

キノリンのラットを用いた経口投与による
がん原性試験（混水試験）報告書

試験番号：0303

APPENDIX

APPENDIXES

APPENDIX A 1	CLINICAL OBSERVATION: SUMMARY, RAT : MALE (2-YEAR STUDY)
APPENDIX A 2	CLINICAL OBSERVATION: SUMMARY, RAT : FEMALE (2-YEAR STUDY)
APPENDIX B 1	BODY WEIGHT CHANGES: SUMMARY, RAT: MALE (2-YEAR STUDY)
APPENDIX B 2	BODY WEIGHT CHANGES: SUMMARY, RAT: FEMALE (2-YEAR STUDY)
APPENDIX C 1	WATER CONSUMPTION CHANGES: SUMMARY, RAT: MALE (2-YEAR STUDY)
APPENDIX C 2	WATER CONSUMPTION CHANGES: SUMMARY, RAT: FEMALE (2-YEAR STUDY)
APPENDIX D 1	FOOD CONSUMPTION CHANGES: SUMMARY, RAT: MALE (2-YEAR STUDY)
APPENDIX D 2	FOOD CONSUMPTION CHANGES: SUMMARY, RAT: FEMALE (2-YEAR STUDY)
APPENDIX E 1	CHEMICAL INTAKE CHANGES: SUMMARY, RAT: MALE (2-YEAR STUDY)
APPENDIX E 2	CHEMICAL INTAKE CHANGES: SUMMARY, RAT: FEMALE (2-YEAR STUDY)
APPENDIX F 1	HEMATOLOGY: SUMMARY, RAT: MALE (2-YEAR STUDY)
APPENDIX F 2	HEMATOLOGY: SUMMARY, RAT: FEMALE (2-YEAR STUDY)
APPENDIX G 1	BIOCHEMISTRY: SUMMARY, RAT: MALE (2-YEAR STUDY)
APPENDIX G 2	BIOCHEMISTRY: SUMMARY, RAT: FEMALE (2-YEAR STUDY)
APPENDIX H 1	URINALYSIS: SUMMARY, RAT: MALE (2-YEAR STUDY)
APPENDIX H 2	URINALYSIS: SUMMARY, RAT: FEMALE (2-YEAR STUDY)

APPENDIXES (CONTINUED)

APPENDIX I 1	GROSS FINDINGS: SUMMARY, RAT: MALE: ALL ANIMALS (2-YEAR STUDY)
APPENDIX I 2	GROSS FINDINGS: SUMMARY, RAT: FEMALE: ALL ANIMALS (2-YEAR STUDY)
APPENDIX I 3	GROSS FINDINGS: SUMMARY, RAT: MALE: DEAD AND MORIBUND ANIMALS (2-YEAR STUDY)
APPENDIX I 4	GROSS FINDINGS: SUMMARY, RAT: FEMALE: DEAD AND MORIBUND ANIMALS (2-YEAR STUDY)
APPENDIX I 5	GROSS FINDINGS: SUMMARY, RAT: MALE: SACRIFICED ANIMALS (2-YEAR STUDY)
APPENDIX I 6	GROSS FINDINGS: SUMMARY, RAT: FEMALE: SACRIFICED ANIMALS (2-YEAR STUDY)
APPENDIX J 1	ORGAN WEIGHT: ABSOLUTE: SUMMARY, RAT: MALE (2-YEAR STUDY)
APPENDIX J 2	ORGAN WEIGHT: ABSOLUTE: SUMMARY, RAT: FEMALE (2-YEAR STUDY)
APPENDIX K 1	ORGAN WEIGHT: RELATIVE: SUMMARY, RAT: MALE (2-YEAR STUDY)
APPENDIX K 2	ORGAN WEIGHT: RELATIVE: SUMMARY, RAT: FEMALE (2-YEAR STUDY)
APPENDIX L 1	HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, RAT: MALE: ALL ANIMALS (2-YEAR STUDY)
APPENDIX L 2	HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, RAT: FEMALE: ALL ANIMALS (2-YEAR STUDY)
APPENDIX L 3	HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, RAT: MALE: DEAD AND MORIBUND ANIMALS (2-YEAR STUDY)
APPENDIX L 4	HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, RAT: FEMALE: DEAD AND MORIBUND ANIMALS (2-YEAR STUDY)
APPENDIX L 5	HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, RAT: MALE: SACRIFICED ANIMALS (2-YEAR STUDY)

APPENDIXES (CONTINUED)

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

APPENDIXES (CONTINUED)

APPENDIX Q 1	IDENTITY AND IMPURITY OF QUINOLINE IN THE 2-YEAR DRINKING WATER STUDY
APPENDIX Q 2	STABILITY OF QUINOLINE IN THE 2-YEAR DRINKING WATER STUDY
APPENDIX Q 3	CONCENTRATION OF QUINOLINE IN FORMULATED WATER IN THE 2-YEAR DRINKING WATER STUDY
APPENDIX Q 4	STABILITY OF QUINOLINE IN FORMULATED WATER IN THE 2-YEAR DRINKING WATER STUDY
APPENDIX R 1	METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS IN THE 2-YEAR DRINKING WATER STUDY OF QUINOLINE
APPENDIX R 2	UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-YEAR DRINKING WATER STUDY OF QUINOLINE
APPENDIX S 1	HISTORICAL CONTROL DATA OF CELECTED NEOPLASTIC LESIONS F344/DuCrj(FISHER) RATS IN JAPAN BIOASSAY RESEARCH CENTER

APPENDIX A 1

CLINICAL OBSERVATION : SUMMARY, RAT : MALE
(2-YEAR STUDY)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 2

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 3

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	800 ppm	1	1	2	2	2	3	3	6	7	7	7	9	9	9
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 4

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400 ppm	2	2	2	2	2	2	2	2	2	2	2	2	3	4
	800 ppm	11	13	13	17	19	19	23	26	27	29	29	31	32	33
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	2	2	2	2	2	2	2	2	3	3	3
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	1	0	0	0	0	0	0	0	1	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 5

Clinical sign	Group Name	Administration Week-day													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	1	1	1	2	2	2	2	2	2
	400 ppm	4	4	5	5	5	6	7	11	13	15	15	15	17	18
	800 ppm	35	38	39	39	41	42	42	42	42	42	42	42	43	43
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	1	1	2	2	2	2	2	2
	800 ppm	3	3	4	4	4	4	4	5	5	5	5	5	5	5
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	1	1	1	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	1	0	1	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 6

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	200 ppm	2	2	2	2	3	3	6	6	6	7	7	8	9	10
	400 ppm	21	24	27	29	30	31	33	33	35	37	38	38	38	38
	800 ppm	43	43	43	44	44	45	-	-	-	-	-	-	-	-
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	2	2	2	2
	400 ppm	2	2	2	2	4	5	7	7	7	7	7	7	7	7
	800 ppm	5	5	5	5	5	5	-	-	-	-	-	-	-	-
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	3	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	1	1	1	1	-	-	-	-	-	-	-	-	-

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 7

Clinical sign	Group Name	Administration Week-day											
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7
DEATH	Control	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	10	13	15	17	19	20	22	23	23	24	27	28
	400 ppm	38	38	40	40	40	40	40	40	40	40	41	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	2	2	2	3	3	3	3	3	3	3	3	3
	400 ppm	7	7	8	8	8	8	8	8	8	8	9	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	1	0	0	0	0	0	0	0	0	0	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 8

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 9

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 10

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	1	1	1	1	1	1	1	1	1	1	1	1	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	1	1	1	1	1	1	1	1	1	1	1	1	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 11

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	1	1	1	1	2	2	2	2	2	2	2	2	2	2
	200 ppm	2	1	1	1	1	1	2	2	2	1	2	2	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	200 ppm	1	1	1	1	1	1	1	1	1	1	2	2	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	1	1	1	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 12

Clinical sign	Group Name	Administration Week-day													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
EXOPIITIALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	2	2	2	2	2	3	4	4	4	4	4	4	4	4
	200 ppm	2	2	2	2	2	3	3	3	3	4	4	5	5	5
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	1	1	1	1	1	1	2	2	2	2	2	2	2	2
	200 ppm	2	2	2	2	2	3	3	3	3	4	4	5	5	5
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	Control	1	1	1	1	1	2	2	2	2	2	2	2	2	2
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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	1	1
	200 ppm	1	1	1	1	1	1	1	2	2	2	2	2	2	2
	400 ppm	2	2	2	2	2	1	1	1	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0	0
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 13

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
EXOPHTHALMOS	Control	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
EYE OPACITY	Control	4	4	4	4	4	4	4	4	4	5	5	5	5	5
	200 ppm	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	400 ppm	0	0	0	1	1	2	2	3	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
CATARACT	Control	2	2	2	2	2	2	2	2	2	3	3	3	3	3
	200 ppm	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	400 ppm	0	0	0	1	1	2	2	3	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
CORNEAL OPACITY	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
EXTERNAL MASS	Control	1	1	2	3	3	3	3	4	4	4	4	5	6	7
	200 ppm	3	3	3	3	3	3	3	3	5	6	5	5	6	6
	400 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	800 ppm	1	1	1	0	0	-	-	-	-	-	-	-	-	-
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	400 ppm	0	1	1	0	1	1	1	1	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
M. NOSE	Control	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
M. PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	1	1	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 14

Clinical sign	Group Name	Administration Week-day											
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7
EXOPHTHALMOS	Control	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	2	2	1	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
EYE OPACITY	Control	5	5	5	5	5	5	5	5	5	5	5	5
	200 ppm	5	5	4	4	4	4	4	4	4	4	4	4
	400 ppm	1	1	0	0	0	0	0	0	0	1	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
CATARACT	Control	3	3	3	3	3	3	3	3	3	3	3	3
	200 ppm	5	5	4	4	4	4	4	4	4	4	4	4
	400 ppm	1	1	0	0	0	0	0	0	0	1	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
CORNEAL OPACITY	Control	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
EXTERNAL MASS	Control	8	8	8	9	10	9	9	9	9	10	10	10
	200 ppm	6	6	5	4	4	4	4	4	4	4	4	4
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	1	0	0	0	0	0	0	0	0	0
	400 ppm	1	1	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
M. NOSE	Control	1	1	1	2	2	2	2	2	2	2	2	2
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
M. PERI MOUTH	Control	0	0	0	0	1	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 15

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 16

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 17

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 18

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0	0	0	1	1	0	0	1
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 19

Clinical sign	Group Name	Administration Week-day			60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		57-7	58-7	59-7											
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	1	1	1	1	1	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400 ppm	1	1	1	1	1	1	1	1	0	0	0	0	0	0
	800 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	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	1	1	1	1	2	1	1	2	0	0	0	0	1	1
	800 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 20

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	200 ppm	2	2	2	2	2	2	2	2	2	2	2	2	3	3
	400 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
M. ANTERIOR. DORSUM	Control	1	1	1	2	2	2	2	2	2	2	2	3	4	4
	200 ppm	0	0	0	0	0	0	0	0	1	2	2	2	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	0	0	-	-	-	-	-	-	-	-	-
M. HINDLIMB	Control	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	1	0	0	0	0	0	1	1	1	0	1
	400 ppm	3	1	2	4	2	3	0	0	1	1	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 21

Clinical sign	Group Name	Administration Week-day											
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
M. NECK	Control	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
M. ABDOMEN	Control	1	1	1	1	1	1	1	1	1	2	2	2
	200 ppm	3	3	2	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
M. ANTERIOR. DORSUM	Control	4	4	4	4	4	4	4	4	4	4	4	4
	200 ppm	2	2	2	2	2	2	2	2	2	2	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
M. HINDLIMB	Control	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	3	0	1	0	0	1	3	3	3	5	4	4
	400 ppm	1	1	0	0	0	0	0	1	1	1	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	1	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 22

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 23

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 24

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
TACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 25

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 26

Clinical sign	Group Name	Administration Week-day													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	2	1	1	1	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	1	1	2	2	2	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	1	0	0	2	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	400 ppm	0	0	0	0	1	1	0	2	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	1	1	1	1	1	1	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 27

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
TORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	2	2	2	2	2	3	3	3	3	3	3	3	3	3
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	400 ppm	0	0	0	2	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	400 ppm	1	0	0	2	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
TACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 28

Clinical sign	Group Name	Administration Week-day											
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
TORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	3	3	3	3	3	3	3	3	3	3	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	1	1	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	1	1	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
TACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 29

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 30

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 31

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	1	1	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0

(HAN190)

BAIS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 32

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	1	1	0	0	0	0	0	0	0	0	0	0
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	1
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	800 ppm	0	0	1	1	1	0	0	1	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 33

Clinical sign	Group Name	Administration Week-day													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	1	1	1	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	1	0	1	0	0	0	3	1	1
	800 ppm	0	0	0	1	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
	200 ppm	0	0	0	0	0	1	1	1	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	2	1	2	0	0	0	3	1	1
	800 ppm	0	0	0	1	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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 3

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 34

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	400 ppm	2	1	1	2	2	1	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	1	1	1	0	0
	200 ppm	0	0	0	0	0	0	0	0	1	1	1	0	0	0
	400 ppm	2	1	0	4	1	1	0	0	0	1	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	1	1	1	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	2	1	0	1	1
	400 ppm	1	1	0	4	1	1	0	0	0	1	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	-	-	-	-	-	-	-	-	-

(HAN190)

BAIS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 96

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 35

Clinical sign	Group Name	Administration Week-day											
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	0	0	0	0	0	2	1	1	2	1	1
	400 ppm	1	2	0	0	0	0	0	1	1	1	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
SMALL STOOL	Control	0	0	0	0	0	0	1	1	1	0	0	0
	200 ppm	2	1	0	0	0	0	2	2	2	1	1	1
	400 ppm	1	1	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	0	0	0	0	1	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	-	-
	800 ppm	-	-	-	-	-	-	-	-	-	-	-	-

(HAN190)

BAIS 3

APPENDIX A 2

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATAXIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 2

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATAXIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 3

Clinical sign	Group Name	Administration Week day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATAXIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 4

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	1	1	1	1	1	1	1	1	1	1	1	2	2
	600 ppm	2	2	2	2	2	2	3	3	3	3	4	6	6	8
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATAXIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 5

Clinical sign	Group Name	Administration Week-day													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
DEATH	Control	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	300 ppm	2	3	3	3	3	3	4	5	5	5	6	6	7	7
	600 ppm	9	9	12	12	14	15	16	16	17	18	23	23	24	27
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	1	1	1	1	2	2	2	2	2	2	2	2	2
	600 ppm	1	1	1	2	3	3	3	5	5	5	5	6	7	8
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	1	0	1	0	1	1
ATAXIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	1	0	1	1	1	1

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 6

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
DEATH	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	150 ppm	1	1	1	1	3	3	3	4	4	5	5	5	5	5
	300 ppm	9	10	10	10	11	12	15	16	16	20	21	21	22	23
	600 ppm	29	30	30	33	34	35	36	36	37	37	37	38	38	38
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	1	1	1	1	1	2	2	2
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	2	3	3	3	3	3	3	3	3	3	3	4	4	8
	600 ppm	9	9	9	10	10	10	10	10	10	11	11	11	11	11
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATAXIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOCERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	Control	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	1	1	0	0	1	0	0	0	0	0	0	0	0

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 7

Clinical sign	Group Name	Administration Week-day													
		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	98-7
DEATH	Control	1	1	1	1	1	1	1	1	2	2	2	2	2	2
	150 ppm	5	10	12	12	12	12	13	14	15	15	15	17	17	18
	300 ppm	23	23	24	26	27	28	28	29	29	30	32	33	33	34
	600 ppm	38	38	38	38	-	-	-	-	-	-	-	-	-	-
MORIBUND SACRIFICE	Control	2	2	2	2	2	2	2	2	2	2	3	3	3	3
	150 ppm	0	0	1	1	1	1	1	2	5	5	6	6	6	6
	300 ppm	8	8	8	8	9	9	9	9	9	10	10	10	11	11
	600 ppm	11	11	11	11	-	-	-	-	-	-	-	-	-	-
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	1	0	0	0	0	0	0	0	0	1	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	1	-	-	-	-	-	-	-	-	-	-
ATAXIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 8

Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
DEATH	Control	2	3	3	3	4	4
	150 ppm	20	20	20	21	25	27
	300 ppm	34	34	34	34	35	36
	600 ppm	-	-	-	-	-	-
MORIBUND SACRIFICE	Control	4	5	5	5	5	5
	150 ppm	6	6	6	6	6	6
	300 ppm	12	12	12	12	12	12
	600 ppm	-	-	-	-	-	-
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
HUNCHBACK POSITION	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
ATAXIC GAIT	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	1	1
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
PILOERECTION	Control	0	0	0	0	0	0
	150 ppm	0	0	0	1	1	1
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
FROG BELLY	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
SOILED PERI GENITALIA	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 9

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL GROWTH OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 10

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL GROWTH OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 11

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	600 ppm	0	0	0	0	0	1	1	1	1	1	1	1	1	1
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL GROWTH OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	1	1	0	0	0	0	0	0	0	0	0	1
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 12

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	600 ppm	1	1	1	1	1	1	1	1	2	2	2	2	2	2
EYE OPACITY	Control	1	2	2	2	2	2	2	2	2	2	2	2	2	1
	150 ppm	0	0	1	1	1	1	1	1	1	1	2	2	2	2
	300 ppm	1	1	1	1	1	1	2	2	2	2	2	2	2	2
	600 ppm	0	0	0	0	0	0	0	0	1	1	1	0	0	0
CATARACT	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	150 ppm	0	0	1	1	1	1	1	1	1	1	2	2	2	2
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	1	1	1	0	0	0
CORNEAL OPACITY	Control	0	1	1	1	1	1	1	1	1	1	1	1	1	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	1	1	1	1	1	2	2	2	2	2	2	2	2
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL GROWTH OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	1	0	0	0	0	0	0	1	1	1	1	1	1
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 13

Clinical sign	Group Name	Administration Week-day													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	600 ppm	2	2	2	2	2	2	1	1	1	1	1	1	0	0
EYE OPACITY	Control	1	1	1	2	2	2	2	2	2	2	2	2	2	2
	150 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	300 ppm	1	1	1	1	1	1	1	1	1	1	1	1	2	2
	600 ppm	0	0	0	0	0	0	1	1	1	1	1	1	0	0
CATARACT	Control	1	1	1	2	2	2	2	2	2	2	2	2	2	2
	150 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	300 ppm	0	0	0	0	1	1	1	1	1	1	1	1	2	2
	600 ppm	0	0	0	0	0	0	1	1	1	1	1	1	0	0
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	1	1	1	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL GROWTH OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	150 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	300 ppm	1	1	1	1	1	0	0	1	1	1	1	1	1	1
	600 ppm	0	1	1	1	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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	2	1	1	1	2	2	0	1	1	1	1	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 14

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	2	3	3	3	3	3	3	3	3	3	3	3	3	3
	150 ppm	2	2	2	3	3	3	3	3	3	3	3	3	3	3
	300 ppm	2	2	2	3	3	3	3	3	3	3	3	3	3	2
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	2	3	3	3	3	3	3	3	3	3	3	3	3	3
	150 ppm	2	2	2	3	3	3	3	3	3	3	3	3	3	3
	300 ppm	2	2	2	3	3	3	3	3	3	3	3	3	3	2
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL GROWTH OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	1	2	2	2	2	2	1	1	1	1	1	2	4	4
	150 ppm	2	3	3	3	2	2	2	2	2	4	4	5	5	5
	300 ppm	0	0	1	1	2	2	2	2	2	1	0	1	1	1
	600 ppm	0	1	1	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
	150 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	2
	300 ppm	0	0	0	0	0	0	0	0	3	2	2	1	3	1
	600 ppm	0	0	1	0	0	0	0	0	1	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 15

Clinical sign	Group Name	Administration Week-day													
		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	98-7
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
EYE OPACITY	Control	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	150 ppm	3	3	3	3	3	4	4	4	4	4	4	4	4	4
	300 ppm	2	2	2	1	1	1	1	1	1	1	1	1	1	1
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
CATARACT	Control	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	150 ppm	3	3	3	3	3	4	4	4	4	4	4	4	4	4
	300 ppm	2	2	2	1	1	1	1	1	1	1	1	1	1	1
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
ANTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
ABNORMAL GROWTH OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
EXTERNAL MASS	Control	4	5	5	5	6	6	6	5	5	6	6	6	7	7
	150 ppm	5	2	3	3	4	4	4	4	4	4	4	3	3	3
	300 ppm	1	1	1	1	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	2	1	0	0	0	1	1	1	1	1	2	1	1	1
	300 ppm	1	4	3	3	2	3	3	2	2	1	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 16

Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
EXOPHTHALMOS	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
EYE OPACITY	Control	4	4	4	4	4	4
	150 ppm	4	4	4	3	2	2
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
CATARACT	Control	3	3	3	3	3	3
	150 ppm	4	4	4	3	2	2
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
CORNEAL OPACITY	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
ANTERIOR CHAMBER OPACITY	Control	1	1	1	1	1	1
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
ABNORMAL GROWTH OF TEETH	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
EXTERNAL MASS	Control	8	7	8	8	7	7
	150 ppm	3	3	4	5	4	4
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
INTERNAL MASS	Control	0	0	0	0	0	0
	150 ppm	1	1	2	2	2	2
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 17

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 18

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 19

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 20

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	1	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. FORLIMB	Control	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 21

Clinical sign	Group Name	Administration Week-day													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. FORLIMB	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 22

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	Control	0	1	1	1	1	1	0	0	0	0	0	0	1	1
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	1	1	1	0	0	0	0	0	1	1	1	1	1
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	1	1	1	1	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. FORLIMB	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 23

Clinical sign	Group Name	Administration Week-day													
		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	98-7
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
M. EYE	Control	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
M. PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
M. MANDIBULAR	Control	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
M. FORLIMB	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	150 ppm	2	1	1	1	1	1	1	1	1	1	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 24

Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
M. NOSE	Control	0	0	0	0	0	0
	150 ppm	1	1	1	1	1	1
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
M. EYE	Control	1	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
M. PERI MOUTH	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
M. MANDIBULAR	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
M. PERI EAR	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
M. NECK	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
M. FORLIMB	Control	2	2	2	2	2	2
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
M. BREAST	Control	1	1	2	2	2	2
	150 ppm	0	0	0	1	1	1
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 25

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 26

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 27

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	1	1	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
TORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 28

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	1	1	1	0	1
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	1	1	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 29

Clinical sign	Group Name	Administration Week-day				60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		57-7	58-7	59-7												
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	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	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	1	1	1	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	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	600 ppm	0	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	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	1	1	1	1	1	0	0	0	0	0	0	1	3	3	3
	600 ppm	0	3	1	1	1	1	2	1	1	2	1	2	1	0	0
TORTICOLLIS	Control	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	150 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1
	300 ppm	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	600 ppm	1	1	1	1	1	1	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	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	2	0	1	1	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 30

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	150 ppm	0	0	0	0	0	0	0	0	0	1	1	2	2	2
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	600 ppm	0	1	1	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	1	1
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	1	1	1	1	1	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	1	1	1	1	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	1	2	3	4
	300 ppm	1	0	0	1	0	1	1	0	1	1	1	0	2	1
	600 ppm	0	1	1	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	150 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	300 ppm	1	1	1	1	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	1	1	1	1	1	1	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	1	0	0	0	0	0	1	0
	600 ppm	0	1	1	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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	1	1	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 31

Clinical sign	Group Name	Administration Week-day													
		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	98-7
M. ABDOMEN	Control	1	1	1	1	1	1	1	1	1	1	1	1	2	2
	150 ppm	2	1	1	1	2	2	2	2	2	2	2	2	2	2
	300 ppm	1	1	1	1	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
M. ANTERIOR. DORSUM	Control	1	1	1	1	1	2	2	1	1	1	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
M. GENITALIA	Control	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
ANEMIA	Control	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	150 ppm	4	2	0	0	0	0	1	1	1	1	1	0	1	0
	300 ppm	1	1	1	0	0	1	1	0	1	1	0	0	0	0
	600 ppm	0	0	0	1	-	-	-	-	-	-	-	-	-	-
TORTICOLLIS	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	150 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	1	0	0	0	0	0	1	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 32

Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
M. ABDOMEN	Control	3	3	3	3	2	2
	150 ppm	2	2	3	3	2	2
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
M. ANTERIOR. DORSUM	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
M. HINDLIMB	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
M. GENITALIA	Control	1	1	1	1	1	1
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
ANEMIA	Control	1	1	1	1	1	1
	150 ppm	0	0	1	1	0	1
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
TORTICOLLIS	Control	1	1	1	1	1	1
	150 ppm	1	1	1	1	1	1
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
IRREGULAR BREATHING	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	1	1
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 33

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 34

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 35

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	0
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 36

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	1	1	1	0	1
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	1	1	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	1	1	0	0	0	0
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	1	1	1	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 37

Clinical sign	Group Name	Administration Week-day				60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		57-7	58-7	59-7												
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	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	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	2	0	1	1	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	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	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	1	2	2	2	2
	600 ppm	0	0	0	0	0	0	1	1	1	0	0	1	1	0	0
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	600 ppm	0	1	0	0	0	0	1	1	2	1	1	1	2	1	1
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	1	3	3	3	3
	600 ppm	0	1	0	0	0	0	0	0	2	2	3	2	1	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 38

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	1	1	1	1	1	1	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	1	1	1	1	1	1	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	1	0	0	0	0	0	1	0
	600 ppm	0	1	1	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 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
	150 ppm	0	1	1	1	1	1	1	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	1	1	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0	0
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	1	2	2	2
	300 ppm	1	0	0	0	0	1	1	0	0	1	1	0	1	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SMALL STOOL	Control	0	0	0	0	0	2	0	0	0	0	1	0	0	0
	150 ppm	0	0	0	1	0	1	1	0	0	0	0	1	1	1
	300 ppm	1	0	0	0	0	1	1	0	0	1	1	0	1	0
	600 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0	0
OLIGO-STOOL	Control	0	0	0	0	0	2	0	0	0	0	1	0	0	0
	150 ppm	0	0	0	1	0	1	1	0	0	0	0	0	0	0
	300 ppm	1	0	0	0	0	1	1	0	1	0	0	0	2	0
	600 ppm	0	0	0	0	0	1	0	0	1	0	0	0	0	0

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 39

Clinical sign	Group Name	Administration Week-day													
		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	98-7
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	1	1	1	1	1	1	1	1	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	2	1	0	0	1	1	2	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	1	1	0	0	1	1	1	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	1	1	1	1	1	1	1	1	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	1	1	1	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	3	1	0	0	0	0	1	1	1	1	1	0	0	0
	300 ppm	0	1	1	1	1	0	1	0	0	0	0	0	0	0
	600 ppm	0	0	0	1	-	-	-	-	-	-	-	-	-	-
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	1	1	0	0	0	0	1	1	1	1	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	1	-	-	-	-	-	-	-	-	-	-
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	2	1	1	0	0	0	0	1	1	1	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	1	1	-	-	-	-	-	-	-	-	-	-

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 40

Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
NOISY	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	1	1
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
DEEP BREATHING	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
RED URINE	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
YELLOW URINE	Control	0	0	0	0	0	0
	150 ppm	0	0	2	2	3	3
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
SMALL STOOL	Control	0	0	0	0	0	0
	150 ppm	0	0	0	1	1	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-
OLIGO-STOOL	Control	0	0	0	0	0	0
	150 ppm	0	1	1	1	1	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 41

Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 42

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 43

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 44

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 45

Clinical sign	Group Name	Administration Week-day													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 46

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BATS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 47

Clinical sign	Group Name	Administration Week-day			88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		85-7	86-7	87-7											
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	600 ppm	0	0	0	0	-	-	-	-	-	-	-	-	-	-

(HAN190)

BAIS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 48

Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
SUBNORMAL TEMP	Control	0	0	0	0	0	0
	150 ppm	0	0	0	0	0	0
	300 ppm	0	0	0	0	0	0
	600 ppm	-	-	-	-	-	-

(HAN190)

BAIS 3

APPENDIX B 1

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCri
UNIT : g
REPORT TYPE : A1 96
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration week													
	0		1		2		3		4		5		6	
Control	119 ±	4	145 ±	6	179 ±	8	201 ±	9	225 ±	11	239 ±	12	252 ±	13
200 ppm	119 ±	4	143 ±	5	176 ±	8	198 ±	8	222 ±	8	236 ±	9	248 ±	9
400 ppm	119 ±	4	139 ±	6**	171 ±	8**	193 ±	10**	216 ±	11**	230 ±	12**	243 ±	13**
800 ppm	119 ±	4	124 ±	8**	154 ±	10**	178 ±	10**	202 ±	10**	217 ±	11**	229 ±	12**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-86 weeks)
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (90-96 weeks)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCri
UNIT : g
REPORT TYPE : A1 96
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

Group Name	Administration week						
	7	8	9	10	11	12	13
Control	264 ± 14	272 ± 16	284 ± 16	294 ± 16	300 ± 17	307 ± 18	312 ± 18
200 ppm	260 ± 10	269 ± 10	280 ± 10	290 ± 10	295 ± 11	303 ± 12	309 ± 12
400 ppm	254 ± 14**	263 ± 15*	274 ± 16**	283 ± 17**	287 ± 17**	294 ± 17**	299 ± 17**
800 ppm	240 ± 13**	247 ± 13**	259 ± 14**	268 ± 14**	273 ± 15**	281 ± 15**	287 ± 15**

Significant difference ;	* : $P \leq 0.05$	** : $P \leq 0.01$	Test of Dunnett (0-86 weeks)
Significant difference ;	* : $P \leq 0.05$	** : $P \leq 0.01$	Test of t (90-96 weeks)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCri
UNIT : g
REPORT TYPE : A1 96
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 3

Group Name	Administration week									
	14		18		22		26		30	
	34		38							
Control	317 ±	18	336 ±	19	352 ±	21	367 ±	22	377 ±	23
	385 ± 25		392 ± 24							
200 ppm	313 ±	12	332 ±	14	346 ±	16	359 ±	18	367 ±	19
	375 ± 20		384 ± 19							
400 ppm	304 ±	17**	322 ±	19**	337 ±	20**	350 ±	22**	358 ±	23**
	364 ± 25**		371 ± 26**							
800 ppm	291 ±	16**	310 ±	18**	323 ±	20**	334 ±	22**	343 ±	23**
	346 ± 26**		351 ± 28**							

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-86 weeks)
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (90-96 weeks)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCri
 UNIT : g
 REPORT TYPE : A1 96
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week						
	42	46	50	54	58	62	66
Control	403 ± 26	411 ± 26	418 ± 25	422 ± 26	427 ± 26	431 ± 26	433 ± 27
200 ppm	394 ± 20	399 ± 21	406 ± 21*	412 ± 22	414 ± 20*	414 ± 23*	416 ± 22**
400 ppm	378 ± 27**	384 ± 27**	390 ± 26**	391 ± 30**	393 ± 28**	387 ± 36**	393 ± 28**
800 ppm	356 ± 31**	356 ± 31**	361 ± 21**	362 ± 22**	357 ± 17**	358 ± 24**	349 ± 37**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-86 weeks)
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (90-96 weeks)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCri
 UNIT : g
 REPORT TYPE : A1 96
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

Group Name	Administration week											
	70		74		78		82		86		90	
Control	436 ±	28	440 ±	28	444 ±	28	442 ±	31	442 ±	30	442 ±	34
200 ppm	416 ±	22**	418 ±	27**	416 ±	28**	413 ±	33**	404 ±	55**	398 ±	31**
400 ppm	381 ±	31**	376 ±	39**	372 ±	25**	359 ±	32**	329 ±	55**	353 ±	2 ?
800 ppm	355 ±	45 ?	298 ±	0 ?	—		—		—		—	

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-86 weeks)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (90-96 weeks)

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCri
UNIT : g
REPORT TYPE : A1 96
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 6

Group Name	Administration week
	96
Control	438 ± 34
200 ppm	379 ± 55**
400 ppm	—
800 ppm	—
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-86 weeks)	
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (90-96 weeks)	

APPENDIX B 2

BODY WEIGHT CHANGES : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCri
UNIT : g
REPORT TYPE : A2 104
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week													
	0		1		2		3		4		5		6	
Control	99 ±	4	111 ±	5	125 ±	5	132 ±	6	144 ±	6	149 ±	7	155 ±	7
150 ppm	99 ±	4	109 ±	4	122 ±	5*	129 ±	6*	140 ±	6*	146 ±	7*	151 ±	8*
300 ppm	99 ±	4	107 ±	4**	119 ±	4**	126 ±	5**	136 ±	5**	141 ±	6**	146 ±	7**
600 ppm	99 ±	4	100 ±	5**	113 ±	5**	122 ±	6**	131 ±	6**	136 ±	7**	141 ±	7**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-102 weeks)
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (104 weeks)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCri
UNIT : g
REPORT TYPE : A2 104
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

Group Name	Administration week											
	7		8		9		10		11		12	
Control	158 ±	8	162 ±	7	166 ±	8	170 ±	8	172 ±	9	174 ±	9
150 ppm	154 ±	8*	158 ±	9*	163 ±	9	167 ±	9	169 ±	9	171 ±	10
300 ppm	149 ±	7**	151 ±	8**	156 ±	9**	159 ±	9**	160 ±	10**	163 ±	10**
600 ppm	144 ±	7**	146 ±	8**	150 ±	9**	153 ±	9**	154 ±	10**	157 ±	10**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-102 weeks)
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (104 weeks)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCri
UNIT : g
REPORT TYPE : A2 104
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 3

Group Name	Administration week						
	14	18	22	26	30	34	38
Control	177 ± 9	185 ± 9	190 ± 10	196 ± 11	201 ± 11	204 ± 12	209 ± 13
150 ppm	174 ± 10	182 ± 11	188 ± 12	194 ± 12	198 ± 13	201 ± 14	206 ± 14
300 ppm	166 ± 10**	173 ± 11**	178 ± 12**	182 ± 13**	187 ± 14**	189 ± 14**	193 ± 15**
600 ppm	161 ± 10**	166 ± 11**	170 ± 12**	174 ± 12**	179 ± 13**	180 ± 13**	184 ± 15**

Significant difference ;	* : $P \leq 0.05$	** : $P \leq 0.01$	Test of Dunnett (0-102 weeks)
Significant difference ;	* : $P \leq 0.05$	** : $P \leq 0.01$	Test of t (104 weeks)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCri
UNIT : g
REPORT TYPE : A2 104
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 4

Group Name	Administration week													
	42		46		50		54		58		62		66	
Control	214 ±	14	219 ±	15	225 ±	15	230 ±	18	233 ±	19	238 ±	22	244 ±	23
150 ppm	213 ±	15	219 ±	16	224 ±	16	229 ±	18	234 ±	21	239 ±	22	245 ±	23
300 ppm	196 ±	16**	201 ±	18**	206 ±	19**	208 ±	20**	211 ±	20**	214 ±	20**	219 ±	19**
600 ppm	185 ±	15**	189 ±	16**	193 ±	17**	197 ±	17**	196 ±	18**	195 ±	20**	189 ±	23**

Significant difference ;	* : $P \leq 0.05$	** : $P \leq 0.01$	Test of Dunnett (0-102 weeks)
Significant difference ;	* : $P \leq 0.05$	** : $P \leq 0.01$	Test of t (104 weeks)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCri
UNIT : g
REPORT TYPE : A2 104
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 5

Group Name	Administration week											
	70		74		78		82		86		90	
Control	249 ±	24	256 ±	26	263 ±	26	266 ±	26	269 ±	26	273 ±	29
150 ppm	250 ±	24	254 ±	30	262 ±	24	258 ±	28	253 ±	36*	258 ±	33*
300 ppm	215 ±	19**	217 ±	20**	222 ±	19**	221 ±	20**	213 ±	21**	215 ±	21**
600 ppm	180 ±	23**	188 ±	12**	181 ±	10**	180 ±	0 ?	177 ±	0 ?	—	—

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-102 weeks)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (104 weeks)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCri
 UNIT : g
 REPORT TYPE : A2 104
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 6

Group Name	Administration week			
	96	98	102	104
Control	279 ± 33	278 ± 33	284 ± 41	284 ± 47
150 ppm	257 ± 30*	255 ± 42*	252 ± 56**	234 ± 34**
300 ppm	211 ± 15**	201 ± 14**	192 ± 2**	184 ± 13 ?
600 ppm	—	—	—	—

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-102 weeks)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (104 weeks)

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

APPENDIX C 1

WATER CONSUMPTION CHANGES : SUMMARY, RAT : MALE
(2-YEAR STUDY)

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : g

SEX : MALE

WATER 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	17.0	18.3	19.8	21.6	21.4	21.3	21.9
200ppm	14.7	15.3	15.8	16.6	16.8	16.4	16.1
400ppm	11.9	12.7	13.1	13.3	13.6	13.7	13.5
800ppm	9.3	11.2	12.0	12.5	12.6	12.6	12.3

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : g

SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 2

Group Name	Administration week-day(effective)						
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	—	24.8	24.0	25.2	18.9	18.6	18.2
200ppm	16.2	16.8	16.6	16.2	16.8	16.9	16.9
400ppm	13.6	14.2	13.7	13.5	14.2	13.6	13.4
800ppm	12.4	12.8	12.6	12.6	14.4	15.2	12.7

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : g

SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 3

Group Name	Administration week-day(effective)						
	18-7(7)	22-7(7)	26-7(7)	30-7(7)	34-7(7)	38-7(7)	42-7(7)
Control	17.9	18.4	18.8	18.4	17.3	19.2	18.5
200ppm	15.4	15.4	15.5	15.5	15.2	15.2	14.9
400ppm	13.1	13.2	13.1	13.0	13.0	13.8	13.2
800ppm	12.1	12.0	12.0	12.3	12.0	12.6	12.3

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : g

SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 4

Group Name	Administration week-day(effective)						
	46-7(7)	50-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)	70-7(7)
Control	17.7	18.1	18.9	17.6	18.3	18.3	18.7
200ppm	15.0	15.7	15.7	15.6	15.3	15.7	14.6
400ppm	13.4	14.1	14.2	14.6	13.3	13.3	12.7
800ppm	12.4	12.0	11.8	10.9	11.0	10.9	11.3

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : g

SEX : MALE

WATER CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 5

Group Name	Administration week-day(effective)						
	74-7(7)	78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)	96-7(7)
Control	18.6	18.7	19.3	19.5	20.4	22.4	22.7
200ppm	14.9	15.1	15.1	15.2	14.8	15.5	14.9
400ppm	12.1	12.4	11.5	13.4	13.1	6.7	
800ppm	9.7						

APPENDIX C 2

WATER CONSUMPTION CHANGES : SUMMARY, RAT : FEMALE
(2-YEAR STUDY)

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : g

SEX : FEMALE

WATER 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	14.7	16.0	15.9	17.2	18.8	19.8	18.8
150ppm	12.8	12.3	12.2	13.0	13.0	12.8	12.3
300ppm	10.2	9.8	9.5	9.3	9.0	9.1	8.7
600ppm	7.5	8.2	8.3	8.1	7.8	8.9	8.3

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : g

SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 2

Group Name	Administration week-day(effective)						
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	18.3	17.8	17.7	19.4	19.7	19.3	17.5
150ppm	11.6	12.7	12.6	12.4	12.9	13.0	12.5
300ppm	8.2	8.4	8.2	8.5	8.5	8.7	9.1
600ppm	7.5	7.4	7.1	7.4	7.3	7.7	8.4

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : g

SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 3

Group Name	Administration week-day(effective)						
	18-7(7)	22-7(7)	26-7(7)	30-7(7)	34-7(7)	38-7(7)	42-7(7)
Control	15.8	16.4	16.2	15.9	14.9	15.9	16.1
150ppm	12.2	11.8	12.2	12.3	14.6	13.1	12.6
300ppm	8.9	8.5	13.0	10.1	10.3	11.4	9.9
600ppm	10.1	11.9	8.3	8.6	8.6	8.9	8.6

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : g

SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 4

Group Name	Administration week-day(effective)						
	46-7(7)	50-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)	70-7(7)
Control	15.4	17.4	15.9	16.2	16.2	17.3	16.3
150ppm	13.1	13.0	13.4	12.8	15.2	14.1	14.3
300ppm	—	10.3	10.2	10.8	12.2	13.1	11.0
600ppm	—	9.4	9.3	9.4	10.2	10.5	11.3

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : g

SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 5

Group Name	Administration week-day(effective)						
	74-7(7)	78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)	96-7(7)
Control	20.1	19.0	22.2	19.9	18.5	19.1	17.8
150ppm	14.1	14.4	13.4	14.4	15.1	16.1	16.0
300ppm	11.7	12.7	13.2	14.4	14.2	16.7	15.5
600ppm	11.7	11.7	8.4	9.7			

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : g

SEX : FEMALE

WATER CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 6

Group Name	Administration week-day(effective)		
	98-7(7)	102-7(7)	104-7(7)
Control	20.6	20.8	21.2
150ppm	16.4	16.7	21.7
300ppm	12.7	14.3	15.8
600ppm			

APPENDIX D 1

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCri
 UNIT : g
 REPORT TYPE : A1 96
 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)	
Control	13.3 ± 0.9		14.8 ± 0.9		16.1 ± 1.0		16.3 ± 1.0		15.9 ± 1.2	
200 ppm	12.9 ± 0.6		14.4 ± 0.9		15.5 ± 0.8**		15.9 ± 1.0		15.7 ± 0.9	
400 ppm	12.2 ± 0.7**		13.8 ± 0.9**		14.8 ± 1.0**		15.2 ± 0.9**		15.2 ± 1.0**	
800 ppm	10.1 ± 1.1**		12.6 ± 0.9**		14.0 ± 0.8**		14.7 ± 0.8**		14.6 ± 0.9**	

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-86 weeks)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (90-96 weeks)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCri
 UNIT : g
 REPORT TYPE : A1 96
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day(effective)													
	8-7 (7)		9-7 (7)		10-7 (7)		11-7 (7)		12-7 (7)		13-7 (7)		14-7 (7)	
Control	15.8 ±	1.2	15.9 ±	1.1	15.9 ±	1.2	15.8 ±	1.1	15.6 ±	1.1	15.2 ±	1.0	15.3 ±	1.0
200 ppm	15.8 ±	1.0	15.8 ±	0.9	15.8 ±	0.9	15.6 ±	0.9	15.7 ±	1.0	15.2 ±	0.9	15.3 ±	0.9
400 ppm	15.0 ±	1.1**	15.3 ±	1.0*	15.4 ±	1.0*	15.1 ±	1.1**	15.2 ±	1.0	14.7 ±	0.9*	14.8 ±	0.9*
800 ppm	14.3 ±	1.1**	14.6 ±	0.9**	14.5 ±	1.0**	14.6 ±	1.0**	14.9 ±	1.0**	14.6 ±	1.0**	14.5 ±	1.1**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-86 weeks)
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (90-96 weeks)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCri
UNIT : g
REPORT TYPE : A1 96
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective)									
	18-7 (7)		22-7 (7)		26-7 (7)		30-7 (7)		34-7 (7)	
Control	15.3 ±	1.0	15.0 ±	0.9	15.3 ±	1.0	15.3 ±	0.9	15.2 ±	1.0
200 ppm	15.3 ±	1.0	14.9 ±	0.9	15.2 ±	1.0	15.3 ±	1.0	15.1 ±	0.9
400 ppm	15.0 ±	1.1	14.9 ±	1.0	15.0 ±	1.1	15.0 ±	1.2	14.8 ±	1.1
800 ppm	14.6 ±	1.0**	14.3 ±	1.0**	14.4 ±	1.3**	14.7 ±	1.0**	14.6 ±	1.1**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-86 weeks)
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (90-96 weeks)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCri
 UNIT : g
 REPORT TYPE : A1 96
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE: 4

Group Name	Administration week-day(effective)													
	46-7 (7)		50-7 (7)		54-7 (7)		58-7 (7)		62-7 (7)		66-7 (7)		70-7 (7)	
Control	15.9 ±	1.0	16.2 ±	0.9	16.7 ±	1.4	16.2 ±	0.9	15.7 ±	0.9	16.3 ±	1.0	16.4 ±	1.0
200 ppm	15.9 ±	1.0	16.1 ±	1.0	15.7 ±	1.2**	16.1 ±	0.9	15.4 ±	1.6	16.2 ±	1.2	15.9 ±	1.0*
400 ppm	15.6 ±	1.1	15.8 ±	1.1	15.1 ±	1.7**	15.7 ±	1.2**	14.5 ±	2.7**	15.8 ±	1.3	14.7 ±	2.2**
800 ppm	14.7 ±	2.0**	15.0 ±	1.4**	14.8 ±	1.4**	14.3 ±	2.6**	14.3 ±	1.0*	15.6 ±	1.2	15.5 ±	0.0 ?

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-86 weeks)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (90-96 weeks)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 UNIT : g
 REPORT TYPE : A1 96
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

Group Name	Administration week-day(effective)											
	74-7 (7)		78-7 (7)		82-7 (7)		86-7 (7)		90-7 (7)		94-7 (7)	
Control	16.3 ±	1.2	16.6 ±	1.1	16.0 ±	2.2	15.9 ±	1.4	16.4 ±	1.6	16.3 ±	1.3
200 ppm	15.5 ±	1.4*	16.0 ±	1.4*	15.4 ±	2.0	14.7 ±	2.0**	14.9 ±	2.4**	14.9 ±	2.0**
400 ppm	13.6 ±	3.2**	14.5 ±	2.1**	14.0 ±	1.8	11.0 ±	3.6**	14.4 ±	0.6	4.7 ±	3.3 ?
800 ppm	13.9 ±	0.0 ?	—		—		—		—		—	

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-86 weeks)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (90-96 weeks)

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

APPENDIX D 2

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCri
UNIT : g
REPORT TYPE : A2 104
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective)									
	1-7 (7)		2-7 (7)		3-7 (7)		4-7 (7)		5-7 (7)	
Control	10.7 ± 0.6	10.5 ± 0.8	10.6 ± 0.6	10.9 ± 0.7	10.3 ± 0.6	10.4 ± 1.1	10.0 ± 0.7			
150 ppm	10.2 ± 0.7**	10.0 ± 0.7**	10.2 ± 0.7**	10.2 ± 0.7**	9.8 ± 0.7**	10.0 ± 0.8	9.5 ± 0.8**			
300 ppm	9.9 ± 0.6**	9.9 ± 0.6**	9.9 ± 0.6**	10.0 ± 0.7**	9.6 ± 0.7**	10.5 ± 1.5	9.4 ± 0.8**			
600 ppm	8.6 ± 0.6**	9.6 ± 0.7**	9.9 ± 0.7**	9.8 ± 0.8**	9.4 ± 0.7**	9.6 ± 0.8**	9.3 ± 0.8**			

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-102 weeks)
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (104 weeks)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCri
UNIT : g
REPORT TYPE : A2 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)	
Control	10.1 ±	0.7	10.1 ±	0.7	10.2 ±	0.8	10.1 ±	0.7	10.3 ±	0.7
									10.0 ±	0.7
										10.1 ±
										0.7
150 ppm	9.6 ±	0.8**	9.8 ±	0.7	9.9 ±	0.7	9.8 ±	0.6	9.8 ±	0.8**
									9.7 ±	0.7
										9.8 ±
										0.7
300 ppm	9.5 ±	0.8**	9.6 ±	0.8**	9.6 ±	0.8**	9.5 ±	0.8**	9.6 ±	0.8**
									9.4 ±	0.8**
										9.7 ±
										0.8*
600 ppm	9.2 ±	0.8**	9.4 ±	0.8**	9.2 ±	0.8**	9.1 ±	0.9**	9.3 ±	0.8**
									9.3 ±	0.8**
										9.7 ±
										0.8*

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-102 weeks)
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (104 weeks)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCri
 UNIT : g
 REPORT TYPE : A2 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week-day(effective)									
	18-7 (7)		22-7 (7)		26-7 (7)		30-7 (7)		34-7 (7)	
Control	9.6 ± 0.7		10.0 ± 0.7		10.1 ± 0.8		10.2 ± 0.6		10.1 ± 0.8	
150 ppm	9.4 ± 0.7		9.6 ± 0.7		9.6 ± 0.7*		9.9 ± 0.7		9.0 ± 1.5**	
300 ppm	9.7 ± 0.7		9.4 ± 0.8**		9.6 ± 0.8*		9.7 ± 0.7**		9.9 ± 0.7	
600 ppm	9.4 ± 0.7		9.4 ± 0.7**		9.4 ± 0.8**		9.5 ± 0.8**		9.8 ± 0.7	

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-102 weeks)
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (104 weeks)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCri
 UNIT : g
 REPORT TYPE : A2 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE: 4

Group Name	Administration week-day(effective)									
	46-7 (7)		50-7 (7)		54-7 (7)		58-7 (7)		62-7 (7)	
Control	10.9 ±	1.0	11.2 ±	0.9	10.8 ±	1.0	11.1 ±	0.9	11.3 ±	1.4
									11.7 ±	1.0
										11.5 ±
										1.0
150 ppm	10.7 ±	0.8	10.8 ±	0.8	10.6 ±	0.8	10.8 ±	1.0	11.1 ±	0.9
									11.6 ±	1.0
										11.3 ±
										1.0
300 ppm	10.3 ±	0.9*	10.7 ±	1.0*	10.5 ±	1.7	10.8 ±	1.0	10.7 ±	1.0**
									11.3 ±	1.2
										10.6 ±
										1.6**
600 ppm	9.9 ±	1.0**	10.3 ±	1.1**	10.3 ±	0.9	10.2 ±	1.1**	10.1 ±	1.1**
									9.9 ±	2.2**
										9.8 ±
										1.3**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-102 weeks)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (104 weeks)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCri
 UNIT : g
 REPORT TYPE : A2 104
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 5

Group Name	Administration week-day(effective)												
	74-7 (7)		78-7 (7)		82-7 (7)		86-7 (7)		90-7 (7)		94-7 (7)		96-7 (7)
Control	11.8 ±	1.5	12.0 ±	1.1	11.6 ±	0.9	11.8 ±	1.2	12.1 ±	1.4	11.7 ±	1.5	—
150 ppm	11.2 ±	2.1	11.7 ±	1.2	10.8 ±	1.7*	11.0 ±	2.5	11.7 ±	2.0	11.8 ±	1.4	—
300 ppm	10.6 ±	1.6**	11.3 ±	1.2*	10.8 ±	1.7*	10.3 ±	1.5**	11.2 ±	1.1*	11.0 ±	0.6	—
600 ppm	9.8 ±	1.9*	10.7 ±	0.8	10.1 ±	0.0 ?	9.7 ±	0.0 ?	—		—		—

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-102 weeks)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (104 weeks)

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCri
UNIT : g
REPORT TYPE : A2 104
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 6

Group Name	Administration week-day(effective)					
	98-7 (7)		102-7 (7)		104-7 (7)	
Control	11.7 ±	2.0	11.9 ±	1.8	12.0 ±	2.2
150 ppm	11.5 ±	2.2	10.7 ±	2.4*	10.8 ±	2.7
300 ppm	9.3 ±	1.7*	8.8 ±	1.3**	8.7 ±	3.3 ?
600 ppm	—		—		—	

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (0-102 weeks)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of t (104 weeks)

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

APPENDIX E 1

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

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : mg/kgBW/day

SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 1

Group Name	Administration week						
	1	2	3	4	5	6	7
Control	0	0	0	0	0	0	0
200ppm	21	17	16	15	14	13	12
400ppm	34	30	27	25	24	22	21
800ppm	60	58	54	50	47	44	41

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : mg/kgBW/day

SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 2

Group Name	Administration week						
	8	9	10	11	12	13	14
Control	0	0	0	0	0	0	0
200ppm	12	12	11	11	11	11	11
400ppm	21	21	19	19	19	18	18
800ppm	40	40	38	37	41	42	35

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : mg/kgBW/day

SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 3

Group Name	Administration week						
	18	22	26	30	34	38	42
Control	0	0	0	0	0	0	0
200ppm	9	9	9	8	8	8	8
400ppm	16	16	15	15	14	15	14
800ppm	31	30	29	29	28	29	28

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : mg/kgBW/day

SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 4

Group Name	Administration week						
	46	50	54	58	62	66	70
Control	0	0	0	0	0	0	0
200ppm	8	8	8	8	7	8	7
400ppm	14	14	15	15	14	14	13
800ppm	28	27	26	24	25	25	25

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : mg/kgBW/day

SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 5

Group Name	Administration week						
	74	78	82	86	90	94	96
Control	0	0	0	0	0	0	0
200ppm	7	7	7	8	7	8	8
400ppm	13	13	13	16	15	10	
800ppm	26						

APPENDIX E 2

CHEMICAL INTAKE CHANGES : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : mg/kgBW/day

SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 1

Group Name	Administration week						
	1	2	3	4	5	6	7
Control	0	0	0	0	0	0	0
150ppm	18	15	14	14	13	13	12
300ppm	29	25	23	20	19	19	17
600ppm	45	44	41	37	35	38	35

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : mg/kgBW/day

SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 2

Group Name	Administration week						
	8	9	10	11	12	13	14
Control	0	0	0	0	0	0	0
150ppm	11	12	11	11	11	11	11
300ppm	16	16	16	16	16	16	16
600ppm	31	30	28	29	28	30	31

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : mg/kgBW/day

SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 3

Group Name	Administration week						
	18	22	26	30	34	38	42
Control	0	0	0	0	0	0	0
150ppm	10	9	9	9	11	10	9
300ppm	15	14	21	16	16	18	15
600ppm	37	42	29	29	29	29	28

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : mg/kgBW/day

SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 4

Group Name	Administration week						
	46	50	54	58	62	66	70
Control	0	0	0	0	0	0	0
150ppm	9	9	9	8	10	9	9
300ppm	—	15	15	15	17	18	15
600ppm	—	29	28	29	31	33	38

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : mg/kgBW/day

SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 5

Group Name	Administration week						
	74	78	82	86	90	94	96
Control	0	0	0	0	0	0	0
150ppm	8	8	8	9	9	9	9
300ppm	16	17	18	20	20	23	22
600ppm	37	39	28	33			

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

UNIT : mg/kgBW/day

SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

PAGE:6

Group Name	Administration week		
	98	102	104
Control	0	0	0
150ppm	10	10	14
300ppm	19	22	26
600ppm			

APPENDIX F 1

HEMATOLOGY : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 MEASURE. TIME : 1
 SEX : MALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (97W)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ³ /μl	
Control	49	8.24±	1.43	14.2±	2.1	42.8±	5.2	53.3±	9.7	17.5±	2.0	33.0±	1.8	800±	170
200 ppm	16	8.09±	1.40	12.5±	2.6**	38.8±	6.7*	48.0±	2.5**	15.3±	1.4**	31.8±	1.9*	960±	223**
400 ppm	0	-		-		-		-		-		-		-	
800 ppm	0	-		-		-		-		-		-		-	

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

Test of t

(HCL070)

BAIS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : MALE

HEMATOLOGY (SUMMARY)
ALL ANIMALS (97W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	WBC 10 ⁹ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	49	6.04±	5.04	2±	3	53±	10	1±	1	0±	0	4±	2	32±	9	8±	11
200 ppm	16	6.09±	2.59	4±	3	49±	8	1±	1	0±	0	4±	2	33±	8	10±	5
400 ppm	0	-		-		-		-		-		-		-		-	
800 ppm	0	-		-		-		-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of t

(HCL070)

BAIS 3

APPENDIX F 2

HEMATOLOGY : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 MEASURE. TIME : 2
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A2

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ³ /μl	
Control	41	7.91±	1.16	14.2±	2.0	42.8±	5.4	54.3±	3.1	17.9±	0.8	33.1±	1.1	710±	207
150 ppm	17	6.14±	2.34**	11.1±	3.6**	34.9±	9.3**	62.0±	16.6	19.1±	3.6	31.3±	2.6*	674±	333
300 ppm	! 2	7.73±	0.33	12.2±	0.3	38.7±	1.0	50.1±	0.8	15.8±	0.3	31.5±	0.0	853±	178
600 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

Test of t

! : Significant test is not applied to this group.

STUDY NO. : 0303

ANIMAL : RAT F344/DuCrj

MEASURE. TIME : 2

SEX : FEMALE

REPORT TYPE : A2

HEMATOLOGY (SUMMARY)

ALL ANIMALS (105W)

PAGE : 2

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	41	2.62±	2.13	2±	2	46±	12	1±	1	0±	0	4±	2	36±	12	10±	12
150 ppm	17	18.19±	57.85	5±	5*	44±	18	1±	1	0±	0	3±	2	26±	11**	20±	22
300 ppm	! 2	6.27±	5.35	5±	2	29±	20	2±	2	0±	0	1±	1	30±	2	35±	23
600 ppm	0	-		-		-		-		-		-		-		-	

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

Test of t

! : Significant test is not applied to this group.

(HCL070)

BAIS 3

APPENDIX G 1

BIOCHEMISTRY : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (97W)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g /dl		ALBUMIN g /dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	49	6.8±	0.3	3.5±	0.2	1.1±	0.1	0.19±	0.22	147±	19	186±	54	102±	76
200 ppm	16	6.8±	0.4	3.6±	0.2	1.1±	0.1	0.18±	0.04	133±	20*	217±	79	117±	100
400 ppm	0	-		-		-		-		-		-		-	
800 ppm	0	-		-		-		-		-		-		-	

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

Test of t

(HCL074)

BAIS 3

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (97W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT I U / ℓ		GPT I U / ℓ		LDH I U / ℓ		ALP I U / ℓ		G-GTP I U / ℓ		CPK I U / ℓ	
Control	49	258±	70	79±	53	38±	12	205±	300	202±	55	9±	4	87±	44
200 ppm	16	309±	114	1370±	3692	495±	1165	391±	494	304±	158*	47±	79	102±	33
400 ppm	0	-		-		-		-		-		-		-	
800 ppm	0	-		-		-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of t

(HCL074)

BAIS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (97W)

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	49	18.2±	4.4	0.6±	0.1	143±	2	3.8±	0.3	108±	2	10.6±	0.3	4.0±	0.8
200 ppm	16	17.7±	2.4	0.5±	0.1	143±	2	3.9±	0.3	108±	2	10.7±	0.3	4.3±	0.6
400 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-	-
800 ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of t

(HCL074)

BAIS 3

APPENDIX G 2

BIOCHEMISTRY : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 MEASURE. TIME : 2
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A2

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g /dl		ALBUMIN g /dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	41	7.0±	0.5	4.0±	0.3	1.4±	0.1	0.16±	0.13	144±	18	137±	32	66±	56
150 ppm	17	6.8±	0.7	3.7±	0.4**	1.2±	0.2**	0.67±	1.21	115±	24**	185±	55**	132±	79**
300 ppm	! 2	7.5±	0.4	4.2±	0.3	1.3±	0.0	0.49±	0.30	114±	24	269±	74	345±	333
600 ppm	0	-		-		-		-		-		-		-	

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

Test of t

! : Significant test is not applied to this group.

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 MEASURE. TIME : 2
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A2

PAGE : 2

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT I U / ℓ		GPT I U / ℓ		LDH I U / ℓ		ALP I U / ℓ		G-GTP I U / ℓ		CPK I U / ℓ	
Control	41	245±	51	127±	118	52±	26	212±	96	117±	71	4±	3	92±	39
150 ppm	17	329±	87**	678±	683**	238±	252**	735±	773*	274±	183**	43±	49**	155±	118*
300 ppm	! 2	470±	166	3174±	423	1108±	425	956±	308	597±	382	264±	62	135±	25
600 ppm	0	-		-		-		-		-		-		-	

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

! : Significant test is not applied to this group.

(HCL074)

BAIS 3

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 MEASURE. TIME : 2
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (105W)

REPORT TYPE : A2

PAGE : 3

Group Name	NO. of Animals	UREA NITROGEN mg/dℓ		CREATININE mg/dℓ		SODIUM mEq/ℓ		POTASSIUM mEq/ℓ		CHLORIDE mEq/ℓ		CALCIUM mg/dℓ		INORGANIC PHOSPHORUS mg/dℓ	
Control	41	16.4±	2.7	0.5±	0.1	141±	2	3.4±	0.3	105±	2	10.5±	0.3	3.9±	0.6
150 ppm	17	17.4±	3.6	0.5±	0.1	142±	2	3.6±	0.5	105±	5	10.4±	0.5	4.2±	1.1
300 ppm	! 2	24.2±	0.4	0.5±	0.0	142±	1	4.1±	0.4	107±	4	11.2±	0.4	4.1±	0.4
600 ppm	0	-		-		-		-		-		-		-	

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of t

! : Significant test is not applied to this group.

(HCL074)

BAIS 3

APPENDIX H 1

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 MEASURE. TIME : 1
 SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	pH							CHI	Protein						CHI	Glucose						CHI	Ketone body						CHI	Bilirubin				CHI	
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+	4+		-	±	+	2+	3+	4+		-	±	+	2+	3+	4+		-	+	2+	3+		
Control	49	0	0	1	12	20	13	3		0	0	0	18	30	1		49	0	0	0	0	0	0		49	0	0	0	0	0		47	2	0	0	
200 ppm	19	0	0	4	6	4	4	1		0	0	0	2	14	3	*	19	0	0	0	0	0	0		14	5	0	0	0	0	**	16	3	0	0	
400 ppm	0	-	-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-		
800 ppm	0	-	-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-		

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

Test of CHI SQUARE

(HCL101)

BAIS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		—	±	+	2+	3+		±	+	2+	3+	4+	
Control	49	48	0	1	0	0		49	0	0	0	0	
200 ppm	19	18	0	1	0	0		19	0	0	0	0	
400 ppm	0	—	—	—	—	—		—	—	—	—	—	
800 ppm	0	—	—	—	—	—		—	—	—	—	—	

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

Test of CHI SQUARE

(HCL101)

BAIS 3

APPENDIX H 2

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 MEASURE. TIME : 2
 SEX : FEMALE

URINALYSIS

REPORT TYPE : A2

PAGE : 1

Group Name	NO. of Animals	pH_____								CHI	Protein_____						CHI	Glucose_____						CHI	Ketone body						CHI	Bilirubin				CHI
		5.0	6.0	6.5	7.0	7.5	8.0	8.5	-		±	+	2+	3+	4+	-		±	+	2+	3+	4+	-		±	+	2+	3+	4+	-		+	2+	3+		
Control	41	0	1	2	9	9	19	1		0	1	11	14	9	6		41	0	0	0	0	0		24	15	2	0	0	0		41	0	0	0		
150 ppm	17	0	4	9	1	2	1	0	**	0	0	3	6	7	1		17	0	0	0	0	0		10	6	1	0	0	0		15	0	1	1		
300 ppm	2	0	1	1	0	0	0	0	?	0	0	0	0	1	1	?	2	0	0	0	0	0	?	2	0	0	0	0	0	?	2	0	0	0	?	
600 ppm	0	-	-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-		

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

Test of CHI SQUARE

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

STUDY NO. : 0303

URINALYSIS

ANIMAL : RAT F344/DuCrj

MEASURE. TIME : 2

SEX : FEMALE

REPORT TYPE : A2

PAGE : 2

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		—	±	+	2+	3+		±	+	2+	3+	4+	
Control	41	40	1	0	0	0		41	0	0	0	0	
150 ppm	17	17	0	0	0	0		16	1	0	0	0	
300 ppm	2	0	0	0	0	2	?	2	0	0	0	0	?
600 ppm	0	—	—	—	—	—		—	—	—	—	—	

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

Test of CHI SQUARE

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

(HCL101)

BAIS 3

APPENDIX I 1

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 ALL ANIMALS (0 97W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 50 (%)	200 ppm 50 (%)	400 ppm 50 (%)	800 ppm 50 (%)
skin/app	nodule		5 (10)	2 (4)	0 (0)	0 (0)
subcutis	jaundice		0 (0)	0 (0)	1 (2)	0 (0)
	mass		3 (6)	3 (6)	2 (4)	1 (2)
nasal cavit	hemorrhage		0 (0)	0 (0)	1 (2)	0 (0)
lung	red		0 (0)	2 (4)	3 (6)	5 (10)
	red zone		0 (0)	9 (18)	17 (34)	16 (32)
	brown zone		1 (2)	1 (2)	0 (0)	0 (0)
	edema		0 (0)	1 (2)	0 (0)	0 (0)
	nodule		3 (6)	6 (12)	8 (16)	5 (10)
	voluminus		0 (0)	1 (2)	0 (0)	0 (0)
lymph node	enlarged		0 (0)	0 (0)	0 (0)	1 (2)
spleen	enlarged		3 (6)	8 (16)	9 (18)	4 (8)
	black zone		0 (0)	1 (2)	0 (0)	0 (0)
	nodule		0 (0)	1 (2)	0 (0)	0 (0)
	deformed		0 (0)	1 (2)	0 (0)	0 (0)
salivary gl	enlarged		1 (2)	0 (0)	0 (0)	0 (0)
esophagus	nodule		0 (0)	0 (0)	0 (0)	1 (2)
gl stomach	red zone		0 (0)	1 (2)	0 (0)	0 (0)
	ulcer		0 (0)	0 (0)	2 (4)	0 (0)
stomach	nodule		0 (0)	0 (0)	0 (0)	1 (2)
	gas		0 (0)	0 (0)	2 (4)	0 (0)
small intes	nodule		0 (0)	0 (0)	1 (2)	0 (0)

STUDY NO. : 0303
 ANIMAL : RAT F344/Du6rj
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 ALL ANIMALS (0 97W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 50 (%)	200 ppm 50 (%)	400 ppm 50 (%)	800 ppm 50 (%)
liver	pale		0 (0)	0 (0)	1 (2)	0 (0)
	white		0 (0)	0 (0)	1 (2)	0 (0)
	brown		0 (0)	0 (0)	1 (2)	0 (0)
	red zone		0 (0)	3 (6)	0 (0)	1 (2)
	nodule		1 (2)	42 (84)	45 (90)	47 (94)
	cyst		0 (0)	1 (2)	2 (4)	0 (0)
	rough		1 (2)	1 (2)	0 (0)	0 (0)
	nodular		0 (0)	0 (0)	0 (0)	1 (2)
	adhesion		0 (0)	0 (0)	0 (0)	1 (2)
	herniation		2 (4)	5 (10)	3 (6)	0 (0)
pancreas	nodule		0 (0)	2 (4)	1 (2)	2 (4)
kidney	white patch/zone		0 (0)	1 (2)	0 (0)	0 (0)
	deformed		0 (0)	0 (0)	1 (2)	0 (0)
	granular		14 (28)	4 (8)	0 (0)	0 (0)
	compressed		1 (2)	0 (0)	0 (0)	0 (0)
urin bladd	hemorrhage		0 (0)	0 (0)	1 (2)	0 (0)
	urine:marked retention		0 (0)	0 (0)	0 (0)	1 (2)
pituitary	enlarged		4 (8)	4 (8)	2 (4)	0 (0)
	red		1 (2)	0 (0)	0 (0)	0 (0)
	red zone		2 (4)	0 (0)	2 (4)	0 (0)
	black zone		2 (4)	1 (2)	0 (0)	0 (0)
	nodule		2 (4)	2 (4)	2 (4)	0 (0)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 ALL ANIMALS (0 97W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 50 (%)	200 ppm 50 (%)	400 ppm 50 (%)	800 ppm 50 (%)
thyroid	enlarged		2 (4)	3 (6)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	1 (2)	0 (0)
adrenal	enlarged		1 (2)	0 (0)	1 (2)	0 (0)
testis	atrophic		1 (2)	1 (2)	2 (4)	2 (4)
	red zone		0 (0)	1 (2)	0 (0)	0 (0)
	nodule		30 (60)	22 (44)	9 (18)	0 (0)
prostate	brown zone		0 (0)	0 (0)	1 (2)	0 (0)
prep/cli gl	nodule		0 (0)	2 (4)	0 (0)	0 (0)
brain	red zone		0 (0)	0 (0)	0 (0)	1 (2)
	nodule		0 (0)	0 (0)	0 (0)	1 (2)
spinal cord	red zone		0 (0)	0 (0)	0 (0)	1 (2)
eye	turbid		1 (2)	0 (0)	0 (0)	0 (0)
	white		4 (8)	5 (10)	2 (4)	1 (2)
Zymbal gl	nodule		1 (2)	0 (0)	1 (2)	0 (0)
pleura	hemorrhage		0 (0)	0 (0)	1 (2)	0 (0)
mediastinum	mass		0 (0)	1 (2)	0 (0)	1 (2)
peritoneum	nodule		0 (0)	1 (2)	1 (2)	0 (0)
	mass		0 (0)	0 (0)	2 (4)	3 (6)
abdominal c	hemorrhage		0 (0)	12 (24)	20 (40)	31 (62)
	mass		0 (0)	0 (0)	1 (2)	1 (2)
	ascites		0 (0)	2 (4)	2 (4)	6 (12)
mesentorium	mass		0 (0)	0 (0)	2 (4)	3 (6)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0 97W)

PAGE : 4

Organ	Findings	Group Name	Control	200 ppm	400 ppm	800 ppm
		NO. of Animals	50 (%)	50 (%)	50 (%)	50 (%)
adipose	nodule		0 (0)	1 (2)	0 (0)	0 (0)
thoracic ca	hemorrhage		0 (0)	9 (18)	9 (18)	7 (14)
	mass		0 (0)	0 (0)	1 (2)	0 (0)
	pleural fluid		1 (2)	4 (8)	3 (6)	7 (14)
other	nose:elevated		0 (0)	1 (2)	0 (0)	0 (0)
	nose:nodule		2 (4)	0 (0)	0 (0)	0 (0)

(HPT080)

BAIS 3

APPENDIX I 2

GROSS FINDINGS : SUMMARY, RAT : FEMALE ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 50 (%)	150 ppm 50 (%)	300 ppm 50 (%)	600 ppm 50 (%)
skin/app	nodule		0 (0)	1 (2)	0 (0)	0 (0)
subcutis	jaundice		0 (0)	0 (0)	1 (2)	0 (0)
	mass		11 (22)	8 (16)	5 (10)	3 (6)
lung	white		0 (0)	1 (2)	0 (0)	0 (0)
	red		0 (0)	2 (4)	3 (6)	3 (6)
	yellow patch/zone		0 (0)	0 (0)	1 (2)	0 (0)
	white zone		0 (0)	0 (0)	1 (2)	0 (0)
	red zone		0 (0)	7 (14)	12 (24)	12 (24)
	black zone		0 (0)	1 (2)	0 (0)	0 (0)
	red patch		0 (0)	1 (2)	0 (0)	0 (0)
	edema		0 (0)	1 (2)	0 (0)	0 (0)
	nodule		0 (0)	3 (6)	4 (8)	9 (18)
	voluminus		0 (0)	1 (2)	0 (0)	0 (0)
lymph node	enlarged		0 (0)	3 (6)	2 (4)	1 (2)
spleen	enlarged		4 (8)	15 (30)	8 (16)	3 (6)
	black zone		0 (0)	1 (2)	0 (0)	0 (0)
forestomach	ulcer		1 (2)	0 (0)	2 (4)	0 (0)
gl stomach	hemorrhage		1 (2)	0 (0)	0 (0)	0 (0)
	ulcer		1 (2)	1 (2)	0 (0)	0 (0)
	erosion		0 (0)	0 (0)	1 (2)	0 (0)
liver	enlarged		0 (0)	0 (0)	0 (0)	1 (2)
	brown		0 (0)	0 (0)	1 (2)	0 (0)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 50 (%)	150 ppm 50 (%)	300 ppm 50 (%)	600 ppm 50 (%)
liver	white zone		1 (2)	1 (2)	1 (2)	0 (0)
	red zone		0 (0)	2 (4)	0 (0)	2 (4)
	black zone		0 (0)	1 (2)	0 (0)	0 (0)
	nodule		1 (2)	40 (80)	38 (76)	44 (88)
	cyst		0 (0)	1 (2)	0 (0)	0 (0)
	deformed		0 (0)	0 (0)	1 (2)	1 (2)
	rough		1 (2)	7 (14)	1 (2)	0 (0)
	nodular		0 (0)	0 (0)	3 (6)	1 (2)
	adhesion		0 (0)	0 (0)	0 (0)	1 (2)
	herniation		11 (22)	3 (6)	2 (4)	4 (8)
pancreas	nodule		0 (0)	2 (4)	2 (4)	2 (4)
kidney	white zone		0 (0)	0 (0)	1 (2)	0 (0)
	cyst		0 (0)	0 (0)	0 (0)	1 (2)
	granular		2 (4)	0 (0)	0 (0)	0 (0)
	hydronephrosis		0 (0)	0 (0)	1 (2)	0 (0)
urin bladd	nodule		0 (0)	1 (2)	0 (0)	0 (0)
pituitary	enlarged		12 (24)	10 (20)	0 (0)	1 (2)
	red zone		7 (14)	5 (10)	7 (14)	0 (0)
	brown zone		1 (2)	0 (0)	0 (0)	0 (0)
	red patch		0 (0)	1 (2)	0 (0)	0 (0)
	nodule		2 (4)	8 (16)	4 (8)	1 (2)
	cyst		5 (10)	1 (2)	0 (0)	0 (0)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (O 105W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 50 (%)	150 ppm 50 (%)	300 ppm 50 (%)	600 ppm 50 (%)
thyroid	enlarged		1 (2)	0 (0)	1 (2)	0 (0)
	nodule		1 (2)	1 (2)	0 (0)	0 (0)
adrenal	enlarged		0 (0)	2 (4)	1 (2)	0 (0)
ovary	enlarged		0 (0)	2 (4)	0 (0)	0 (0)
	cyst		0 (0)	1 (2)	1 (2)	1 (2)
uterus	enlarged		0 (0)	1 (2)	0 (0)	0 (0)
	nodule		5 (10)	3 (6)	2 (4)	2 (4)
prep/cli gl	nodule		0 (0)	0 (0)	1 (2)	0 (0)
brain	red zone		0 (0)	3 (6)	2 (4)	0 (0)
spinal cord	red zone		0 (0)	1 (2)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	1 (2)	0 (0)
eye	turbid		1 (2)	0 (0)	1 (2)	0 (0)
	white		4 (8)	4 (8)	3 (6)	1 (2)
Zymbal gl	nodule		0 (0)	1 (2)	0 (0)	0 (0)
muscle	nodule		0 (0)	1 (2)	0 (0)	0 (0)
mediastinum	mass		0 (0)	0 (0)	1 (2)	0 (0)
peritoneum	mass		0 (0)	0 (0)	2 (4)	0 (0)
retroperit	mass		0 (0)	0 (0)	0 (0)	1 (2)
abdominal c	hemorrhage		0 (0)	6 (12)	19 (38)	25 (50)
	ascites		0 (0)	2 (4)	2 (4)	3 (6)
adipose	nodule		0 (0)	0 (0)	1 (2)	0 (0)
thoracic ca	hemorrhage		0 (0)	5 (10)	5 (10)	2 (4)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 4

Organ	Findings	Group Name	Control	150 ppm	300 ppm	600 ppm
		NO. of Animals	50 (%)	50 (%)	50 (%)	50 (%)
thoracic ca	pleural fluid		0 (0)	1 (2)	6 (12)	6 (12)
other	lower jaw: nodule		0 (0)	1 (2)	0 (0)	0 (0)

(HPT080)

BAIS 3

APPENDIX I 3

GROSS FINDINGS : SUMMARY, RAT : MALE

DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 1 (%)	200 ppm 31 (%)	400 ppm 50 (%)	800 ppm 50 (%)
subcutis	jaundice		0 (0)	0 (0)	1 (2)	0 (0)
	mass		0 (0)	2 (6)	2 (4)	1 (2)
nasal cavit	hemorrhage		0 (0)	0 (0)	1 (2)	0 (0)
lung	red		0 (0)	2 (6)	3 (6)	5 (10)
	red zone		0 (0)	8 (26)	17 (34)	16 (32)
	edema		0 (0)	1 (3)	0 (0)	0 (0)
	nodule		0 (0)	6 (19)	8 (16)	5 (10)
	voluminus		0 (0)	1 (3)	0 (0)	0 (0)
lymph node	enlarged		0 (0)	0 (0)	0 (0)	1 (2)
spleen	enlarged		1 (100)	5 (16)	9 (18)	4 (8)
	black zone		0 (0)	1 (3)	0 (0)	0 (0)
	nodule		0 (0)	1 (3)	0 (0)	0 (0)
	deformed		0 (0)	1 (3)	0 (0)	0 (0)
esophagus	nodule		0 (0)	0 (0)	0 (0)	1 (2)
gl stomach	red zone		0 (0)	1 (3)	0 (0)	0 (0)
	ulcer		0 (0)	0 (0)	2 (4)	0 (0)
stomach	nodule		0 (0)	0 (0)	0 (0)	1 (2)
	gas		0 (0)	0 (0)	2 (4)	0 (0)
small intes	nodule		0 (0)	0 (0)	1 (2)	0 (0)
liver	pale		0 (0)	0 (0)	1 (2)	0 (0)
	white		0 (0)	0 (0)	1 (2)	0 (0)
	brown		0 (0)	0 (0)	1 (2)	0 (0)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 1 (%)	200 ppm 31 (%)	400 ppm 50 (%)	800 ppm 50 (%)
liver	red zone		0 (0)	1 (3)	0 (0)	1 (2)
	nodule		0 (0)	25 (81)	45 (90)	47 (94)
	cyst		0 (0)	1 (3)	2 (4)	0 (0)
	rough		0 (0)	1 (3)	0 (0)	0 (0)
	nodular		0 (0)	0 (0)	0 (0)	1 (2)
	adhesion		0 (0)	0 (0)	0 (0)	1 (2)
	herniation		0 (0)	4 (13)	3 (6)	0 (0)
pancreas	nodule		0 (0)	2 (6)	1 (2)	2 (4)
kidney	white patch/zone		0 (0)	1 (3)	0 (0)	0 (0)
	deformed		0 (0)	0 (0)	1 (2)	0 (0)
	granular		1 (100)	1 (3)	0 (0)	0 (0)
urin bladd	hemorrhage		0 (0)	0 (0)	1 (2)	0 (0)
	urine:marked retention		0 (0)	0 (0)	0 (0)	1 (2)
pituitary	enlarged		0 (0)	2 (6)	2 (4)	0 (0)
	red zone		0 (0)	0 (0)	2 (4)	0 (0)
	nodule		0 (0)	1 (3)	2 (4)	0 (0)
thyroid	enlarged		0 (0)	1 (3)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	1 (2)	0 (0)
adrenal	enlarged		0 (0)	0 (0)	1 (2)	0 (0)
testis	atrophic		0 (0)	1 (3)	2 (4)	2 (4)
	nodule		0 (0)	11 (35)	9 (18)	0 (0)
prostate	brown zone		0 (0)	0 (0)	1 (2)	0 (0)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 1 (%)	200 ppm 31 (%)	400 ppm 50 (%)	800 ppm 50 (%)
brain	red zone		0 (0)	0 (0)	0 (0)	1 (2)
	nodule		0 (0)	0 (0)	0 (0)	1 (2)
spinal cord	red zone		0 (0)	0 (0)	0 (0)	1 (2)
eye	white		0 (0)	1 (3)	2 (4)	1 (2)
Zymbal gl	nodule		0 (0)	0 (0)	1 (2)	0 (0)
pleura	hemorrhage		0 (0)	0 (0)	1 (2)	0 (0)
mediastinum	mass		0 (0)	1 (3)	0 (0)	1 (2)
peritoneum	nodule		0 (0)	1 (3)	1 (2)	0 (0)
	mass		0 (0)	0 (0)	2 (4)	3 (6)
abdominal c	hemorrhage		0 (0)	9 (29)	20 (40)	31 (62)
	mass		0 (0)	0 (0)	1 (2)	1 (2)
	ascites		0 (0)	2 (6)	2 (4)	6 (12)
mesenterium	mass		0 (0)	0 (0)	2 (4)	3 (6)
adipose	nodule		0 (0)	1 (3)	0 (0)	0 (0)
thoracic ca	hemorrhage		0 (0)	9 (29)	9 (18)	7 (14)
	mass		0 (0)	0 (0)	1 (2)	0 (0)
	pleural fluid		0 (0)	4 (13)	3 (6)	7 (14)
other	nose elevated		0 (0)	1 (3)	0 (0)	0 (0)

APPENDIX I 4

GROSS FINDINGS : SUMMARY, RAT : FEMALE

DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 9 (%)	150 ppm 33 (%)	300 ppm 48 (%)	600 ppm 50 (%)
subcutis	jaundice		0 (0)	0 (0)	1 (2)	0 (0)
	mass		3 (33)	5 (15)	5 (10)	3 (6)
lung	red		0 (0)	2 (6)	3 (6)	3 (6)
	yellow patch/zone		0 (0)	0 (0)	1 (2)	0 (0)
	white zone		0 (0)	0 (0)	1 (2)	0 (0)
	red zone		0 (0)	5 (15)	12 (25)	12 (24)
	red patch		0 (0)	1 (3)	0 (0)	0 (0)
	edema		0 (0)	1 (3)	0 (0)	0 (0)
	nodule		0 (0)	1 (3)	4 (8)	9 (18)
	voluminus		0 (0)	1 (3)	0 (0)	0 (0)
lymph node	enlarged		0 (0)	2 (6)	2 (4)	1 (2)
spleen	enlarged		1 (11)	10 (30)	8 (17)	3 (6)
	black zone		0 (0)	1 (3)	0 (0)	0 (0)
forestomach	ulcer		1 (11)	0 (0)	2 (4)	0 (0)
gl stomach	hemorrhage		1 (11)	0 (0)	0 (0)	0 (0)
	ulcer		0 (0)	1 (3)	0 (0)	0 (0)
	erosion		0 (0)	0 (0)	1 (2)	0 (0)
liver	enlarged		0 (0)	0 (0)	0 (0)	1 (2)
	brown		0 (0)	0 (0)	1 (2)	0 (0)
	white zone		0 (0)	0 (0)	1 (2)	0 (0)
	red zone		0 (0)	1 (3)	0 (0)	2 (4)
	black zone		0 (0)	1 (3)	0 (0)	0 (0)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 9 (%)	150 ppm 33 (%)	300 ppm 48 (%)	600 ppm 50 (%)
liver	nodule		0 (0)	24 (73)	36 (75)	44 (88)
	deformed		0 (0)	0 (0)	1 (2)	1 (2)
	rough		0 (0)	6 (18)	1 (2)	0 (0)
	nodular		0 (0)	0 (0)	3 (6)	1 (2)
	adhesion		0 (0)	0 (0)	0 (0)	1 (2)
	herniation		2 (22)	2 (6)	2 (4)	4 (8)
pancreas	nodule		0 (0)	1 (3)	2 (4)	2 (4)
kidney	white zone		0 (0)	0 (0)	1 (2)	0 (0)
	cyst		0 (0)	0 (0)	0 (0)	1 (2)
	hydronephrosis		0 (0)	0 (0)	1 (2)	0 (0)
pituitary	enlarged		3 (33)	6 (18)	0 (0)	1 (2)
	red zone		0 (0)	3 (9)	7 (15)	0 (0)
	red patch		0 (0)	1 (3)	0 (0)	0 (0)
	nodule		0 (0)	5 (15)	4 (8)	1 (2)
thyroid	enlarged		0 (0)	0 (0)	1 (2)	0 (0)
	nodule		1 (11)	1 (3)	0 (0)	0 (0)
adrenal	enlarged		0 (0)	1 (3)	1 (2)	0 (0)
ovary	cyst		0 (0)	1 (3)	1 (2)	1 (2)
uterus	enlarged		0 (0)	1 (3)	0 (0)	0 (0)
	nodule		2 (22)	3 (9)	2 (4)	2 (4)
prep/cli gl	nodule		0 (0)	0 (0)	1 (2)	0 (0)
brain	red zone		0 (0)	2 (6)	2 (4)	0 (0)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 9 (%)	150 ppm 33 (%)	300 ppm 48 (%)	600 ppm 50 (%)
spinal cord	red zone		0 (0)	1 (3)	0 (0)	0 (0)
	nodule		0 (0)	0 (0)	1 (2)	0 (0)
eye	turbid		0 (0)	0 (0)	1 (2)	0 (0)
	white		1 (11)	2 (6)	3 (6)	1 (2)
Zymbal gl	nodule		0 (0)	1 (3)	0 (0)	0 (0)
muscle	nodule		0 (0)	1 (3)	0 (0)	0 (0)
mediastinum	mass		0 (0)	0 (0)	1 (2)	0 (0)
peritoneum	mass		0 (0)	0 (0)	2 (4)	0 (0)
retroperit	mass		0 (0)	0 (0)	0 (0)	1 (2)
abdominal c	hemorrhage		0 (0)	5 (15)	19 (40)	25 (50)
	ascites		0 (0)	2 (6)	2 (4)	3 (6)
adipose	nodule		0 (0)	0 (0)	1 (2)	0 (0)
thoracic ca	hemorrhage		0 (0)	4 (12)	5 (10)	2 (4)
	pleural fluid		0 (0)	1 (3)	6 (13)	6 (12)
other	lower jaw:nodule		0 (0)	1 (3)	0 (0)	0 (0)

(HPT080)

BAIS 3

APPENDIX I 5

GROSS FINDINGS : SUMMARY, RAT : MALE

SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (97W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 49 (%)	200 ppm 19 (%)	400 ppm 0 (%)	800 ppm 0 (%)
skin/app	nodule		5 (10)	2 (11)	- (-)	- (-)
subcutis	mass		3 (6)	1 (5)	- (-)	- (-)
lung	red zone		0 (0)	1 (5)	- (-)	- (-)
	brown zone		1 (2)	1 (5)	- (-)	- (-)
	nodule		3 (6)	0 (0)	- (-)	- (-)
spleen	enlarged		2 (4)	3 (16)	- (-)	- (-)
salivary gl	enlarged		1 (2)	0 (0)	- (-)	- (-)
liver	red zone		0 (0)	2 (11)	- (-)	- (-)
	nodule		1 (2)	17 (89)	- (-)	- (-)
	rough		1 (2)	0 (0)	- (-)	- (-)
	herniation		2 (4)	1 (5)	- (-)	- (-)
kidney	granular		13 (27)	3 (16)	- (-)	- (-)
	compressed		1 (2)	0 (0)	- (-)	- (-)
pituitary	enlarged		4 (8)	2 (11)	- (-)	- (-)
	red		1 (2)	0 (0)	- (-)	- (-)
	red zone		2 (4)	0 (0)	- (-)	- (-)
	black zone		2 (4)	1 (5)	- (-)	- (-)
	nodule		2 (4)	1 (5)	- (-)	- (-)
thyroid	enlarged		2 (4)	2 (11)	- (-)	- (-)
adrenal	enlarged		1 (2)	0 (0)	- (-)	- (-)
testis	atrophic		1 (2)	0 (0)	()	()
	red zone		0 (0)	1 (5)	- (-)	- (-)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (97W)

PAGE : 2

Organ	Findings	Group Name	Control	200 ppm	400 ppm	800 ppm
		NO. of Animals	49 (%)	19 (%)	0 (%)	0 (%)
testis	nodule		30 (61)	11 (58)	- (-)	- (-)
prep/cli gl	nodule		0 (0)	2 (11)	- (-)	- (-)
eye	turbid		1 (2)	0 (0)	- (-)	- (-)
	white		4 (8)	4 (21)	- (-)	- (-)
Zymbal gl	nodule		1 (2)	0 (0)	- (-)	- (-)
abdominal c	hemorrhage		0 (0)	3 (16)	- (-)	- (-)
thoracic ca	pleural fluid		1 (2)	0 (0)	- (-)	- (-)
other	nose:nodule		2 (4)	0 (0)	- (-)	- (-)

(HPT080)

BAIS 3

APPENDIX I 6

GROSS FINDINGS : SUMMARY, RAT : FEMALE

SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)
 SACRIFICED ANIMALS (105W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control	150 ppm	300 ppm	600 ppm
			41 (%)	17 (%)	2 (%)	0 (%)
skin/app	nodule		0 (0)	1 (6)	0 (0)	- (-)
subcutis	mass		8 (20)	3 (18)	0 (0)	- (-)
lung	white		0 (0)	1 (6)	0 (0)	- (-)
	red zone		0 (0)	2 (12)	0 (0)	- (-)
	black zone		0 (0)	1 (6)	0 (0)	- (-)
	nodule		0 (0)	2 (12)	0 (0)	- (-)
lymph node	enlarged		0 (0)	1 (6)	0 (0)	- (-)
spleen	enlarged		3 (7)	5 (29)	0 (0)	- (-)
gl stomach	ulcer		1 (2)	0 (0)	0 (0)	- (-)
liver	white zone		1 (2)	1 (6)	0 (0)	- (-)
	red zone		0 (0)	1 (6)	0 (0)	- (-)
	nodule		1 (2)	16 (94)	2 (100)	- (-)
	cyst		0 (0)	1 (6)	0 (0)	- (-)
	rough		1 (2)	1 (6)	0 (0)	- (-)
	herniation		9 (22)	1 (6)	0 (0)	- (-)
pancreas	nodule		0 (0)	1 (6)	0 (0)	- (-)
kidney	granular		2 (5)	0 (0)	0 (0)	- (-)
urin bladd	nodule		0 (0)	1 (6)	0 (0)	- (-)
pituitary	enlarged		9 (22)	4 (24)	0 (0)	- (-)
	red zone		7 (17)	2 (12)	0 (0)	- (-)
	brown zone		1 (2)	0 (0)	0 (0)	()
	nodule		2 (5)	3 (18)	0 (0)	- (-)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (105W)

PAGE : 2

Organ	Findings	Group Name	Control	150 ppm	300 ppm	600 ppm
		NO. of Animals	41 (%)	17 (%)	2 (%)	0 (%)
pituitary	cyst		5 (12)	1 (6)	0 (0)	- (-)
thyroid	enlarged		1 (2)	0 (0)	0 (0)	- (-)
adrenal	enlarged		0 (0)	1 (6)	0 (0)	- (-)
ovary	enlarged		0 (0)	2 (12)	0 (0)	- (-)
uterus	nodule		3 (7)	0 (0)	0 (0)	- (-)
brain	red zone		0 (0)	1 (6)	0 (0)	- (-)
eye	turbid		1 (2)	0 (0)	0 (0)	- (-)
	white		3 (7)	2 (12)	0 (0)	- (-)
abdominal c	hemorrhage		0 (0)	1 (6)	0 (0)	- (-)
thoracic ca	hemorrhage		0 (0)	1 (6)	0 (0)	- (-)

(HPT080)

BAIS 3

APPENDIX J 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (97W)

PAGE : 1

Group Name	NO. of Animals	Body Weight	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	49	413± 33	0.111± 0.264	3.283± 1.781	1.284± 0.108	1.482± 0.241	2.704± 0.271
200 ppm	19	357± 52**	0.067± 0.008	2.734± 1.021	1.274± 0.168	1.695± 0.576	2.913± 0.222**
400 ppm	0	-	-	-	-	-	-
800 ppm	0	-	-	-	-	-	-

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

Test of t

(HCL040)

BAIS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (97W)

PAGE : 2

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	49	1.291±	1.848	11.252±	1.345	2.029±	0.053
200 ppm	19	1.192±	0.599	15.558±	4.833**	2.034±	0.051
400 ppm	0	-		-		-	
800 ppm	0	-		-		-	

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

Test of t

(HCL040)

BAIS 3

APPENDIX J 2

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE
 UNIT: g

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

PAGE : 1

Group Name	NO. of Animals	Body Weight		ADRENALS		OVARIES		HEART		LUNGS		KIDNEYS	
Control	41	266±	44	0.092±	0.017	0.143±	0.022	0.881±	0.090	1.073±	0.126	1.762±	0.166
150 ppm	17	218±	33**	0.286±	0.762	0.280±	0.444	0.955±	0.114*	1.510±	0.791*	2.013±	0.154**
300 ppm	! 2	169±	15	0.075±	0.007	0.098±	0.018	0.778±	0.023	1.124±	0.156	1.786±	0.097
600 ppm	0	-		-		-		-		-		-	

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

! : Significant test is not applied to this group.

(HCL040)

BAIS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE
UNIT: g

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

PAGE : 2

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	41	0.806±	1.052	7.014±	1.556	1.832±	0.058
150 ppm	17	1.959±	2.778	11.427±	6.684*	1.846±	0.036
300 ppm	! 2	0.903±	0.646	13.972±	1.694	1.838±	0.006
600 ppm	0	-		-		-	

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

! : Significant test is not applied to this group.

(HCL040)

BAIS 3

APPENDIX K 1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE
 UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
 SURVIVAL ANIMALS (97W)

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	49	413± 33	0.028± 0.069	0.792± 0.393	0.312± 0.029	0.360± 0.057	0.656± 0.064
200 ppm	19	357± 52**	0.019± 0.004	0.751± 0.250	0.362± 0.056**	0.501± 0.266*	0.837± 0.184**
400 ppm	0	-	-	-	-	-	-
800 ppm	0	-	-	-	-	-	-

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

Test of t

(HCL042)

BAIS 3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (97%)

PAGE : 2

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	49	0.314± 0.454	2.726± 0.281	0.494± 0.037
200 ppm	19	0.325± 0.137	4.421± 1.406**	0.588± 0.143*
400 ppm	0	-	-	-
800 ppm	0	-	-	-

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

(HCL042)

BAIS 3

APPENDIX K 2

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE
UNIT: %

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

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	41	266± 44	0.035± 0.007	0.055± 0.011	0.337± 0.043	0.414± 0.090	0.678± 0.129
150 ppm	17	218± 33**	0.155± 0.446	0.140± 0.236	0.448± 0.090**	0.725± 0.425**	0.945± 0.177**
300 ppm	! 2	169± 15	0.045± 0.001	0.058± 0.005	0.464± 0.055	0.674± 0.152	1.062± 0.036
600 ppm	0	-	-	-	-	-	-

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

Test of t

! : Significant test is not applied to this group.

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE
UNIT: %

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

PAGE : 2

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	41	0.313± 0.429	2.654± 0.490	0.708± 0.128
150 ppm	17	1.027± 1.613	5.426± 3.474**	0.865± 0.136**
300 ppm	! 2	0.555± 0.432	8.280± 0.276	1.095± 0.093
600 ppm	0	-	-	-

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

! : Significant test is not applied to this group.

APPENDIX L 1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 1

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				200 ppm 50				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appandage}																		
skin/app			<50>				<50>				<50>				<50>			
	inflammation		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia:epidermis		2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	epidermal cyst		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Respiratory system}																		
nasal cavit			<50>				<50>				<50>				<50>			
	hemorrhage		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	mineralization		0	0	0	0	12	0	0	0 **	7	0	0	0 *	13	2	0	0 **
			(0)	(0)	(0)	(0)	(24)	(0)	(0)	(0)	(14)	(0)	(0)	(0)	(26)	(4)	(0)	(0)
	eosinophilic change:olfactory epithelium		21	13	2	0	17	1	0	0 **	8	3	0	0 **	2	0	0	0 **
			(42)	(26)	(4)	(0)	(34)	(2)	(0)	(0)	(16)	(6)	(0)	(0)	(4)	(0)	(0)	(0)
	eosinophilic change:respiratory epithelium		6	0	0	0	8	0	0	0	6	0	0	0	2	0	0	0
			(12)	(0)	(0)	(0)	(16)	(0)	(0)	(0)	(12)	(0)	(0)	(0)	(4)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 97W)

PAGE : 2

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				200 ppm 50				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit			<50>				<50>				<50>				<50>			
	inflammation:foreign body		5	2	0	0	15	0	0	0 *	10	0	0	0	3	0	0	0
			(10)	(4)	(0)	(0)	(30)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(6)	(0)	(0)	(0)
	inflammation:respiratory epithelium		0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	respiratory metaplasia:olfactory epithelium		6	0	0	0	8	0	0	0	8	0	0	0	0	0	0	0 *
			(12)	(0)	(0)	(0)	(16)	(0)	(0)	(0)	(16)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	respiratory metaplasia:gland		46	0	0	0	47	1	0	0	33	4	0	0 **	32	3	0	0 **
			(92)	(0)	(0)	(0)	(94)	(2)	(0)	(0)	(66)	(8)	(0)	(0)	(64)	(6)	(0)	(0)
	basal cell hyperplasia:olfactory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	6	4	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(12)	(8)	(0)	(0)
	atrophy:olfactory epithelium		0	0	0	0	2	0	0	0	6	0	0	0 *	19	2	0	0 **
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(12)	(0)	(0)	(0)	(38)	(4)	(0)	(0)
	hyperplasia:respiratory epithelium		0	0	0	0	0	0	0	0	0	1	0	0	1	1	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(2)	(2)	(0)	(0)
	atypical dilatation:olfactory gland		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)	(4)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				200 ppm 50				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
larynx	mineralization		<50>				<50>				<50>				<50>			
			0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammation		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
trachea	mineralization		<50>				<50>				<50>				<50>			
			0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
lung	congestion		<50>				<50>				<50>				<50>			
			0	0	0	0	0	2	0	0	0	2	0	0	0	2	0	0
			(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(4)	(0)	(0)
	hemorrhage		0	0	0	0	8	5	3	0 **	13	7	0	0 **	7	5	2	0 **
			(0)	(0)	(0)	(0)	(16)	(10)	(6)	(0)	(26)	(14)	(0)	(0)	(14)	(10)	(4)	(0)
	inflammatory infiltration		0	0	1	0	1	1	0	0	1	1	0	0	6	2	0	0 *
			(0)	(0)	(2)	(0)	(2)	(2)	(0)	(0)	(2)	(2)	(0)	(0)	(12)	(4)	(0)	(0)
	osseous metaplasia		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				200 ppm 50				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
lung			<50>				<50>				<50>				<50>			
	bronchiolar-alveolar cell hyperplasia		0	1	1	0	2	0	0	0	0	0	0	0	1	0	0	0
			(0)	(2)	(2)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
{Hematopoietic system}																		
bone marrow			<50>				<50>				<50>				<50>			
	granulation		1	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0
			(2)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	increased hematopoiesis		4	0	0	0	25	0	0	0	38	0	0	0	38	0	0	0
			(8)	(0)	(0)	(0)	(50)	(0)	(0)	(0)	(76)	(0)	(0)	(0)	(76)	(0)	(0)	(0)
	granulopoiesis:increased		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
lymph node			<50>				<50>				<50>				<50>			
	lymphadenitis		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
spleen			<50>				<50>				<50>				<50>			
	atrophy		0	0	0	0	1	3	0	0	4	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(6)	(0)	(0)	(8)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 5

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																		
spleen			<50>				<50>				<50>				<50>			
	congestion		0	1	0	0	1	2	0	0	0	0	0	0	0	0	0	0
			(0)	(2)	(0)	(0)	(2)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	deposit of hemosiderin		0	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory infiltration		0	0	0	0	3	1	0	0	5	0	0	0	2	1	0	0
			(0)	(0)	(0)	(0)	(6)	(2)	(0)	(0)	(10)	(0)	(0)	(0)	(4)	(2)	(0)	(0)
	fibrosis		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	extramedullary hematopoiesis		2	0	0	0	9	12	0	0 **	29	11	0	0 **	13	20	0	0 **
			(4)	(0)	(0)	(0)	(18)	(24)	(0)	(0)	(58)	(22)	(0)	(0)	(26)	(40)	(0)	(0)
{Circulatory system}																		
heart			<50>				<50>				<50>				<50>			
	mineralization		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory cell nest		0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Grade	1 : Slight	2 : Moderate	3 : Marked	4 : Severe														
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
(c)	c : b / a * 100																	
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESTONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 6

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				200 ppm 50				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Circulatory system}																		
heart	myocardial fibrosis		<50>				<50>				<50>				<50>			
			20	1	0	0	13	5	0	0	11	1	0	0	9	0	0	0 *
			(40)	(2)	(0)	(0)	(26)	(10)	(0)	(0)	(22)	(2)	(0)	(0)	(18)	(0)	(0)	(0)
{Digestive system}																		
tooth	inflammation		<50>				<50>				<50>				<50>			
			0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	dysplasia		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
salivary gl	lymphocytic infiltration		<50>				<50>				<50>				<50>			
			0	0	0	0	4	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(8)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
stomach	mineralization		<50>				<50>				<50>				<50>			
			0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	ulcer:forestomach		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)	(6)	(0)	(0)	(0)	(0)	(0)	(0)

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 97W)

PAGE : 7

Organ	Findings	Group Name No. of Animals on Study Grade				Control 50				200 ppm 50				400 ppm 50				800 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Digestive system)																					
stomach		<50>				<50>				<50>				<50>				<50>			
	hyperplasia:forestomach	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	erosion:glandular stomach	0	0	0	0	0	0	0	0	2	0	0	0	2	0	0	0	2	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(4)	(0)	(0)	(0)
	ulcer:glandular stomach	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia:glandular stomach	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hemorrhage:glandular stomach	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
small intes		(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hemorrhage	<50>				<50>				<50>				<50>				<50>			
liver		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
	herniation	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
		<50>				<50>				<50>				<50>				<50>			
		2	0	0	0	5	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0
		(4)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 8

Organ	Findings	Group Name No. of Animals on Study Grade				Control 50				200 ppm 50				400 ppm 50				800 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
liver		<50>				<50>				<50>				<50>				<50>			
	congestion	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	angiectasis	0	0	0	0	3	2	0	0	1	0	0	0	0	1	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(6)	(4)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)
	thrombus	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)
	necrosis:central	0	0	0	0	7	3	0	0 **	10	11	1	0 **	5	4	2	0 **	(10)	(8)	(4)	(0)
		(0)	(0)	(0)	(0)	(14)	(6)	(0)	(0)	(20)	(22)	(2)	(0)	(10)	(8)	(4)	(0)	(10)	(8)	(4)	(0)
	necrosis:focal	0	0	0	0	1	5	1	0	6	10	1	0 **	5	7	4	0 **	(10)	(14)	(8)	(0)
		(0)	(0)	(0)	(0)	(2)	(10)	(2)	(0)	(12)	(20)	(2)	(0)	(10)	(14)	(8)	(0)	(10)	(14)	(8)	(0)
	fatty change	1	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		(2)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	fatty change:central	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory infiltration	0	1	0	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(2)	(0)	(0)	(2)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b b : Number of animals with lesion

(c) c : b / a * 100

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 97W)

PAGE : 9

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				200 ppm 50				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver			<50>				<50>				<50>				<50>			
	granulation		1	7	0	0	1	0	0	0 *	0	1	0	0 *	1	0	0	0 *
			(2)	(14)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(2)	(0)	(0)	(0)
	hyperplasia:vascular		0	0	0	0	1	1	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(2)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	clear cell focus		2	1	0	0	4	9	2	0 *	1	3	0	0	0	0	0	0
			(4)	(2)	(0)	(0)	(8)	(18)	(4)	(0)	(2)	(6)	(0)	(0)	(0)	(0)	(0)	(0)
	acidophilic cell focus		4	2	0	0	6	4	4	0	2	2	0	0	0	0	1	0
			(8)	(4)	(0)	(0)	(12)	(8)	(8)	(0)	(4)	(4)	(0)	(0)	(0)	(0)	(2)	(0)
	basophilic cell focus		4	3	0	1	8	14	1	1 *	2	10	0	0	5	3	1	0
			(8)	(6)	(0)	(2)	(16)	(28)	(2)	(2)	(4)	(20)	(0)	(0)	(10)	(6)	(2)	(0)
	vacuolated cell focus		2	1	0	0	2	0	0	0	0	0	0	0	1	0	0	0
			(4)	(2)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	spongiosis hepatitis		4	0	0	0	12	5	0	0 **	0	1	0	0	2	3	0	0
			(8)	(0)	(0)	(0)	(24)	(10)	(0)	(0)	(0)	(2)	(0)	(0)	(4)	(6)	(0)	(0)
	bile duct hyperplasia		0	30	20	0	11	30	4	0 **	10	23	1	0 **	6	3	0	0 **
			(0)	(60)	(40)	(0)	(22)	(60)	(8)	(0)	(20)	(46)	(2)	(0)	(12)	(6)	(0)	(0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 10

Organ	Findings	Group Name	Control				200 ppm				400 ppm				800 ppm				
		No. of Animals on Study	50				50				50				50				
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
{Digestive system}																			
liver			<50>				<50>				<50>				<50>				
	biliary cyst		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	regenerative hyperplasia		0	0	0	0	0	0	0	0	1	3	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
pancreas			<50>				<50>				<50>				<50>				
	atrophy		6	4	0	0	6	2	1	0	3	2	0	0	0	0	0	0	0 **
			(12)	(8)	(0)	(0)	(12)	(4)	(2)	(0)	(6)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	islet cell hyperplasia		1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
{Urinary system}																			
kidney			<50>				<50>				<50>				<50>				
	cyst		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	basophilic change		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																		
< a >	a : Number of animals examined at the site																		
b	b : Number of animals with lesion																		
(c)	c : b / a * 100																		
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																			

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 11

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney			<50>				<50>				<50>				<50>			
	deposit of hemosiderin		1	0	0	0	4	2	0	0	6	7	0	0 **	3	4	0	0
			(2)	(0)	(0)	(0)	(8)	(4)	(0)	(0)	(12)	(14)	(0)	(0)	(6)	(8)	(0)	(0)
	chronic nephropathy		23	16	7	1	15	8	2	0 **	5	3	0	0 **	5	0	0	0 **
			(46)	(32)	(14)	(2)	(30)	(16)	(4)	(0)	(10)	(6)	(0)	(0)	(10)	(0)	(0)	(0)
	pyelonephritis		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	tubular necrosis		0	1	0	0	5	10	3	0 **	7	9	7	0 **	2	14	4	0 **
			(0)	(2)	(0)	(0)	(10)	(20)	(6)	(0)	(14)	(18)	(14)	(0)	(4)	(28)	(8)	(0)
papillary necrosis		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	
mineralization:cortico-medullary junction		0	0	0	0	1	0	1	0	0	0	0	0	0	2	0	0	
		(0)	(0)	(0)	(0)	(2)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	
mineralization:papilla		3	0	0	0	7	0	0	0	4	0	0	0	5	2	0	0	
		(6)	(0)	(0)	(0)	(14)	(0)	(0)	(0)	(8)	(0)	(0)	(0)	(10)	(4)	(0)	(0)	
mineralization:pelvis		0	1	0	0	0	0	0	0	0	0	0	0	2	0	0	0	
		(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																	
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
(c)	c : b / a * 100																	
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 97#)

PAGE : 12

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				200 ppm 50				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney	mineralization:cortex		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	1	0	1	0	0	1	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(2)	(0)	(0)	(2)	(0)	(0)
	urothelial hyperplasia:pelvis		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
urin bladd	simple hyperplasia:transitional epithelium		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Endocrine system}																		
pituitary	angiectasis		<50>				<50>				<50>				<50>			
			1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	cyst		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia		4	9	0	0	6	5	0	0	2	2	0	0 *	1	1	0	0 **
			(8)	(18)	(0)	(0)	(12)	(10)	(0)	(0)	(4)	(4)	(0)	(0)	(2)	(2)	(0)	(0)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 13

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				200 ppm 50				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
pituitary	Rathke pouch		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
thyroid	ultimibranhial body remanet		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	C-cell hyperplasia		7	2	0	0	1	1	0	0	1	0	0	0 *	1	0	0	0 *
			(14)	(4)	(0)	(0)	(2)	(2)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
adrenal	cyst		<50>				<50>				<50>				<50>			
			1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia:cortical cell		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia:medulla		0	1	0	0	4	0	0	0	2	1	0	0	0	0	0	0
			(0)	(2)	(0)	(0)	(8)	(0)	(0)	(0)	(4)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	focal fatty change:cortex		2	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 14

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				200 ppm 50				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
testis	atrophy		<50>				<50>				<50>				<50>			
			11	5	0	0	7	4	0	0	0	2	2	0 **	3	1	1	0 *
			(22)	(10)	(0)	(0)	(14)	(8)	(0)	(0)	(0)	(4)	(4)	(0)	(6)	(2)	(2)	(0)
	arteritis		16	1	0	0	8	0	0	0	5	0	0	0 *	2	0	0	0 **
			(32)	(2)	(0)	(0)	(16)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(4)	(0)	(0)	(0)
	interstitial cell hyperplasia		26	2	0	0	35	3	0	0	27	1	0	0	7	0	0	0 **
			(52)	(4)	(0)	(0)	(70)	(6)	(0)	(0)	(54)	(2)	(0)	(0)	(14)	(0)	(0)	(0)
epididymis	coll debris		<50>				<50>				<50>				<50>			
			5	1	0	0	1	0	0	0	0	0	0	0 *	0	0	0	0 *
			(10)	(2)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
prostate	hemorrhage		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammation		9	1	0	0	3	0	0	0	6	1	0	0	3	0	0	0
			(18)	(2)	(0)	(0)	(6)	(0)	(0)	(0)	(12)	(2)	(0)	(0)	(6)	(0)	(0)	(0)
	hyperplasia		4	0	0	0	1	2	0	0	0	0	0	0	0	0	0	0
			(8)	(0)	(0)	(0)	(2)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 15

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				200 ppm 50				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
mammary gl			<50>				<50>				<50>				<50>			
	galactoceles		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Nervous system}																		
brain			<50>				<50>				<50>				<50>			
	hemorrhage		0	0	0	0	1	0	0	0	1	0	0	0	1	1	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(2)	(0)	(0)
			<50>				<50>				<50>				<50>			
	gliosis		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
{Special sense organs/appendage}																		
eye			<50>				<50>				<50>				<50>			
	cataract		3	1	0	0	6	0	0	0	4	0	0	0	1	0	0	0
			(6)	(2)	(0)	(0)	(12)	(0)	(0)	(0)	(8)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
			<50>				<50>				<50>				<50>			
	retinal atrophy		18	4	0	0	10	4	0	0	4	3	0	0 **	1	0	0	0 **
			(36)	(8)	(0)	(0)	(20)	(8)	(0)	(0)	(8)	(6)	(0)	(0)	(2)	(0)	(0)	(0)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 16

		Group Name	Control				200 ppm				400 ppm				800 ppm				
		No. of Animals on Study	50				50				50				50				
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
{Special sense organs/appendage}																			
Harder gl			<50>				<50>				<50>				<50>				
	lymphocytic infiltration		0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Musculoskeletal system}																			
bone			<50>				<50>				<50>				<50>				
	osteosclerosis		0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Body cavities}																			
pleura			<50>				<50>				<50>				<50>				
	hemorrhage		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mediastinum			<50>				<50>				<50>				<50>				
	hemorrhage		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																		
< a >	a : Number of animals examined at the site																		
b	b : Number of animals with lesion																		
(c)	c : b / a * 100																		
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																			

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 17

Organ	Findings	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Body cavities}																		
peritoneum	hemorrhage		<50>				<50>				<50>				<50>			
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
	thrombus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
adipose	thrombus		<50>				<50>				<50>				<50>			
		0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Grade	1 : Slight	2 : Moderate	3 : Marked	4 : Severe														
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
(c)	c : b / a * 100																	
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

((IPT150))

BAIS3

APPENDIX L 2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE: ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 1

Organ	Findings	Control No. of Animals on Study Grade				150 ppm 50				300 ppm 50				600 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appandage}																	
skin/app		<50>				<50>				<50>				<50>			
	inflammation	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Respiratory system}																	
nasal cavit		<50>				<50>				<50>				<50>			
	mineralization	4	0	0	0	2	0	0	0	7	0	0	0	2	0	0	0
		(8)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(14)	(0)	(0)	(0)	(4)	(0)	(0)	(0)
	eosinophilic change:olfactory epithelium	10	29	8	0	16	19	0	0 **	12	10	0	0 **	13	18	0	0 **
		(20)	(58)	(16)	(0)	(32)	(38)	(0)	(0)	(24)	(20)	(0)	(0)	(26)	(36)	(0)	(0)
	eosinophilic change:respiratory epithelium	26	2	0	0	6	0	0	0 **	3	0	0	0 **	12	0	0	0 **
		(52)	(4)	(0)	(0)	(12)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(24)	(0)	(0)	(0)
	inflammation:foreign body	2	0	0	0	1	0	0	0	3	0	0	0	0	0	0	0
		(4)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammation:olfactory epithelium	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	respiratory metaplasia:olfactory epithelium	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	0
		(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 2

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				150 ppm 50				300 ppm 50				600 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit	respiratory metaplasia:gland		44 (88)	0 (0)	0 (0)	0 (0)	40 (80)	4 (8)	0 (0)	0 (0)	35 (70)	0 (0)	0 (0)	0 * (0)	39 (78)	0 (0)	0 (0)	0 (0)
	basal cell hyperplasia:olfactory epithelium		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	1 (2)	0 (0)	0 (0)
	atrophy:olfactory epithelium		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	4 (8)	1 (2)	0 (0)	0 (0)	12 (24)	6 (12)	2 (4)	0 ** (0)
	atypical dilatation:olfactory gland		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (6)	0 (0)	0 (0)	0 (0)
	atypical hyperplasia:olfactory gland		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (6)	0 (0)	0 (0)	0 (0)
larynx	inflammation		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
			<50>				<50>				<49>				<50>			
trachea	inflammatory infiltration		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
			<50>				<50>				<49>				<50>			

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 3

		Group Name	Control				150 ppm				300 ppm				600 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ	Findings		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
trachea			<50>				<50>				<49>				<50>			
	xanthogranuloma		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
lung			<50>				<50>				<50>				<50>			
	congestion		1	0	0	0	2	1	0	0	1	1	0	0	4	1	0	0
			(2)	(0)	(0)	(0)	(4)	(2)	(0)	(0)	(2)	(2)	(0)	(0)	(8)	(2)	(0)	(0)
	hemorrhage		0	0	0	0	3	6	0	0 **	13	4	0	0 **	14	4	0	0 **
			(0)	(0)	(0)	(0)	(6)	(12)	(0)	(0)	(26)	(8)	(0)	(0)	(28)	(8)	(0)	(0)
	thrombus		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory infiltration		0	1	0	0	4	0	0	0	1	2	0	0	1	1	0	0
			(0)	(2)	(0)	(0)	(8)	(0)	(0)	(0)	(2)	(4)	(0)	(0)	(2)	(2)	(0)	(0)
	accumulation of foamy cells		1	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	bronchiolar-alveolar cell hyperplasia		2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Hematopoietic system}																		
bone marrow			<50>				<50>				<50>				<50>			
	granulation		2	0	0	0	0	0	0	0	1	2	0	0	0	1	0	0
			(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(4)	(0)	(0)	(0)	(2)	(0)	(0)

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 4

Organ	Findings	Control No. of Animals on Study Grade				150 ppm 50				300 ppm 50				600 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Hematopoietic system)																	
bone marrow		<50>				<50>				<50>				<50>			
	increased hematopoiesis	7	0	0	0	18	0	0	0 *	29	0	0	0 **	40	0	0	0 **
		(14)	(0)	(0)	(0)	(36)	(0)	(0)	(0)	(58)	(0)	(0)	(0)	(80)	(0)	(0)	(0)
	decreased hematopoiesis	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	myelofibrosis	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	granulopoiesis:increased	1	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
		(2)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
lymph node		<50>				<50>				<50>				<50>			
	lymphadenitis	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
spleen		<50>				<50>				<50>				<50>			
	atrophy	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	congestion	4	0	0	0	2	0	0	0	2	0	0	0	0	0	0	0
		(8)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 5

Organ	Findings	Control No. of Animals on Study Grade				150 ppm 50				300 ppm 50				600 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																	
spleen		<50>				<50>				<50>				<50>			
	necrosis:focal	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	deposit of hemosiderin	18	15	0	0	16	5	2	0 *	13	7	0	0 *	18	4	2	0 *
		(36)	(30)	(0)	(0)	(32)	(10)	(4)	(0)	(26)	(14)	(0)	(0)	(36)	(8)	(4)	(0)
	inflammatory infiltration	1	0	0	0	1	1	0	0	3	1	0	0	1	0	0	0
		(2)	(0)	(0)	(0)	(2)	(2)	(0)	(0)	(6)	(2)	(0)	(0)	(2)	(0)	(0)	(0)
	extramedullary hematopoiesis	7	1	0	0	8	8	0	0 *	20	7	0	0 **	28	8	0	0 **
		(14)	(2)	(0)	(0)	(16)	(16)	(0)	(0)	(40)	(14)	(0)	(0)	(56)	(16)	(0)	(0)
{Circulatory system}																	
heart		<50>				<50>				<50>				<50>			
	inflammatory cell nest	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	myocardial fibrosis	5	0	0	0	10	1	0	0	4	0	0	0	5	0	0	0
		(10)	(0)	(0)	(0)	(20)	(2)	(0)	(0)	(8)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Digestive system}																	
tooth		<50>				<50>				<50>				<50>			
	dysplasia	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 6

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				150 ppm 50				300 ppm 50				600 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
stomach	mineralization		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	erosion:forestomach		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	ulcer:forestomach		0	1	1	0	3	0	0	0	1	2	0	0	1	2	0	0
			(0)	(2)	(2)	(0)	(6)	(0)	(0)	(0)	(2)	(4)	(0)	(0)	(2)	(4)	(0)	(0)
	hyperplasia:forestomach		0	0	0	0	2	0	0	0	3	1	0	0	2	1	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(6)	(2)	(0)	(0)	(4)	(2)	(0)	(0)
	erosion:glandular stomach		2	0	0	0	3	0	0	0	1	0	0	0	2	0	0	0
			(4)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(4)	(0)	(0)	(0)
	ulcer:glandular stomach		0	0	0	0	5	0	0	0	4	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(8)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
liver	herniation		<50>				<50>				<50>				<50>			
			11	0	0	0	4	0	0	0	2	0	0	0 *	4	0	0	0
			(22)	(0)	(0)	(0)	(8)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(8)	(0)	(0)	(0)
	congestion		1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 7

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				150 ppm 50				300 ppm 50				600 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver			<50>				<50>				<50>				<50>			
	angiectasis		0	0	0	0	2	2	0	0	0	2	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(4)	(4)	(0)	(0)	(0)	(4)	(0)	(0)	(2)	(0)	(0)	(0)
	thrombus		1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
	peliosis-like lesion		0	0	0	0	0	0	0	0	2	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	necrosis:central		0	1	0	0	4	6	0	0 *	9	5	0	0 **	7	4	0	0 **
			(0)	(2)	(0)	(0)	(8)	(12)	(0)	(0)	(18)	(10)	(0)	(0)	(14)	(8)	(0)	(0)
	necrosis:focal		0	0	0	0	7	11	0	0 **	9	5	1	0 **	8	9	0	0 **
			(0)	(0)	(0)	(0)	(14)	(22)	(0)	(0)	(18)	(10)	(2)	(0)	(16)	(18)	(0)	(0)
	fatty change		0	0	0	0	1	0	1	0	3	0	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(2)	(0)	(6)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
	fatty change:central		0	0	0	0	0	2	1	0	1	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(4)	(2)	(0)	(2)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory infiltration		0	1	0	0	2	1	0	0	0	3	0	0	0	0	0	0
			(0)	(2)	(0)	(0)	(4)	(2)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 8

Organ_____	Findings_____	Group Name	Control				150 ppm				300 ppm				600 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver			<50>				<50>				<50>				<50>			
	granulation		15	5	2	0	3	0	0	0 **	0	2	0	0 **	3	0	0	0 **
			(30)	(10)	(4)	(0)	(6)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(6)	(0)	(0)	(0)
	hyperplasia:vascular		0	0	0	0	5	0	0	0	1	0	0	0	8	1	0	0 **
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(16)	(2)	(0)	(0)
	clear cell focus		0	1	0	0	1	3	1	0	1	5	0	0	2	5	0	0
			(0)	(2)	(0)	(0)	(2)	(6)	(2)	(0)	(2)	(10)	(0)	(0)	(4)	(10)	(0)	(0)
	acidophilic cell focus		1	0	0	0	2	4	0	0	0	6	3	0 *	1	4	0	0
		(2)	(0)	(0)	(0)	(4)	(8)	(0)	(0)	(0)	(12)	(6)	(0)	(2)	(8)	(0)	(0)	
basophilic cell focus		19	2	0	0	3	3	0	0 **	3	4	0	0 **	4	4	0	0 **	
		(38)	(4)	(0)	(0)	(6)	(6)	(0)	(0)	(6)	(8)	(0)	(0)	(8)	(8)	(0)	(0)	
vacuolated cell focus		1	0	0	0	3	1	0	0	4	1	0	0	1	0	0	0	
		(2)	(0)	(0)	(0)	(6)	(2)	(0)	(0)	(8)	(2)	(0)	(0)	(2)	(0)	(0)	(0)	
spongiosis hepatitis		0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	
bile duct hyperplasia		12	5	1	0	8	1	0	0	6	0	1	0 *	2	0	0	0 **	
		(24)	(10)	(2)	(0)	(16)	(2)	(0)	(0)	(12)	(0)	(2)	(0)	(4)	(0)	(0)	(0)	

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 9

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				150 ppm 50				300 ppm 50				600 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver			<50>				<50>				<50>				<50>			
	bile ductular proliferation		0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)
	cholangiofibrosis		0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	biliary cyst		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
	regenerative hyperplasia		0	0	0	0	4	1	0	0	4	0	0	0	3	2	0	0
			(0)	(0)	(0)	(0)	(8)	(2)	(0)	(0)	(8)	(0)	(0)	(0)	(6)	(4)	(0)	(0)
pancreas			<50>				<50>				<50>				<50>			
	atrophy		4	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(8)	(2)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hemorrhage		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Urinary system}																		
kidney			<50>				<50>				<50>				<50>			
	cyst		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 10

Organ_____	Findings_____	Group Name	Control				150 ppm				300 ppm				600 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney			<50>				<50>				<50>				<50>			
	hyaline droplet		1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	basophilic change		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	deposit of hemosiderin		0	0	0	0	1	2	0	0	3	1	0	0	5	3	0	0 *
			(0)	(0)	(0)	(0)	(2)	(4)	(0)	(0)	(6)	(2)	(0)	(0)	(10)	(6)	(0)	(0)
	chronic nephropathy		10	2	1	0	2	0	0	0 *	2	0	0	0 *	0	0	0	0 **
			(20)	(4)	(2)	(0)	(4)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
hydronephrosis		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	
pyelonephritis		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	
tubular necrosis		1	1	1	0	5	7	1	0 *	7	11	1	0 **	3	14	3	0 **	
		(2)	(2)	(2)	(0)	(10)	(14)	(2)	(0)	(14)	(22)	(2)	(0)	(6)	(28)	(6)	(0)	
papillary necrosis		0	0	0	0	18	0	0	0 **	22	11	2	0 **	17	12	0	0 **	
		(0)	(0)	(0)	(0)	(36)	(0)	(0)	(0)	(44)	(22)	(4)	(0)	(34)	(24)	(0)	(0)	

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 11

Organ_____	Findings_____	Group Name	Control				150 ppm				300 ppm				600 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney			<50>				<50>				<50>				<50>			
	mineralization:papilla	8	0	0	0	11	1	0	0	18	3	0	0 **	21	7	0	0 **	
		(16)	(0)	(0)	(0)	(22)	(2)	(0)	(0)	(36)	(6)	(0)	(0)	(42)	(14)	(0)	(0)	
	mineralization:pelvis	8	2	0	0	3	1	0	0	0	0	0	0 **	1	0	0	0 *	
		(16)	(4)	(0)	(0)	(6)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	
	mineralization:cortex	1	0	0	0	0	0	0	0	1	0	0	0	2	1	0	0	
		(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(4)	(2)	(0)	(0)	
	urothelial hyperplasia:pelvis	0	0	0	0	0	0	0	0	3	2	0	0	2	0	0	0	
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(6)	(4)	(0)	(0)	(4)	(0)	(0)	(0)	
	eosinophilic droplet:proximal tubule	2	0	0	0	4	2	0	0	4	0	0	0	0	0	0	0	
		(4)	(0)	(0)	(0)	(8)	(4)	(0)	(0)	(8)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
{Endocrine system}																		
pituitary			<50>				<49>				<50>				<50>			
	angiectasis	4	0	0	0	6	1	0	0	1	0	0	0	2	0	0	0	
		(8)	(0)	(0)	(0)	(12)	(2)	(0)	(0)	(2)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	
	cyst	15	2	0	0	7	1	0	0	5	0	0	0 *	3	0	0	0 **	
		(30)	(4)	(0)	(0)	(14)	(2)	(0)	(0)	(10)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																	
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
(c)	c : b / a * 100																	
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 12

Organ	Findings	Control No. of Animals on Study Grade				150 ppm 50				300 ppm 50				600 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																	
pituitary	hyperplasia	<50>				<49>				<50>				<50>			
		3	5	0	0	4	2	0	0	4	0	0	0	3	0	0	0
		(6)	(10)	(0)	(0)	(8)	(4)	(0)	(0)	(8)	(0)	(0)	(0)	(6)	(0)	(0)	(0)
	Rathke pouch	1	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
		(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
thyroid	ultimibranchial body remanet	<50>				<50>				<48>				<50>			
		0	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)	(0)	(0)	(0)	(0)
	C-cell hyperplasia	5	2	0	0	1	3	0	0	0	0	0	0 *	0	0	0	0 *
		(10)	(4)	(0)	(0)	(2)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	focal follicular cell hyperplasia	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
adrenal	peliosis-like lesion	<50>				<50>				<50>				<50>			
		10	2	0	0	1	1	0	0 *	0	1	0	0 **	1	0	0	0 **
		(20)	(4)	(0)	(0)	(2)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(2)	(0)	(0)	(0)
	hyperplasia:cortical cell	2	2	0	0	1	0	0	0	4	1	0	0	0	0	0	0
		(4)	(4)	(0)	(0)	(2)	(0)	(0)	(0)	(8)	(2)	(0)	(0)	(0)	(0)	(0)	(0)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 13

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				150 ppm 50				300 ppm 50				600 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
adrenal			<50>				<50>				<50>				<50>			
	hyperplasia:medulla		1	0	0	0	3	1	0	0	0	0	0	0	0	0	0	0
			(2)	(0)	(0)	(0)	(6)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	focal fatty change:cortex		9	2	0	0	3	0	0	0	3	0	0	0	1	1	0	0 *
			(18)	(4)	(0)	(0)	(6)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(2)	(2)	(0)	(0)
	cortical vacuolation:diffuse		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Reproductive system}																		
ovary			<50>				<50>				<50>				<50>			
	cyst		0	0	0	0	2	0	0	0	1	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
uterus			<50>				<50>				<50>				<50>			
	dilatation		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	squamous cell metaplasia		0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 14

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				150 ppm 50				300 ppm 50				600 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
uterus	cystic endometrial hyperplasia		<50>				<50>				<50>				<50>			
			1	3	0	0	3	3	0	0	1	2	0	0	0	1	0	0
			(2)	(6)	(0)	(0)	(6)	(6)	(0)	(0)	(2)	(4)	(0)	(0)	(0)	(2)	(0)	(0)
vagina	squamous cell hyperplasia		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
mammary gl	hyperplasia		<50>				<50>				<50>				<50>			
			0	2	0	0	0	0	1	0	0	0	0	0	1	1	0	0
			(0)	(4)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(2)	(2)	(0)	(0)
	galactoceles		<50>				<50>				<50>				<50>			
			0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Nervous system}																		
brain	hemorrhage		<50>				<50>				<50>				<50>			
			0	0	0	0	1	0	0	0	2	0	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
spinal cord	hemorrhage		<50>				<50>				<50>				<50>			
			0	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 15

Organ_____	Findings_____	Group Name	Control				150 ppm				300 ppm				600 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Special sense organs/appendage)																		
eye			<50>				<50>				<50>				<50>			
	cataract		3	1	0	0	2	1	0	0	4	0	0	0	2	0	0	0
			(6)	(2)	(0)	(0)	(4)	(2)	(0)	(0)	(8)	(0)	(0)	(0)	(4)	(0)	(0)	(0)
	retinal atrophy		33	10	1	0	32	3	0	0 *	11	2	0	0 **	5	1	0	0 **
			(66)	(20)	(2)	(0)	(64)	(6)	(0)	(0)	(22)	(4)	(0)	(0)	(10)	(2)	(0)	(0)
	keratitis		0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(2)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Harder gl			<50>				<50>				<50>				<50>			
	lymphocytic infiltration		4	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(8)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
nasolacr d			<50>				<50>				<50>				<50>			
	inflammation		5	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
(Musculoskeletal system)																		
muscle			<50>				<50>				<50>				<50>			
	hemorrhage		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 16

Organ_____	Findings_____	Group Name	Control				150 ppm				300 ppm				600 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Musculoskeletal system}																		
muscle	mineralization		<50>				<50>				<50>				<50>			
		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
bone	osteosclerosis		<50>				<50>				<50>				<50>			
		2	2	0	0	3	1	0	0	0	0	0	0	0	2	1	0	0
		(4)	(4)	(0)	(0)	(6)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(2)	(0)	(0)	
{Body cavities}																		
adipose	hemorrhage		<50>				<50>				<50>				<50>			
		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
Grade	1 : Slight	2 : Moderate	3 : Marked	4 : Severe														
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
(c)	c : b / a * 100																	
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

(HPT150)

BAIS3

APPENDIX L 3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 1

Organ	Findings	Group Name No. of Animals on Study Grade	Control 1				200 ppm 31				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit			< 1>				<31>				<50>				<50>			
	hemorrhage		0	0	0	0 ?	1	0	0	0 **	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	mineralization		0	0	0	0 ?	9	0	0	0	7	0	0	0	13	2	0	0
			(0)	(0)	(0)	(0)	(29)	(0)	(0)	(0)	(14)	(0)	(0)	(0)	(26)	(4)	(0)	(0)
	eosinophilic change:olfactory epithelium		1	0	0	0 ?	6	0	0	0	8	3	0	0	2	0	0	0
			(100)	(0)	(0)	(0)	(19)	(0)	(0)	(0)	(16)	(6)	(0)	(0)	(4)	(0)	(0)	(0)
	eosinophilic change:respiratory epithelium		0	0	0	0 ?	5	0	0	0	6	0	0	0	2	0	0	0 *
			(0)	(0)	(0)	(0)	(16)	(0)	(0)	(0)	(12)	(0)	(0)	(0)	(4)	(0)	(0)	(0)
	inflammation:foreign body		0	0	0	0 ?	9	0	0	0	10	0	0	0	3	0	0	0
			(0)	(0)	(0)	(0)	(29)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(6)	(0)	(0)	(0)
	inflammation:respiratory epithelium		0	0	0	0 ?	1	0	0	0 **	0	1	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	respiratory metaplasia:olfactory epithelium		0	0	0	0 ?	2	0	0	0	8	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(16)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESTONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 2

Organ_____	Findings_____	Group Name No. of Animals on Study Grade	Control 1				200 ppm 31				400 ppm 50				800 ppm 50					
			1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)		
{Respiratory system}																				
nasal cavit			< 1>				<31>				<50>				<50>					
	respiratory metaplasia:gland		1 (100)	0 (0)	0 (0)	0 (0)	?	29 (94)	0 (0)	0 (0)	0 (0)	33 (66)	4 (8)	0 (0)	0 (0)	32 (64)	3 (6)	0 (0)	0 (0)	
	basal cell hyperplasia:olfactory epithelium		0 (0)	0 (0)	0 (0)	0 (0)	?	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	6 (12)	4 (8)	0 (0)	0 (0)	
	atrophy:olfactory epithelium		0 (0)	0 (0)	0 (0)	0 (0)	?	1 (3)	0 (0)	0 (0)	0 (0)	**	6 (12)	0 (0)	0 (0)	0 (0)	19 (38)	2 (4)	0 (0)	0 (0)
	hyperplasia:respiratory epithelium		0 (0)	0 (0)	0 (0)	0 (0)	?	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	**	1 (2)	1 (2)	0 (0)	0 (0)
	atypical dilatation:olfactory gland		0 (0)	0 (0)	0 (0)	0 (0)	?	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)
larynx			< 1>				<31>				<50>				<50>					
	mineralization		0 (0)	0 (0)	0 (0)	0 (0)	?	1 (3)	0 (0)	0 (0)	0 (0)	**	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

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

< a > a : Number of animals examined at the site

b b : Number of animals with lesion

(c) c : b / a * 100

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

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

(HPT150)

BAIS3

STUDY NO. : C303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study Grade	Control 1				200 ppm 31				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
larynx	inflammation		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	0	1	0	0 **	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
trachea	mineralization		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	0	1	0	0 **	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
lung	congestion		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	0	2	0	0	0	2	0	0 *	0	2	0	0 *
			(0)	(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(4)	(0)	(0)
	hemorrhage		0	0	0	0 ?	8	4	3	0	13	7	0	0	7	5	2	0
			(0)	(0)	(0)	(0)	(26)	(13)	(10)	(0)	(26)	(14)	(0)	(0)	(14)	(10)	(4)	(0)
	inflammatory infiltration		0	0	1	0 ?	1	1	0	0 **	1	1	0	0 **	6	2	0	0 **
			(0)	(0)	(100)	(0)	(3)	(3)	(0)	(0)	(2)	(2)	(0)	(0)	(12)	(4)	(0)	(0)
	osseous metaplasia		1	0	0	0 ?	1	0	0	0	0	0	0	0 **	0	0	0	0 **
			(100)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b b : Number of animals with lesion

(c) c : b / a * 100

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

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 4

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	1				31				50				50			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
lung			< 1>				<31>				<50>				<50>			
	bronchiolar-alveolar cell hyperplasia		0	0	0	0 ?	1	0	0	0 **	0	0	0	0	1	0	0	0 **
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
{Hematopoietic system}																		
bone marrow			< 1>				<31>				<50>				<50>			
	granulation		0	0	0	0 ?	0	0	0	0	0	0	0	0	1	0	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	increased hematopoiesis		1	0	0	0 ?	19	0	0	0	38	0	0	0	38	0	0	0
			(100)	(0)	(0)	(0)	(61)	(0)	(0)	(0)	(76)	(0)	(0)	(0)	(76)	(0)	(0)	(0)
	granulopoiesis:increased		0	0	0	0 ?	1	0	0	0 **	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
lymph node			< 1>				<31>				<50>				<50>			
	lymphadenitis		0	0	0	0 ?	1	0	0	0 **	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b b : Number of animals with lesion

(c) c : b / a * 100

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

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

(HPT150)

BAIS3

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 5

Organ	Findings	Group Name No. of Animals on Study Grade	Control 1				200 ppm 31				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																		
spleen			< 1>				<31>				<50>				<50>			
	atrophy		0	0	0	0 ?	1	2	0	0	4	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(3)	(6)	(0)	(0)	(8)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	congestion		0	1	0	0 ?	1	0	0	0 **	0	0	0	0 **	0	0	0	0 **
			(0)	(100)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	deposit of hemosiderin		0	0	0	0 ?	2	0	0	0	1	0	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory infiltration		0	0	0	0 ?	2	1	0	0	5	0	0	0	2	1	0	0
			(0)	(0)	(0)	(0)	(6)	(3)	(0)	(0)	(10)	(0)	(0)	(0)	(4)	(2)	(0)	(0)
	fibrosis		1	0	0	0 ?	0	0	0	0 **	0	0	0	0 **	0	0	0	0 **
			(100)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	extramedullary hematopoiesis		0	0	0	0 ?	8	12	0	0	29	11	0	0	13	20	0	0
			(0)	(0)	(0)	(0)	(26)	(39)	(0)	(0)	(58)	(22)	(0)	(0)	(26)	(40)	(0)	(0)

{Circulatory system}

heart			< 1>				<31>				<50>				<50>			
	mineralization		0	0	0	0 ?	0	0	0	0	1	0	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 6

Organ	Findings	Group Name No. of Animals on Study Grade	Control 1				200 ppm 31				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Circulatory system}																		
heart	inflammatory cell nest		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	1	0	0	0 **	1	0	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	myocardial fibrosis		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	12	5	0	0	11	1	0	0	9	0	0	0
			(0)	(0)	(0)	(0)	(39)	(16)	(0)	(0)	(22)	(2)	(0)	(0)	(18)	(0)	(0)	(0)
{Digestive system}																		
tooth	dysplasia		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	1	0	0	0 **	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
stomach	mineralization		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	0	1	0	0 **	0	1	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	ulcer:forestomach		< 1>				<31>				<50>				<50>			
			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)	(6)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

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

(HPT150)

BAIS3

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 7

Organ	Findings	Group Name No. of Animals on Study Grade	Control 1				200 ppm 31				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Digestive system)																		
stomach			< 1>				<31>				<50>				<50>			
	hyperplasia:forestomach		0	0	0	0 ?	0	1	0	0 **	1	0	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	erosion:glandular stomach		0	0	0	0 ?	0	0	0	0	2	0	0	0 *	2	0	0	0 *
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(4)	(0)	(0)	(0)
	ulcer:glandular stomach		0	0	0	0 ?	0	1	0	0 **	1	0	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia:glandular stomach		0	0	0	0 ?	0	0	0	0	1	0	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hemorrhage:glandular stomach		0	0	0	0 ?	1	0	0	0 **	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
small intes			< 1>				<31>				<50>				<50>			
	hemorrhage		0	0	0	0 ?	0	0	0	0	1	0	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b 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

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

(HPT150)

BAIS3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : AI
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 8

Organ	Findings	Group Name No. of Animals on Study Grade	Control 1				200 ppm 31				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver			< 1>				<31>				<50>				<50>			
	herniation		0	0	0	?	4	0	0	0	3	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(13)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	congestion		0	0	0	?	0	0	0	0	0	1	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	angiectasis		0	0	0	?	1	0	0	0 **	1	0	0	0 **	0	1	0	0 **
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
	thrombus		0	0	0	?	0	0	0	0	0	1	0	0 **	0	1	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)
	necrosis:central		0	0	0	?	6	3	0	0	10	11	1	0	5	4	2	0
			(0)	(0)	(0)	(0)	(19)	(10)	(0)	(0)	(20)	(22)	(2)	(0)	(10)	(8)	(4)	(0)
	necrosis:focal		0	0	0	?	1	5	1	0	6	10	1	0	5	7	4	0
			(0)	(0)	(0)	(0)	(3)	(16)	(3)	(0)	(12)	(20)	(2)	(0)	(10)	(14)	(8)	(0)
	fatty change		0	0	0	?	0	0	0	0	1	0	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 9

Organ	Findings	Control 1 No. of Animals on Study Grade				200 ppm 31				400 ppm 50				800 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																	
liver		< 1>				<31>				<50>				<50>			
	fatty change:central	0	0	0	0 ?	0	1	0	0 **	0	1	0	0 **	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory infiltration	0	1	0	0 ?	1	2	0	0 **	0	0	0	0 **	0	0	0	0 **
		(0)	(100)	(0)	(0)	(3)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	granulation	0	0	0	0 ?	0	0	0	0	0	1	0	0 **	1	0	0	0 **
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(2)	(0)	(0)	(0)
	hyperplasia:vascular	0	0	0	0 ?	1	0	0	0 **	1	0	0	0 **	0	0	0	0
		(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	clear cell focus	0	0	0	0 ?	3	3	0	0	1	3	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(10)	(10)	(0)	(0)	(2)	(6)	(0)	(0)	(0)	(0)	(0)	(0)
	acidophilic cell focus	0	0	0	0 ?	4	1	1	0	2	2	0	0	0	0	1	0 **
		(0)	(0)	(0)	(0)	(13)	(3)	(3)	(0)	(4)	(4)	(0)	(0)	(0)	(0)	(2)	(0)
	basophilic cell focus	0	0	0	0 ?	4	5	0	0	2	10	0	0	5	3	1	0
		(0)	(0)	(0)	(0)	(13)	(16)	(0)	(0)	(4)	(20)	(0)	(0)	(10)	(6)	(2)	(0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 10

Organ	Findings	Group Name No. of Animals on Study Grade	Control 1				200 ppm 31				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Digestive system)																		
liver			< 1>				<31>				<50>				<50>			
	vacuolated cell focus		0	0	0	0 ?	1	0	0	0 **	0	0	0	0	1	0	0	0 **
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	spongiosis hepatitis		0	0	0	0 ?	7	2	0	0	0	1	0	0 **	2	3	0	0
			(0)	(0)	(0)	(0)	(23)	(6)	(0)	(0)	(0)	(2)	(0)	(0)	(4)	(6)	(0)	(0)
	bile duct hyperplasia		0	0	1	0 ?	9	16	2	0 *	10	23	1	0 **	6	3	0	0 **
			(0)	(0)	(100)	(0)	(29)	(52)	(6)	(0)	(20)	(46)	(2)	(0)	(12)	(6)	(0)	(0)
	biliary cyst		0	0	0	0 ?	0	0	0	0	1	0	0	0 **	1	0	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	regenerative hyperplasia		0	0	0	0 ?	0	0	0	0	1	3	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(6)	(0)	(0)	(0)	(0)	(0)	(0)
pancreas			< 1>				<31>				<50>				<50>			
	atrophy		1	0	0	0 ?	5	1	1	0	3	2	0	0 **	0	0	0	0 **
			(100)	(0)	(0)	(0)	(16)	(3)	(3)	(0)	(6)	(4)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

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

(HPT150)

BAIS3

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 11

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	1				31				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ_____	Findings_____		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>																		
{Digestive system}																		
pancreas			< 1>				<31>				<50>				<50>			
	islet cell hyperplasia		1	0	0	0 ?	0	1	0	0 **	0	0	0	0 **	0	0	0	0 **
			(100)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Urinary system}																		
kidney			< 1>				<31>				<50>				<50>			
	basophilic change		0	0	0	0 ?	0	0	0	0	0	0	0	0	0	1	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
	deposit of hemosiderin		0	0	0	0 ?	3	1	0	0	6	7	0	0	3	4	0	0
			(0)	(0)	(0)	(0)	(10)	(3)	(0)	(0)	(12)	(14)	(0)	(0)	(6)	(8)	(0)	(0)
	chronic nephropathy		0	0	0	0 ?	4	2	1	0	5	3	0	0	5	0	0	0
			(0)	(0)	(0)	(0)	(13)	(6)	(3)	(0)	(10)	(6)	(0)	(0)	(10)	(0)	(0)	(0)
	pyelonephritis		0	0	0	0 ?	0	1	0	0 **	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

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

(HPT150)

BAIS3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 12

Organ	Findings	Group Name No. of Animals on Study Grade	Control 1				200 ppm 31				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Urinary system)																		
kidney			< 1>				<31>				<50>				<50>			
	tubular necrosis		0	1	0	0 ?	4	10	3	0	7	9	7	0	2	14	4	0
			(0)	(100)	(0)	(0)	(13)	(32)	(10)	(0)	(14)	(18)	(14)	(0)	(4)	(28)	(8)	(0)
	papillary necrosis		0	0	0	0 ?	0	0	0	0	0	0	0	0	0	1	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
	mineralization:cortico-medullary junction		0	0	0	0 ?	1	0	1	0	0	0	0	0	0	2	0	0 *
			(0)	(0)	(0)	(0)	(3)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(0)	(0)
	mineralization:papilla		0	0	0	0 ?	5	0	0	0	4	0	0	0	5	2	0	0
			(0)	(0)	(0)	(0)	(16)	(0)	(0)	(0)	(8)	(0)	(0)	(0)	(10)	(4)	(0)	(0)
	mineralization:pelvis		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)	(4)	(0)	(0)	(0)
	mineralization:cortex		0	0	0	0 ?	0	0	0	0	1	0	1	0	0	1	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(2)	(0)	(0)	(2)	(0)	(0)
urin bladd			< 1>				<31>				<50>				<50>			
	simple hyperplasia:transitional epithelium		0	0	0	0 ?	0	0	0	0	1	0	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b 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

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 13

Organ	Findings	Group Name No. of Animals on Study Grade	Control 1				200 ppm 31				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Endocrine system)																		
pituitary			< 1>				<31>				<50>				<50>			
	cyst		0	0	0	0 ?	0	0	0	0	1	0	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia		0	0	0	0 ?	3	2	0	0	2	2	0	0	1	1	0	0
			(0)	(0)	(0)	(0)	(10)	(6)	(0)	(0)	(4)	(4)	(0)	(0)	(2)	(2)	(0)	(0)
	Rathke pouch		0	0	0	0 ?	0	0	0	0	1	0	0	0 **	1	0	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
thyroid			< 1>				<31>				<50>				<50>			
	ultimibranhial body remanet		0	0	0	0 ?	0	0	0	0	1	0	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	C-cell hyperplasia		0	0	0	0 ?	0	1	0	0 **	1	0	0	0 **	1	0	0	0 **
			(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	adrenal		< 1>				<31>				<50>				<50>			
	hyperplasia:medulla		0	0	0	0 ?	2	0	0	0	2	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(4)	(2)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square
 ? : Significant test is not applied,because No. of data in this group is less than 3.

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 97#)

PAGE : 14

Organ_____	Findings_____	Group Name No. of Animals on Study				Control 1				200 ppm 31				400 ppm 50				800 ppm 50			
		Grade				1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																					
adrenal		< 1>				<31>				<50>				<50>							
	focal fatty change:cortex	0 (0)	0 (0)	0 (0)	0 (0)	? (0)	1 (3)	0 (0)	0 (0)	0 (0)	** (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
{Reproductive system}																					
testis		< 1>				<31>				<50>				<50>							
	atrophy	0 (0)	0 (0)	0 (0)	0 (0)	? (0)	3 (10)	2 (6)	0 (0)	0 (0)	0 (0)	2 (4)	2 (4)	0 (0)	3 (6)	1 (2)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)
	arteritis	1 (100)	0 (0)	0 (0)	0 (0)	? (0)	3 (10)	0 (0)	0 (0)	0 (0)	0 (0)	5 (10)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)	0 (0)
	interstitial cell hyperplasia	1 (100)	0 (0)	0 (0)	0 (0)	? (0)	22 (71)	1 (3)	0 (0)	0 (0)	0 (0)	27 (54)	1 (2)	0 (0)	0 (0)	0 (0)	7 (14)	0 (0)	0 (0)	0 (0)	0 (0)
epididymis		< 1>				<31>				<50>				<50>							
	coll debris	0 (0)	1 (100)	0 (0)	0 (0)	? (0)	0 (0)	0 (0)	0 (0)	0 (0)	** (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	** (0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

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

(HPT150)

BAIS3

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 15

Organ	Findings	Group Name No. of Animals on Study Grade	Control 1				200 ppm 31				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
prostate			< 1>				<31>				<50>				<50>			
	hemorrhage		0	0	0	0 ?	0	0	0	0	1	0	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammation		0	0	0	0 ?	2	0	0	0	6	1	0	0	3	0	0	0
			(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(12)	(2)	(0)	(0)	(6)	(0)	(0)	(0)
	hyperplasia		0	0	0	0 ?	0	1	0	0 **	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Nervous system}																		
brain			< 1>				<31>				<50>				<50>			
	hemorrhage		0	0	0	0 ?	1	0	0	0 **	1	0	0	0 **	1	1	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(2)	(0)	(0)
	gliosis		0	0	0	0 ?	0	0	0	0	0	1	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 16

Organ	Findings	Group Name No. of Animals on Study Grade	Control 1				200 ppm 31				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Special sense organs/appendage}																		
eye	cataract		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	2	0	0	0	4	0	0	0	1	0	0	0 **
			(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(8)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	retinal atrophy		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	2	1	0	0	4	3	0	0	1	0	0	0 **
			(0)	(0)	(0)	(0)	(6)	(3)	(0)	(0)	(8)	(6)	(0)	(0)	(2)	(0)	(0)	(0)
Harder gl	lymphocytic infiltration		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	1	0	0	0 **	0	1	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
{Musculoskeletal system}																		
bone	osteosclerosis		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	1	0	0	0 **	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Body cavities}																		
pleura	hemorrhage		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	0	0	0	0	0	1	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 17

Organ	Findings	Group Name No. of Animals on Study Grade	Control 1				200 ppm 31				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Body cavities)																		
mediastinum	hemorrhage		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	0	0	0	0	0	1	0	0 **	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
peritoneum	hemorrhage		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	0	0	0	0	0	0	0	0	0	1	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
	thrombus		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	0	0	0	0	0	0	0	0	0	1	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
adipose	thrombus		< 1>				<31>				<50>				<50>			
			0	0	0	0 ?	0	2	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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

< a > a : Number of animals examined at the site

b b : Number of animals with lesion

(c) c : b / a * 100

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

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

(IPT150)

BAIS3

APPENDIX L 4

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE: DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 1

Organ	Findings	Group Name No. of Animals on Study Grade				Control 9				150 ppm 33				300 ppm 48				600 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																					
nasal cavit		< 9>				<33>				<48>				<50>							
	mineralization	0	0	0	0	0	0	0	0	6	0	0	0	2	0	0	0				
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(13)	(0)	(0)	(0)	(4)	(0)	(0)	(0)				
	eosinophilic change:olfactory epithelium	4	3	1	0	11	9	0	0	12	8	0	0 *	13	18	0	0 *				
		(44)	(33)	(11)	(0)	(33)	(27)	(0)	(0)	(25)	(17)	(0)	(0)	(26)	(36)	(0)	(0)				
	eosinophilic change:respiratory epithelium	5	0	0	0	2	0	0	0 **	3	0	0	0 **	12	0	0	0				
		(56)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(24)	(0)	(0)	(0)				
	inflammation:foreign body	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0				
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)				
	inflammation:olfactory epithelium	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0				
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)				
	respiratory metaplasia:olfactory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0				
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)				
	respiratory metaplasia:gland	7	0	0	0	24	3	0	0	33	0	0	0	39	0	0	0				
		(78)	(0)	(0)	(0)	(73)	(9)	(0)	(0)	(69)	(0)	(0)	(0)	(78)	(0)	(0)	(0)				
	basal cell hyperplasia:olfactory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0				
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(2)	(0)	(0)				

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 2

Organ	Findings	Group Name No. of Animals on Study Grade				Control 9				150 ppm 33				300 ppm 48				600 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Respiratory system)																					
nasal cavit		< 9>				<33>				<48>				<50>							
	atrophy:olfactory epithelium	0	0	0	0	0	0	0	0	4	1	0	0	12	6	2	0				
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(8)	(2)	(0)	(0)	(24)	(12)	(4)	(0)				
	atypical dilatation:olfactory gland	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)	(6)	(0)	(0)	(0)				
	atypical hyperplasia:olfactory gland	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)	(6)	(0)	(0)	(0)				
larynx		< 9>				<33>				<47>				<50>							
	inflammation	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0				
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)				
trachea		< 9>				<33>				<47>				<50>							
	inflammatory infiltration	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0				
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)				
lung		< 9>				<33>				<48>				<50>							
	congestion	1	0	0	0	2	1	0	0	1	1	0	0	4	1	0	0				
		(11)	(0)	(0)	(0)	(6)	(3)	(0)	(0)	(2)	(2)	(0)	(0)	(8)	(2)	(0)	(0)				
	hemorrhage	0	0	0	0	2	5	0	0	13	4	0	0	14	4	0	0				
		(0)	(0)	(0)	(0)	(6)	(15)	(0)	(0)	(27)	(8)	(0)	(0)	(28)	(8)	(0)	(0)				

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 3

		Group Name	Control				150 ppm				300 ppm				600 ppm			
		No. of Animals on Study	9				33				48				50			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
<hr/>																		
{Respiratory system}																		
lung			< 9>				<33>				<48>				<50>			
	thrombus		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory infiltration		0	1	0	0	4	0	0	0	1	2	0	0	1	1	0	0
			(0)	(11)	(0)	(0)	(12)	(0)	(0)	(0)	(2)	(4)	(0)	(0)	(2)	(2)	(0)	(0)
	accumulation of foamy cells		0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
	bronchiolar-alveolar cell hyperplasia		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(11)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Hematopoietic system}																		
bone marrow			< 9>				<33>				<48>				<50>			
	granulation		0	0	0	0	0	0	0	0	1	2	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(4)	(0)	(0)	(0)	(2)	(0)	(0)
	increased hematopoiesis		2	0	0	0	12	0	0	0	28	0	0	0	40	0	0	0 **
		(22)	(0)	(0)	(0)	(36)	(0)	(0)	(0)	(58)	(0)	(0)	(0)	(80)	(0)	(0)	(0)	
	decreased hematopoiesis		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																	
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
(c)	c : b / a * 100																	
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square																		

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 4

Organ	Findings	Control No. of Animals on Study Grade				150 ppm 33				300 ppm 48				600 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																	
bone marrow		< 9>				<33>				<48>				<50>			
	myelofibrosis	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	granulopoiesis:increased	1 (11)	0 (0)	0 (0)	0 (0)	2 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
lymph node		< 9>				<33>				<48>				<50>			
	lymphadenitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
spleen		< 9>				<33>				<48>				<50>			
	atrophy	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	congestion	0 (0)	0 (0)	0 (0)	0 (0)	2 (6)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	necrosis:focal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	deposit of hemosiderin	1 (11)	3 (33)	0 (0)	0 (0)	10 (30)	3 (9)	2 (6)	0 (0)	13 (27)	7 (15)	0 (0)	0 (0)	18 (36)	4 (8)	2 (4)	0 (0)

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 5

Organ	Findings	Group Name No. of Animals on Study Grade				Control 9				150 ppm 33				300 ppm 48				600 ppm 50			
		1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)				
(Hematopoietic system)																					
spleen		< 9>				<33>				<48>				<50>							
	inflammatory infiltration	1 (11)	0 (0)	0 (0)	0 (0)	1 (3)	1 (3)	0 (0)	0 (0)	3 (6)	1 (2)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)				
	extramedullary hematopoiesis	2 (22)	1 (11)	0 (0)	0 (0)	6 (18)	7 (21)	0 (0)	0 (0)	20 (42)	7 (15)	0 (0)	0 (0)	28 (56)	8 (16)	0 (0)	0 (0)				
(Circulatory system)																					
heart		< 9>				<33>				<48>				<50>							
	inflammatory cell nest	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
	myocardial fibrosis	2 (22)	0 (0)	0 (0)	0 (0)	9 (27)	1 (3)	0 (0)	0 (0)	4 (8)	0 (0)	0 (0)	0 (0)	5 (10)	0 (0)	0 (0)	0 (0)				
(Digestive system)																					
tooth		< 9>				<33>				<48>				<50>							
	dysplasia	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																				
< a >	a : Number of animals examined at the site																				
b	b : Number of animals with lesion																				
(c)	c : b / a * 100																				
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																					
(HPT150)																					

BAIS3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 6

Organ	Findings	Control No. of Animals on Study Grade				150 ppm 33				300 ppm 48				600 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Digestive system)																	
stomach	mineralization	< 9>				<33>				<48>				<50>			
		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	erosion:forestomach	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	ulcer:forestomach	0	1	1	0	3	0	0	0 *	1	2	0	0	1	2	0	0
		(0)	(11)	(11)	(0)	(9)	(0)	(0)	(0)	(2)	(4)	(0)	(0)	(2)	(4)	(0)	(0)
liver	hyperplasia:forestomach	0	0	0	0	2	0	0	0	3	1	0	0	2	1	0	0
		(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(6)	(2)	(0)	(0)	(4)	(2)	(0)	(0)
	erosion:glandular stomach	1	0	0	0	3	0	0	0	1	0	0	0	2	0	0	0
		(11)	(0)	(0)	(0)	(9)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(4)	(0)	(0)	(0)
	ulcer:glandular stomach	0	0	0	0	5	0	0	0	4	0	0	0	1	0	0	0
		(0)	(0)	(0)	(0)	(15)	(0)	(0)	(0)	(8)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
liver	herniation	< 9>				<33>				<48>				<50>			
		2	0	0	0	3	0	0	0	2	0	0	0	4	0	0	0
		(22)	(0)	(0)	(0)	(9)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(8)	(0)	(0)	(0)
liver	congestion	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		(11)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe < a > a : Number of animals examined at the site b : Number of animals with lesion (c) c : b / a * 100 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																	

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 7

Organ	Findings	Group Name No. of Animals on Study Grade				Control 9				150 ppm 33				300 ppm 48				600 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Digestive system)																					
liver		< 9 >				<33>				<48>				<50>							
	angiectasis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (6)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	thrombus	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	peliosis-like lesion	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	necrosis:central	0 (0)	1 (11)	0 (0)	0 (0)	4 (12)	6 (18)	0 (0)	0 (0)	9 (19)	5 (10)	0 (0)	0 (0)	7 (14)	4 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	necrosis:focal	0 (0)	0 (0)	0 (0)	0 (0)	6 (18)	7 (21)	0 (0)	0 (0)	8 (17)	5 (10)	1 (2)	0 (0)	8 (16)	9 (18)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	fatty change	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	1 (3)	0 (0)	3 (6)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	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)	2 (6)	1 (3)	0 (0)	1 (2)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	inflammatory infiltration	0 (0)	1 (11)	0 (0)	0 (0)	2 (6)	1 (3)	0 (0)	0 (0)	0 (0)	3 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 8

Organ	Findings	Control No. of Animals on Study Grade				150 ppm 33				300 ppm 48				600 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Digestive system)																	
liver		< 9 >				<33>				<48>				<50>			
	granulation	1 (11)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	3 (6)	0 (0)	0 (0)	0 (0)
	hyperplasia:vascular	0 (0)	0 (0)	0 (0)	0 (0)	5 (15)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	8 (16)	1 (2)	0 (0)	0 (0)
	clear cell focus	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	1 (2)	3 (6)	0 (0)	0 (0)	2 (4)	5 (10)	0 (0)	0 (0)
	acidophilic cell focus	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	4 (8)	3 (6)	0 (0)	1 (2)	4 (8)	0 (0)	0 (0)
	basophilic cell focus	2 (22)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	3 (6)	4 (8)	0 (0)	0 (0)	4 (8)	4 (8)	0 (0)	0 (0)
	vacuolated cell focus	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	1 (3)	0 (0)	0 (0)	4 (8)	1 (2)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
	spongiosis hepatitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	bile duct hyperplasia	0 (0)	0 (0)	0 (0)	0 (0)	3 (9)	0 (0)	0 (0)	0 (0)	5 (10)	0 (0)	1 (2)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)

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

< a > a : Number of animals examined at the site

b b : Number of animals with lesion

(c) c : b / a * 100

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 9

Organ	Findings	Control No. of Animals on Study Grade				150 ppm 33				300 ppm 48				600 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																	
liver		< 9>				<33>				<48>				<50>			
	bile ductular proliferation	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)
	biliary cyst	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
	regenerative hyperplasia	0	0	0	0	3	1	0	0	4	0	0	0	3	2	0	0
		(0)	(0)	(0)	(0)	(9)	(3)	(0)	(0)	(8)	(0)	(0)	(0)	(6)	(4)	(0)	(0)
pancreas		< 9>				<33>				<48>				<50>			
	atrophy	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		(11)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hemorrhage	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Urinary system}																	
kidney		< 9>				<33>				<48>				<50>			
	cyst	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 10

Organ	Findings	Control No. of Animals on Study Grade				150 ppm 33				300 ppm 48				600 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																	
kidney		< 9>				<33>				<48>				<50>			
	hyaline droplet	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	basophilic change	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	deposit of hemosiderin	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	1 (3)	0 (0)	0 (0)	2 (4)	1 (2)	0 (0)	0 (0)	5 (10)	3 (6)	0 (0)	0 (0)
	chronic nephropathy	2 (22)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 *
	hydronephrosis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	pyelonephritis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	tubular necrosis	1 (11)	1 (11)	1 (11)	0 (0)	4 (12)	7 (21)	1 (3)	0 (0)	7 (15)	11 (23)	1 (2)	0 (0)	3 (6)	14 (28)	3 (6)	0 (0)
	papillary necrosis	0 (0)	0 (0)	0 (0)	0 (0)	14 (42)	0 (0)	0 (0)	0 *	21 (44)	10 (21)	2 (4)	0 **	17 (34)	12 (24)	0 (0)	0 **

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

< a > a : Number of animals examined at the site

b b : Number of animals with lesion

(c) c : b / a * 100

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 11

Organ	Findings	Group Name	Control				150 ppm				300 ppm				600 ppm			
		No. of Animals on Study	9				33				48				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney			< 9>				<33>				<48>				<50>			
	mineralization:papilla		1	0	0	0	8	1	0	0	16	3	0	0	21	7	0	0 *
			(11)	(0)	(0)	(0)	(24)	(3)	(0)	(0)	(33)	(6)	(0)	(0)	(42)	(14)	(0)	(0)
	mineralization:pelvis		2	1	0	0	2	0	0	0 *	0	0	0	0 **	1	0	0	0 **
			(22)	(11)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
	mineralization:cortex		0	0	0	0	0	0	0	0	1	0	0	0	2	1	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(4)	(2)	(0)	(0)
	urothelial hyperplasia:pelvis		0	0	0	0	0	0	0	0	3	2	0	0	2	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(6)	(4)	(0)	(0)	(4)	(0)	(0)	(0)
	eosinophilic droplet:proximal tubule		0	0	0	0	3	0	0	0	3	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(9)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Endocrine system}																		
pituitary			< 9>				<32>				<48>				<50>			
	angiectasis		1	0	0	0	3	1	0	0	1	0	0	0	2	0	0	0
			(11)	(0)	(0)	(0)	(9)	(3)	(0)	(0)	(2)	(0)	(0)	(0)	(4)	(0)	(0)	(0)
	cyst		3	0	0	0	5	1	0	0	4	0	0	0	3	0	0	0
			(33)	(0)	(0)	(0)	(16)	(3)	(0)	(0)	(8)	(0)	(0)	(0)	(6)	(0)	(0)	(0)
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																	
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
(c)	c : b / a * 100																	
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 12

Organ	Findings	Group Name No. of Animals on Study Grade	Control 9				150 ppm 33				300 ppm 48				600 ppm 50			
			1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
{Endocrine system}																		
pituitary			< 9>				<32>				<48>				<50>			
	hyperplasia		1 (11)	1 (11)	0 (0)	0 (0)	3 (9)	2 (6)	0 (0)	0 (0)	4 (8)	0 (0)	0 (0)	0 (0)	3 (6)	0 (0)	0 (0)	0 * (0)
	Rathke pouch		1 (11)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
thyroid			< 9>				<33>				<46>				<50>			
	ultimibranhial body remanet		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	C-cell hyperplasia		1 (11)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	focal follicular cell hyperplasia		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
adrenal			< 9>				<33>				<48>				<50>			
	peliosis-like lesion		3 (33)	0 (0)	0 (0)	0 (0)	1 (3)	1 (3)	0 (0)	0 * (0)	0 (0)	1 (2)	0 (0)	0 ** (0)	1 (2)	0 (0)	0 (0)	0 ** (0)
	hyperplasia:cortical cell		1 (11)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	4 (8)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																	
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
(c)	c : b / a * 100																	
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 13

		Group Name	Control				150 ppm				300 ppm				600 ppm			
		No. of Animals on Study	9				33				48				50			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
adrenal			< 9>				<33>				<48>				<50>			
	hyperplasia:medulla		0	0	0	0	2	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(6)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	focal fatty change:cortex		0	0	0	0	2	0	0	0	3	0	0	0	1	1	0	0
			(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(2)	(2)	(0)	(0)
	cortical vacuolation:diffuse		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Reproductive system}																		
ovary			< 9>				<33>				<48>				<50>			
	cyst		0	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
uterus			< 9>				<33>				<48>				<50>			
	squamous cell metaplasia		0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)
	cystic endometrial hyperplasia		0	1	0	0	2	2	0	0	1	2	0	0	0	1	0	0
			(0)	(11)	(0)	(0)	(6)	(6)	(0)	(0)	(2)	(4)	(0)	(0)	(0)	(2)	(0)	(0)
Grade	1 : Slight	2 : Moderate	3 : Marked	4 : Severe														
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
(c)	c : b / a * 100																	
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		
{HPT150}																		

BAIS3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 14

Organ	Findings	Group Name No. of Animals on Study Grade	Control 9				150 ppm 33				300 ppm 48				600 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
vagina	squamous cell hyperplasia		< 9>				<33>				<48>				<50>			
			0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
mammary gl	hyperplasia		< 9>				<33>				<48>				<50>			
			0	0	0	0	0	0	1	0	0	0	0	0	1	1	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(2)	(2)	(0)	(0)
	galactoceles		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(11)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Nervous system}																		
brain	hemorrhage		< 9>				<33>				<48>				<50>			
			0	0	0	0	1	0	0	0	2	0	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(4)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
spinal cord	hemorrhage		< 9>				<33>				<48>				<50>			
			0	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(2)	(0)	(0)	(0)
{Special sense organs/appendage}																		
eye	cataract		< 9>				<33>				<48>				<50>			
			1	0	0	0	1	1	0	0	4	0	0	0	2	0	0	0
			(11)	(0)	(0)	(0)	(3)	(3)	(0)	(0)	(8)	(0)	(0)	(0)	(4)	(0)	(0)	(0)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 15

		Group Name No. of Animals on Study Grade				Control 9				150 ppm 33				300 ppm 48				600 ppm 50			
Organ_____	Findings_____	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4				
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)				
{Special sense organs/appendage}																					
eye		< 9>				<33>				<48>				<50>							
	retinal atrophy	3 (33)	1 (11)	0 (0)	0 (0)	18 (55)	1 (3)	0 (0)	0 (0)	9 (19)	2 (4)	0 (0)	0 (0)	5 (10)	1 (2)	0 (0)	0 (0)				
	keratitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
Harder gl		< 9>				<33>				<48>				<50>							
	lymphocytic infiltration	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
nasolacr d		< 9>				<33>				<48>				<50>							
	inflammation	0 (0)	0 (0)	0 (0)	0 (0)	2 (6)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
{Musculoskeletal system}																					
muscle		< 9>				<33>				<48>				<50>							
	hemorrhage	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
	mineralization	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																				
< a >	a : Number of animals examined at the site																				
b	b : Number of animals with lesion																				
(c)	c : b / a * 100																				
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																					

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 16

		Control No. of Animals on Study Grade				150 ppm 33				300 ppm 48				600 ppm 50			
Organ	Findings	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Musculoskeletal system}																	
bone	osteosclerosis	< 9>				<33>				<48>				<50>			
		0	1	0	0	3	0	0	0	0	0	0	0	2	1	0	0
		(0)	(11)	(0)	(0)	(9)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(4)	(2)	(0)	(0)
{Body cavities}																	
adipose	hemorrhage	< 9>				<33>				<48>				<50>			
		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe																	
< a >		a : Number of animals examined at the site															
b		b : Number of animals with lesion															
(c)		c : b / a * 100															
Significant difference :		* : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square															

(HPT150)

BAIS3

APPENDIX L 5

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (97W)

PAGE : 1

		Group Name No. of Animals on Study Grade	Control 49				200 ppm 19				400 ppm 0				800 ppm 0			
Organ_____	Findings_____		1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
{Integumentary system/appandage}																		
skin/app			<49>				<19>				< 0>				< 0>			
	inflammation		1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
	hyperplasia:epidermis		2 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
	epidermal cyst		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
{Respiratory system}																		
nasal cavit			<49>				<19>				< 0>				< 0>			
	mineralization		0 (0)	0 (0)	0 (0)	0 (0)	3 (16)	0 (0)	0 (0)	0 * (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
	eosinophilic change:olfactory epithelium		20 (41)	13 (27)	2 (4)	0 (0)	11 (58)	1 (5)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
	eosinophilic change:respiratory epithelium		6 (12)	0 (0)	0 (0)	0 (0)	3 (16)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
	inflammation:foreign body		5 (10)	2 (4)	0 (0)	0 (0)	6 (32)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																	
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
(c)	c : b / a * 100																	
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (97W)

PAGE : 2

Organ	Findings	Group Name No. of Animals on Study Grade	Control 49				200 ppm 19				400 ppm 0				800 ppm 0			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit			<49>				<19>				< 0>				< 0>			
	respiratory metaplasia:olfactory epithelium		6	0	0	0	6	0	0	0	-	-	-	-	-	-	-	-
			(12)	(0)	(0)	(0)	(32)	(0)	(0)	(0)	()	()	()	()	()	()	()	()
	respiratory metaplasia:gland		45	0	0	0	18	1	0	0	-	-	-	-	-	-	-	-
			(92)	(0)	(0)	(0)	(95)	(5)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	atrophy:olfactory epithelium		0	0	0	0	1	0	0	0	-	-	-	-	-	-	-	-
			(0)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
lung			<49>				<19>				< 0>				< 0>			
	hemorrhage		0	0	0	0	0	1	0	0	-	-	-	-	-	-	-	-
			(0)	(0)	(0)	(0)	(0)	(5)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	bronchiolar-alveolar cell hyperplasia		0	1	1	0	1	0	0	0	-	-	-	-	-	-	-	-
			(0)	(2)	(2)	(0)	(5)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
{Hematopoietic system}																		
bone marrow			<49>				<19>				< 0>				< 0>			
	granulation		1	0	0	0	0	1	0	0	-	-	-	-	-	-	-	-
			(2)	(0)	(0)	(0)	(0)	(5)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe																		
< a > a : Number of animals examined at the site																		
b b : Number of animals with lesion																		
(c) c : b / a * 100																		
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (97W)

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study Grade	Control 49				200 ppm 19				400 ppm 0				800 ppm 0			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Hematopoietic system)																		
bone marrow	increased hematopoiesis		<49>				<19>				< 0>				< 0>			
			3	0	0	0	6	0	0	0 *	-	-	-	-	-	-	-	-
			(6)	(0)	(0)	(0)	(32)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
spleen	atrophy		<49>				<19>				< 0>				< 0>			
			0	0	0	0	0	1	0	0	-	-	-	-	-	-	-	-
			(0)	(0)	(0)	(0)	(0)	(5)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	congestion		<49>				<19>				< 0>				< 0>			
			0	0	0	0	0	2	0	0	-	-	-	-	-	-	-	-
			(0)	(0)	(0)	(0)	(0)	(11)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	inflammatory infiltration		<49>				<19>				< 0>				< 0>			
			0	0	0	0	1	0	0	0	-	-	-	-	-	-	-	-
			(0)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	extramedullary hematopoiesis		<49>				<19>				< 0>				< 0>			
			2	0	0	0	1	0	0	0	-	-	-	-	-	-	-	-
			(4)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
(Circulatory system)																		
heart	myocardial fibrosis		<49>				<19>				< 0>				< 0>			
			20	1	0	0	1	0	0	0 *	-	-	-	-	-	-	-	-
			(41)	(2)	(0)	(0)	(5)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (97W)

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study Grade				Control 49				200 ppm 19				400 ppm 0				800 ppm 0			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Digestive system)																					
tooth		<49>				<19>				< 0>				< 0>				< 0>			
	inflammation	0	1	0	0	0	0	0	0	-	-	-	-	-	-	-	-	-	-	-	-
		(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	dysplasia	1	0	0	0	0	0	0	0	-	-	-	-	-	-	-	-	-	-	-	-
		(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
salivary gl		<49>				<19>				< 0>				< 0>				< 0>			
	lymphocytic infiltration	0	0	0	0	4	1	0	0 **	-	-	-	-	-	-	-	-	-	-	-	-
		(0)	(0)	(0)	(0)	(21)	(5)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
stomach		<49>				<19>				< 0>				< 0>				< 0>			
	hyperplasia:glandular stomach	1	0	0	0	0	0	0	0	-	-	-	-	-	-	-	-	-	-	-	-
		(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
liver		<49>				<19>				< 0>				< 0>				< 0>			
	herniation	2	0	0	0	1	0	0	0	-	-	-	-	-	-	-	-	-	-	-	-
		(4)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	angiectasis	0	0	0	0	2	2	0	0 **	-	-	-	-	-	-	-	-	-	-	-	-
		(0)	(0)	(0)	(0)	(11)	(11)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	necrosis:central	0	0	0	0	1	0	0	0	-	-	-	-	-	-	-	-	-	-	-	-
		(0)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (97W)

PAGE : 5

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 19				400 ppm 0				800 ppm 0			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																	
liver		<49>				<19>				< 0>				< 0>			
	fatty change	1 (2)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
	granulation	1 (2)	7 (14)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
	hyperplasia:vascular	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
	clear cell focus	2 (4)	1 (2)	0 (0)	0 (0)	1 (5)	6 (32)	2 (11)	0 ** (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
	acidophilic cell focus	4 (8)	2 (4)	0 (0)	0 (0)	2 (11)	3 (16)	3 (16)	0 ** (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
	basophilic cell focus	4 (8)	3 (6)	0 (0)	1 (2)	4 (21)	9 (47)	1 (5)	1 ** (5)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
	vacuolated cell focus	2 (4)	1 (2)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
	spongiosis hepatitis	4 (8)	0 (0)	0 (0)	0 (0)	5 (26)	3 (16)	0 (0)	0 ** (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (97W)

PAGE : 6

Organ	Findings	Group Name No. of Animals on Study Grade	Control 49				200 ppm 19				400 ppm 0				800 ppm 0			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver			<49>				<19>				< 0>				< 0>			
	bile duct hyperplasia		0	30	19	0	2	14	2	0 **	-	-	-	-	-	-	-	-
			(0)	(61)	(39)	(0)	(11)	(74)	(11)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	biliary cyst		1	0	0	0	0	0	0	0	-	-	-	-	-	-	-	-
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
pancreas			<49>				<19>				< 0>				< 0>			
	atrophy		5	4	0	0	1	1	0	0	-	-	-	-	-	-	-	-
			(10)	(8)	(0)	(0)	(5)	(5)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
{Urinary system}																		
kidney			<49>				<19>				< 0>				< 0>			
	cyst		0	1	0	0	0	0	0	0	-	-	-	-	-	-	-	-
			(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	deposit of hemosiderin		1	0	0	0	1	1	0	0	-	-	-	-	-	-	-	-
			(2)	(0)	(0)	(0)	(5)	(5)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	chronic nephropathy		23	16	7	1	11	6	1	0	-	-	-	-	-	-	-	-
			(47)	(33)	(14)	(2)	(58)	(32)	(5)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (97W)

PAGE : 7

Organ	Findings	Group Name No. of Animals on Study Grade	Control 49				200 ppm 19				400 ppm 0				800 ppm 0			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney			<49>				<19>				< 0>				< 0>			
	tubular necrosis		0	0	0	0	1	0	0	0	-	-	-	-	-	-	-	-
			(0)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	mineralization:papilla		3	0	0	0	2	0	0	0	-	-	-	-	-	-	-	-
			(6)	(0)	(0)	(0)	(11)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	mineralization:pelvis		0	1	0	0	0	0	0	0	-	-	-	-	-	-	-	-
			(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	urothelial hyperplasia:pelvis		1	0	0	0	0	0	0	0	-	-	-	-	-	-	-	-
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
{Endocrine system}																		
pituitary			<49>				<19>				< 0>				< 0>			
	angiectasis		1	0	0	0	0	0	0	0	-	-	-	-	-	-	-	-
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	hyperplasia		4	9	0	0	3	3	0	0	-	-	-	-	-	-	-	-
			(8)	(18)	(0)	(0)	(16)	(16)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
thyroid			<49>				<19>				< 0>				< 0>			
	C-cell hyperplasia		7	2	0	0	1	0	0	0	-	-	-	-	-	-	-	-
			(14)	(4)	(0)	(0)	(5)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe																		
< a > a : Number of animals examined at the site																		
b b : Number of animals with lesion																		
(c) c : b / a * 100																		
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (97#)

PAGE : 8

		Group Name No. of Animals on Study Grade				Control 49				200 ppm 19				400 ppm 0				800 ppm 0			
Organ	Findings	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)				
{Endocrine system}																					
adrenal		<49>				<19>				< 0>				< 0>							
	cyst	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	- ()	- ()	- ()	- ()	- ()	- ()	- ()	- ()				
	hyperplasia:cortical cell	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)				
	hyperplasia:medulla	0 (0)	1 (2)	0 (0)	0 (0)	2 (11)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)				
	focal fatty change:cortex	2 (4)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)				
{Reproductive system}																					
testis		<49>				<19>				< 0>				< 0>							
	atrophy	11 (22)	5 (10)	0 (0)	0 (0)	4 (21)	2 (11)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)				
	arteritis	15 (31)	1 (2)	0 (0)	0 (0)	5 (26)	0 (0)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)				
	interstitial cell hyperplasia	25 (51)	2 (4)	0 (0)	0 (0)	13 (68)	2 (11)	0 (0)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)				
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																				
< a >	a : Number of animals examined at the site																				
b	b : Number of animals with lesion																				
(c)	c : b / a * 100																				
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																					

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (97W)

PAGE : 9

Organ	Findings	Group Name No. of Animals on Study Grade	Control 49				200 ppm 19				400 ppm 0				800 ppm 0			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
epididymis	cell debris		<49>				<19>				< 0>				< 0>			
			5	0	0	0	1	0	0	0	-	-	-	-	-	-	-	-
			(10)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
prostate	inflammation		<49>				<19>				< 0>				< 0>			
			9	1	0	0	1	0	0	0	-	-	-	-	-	-	-	-
			(18)	(2)	(0)	(0)	(5)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	hyperplasia		<49>				<19>				< 0>				< 0>			
			4	0	0	0	1	1	0	0	-	-	-	-	-	-	-	-
			(8)	(0)	(0)	(0)	(5)	(5)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
mammary gl	galactoceles		<49>				<19>				< 0>				< 0>			
			0	1	0	0	0	0	0	0	-	-	-	-	-	-	-	-
			(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
{Special sense organs/appendage}																		
eye	cataract		<49>				<19>				< 0>				< 0>			
			3	1	0	0	4	0	0	0	-	-	-	-	-	-	-	-
			(6)	(2)	(0)	(0)	(21)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	retinal atrophy		<49>				<19>				< 0>				< 0>			
			18	4	0	0	8	3	0	0	-	-	-	-	-	-	-	-
			(37)	(8)	(0)	(0)	(42)	(16)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe																		
< a > a : Number of animals examined at the site																		
b : Number of animals with lesion																		
(c) c : b / a * 100																		
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (97W)

PAGE : 10

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	49				19				0				0			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Special sense organs/appendage}																		
Harder gl			<49>				<19>				< 0>				< 0>			
	hyperplasia		1	0	0	0	0	0	0	0	-	-	-	-	-	-	-	-
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	()	()	()	()	()	()	()	()
{Musculoskeletal system}																		
bone			<49>				<19>				< 0>				< 0>			
	osteosclerosis		0	0	0	0	1	0	0	0	-	-	-	-	-	-	-	-
			(0)	(0)	(0)	(0)	(5)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

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

(HPT150)

BAIS3

APPENDIX L 6

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE: SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 1

Organ	Findings	Group Name No. of Animals on Study Grade				Control 41				150 ppm 17				300 ppm 2				600 ppm 0			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appandage}																					
skin/app		<41>				<17>				< 2>				< 0>							
	inflammation	0	0	0	0	1	0	0	0	0	0	0	0	?	-	-	-	-	-	-	-
		(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
{Respiratory system}																					
nasal cavit		<41>				<17>				< 2>				< 0>							
	mineralization	4	0	0	0	2	0	0	0	1	0	0	0	?	-	-	-	-	-	-	-
		(10)	(0)	(0)	(0)	(12)	(0)	(0)	(0)	(50)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	eosinophilic change:olfactory epithelium	6	26	7	0	5	10	0	0	0	2	0	0	?	-	-	-	-	-	-	-
		(15)	(63)	(17)	(0)	(29)	(59)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	eosinophilic change:respiratory epithelium	21	2	0	0	4	0	0	0	0	0	0	0	?	-	-	-	-	-	-	-
		(51)	(5)	(0)	(0)	(24)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	inflammation:foreign body	2	0	0	0	1	0	0	0	0	0	0	0	?	-	-	-	-	-	-	-
		(5)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

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

(IPT150)

BAIS3

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 2

Organ	Findings	Group Name No. of Animals on Study Grade	Control 41				150 ppm 17				300 ppm 2				600 ppm 0			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Respiratory system)																		
nasal cavit	respiratory metaplasia:olfactory epithelium		<41>				<17>				< 2>				< 0>			
			0	0	0	0	1	0	0	0	0	0	0	0	?	-	-	-
			(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	?	(-)	(-)	(-)
	respiratory metaplasia:gland		37	0	0	0	16	1	0	0	2	0	0	0	?	-	-	-
			(90)	(0)	(0)	(0)	(94)	(6)	(0)	(0)	(100)	(0)	(0)	(0)	?	(-)	(-)	(-)
trachea	xanthogranuloma		<41>				<17>				< 2>				< 0>			
			0	0	0	0	0	0	0	0	0	1	0	0	?	-	-	-
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(50)	(0)	(0)	?	(-)	(-)	(-)
lung	hemorrhage		<41>				<17>				< 2>				< 0>			
			0	0	0	0	1	1	0	0	0	0	0	0	?	-	-	-
			(0)	(0)	(0)	(0)	(6)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	?	(-)	(-)	(-)
	accumulation of foamy cells		1	0	0	0	0	0	0	0	0	0	0	0	?	-	-	-
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	?	(-)	(-)	(-)
	bronchiolar-alveolar cell hyperplasia		1	0	0	0	0	0	0	0	0	0	0	0	?	-	-	-
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	?	(-)	(-)	(-)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 3

		Group Name No. of Animals on Study Grade	Control 41				150 ppm 17				300 ppm 2				600 ppm 0				
Organ	Findings		1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	
{Hematopoietic system}																			
bone marrow			<41>				<17>				< 2>				< 0>				
	granulation		2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	?	- ()	- ()	- ()	- ()
	increased hematopoiesis		5 (12)	0 (0)	0 (0)	0 (0)	6 (35)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	?	- (-)	- (-)	- (-)
spleen			<41>				<17>				< 2>				< 0>				
	congestion		4 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	?	- (-)	- (-)	- (-)	- (-)
	deposit of hemosiderin		17 (41)	12 (29)	0 (0)	0 (0)	6 (35)	2 (12)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	?	- (-)	- (-)	- (-)	- (-)
	extramedullary hematopoiesis		5 (12)	0 (0)	0 (0)	0 (0)	2 (12)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	?	- (-)	- (-)	- (-)	- (-)
{Circulatory system}																			
heart			<41>				<17>				< 2>				< 0>				
	myocardial fibrosis		3 (7)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	?	- ()	- ()	- ()	- ()
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																		
< a >	a : Number of animals examined at the site																		
b	b : Number of animals with lesion																		
(c)	c : b / a * 100																		
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																			
? : Significant test is not applied,because No. of data in this group is less than 3.																			

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 4

Organ	Findings	Control No. of Animals on Study Grade				150 ppm 17				300 ppm 2				600 ppm 0			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																	
stomach	erosion:glandular stomach	<41>				<17>				< 2>				< 0>			
		1	0	0	0	0	0	0	0	0	0	0	0 ?	-	-	-	-
		(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)
liver	herniation	<41>				<17>				< 2>				< 0>			
		9	0	0	0	1	0	0	0	0	0	0	0 ?	-	-	-	-
		(22)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)
	angiectasis	0	0	0	0	2	0	0	0	0	0	0	0 ?	-	-	-	-
		(0)	(0)	(0)	(0)	(12)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)
	necrosis:focal	0	0	0	0	1	4	0	0 **	1	0	0	0 ?	-	-	-	-
		(0)	(0)	(0)	(0)	(6)	(24)	(0)	(0)	(50)	(0)	(0)	(0)	(-)	(-)	(-)	(-)
	granulation	14	5	2	0	2	0	0	0 *	0	0	0	0 ?	-	-	-	-
		(34)	(12)	(5)	(0)	(12)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)
	clear cell focus	0	1	0	0	1	2	1	0	0	2	0	0 ?	-	-	-	-
		(0)	(2)	(0)	(0)	(6)	(12)	(6)	(0)	(0)	(100)	(0)	(0)	(-)	(-)	(-)	(-)

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

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

(HPT150)

BAIS3

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 5

		Group Name No. of Animals on Study				Control 41				150 ppm 17				300 ppm 2				600 ppm 0			
		Grade																			
Organ	Findings	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
liver		<41>				<17>				< 2>				< 0>							
	acidophilic cell focus	1	0	0	0	1	4	0	0 **	0	2	0	0 ?	-	-	-	-	-	-	-	-
		(2)	(0)	(0)	(0)	(6)	(24)	(0)	(0)	(0)	(100)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	basophilic cell focus	17	2	0	0	2	3	0	0 *	0	0	0	0 ?	-	-	-	-	-	-	-	-
		(41)	(5)	(0)	(0)	(12)	(18)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	vacuolated cell focus	1	0	0	0	2	0	0	0	0	0	0	0 ?	-	-	-	-	-	-	-	-
		(2)	(0)	(0)	(0)	(12)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	bile duct hyperplasia	12	5	1	0	5	1	0	0	1	0	0	0 ?	-	-	-	-	-	-	-	-
		(29)	(12)	(2)	(0)	(29)	(6)	(0)	(0)	(50)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	cholangiofibrosis	0	0	1	0	0	0	0	0	0	0	0	0 ?	-	-	-	-	-	-	-	-
		(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	regenerative hyperplasia	0	0	0	0	1	0	0	0	0	0	0	0 ?	-	-	-	-	-	-	-	-
		(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	pancreas		<41>				<17>				< 2>				< 0>						
	atrophy	3	1	0	0	1	0	0	0	0	0	0	0 ?	-	-	-	-	-	-	-	-
		(7)	(2)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Grade	1 : Slight	2 : Moderate	3 : Marked	4 : Severe																	
< a >	a : Number of animals examined at the site																				
b	b : Number of animals with lesion																				
(c)	c : b / a * 100																				
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																					
? : Significant test is not applied, because No. of data in this group is less than 3.																					

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 6

Organ	Findings	Group Name No. of Animals on Study Grade	Control 41				150 ppm 17				300 ppm 2				600 ppm 0			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Urinary system)																		
kidney			<41>				<17>				< 2>				< 0>			
	hyaline droplet		1	0	0	0	0	0	0	0	0	0	0	?	-	-	-	-
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)
	deposit of hemosiderin		0	0	0	0	0	1	0	0	1	0	0	?	-	-	-	-
			(0)	(0)	(0)	(0)	(0)	(6)	(0)	(0)	(50)	(0)	(0)	(0)	(-)	(-)	(-)	(-)
	chronic nephropathy		8	2	1	0	1	0	0	0	0	0	0	?	-	-	-	-
			(20)	(5)	(2)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)
	tubular necrosis		0	0	0	0	1	0	0	0	0	0	0	?	-	-	-	-
			(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)
	papillary necrosis		0	0	0	0	4	0	0	0 **	1	1	0	?	-	-	-	-
			(0)	(0)	(0)	(0)	(24)	(0)	(0)	(0)	(50)	(50)	(0)	(0)	(-)	(-)	(-)	(-)
	mineralization:papilla		7	0	0	0	3	0	0	0	2	0	0	?	-	-	-	-
			(17)	(0)	(0)	(0)	(18)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(-)	(-)	(-)	(-)
	mineralization:pelvis		6	1	0	0	1	1	0	0	0	0	0	?	-	-	-	-
			(15)	(2)	(0)	(0)	(6)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)

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

< a > a : Number of animals examined at the site

b b : Number of animals with lesion

(c) c : b / a * 100

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

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 7

		Group Name	Control				150 ppm				300 ppm				600 ppm				
		No. of Animals on Study	41				17				2				0				
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
{Urinary system}																			
kidney			<41>				<17>				< 2>				< 0>				
	mineralization:cortex		1	0	0	0	0	0	0	0	0	0	0	0	?	-	-	-	-
			(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	
	eosinophilic droplet:proximal tubule		2	0	0	0	1	2	0	0	1	0	0	0	?	-	-	-	-
			(5)	(0)	(0)	(0)	(6)	(12)	(0)	(0)	(50)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	
{Endocrine system}																			
pituitary			<41>				<17>				< 2>				< 0>				
	angiectasis		3	0	0	0	3	0	0	0	0	0	0	0	?	-	-	-	-
			(7)	(0)	(0)	(0)	(18)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	
	cyst		12	2	0	0	2	0	0	0	1	0	0	0	?	-	-	-	-
			(29)	(5)	(0)	(0)	(12)	(0)	(0)	(0)	(50)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	
	hyperplasia		2	4	0	0	1	0	0	0	0	0	0	0	?	-	-	-	-
			(5)	(10)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																		
< a >	a : Number of animals examined at the site																		
b	b : Number of animals with lesion																		
(c)	c : b / a * 100																		
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																			
? : Significant test is not applied,because No. of data in this group is less than 3.																			

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 8

		Group Name No. of Animals on Study Grade				Control 41				150 ppm 17				300 ppm 2				600 ppm 0			
Organ	Findings	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)				
{Endocrine system}																					
thyroid		<41>				<17>				< 2>				< 0>							
	C-cell hyperplasia	4 (10)	2 (5)	0 (0)	0 (0)	1 (6)	2 (12)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	?	- (-)	- (-)	- (-)	- (-)			
adrenal		<41>				<17>				< 2>				< 0>							
	peliosis-like lesion	7 (17)	2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	?	- (-)	- (-)	- (-)	- (-)			
	hyperplasia:cortical cell	1 (2)	2 (5)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	?	- (-)	- (-)	- (-)	- (-)			
	hyperplasia:medulla	1 (2)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	?	- (-)	- (-)	- (-)	- (-)			
	focal fatty change:cortex	9 (22)	2 (5)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	?	- (-)	- (-)	- (-)	- (-)			
{Reproductive system}																					
ovary		<41>				<17>				< 2>				< 0>							
	cyst	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	?	- (-)	- (-)	- (-)	- (-)			
Grade	1 : Slight 2 : Moderate 3 : Marked 4 : Severe																				
< a >	a : Number of animals examined at the site																				
b	b : Number of animals with lesion																				
(c)	c : b / a * 100																				
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																					
? : Significant test is not applied,because No. of data in this group is less than 3.																					

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 9

Organ	Findings	Group Name	Control				150 ppm				300 ppm				600 ppm				
		No. of Animals on Study	41				17				2				0				
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
{Reproductive system}																			
uterus			<41>				<17>				< 2>				< 0>				
	dilatation		0	1	0	0	0	0	0	0	0	0	0	0	?	-	-	-	-
			(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	
	cystic endometrial hyperplasia		1	2	0	0	1	1	0	0	0	0	0	0	?	-	-	-	-
			(2)	(5)	(0)	(0)	(6)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	
mammary gl			<41>				<17>				< 2>				< 0>				
	hyperplasia		0	2	0	0	0	0	0	0	0	0	0	0	?	-	-	-	-
			(0)	(5)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	
{Special sense organs/appendage}																			
eye			<41>				<17>				< 2>				< 0>				
	cataract		2	1	0	0	1	0	0	0	0	0	0	0	?	-	-	-	-
			(5)	(2)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	
	retinal atrophy		30	9	1	0	14	2	0	0	2	0	0	0	?	-	-	-	-
			(73)	(22)	(2)	(0)	(82)	(12)	(0)	(0)	(100)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	

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

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

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

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

(HPT150)

BAIS3

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 10

		Group Name	Control				150 ppm				300 ppm				600 ppm				
		No. of Animals on Study	41				17				2				0				
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
Organ	Findings		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
{Special sense organs/appendage}																			
eye	keratitis		<41>				<17>				< 2>				< 0>				
		0	0	0	0	1	0	0	0	0	0	0	0	0	?	-	-	-	-
		(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
Harder gl	lymphocytic infiltration		<41>				<17>				< 2>				< 0>				
		3	0	0	0	0	0	0	0	0	0	0	0	0	?	-	-	-	-
		(7)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)
nasolacr d	inflammation		<41>				<17>				< 2>				< 0>				
		5	0	0	0	0	0	0	0	0	0	0	0	0	?	-	-	-	-
		(12)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)
{Musculoskeletal system}																			
bone	osteosclerosis		<41>				<17>				< 2>				< 0>				
		2	1	0	0	0	1	0	0	0	0	0	0	0	?	-	-	-	-
	(5)	(2)	(0)	(0)	(0)	(0)	(6)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)
Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe																			
< a >		a : Number of animals examined at the site																	
b		b : Number of animals with lesion																	
(c)		c : b / a * 100																	
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																			
? : Significant test is not applied,because No. of data in this group is less than 3.																			

APPENDIX M 1

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

RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

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

PAGE : 1

Time-related Weeks	Items	Group Name	Control	200 ppm	400 ppm	800 ppm
0 - 25	NO. OF EXAMINED ANIMALS		0	0	0	1
	NO. OF ANIMALS WITH TUMORS		0	0	0	1
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	0	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0
	NO. OF BENIGN TUMORS		0	0	0	0
	NO. OF MALIGNANT TUMORS		0	0	0	1
	NO. OF TOTAL TUMORS		0	0	0	1
26 - 45	NO. OF EXAMINED ANIMALS		0	1	2	13
	NO. OF ANIMALS WITH TUMORS		0	0	2	13
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	2	8
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	5
	NO. OF BENIGN TUMORS		0	0	0	4
	NO. OF MALIGNANT TUMORS		0	0	2	14
	NO. OF TOTAL TUMORS		0	0	2	18
46 - 65	NO. OF EXAMINED ANIMALS		0	1	13	33
	NO. OF ANIMALS WITH TUMORS		0	0	13	32
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	4	11
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	9	21
	NO. OF BENIGN TUMORS		0	0	9	9
	NO. OF MALIGNANT TUMORS		0	0	16	57
	NO. OF TOTAL TUMORS		0	0	25	66
66 - 85	NO. OF EXAMINED ANIMALS		1	10	30	3
	NO. OF ANIMALS WITH TUMORS		0	10	30	3
	NO. OF ANIMALS WITH SINGLE TUMORS		0	2	8	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	8	22	3
	NO. OF BENIGN TUMORS		0	8	23	1
	NO. OF MALIGNANT TUMORS		0	12	49	6
	NO. OF TOTAL TUMORS		0	20	72	7

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

Time-related Weeks	Items	Group Name	Control	200 ppm	400 ppm	800 ppm
86 - 96	NO. OF EXAMINED ANIMALS		0	19	5	0
	NO. OF ANIMALS WITH TUMORS		0	19	5	0
	NO. OF ANIMALS WITH SINGLE TUMORS		0	3	2	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	16	3	0
	NO. OF BENIGN TUMORS		0	26	3	0
	NO. OF MALIGNANT TUMORS		0	23	8	0
	NO. OF TOTAL TUMORS		0	49	11	0
97 - 97	NO. OF EXAMINED ANIMALS		49	19	0	0
	NO. OF ANIMALS WITH TUMORS		47	19	0	0
	NO. OF ANIMALS WITH SINGLE TUMORS		21	2	0	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		26	17	0	0
	NO. OF BENIGN TUMORS		75	29	0	0
	NO. OF MALIGNANT TUMORS		6	18	0	0
	NO. OF TOTAL TUMORS		81	47	0	0
0 - 97	NO. OF EXAMINED ANIMALS		50	50	50	50
	NO. OF ANIMALS WITH TUMORS		47	48	50	49
	NO. OF ANIMALS WITH SINGLE TUMORS		21	7	16	20
	NO. OF ANIMALS WITH MULTIPLE TUMORS		26	41	34	29
	NO. OF BENIGN TUMORS		75	63	35	14
	NO. OF MALIGNANT TUMORS		6	53	75	78
	NO. OF TOTAL TUMORS		81	116	110	92

(HPT070)

BAIS3

APPENDIX M 2

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

RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 3

Time-related Weeks	Items	Group Name	Control	150 ppm	300 ppm	600 ppm
0 - 25	NO. OF EXAMINED ANIMALS		0	0	0	0
	NO. OF ANIMALS WITH TUMORS		0	0	0	0
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	0	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0
	NO. OF BENIGN TUMORS		0	0	0	0
	NO. OF MALIGNANT TUMORS		0	0	0	0
	NO. OF TOTAL TUMORS		0	0	0	0
26 - 45	NO. OF EXAMINED ANIMALS		0	0	1	3
	NO. OF ANIMALS WITH TUMORS		0	0	1	2
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	1	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	1
	NO. OF BENIGN TUMORS		0	0	0	1
	NO. OF MALIGNANT TUMORS		0	0	1	2
	NO. OF TOTAL TUMORS		0	0	1	3
46 - 65	NO. OF EXAMINED ANIMALS		1	0	6	19
	NO. OF ANIMALS WITH TUMORS		0	0	5	18
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	4	3
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	1	15
	NO. OF BENIGN TUMORS		0	0	3	13
	NO. OF MALIGNANT TUMORS		0	0	3	23
	NO. OF TOTAL TUMORS		0	0	6	36
66 - 85	NO. OF EXAMINED ANIMALS		2	5	24	27
	NO. OF ANIMALS WITH TUMORS		2	5	24	27
	NO. OF ANIMALS WITH SINGLE TUMORS		2	2	7	2
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	3	17	25
	NO. OF BENIGN TUMORS		1	2	27	25
	NO. OF MALIGNANT TUMORS		1	6	27	40
	NO. OF TOTAL TUMORS		2	8	54	65

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 4

Time-related Weeks	Items	Group Name	Control	150 ppm	300 ppm	600 ppm
86 - 104	NO. OF EXAMINED ANIMALS		6	28	17	1
	NO. OF ANIMALS WITH TUMORS		6	27	17	1
	NO. OF ANIMALS WITH SINGLE TUMORS		3	8	3	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		3	19	14	1
	NO. OF BENIGN TUMORS		5	37	22	0
	NO. OF MALIGNANT TUMORS		4	21	25	3
	NO. OF TOTAL TUMORS		9	58	47	3
105 - 105	NO. OF EXAMINED ANIMALS		41	17	2	0
	NO. OF ANIMALS WITH TUMORS		29	17	2	0
	NO. OF ANIMALS WITH SINGLE TUMORS		18	3	1	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		11	14	1	0
	NO. OF BENIGN TUMORS		38	27	3	0
	NO. OF MALIGNANT TUMORS		3	12	2	0
	NO. OF TOTAL TUMORS		41	39	5	0
0 - 105	NO. OF EXAMINED ANIMALS		50	50	50	50
	NO. OF ANIMALS WITH TUMORS		37	49	49	48
	NO. OF ANIMALS WITH SINGLE TUMORS		23	13	16	6
	NO. OF ANIMALS WITH MULTIPLE TUMORS		14	36	33	42
	NO. OF BENIGN TUMORS		44	66	55	39
	NO. OF MALIGNANT TUMORS		8	39	58	68
	NO. OF TOTAL TUMORS		52	105	113	107

(HPT070)

BAIS3

APPENDIX N 1

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS : SUMMARY

RAT : MALE: ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 1

Organ	Findings	Group Name No. of animals on Study	Control 50	200 ppm 50	400 ppm 50	800 ppm 50
{Integumentary system/appandage}						
skin/app			<50>	<50>	<50>	<50>
	keratoacanthoma		2 (4%)	2 (4%)	0 (0%)	1 (2%)
subcutis			<50>	<50>	<50>	<50>
	fibroma		3 (6%)	2 (4%)	0 (0%)	0 (0%)
{Respiratory system}						
nasal cavit			<50>	<50>	<50>	<50>
	adenoma		0 (0%)	0 (0%)	0 (0%)	1 (2%)
	hemangioma		0 (0%)	0 (0%)	1 (2%)	0 (0%)
	sarcoma:NOS		0 (0%)	1 (2%)	5 (10%)	1 (2%)
	ethesioneuroepithelioma		0 (0%)	0 (0%)	1 (2%)	6 (12%)
lung			<50>	<50>	<50>	<50>
	bronchiolar-alveolar adenoma		2 (4%)	0 (0%)	0 (0%)	0 (0%)
	adenosquamous carcinoma		0 (0%)	0 (0%)	1 (2%)	0 (0%)
	bronchiolar-alveolar carcinoma		1 (2%)	0 (0%)	0 (0%)	0 (0%)
	hemangiosarcoma		0 (0%)	0 (0%)	2 (4%)	1 (2%)
{Hematopoietic system}						
spleen			<50>	<50>	<50>	<50>
	mononuclear cell leukemia		2 (4%)	1 (2%)	1 (2%)	0 (0%)

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

(HPT085)

BAIS3

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 2

Organ	Findings	Group Name No. of animals on Study	Control 50	200 ppm 50	400 ppm 50	800 ppm 50
{Digestive system}						
oral cavity			<50>	<50>	<50>	<50>
	squamous cell papilloma		0 (0%)	1 (2%)	0 (0%)	0 (0%)
salivary gl			<50>	<50>	<50>	<50>
	adenoma		1 (2%)	0 (0%)	0 (0%)	0 (0%)
liver			<50>	<50>	<50>	<50>
	hepatocellular adenoma		1 (2%)	10 (20%)	10 (20%)	9 (18%)
	hemangiosarcoma		0 (0%)	25 (50%)	34 (68%)	43 (86%)
	hepatocellular carcinoma		0 (0%)	22 (44%)	24 (48%)	18 (36%)
pancreas			<50>	<50>	<50>	<50>
	islet cell adenoma		0 (0%)	1 (2%)	1 (2%)	0 (0%)
{Endocrine system}						
pituitary			<50>	<50>	<50>	<50>
	adenoma		16 (32%)	9 (18%)	6 (12%)	0 (0%)
thyroid			<50>	<50>	<50>	<50>
	C-cell adenoma		7 (14%)	4 (8%)	2 (4%)	1 (2%)
	follicular adenoma		0 (0%)	1 (2%)	0 (0%)	0 (0%)
	C-cell carcinoma		1 (2%)	1 (2%)	0 (0%)	0 (0%)
adrenal			<50>	<50>	<50>	<50>
	pheochromocytoma		1 (2%)	0 (0%)	0 (0%)	0 (0%)
	cortical adenoma		1 (2%)	0 (0%)	0 (0%)	0 (0%)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 3

Organ	Findings	Group Name No. of animals on Study	Control 50	200 ppm 50	400 ppm 50	800 ppm 50
{Endocrine system}						
adrenal	pheochromocytoma:malignant		<50> 1 (2%)	<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)
{Reproductive system}						
testis	interstitial cell tumor		<50> 39 (78%)	<50> 31 (62%)	<50> 13 (26%)	<50> 0 (0%)
prep/cli gl	adenoma		<50> 1 (2%)	<50> 2 (4%)	<50> 2 (4%)	<50> 0 (0%)
{Special sense organs/appendage}						
eye	melanoma		<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
Zymbal gl	squamous cell carcinoma		<50> 1 (2%)	<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)
{Body cavities}						
mediastinum	sarcoma:NOS		<50> 0 (0%)	<50> 1 (2%)	<50> 2 (4%)	<50> 3 (6%)
peritoneum	hemangioma		<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
	mesothelioma		0 (0%)	0 (0%)	1 (2%)	0 (0%)
	hemangiosarcoma		0 (0%)	0 (0%)	0 (0%)	1 (2%)
mesenterium	hemangioma		<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 97W)

PAGE : 4

Organ	Findings	Group Name No. of animals on Study	Control 50	200 ppm 50	400 ppm 50	800 ppm 50
(Body cavities)						
mesenterium	hemangiosarcoma		<50> 0 (0%)	<50> 0 (0%)	<50> 2 (4%)	<50> 2 (4%)
adipose	hemangiosarcoma		<50> 0 (0%)	<50> 2 (4%)	<50> 0 (0%)	<50> 3 (6%)

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

(IPT085)

BAIS3

APPENDIX N 2

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE: ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 1

Organ	Findings	Group Name No. of animals on Study	Control 50	150 ppm 50	300 ppm 50	600 ppm 50
{Integumentary system/appandage}						
subcutis			<50>	<50>	<50>	<50>
	fibroma		0 (0%)	0 (0%)	0 (0%)	1 (2%)
	schwannoma		0 (0%)	1 (2%)	0 (0%)	0 (0%)
	fibrosarcoma		0 (0%)	0 (0%)	1 (2%)	0 (0%)
	sarcoma:NOS		0 (0%)	0 (0%)	1 (2%)	0 (0%)
	carcinosarcoma		1 (2%)	0 (0%)	0 (0%)	0 (0%)
{Respiratory system}						
nasal cavit			<50>	<50>	<50>	<50>
	sarcoma:NOS		0 (0%)	0 (0%)	1 (2%)	1 (2%)
trachea			<50>	<50>	<49>	<50>
	carcinoid tumor		0 (0%)	1 (2%)	0 (0%)	0 (0%)
	sarcoma:NOS		0 (0%)	1 (2%)	1 (2%)	0 (0%)
lung			<50>	<50>	<50>	<50>
	hemangiosarcoma		0 (0%)	2 (4%)	0 (0%)	0 (0%)
{Hematopoietic system}						
lymph node			<50>	<50>	<50>	<50>
	malignant lymphoma		0 (0%)	0 (0%)	1 (2%)	0 (0%)
spleen			<50>	<50>	<50>	<50>
	mononuclear cell leukemia		4 (8%)	11 (22%)	6 (12%)	2 (4%)

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 2

Organ	Findings	Group Name No. of animals on Study	Control 50	150 ppm 50	300 ppm 50	600 ppm 50
{Digestive system}						
oral cavity			<50>	<50>	<50>	<50>
	squamous cell papilloma		0 (0%)	1 (2%)	0 (0%)	0 (0%)
salivary gl			<50>	<50>	<50>	<50>
	adenoma		0 (0%)	0 (0%)	0 (0%)	1 (2%)
liver			<50>	<50>	<50>	<50>
	hepatocellular adenoma		1 (2%)	30 (60%)	31 (62%)	33 (66%)
	hemangiosarcoma		0 (0%)	15 (30%)	27 (54%)	41 (82%)
	hepatocellular carcinoma		0 (0%)	5 (10%)	16 (32%)	21 (42%)
	Ito-cell tumor:malignant		0 (0%)	1 (2%)	0 (0%)	0 (0%)
pancreas			<50>	<50>	<50>	<50>
	islet cell adenoma		0 (0%)	1 (2%)	0 (0%)	0 (0%)
{Urinary system}						
urin bladd			<50>	<50>	<50>	<50>
	transitional cell papilloma		0 (0%)	1 (2%)	0 (0%)	0 (0%)
{Endocrine system}						
pituitary			<50>	<49>	<50>	<50>
	adenoma		16 (32%)	15 (31%)	9 (18%)	1 (2%)
	adenocarcinoma		0 (0%)	2 (4%)	0 (0%)	0 (0%)
thyroid			<50>	<50>	<48>	<50>
	C-cell adenoma		5 (10%)	2 (4%)	2 (4%)	0 (0%)

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

(HPT085)

BAIS3

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 3

Organ	Findings	Group Name No. of animals on Study	Control 50	150 ppm 50	300 ppm 50	600 ppm 50
[Endocrine system]						
thyroid	follicular adenoma		<50> 1 (2%)	<50> 0 (0%)	<48> 1 (2%)	<50> 0 (0%)
	C cell carcinoma		1 (2%)	0 (0%)	0 (0%)	0 (0%)
adrenal	pheochromocytoma		<50> 0 (0%)	<50> 2 (4%)	<50> 0 (0%)	<50> 0 (0%)
	cortical adenocarcinoma		0 (0%)	1 (2%)	0 (0%)	0 (0%)
{Reproductive system}						
ovary	hemangioma		<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)
uterus	endometrial stromal polyp		<50> 10 (20%)	<50> 4 (8%)	<50> 9 (18%)	<50> 2 (4%)
	endometrial stromal sarcoma		1 (2%)	0 (0%)	0 (0%)	1 (2%)
mammary gl	fibroma		<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)
	fibroadenoma		8 (16%)	5 (10%)	1 (2%)	1 (2%)
	adenocarcinoma		1 (2%)	0 (0%)	1 (2%)	1 (2%)
prep/cli gl	adenoma		<50> 1 (2%)	<50> 0 (0%)	<50> 2 (4%)	<50> 0 (0%)
{Special sense organs/appendage}						
eye	melanoma		<50> 2 (4%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
< a > a : Number of animals examined at the site b (c) b : Number of animals with neoplasm c : b / a * 100						

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 4

Organ	Findings	Group Name No. of animals on Study	Control 50	150 ppm 50	300 ppm 50	600 ppm 50
{Special sense organs/appendage}						
Zymbal gl	adenoma		<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)
	squamous cell carcinoma		0 (0%)	1 (2%)	0 (0%)	0 (0%)
{Body cavities}						
peritoneum	hemangiosarcoma		<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)
retroperit	hemangiosarcoma		<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
adipose	hemangiosarcoma		<50> 0 (0%)	<50> 0 (0%)	<50> 2 (4%)	<50> 0 (0%)

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

(HPT085)

BAIS3

APPENDIX O 1

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

RAT : MALE: (2-YEAR STUDY)

STUDY No. : 0303
ANIMAL : RAT F344/DuCrj
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 1

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : subcutis TUMOR : fibroma				
Tumor rate				
Overall rates(a)	3/50(6.0)	2/50(4.0)	0/50(0.0)	0/50(0.0)
Adjusted rates(b)	6.12	2.94	0.0	0.0
Terminal rates(c)	3/49(6.1)	0/19(0.0)	0/ 0(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1911			
Prevalence method(d)	P = 0.7877			
Combined analysis(d)	P = 0.6074			
Cochran-Armitage test(e)	P = 0.0387*			
Fisher Exact test(e)		P = 0.5000	P = 0.1212	P = 0.1212
SITE : nasal cavity TUMOR : sarcoma:NOS				
Tumor rate				
Overall rates(a)	0/50(0.0)	1/50(2.0)	5/50(10.0)	1/50(2.0)
Adjusted rates(b)	0.0	0.0	8.33	33.33
Terminal rates(c)	0/49(0.0)	0/19(0.0)	0/ 0(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0929			
Prevalence method(d)	P = 0.0023**			
Combined analysis(d)	P = 0.0017**			
Cochran-Armitage test(e)	P = 0.4744			
Fisher Exact test(e)		P = 0.5000	P = 0.0281*	P = 0.5000
SITE : nasal cavity TUMOR : ethesioneuroepithelioma				
Tumor rate				
Overall rates(a)	0/50(0.0)	0/50(0.0)	1/50(2.0)	6/50(12.0)
Adjusted rates(b)	0.0	0.0	2.86	30.00
Terminal rates(c)	0/49(0.0)	0/19(0.0)	0/ 0(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0023**?			
Prevalence method(d)	P = 0.0001**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P = 0.0003**			
Fisher Exact test(e)		P = N.C.	P = 0.5000	P = 0.0133*

STUDY No. : 0303
ANIMAL : RAT F344/DuCrj
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 2

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : liver TUMOR : hepatocellular adenoma				
Tumor rate				
Overall rates(a)	1/50(2.0)	10/50(20.0)	10/50(20.0)	9/50(18.0)
Adjusted rates(b)	2.04	28.00	25.00	22.22
Terminal rates(c)	1/49(2.0)	4/19(21.1)	0/ 0(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0155*			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0707			
Fisher Exact test(e)		P = 0.0039**	P = 0.0039**	P = 0.0078**
SITE : liver TUMOR : hemangiosarcoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	25/50(50.0)	34/50(68.0)	43/50(86.0)
Adjusted rates(b)	0.0	36.84	16.67	100.00
Terminal rates(c)	0/49(0.0)	7/19(36.8)	0/ 0(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**			
Prevalence method(d)	P = 0.0010**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P < 0.0001**	P < 0.0001**	P < 0.0001**
SITE : liver TUMOR : hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	22/50(44.0)	24/50(48.0)	18/50(36.0)
Adjusted rates(b)	0.0	47.37	100.00	100.00
Terminal rates(c)	0/49(0.0)	9/19(47.4)	0/ 0(0.0)	0/ 0(0.0)
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 = 0.0021**			
Fisher Exact test(e)		P < 0.0001**	P < 0.0001**	P < 0.0001**

STUDY No. : 0303
ANIMAL : RAT F344/DuCrj
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 3

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : liver TUMOR : hemangioma, hemangiosarcoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	25/50(50.0)	34/50(68.0)	43/50(86.0)
Adjusted rates(b)	0.0	36.84	16.67	100.00
Terminal rates(c)	0/49(0.0)	7/19(36.8)	0/ 0(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**			
Prevalence method(d)	P = 0.0010**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P < 0.0001**	P < 0.0001**	P < 0.0001**
SITE : liver TUMOR : hepatocellular adenoma, hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	1/50(2.0)	31/50(62.0)	29/50(58.0)	23/50(46.0)
Adjusted rates(b)	2.04	70.83	100.00	100.00
Terminal rates(c)	1/49(2.0)	13/19(68.4)	0/ 0(0.0)	0/ 0(0.0)
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 = 0.0010**			
Fisher Exact test(e)		P < 0.0001**	P < 0.0001**	P < 0.0001**
SITE : pituitary gland TUMOR : adenoma				
Tumor rate				
Overall rates(a)	16/50(32.0)	9/50(18.0)	6/50(12.0)	0/50(0.0)
Adjusted rates(b)	32.65	26.32	12.12	0.0
Terminal rates(c)	16/49(32.7)	5/19(26.3)	0/ 0(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1956			
Prevalence method(d)	P = 0.6539			
Combined analysis(d)	P = 0.4718			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.0826	P = 0.0142*	P < 0.0001**

(HPT360A)

BAIS3

STUDY No. : 0303
 ANIMAL : RAT F344/DuCrj
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 4

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : pituitary gland TUMOR : adenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	16/50(32.0)	9/50(18.0)	6/50(12.0)	0/50(0.0)
Adjusted rates(b)	32.65	26.32	12.12	0.0
Terminal rates(c)	16/49(32.7)	5/19(26.3)	0/ 0(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1956			
Prevalence method(d)	P = 0.6539			
Combined analysis(d)	P = 0.4718			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.0826	P = 0.0142*	P < 0.0001**
SITE : thyroid TUMOR : C-cell adenoma				
Tumor rate				
Overall rates(a)	7/50(14.0)	4/50(8.0)	2/50(4.0)	1/50(2.0)
Adjusted rates(b)	14.29	13.79	9.52	2.78
Terminal rates(c)	7/49(14.3)	2/19(10.5)	0/ 0(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.2895			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0192*			
Fisher Exact test(e)		P = 0.2623	P = 0.0798	P = 0.0297*
SITE : testis TUMOR : interstitial cell tumor				
Tumor rate				
Overall rates(a)	39/50(78.0)	31/50(62.0)	13/50(26.0)	0/50(0.0)
Adjusted rates(b)	79.59	71.43	100.00	0.0
Terminal rates(c)	39/49(79.6)	13/19(68.4)	0/ 0(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.8927			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.0630	P < 0.0001**	P < 0.0001**

(HPT360A)

BAIS3

STUDY No. : 0303
ANIMAL : RAT F344/DuCrj
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 5

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : mediastinum TUMOR : sarcoma:NOS				
Tumor rate				
Overall rates(a)	0/50(0.0)	1/50(2.0)	2/50(4.0)	3/50(6.0)
Adjusted rates(b)	0.0	0.0	0.0	7.14
Terminal rates(c)	0/49(0.0)	0/19(0.0)	0/ 0(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0049**			
Prevalence method(d)	P = 0.0261* ?			
Combined analysis(d)	P = 0.0006**			
Cochran-Armitage test(e)	P = 0.0685			
Fisher Exact test(e)		P = 0.5000	P = 0.2475	P = 0.1212
SITE : adipose tissue TUMOR : hemangiosarcoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	2/50(4.0)	0/50(0.0)	3/50(6.0)
Adjusted rates(b)	0.0	2.78	0.0	6.90
Terminal rates(c)	0/49(0.0)	0/19(0.0)	0/ 0(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0720			
Prevalence method(d)	P = 0.0358*			
Combined analysis(d)	P = 0.0083**			
Cochran-Armitage test(e)	P = 0.1079			
Fisher Exact test(e)		P = 0.2475	P = N. C.	P = 0.1212

(HPT360A)

BAIS3

- (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 ; * : $P \leq 0.05$ ** : $P \leq 0.01$
N.C.:Statistical value cannot be calculated and was not significant.

STUDY No. : 0303
ANIMAL : RAT F344/DuCrj
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 1

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : mesenterium				
TUMOR : hemangioma, hemangiosarcoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	0/50(0.0)	2/50(4.0)	3/50(6.0)
Adjusted rates(b)	0.0	0.0	4.55	3.23
Terminal rates(c)	0/49(0.0)	0/19(0.0)	0/ 0(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0007**			
Prevalence method(d)	P = 0.0805			
Combined analysis(d)	P = 0.0004**			
Cochran-Armitage test(e)	P = 0.0264*			
Fisher Exact test(e)		P = N.C.	P = 0.2475	P = 0.1212

(HPT360A)

BAIS3

(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 ; * : $P \leq 0.05$ ** : $P \leq 0.01$
N.C. : Statistical value cannot be calculated and was not significant.

STUDY No. : 0303
ANIMAL : RAT F344/DuCrj
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 1

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : ALL SITE				
TUMOR : hemangiosarcoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	26/50(52.0)	36/50(72.0)	45/50(90.0)
Adjusted rates(b)	0.0	36.84	33.33	100.00
Terminal rates(c)	0/49(0.0)	7/19(36.8)	0/ 0(0.0)	0/ 0(0.0)
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 < 0.0001**	P < 0.0001**	P < 0.0001**

(HPT360A)

BAIS3

(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 ; * : $P \leq 0.05$ ** : $P \leq 0.01$

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

APPENDIX O 2

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

RAT : FEMALE: (2-YEAR STUDY)

STUDY No. : 0303
ANIMAL : RAT F344/DuCrj
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 6

Group Name	Control	150 ppm	300 ppm	600 ppm
SITE : spleen TUMOR : mononuclear cell leukemia				
Tumor rate				
Overall rates(a)	4/50(8.0)	11/50(22.0)	6/50(12.0)	2/50(4.0)
Adjusted rates(b)	7.32	23.53	50.00	2.63
Terminal rates(c)	3/41(7.3)	4/17(23.5)	1/ 2(50.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0001**			
Prevalence method(d)	P = 0.0069**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P = 0.1657			
Fisher Exact test(e)		P = 0.0453*	P = 0.3703	P = 0.3389
SITE : liver TUMOR : hepatocellular adenoma				
Tumor rate				
Overall rates(a)	1/50(2.0)	30/50(60.0)	31/50(62.0)	33/50(66.0)
Adjusted rates(b)	2.44	79.17	100.00	87.50
Terminal rates(c)	1/41(2.4)	13/17(76.5)	2/ 2(100.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P < 0.0001**			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P < 0.0001**	P < 0.0001**	P < 0.0001**
SITE : liver TUMOR : hemangiosarcoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	15/50(30.0)	27/50(54.0)	41/50(82.0)
Adjusted rates(b)	0.0	17.65	0.0	100.00
Terminal rates(c)	0/41(0.0)	3/17(17.6)	0/ 2(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**			
Prevalence method(d)	P = 0.0005**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P < 0.0001**	P < 0.0001**	P < 0.0001**

STUDY No. : 0303
ANIMAL : RAT F344/DuCrj
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 7

Group Name	Control	150 ppm	300 ppm	600 ppm
SITE : liver TUMOR : hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	5/50(10.0)	16/50(32.0)	21/50(42.0)
Adjusted rates(b)	0.0	15.38	50.00	100.00
Terminal rates(c)	0/41(0.0)	2/17(11.8)	1/ 2(50.0)	0/ 0(0.0)
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 = 0.0281*	P < 0.0001**	P < 0.0001**
SITE : liver TUMOR : hemangioma, hemangiosarcoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	15/50(30.0)	27/50(54.0)	41/50(82.0)
Adjusted rates(b)	0.0	17.65	0.0	100.00
Terminal rates(c)	0/41(0.0)	3/17(17.6)	0/ 2(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**			
Prevalence method(d)	P = 0.0005**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P < 0.0001**	P < 0.0001**	P < 0.0001**
SITE : liver TUMOR : hepatocellular adenoma, hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	1/50(2.0)	32/50(64.0)	38/50(76.0)	42/50(84.0)
Adjusted rates(b)	2.44	79.17	100.00	100.00
Terminal rates(c)	1/41(2.4)	13/17(76.5)	2/ 2(100.0)	0/ 0(0.0)
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 < 0.0001**	P < 0.0001**	P < 0.0001**

(HPT360A)

BAIS3

STUDY No. : 0303
 ANIMAL : RAT F344/DuCrj
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 8

Group Name	Control	150 ppm	300 ppm	600 ppm
SITE : pituitary gland TUMOR : adenoma				
Tumor rate				
Overall rates(a)	16/50(32.0)	15/49(30.6)	9/50(18.0)	1/50(2.0)
Adjusted rates(b)	31.71	40.91	31.82	4.00
Terminal rates(c)	13/41(31.7)	6/17(35.3)	0/ 2(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.4854			
Prevalence method(d)	P = 0.2283			
Combined analysis(d)	P = 0.2598			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.5271	P = 0.0826	P < 0.0001**
SITE : pituitary gland TUMOR : adenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	16/50(32.0)	17/49(34.7)	9/50(18.0)	1/50(2.0)
Adjusted rates(b)	31.71	45.45	31.82	4.00
Terminal rates(c)	13/41(31.7)	7/17(41.2)	0/ 2(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.4915			
Prevalence method(d)	P = 0.1933			
Combined analysis(d)	P = 0.2356			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.4716	P = 0.0826	P < 0.0001**
SITE : thyroid TUMOR : C-cell adenoma				
Tumor rate				
Overall rates(a)	5/50(10.0)	2/50(4.0)	2/48(4.2)	0/50(0.0)
Adjusted rates(b)	10.64	8.00	16.67	0.0
Terminal rates(c)	4/41(9.8)	1/17(5.9)	0/ 2(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.5378			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0256*			
Fisher Exact test(e)		P = 0.2180	P = 0.2351	P = 0.0281*

(HPT360A)

BAIS3

STUDY No. : 0303
 ANIMAL : RAT F344/DuCrj
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 9

Group Name	Control	150 ppm	300 ppm	600 ppm
SITE : uterus TUMOR : endometrial stromal polyp				
Tumor rate				
Overall rates(a)	10/50(20.0)	4/50(8.0)	9/50(18.0)	2/50(4.0)
Adjusted rates(b)	22.73	8.82	66.67	25.00
Terminal rates(c)	9/41(22.0)	0/17(0.0)	1/ 2(50.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1572			
Prevalence method(d)	P = 0.1427			
Combined analysis(d)	P = 0.1102			
Cochran-Armitage test(e)	P = 0.0468*			
Fisher Exact test(e)		P = 0.0739	P = 0.5000	P = 0.0139*
SITE : mammary gland TUMOR : fibroadenoma				
Tumor rate				
Overall rates(a)	8/50(16.0)	5/50(10.0)	1/50(2.0)	1/50(2.0)
Adjusted rates(b)	19.05	17.65	0.0	4.76
Terminal rates(c)	7/41(17.1)	3/17(17.6)	0/ 2(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1126			
Prevalence method(d)	P = 0.6026			
Combined analysis(d)	P = 0.4221			
Cochran-Armitage test(e)	P = 0.0056**			
Fisher Exact test(e)		P = 0.2768	P = 0.0154*	P = 0.0154*

(HPT360A)

BAIS3

STUDY No. : 0303
 ANIMAL : RAT F344/DuCrj
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 10

Group Name	Control	150 ppm	300 ppm	600 ppm
SITE : mammary gland				
TUMOR : fibroma, fibroadenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	9/50(18.0)	6/50(12.0)	2/50(4.0)	2/50(4.0)
Adjusted rates(b)	19.05	17.65	0.0	11.11
Terminal rates(c)	7/41(17.1)	3/17(17.6)	0/ 2(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1341			
Prevalence method(d)	P = 0.3856			
Combined analysis(d)	P = 0.2038			
Cochran-Armitage test(e)	P = 0.0129*			
Fisher Exact test(e)		P = 0.2883	P = 0.0256*	P = 0.0256*

(HPT360A)

BAIS3

- (a): Number of tumor-bearing animals/number of animals examined at the site.
 (b): Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.
 (c): Observed tumor incidence at terminal kill.
 (d): Beneath the control incidence are the P-values associated with the trend test.
 Standard method : Death analysis
 Prevalence method : Incidental tumor test
 Combined analysis : Death analysis + Incidental tumor test
 (e): The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.
 ? : The conditional probabilities of the largest and smallest possible outcomes can not be estimated or this P-value is beyond the estimated P-value.
 ----- : There is no data which should be statistical analysis.
 Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$
 N.C. : Statistical value cannot be calculated and was not significant.

STUDY No. : 0303
ANIMAL : RAT F344/DuCrj
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 2

Group Name	Control	150 ppm	300 ppm	600 ppm
SITE : ALL SITE TUMOR : hemangiosarcoma				
Tumor rate				
Overall rates(a)	0/50(0.0)	17/50(34.0)	28/50(56.0)	42/50(84.0)
Adjusted rates(b)	0.0	17.65	0.0	100.00
Terminal rates(c)	0/41(0.0)	3/17(17.6)	0/ 2(0.0)	0/ 0(0.0)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**			
Prevalence method(d)	P = 0.0005**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P < 0.0001**	P < 0.0001**	P < 0.0001**

(HPT360A)

BAIS3

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

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

(c): Observed tumor incidence at terminal kill.

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

Standard method : Death analysis

Prevalence method : Incidental tumor test

Combined analysis : Death analysis + Incidental tumor test

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

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

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

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

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

APPENDIX P 1

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

RAT : MALE: ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 1

Organ	Findings	Group Name No. of Animals on Study	Control 50	200 ppm 50	400 ppm 50	800 ppm 50
{Respiratory system}						
nasal cavit			<50>	<50>	<50>	<50>
	metastasis:liver tumor		0	0	0	1
trachea			<50>	<50>	<50>	<50>
	metastasis:mediastinum tumor		0	0	1	1
lung			<50>	<50>	<50>	<50>
	leukemic cell infiltration		2	0	1	0
	metastasis:liver tumor		0	22	27	25
	metastasis:mesenterium tumor		0	0	1	0
{Hematopoietic system}						
bone marrow			<50>	<50>	<50>	<50>
	leukemic cell infiltration		0	0	1	0
lymph node			<50>	<50>	<50>	<50>
	leukemic cell infiltration		0	0	1	0
	metastasis:liver tumor		0	0	0	1
spleen			<50>	<50>	<50>	<50>
	metastasis:liver tumor		0	0	1	0
{Digestive system}						
salivary gl			<50>	<50>	<50>	<50>
	metastasis:nasal tumor		0	0	1	0
stomach			<50>	<50>	<50>	<50>
	metastasis:liver tumor		0	0	0	1
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 ALL ANIMALS (0- 97W)

PAGE : 2

Organ	Findings	Group Name No. of Animals on Study	Control 50	200 ppm 50	400 ppm 50	800 ppm 50
{Digestive system}						
stomach	metastasis:peritoneum tumor		<50> 0	<50> 0	<50> 1	<50> 0
liver	leukemic cell infiltration		<50> 2	<50> 0	<50> 1	<50> 0
pancreas	metastasis:liver tumor		<50> 0	<50> 2	<50> 3	<50> 0
	metastasis:mesenterium tumor		0	0	1	0
{Endocrine system}						
pituitary	metastasis:nasal tumor		<50> 0	<50> 0	<50> 1	<50> 0
thyroid	metastasis:mediastinum tumor		<50> 0	<50> 0	<50> 1	<50> 0
adrenal	metastasis:liver tumor		<50> 0	<50> 1	<50> 0	<50> 0
{Nervous system}						
brain	metastasis:nasal tumor		<50> 0	<50> 0	<50> 0	<50> 2
spinal cord	metastasis:liver tumor		<50> 0	<50> 0	<50> 0	<50> 1
{Special sense organs/appendage}						
Harder gl	metastasis:nasal tumor		<50> 0	<50> 0	<50> 1	<50> 0
< a > a : Number of animals examined at the site b b : Number of animals with lesion						

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
ALL ANIMALS (0- 97%)

PAGE : 3

		Group Name	Control	200 ppm	400 ppm	800 ppm
		No. of Animals on Study	50	50	50	50
Organ	Findings					
{Body cavities}						
mediastinum			<50>	<50>	<50>	<50>
	metastasis:liver tumor		0	0	0	2
peritoneum			<50>	<50>	<50>	<50>
	metastasis:liver tumor		0	1	2	0
mesenterium			<50>	<50>	<50>	<50>
	metastasis:liver tumor		0	0	2	0
adipose			<50>	<50>	<50>	<50>
	metastasis:liver tumor		0	1	2	1
< a >		a : Number of animals examined at the site				
b		b : Number of animals with lesion				

(JPT150)

BAIS3

APPENDIX P 2

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

RAT : FEMALE: ALL ANIMALS

(2-YEAR STUDY)

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

Organ	Findings	Group Name No. of Animals on Study	Control 50	150 ppm 50	300 ppm 50	600 ppm 50
{Respiratory system}						
nasal cavit			<50>	<50>	<50>	<50>
	metastasis:subcutis tumor		1	0	0	0
trachea			<50>	<50>	<50>	<50>
	leukemic cell infiltration		0	0	1	0
	metastasis:thyroid tumor		1	0	0	0
lung			<50>	<50>	<50>	<50>
	leukemic cell infiltration		2	7	5	2
	metastasis:liver tumor		0	13	19	27
	metastasis:adrenal tumor		0	1	0	0
	metastasis:thyroid tumor		1	0	0	0
	metastasis:subcutis tumor		0	0	1	0
{Hematopoietic system}						
bone marrow			<50>	<50>	<50>	<50>
	leukemic cell infiltration		1	6	4	0
lymph node			<50>	<50>	<50>	<50>
	leukemic cell infiltration		2	4	2	0
	metastasis:uterus tumor		0	0	0	1
	metastasis:trachea tumor		0	1	1	0
spleen			<50>	<50>	<50>	<50>
	metastasis:uterus tumor		0	0	0	1
{Circulatory system}						
heart			<50>	<50>	<50>	<50>
	leukemic cell infiltration		0	2	0	0
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 2

Organ	Findings	Group Name No. of Animals on Study	Control 50	150 ppm 50	300 ppm 50	600 ppm 50
{Digestive system}						
salivary gl	leukemic cell infiltration		<50> 0	<50> 1	<50> 0	<50> 0
stomach	metastasis:liver tumor		<50> 0	<50> 1	<50> 1	<50> 2
liver	leukemic cell infiltration		<50> 3	<50> 10	<50> 4	<50> 2
	metastasis:adrenal tumor		0	1	0	0
pancreas	metastasis:liver tumor		<50> 0	<50> 0	<50> 0	<50> 1
{Urinary system}						
kidney	leukemic cell infiltration		<50> 0	<50> 4	<50> 2	<50> 2
{Endocrine system}						
pituitary	leukemic cell infiltration		<50> 0	<50> 1	<50> 2	<50> 0
adrenal	leukemic cell infiltration		<50> 0	<50> 5	<50> 2	<50> 1
	metastasis:liver tumor		0	0	0	1
{Reproductive system}						
ovary	leukemic cell infiltration		<50> 0	<50> 2	<50> 2	<50> 1

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

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study	Control 50	150 ppm 50	300 ppm 50	600 ppm 50
{Reproductive system}						
ovary	metastasis:adrenal tumor		<50> 0	<50> 1	<50> 0	<50> 0
{Nervous system}						
brain	leukemic cell infiltration		<50> 0	<50> 3	<50> 2	<50> 0
	metastasis:pituitary tumor		0	2	0	0
spinal cord	leukemic cell infiltration		<50> 0	<50> 2	<50> 3	<50> 0
{Special sense organs/appendage}						
eye	leukemic cell infiltration		<50> 0	<50> 1	<50> 1	<50> 0
Harder gl	leukemic cell infiltration		<50> 0	<50> 1	<50> 1	<50> 0
{Body cavities}						
adipose	metastasis:liver tumor		<50> 0	<50> 0	<50> 1	<50> 0
< a > a : Number of animals examined at the site b b : Number of animals with lesion						

(JPT150)

BAIS3

APPENDIX P 3

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

RAT : MALE: DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 1

Group Name No. of Animals on Study		Control 1	200 ppm 31	400 ppm 50	800 ppm 50
Organ	Findings				
{Respiratory system}					
nasal cavit		< 1>	<31>	<50>	<50>
	metastasis:liver tumor	0	0	0	1
trachea		< 1>	<31>	<50>	<50>
	metastasis:mediastinum tumor	0	0	1	1
lung		< 1>	<31>	<50>	<50>
	leukemic cell infiltration	0	0	1	0
	metastasis:liver tumor	0	19	27	25
	metastasis:mesenterium tumor	0	0	1	0
{Hematopoietic system}					
bone marrow		< 1>	<31>	<50>	<50>
	leukemic cell infiltration	0	0	1	0
lymph node		< 1>	<31>	<50>	<50>
	leukemic cell infiltration	0	0	1	0
	metastasis:liver tumor	0	0	0	1
spleen		< 1>	<31>	<50>	<50>
	metastasis:liver tumor	0	0	1	0
{Digestive system}					
salivary gl		< 1>	<31>	<50>	<50>
	metastasis:nasal tumor	0	0	1	0
stomach		< 1>	<31>	<50>	<50>
	metastasis:liver tumor	0	0	0	1
< a >	a : Number of animals examined at the site				
b	b : Number of animals with lesion				

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 2

Organ	Findings	Group Name No. of Animals on Study	Control 1	200 ppm 31	400 ppm 50	800 ppm 50
{Digestive system}						
stomach			< 1>	<31>	<50>	<50>
	metastasis:peritoneum tumor		0	0	1	0
liver			< 1>	<31>	<50>	<50>
	leukemic cell infiltration		0	0	1	0
pancreas			< 1>	<31>	<50>	<50>
	metastasis:liver tumor		0	2	3	0
	metastasis:mesenterium tumor		0	0	1	0
{Endocrine system}						
pituitary			< 1>	<31>	<50>	<50>
	metastasis:nasal tumor		0	0	1	0
thyroid			< 1>	<31>	<50>	<50>
	metastasis:mediastinum tumor		0	0	1	0
adrenal			< 1>	<31>	<50>	<50>
	metastasis:liver tumor		0	1	0	0
{Nervous system}						
brain			< 1>	<31>	<50>	<50>
	metastasis:nasal tumor		0	0	0	2
spinal cord			< 1>	<31>	<50>	<50>
	metastasis:liver tumor		0	0	0	1
{Special sense organs/appendage}						
Harder gl			< 1>	<31>	<50>	<50>
	metastasis:nasal tumor		0	0	1	0
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 97W)

PAGE : 3

		Group Name No. of Animals on Study	Control 1	200 ppm 31	400 ppm 50	800 ppm 50
Organ	Findings					
{Body cavities}						
mediastinum			< 1>	<31>	<50>	<50>
	metastasis:liver tumor		0	0	0	2
peritoneum			< 1>	<31>	<50>	<50>
	metastasis:liver tumor		0	1	2	0
mesenterium			< 1>	<31>	<50>	<50>
	metastasis:liver tumor		0	0	2	0
adipose			< 1>	<31>	<50>	<50>
	metastasis:liver tumor		0	1	2	1
< a >		a : Number of animals examined at the site				
b		b : Number of animals with lesion				

(JPT150)

BAIS3

APPENDIX P 4

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

RAT : FEMALE: DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)
SACRIFICED ANIMALS (97W)

PAGE : 1

Group Name		Control	200 ppm	400 ppm	800 ppm
No. of Animals on Study		49	19	0	0
Organ	Findings				
{Respiratory system}					
lung	leukemic cell infiltration	<49> 2	<19> 0	< 0> -	< 0> -
	metastasis:liver tumor	0	3	-	-
{Digestive system}					
liver	leukemic cell infiltration	<49> 2	<19> 0	< 0> -	< 0> -
< a >	a : Number of animals examined at the site				
b	b : Number of animals with lesion				
(JPT150)					

BAIS3

APPENDIX P 5

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

RAT : MALE: SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 1

Group Name No. of Animals on Study		Control 9	150 ppm 33	300 ppm 48	600 ppm 50
Organ	Findings				
{Respiratory system}					
nasal cavit		< 9>	<33>	<48>	<50>
	metastasis:subcutis tumor	1	0	0	0
trachea		< 9>	<33>	<48>	<50>
	leukemic cell infiltration	0	0	1	0
	metastasis:thyroid tumor	1	0	0	0
lung		< 9>	<33>	<48>	<50>
	leukemic cell infiltration	1	5	5	2
	metastasis:liver tumor	0	9	19	27
	metastasis:thyroid tumor	1	0	0	0
	metastasis:subcutis tumor	0	0	1	0
{Hematopoietic system}					
bone marrow		< 9>	<33>	<48>	<50>
	leukemic cell infiltration	1	5	4	0
lymph node		< 9>	<33>	<48>	<50>
	leukemic cell infiltration	0	3	2	0
	metastasis:uterus tumor	0	0	0	1
	metastasis:trachea tumor	0	1	1	0
spleen		< 9>	<33>	<48>	<50>
	metastasis:uterus tumor	0	0	0	1
{Circulatory system}					
heart		< 9>	<33>	<48>	<50>
	leukemic cell infiltration	0	2	0	0
< a >	a : Number of animals examined at the site				
b	b : Number of animals with lesion				

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 2

Organ	Findings	Group Name No. of Animals on Study	Control 9	150 ppm 33	300 ppm 48	600 ppm 50
{Digestive system}						
salivary gl	leukemic cell infiltration		< 9> 0	<33> 1	<48> 0	<50> 0
stomach	metastasis:liver tumor		< 9> 0	<33> 1	<48> 1	<50> 2
liver	leukemic cell infiltration		< 9> 1	<33> 7	<48> 4	<50> 2
pancreas	metastasis:liver tumor		< 9> 0	<33> 0	<48> 0	<50> 1
{Urinary system}						
kidney	leukemic cell infiltration		< 9> 0	<33> 4	<48> 2	<50> 2
{Endocrine system}						
pituitary	leukemic cell infiltration		< 9> 0	<33> 1	<48> 2	<50> 0
adrenal	leukemic cell infiltration		< 9> 0	<33> 4	<48> 2	<50> 1
	metastasis:liver tumor		0	0	0	1
{Reproductive system}						
ovary	leukemic cell infiltration		< 9> 0	<33> 2	<48> 2	<50> 1
{Nervous system}						
brain	leukemic cell infiltration		< 9> 0	<33> 3	<48> 2	<50> 0

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

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 3

Group Name No. of Animals on Study		Control 9	150 ppm 33	300 ppm 48	600 ppm 50
Organ	Findings				
{Nervous system}					
brain	metastasis:pituitary tumor	< 9> 0	<33> 1	<48> 0	<50> 0
spinal cord	leukemic cell infiltration	< 9> 0	<33> 2	<48> 3	<50> 0
{Special sense organs/appendage}					
eye	leukemic cell infiltration	< 9> 0	<33> 1	<48> 1	<50> 0
Harder gl	leukemic cell infiltration	< 9> 0	<33> 1	<48> 1	<50> 0
{Body cavities}					
adipose	metastasis:liver tumor	< 9> 0	<33> 0	<48> 1	<50> 0
< a > a : Number of animals examined at the site b b : Number of animals with lesion					

(JPT150)

BAIS3

APPENDIX P 6

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

RAT : FEMALE: SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0303
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A2
 SEX : FEMALE

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

PAGE : 1

Group Name No. of Animals on Study		Control 41	150 ppm 17	300 ppm 2	600 ppm 0
Organ	Findings				
{Respiratory system}					
lung		<41>	<17>	< 2>	< 0>
	leukemic cell infiltration	1	2	0	-
	metastasis:liver tumor	0	4	0	-
	metastasis:adrenal tumor	0	1	0	-
{Hematopoietic system}					
bone marrow		<41>	<17>	< 2>	< 0>
	leukemic cell infiltration	0	1	0	-
lymph node		<41>	<17>	< 2>	< 0>
	leukemic cell infiltration	2	1	0	-
{Digestive system}					
liver		<41>	<17>	< 2>	< 0>
	leukemic cell infiltration	2	3	0	-
	metastasis:adrenal tumor	0	1	0	-
{Endocrine system}					
adrenal		<41>	<17>	< 2>	< 0>
	leukemic cell infiltration	0	1	0	-
{Reproductive system}					
ovary		<41>	<17>	< 2>	< 0>
	metastasis:adrenal tumor	0	1	0	-
< a >	a : Number of animals examined at the site				
b	b : Number of animals with lesion				

STUDY NO. : 0303
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A2
SEX : FEMALE

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

PAGE : 2

		Group Name	Control	150 ppm	300 ppm	600 ppm
		No. of Animals on Study	41	17	2	0
Organ_____	Findings_____					
{Nervous system}						
brain			<41>	<17>	< 2>	< 0>
	metastasis:pituitary tumor		0	1	0	-
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					
{JPT150}						

BAIS3

APPENDIX Q 1

IDENTITY AND IMPURITY OF QUINOLINE IN THE 2-YEAR DRINKING WATER STUDY

IDENTITY AND IMPURITY OF QUINOLINE IN THE 2-YEAR DRINKING WATER STUDY

Test Substance : Quinoline (Tokyo Kasei Kogyo Co., Ltd.)

A. Lot No. : FHE02

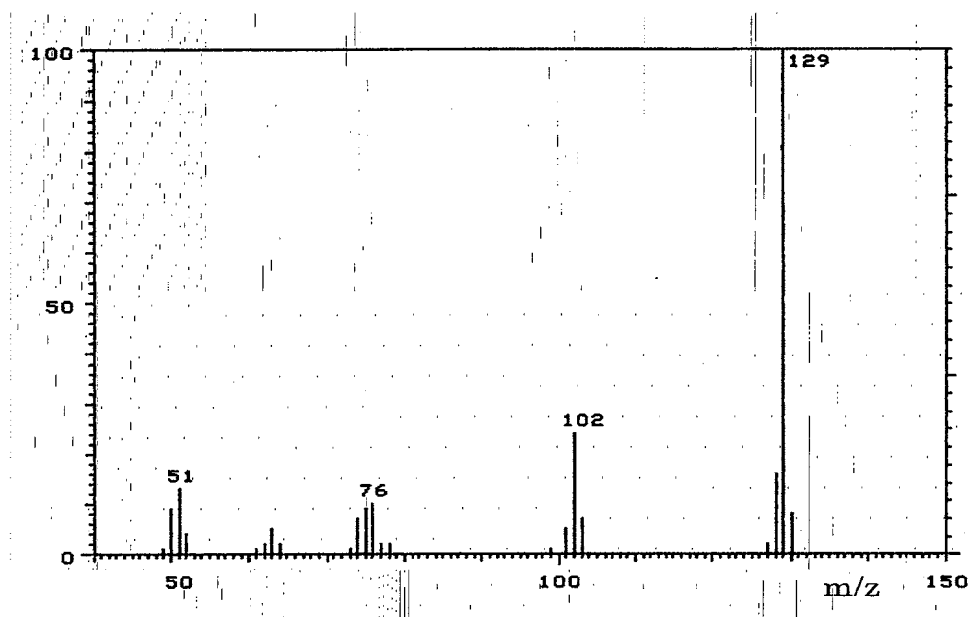
1. Spectral Data

Mass Spectrometry

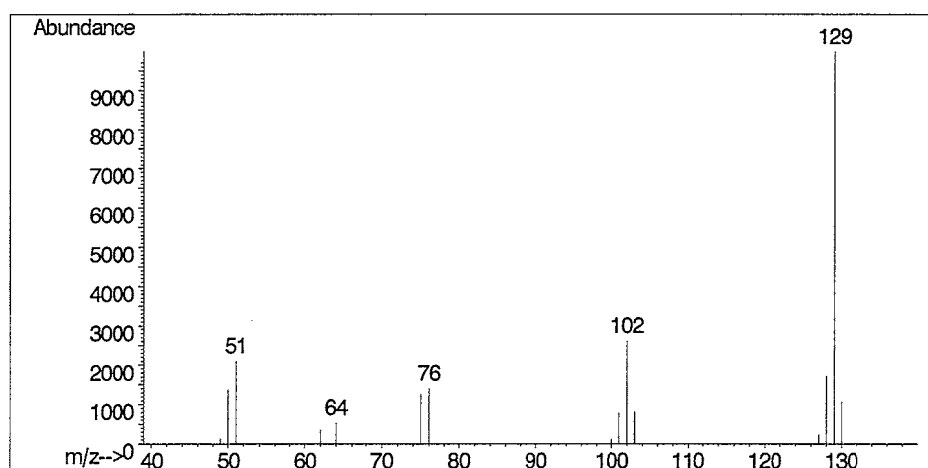
Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance



Mass Spectrum of Literature Data*

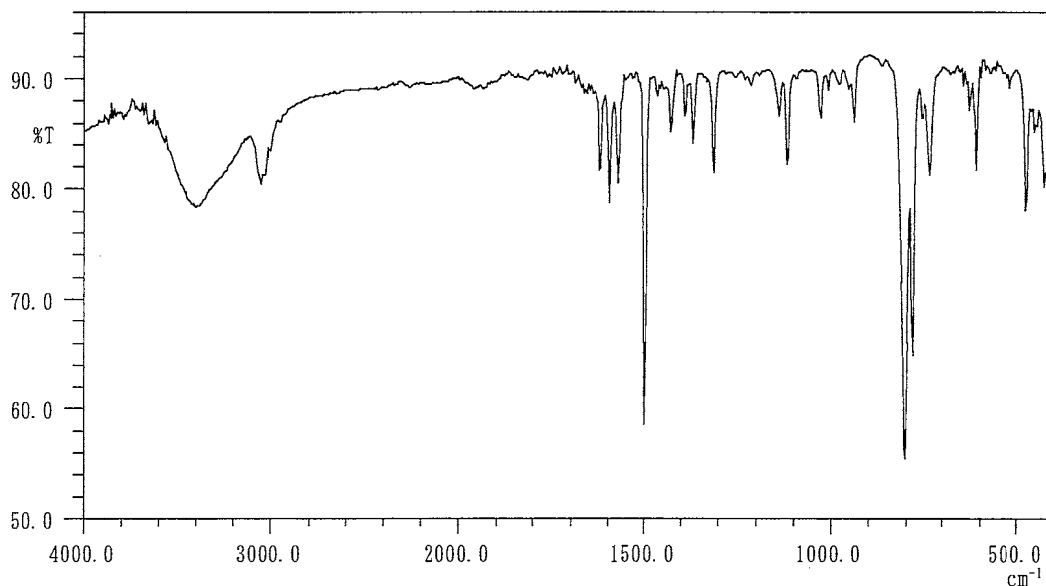
Results: The mass spectrum was consistent with literature spectrum.

(*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition.
John Wiley and Sons, Inc. (U.S.), Entry Number 6221)

Infrared Spectrometry

Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr

Resolution : 4 cm^{-1} 

Infrared Spectrum of Test Substance

<u>Determined Values</u>	<u>Literature Values</u> *
Wave Number (cm^{-1})	Wave Number (cm^{-1})
440~ 460	440~ 460
460~ 500	460~ 500
600~ 640	600~ 640
720~ 760	720~ 760
760~ 800	760~ 800
800~ 840	800~ 840
920~ 960	920~ 960
1020~1040	1020~1040
1100~1130	1100~1130
1130~1160	1130~1160
1300~1320	1300~1320
1340~1380	1340~1380
1380~1400	1380~1400
1400~1440	1400~1440
1480~1520	1480~1520
1560~1580	1560~1580
1580~1600	1580~1600
1600~1640	1600~1640
2890~3120	
3120~3720	3120~3720

Results: The infrared spectrum was consistent with literature spectrum.

(*William W. Simons (1978) The Sadtler Handbook of Infrared Spectra.

Sadtler Research Laboratories, Inc. (U.K.), p.218)

2. Impurity

Instrument : Hewlett Packard 5890A Gas Chromatograph
Column : INNOWAX (0.2 mm ϕ \times 50 m)
Column Temperature : 190° C
Flow Rate : 1 mL/min
Detector : FID (Flame Ionization Detector)
Injection Volume : 1 μ L

Sample Name	Peak No.	Area (%)	Peak Name
Test Substance	1	0.205	2-Methyl Naphthalene
	2	99.671	Quinoline
	3	0.124	Isoquinoline

Results: Gas chromatography indicated one major peak (peak No.2) and two impurities. It was identified only by comparing its gas chromatograph with that of 2-methyl naphthalene (peak No.1), and isoquinoline (peak No.3) in the quinoline, the amount in the test substance were 0.205%, and 0.124%.

3. Conclusions: The test substance was identified as quinoline, by the mass spectrum and the infrared spectrum. Gas chromatography indicated one major peak (peak No.2) and two impurities. It was identified only by comparing its gas chromatograph with that of 2-methyl naphthalene, and isoquinoline, the amount in the test substance were 0.205%, and 0.124%.

B. Lot No. : FHE03

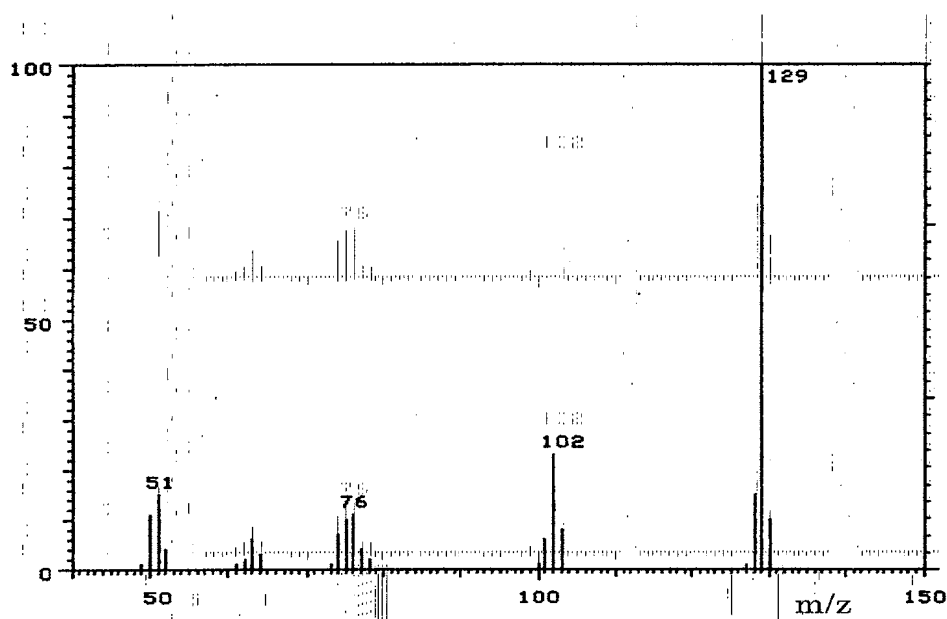
1. Spectral Data

Mass Spectrometry

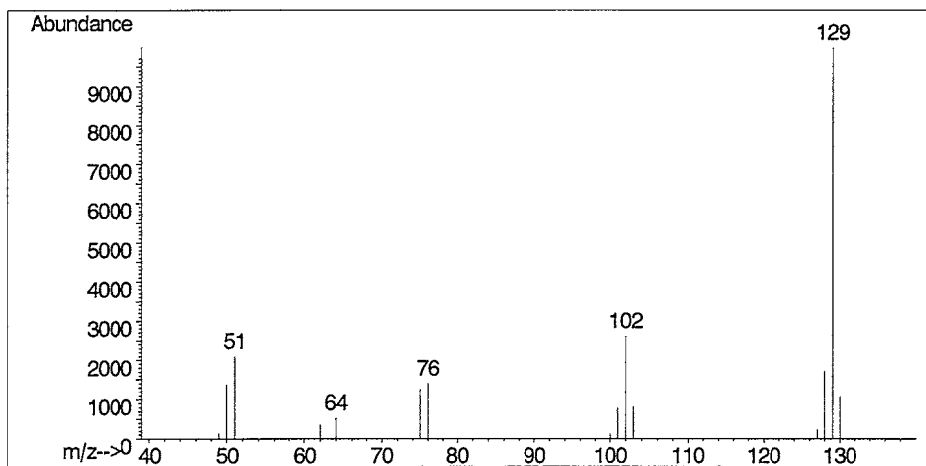
Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance



Mass Spectrum of Literature Data*

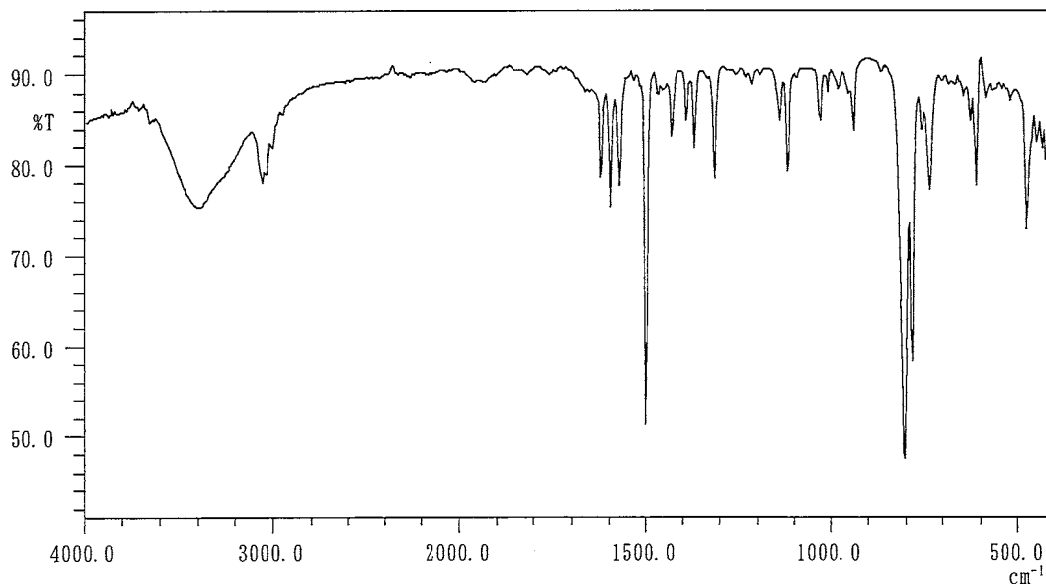
Results: The mass spectrum was consistent with literature spectrum.

(*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition.
John Wiley and Sons, Inc. (U.S.), Entry Number 6221)

Infrared Spectrometry

Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr

Resolution : 4 cm^{-1} 

Infrared Spectrum of Test Substance

<u>Determined Values</u>	<u>Literature Values</u> *
Wave Number (cm^{-1})	Wave Number (cm^{-1})
440~460	440~460
460~500	460~500
600~640	600~640
720~760	720~760
760~800	760~800
800~840	800~840
920~960	920~960
1020~1040	1020~1040
1100~1130	1100~1130
1130~1160	1130~1160
1300~1320	1300~1320
1340~1380	1340~1380
1380~1400	1380~1400
1400~1440	1400~1440
1480~1520	1480~1520
1560~1580	1560~1580
1580~1600	1580~1600
1600~1640	1600~1640
2890~3120	
3120~3720	3120~3720

Results: The infrared spectrum was consistent with literature spectrum.

(*William W. Simons (1978) The Sadtler Handbook of Infrared Spectra.
Sadtler Research Laboratories, Inc. (U.K.), p.218)

2. Impurity

Instrument : Hewlett Packard 5890A Gas Chromatograph
Column : INNOWAX (0.2 mm ϕ \times 50 m)
Column Temperature : 190° C
Flow Rate : 1 mL/min
Detector : FID (Flame Ionization Detector)
Injection Volume : 1 μ L

Sample Name	Peak No.	Area (%)	Peak Name
Test Substance	1	0.166	2-Methyl Naphthalene
	2	99.692	Quinoline
	3	0.142	Isoquinoline

Results: Gas chromatography indicated one major peak (peak No.2) and two impurities. It was identified only by comparing its gas chromatograph with that of 2-methyl naphthalene (peak No.1), and isoquinoline (peak No.3) in the quinoline, the amount in the test substance were 0.166%, and 0.142%.

3. Conclusions: The test substance was identified as quinoline, by the mass spectrum and the infrared spectrum. Gas chromatography indicated one major peak (peak No.2) and two impurities. It was identified only by comparing its gas chromatograph with that of 2-methyl naphthalene, and isoquinoline, the amount in the test substance were 0.166%, and 0.142%.

APPENDIX Q 2

STABILITY OF QUINOLINE IN THE 2-YEAR DRINKING WATER STUDY

STABILITY OF QUINOLINE IN THE 2-YEAR DRINKING WATER STUDY

Test Substance : Quinoline (Tokyo Kasei Kogyo Co., Ltd.)

A. Lot No. : FHE02

1. Sample : This lot was used from 1996.2.21 to 1996.8.28. Test substance was stored in a dark place at room temperature.

2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

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

Column Temperature : 190° C

Flow Rate : 1 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
1996.2.9	1	5.680	0.205
	2	6.726	99.671
	3	7.186	0.124
1996.8.30	1	5.680	0.205
	2	6.728	99.671
	3	7.186	0.124

Results: Gas chromatography indicated one major peak (peak No.2) and two impurities (peaks No.1 and No.3 < 1% of total area) analyzed on 1996.2.9 and one major peak (peak No.2) and two impurities (peaks No.1 and No.3 < 1% of total area) analyzed on 1996.8.30. No new trace impurity peak in the test substance analyzed on 1996.8.30 was detected.

3. Conclusions: The test substance was stable for about 6 months in a dark place at room temperature.

B. Lot No. : FHE03

1. Sample : This lot was used from 1996.8.28 to 1998.2.19. Test substance was stored in a dark place at room temperature.

2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

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

Column Temperature : 190° C

Flow Rate : 1 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
1996.8.22	1	5.683	0.166
	2	6.728	99.692
	3	7.188	0.142
1998.2.28	1	5.675	0.165
	2	6.727	99.692
	3	7.182	0.143

Results: Gas chromatography indicated one major peak (peak No.2) and two impurities (peaks No.1 and No.3 < 1% of total area) analyzed on 1996.8.22 and one major peak (peak No.2) and two impurities (peak No.1 and No.3 < 1% of total area) analyzed on 1998.2.28. No new trace impurity peak in the test substance analyzed on 1998.2.28 was detected.

3. Conclusions: The test substance was stable for about 18 months in a dark place at room temperature.

APPENDIX Q 3

CONCENTRATION OF QUINOLINE IN FORMULATED WATER IN THE
2-YEAR DRINKING WATER STUDY

CONCENTRATION OF QUINOLINE IN FORMULATED WATER IN THE 2-YEAR DRINKING WATER STUDY

Date Analyzed	Target Concentration					
	Male			Female		
	200 ^a	400	800	150	300	600
1996.02.20	197 (98.5) ^b	396 (99.0)	792 (99.0)	148 (98.7)	297 (99.0)	599 (99.8)
1996.05.14	202 (101)	399 (99.8)	794 (99.3)	151 (101)	299 (99.7)	591 (98.5)
1996.08.06	191 (95.5)	389 (97.3)	781 (97.6)	143 (95.3)	294 (98.0)	592 (98.7)
1996.10.29	195 (97.5)	389 (97.3)	784 (98.0)	149 (99.3)	293 (97.7)	588 (98.0)
1997.01.21	193 (96.5)	391 (97.8)	788 (98.5)	144 (96.0)	291 (97.0)	587 (97.8)
1997.04.15	197 (98.5)	388 (97.0)	777 (97.1)	148 (98.7)	295 (98.3)	593 (98.8)
1997.07.15	198 (99.0)	395 (98.8)	789 (98.6)	148 (98.7)	297 (99.0)	598 (99.7)
1997.09.30	202 (101)	403 (101)	- ^c	149 (99.3)	304 (101)	603 (101)
1997.12.16	199 (99.5)	-	-	150 (100)	297 (99.0)	-

^a ppm

^b %

^c No preparation for this concentration was made due to no survival animal.

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

Instrument : Hewlett Packard 1090 High Performance Liquid Chromatograph

Column : TSK GEL ODS-80TM (4.6 mm ϕ \times 15 cm)

Column Temperature : 50° C

Flow Rate : 1 mL/min

Mobile Phase : Methanol : Distilled Water = 3 : 2

Detector : UV (280 nm)

Injection Volume : 2.5 μ L

APPENDIX Q 4

STABILITY OF QUINOLINE IN FORMULATED WATER IN THE 2-YEAR DRINKING WATER STUDY

STABILITY OF QUINOLINE IN FORMULATED WATER IN THE 2-YEAR DRINKING WATER STUDY

Date Prepared	Date Analyzed	Target Concentration	
		150 ^a	800
1996.2.20	1996.2.20	148 (100) ^b	792 (100)
	1996.2.28	152 (103)	791 (99.9)

^a ppm

^b % (Percentage was based on the concentration on date of preparation.)

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

Instrument : Hewlett Packard 1090 High Performance Liquid Chromatograph

Column : TSK GEL ODS-80TM (4.6 mm ϕ \times 15 cm)

Column Temperature : 50° C

Flow Rate : 1 mL/min

Mobile Phase : Methanol : Distilled Water = 3 : 2

Detector : UV (280 nm)

Injection Volume : 2.5 μ L

APPENDIX R 1

METHODS FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-YEAR DRINKING WATER STUDY OF QUINOLINE

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS
IN THE 2-YEAR DRINKING WATER STUDY OF QUINOLINE

Item	Method
Hematology	
Red blood cell (RBC)	Light scattering method ¹⁾
Hemoglobin (Hgb)	Cyanmethemoglobin method ¹⁾
Hematocrit (Hct)	Calculated as $RBC \times MCV / 10$ ¹⁾
Mean corpuscular volume (MCV)	Light scattering method ¹⁾
Mean corpuscular hemoglobin (MCH)	Calculated as $Hgb / RBC \times 10$ ¹⁾
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as $Hgb / Hct \times 100$ ¹⁾
Platelet	Light scattering method ¹⁾
White blood cell (WBC)	Light scattering method ¹⁾
Differential WBC	Pattern recognition method ²⁾ (May-Grunwald-Giemsa staining)
Biochemistry	
Total protein (TP)	Biuret method ³⁾
Albumin (Alb)	BCG method ³⁾
A/G ratio	Calculated as $Alb / (TP - Alb)$ ³⁾
T-bilirubin	Alkaline azobilirubin method ³⁾
Glucose	GlcK · G-6-PDH method ³⁾
T-cholesterol	CE · COD · POD method ³⁾
Triglyceride	LPL · GK · GPO · POD method ³⁾
Phospholipid	PLD · ChOD · POD method ³⁾
Glutamic oxaloacetic transaminase (GOT)	JSCC method ³⁾
Glutamic pyruvic transaminase (GPT)	JSCC method ³⁾
Lactate dehydrogenase (LDH)	SFBC method ³⁾
Alkaline phosphatase (ALP)	GSCC method ³⁾
γ -Glutamyl transpeptidase (γ -GTP)	L- γ -Glutamyl-p-nitroanilide method ³⁾
Creatine phosphokinase (CPK)	JSCC method ³⁾
Urea nitrogen	Urease · GLDH method ³⁾
Creatinine	Jaffe method ³⁾
Sodium	Ion selective electrode method ³⁾
Potassium	Ion selective electrode method ³⁾
Chloride	Ion selective electrode method ³⁾
Calcium	OCPC method ³⁾
Inorganic phosphorus	PNP · XOD · POD method ³⁾
Urinalysis	
pH, Protein, Glucose, Ketone body, Bilirubin, Occult blood, Urobilinogen	Urinalysis reagent paper method ⁴⁾

1) Automatic blood cell analyzer (Technicon H·1 : Bayer Corporation)

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

3) Automatic analyzer (Hitachi 7070 : Hitachi, Ltd.)

4) Ames reagent strips for urinalysis (Multistix : Bayer Corporation)

APPENDIX R 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE
2-YEAR DRINKING WATER STUDY OF QUINOLINE

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY
IN THE 2-YEAR DRINKING WATER STUDY OF QUINOLINE

Item	Unit	Decimal place
Hematology		
Red blood cell (RBC)	$\times 10^6 / \mu\text{L}$	2
Hemoglobin	g/dL	1
Hematocrit	%	1
Mean corpuscular volume (MCV)	fL	1
Mean corpuscular hemoglobin (MCH)	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	g/dL	1
Platelet	$\times 10^3 / \mu\text{L}$	0
White blood cell (WBC)	$\times 10^3 / \mu\text{L}$	2
Differential WBC	%	0
Biochemistry		
Total protein	g/dL	1
Albumin	g/dL	1
A/G ratio	—	1
T-bilirubin	mg/dL	2
Glucose	mg/dL	0
T-cholesterol	mg/dL	0
Triglyceride	mg/dL	0
Phospholipid	mg/dL	0
Glutamic oxaloacetic transaminase (GOT)	IU/L	0
Glutamic pyruvic transaminase (GPT)	IU/L	0
Lactate dehydrogenase (LDH)	IU/L	0
Alkaline phosphatase (ALP)	IU/L	0
γ -Glutamyl transpeptidase (γ -GTP)	IU/L	0
Creatine phosphokinase (CPK)	IU/L	0
Urea nitrogen	mg/dL	1
Creatinine	mg/dL	1
Sodium	mEq/L	0
Potassium	mEq/L	1
Chloride	mEq/L	0
Calcium	mg/dL	1
Inorganic phosphorus	mg/dL	1

APPENDIX S 1

HISTORICAL CONTROL DATA OF CELECTED NEOPLASTIC LESIONS

F344/DuCrj (FISHER) RATS IN JAPAN BIOASSAY RESEARCH CENTER

Historical Control Data of Selected Neoplastic Lesions F344/DuCrj(Fisher) Rats
in Japan Bioassay Research Center

Lesions(*:malignant)	Male n=1199			Female n=1097		
	Animal with Tumors	Rate %	Range %	Animal with Tumors	Rate %	Range %
Liver						
Hemangiosarcoma*	0	0	0	1	0.1	0-2
Hepatocellular adenoma	20	1.7	0-6	15	1.4	0-6
Hepatocellular carcinoma*	3	0.3	0-2	1	0.1	0-2
Nasal cavity						
Hemangioma	0	0	0	0	0	0
Sarcoma NOS*	0	0	0	0	0	0
Ethesioneuroepithelioma*	0	0	0	0	0	0
Adipose tissue						
Hemangiosarcoma*	0	0	0	0	0	0
Mesenterium						
Hemangioma	0	0	0	0	0	0
Hemangiosarcoma*	0	0	0	0	0	0
Peritoneum						
Hemangioma	0	0	0	0	0	0
Hemangiosarcoma*	0	0	0	0	0	0
Retroperitoneum						
Hemangiosarcoma*	0	0	0	0	0	0
Lung						
Hemangiosarcoma*	0	0	0	0	0	0
Mediastinum						
Sarcoma NOS*	0	0	0	1	0.1	0-2
Ovary						
Hemangiosarcoma*	-	-	-	0	0	0
All site						
Hemangioma	5	0.4	0-2	2	0.2	0-2
Hemangiosarcoma*	3	0.3	0-2	6	0.5	0-2