ( 0) ( 0) ( 9) ( 0)	0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<pre></pre>
uterus	cystic endometrial hyperplasia	5 I 0 0 (19) (4) (0) (0)	<23> 1 3 0 0 ( 4) ( 13) ( 0) ( 0)	20> 2 1 2 0 (10) (5) (10) (0)	<37> 2 4 1 0 ( 5) ( 11) ( 3) ( 0)
{Nervous sy	vstem)				
brain	mineralization	<27> 8 0 0 0 ( 30) ( 0) ( 0) ( 0)	<233> 7 0 0 0 (30) ( 0) ( 0) ( 0)	<20> 4 0 0 0 ( 20) ( 0) ( 0) ( 0)	<37> 11 0 0 0 ( 30) ( 0) ( 0) ( 0)
{Musculoske	eletal system}				
muscle	mineralization	0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<23> 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<20> 1 1 0 0 ( 5) ( 5) ( 0) ( 0)	<37> 1 0 0 0 ( 3) ( 0) ( 0) ( 0)
Grade <a>&gt; b <a>c c c c c c c c c c c c c c c c c c c</a></a>	1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 t difference; *: P ≤ 0.05 **: P ≤				

(HPT150)

BAIS4

# APPENDIX L 1

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

MOUSE: MALE

(2-YEAR STUDY)

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

STUDY NO. : 0402

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

NO. OF MALIGNANT TUMORS
NO. OF TOTAL TUMORS

NO. OF BENIGN TUMORS

NO. OF MALIGNANT TUMORS

NO. OF EXAMINED ANIMALS

NO. OF ANIMALS WITH TUMORS

NO. OF ANIMALS WITH SINGLE TUMORS

NO. OF ANIMALS WITH MULTIPLE TUMORS

NO. OF TOTAL TUMORS

105 - 105

(HPT070)

NO. OF ANIMALS WITH TUMORS

BAIS4

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

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

SEX : MALE

PAGE : 2

fime-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)

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

STUDY NO. : 0402 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

: FEMALE SEX PAGE: 3

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

(HPT070)

STUDY NO. : 0402 NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : FEMALE PAGE : 4

Time-related	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	
(UDMOGO)							RATE

(HPTO70)

# APPENDIX M 1

HISTOPATHOLOGICAL FINDINGS: NEOPLASTIC LESIONS: SUMMARY

MOUSE: MALE

(2-YEAR STUDY)

ANIMAL : MOUSE Crj:BDF1

HISTOPATHOLOGICAL FINDINGS: NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1 SEX : MALE

Organ		oup Name Control o. of animals on Study 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
(Integumentary	system/appandage)				
subcutis	lipoma	(50) 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 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 s	system)				
lung	bronchiolar—alveolar adenoma	<50> 6 ( 12%)	<50> 2 ( 4%)	<50> 1 ( 2%)	<50> 1 ( 2%)
	bronchiolar-alveolar carcinoma	3 ( 6%)	1 ( 2%)	2 ( 4%)	1 ( 2%)
{Hematopoietic	e system)				
bone marrow	hemangioma	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)
lymph node	malignant lymphoma	<50> 8 ( 16%)	<50> 13 ( 26%)	<50> 6 ( 12%)	<50> 3 ( 6%)
spleen	hemangioma	<50> 4 ( 8%)	<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)
	malignant lymphoma	0 ( 0%)	2 ( 4%)	0 ( 0%)	2 (4%)
	mastcytoma:malignant	0 ( 0%)	0 ( 0%)	6 (12%)	0 ( 0%)

b (c) b: Number of animals with neoplasm

c:b/a \* 100

STUDY NO. : 0402 ANIMAL : MOUSE Crj:BDF1 HISTOPATHOLOGICAL FINDINGS: NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1 SEX

: MALE

20000 ppm 10000 ppm Group Name Control 5000 ppm 50 50 50 No. of animals on Study 50 Organ\_\_\_\_ Findings\_ (Hematopoietic system) <50> <50> <50> <50> spleen 0 (0%) 0 (0%) 0 (0%) 1 (2%) hemangiosarcoma (Digestive system) <50> <50> <50> <50> salivary gl 0 (0%) 0 (0%) 2 (4%) 2 (4%) histiocytic sarcoma ⟨50⟩ ⟨50⟩ ⟨50⟩ <50> stomach 0 (0%) 1 (2%) 1 (2%) 0 (0%) squamous cell papilloma <50> <50≻ <50> <50> liver 0 (0%) 2 (4%) 1 (2%) 7 (14%) hemangioma 17 (34%) 18 (36%) 3 (6%) 12 (24%) hepatocellular adenoma 1 (2%) 0 (0%) 2 (4%) 0 (0%) histiocytic sarcoma 0 (0%) 0 (0%) 0 (0%) 1 (2%) mastcytoma:malignant 0 (0%) 0 (0%) 1 (2%) 1 (2%) hemangiosarcoma 14 (28%) 39 (78%) 11 (22%) 16 (32%) hepatocellular carcinoma 38 (76%) 12 (24%) 18 (36%) 1 (2%) hepatoblastoma <50> ⟨50⟩ <50> <50> pancreas 0 (0%) 1 (2%) 1 (2%) 0 (0%) islet cell adenoma {Urinary system} <50> <50> ⟨50⟩ ⟨50⟩ kidney 0 (0%) 1 (2%) 0 (0%) 0 (0%) renal cell carcinoma < a > a: Number of animals examined at the site c:b/a \* 100 b (c) b: Number of animals with neoplasm

<sup>(</sup>HPT085)

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

ANTMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

Organ	Findings	Group Name No. of animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
{Urinary system	$\mathbf{n}$					
ırin bladd	histiocytic sarcoma		<49> 0 ( 0%)	<50> 1 ( 2%)	<50> 1 ( 2%)	<50> 0 ( 0%)
(Endocrine sys	tem)					
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%)
orep/cli gl	histiocytic sarcoma		<49> 1 (2%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)
{Nervous system	m)					
brain	meningioma:malignant		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)
periph nerv	histiocytic sarcouma		<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%)
(Musculoskelet	al system)					
muscle	histiocytic sarcoma		<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)

ANIMAL : MOUSE Crj:BDF1

HISTOPATHOLOGICAL FINDINGS: NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1

SEX : MALE

Organ	Findings No. of animals of	Control n Study 50	5000 ppm 50	10000 ppm 50	20000 ррт 50
(Musculoskelet	tal system)				
oone	hemangioma	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)
Body cavities	5)				
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				
(а) b (с)	b: Number of animals with neoplasm c:b/a*100				
(HPT085)					

## APPENDIX M 2

HISTOPATHOLOGICAL FINDINGS: NEOPLASTIC LESIONS: SUMMARY

MOUSE: FEMALE

(2-YEAR STUDY)

HISTOPATHOLOGICAL FINDINGS: NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

ALL ANIMALS (0-105W)

REPORT TYPE : A1 SEX : FEMALE

(HPT085)

Organ		up Name Co of animals on Study	ontrol 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
{Integumentary	system/appandage)					
skin/app	squamous cell papilloma	1	<50> ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)
	squamous cell carcinoma	0	( 0%)	0 ( 0%)	1 (2%)	0 ( 0%)
subcutis	lipoma	1	<50> ( 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 s	ystem)					
lung	bronchiolar-alveolar adenoma	2	<50> ( 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	1	<50> ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)
lymph node	malignant lymphoma	16	<50> ( 32%)	<50> 16 ( 32%)	<50> 14 ( 28%)	<50> 3 ( 6%)

ANIMAL : MOUSE Crj:BDF1

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1

(HPT085)

SEX : FEMALE

<del> </del>	Findings	No. of animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
{  lematopoietic s	ystem)					
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 syste	•		1 ( 2,0)		· ( )	5 C 3///
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 syste	em) ·					
pituitary	adenoma		<49> 3 (6%)	<50> 7 ( 14%)	<50> 5 ( 10%)	<50> 0 ( 0%)
{Reproductive sy	rstem]					
ovary	cystadenoma		<50> 2 ( 4%)	<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)

ANTMAL : MOUSE Crj:BDF1 ALL ANTMALS (0-105W)

REPORT TYPE : A1

SEX : FEMALE

)rgan		of animals on Study 5		) ppm 10 50	0000 ppm 50	20000 ppm 50
(Reproductive	system]					
ovary	hemangioma		0> 0%) 0	<50> ( 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%)
iterus	endometrial stromal polyp	<5 5 (		<50> ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)
	histiocytic sarcoma	15 (	30%) 16	( 32%)	15 (30%)	12 ( 24%)
ammary gl	adenocarcinoma	<5 0 (	0%) 1	<50> ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)
Special sense	e organs/appendage}					
arder gl	adenoma	<5 3 (	6%) 1	<50> ( 2%)	<50> 2 ( 4%)	<50> 3 (6%)
Musculoskele	tal system)					
uscle	hemangioma	<5 0 (	50> 0%) 0	<50> ( 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%)
oone	osteosarcoma	< 0 (	50> 0%) i	<50> ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)
<a>&gt;<a> b (c)</a></a>	a: Number of animals examined at the site b: Number of animals with neoplasm c: b/a * 100					

: MOUSE Crj:BDF1 ANIMAL

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1

PAGE: 8 SEX : FEMALE 10000 ppm 20000 ppm Group Name Control 5000 ppm No. of animals on Study 50 Findings\_\_ 50 (Body cavities) <50> <50> <50> <50> peritoneum 0 (0%) 0 (0%) 1 (2%) 0 (0%) histiocytic sarcoma < a > a : Number of animals examined at the site b (c) b: Number of animals with neoplasm c : b / a \* 100(IIPT085) BAIS4

# APPENDIX N 1

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS,

MOUSE: MALE

(2-YEAR STUDY)

### NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

STUDY No. : 0402 ANTMAL : MOUSE Crj:BDF1

SEX : MALE

(HPT360A)

Group Name	Control	5000 ppm	10000 ppm	20000 ppm
	SITE : ALL SITE			
Tumor rate	TUMOR : hemangioma			
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) tatistical analysis	7/36(19.4)	1/35 ( 2.9)	0/27( 0.0)	1/16( 6.3)
Peto test	D 0.0505			
Standard method(d) Prevalence method(d)	P = 0.8595 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	0 (70 ( 10 0)	15 (50 ( 0C 5)	C/E0/ 10 0\	F/FA/ 12 2)
Overall rates(a)	8/50 ( 16. 0)	15/50 ( 30. 0)	6/50( 12. 0) 14. 81	5/50( 10.0) 12.50
Adjusted rates(b) Terminal rates(c)	11.11 4/36( 11.1)	25. 71 9/35 (25. 7)	4/27( 14.8)	2/16( 12.5)
Statistical analysis	7/00(11.1/	9/30 ( 20. t)	7/6/ 17.0/	6/ 10 ( 15. 0/
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		n	D 0.0000
Fisher Exact test(e)		P = 0.0765	P ≈ 0.3871	P = 0.2768

BAIS4

### NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANTMAL : MOUSE Crj:BDF1

SEX : MALE

PAGE:

Group Name	Control	5000 ppm	10000 ppm	20000 ррш	
	SITE : ALL SITE				
	TUMOR : mastcytoma:malignant				
Tumor rate	- 4 4		- <b>-</b>		
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				
•	r = 0.0455	D - 0 5000	D - 0.01994	D - N C	
Fisher Exact test(e)		P = 0.5000	P = 0.0133*	P = N. C.	

(HPT360A)

BAIS4

2

- (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 out comes can not estimated or this P-value is beyond the estimated P-value.
- ----: There is no data which should be statistical analysis.

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

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

STUDY No. : 0402 NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : MOUSE Crj:BDF1

SEX : MALE

- 10100				T.F.	
Group Name	Control	5000 ррш	10000 ppm	20000 թթա	
	SITE : lung				
r	TUMOR : bronchiolar-alveol	ar 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	.,	-, , · · ,	7,21,	2,22, 3.3,	
Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.9483				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.0372*	D 0.4040	D 0.0750		
Fisher Exact test(e)		P = 0.1343	P = 0.0559	P = 0.0559	
	SITE : lung				
	SITE : lung TUMOR : bronchiolar-alveol	ar oprojnoma			
Tumor rate	TOMOR - Bronchiolal alveol	ar caremona			
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	D = 0.2007	D - 0 F000	D - 0 2007	
Fisher Exact test(e)		P = 0.3087	P = 0.5000	P = 0.3087	
	SITE : lung				
Tumur rata	TUMUK : bronchiolar alveol	ar adenoma, bronchiolar—alveolar carcinom	a		
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	- · · · · <del>- /</del>	, - <del></del> /	-2		
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*	

(HPT360A)

#### NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE:

2

BAIS4

ANIMAL : MOUSE Crj:BDF1

SEX : MALE

(HPT360A)

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 = 0.8806Prevalence method(d) P = 0.6689Combined analysis(d) P = 0.8716Cochran-Armitage test(e) P = 0.0380\* Fisher Exact test(e) P = 0.1631P = 0.3871P = 0.0999SITE : spleen TUMOR : hemangioma Tumor rate Overall rates(a) 4/50(8.0) 1/50( 2.0) 0/50( 0.0) 0/50( 0.0) 8.11 Adjusted rates(b) 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 = 0.9884Combined analysis (d) P = 0.9961Cochran-Armitage test(e) P = 0.0176\*Fisher Exact test(e) P = 0.1811P = 0.0587P = 0.0587SITE : 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 = 0.3699Prevalence method(d) P = 0.2507Combined analysis(d) P = 0.2390Cochran-Armitage test(e) P = 0.6742Fisher Exact test(e) P = N.C.P = 0.0133\*P = N.C.

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

STUDY No. : 0402 ANTMAL : MOUSE Crj:BDF1

Group Name	Control	5000 ppm	10000 ppm	20000 ppm	· · · · · · · · · · · · · · · · · · ·
	SITE : spleen TUMOR : hemangioma, hemangiosarc				
Tumor rate	tomor - Hemangtoma, Hemangtosarc	oma			
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	-11	- ( (	. ( ()	- (=0 (	
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	n - a coca				
Standard method(d) Prevalence method(d)	P = 0.6963 P = 0.9990				
Combined analysis(d)	P = 0.9968				
Cochran-Armitage test(e)	P = 0.0031**				
Fisher Exact test(e)	1 - 0.0031	P = 0.0798	P = 0.0297*	P = 0.0062**	
	SITE : liver TUMOR : hepatocellular adenoma				
Tumor rate	towor . nebarocettatat adenoma				
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*				
coom an interiorge con co,		P = 0.1891	P = 0.1376	P = 0.0113*	

SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE: 4

STUDY No. : 0402 ANIMAL : MOUSE Crj:BDF1

: MALE

SEX

(HPT360A)

Group Name	Control	5000 ррш	10000 ppm	20000 ррт	
	SITE : liver TUMOR : hepatocellular carcinoma	1			
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 14/36( 38. 9)	22. 86 8/35( 22. 9)	40. 63 10/27( 37. 0)	100.00 16/16(100.0)	
Terminal rates(c) Statistical analysis Peto test	14/30( 30. 3/	0/30 ( 22. 7)	10/2/( 31.0)	10/ 10/100. 0/	
Standard method(d)	P = 0.2489				
Prevalence method(d)	P < 0.0001**?				
Combined analysis(d)	P < 0.0001**?				
Cochran-Armitage test(e) Fisher Exact test(e)	P < 0.0001**	P = 0.1839	P = 0.4138	P < 0.0001**	
Pisher Exact test(e)		r - 0. 1059	1 - 0.4130	r v 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, hemangiosarc	oma			
Tumor rate	<b>0</b> , <b>0</b>				
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 = 0.0903 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**	

BAIS4

### NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANTMAL : MOUSE Crj:BDF1

SEX : MALE

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) 54, 05 Adjusted rates(b) 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 = 0.4509Prevalence method(d) P < 0.0001\*\* Combined analysis (d) P < 0.0001\*\* P = 0.0002\*\*Cochran-Armitage test(e) Fisher Exact test(e) P = 0.2742P = 0.3444P = 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\*\* P < 0.0001\*\* Combined analysis(d) Cochran-Armitage test(e) P < 0.0001\*\* Fisher Exact test(e) P = 0.3377P = 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 19/36 (52.8) 20/35 (57.1) Terminal rates(c) 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 = 0.2119P = 0.0219\*P < 0.0001\*\*

(HPT360A)

PAGE:

5

### NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : MOUSE Crj:BDF1

SEX : MALE

(HPT360A)

· · · · · · · · · · · · · · · · · · ·					
Group Name	Control	5000 ppm	10000 ppm	20000 ապա	
	SITE : epididymis				
T	TUMOR : histiocytic sarcoma				
Tumor rate Overall rates(a)	3/50(6.0)	1/50( 2.0)	1/49( 2.0)	1/50( 2.0)	
	7.32	2.78	2.63	0.0	
Adjusted rates(b) Terminal rates(c)	2/36( 5.6)	0/35( 0.0)	0/27( 0.0)	0/16( 0.0)	
Statistical analysis	2/30( 5.0)	0/35( 0.0)	0/2/( 0.0)	0/10( 0.0)	
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	

(a): Number of tumor-bearing animals/number of animals examined at the site.

Standard method : Death analysis

Prevalence method: Incidental tumor test

PAGE:

6

BAIS4

<sup>(</sup>b): Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.

<sup>(</sup>c): Observed tumor incidence at terminal kill.

<sup>(</sup>d): Beneath the control incidence are the P-values associated with the trend test.

Combined analysis: Death analysis + Incidental tumor test

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

<sup>?:</sup> The conditional probabilities of the largest and smallest possible out comes can not estimated or this P-value is beyond the estimated P-value.

<sup>----:</sup> There is no data which should be statistical analysis.

Significant difference;  $*: P \le 0.05$   $\Leftrightarrow: P \le 0.01$ 

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)

## NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : MOUSE Crj:BDF1

SEX : FEMALE

PAGE: 3

Group Name	Control	5000 ppm	10000 ppm	20000 ppm	
	SITE : ALL SITE				
	TUMOR : hemangioma				
umor rate	<b>5</b>				
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) Fisher Exact test(e)	P = 0.5259	P = 0.1811	P = 0.3389	P = 0.3389	
Pisher Back test(e)			. 0.0000		
	SITE : ALL SITE TUMOR : histiocytic sarcoma				
fumor 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				
	P = 0.1057				
Prevalence method(d)	D - 0 COC7				
Prevalence method(d) Combined analysis(d) Cochran-Armitage test(e)	P = 0.6867 P = 0.4908				

(HPT360A)

BATS4

#### NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : MOUSE Cri:BDF1

SEX	FEMALE	

Group Name	Control	muq 0000	10000 ррт	20000 ррш	
	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

PAGE:

(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 out comes can not estimated or this P-value is beyond the estimated P-value.

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

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

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

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

STUDY No. : 0402

ANTMAL : MOUSE Crj:BDF1

SEX : FEMALE

				•••	
Group Name	Control	5000 ppm	10000 թթա	20000 ppm	
	SITE : lung				
	TUMOR : bronchiolar-alveolar ade	noma			
'umor 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	2750 ( 4.0) 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	27 20 ( 0.17	1,51( 0.1)	5,00( 0.17,		
Peto test				•	
Standard method(d)	P =				
Prevalence method(d)	P = 0.6014				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.6256	B 4 404-	B 0.5	D 0 F05	
Fisher Exact test(e)		P = 0.6913	P = 0.5000	P = 0.5000	
	SITE · lung				
	SITE : lung TUMOR : bronchiolar-alveolar ade	noma bronchiolar-alveolar carcinom	a		
Tumor rate	romon · brononiotal alveolal auc	noma, prononitial alveolal calcinom	•		
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	B = 0.0010	P = 0.0100	P - 0 F000	
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				
Prevalence method(d) Combined analysis(d)	P = 0.8902 P = 0.9973	·			
Prevalence method(d)	P = 0.8902	P = 0.5848	P = 0.4138	P = 0.0008**	

(HPT360A)

BAIS4

STUDY No. : 0402 NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : MOUSE Crj:BDF1

SEX : FEMALE PAGE : 8

Group Name	Control	5000 ppm	10000 ppm	20000 ррш	
	SITE : spleen TUMOR : malignant lymphoma				
Cumor rate	TOMOR - marranar Tymphoma				
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) Statistical analysis	6/23 ( 26. 1)	7/27(25.9)	3/30(10.0)	1/13( 7.7)	
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	3/50(6.0)	1/50( 2.0)	0/50( 0.0)	0/50( 0.0)	
Overall rates(a) Adjusted rates(b)	8.70	3.70	0,50( 0.0)	0,50( 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	5,55 ( 5.1.)	2, 3, 1, 3, 1,	0,000	0, 20 ( 0.0)	
Standard method(d)	P = 0.9439 ?				
Prevalence method(d)	P = 0.9646				
Combined analysis(d)	P = 0.9909				
Cochran-Armitage test(e) Fisher Exact test(e)	P = 0.0405*	P = 0.3087	P = 0.1212	P = 0.1212	
Fisher bxact test(e)		r - 0. 3001	r - 0.1212	r - 0.1212	
	SITE : liver		•		
	TUMOR : hepatocellular adenoma				
Tumor rate	- /- ( , , , , )	and the disease of the		, Imp ( = ->	
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) Statistical analysis	5/23(21.7)	15/27 (55.6)	8/30(26.7)	2/13( 15. 4)	
Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.7657				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.2320				
cocm an unin rage test (e)					

STUDY No. : 0402 NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : MOUSE Crj:BDF1
SEX : FEMALE

					11102
Group Name	Control	5000 ррш	10000 ррш	20000 արտ	
	SITE : liver				
Tumor rate	TUMOR : histiocytic sarcoma				
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) Statistical analysis	0/23( 0.0)	0/27( 0.0)	0/30( 0.0)	0/13( 0.0)	
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	
<del>, , , , , , , , , , , , , , , , , , , </del>	SITE : liver				<del></del>
	TUMOR : hepatocellular carcinoma				
Tumor rate	TORION - Republication del distribute	•			
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**	
<del></del>					
	SITE : liver TUMOR : hepatoblastoma				
Tumor rate	Tomok - nepatoblastoma				
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**? P < 0.0001**				
Cookman-Aumitaga ++(-)	r \ U. UUU1**				
Cochran-Armitage test(e) Fisher Exact test(e)		P = N. C.	P = 0.0029**	P < 0.0001**	

### NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

STUDY No. : 0402

ANIMAL : MOUSE Crj:BDF1

SEX : FEMALE

X : FEMALE					PAGE -
Group Name	Control	5000 ppm	10000 ppm	20000 ppm	
	SITE : liver				
	TUMOR : hepatocellular ade	noma, hepatocellular carcinoma			
umor rate			4. 4. 4. 4.	(	
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	
ferminal rates(c)	6/23(26.1)	19/27 ( 70. 4)	30/30(100.0)	12/13(92.3)	
tatistical analysis					
Peto test	D 0.0405. 0				
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≠≠	P = 0.0002**	P < 0.0001**	P < 0.0001*=*	
Fisher Exact test(e)		1 - 0.0002	1 ( 0, 00014)		
	SITE : liver				
	TUMOR : hepatocellular car	cinoma, hepatoblastoma			
umor 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)	
tatistical 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**	D - 0 000044	P < 0.0001**	P < 0.0001**	
Fisher Exact test(e)		P = 0.0038**	r \ 0.0001++	1 \ 0.0001	
	SITE : liver				
	TUMOR : hepatocellular ade	enoma, hepatocellular carcinoma, hepatoblas	toma		
umor rate				12 (22 ( 22 2)	
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)	
tatistical analysis					
Peto test	D. C.O. GOODS C.O.				
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**	P = 0.0002**	P < 0.0001***	P < 0.0001**	
Fisher Exact test(e)		P ≃ U. UUUZ**	r \ 0.0001***	1 \ 0.0001777	

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### NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE: 11

BAIS4

ANIMAL : MOUSE Cri:BDF1

SEX : FEMALE

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 3/23 (13.0) 0/13( 0.0) Terminal rates(c) 5/27(18.5) 4/30(13.3) Statistical analysis Peto test Standard method(d) P = ----P = 0.9394Prevalence method(d) Combined analysis(d) P = ----P = 0.0882Cochran-Armitage test(e) Fisher Exact test(e) P = 0.1672P = 0.3689P = 0.1175SITE : 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 P = ----Standard method(d) Prevalence method(d) P = 0.9994Combined analysis(d) P = ----Cochran-Armitage test(e) P = 0.0078\*\*P = 0.1022P = 0.0281\*Fisher Exact test(e) P = 0.0281\*SITE : uterus TUMOR : histiocytic sarcoma Tumor rate 15/50(30.0) Overall rates(a) 16/50(32.0) 15/50(30.0) 12/50 (24.0) Adjusted rates(b) 18.52 18.52 23.33 30.77 4/23(17.4) Terminal rates(c) 5/27(18.5) 7/30(23.3) 4/13(30.8) Statistical analysis Peto test Standard method(d) P = 0.9203Prevalence method(d) P = 0.1119Combined analysis(d) P = 0.6656P = 0.4294Cochran-Armitage test(e) Fisher Exact test(e) P = 0.5000P = 0.5862P = 0.3264

(HPT360A)

### NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANTMAL : MOUSE Crj:BDF1

SEX : FEMALE PAGE : 12

Group Name	Control	5000 руш	10000 ррш	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	

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 out comes can not estimated or this P-value is beyond the estimated P-value.

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

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

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)

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

ALL ANIMALS (0-105W)

REPORT TYPE : AI SEX : MALE

	n: //	Group Name No. of Animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
)rgan	Findings					
{Respiratory s	vetan)					
(Nespitator) s	, s centi					
nasal cavit	metastasis:subcutis tumor		<50> 0	<50> 0	<50> 0	<50> 1
	metastasis:peripheral nerve tumor		0	0	1	0
lung			<50>	<50>	<50≻	<50>
-	leukemic cell infiltration		2	4	2	1
	metastasis:liver tumor		2	2	2	10
{Hematopoietic	: system)					
bone marrow			<50>	<50>	<50>	<50>
	leukemic cell infiltration		3	3	3	2
spleen			<50>	<50>	<50>	<50>
	leukemic cell infiltration		2	7	0	2
{Circulatory s	system)					
heart			<50>	<50>	<50>	<50>
	leukemic cell infiltration		0	1	0	0
	metastasis:liver tumor		0	0	0	1
{Digestive sys	etem}					
salivary gl			<50>	<b>(50)</b>	<50>	<50>
	leukemic cell infiltration		0	1	0	0
stomach			<50>	<50>	<50>	<50>
	leukemic cell infiltration		0	1	0	0
< a > b	a: Number of animals examined at the b: Number of animals with lesion	e site				

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

ALL ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

Organ	Findings	Group Name No. of Animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
{Digestive sy	ystem)					
stomach			<50> 0	<50> 0	<50>	<50> 0
	metastasis:spleen tumor		·	•	2	•
	metastasis:epididymis tumor		1	0	0	0
small intes	leukemic cell infiltration		<50> 1	<50> 3	<50> 1	<50> 0
	leukemic cell intilitration					
liver	leukomic cell infiltration		<50> 2	<50> 4	<50> 1	<50> 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 sys	tem)					
kidney			<50>	<b>&lt;50&gt;</b>	<b>&lt;50&gt;</b>	<b>&lt;50&gt;</b>
Kidney	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>	<b>&lt;50&gt;</b>	<b>&lt;50&gt;</b>
	leukemic cell infiltration		1	1	2	0
< a > b	a: Number of animals examined at the s b: Number of animals with lesion	rite				
(700.50)	<u> </u>					RATSA

ANIMAL : MOUSE Crj:BDF1

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1 SEX : MALE

		Group Name Control No. of Animals on Study 50	5000 ppm	10000 ррш 50	20000 ppm 50
rgan	Findings	NO. Of Animals on Study 50	50	50	50
(Endocrine sys	tem)				
oituitary	leukemic cell infiltration	<50> 0	<50> 1	<50> 0	<50> 0
	metastasis:spleen tumor	0	0	1	0
adrena1	leukemic cell infiltration	<50> 1	<50> 1	<50> 0	<50> 0
	metastasis:spleen tumor	0	0	1	0
{Reproductive	system)				
testis	metastasis:epididymis tumor	<50> 0	<50> 0	<50> 1	<50> 0
pididymis	leukemic cell infiltration	<50> 0	<50> 2	<50> 1	<50> 0
	metastasis:subcutis tumor	0	0	1	0
(Musculoskele	tal system)				
muscle	leukemic cell infiltration	<50> 0	<50> 0	<50> 1	<50> 0
{Body cavities	s)				
peritoneum	metastasis:liver tumor	<50> 0	<50> 0	<50> 0	<50> 1
< a > b	a: Number of animals examined at the si b: Number of animals with lesion	te			

## APPENDIX O 2

HISTOPATHOLOGICAL FINDINGS: METATSASIS OF TUMOR: SUMMARY

MOUSE: FEMALE: ALL ANIMALS

(2-YEAR STUDY)

ANIMAL

: MOUSE Crj:BDF1

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

REPORT TYPE : A1 SEX : FEMALE

PAGE: 4 Group Name 5000 ppm 10000 ppm 20000 ppm Control

		Group Name Control No. of Animals on Study 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
Organ	Findings				
(Integumentar)	y system/appandage)				
subcutis	leukemic cell infiltration	<50> 1	<50> 1	<50> I	<50> 0
{Respiratory	system)				
masal 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
{Hematopoieti	c 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 > b	a : Number of animals examined at the si b : Number of animals with lesion	ite			
(TDT1EO)			· · · · · · · · · · · · · · · · · · ·		

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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : FEMALE

Organ		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
pleen			<b>&lt;50&gt;</b>	<50>	<50≻	<50>
	leukemic cell infiltration		11	13	9	1
	metastasis:liver tumor		0	0	1	0
	metastasis:uterus tumor		2	8	4	I
	metastasis:peritoneum tumor		1	0	0	0
(Circulatory :	system)					
			(50)	<b>(50)</b>	(50)	(50)
eart	leukemic cell infiltration		<50> 2	<50> 5	<50> 3	<50> 0
Digestive sys	stem}					
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>	<b>&lt;50&gt;</b>	<50>	<b>&lt;50&gt;</b>
	leukemic cell infiltration		0	1	0	0
	metastasis:uterus tumor		1	0	0	0
(а) b	a: Number of animals examined at the state of animals with lesion	ite			<del> </del>	
U	D . Monthet of suffigie After legion					

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

ANTMAL : MOUSE Crj:BDF1

ALL ANIMALS (0-105W)

REPORT TYPE : A1
SEX : FEMALE

_		Group Name No. of Animals on Study	Control 50	5000 ppm 50	10000 ppm 50	20000 ppm 50
rgan	Findings				<del> </del>	
ín:						
(Digestive sy	stemy					
stomach	metastasis:peritoneum tumor		<50> 1	<50> 0	<50> 0	<50> 0
	metastasis:subcutis tumor		1	0	0	0
small intes	leukemic cell infiltration		<50> 0	<50> 0	<50> 1	<50> 0
	metastasis:subcutis tumor		1	0	0	0
1:	and the second s		<50>	<50>	<50>	<50>
liver	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>	<b>&lt;50&gt;</b>
	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 syst	em)					
kidney			<50>	<50>	<50>	<50>
	leukemic cell infiltration		4	11	9	1
	metastasis:uterus tumor		3	5	2	2
< a > b	a : Number of animals examined at the s b : Number of animals with lesion	ite				

: MOUSE Crj:BDF1

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1

ANTMAL

SEX : FEMALE

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

: MOUSE Crj:BDF1 ANTMAL

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : AI SEX : FEMALE

Group Name 5000 ppm 10000 ppm 20000 ppm Control No. of Animals on Study 50 50 50 50 Findings\_ Organ\_ {Reproductive system} vagina <50> ⟨50⟩ <50> <50> 3 1 1 metastasis:uterus tumor {Nervous system} <50> brain <50> <50> <50> leukemic cell infiltration 1 1 0 {Special sense organs/appendage} Harder gl ⟨50⟩ <50> <50> ⟨50⟩ 0 leukemic cell infiltration 2 metastasis:liver tumor 1 (Musculoskeletal system) <50> <50> <50> <50> muscle leukemic cell infiltration 0 {Body cavities} <50> <50> <50> <50> peritoneum leukemic cell infiltration 0 1 metastasis:liver tumor 0 2 (a) a : Number of animals examined at the site b b: Number of animals with lesion

(JPT150)

BAIS4

## AAPPENDIX O 3

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY

MOUSE: MALE: SACRIFICED ANIMALS

(2-YEAR STUDY)

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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

		Group Name No. of Animals on Study	Control 36	5000 ppm 35	10000 ppm 27	20000 ppm 16
rgan	Findings					
	,					
Respiratory	system)					
ung	leukemic cell infiltration		<36> 0	<35> 2	<27> 1	<16> 1
	metastasis:liver tumor		2	2	1	4
llematopoieti	c system)					
one marrow	leukemic cell infiltration		<36> 0	<35> 0	<27> 2	<16> 0
spleen	leukemic cell infiltration		<36> 2	<35> 5	<27> 0	<16>
Digestive sy	ystem}					
emall intes	leukemic cell infiltration		<36> 0	<35> 2	<b>&lt;27&gt;</b> 1	<16> 0
iver	leukemic cell infiltration		<36> 0	<35> 2	<27> 0	<16> 1
	metastasis:spleen tumor		0	0	3	0
	metastasis:epididymis tumor		1	0	0	0
	metastasis:salivary gland tumor		1	0	0	0
pancreas	leukemic cell infiltration		<36> 0	<35> 1	<27> 0	0
{Urinary sys	tem}					
kidney	leukemic cell infiltration		<36> 0	<35> 1	<27> 0	<16>
< a >	a: Number of animals examined at the s b: Number of animals with lesion	ite				

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

(JPT150)

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

		Group Name	Control	5000 ppm	10000 ppm	20000 ppm
Organ		No. of Animals on Study	36	35	27	16
{Urinary syst	t om)					
urin bladd	leukemic cell infiltration		<36> 0	<35> 0	<27> 2	<16> 0
{Reproductive	e system)					
epididymis	leukemic cell infiltration		<36> 0	<35> 0	<27> 1	<16> 0
{Musculoskel	etal system}					
muscle	leukemic cell infiltration		<36> 0	<35> 0	<27> 1	<16> 0
< a >	a: Number of animals examined at the solution	te				

BAIS4

## APPENDIX O 4

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY

MOUSE: FEMALE: SACRIFICED ANIMALS

(2-YEAR STUDY)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

PAGE: 3

SACRIFICED ANIMALS (105W)

		Group Name Control No. of Animals on Study 23	5000 ppm 27	10000 ppm 30	20000 ppm 13
rgan	Findings				
(Integumentary	y system/appandage)				
subcutis		⟨23⟩	⟨27⟩	⟨30⟩	<13>
subcutis	leukemic cell infiltration	1	0	0	0
{Respiratory	system)				
lung		<23>	⟨27⟩	⟨30⟩	<13>
Idiig	leukemic cell infiltration	4	3	2	1
{Hematopoieti	c system)				
bone marrow		⟨23⟩	⟨27⟩	⟨30⟩	<13>
	leukemic cell infiltration	3	3	2	2
lymph node		<23>	⟨27⟩	⟨30⟩	<13>
	leukemic cell infiltration	1	3	0	0
spleen		⟨23⟩	<27>	⟨30⟩	<13>
	leukemic cell infiltration	5	4	5	1
	metastasis:liver tumor	0	0	1	0
{Circulatory	system)				
heart		<23>	<27>	<30≻	<13>
	leukemic cell infiltration	1	0	1	0
{Digestive sy	rstem)				
salivary gl		<23>	⟨27⟩	<30≻	<13>
	leukemic cell infiltration	9	1	3	2
liver		<23>	<b>(27)</b>	<30>	<13>
	leukemic cell infiltration	7	3	3	1
<a>&gt; b</a>	a: Number of animals examined at the si b: Number of animals with lesion	te			
(JPT150)					,

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

SACRIFICED ANIMALS (105W)

		Group Name Control	5000 ppm	10000 ррш	20000 ppm
gan		No. of Animals on Study 23	27	30	13
Digestive sy	rstem)				
ancreas		⟨23⟩	<27>	<30>	<13>
	leukemic cell infiltration	. 3	3	3	1
	metastasis:uterus tumor	0	0	1	0
Jrinary syst	tem)				
idney		<23>	<27>	<30>	<13>
	leukemic cell infiltration	1	7	3	1
rin bladd		<23>	<27>	<30>	<13>
	leukemic cell infiltration	2	4	1	1
Reproductive	e system}				
vary		⟨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
ıterus		⟨23⟩	<27>	<30>	<13>
	leukemic cell infiltration	1	0	1	0
vagina		<23>	<27>	<30>	<13>
	leukemic cell infiltration	0	1	1	0
Nervous sys	tem)				
orain		<23>	<27>	<30>	<13>
	leukemic cell infiltration	0	1	0	0
(a)	a: Number of animals examined at the s	ite			
ь	b: Number of animals with lesion				

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX

: FEMALE

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

PAGE: 5

SACRIFICED ANIMALS (105W)

Organ		Group Name No. of Animals on Study	Control 23	5000 ppm 27	10000 ppm 30	20000 ppm 13
ody cavities	5)					
eritoneum	metastasis:liver tumor		<23> 0	<27> 0	<30> 0	<13> 2
a > b	a: Number of animals examined at the si b: Number of animals with lesion	te	. <u>-</u>			

### PPENDIX O 5

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY

MOUSE: MALE: DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

. 0402

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

(JPT150)

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

PAGE: 1

BAIS4

DEAD AND MORIBUND ANIMALS (0-105W)

20000 ppm 10000 ppm Group Name Control 5000 ppm 23 34 No. of Animals on Study 15 14 Findings\_ Organ\_ {Respiratory system} <34> ⟨23⟩ (15) <14> nasal cavit 0 1 metastasis:subcutis tumor 0 0 0 metastasis:peripheral nerve tumor <23> <34> <14> <15> lung 2 1 leukemic cell infiltration 1 6 0 metastasis:liver tumor {Hematopoietic system} <34> <15> <23> <14> bone marrow 1 2 leukemic cell infiltration 3 3 <23> <34> <14> <15> spleen leukemic cell infiltration {Circulatory system} <34> <15> ⟨23⟩ <14> heart 1 0 leukemic cell infiltration 1 0 metastasis:liver tumor {Digestive system} ⟨34⟩ ⟨23⟩ <14> <15> salivary gl 0 1 leukemic cell infiltration <23> <34> <14> <15> stomach 0 1 0 leukemic cell infiltration < a > a: Number of animals examined at the site b: Number of animals with lesion

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

		Group Name No. of Animals on Study	Control 14	5000 ppm 15	10000 ppm 23	20000 ppm 34
gan	Findings					
igestive sy	stem)					
tomach	metastasis:spleen tumor		<14> 0	<15> 0	<23> 2	<34> 0
	metastasis:epididymis tumor		1	0	0	0
mall intes	leukemic cell infiltration		<14> 1	<15> 1	<23> 0	<34> 0
iver	leukemic cell infiltration		<14> 2	<15> 2	<23> 1	<34> 0
	metastasis:subcutis tumor		0	0	1	1
	metastasis:peripheral nerve tumor		0	0	1	0
	metastasis:spleen tumor		0	0	3	0
	metastasis:epididymis tumor		1	0	0	1
oancreas	leukemic cell infiltration		<14> 0	<15> 1	<23> 1	<34> 0
(Urinary syst	tem)					
idney	leukemic cell infiltration		<14>	<15> 1	<23> 2	<34>
	metastasis:liver tumor		0	1	0	0
	metastasis:spleen tumor		0	0	1	0
urin bladd	leukemic cell infiltration		<14> 1	<15> 1	<23> 0	<34> 0
(Endocrine s	ystem)					
pituitary	leukemic cell infiltration		<14> 0	<15> I	<23> 0	<34> 0
<a>→ b</a>	a: Number of animals examined at the b: Number of animals with lesion	site				
(IPT150)						

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

PAGE: 3

DEAD AND MORIBUND ANIMALS (0-105W)

		Group Name No. of Animals on Study	Control	5000 ppm 15	10000 ppm 23	20000 ppm 34
)rgan	Findings	wo. Of Antium's on body	**			
{Endocrine sys	stem)					
pituitary			<14>	<15>	<23>	⟨34⟩
pitaltary	metastasis:spleen tumor		0	0	1	0
adrenal			<14>	<15>	<23≻	<34>
ant eng t	leukemic cell infiltration		1	1	0	0
	metastasis:spleen tumor		0	0	1	0
	merastasts.spreem comor		-			
{Reproductive	o evetem)					
	. 0,000,		416	(1E)	⟨23⟩	⟨34⟩
testis	metastasis:epididymis tumor		<14> 0	<15> 0	1	0
	merastasis.epititamis tomor			45	/99\	⟨34⟩
epididymis	leukemic cell infiltration		<14> 0	<15> 2	<23> 0	0
	Tenkewic cell juilituation					2
	metastasis:subcutis tumor		0	0	1	0
{Body cavitie	es)					
peritoneum			<14>	<15>	⟨23⟩	<34>
F 7 44114 mm	metastasis:liver tumor		0	0	0	1
< a >	a : Number of animals examined at the s	ite				
b	b : Number of animals with lesion					
(JPT150)						

### APPENDIX O 6

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY

MOUSE: FEMALE: DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

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

ANTMAL : MOUSE Crj:BDF1

MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : FEMALE

Organ		Group Name Control No. of Animals on Study 27	5000 ppm 23	10000 ppm 20	20000 ppm 37
{Integumentar	y 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>	<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
{Hematopoieti	c 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 > b	a: Number of animals examined at the s b: Number of animals with lesion	ite			
(JPT150)					BAIS4

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY) STUDY NO. : 0402 DEAD AND MORIBUND ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1
SEX : FEMALE

		Group Name No. of Animals on Study	Control 27	5000 ppm 23	10000 ppm 20	20000 ppm 37
rgan	Findings					
Hematopoietic	system)					
ymph node			⟨27⟩	<23>	⟨20⟩	<37>
ympii node	leukemic cell infiltration		0	0	1	0
	metastasis:uterus tumor		1	7	1	0
	metastasis:subcutis tumor		1	0	0	0
			<27>	⟨23⟩	<20>	<37>
spleen	leukemic cell infiltration		6	9	4	0
	metastasis:uterus tumor		2	8	4	1
	metastasis:peritoneum tumor		1	0	0	0
{Circulatory s	system}					
neart			<27>	⟨23⟩	<20>	⟨37⟩
.ear t	leukemic cell infiltration		1	5	2	0
{Digestive sys	stem)					
tongue			<27>	⟨23⟩	<20>	<37> 0
	leukemic cell infiltration		1	I		
salivary gl	leukemic cell infiltration		<27>	<23> 5	<20>	<37> 0
	Tenkemic cell lutilityation			⟨23⟩	<20>	⟨37⟩
stomach	leukemic cell infiltration		<27> 0	1	0	0
	metastasis:uterus tumor		1	0	0	0
	metastasis:peritoneum tumor		i	0	0	0
	a : Number of animals examined a	: the site				-
b	b : Number of animals with lesion	ı				

STUDY NO. : 0402 ANIMAL : MOUSE Crj:BDF1 HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

REPORT TYPE : A1

SEX : FEMALE

		Group Name No. of Animals on Study	Control 27	5000 ppm 23	10000 ppm 20	20000 ppm 37
rgan	Findings					
Digestive sys	stem)					
tomach			<27>	<23>	<20>	<37> 0
	metastasis:subcutis tumor		1	0	0	U
mall intes			<27>	<23>	<20>	<37>
all intes	leukemic cell infiltration		0	0	1	0
	metastasis:subcutis tumor		1	0	0	0
			<27>	⟨23⟩	⟨20⟩	<37>
iver	leukemic cell infiltration		6	11	6	0
			10	11	7	5
	metastasis:uterus tumor				•	0
	metastasis:ovary tumor		0	1	0	U
all bladd			<27>	<23>	<20>	<37>
arr braud	leukemic cell infiltration		1	1	0	0
			⟨27⟩	⟨23⟩	⟨20⟩	<37>
ancreas	leukemic cell infiltration		2	4	3	0
	metastasis:liver tumor		0	0	0	1
	metastasis-iivei bumoi				٥	1
	metastasis:uterus tumor		1	4	0	
	metastasis:subcutis tumor		1	0	0	0
<b>6</b>						
{Urinary sys	tem)				(00)	⟨37⟩
kidney	1		<27> 3	<23> 4	<20>	0
	leukemic cell infiltration		-			0
	metastasis:uterus tumor		3	5	2	2
ırin bladd			<27>	⟨23⟩	<20>	<37>
II IN DIAGO	leukemic cell infiltration		3	5	4	0
< a >	a: Number of animals examined at the s	ite				
b	b : Number of animals with lesion					

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

DEAD AND MORIBUND ANIMALS (0-105W)

REPORT TYPE : A1 SEX : FEMALE

		roup Name Control No. of Animals on Study 27	5000 ppm 23	10000 ppm 20	20000 ppm 37
rgan	Findings	·			
Urinary syste	em)				
		<27>	⟨23⟩	⟨20⟩	<37>
rin bladd	metastasis:uterus tumor	1	1	2	0
Endocrine sys	stem)				
lıyroid		<27>	⟨23⟩	⟨20⟩	<37>
,2014	leukemic cell infiltration	1	1	2	0
		<27>	<23>	<20>	<37>
arathyroid	leukemic cell infiltration	0	1	0	0
		<27>	⟨23⟩	⟨20⟩	<37>
drenal	leukemic cell infiltration	1	1	1	0
	metastasis:uterus tumor	1	1	2	0
(Reproductive	system)				
		<27>	⟨23⟩	⟨20⟩	<37>
ovary	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⟩
1001.02	leukemic cell infiltration	3	5	3	0
	metastasis:peritoneum tumor	1	0	0	0
vagina		<27>	⟨23⟩	⟨20⟩	<37>
. ~61114	leukemic cell infiltration	3	2	2	0
	metastasis:uterus tumor	3	1	3	1
	a: Number of animals examined at the s b: Number of animals with lesion	ite			

ANIMAL : MOUSE Crj:BDF1

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

REPORT TYPE : A1 SEX : FEMALE

PAGE: 8 E000 10000 20000

		Group Name Control No. of Animals on Study 27	5000 ррm 23	10000 ррт 20	20000 ppm 37
Organ	Findings				
Nervous sys	stem}				
brain	leukemic cell infiltration	<27> 0	<23> 0	<20> 1	<37> 0
{Special ser	nse organs/appendage)				
Harder gl	leukemic cell infiltration	<27> 1	<23> 2	<20>	<37> 0
	metastasis:liver tumor	0	0	0	1
{Musculoske	letal system)				
muscle	leukemic cell infiltration	<27> 0	<23> 1	<20> 2	<37> 0
{Body cavit	ies}				
peritoneum	leukemic cell infiltration	<27> 1	<23> 0	<20> 0	<37> 1
< a > b	a : Number of animals examined at the s b : Number of animals with lesion	site			
(IDT150)					R

(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 STUDY

Test Substance

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

Lot No.

: KSJ0005

#### 1. Spectral data

#### Mass Spectrometry

Instrument

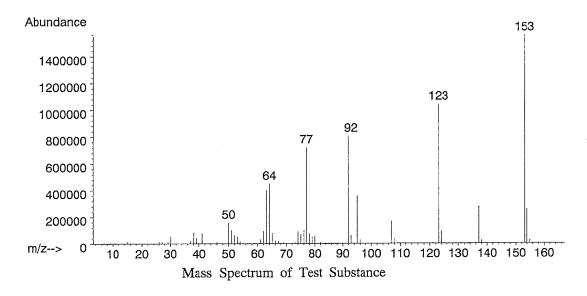
: Hewlett Packard 5989B Mass Spectrometer

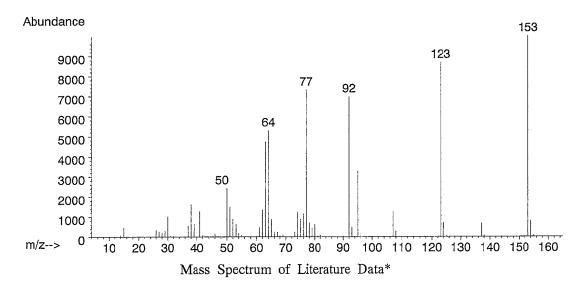
Ionization

: 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.

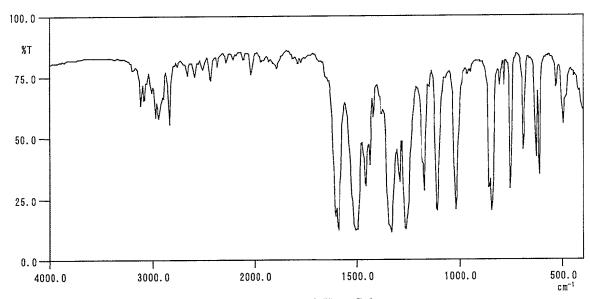
New York, NY: John Wiley and Sons.)

#### Infrared Spectrometry

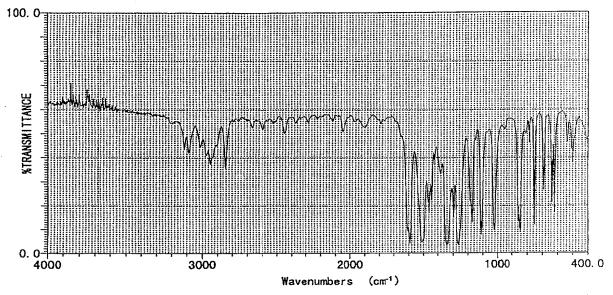
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 2.0 cm<sup>-1</sup>



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 $\phi$  × 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 μL

Sample Name	Peak No.	Area (%)	Peak Name
Test Substance	1	0.25	m-Chloronitrobenzene
	2	99.75	p-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 MOUSES 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  $\phi$  × 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 µL

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

## CONCENTMOUSEION 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

_	Ta	arget Concentration		
Date Analyzed	5000ª	10000	20000	
1999.12.01	5170 (103 ) <sup>b</sup>	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 )	
	· · ·		· · · · · · · · · · · · · · · · · · ·	

<sup>&</sup>lt;sup>a</sup> ppm <sup>b</sup> %

Analytical method : The samples were analyzed by high performance liquid chromatography.

: Hewlett Packard 1090 High Performance Liquid Chromatograph Instrument

: TSK GEL ODS-80TM (4.6 mm  $\phi$  × 15 cm) Column

Column Temperature : Room Temperature

Flow Rate : 1 mL/min

Mobile Phase : Distilled Water : Acetonitrile = 1 : 1

Detector : UV (295 nm)

: 20 μL Injection Volume

## 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

	Target Concentration		
Date Analyzed	300°	40000	
1998.09.24	314 (100 ) <sup>b</sup>	40500 (100 )	
1998.10.02°	264 ( 84.1)	37700 ( 93.1)	
1998.10.29 <sup>d</sup>	304 ( 96.8)	39400 ( 97.3)	
	1998.09.24 1998.10.02°	Date Analyzed 300 <sup>a</sup> 1998.09.24 314 (100 ) <sup>b</sup> 1998.10.02 <sup>c</sup> 264 ( 84.1)	

<sup>&</sup>lt;sup>a</sup> ppm

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  $\phi$  × 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 µL

<sup>&</sup>lt;sup>b</sup> % (Percentage was based on the concentration on date of preparation.)

<sup>&</sup>lt;sup>c</sup> Animal room samples

<sup>&</sup>lt;sup>d</sup> Cold storage samples

## 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°	10000	20000	
Coefficient Variation	3.33 <sup>b</sup>	3.05	1.26	

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  $\phi$  × 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 μL

<sup>&</sup>lt;sup>a</sup> ppm
<sup>b</sup> % (n=7)

## 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 <sup>1)</sup>	×10 <sup>6</sup> /μL	2
Hemoglobin(Hgb)	Cyanmethemoglobin method 1)	g/dL	1
Hematocrit(Hct)	Calculated as RBC×MCV/10 1)	%	1
Mean corpuscular volume(MCV)	Light scattering method 1)	fL	1
Mean corpuscular hemoglobin(MCH)	Calculated as Hgb/RBC×10 1)	pg	1
Mean corpuscular hemoglobin concentration	Calculated as Hgb/Hct×100 10	g/dL	1
(MCHC)			
Platelet	Light scattering method 1)	$ imes 10^3/\mu\mathrm{L}$	0
White blood cell(WBC)	Light scattering method 1)	$ imes 10^3/\mu\mathrm{L}$	2
Differential WBC	Pattern recognition method <sup>2)</sup>	%	0
	(Wright staining)		
Biochemistry			
Total protein(TP)	Biuret method 3)	g/dL	1
Albumin (Alb)	BCG method 3)	g/dL	1
A/G ratio	Calculated as Alb/(TP-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
$\gamma$ -Glutamyl transpeptidase ( $\gamma$ -GTP)	L- $\gamma$ -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

<sup>1)</sup> Automatic blood cell analyzer (ADVIA120 : Bayer Corporation)

<sup>2)</sup> Automatic blood cell differential analyzer (MICROX HEG-120NA : OMRON Corporation )

<sup>3)</sup> Automatic analyzer (Hitachi 7070 : Hitachi, Ltd.)